E-CIGARETTES
A SAFE ALTERNATIVE
TO TOBACCO SMOKING

PROPOSED
STATE AND FEDERAL GOVERNMENT INITIATIVE
TOBACCO HARM REDUCTION

by

Stephen Fitzgerald

14 February 2016

INDEX

COPIES OF THESE LETTERS HAVE BEEN SENT TO:

Jackie Davis - Australian Gov. Dept. of Health - Assistant Sec. Tobacco Control Taskforce
Lloyd Weedall - Australian Gov. Dept. of Health - Tobacco Control Taskforce
Prof John Skerritt - Deputy Secretary, Adjunct - Therapeutic Goods Administration
Jennifer Campain - Director, Strategic Project & Support (NHMRC)
Dr Coral Gartner - University of Queensland - NHMRC e-cig Research Grant
Hon Cameron Dick MP - QLD. Gov. Minister for Health & Ambulance Services
The Hon Sarah Mitchell MLC - NSW Gov. Secretary for Regional & Rural Health
Dr. Jo Mitchell - NSW Gov. Executive Director - Centre for Population Health
The Hon Jill Hennessy MP - Victorian Government - Minister for Health
Anne Congleton - Victorian Government - Dept of Health & Human Services
Hon Michael Ferguson MP - Tasmanian Government - Minister for Health
Hon Jack Snelling M.P. - S.A. Gov. Minister for Mental Health & Substance Abuse
Hon Colin J Barnett MEc MLA - W.A. Premier - Minister for State Development & Science
Hon Dr Kim Hames MB BS JP MLA - W.A. Deputy Premier - Minister for Health & Tourism

THE GOV.UK E-CIG INITIATIVE:

Press release GOV.UK
E-cigarettes around 95% less harmful than tobacco estimates landmark review:
https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review

Research and analysis
E-cigarettes: An evidence update:
https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update
Ecigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf
Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf
McNeill-Hajek_report_authors_note_on_evidence_for_95_estimate.pdf

Consultation outcome:
Draft regulations on the sale and manufacture of tobacco products - Last updated 8 January 2016
https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products
RCP_opinion_acc.pdf
SI_tobacco_products_acc.pdf
TPD_Cons_Gov_Response.pdf
TPD_Consultation_Doc.pdf
TPD_EqA.pdf
TPD_IA.pdf

About the author: http://www.hootgallery.com/#!cv/c1kyo

Ref: THR2016-03
14 February 2016

STATE AND FEDERAL HEALTH
MINISTERS OR THEIR CHOSEN
REPRESENTATIVES

In relation to our previous correspondence regarding e-cigarettes: A copy of your letter and my covering letter to the TGA are attached.

PRESS RELEASE GOV.UK

"E-cigarettes around 95% less harmful than tobacco estimates landmark review." As far as Public Health England are concerned, the evidence is in on e-cigarettes and it's time for action... Reference to the full research, analysis and draft legislation can be found in the GOV.UK e-cig initiative.

An expert independent evidence review published 19 August 2015 by Public Health England (PHE) concludes that e-cigarettes are significantly less harmful to health than tobacco and have the potential to help tobacco smokers quit smoking. In addition the current best estimate is that e-cigarettes are around 95% less harmful than smoking tobacco and, there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers. So that's it for the arguments against e-cigarettes unless you have a vested interest in tobacco.

Everyone knows what the outcome will be if there is inaction on preventing climate change... We don't have time to wait for the solution to come to us - We need to go after that solution. The same applies to death and disease from tobacco - The solution is there and we needs to go after it to save lives. To give this statement impetus: Governments are elected to protect us and inaction will be seen as failure in terms of a missed opportunity to save lives from tobacco related diseases.

Australia is a small country with a small population and we can't afford to loose 250,000 Australians to tobacco related diseases every 15 years! We also can't afford the $475 Billion in social, economic and health costs from tobacco related death and disease for that same 15 year period.

From my ongoing correspondence with State and Federal Health Ministers, one thing has come out that is unanimous. Not one of the Ministers or their chosen representatives acknowledge the statistics from tobacco deaths. That's a 1/4 of a million Australians dead from tobacco so far this century. The same number that have died in the Syrian conflict and the whole world is up in arms about that. These are preventable deaths so, prevent them! PHE is an executive agency, sponsored by the British Department of Health. Our NHMRC needs to look into this...

Up until now our Governments have not been prepared to put money into e-cigarette research. Well, Federal and State Governments are putting time, effort and money into cannabis research to help alleviate the pain and suffering of terminally ill patients. At least some of these patients are terminally ill from tobacco related disease. It's like cannabis is the band aid offered to make up for the horrendous chemotherapy treatments and cancer deaths resulting from tobacco use.

If Government can put money into cannabis research to ease the pain resulting from tobacco related diseases, it follows that they can put some time, money and effort into stopping the tobacco related diseases in the first place. Or, am I the only person left in Australia who hasn't gone completely mad.

...3

PROPOSED ACTION PLAN

To date relevant Australia legislation protects tobacco companies and, more recently pharmaceutical companies who jointly hold the oligopoly on nicotine in Australia. So it's not to hard to work out where the noise against e-cigarettes is coming from. From those with the greatest vested interest. Speaking of vested interest, one needs to ask how tobacco tax revenue can possibly be but ahead of all those Australian lives?

To fit in with existing legislation, the way forward is the same path taken for nicotine replacement products (NRP's) like nicotine sprays, nicotine atomizers, lozenges, patches, gums etc. The key is that the TGA is responsible for leading the implementation of broad-ranging reforms, which support the effective, timely and risk proportionate regulation of therapeutic goods within Australian and that would include e-cigarettes as a tobacco smoking cessation device. (As outlined in the GOV.UK study). The process needs to be sanctioned by State and Federal Governments and funds needs to be made available for product research and TGA investigation. The TGA needs to be fully informed of the Governments objective and commit to 100% support to help develop e-cigarette guidelines.

The outcome will result in a TGA and, consumer acceptable e-cigarette product or family of products and will also establish quality control parameters for market and legislative implementation. This then opens the door for e-cigarettes to enter the Australian market and needs to go hand in hand with e-cigarette education as a safer alternative to tobacco smoking. Once this less expensive and safer alternative is on the market, Government can increase the tax on tobacco until it becomes cost prohibitive and the smoking population moves towards e-cigarettes.

At that point tax can be juggled between tobacco and e-cigarettes - As people start to come off tobacco then, increase the tax on tobacco and e-cigarettes to maintain tax revenue that favours e-cigarettes. The result will be **nicotine tax** revenue maintenance and a healthier population. Win, win. The only losers will be the tobacco companies and, history tells us that, they don't care how many people their products kill.

"Tobacco is nothing less than primitive and e-cigarettes are the future for people who crave nicotine". Studies show that other NRP's are not satisfying and have nominal success. I am making a huge humanitarian effort here so please help take this step into the future and prove to the world that Australia can be the Innovation Nation.

A copy of this letter has been sent to each State and Federal Health Minister or their chosen representative and other associated people as outlined.

Forwarded for your information and early attention to get this project moving and come up with "The GOV.AU e-cig initiative" There are no longer any excuses.

Yours faithfully

Stephen Fitzgerald

....4

Ref: THR2016-04
14 February 2016

Prof John Skerritt Deputy Secretary, Adjunct
Australian Government Department of Health
Regulatory Services Group - (TGA)
136 Narrabundah Lane,
Symonston ACT 2609

E-CIGARETTES AS A NICOTINE REPLACEMENT PRODUCT (NRP)

"I refer to the GOV.UK initiative outlined on the attached letter suggesting that e-cigarettes are a viable smoking cessation device and should be given full support as a Nicotine Replacement Product (NRP).

Nicotine, other than for approved therapeutic use or in tobacco prepared and packed for smoking, is a Schedule 7 dangerous poison under the national Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard). This makes nicotine a Schedule 7 dangerous poison in each States Poisons List.

Keeping in mind that the objective here is to follow the British model and have e-cigarettes made available to the Australian smoking public as a safer alternative to smoking tobacco - From where I stand, there are two options:-

(1) Change legislation - That would mean changing the Poisons Standard to include "E-cigarettes prepared and packed for smoking/vaping" or
(2) E-cigarettes for approved therapeutic use - That would mean TGA approval as a Nicotine Replacement Product. So the TGA controls e-cigarettes the same way it controls other NRP's.

From my correspondence with Government health officials it is unanimous that the safest way to go is TGA control so, the question then becomes why and how do we do this? The reason why is simple - To save 15,000 Australian lives lost to tobacco related diseases every year. The question how is a bit more complicated:-

E-cigarette product research and development:
(To come up with a consumer and TGA acceptable product) This may include:
E-cigarettes with a child proof press 5 times ON/OFF safety button - (Available)
The same vape button "Press for ON" & "Release for OFF" - (Available)
A sealed non tamper unit - Disposable only - (Available)
Nicotine levels: 6mg, 12mg, 18mg or 24mg - (Available)
Flavours: Tobacco Flavour Mild, Medium, Strong or Menthol - (Available)
Vapor Volume inc. Battery Voltage & PG/VG ratios to satisfy users - (Available)
TOTAL COST: Nominal - The products already exist.

TGA scale of fees.
(To obtain TGA approval for e-cigarettes as a NRP) This may include:
Registered devices application fee – high level registration - Fee $4,110
Listed devices Annual charge - Fee $1,380
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used - Fee $17,500
Schedule 3, Clause 1.6 – design examination - Fee $55,100

....5

TGA scale of fees. (cont'd.)

Schedule 3, Part 4 – production management system inspection - Fee $24,500
High level GMP licence – other types of therapeutic goods, including containers in which therapeutic goods are to be packed - Fee $ 11,700
Television or Cinema Commercial up to and including 150 seconds in length with up to 3 variations of the one concept for the one product - Fee $ 1,130
Evaluation fees for new substances based on total page count(s) of Clinical or Toxicological data – per submission > 3000 pages - Fee $ 69,000
TOTAL COST: Between $50,000 and $200,000 per application.

So, there it is. "Take it to the TGA." It's easy to say but hard to do... There are not too many people or organisations who have the resources, or would take the risk, to present e-cigarette products to the TGA for approval keeping in mind the high probability of failure. Since there are no Government or TGA e-cigarette guidelines the project is not risk proportionate and will not attract investment.

The solution then will be to come up with a set of Government and TGA approved guidelines relating to e-cigatettes. To develop these guidelines the TGA needs to become involved in each stage of product development and then ongoing product control. This is where we need bipartisan support from Governments and the TGA.

This can be set up and operational with a minimum of effort as follows:

(1) Set up a Government funded task force within the TGA to investigate what is required to produce the safest possible e-cigarettes for Australian consumers
(2) Come up with e-cigarette product guidelines inc. safety, licensing, taxation etc. (Investigate existing requirements for tobacco and other NRP's)
(3) Prepare the GOV.AU E-CIGARETTE INITIATIVE presentation
(4) Bring all the Parties together - Health Ministers or representatives for approval
(5) Sell strictly controlled e-cigarette licences to the private sector
(6) Coordinate a release date backed up with advertising and promotion
(7) Double or triple the tax on tobacco products to favour e-cigarettes
(8) Fine non compliance

Don't say it's not possible to save those 15,000 Australian lives a year and don't say it's not possible for our Governments to maintain or increase revenue from nicotine - Because it is possible and it needs to be done yesterday.

I have had 10 years previous experience, with the NSW Government, in research analysis and I am available to drive this project forward given the resources.

I would like to know where the TGA stands in relation to this proposal and look forward to your early reply.

Yours faithfully

Stephen Fitzgerald

Australian Government

Department of Health

03 March 2016

Stephen Fitzgerald
Unit 2, 1 Avalon Parade
AVALON BEACH NSW 2107

Dear Mr Fitzgerald,

Re: e-cigarettes as a nicotine replacement therapy

Thank you for your correspondence of 14 February 2016 regarding your proposed plan for the control of electronic cigarettes (e-cigarettes).

I am aware of the ongoing interest in the approach to the regulation of e-cigarettes. The approach internationally differs significantly between countries, ranging from outright prohibition in Singapore and Brazil; regulation as conventional cigarettes (US Food and Drug Administration recently announced this approach) and regulation as a medicine or medical device when used 'therapeutically' in Australia.

In Australia, the Therapeutic Goods Administration (TGA) has responsibility for administering the *Therapeutic Goods Act 1989* (the Act), which provides the national framework for the regulation of 'therapeutic goods'. All products presented as therapeutic goods must be included in the Australian Register of Therapeutic Goods (the Register) to be legally supplied in Australia. In relation to e-cigarettes, a therapeutic purpose would include, for example, to assist smoking cessation.

To date, the TGA has not evaluated any e-cigarettes for a therapeutic purpose, but we would consider any such claims presented as part of a submission for approval. As with all therapeutic goods, to be included in the Register the benefits of the use of an e-cigarette product would need to outweigh the risks associated with its use. The risk-benefit approach assures consumers that the products they take are safe for their intended use, while still providing access to products that are essential to their health needs.

The level of regulatory control over the availability of therapeutic goods containing nicotine is proportionate to the risks they pose to public health and safety. As you have pointed out, nicotine is a Schedule 7 'Poison' under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) because it is harmful to human health. However, you should note that this does not apply to nicotine included in preparations for human therapeutic use that are regulated by the TGA. There are different risks and benefits for nicotine replacement therapies (NRT) and e-cigarettes and therefore different levels of regulatory control.

There are a number of NRT products such as patches, gums, lozenges and buccal inhalers included on the Register. These products have been rigorously evaluated for safety, efficacy

and quality by the TGA. The nicotine contained in these products is not included in a schedule to the SUSMP, meaning they are available for purchase without restriction in supermarkets, pharmacies and the like. The nicotine in NRTs is intended for topical administration via the skin or to the mucosal membranes in the mouth, resulting in slow but steady absorption of nicotine into the plasma to achieve sufficiently consistent plasma nicotine concentration. Evidence provided to the TGA shows that this mechanism of action allows a demonstrated relief of nicotine craving and withdrawal symptoms; thus facilitating smoking cessation.

Nicotine used in e-cigarettes for a therapeutic purpose is included in Schedule 4 of the SUSMP and must be evaluated as a 'Prescription Only Medicine' by the TGA before they can be legally supplied in Australia. E-cigarettes are designed to make mists for inhalation and appear to be primarily intended for administration to the lungs. This mechanism is expected to result in rapid delivery of nicotine into arterial blood and a more rapid rise (possibly also followed by a decline) in plasma nicotine concentration, as opposed to the slow absorption that currently registered NRT methods deliver. As such, the risks and benefits are different to the various forms of NRT that have been approved by the TGA.

Australian health authorities are concerned about the use of e-cigarettes because of a lack of evidence on the safety and efficacy as a smoking cessation aid. For example, after examining the available evidence, the National Health and Medical Research Council recently issued a statement concluding that there is currently insufficient evidence to ascertain whether e-cigarettes can benefit smokers in quitting; there is also a lack of evidence about the extent of their potential harms'.

We would consider any therapeutic claims for an e-cigarette product presented as part of a submission for pre-market approval (inclusion in the Register). It will be the responsibility of the sponsor to provide the appropriate data to demonstrate the safety, efficacy and quality for its intended use.

The TGA operates on a cost recovery basis, and collects both fees and charges from the industry it regulates. The Act provides for the collection of annual charges payable for maintaining registrations, listings or other entries of therapeutic goods entered on the Register. The fees and charges applicable to the sponsor depend on the pathway of registration for the product. I note that you have mentioned a range of fees in your letter, it is important to note that some of these fees are not applicable to e-cigarettes.

Thank you for taking the time to raise this matter with me.

Yours sincerely

Adjunct Prof John Skerritt
Deputy Secretary
Regulatory Services Group
Therapeutic Goods Administration

2 March 2016