

36 Winchester St  
Lyttelton, Christchurch  
New Zealand 8082  
Ph: +64 3 3288 688  
Cell: 027 488 4375  
Skype: murraylaugesen  
HYPERLINK "<mailto:laugesen@healthnz.co.nz>" [laugesen@healthnz.co.nz](mailto:laugesen@healthnz.co.nz) HYPERLINK "<http://www.healthnz.co.nz>" [www.healthnz.co.nz](http://www.healthnz.co.nz)

## Health NEW ZEALAND Ltd

Nicotine and tobacco researchers

**Dr Murray Laugesen**

QSO, MBChB, FAFPHM, FRCS, Dip Obst

*Managing Director*

April 2010.

### **Critique of the WHO TobReg report on e-cigarettes**

**Murray Laugesen**

Report on the scientific basis of tobacco regulation: Third Report of a WHO Study Group  
WHO Study Group on Tobacco Product Regulation. © WHO 2009

HYPERLINK "[http://whqlibdoc.who.int/publications/2009/9789241209557\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241209557_eng.pdf)" [http://whqlibdoc.who.int/publications/2009/9789241209557\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241209557_eng.pdf)

The report on e-cigarettes or ENDS, Electronic Nicotine Delivery Systems – except that some do not contain any nicotine. They are thus best defined as “devices designed for the purpose of nicotine delivery to the respiratory system in which tobacco is not necessary for their operation.”

#### **Abstract of Critique: Swatting insects instead of killing elephants.**

If tobacco smoking is the elephant in the room, electronic cigarettes are like a buzzing insect. The natural instinct is of course to kill the buzzing insect first, just in case it might be harmful. This hostile analogy however, ignores the fact that smokers who like to smoke smoke either tobacco or e-cigarettes, and a move to e-cigarettes implies a move away from tobacco for the smoker concerned. If the real aim is to end cigarette smoking, banning e-cigarettes is not a sensible first move and could be counter-productive.

TobReg, an advisory committee of the World Health Organization, is in effect calling for a ban on electronic cigarettes for the next 3 to 5 years world-wide, until manufacturers apply and regulators accept them as safe to medicinal standards, this while TobReg permits the continued sale of tobacco cigarettes.

As of March 2010, e-cigarettes are not known to have killed anyone anywhere, or caused any threat to life, despite sales of 800,000 in the USA. The same cannot be said for smoking cessation approved medicinals such as bupropion and varenicline.

Tobacco cigarettes are known to cause millions of deaths world wide, and 140,000 per year in the USA.

TobReg has previously made recommendations that WHO should mandate some reduction in the emissions of nine leading toxicants in tobacco smoke, good as far as they went, but for the individual smoker, those reductions are far exceeded by the lesser emissions of e-cigarettes.

TobReg has almost nothing positive to say about electronic cigarettes. This is surprising, and at odds with what many smokers claim – that it helps them stop smoking, or at least cut down. We agree with TobReg that the evidence is lacking whether e-cigarettes assist smokers to quit smoking. Certainly, such claims would be premature. Health New Zealand Ltd is involved in various funding applications to repair this deficit in scientific knowledge through randomized controlled trials, but it will be 2013 or 2014 before results are available. Meantime, the absence of proof is not proof that the devices are ineffective, merely proof that research funds from independent sources are scarce..

**Claims about safety.** TobReg’s report “recommends that claims that ENDS are safer than cigarettes, or that they could be marketed as cigarette substitutes, be prohibited until such claims are substantiated by sufficient evidence to satisfy their accuracy to independent scientific organizations and regulatory authorities.” This requires that in the case of the FDA, manufacturers apply to conduct trials costing millions of dollars and years of delay, which no e-cigarette manufacturer to our knowledge has yet embarked on.

In view of the lack of notified side-effects from the use of e-cigarettes, and the 50% risk of premature death which smokers face if they continue to smoke, Health New Zealand Ltd’s view is that meantime distributors should be entitled to inform smokers as the facts become available, and in lay language. [Health New Zealand research shows that e-cigarettes are safer \(in common parlance\) than tobacco cigarettes:](#)

**Emissions from e-cigarettes are less toxic** and are less harmful to health; Comparative emissions testing commissioned by Health New Zealand Ltd that harmful cigarette smoke emissions are almost entirely absent from e-cigarette mist, or present in quantities about 100 times less than in the case of tobacco cigarettes.

**E-cigarettes do not cause burns or fires.** (There is no flame). Among over 1000 New Zealand smokers, we found tobacco cigarettes had caused burns in 60%, 5% requiring medical attention, and fires in 7% in their lifetime.

**No evidence of harm in first day users.** In a cross-over study by the Clinical Trials Research Unit, University of Auckland in 2008, questioning of 40 volunteers for adverse effects after a day of use of the e-cigarette (blinded for nicotine presence or absence), showed no difference between either and nor when compared with medicinal Nicorette inhaler.

**E-cigarettes did not grow bacteria,**<sup>1</sup> whereas tobacco cigarettes do, associated with inflammatory lung disease.

**E-cigarettes do not produce second-hand smoke.** No sidestream smoke is produced, nor any mainstream smoke; mist is inhaled and some propylene glycol is exhaled. Propylene glycol has been used in a children’s hospital to reduce risk of influenza and colds.

**E-cigarettes are as safe as medicinal nicotine patches and gum with respect to nitrosamine carcinogen content.** (8ng /g)<sup>1</sup> This is hundreds of times lower than the 2 ug/g ceiling on nitrosamines recommended by this same TobReg report. for smokeless tobacco.

**E-cigarettes do not contain tobacco and work by vaporization.** Cigarettes burn tobacco at much higher temperatures, which break up the plant material to form small toxic molecules.

**Claims that e-cigarettes are cigarette substitutes.** TobReg’s report recommends a prohibition on claims that e-cigarettes are cigarette substitutes. As TobReg fails to state whether in their opinion, e-cigarettes are less harmful than cigarettes, and fail to say whether they are more harmful, TobReg is unable to say much. Nevertheless, TobReg goes further and recommends (governments) prohibit

claims that e-cigarettes are cigarette substitutes – presumably because it implies they are being touted as safer than cigarettes, and TobReg is not happy about marketers making such claims until regulators confirm this is true. This seems a constriction on commercial speech.

**Denial of the harm reduction principle.** This report is a denial of the harm reduction principle, that smokers unwilling to quit should be allowed to maintain their previous behaviour if they must, but be encouraged to do so in a safer way. Reduction of relative harm is seen as not permissible, unless near absolute reduction of risk is proven. For example, condoms for safer sex, seatbelts for safer driving, are accepted by society, but electronic cigarettes for safer inhalation of nicotine are not yet accepted by TobReg.

**Regulation as medicines or as tobacco products?** TobReg recommends regulation of e-cigarettes as medicines, and approval is acknowledged as theoretically possible in the future. TobReg opposes regulation of e-cigarettes as tobacco products, but if regulated as tobacco products wants them regulated as required under the Framework Convention on Tobacco Control. However e-cigarettes do not contain tobacco, and FCTC only applies to products which do.

Regulation as medicine and as recreational product is seen in either/or terms, not both/and. TobReg proposes no middle way to regulate e-cigarettes, as has been suggested by the Royal College of Physicians London tobacco working group, which proposes lighter regulation to permit the sale of non-medicinal cigarette substitutes.

## **Conclusion**

The report says nothing against continued sales of recreational tobacco, and in effect, wants to put e-cigarettes out of reach, regulated as medicines - equivalent to a world wide ban on their sale if governments adopted the recommendation, as none have been approved as medicines and few if any are likely to be approved in the next five years. TobReg recommends virtually no claims should be made of any kind in the meantime.

TobReg assumes that e-cigarettes are a public health threat. Certainly the global distribution of low cost e-cigarettes not manufactured under any recognized international controls, are a threat to the high standards and huge investments required to bring a medicine to market, which have created an oligopolistic market for major pharmaceutical manufacturers of medicinal nicotine. But that is not to say that e-cigarettes are a public health threat in the same league as tobacco cigarettes, which is the alternative. TobReg goes after e-cigarettes with a determination more logically directed at tobacco cigarettes.

TobReg's report has little to say about patents in the e-cigarette industry which are narrowly held and not widely enforced. Fear of enforcement combined with lack of enforcement promotes cheap products and inhibits further investment in the industry.

This TobReg report is written for governments and regulators, but it is out of tune with many smokers who, unasked, have told this author and many others across the world, ( [HYPERLINK "http://www.vapersclub.com" www.vapersclub.com](http://www.vapersclub.com) ) that these devices have helped them quit smoking, cut down or “smoke” with reduced risk.

TobReg has failed to appreciate the potential of e-cigarettes, preferring to focus on their current imperfections. Yet e-cigarettes could be the next best step, both for governments, as in New

Zealand, obtaining only slow reduction in smoking despite wide and subsidized use of NRT; and for those continuing smokers, who have already tried and failed to quit using NRT, facing a one in two risk of dying early.

One regulation size does not fit all and the TobReg take on e-cigarettes does not assist recent moves in New Zealand aiming to end tobacco cigarette sales by 2020. E--cigarettes could be the catalyst society and smokers need, for sweetening the implementation of a national cigarette and tobacco sales ban, as proposed this year by voluntary agencies. As e-cigarettes are classifiable as tobacco products under NZ law, regulation should be achievable to a reasonable non-medicinal standard.

**Competing interests:** In 2008, Health New Zealand Ltd was commissioned by Ruyan to research the Ruyan e-cigarette in 2008, but has no financial interest in e-cigarettes or any e-cigarette company. In 2009, Dr Laugesen was commissioned by WHO along with Dr Richard O'Connor (Roswell Park USA) to write a background paper for TobReg on Electronic Cigarettes.

Burns DM, Dybing E, Gray N, et al. Mandated lowering of toxicants in cigarette smoke: a description of the World Health Organization TobReg Proposal. *Tobacco Control* 2008;17:132-41.

HYPERLINK "<http://www.healthnz.co.nz/Dublin.htm>" [www.healthnz.co.nz/Dublin.htm](http://www.healthnz.co.nz/Dublin.htm)

Smith J, Bullen C, Laugesen M, Glover M. Cigarette fires and burns in a population of New Zealand smokers. *Tob Control* 2009; 18: 29-33.

Bullen C, Glover M, Laugesen M, et al. Effect of an e-cigarette on cravings and withdrawal, acceptability and nicotine delivery: Randomised cross-over trial. *Tobacco Control*, in press, 2010. HYPERLINK "[http://www.healthnz.co.nz/ecig\\_effect-2.pdf](http://www.healthnz.co.nz/ecig_effect-2.pdf)" [http://www.healthnz.co.nz/ecig\\_effect-2.pdf](http://www.healthnz.co.nz/ecig_effect-2.pdf)

Pauly JL, Smith LA, Rickert MH, et al. Review: Is lung inflammation associated with microbes and microbial toxins in cigarette tobacco smoke? *Immunol Res* 2010 March. On line 11 Sept 2009. DOI 10.1007/s12026-009-8117-6.

Royal College of Physicians. Ending tobacco smoking in Britain: radical strategies for prevention and harm reduction in nicotine addiction. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, Sept. 2008.