Ministry of Health
New Zealand Medicines and Medical Devices Safety Authority
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SUBMISSION

**MEDSAFE PROPOSED AMENDMENT TO MEDICINES ACT 1981 FOR THE CLAIMED PURPOSE OF ENABLING FLUORIDATION OF PUBLIC WATER SUPPLIES TO BYPASS STATUTORY SAFETY REQUIREMENTS IN THAT ACT AND IN THE HEALTH AND DISABILITY SERVICES (SAFETY) ACT 2001**

The Secretary

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**Medsafe proposed amendment To Medicines Act 1981 for the claimed purpose of enabling fluoridation of public water supplies to bypass statutory safety requirements in that Act and in the Health And Disability Services (Safety) Act 2001**

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## 1.0 Introduction

1.1 This Submission is made for and on behalf of Physicians and Scientists for Global Responsibility (PSGR).

1.2 The purpose of PSGR is to promote education, research and analyses so as to facilitate public debate on and awareness of issues of science, medicine and technology.

1.3 Thus, PSGR has a particular role in matters of the public interest – especially in cases where there are arguably issues of public safety involved.

1.4 Therefore, PSGR has a need to take action when it considers that a proposed government action appears to be irresponsible, contrary to the public interest and otherwise possibly contrary to the purposes of established statutory law and administrative law principle.

1.5 PSRG considers the proposed Medsafe amendment to the Medicines Act 1981 to qualify under the action-required headings set out in 1.4 above.

## 2.0 The Health & Disability (Safety) Act 2001

2.1 The Health & Disability (Safety) Act 2001 at Section 3 requires the Ministry of Health (MoH) to:

(a) promote the safe provision of health and disability services to the public; and

(b) enable the establishment of consistent and reasonable standards for providing health and disability services to the public safely.

2.2 Parliament's purpose and intent is arguably very clear. It is not therefore 'open' to a 'business unit' of the MoH (i.e. Medsafe) to advance an amendment to the Medicines Act 1981 when there is clear evidence that its proposed amendment has an arguably material probability of endangering public safety and health as well as being contrary to the public interest.

2.3 An advisor to PSGR on machinery of government and public law matters requested Medsafe (on 12 December 2014) to provide documentation setting out clearly the issue that its amendment seeks to address together with its Regulatory Impact Analysis (RIA) and its associated Regulatory Impact Statement (RIS) as well as its compliance with the requirements set out by the Regulations Review Committee of the House of Representatives as well as compliance with the Legislative Advisory Committee Guidelines (LAC Guidelines) so that PSGR would be in a position to make a properly informed approach to making a submission within the time-frame requested by Medsafe.

2.4 However, Medsafe did not provide any of that documentation that is reasonably required to demonstrate that due care has identified all relevant considerations and that such considerations have been accorded due weight in the formulation of a proposed amendment.

2.5 It therefore seems to be a reasonable assumption that Medsafe had not formulated its proposed amendment to the Medicines Act 1981 with any due regard to the disciplines required by due process.

2.6 It is a matter of note and concern to PSGR that Medsafe responded with a delaying tactic – a decision to regard the request for required documentation as being a request under the Official Information Act 1982, thus triggering a delay for its required response that would extend to 3 February 2015; too late for that documentation (if it exists) to be available to inform PSGR submission and other submitters in time for them to comply with Medsafe's date for submissions.

2.7 Such a delay in the provision of required documentation renders impossible informed submissions.

2.8 Thus, submitters are left with attempting to undertake some of the work of those in the MoH and Medsafe who are supposed to have complied with their duty of care prior to advancing their proposed amendment for submissions.

2.9 In the view of PSGR, such conduct by MoH is not only reprehensible from the point of view of compliance with Parliamentary standards and principles that are supposed to inform safe and effective regulation, they are also an affront to the fiduciary obligation that the Crown is supposed to observe so as to be seen to act with utmost good faith towards the general public that it is supposed to serve.

2.10 Notably, the documentation that was reasonably requested is of the essence to inform the relevant Parliament organisations and the general public about any proposed amendment to an important statute.

2.11 Thus, PSGR regards the matter of the MoH approach to this amendment as being appropriate for formal complaints to the control agencies within the machinery of government.

2.12 Notwithstanding an intention to proceed with such complaints, PSGR now sets out further reasons why MoH cannot proceed lawfully with such a proposed amendment.

**3. Relevant tests of risks and safety**

3.1 Formulation of public policy (a species of delegated regulation) – such as the MoH policy encouraging the fluoridation of NZ public water supplies – requires similar rigour for its formulation as that for formulating a statutory provision.

3.2 That rigour requires MoH to identify 'all relevant considerations' in its research and then to accord

each relevant consideration 'an appropriate weight'.

3.3 Necessarily, considerations relating to public safety and the broader public interest (e.g. economic damage that could be caused) are particularly relevant considerations because a primary statute – the Health & Disability Services (Safety) Act 2001 at section 2, (a) and (b) establishes that purpose.

3.4 Such relevant considerations may meet three relevant tests as to level of solidity of evidence about any safety concerns:-

3.4.1 the scientific test (circa 95 per cent certainty that something is safe);

3.4.2 the legal test (circa greater than a 50 per cent chance that there is a material risk); and

3.4.3 the precautionary principle test that is invoked if there is a reasonable suspicion that there may be widespread harm caused by a proposed action.

3.5 It is submitted that the established MoH policy of promoting fluoridation of NZ public water supplies is firmly captured and rendered unlawful by at least the second and third tests.

3.6 If the strength of the evidence is such as to make the established MoH policy on fluoridation of public water supplies unlawful, then arguably it follows that the Medsafe proposed amendment to the Medicines Act 1981 is thus also rendered unlawful.

3.7 Therefore the balance of this submission – primarily in the form of Attachments - sets out some of the peer-reviewed scientific research findings and (in Attachment B) strategic issues relating to public safety and the public interest.

3.8 It is submitted that these relevant consideration arguably more than qualify that the MoH practice of adding fluoride to NZ public water supplies is both a dangerous and ineffective policy – and should not therefore now also be 'enabled' by Medsafe's proposed amendment to the Medicines Act 1981.

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## ATTACHMENT A

## EVIDENCE OF MoH UNSAFE FLUORIDATION POLICY & EVIDENCE OF VERY DOUBTFUL EFFICACY OF THAT POLICY:

## THE IRRELEVANCE OF MoH PURSING AN ASSOCIATED AMENDMENT TO THE MEDICINES ACT 1981

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### 1. Introduction

1.1 The New Zealand Ministry of Health (MoH) has had a long-standing policy that has pursued addition of fluoride[1] to New Zealand public water supplies solely for the claimed purpose of giving effect to a 'belief' that to do so imparts medicinal properties to that water which MoH apparently considers will cause a significant reduction in the incidence of dental carries.

1.2 Therefore, by the tests of reasonable logic, statutory definition and purpose, MoH policy to insert fluoride into public water supplies is to employ fluoride as a 'therapeutic substance' and therefore 'a medicine'.

1.3 The dominant purpose and intent of New Zealand statutes relating to health is dominated by considerations of achieving a high level of public safety in relation to approval of claimed medicinal products.

1.4 Since the Crown is bound to observe provisions in the cluster of statutes relating to health matters, it is

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1 Fluoride added to public water supplies is an industrial waste product that is contaminated with many toxic metals – many of which are bio-accumulative and mutually-synergistic in their toxicity.

also arguably required to comply with those relevant statutes.

1.5 Such compliance involves due care to matters of public health and safety – and particularly identifying all such 'relevant considerations' as well as transparently giving due weight to each such relevant consideration.

1.6 Such a required approach also applies to the formulation of the MoH policy (subordinate legislation) of encouraging fluoridation of public water supplies (and its periodic review of that policy).

1.7 Equally, the same approach is required to apply to any use of MoH statutory administrative powers to propose statutory or regulatory changes or amendments: i.e. such changes or amendments must be consistent with the purpose and intent of related statutes. The MoH current proposed amendment to the Medicines Act 1981 is of that species.

1.8 The current MoH proposed amendment to that Act would arguably bypass, in an arbitrary and absurd manner, the purpose and intent of relevant NZ health statutes.

1.9 As an administrator of health statutes, the MoH is in a special position of fiduciary obligation and trust with respect to the public that it is supposed to serve and protect.
It would be unreasonable for the MoH to claim that it does not have much of a duty of care because it can give the public access to an arguably sham 'consultation process' about its proposed administrative approach to the use of its statutory powers.

1.10 This Attachment A sets out, in its predominant first part, an illustration of a number of relevant safety issues associated with the established MoH policy of fluoridation of public water supplies. Arguably, any one or group of the associated referenced papers and authorities should be sufficient to cause MoH to abandon its fluoride policy – and therefore also abandon its associated tactic to pursue its proposed amendment to the Medicines Act 1981 that appears to seek to make 'lawful' a clearly unsafe and damaging use of fluoride as a medicine.

1.11 Towards the end of this Attachment A, it sets out compelling authorities that indicate that the MoH claimed efficacy for an association between its policy of fluoridating public water supplies and a reduction of dental carries in the population is a 'belief' and that it is not based upon any proven basis that such fluoridation of public water supplies brings about any proven and statistically significant reduction in the incidence of dental carries.

1.12 This Attachment A finishes with a brief conclusion and a recommendation.

## 2. Absurdity

2.1 The purpose of the aggregate of the provisions incorporated in the Medicines Act 1981 may reasonably be described as 'designed to protect people from the risk of exposure to unsafe medicines'.

2.2 Therefore unsafe and arbitrary use of medicines is an offence under the Act.

2.3 For the MoH to argue that the multiple adverse health effects of fluoride and its industrial waste co-contaminants can be added to public water supplies safely is an absurdity.

2.4 Therefore, the move by the MoH to seek a statutory amendment for the purpose of giving statutory authority to its established fluoridation policy places the rule of law and the foundations of peoples' trust in the credibility and authority of Parliament in jeopardy.

2.5 Under New Zealand constitutional law it is not lawful to invite Parliament to do an absurd thing – making an unsafe amendment to an Act intended to protect peoples' safety.

2.6 There is no evidence to suggest that putting fluoride into drinking water is safe for people who drink it or for the environment area in which waste-water disposal accumulates the many toxic metals that the fluoridated water contains.

2.7 However, this submission includes references to many authoritative references that point to the dangers to health and environmental safety of the substances that are involved.

## 3.0 Lack of safety data

3.1 A number of government-appointed bodies have all raised concerns about a lack of any safety data relating to fluoridation of public water supplies:-

3.1.1 The U.S. Agency for Toxic Substances and Disease Register (ATSDR) in 1993 and 2003.

3.1.2 The “York Report” a British National Health Service investigation (McDonagh et al. 2000).

3.1.3 The National Research Council (NRC-USA) 2006.

3.1.4 The Scientific Committee on Health and Environmental Research (SCHER-EU) in 2011.

3.2 Following is a quotation from the ATSDR: “*very limited human and animal data were located to evaluate the immunological effects of fluoride.*”

3.3 And a further quote from the NRC report: “*The existing data base does not permit a complete assessment of the immunotoxic potential for fluoride.*”

3.4 All of the organisations referred to in 3.1 above requested that definitive research had to be done into the potential for adverse health effects.

3.5 Not surprisingly, governments that have established policies to fluoridate public water supplies (e.g. America, Australia, New Zealand and the Republic of Ireland) have been reluctant to undertake such research. Nevertheless, health officials in these countries have repeatedly provided to their respective Governments and public unfounded assurances about the safety of their policies – and persistently refused to consider relevant evidence about the likely harm that their policy may be causing.

3.6 But as biological sciences have been advancing, so has the evidence of the probability of such harm.

3.7 It is arguably unconscionable that policy administrators should continue to refuse to review their policies against the growing weight of evidence that their established policies to fluoridate public water supplies have a likely greater than 50 per cent probability of causing harm to people and the environment.

**4.0 Disease incidence correlated with water fluoridation**

4.1 In February 2013 a report was presented to the Government in Ireland that was titled: “*Public Health Investigation of Epidemiological data on disease and mortality in Ireland related to water fluoridation and fluoride exposure*”.

4.2 This presentation compared the incidences of 28 diseases in the Republic of Ireland (RoI) with both unfluoridated Northern Ireland (NI) and the EU. (Waugh D. available at: www.enviro.ie).

4.3 Notably, the RoI has had mandatory water fluoridation for 50 years. Although it has to be acknowledged that epidemiological studies cannot prove cause and effect, they do reveal statistical correlation; and such correlations are evidence of a required 'relevant consideration' for public policy formulation relating to public safety issues and regulation.

4.4 Here are some examples of some of the correlations contained in that RoI presentation.

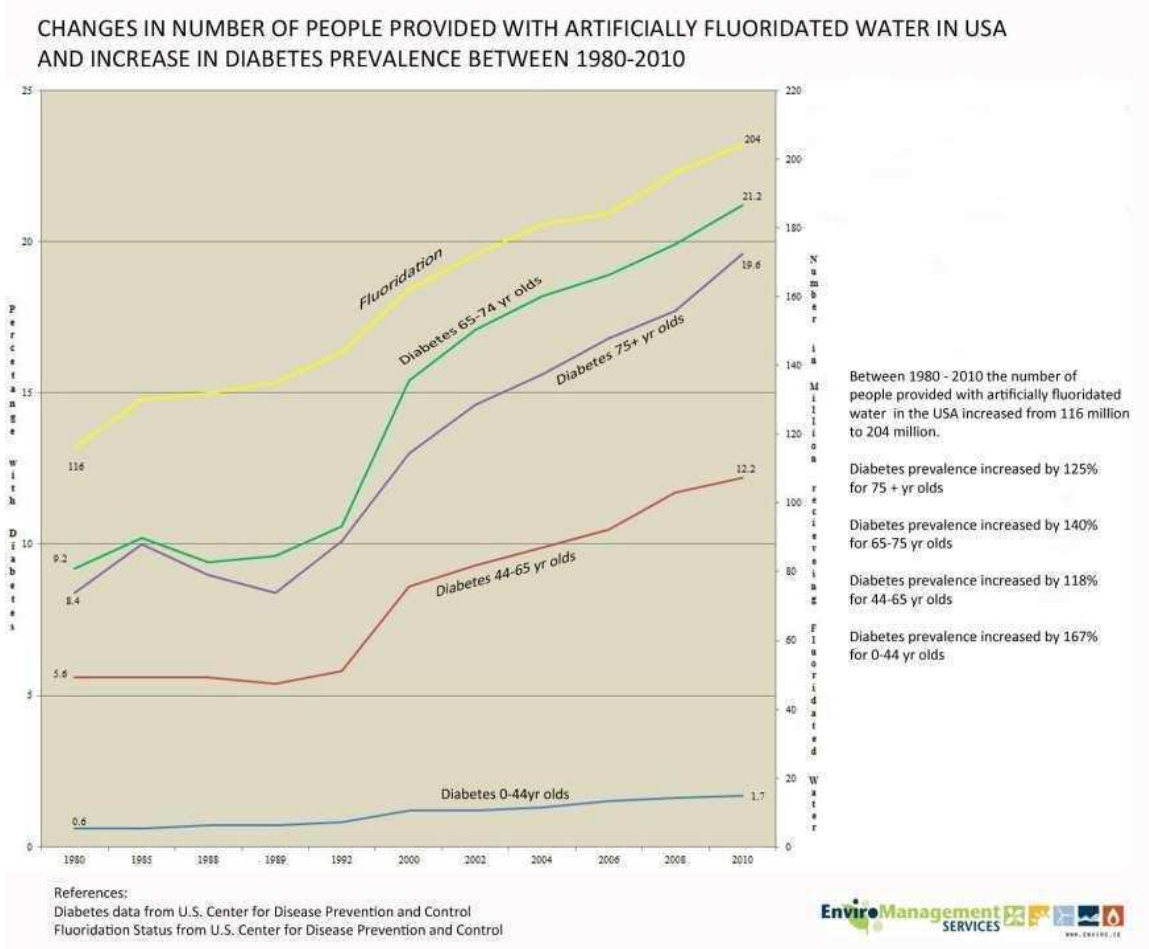
4.4.1 Comparing the Republic of Ireland with Northern Ireland, the incidence of Type 2 diabetes was 60 per cent higher in the fluoridated Republic.

New Zealand is also experiencing a current epidemic of diabetes according to NZ government statistics. In 1996 there were 81,000 diagnosed cases: by 2009 there were greater than 270,000 diagnosed cases.

A similar pattern of increase in diabetes occurs in both the USA and Australia.

It is reported that Pacific Islander and Maori populations have three times higher rates of diabetes than Caucasians.

The U.S. increase in diabetes appears to have followed the increase in water fluoridation as shown below.



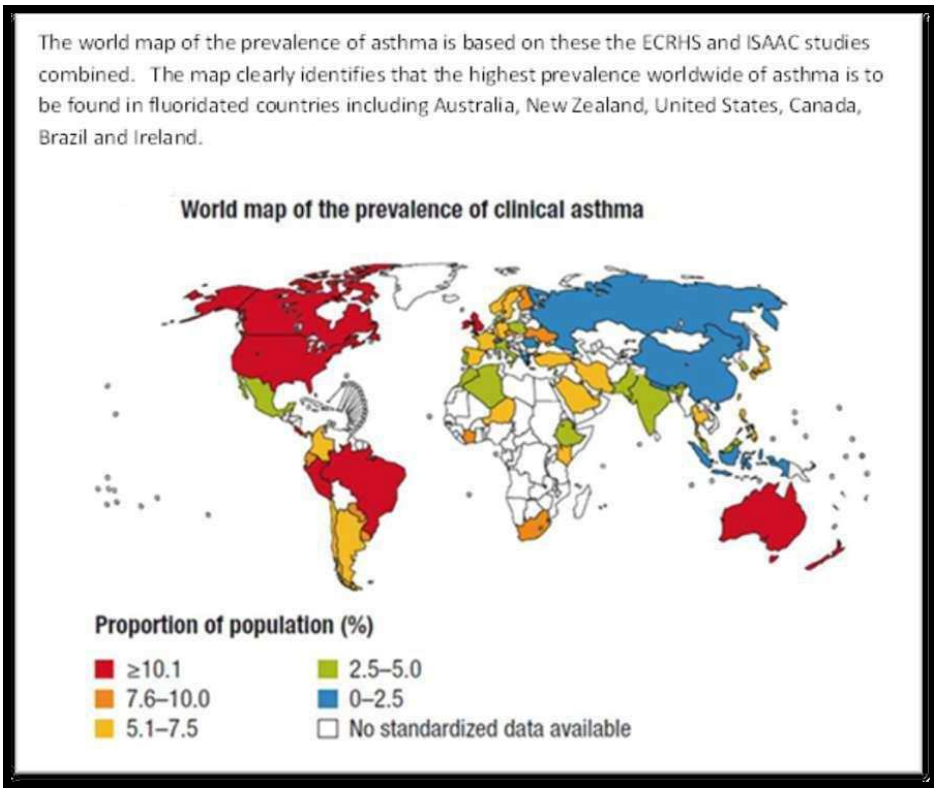

4.4.2 Endocrine/metabolic disorders including hypothyroidism and blood/immunological disorders were all markedly elevated in the Republic compared with N Ireland.

4.4.3 Admission rates for Chronic Obstructive Pulmonary Disease (COPD) were highest for the Republic at 364 per100,000. The rate for NZ is similar at 319 per 100,000. Australia is also similar at 312. By comparison the EU is <200 per100,000 for the (OECD 2012).

4.4.4 Asthma rates in the Republic were double those seen in N Ireland. The Republic's figure was the highest in the EU – ref. the ISAAC study (1998).

4.4.5 Asthma incidence world-wide shows that all of the fluoridating countries share equally elevated rates (Masoli 2004). [See map below.]

The world map of the prevalence of asthma is based on these the ECRHS and ISAAC studies combined. The map clearly identifies that the highest prevalence worldwide of asthma is to be found in fluoridated countries including Australia, New Zealand, United States, Canada, Brazil and Ireland.




4.4.6 Deaths in males from ischaemic heart disease were highest in the USA with NZ next followed by Canada and then the RoI (WHO 2011).

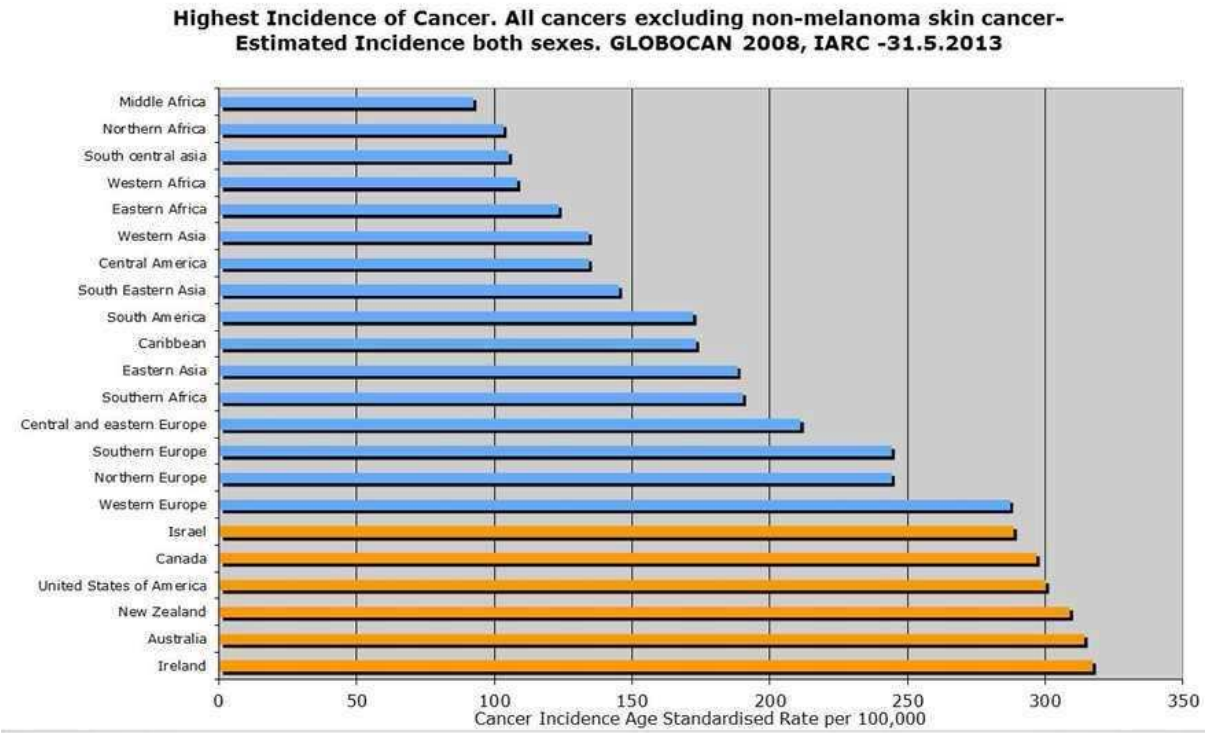
4.4.7 NZ leads the world for sudden infant death syndrome (SIDS) per 100,000; next in sequence are the USA, Argentina, Australia and the RoI.

4.4.8 Infants that are still breast fed at six months of age are less than 10 per cent in the Republic whereas in the EU the figure is more than 40per cent. RoI infants would therefore have significantly greater fluoride exposure and increased risks of neurotoxicity and lowered I.Q. - a well-documented adverse effect of fluoridated water (Choi et al 2012). The US EPA website includes fluoride in the 100 chemicals having "substantial" evidence of developmental neurotoxicity.

4.4.9 The RoI has the highest rates in the EU for prostate, ovarian, colon, rectal and pancreatic cancers as well as Non-Hodgkin's lymphoma (all of which are notably of concern in NZ).

4.4.10 A statistically significant increase in uterine cancer was also detected following water fluoridation during the American occupation of Okinawa, Japan, between 1945 and 1972 (Tohyama 1996).

4.4.11 The following chart demonstrates the overall increased cancer incidence in the fluoridating countries (orange bars are fluoridating countries):-




## 5.0 Higher rates of osteosarcoma

5.1 In all four of the long-term fluoridating countries, compared with the rest of the world, osteosarcoma rates are also significantly elevated.

5.2 Significantly, the NRC scientific committee highlighted the carcinogenic potential of fluoride and unanimously concluded that fluoride appeared to have the potential to initiate and promote cancers including: "Osteosarcoma presents the greatest *a priori* plausibility as a potential cancer target site, the NTP animal study findings of borderline increased osteosarcomas in male rats, and the known mitogenic effect of fluoride on bone cells in culture (NRC (2006) p275).

5.3 Notably, Bassin's landmark study showing >500 per cent increased risk of osteosarcoma in boys if exposed to fluoridated water during the mid-childhood growth spurt occurring between age 6 and 8 years has not been refuted (Bassin 2006).

5.4 A recent paper has also confirmed elevated serum fluoride levels in patients with osteosarcoma compared to healthy controls (Kharb 2013).

5.5 The elevated rate of bone cancers that are mainly osteosarcoma occurs in two peaks: one in young men (where it is frequently fatal); and another peak in the elderly where the comparative increased incidence is even more marked at treble the rates seen in non-fluoridated populations of the mainland Europe.

5.6 Age-specific rates for NZ confirmed this pattern with peaks reaching 3 per 100,000 in both teenagers and the 65-85 age cohort (NZ Health Dept. statistics accessed 2013) with the latter age cohort exceeding the latest Australian rates of 1.8 per 100,000 compared to 0.4 per 100,000 for the EU (Mirabello 2009). New Zealand's lower soil selenium levels may make NZ people more susceptible to cancerous effects of fluoride.

## 6.0 Fluoride - the common denominator of multi-system diseases

6.1 From the foregoing swathe of evidence, reason suggests that there is a likely greater than 50 per cent probability that fluoridation of public water supplies is linked with the markedly-higher incidence of multi-system disease.

6.2 Fluoride is a known endocrine disrupter (*State of the Science of Endocrine Disrupting Chemicals,* UNEP / WHO report 2012) and from the NRC (2006) "an endocrine disruptor in the broad sense of altering normal endocrine function."

6.3 Notably, American adults ingest daily an average of 3mg of fluoride and a 1-3 year old (under 14kg) over 1.5mg/day - or double an amount that would alter thyroid function (EPA 2010).

**7.0 Industrial waste disposal**

7.1 Water fluoridation uses hexafluorosilicic acid ($H_2SiF_6$ ) and its sodium salt (Na SiF ) almost exclusively. They are hazard substances - HazChem class 7.

7.2 These fluoride forms are recovered ('scrubbings') from gaseous emissions following treatment of phosphate ores with sulphuric acid.

7.3 Such scrubbings are contaminated with variable amounts of lead, arsenic, beryllium, vanadium, cadmium, and mercury. Therefore, because of the different chemicals used, old studies based on the use of natural calcium fluoride are irrelevant.

7.4 Disposal of such highly-toxic and corrosive chemicals from the super-phosphate fertiliser production was a major problem until approval was orchestrated in the USA to permit dilution into municipal water supplies in the 1940s and 50s (Kauffman 2005).

7.5 If the fertiliser production companies had to store or destroy such unwanted and dangerous chemicals, it is likely that the cost of fertiliser would rise significantly. It has been fortunate for them that governments have turned a blind-eye to health and safety considerations and allowed these mainly bio-accumulative toxins to accrue in peoples' bodies and in the environments around municipal waste-water disposal sites.

**8.0 Lack of safety testing**

8.1 Such silico-fluoride and toxic metal fertiliser-production waste products added to public water supplies have never been tested for their likely adverse effects on peoples' health and safety and upon the environment associated with waste-water disposal.

8.2 The Republic of Ireland and NZ both have generally 'soft' water supplies that have low calcium levels.

8.3 Low calcium levels increase potential toxicity of fluoride added to water supplies.

8.4 Fluoride is a halogen that has a particularly high negative electron charge: that gives it a bias to be highly reactive with other substances – for example, aluminium cooking utensils and lead in brass plumbing fittings.

8.5 Increasing peoples' bio-accumulation of aluminium and lead would be a most serious matter; sufficient to invoke the precautionary principle or, more likely, to meet the legal test of a greater than 50 per cent probability of causing harm.

8.6 Such factors would more than offset any MoH claimed benefit of any minuscule reduction in the incidence of dental carries caused by sugar-laden diets in a proportion of the population.

**9.0 Health effects**

9.1 Chronic exposures to sodium fluoride – on its own - may cause damage to kidneys, lungs, the nervous system, heart, gastrointestinal tract, cardiovascular system, bones and teeth (2008 MSDS Sodium fluoride NaF 100% - sciencelab.com Texas. Accessed July 2013).

9.2 But, because fluoride is aggressive in its association with other toxic substances like lead and aluminium, it seems reasonable to suspect that reported adverse health effects of its use in public water supplies may be due to a variety (or combination) of various silicofluoride compounds.

9.3 Arsenic, lead and mercury form three of the bio-accumulative and synergistic contaminants in the fluoride mix that is added to public water supplies by the MoH fluoridation policy.

9.4 The deliberate addition of an arsenic contaminated substance at any level would not normally be permitted.

9.5 Where is the MoH research that shows that the synergistic factors between bio-accumulative toxic substances are not 'a relevant consideration' and that such factors and metal-stripping abilities of fluoride pose no health and environmental safety issues of any material weight?

9.6 Fluoride is the lightest and most bioactive of the halogens (fluorine, chlorine, bromine and iodine).

9.7 That means that fluoride by preferential uptake decreases dietary iodine availability.

9.8 Because the majority of the NZ population is already iodine (and selenium) deficient, further iodine depletion will have potentially serious adverse health effects - not only on peoples' thyroid function but

also on the health of breasts with subsequent risks of fibrocystic breast disease (FBD) and cancer. It is noteworthy that daily high dose iodine supplementation is an effective treatment for FBD.

9.9 Why is it that the MoH refuses to say that it has considered such factors; that has given them due weight to each of them; and that it has done so while advancing compelling and documented reasoning available to the public?

9.10 Regarding the fluoride-iodine association, Susheela and associates commented : "*Our findings further strengthen the possibility that fluoride is often responsible for thyroid hormone alterations normally ascribed to iodine deficiency disorder.*" And:"*The role of excess fluoride in aggravating health problems in children by inducing iodine deficiency disorders appears to be either overlooked or has remained largely unnoticed." (Susheela et al. 2005)*

9.11 A physiological review of fluoridation was published recently that demolished MoH claimed benefit for fluoride being responsible for material reduction in dental carries as a result of fluoridated public water supplies.

9.12 That same review also revealed widespread adverse effects including serious cardiovascular adverse events due to fluoride-induced hypocalcaemia (Sauerheber 2013).

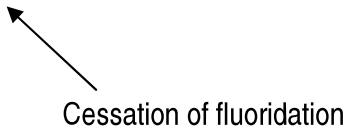
9.13 According to Sauerheber, industrial fluoride at blood levels typically found in residents of fluoridated cities is recognized as a neurotoxin, a non-physiologic mitogen, a general enzyme inhibitor, and a permanent bone perturbant during chronic consumption (Sauerheber 2013).

9.14 Support for adverse cardiovascular effects also appeared in a 2012 paper that concluded "*An increased fluoride uptake in coronary arteries may be associated with an increased cardiovascular risk*" (Li et al.2012).

9.15 Finally, although there is international epidemiological evidence associating asthma with fluoride, the following local NZ example is pertinent.

9.15 New Plymouth ceased fluoridation in 2011: subsequently, the hospital asthma admission rate has fallen by approximately 50 percent in following years to 2014 (Taranaki DHB Figures obtained under OIA July 2014). [See Table below.]

| Summary Table | |
|---|---|
| **Year** | **# of Asthma Discharges** |
| 2003 | 75 |
| 2004 | 77 |
| 2005 | 79 |
| 2006 | 54 |
| 2007 | 45 |
| 2008 | 62 |
| 2009 | 86 |
| 2010 | 88 |
| 2011 | 52 |
| 2012 | 32 |
| 2013 | 42 |




9.16 In 2007 in the Republic of Ireland, following a nationwide 30 per cent reduction in water fluoride concentration (to 0.7 from 1.0ppm), there was a 27 per cent decline in hospital admissions for asthma among children under 15 years of age; the largest decline was observed among children aged 0-4years.

**10.0 Minimal reduction in dental decay**

10.1 Currently, the MoH claims what appears to be an impressive 25 per cent reduction in dental decay from its policy of adding fluoride to public water supplies. But, in practical terms, this translates to only a reduction of less than one dental surface of a child's 128 dental surfaces. [In earlier times the MoH

had claimed that its policy achieved a 40 per cent reduction.]

10.2 This unimpressive low reduction in dental carries on teeth surfaces has been repeated in American and Australian dental research that sought to measure fluoride benefits. Those further research results were as follows:- Brunelle and Carlos 1990 (**0.6 surface**); Spencer AJ and Slade 1996 (**0.3 surface**); and Armfield and Spencer 2004 (**1.5 surfaces**).

10.3 Furthermore, the latest findings (Slade and Spencer 2013) on lifelong - 45 years - exposure in Australia, showed that fluoridation of public water supplies had a maximum benefit of 1 tooth saved – but even that result was at the margin of questionable statistical relevance.

10.4 Notwithstanding that a policy of fluoridation of public water supplies apparently results in such minuscule reductions in dental carries, policy proponents continue to mislead and deceive government decision-making – apparently intentionally - by using a percentage figure rather than an absolute measure.

10.5 Meanwhile, officials in fluoridating countries continue to ignore the probability of serious adverse health and environmental effects of their policy of adding fluoride to public drinking water. There is, consequently, no proper risk/benefit assessment to inform proper and trust-worthy public policy formulation and use of statutory powers.

10.6 Arguably, that conduct is a serious breach of government fiduciary obligation (and trust that the public necessarily resides in its machinery of government); a breach of the principles of constitutional and administrative law; and a breach of the purpose and intent of established statutory provisions relating to health and safety of people and the environment.

10.7 In addition, the established MoH policy to pursue fluoridation of public water supplies as a route to making what turns out to be – at most - a minuscule reduction in dental carries ignores the fundamental dietary cause of dental carries and its portent for resulting in even more serious disease. That may perhaps be reasonably described as gross negligence.

**11.0 Dietary link with dental caries**

11.1 During the 1950-60s Ralph Steinman, Professor of Dentistry at Loma Linda University, California, published over 20 relevant primary animal research papers. He was the co-discoverer of the hypothalamic-parotid endocrine axis that controls the rate of fluid movement through the dentine (Steinman and Leonora 1968).

11.2 Steinman demonstrated that dental caries mainly resulted from chronically elevated levels of sugars in the blood.

11.3 Systemic sucrose resulted in the normal caries-protective retrograde dentinal fluid movement ceasing and even reversing. This reversal facilitated bacterial invasion of the several kilometres of dentinal tubules per tooth.

11.4 Physiological failure therefore preceded structural failure that Steinman also showed occurring in the dentine prior to enamel breakdown (Steinman 1971).

11.5 The dental “fluoride bomb” where much of the underlying tooth has already decayed by the time a pinhole appears in the fluoride-hardened enamel is entirely consistent with Steinman’s research.

11.6 This delayed caries detection occurs in the young adult at a time when the unexpected and significant financial costs are even more burdensome.

11.7 Dental caries therefore appears to be a systemic disease that is eminently controllable by diet and not a fluoride-deficiency condition.

11.8 Notably, the Maori population on their ancestral diet and drinking “fluoride-deficient” waters had less than 1:1000 teeth showing any decay until adopting foods of commerce based on white flour and sugar.

11.9 That shift in diet and the incidence of dental caries then increased to 40 per cent within a generation (Price 2010).

11.10 A 1.5L bottle of cola in a supermarket that some children drink on a daily basis is cheaper than bottled water but contains 162 grams - or about 40 teaspoons - of sugar. Even a tin of baked beans contains significant quantities of sugar. It is a substance that predisposes people to obesity and diabetes Type

2.

11.11 Thus, government officials in any administration that simply focus policies on addressing symptoms (i.e. dental caries) of serious and life-threatening dietary habits may arguably and reasonably be regarded as conduct verging on the seriously negligent.

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**ATTACHMENT B**

## MoH FLUORIDATION OF PUBLIC WATER SUPPLIES POLICY: ECONOMIC AND OTHER STRATEGIC RELEVANT CONSIDERATIONS

### 1. Introduction

1.1 Policies made pursuant to a statute are a species of subordinate legislation. To be lawful, policies cannot be formulated such as to contravene a statutory purpose or otherwise not be reasonably in the public interest.

1.2 Arguably, therefore, if there is no documented evidence that a policy has been formulated taking into account all relevant considerations, then it would be absurd for Parliament to be asked to pass an amendment to a related act in order to facilitate a likely deficient and unlawful policy.

1.3 It seems plain from correspondence with the Ministry of Health (MoH) that it made an arguably arbitrary policy decision, many decades ago, to fluoridate public water supplies. Arbitrariness may reasonably be suspected because the MoH has failed to produce documentation that shows that it identified all relevant policy considerations and that it was consequently able to give due weight and acceptable reasoning in its documentation relating to all such relevant matters.

1.4 Such a gross deficiency in due process is reasonably likely to have resulted in a materially deficient or possibly an unlawful policy: 'an error in making findings of relevant fact'; and 'an error inconsistent with relevant legislative purpose and intent'.

1.5 Such a circumstance is hardly a proper and lawful foundation for advancing a directly-associated amendment to an associated act for the express purpose of enabling delivery of the possibly deficient and illegal policy.

1.6 Such MoH conduct gives the appearance of being 'arbitrary'; possibly 'unlawful and illegal'; and therefore likely to have a high probability of producing results contrary to statutory purpose and the public interest.

1.7 The MoH has been unable to produce to date and in a timely manner for these submission purposes any documentation that demonstrates that it took into account relevant:

1.7.1 accumulative biological risks to health;

1.7.2 accumulative risks to environmental safety; and

1.7.3 possible serious and accumulative adverse economic and strategic risks to the national interest.

1.8 The MoH has simply persisted in a claim that its policy is necessary because MoH claims that fluoride in public water supplies has a material beneficial effect on reduction of dental carries – (although that claim is not supported by the facts as set out in the preceding Attachment A).

1.9 The MoH seems to have decided that it can rely upon simply taking comfort in adopting 'water treatment standards' imported from overseas entities. But there is no evidence that those so called 'standards' were formulated with any due regard to all relevant safety considerations (such as those examples set out in this submission).

1.10 Also, as mentioned in Attachment A, NZ people have relevant characteristics of low calcium levels that risks fluoride in water supplies being more toxic. Yet MoH has not advanced any evidence that it has taken into account such relevant factors in its adoption of 'standards' for fluoridation of NZ water supplies.

1.11 Now, the MoH is proposing to seek an amendment to the Medicines Act 1981 so as to set aside fluoridation of public water supplies from the safety provisions of that Act – despite established health statutes emphasising that the purpose and intent of the health statutes that the MoH administers is focussed primarily upon securing *protection* of the health and safety of New Zealanders.

1.12 While MoH appears to be seeking that amendment to enable implementation of its established policy to encourage fluoridation of public water supplies, the seeking of that amendment draws into focus whether or not the MoH established *policy* is in the public interest; and whether or not the amendment complies with the purpose and intent of the established health statutes.

1.13 It would arguably be absurd for MoH to claim that its proposed *amendment* does not rely upon its long-established *policy* to encourage delivery of fluoridation of public water supplies.

1.14 However, the MoH has not been able to advance to the PSGR advisor on machinery of government matters any of the required regulatory impact assessment (RIA) and regulatory impact statement (RIS) documentation that is supposed to show to the control agencies in government and to the general public that the MoH policy formulation considered all relevant matters and that it gave those matters due weight with acceptable and documented reasoning when it formulated its policy. [See para 1.20 for details about requests for documentation.]

1.15 Thus there is arguably no documented sound policy foundation to support the MoH proposed advance of a statutory amendment proposal to Parliament.

1.16 Therefore, it follows that the principal Parliamentary committees concerned with maintaining quality of regulatory matters – the Regulations Review Committee and the Legislative Advisory Committee – will not be informed in the manner that they require for proper purview of such an amendment.

1.17 In addition, Government policy requires regulatory impact assessments and associated statements to be produced: thus it seems that the Treasury's Regulatory Impact Assessment Team (RIAT) will apparently have no relevant documentation to assess for the carrying out of its task on this amendment and related policy matter.

1.18 Similarly, it seems that the Law Society will not be equipped with adequate documentation so that it may undertake properly its statutory observer role.

1.19 Also, there is arguably no proper documented basis for enabling timely consultation with the general public about this proposed amendment.

1.20 A written request for such documentation was made on behalf of PSGR on 12 December 2014. MoH did not comply with that request indicating in a reply that it wished to treat the request as an OIA procedural matter; MoH also advised that such treatment would result in a delay; and the extent of the likely OIA delay would mean that the adequacy or otherwise of the MoH documentation relating to this matter could not inform the PSGR submission (or other submissions) about MoH consideration (or non-consideration) of relevant matters.

1.21 Such a MoH response raises a suspicion that the MoH had not carried out the required regulatory impact assessment prior to advancing its proposed amendment.

1.22 Such conduct by MoH – coupled with the MoH timing of its public consultation and submission matter to occur over the Christmas/ New Year holiday period - seems to suggest that the MoH was intent upon a cynical and possibly bad faith course to push through the amendment that it wanted in what might reasonably be described as an unaccountable, arbitrary, unlawful and tyrannical manner.

1.23 On examination, it is clear that the imported 'water treatment standards' that MoH adopted within its policy to encourage fluoridation of public water supplies did not take into account the due spectrum of risks as set out in paragraph 7.1 above – and in particular long-term and accumulative effects and strategic implications for the national interest.

**2. Second-order effects of fluoride in water supplies**

2.1 It is arguably not adequate for MoH to formulate a policy on fluoridation of public water supplies without having due regard to (and documenting) such reasonably relevant factors as:

2.1.1 elemental chemical synergy effects on people (e.g. mercury with lead); and

2.1.2 bio-accumulative effects of introduced toxic substances and their synergistic effects on people; and

2.2.3 similar effects associated with safety of concentrated waste-water disposal into the environment.

2.2 For example, the typical form of fluoride used for fluoridation of public water supplies contains the following additional substances – some of which are particularly toxic as well as bio-accumulative and synergistic with one another (increasing their toxicity) in both people and the environment. (Source of the table below is Prayon Rupel S.A., Belgium – a supplier to NZ.)

| Substance | Max. allowable level (MAL) micrograms/l |
|---|---|
| Arsenic | 5 |
| Barium | 200 |
| Beryllium | 0.4 |
| Cadmium | 0.5 |
| Chromium | 10 |
| Copper | 130 |
| Nickel | 10 |
| Lead | 1.5 |
| Antimony | 0.5 |
| Selenium | 5 |
| Thallium | 0.2 |
| Mercury | 0.2 |

2.3 Mercury and lead are particularly synergistic in both their neurotoxicity and their cytoxicity. Neurotoxicity of methyl-mercury is amplified at least 2000 times by the presence of a relatively very small quantity of lead. Both elements are particularly bio-accumulative.

2.4 Lead in the presence of cadmium also enhances materially the toxicity of lead.

2.5 Mercury-containing thimerosal used in vaccines is made a great deal more toxic by being associated with aluminium.

2.6 Fluoride in water supplies has the capacity to strip aluminium from kettles and cooking pots.

2.7 Fluoride in water supplies has the capacity to strip lead from plumbing systems – particularly if water disinfection is also added in the form of chlorine (and that is usually the case in most large municipal water supply systems).

2.8 Lead in brass plumbing systems is usually stabilised and contained by formation of lead oxide and lead dioxide coatings. When chlorine is used as a disinfection agent it tends to disrupt those protective coatings; but the addition of fluoride strips those protective coatings away allowing remaining fluoride to burrow into the lead concentrated on the outer skins of brass fittings.

2.8 There is growing evidence that these examples of toxicity are having epigenetic effects on eggs and sperm; and further are having accumulative toxic effects from gestation through to the end of a person's life.

2.9 Where is the MoH documentation that shows that it has considered all of these categories of likely toxicity in a reasonable way and given them due weight in its formulation of its policy to add fluoride to public drinking water?

2.10 Yet these few factors illustrated above are not an exhaustive list of the likely scale of the combined accumulative and synergistic effect of toxicities associated with the addition of fluoride to public water supplies.

**3. Third-order adverse effects of fluoride in drinking water**

3.1 There is mounting evidence that fluoride in drinking water causes both direct and indirect brain damage *in utero* as well as accumulative material damage to a person's brain during their lifetime. That evidence points to effects that range from materially-lowered IQ; chronic raised levels of inflammation; carcinogenicity; and brain-functioning disorders ranging from ASD through to early Alzheimer's disease (AD).

3.2 Municipal waste water from fluoridated water supplies tends to be disposed of in a concentrated area where the range of toxic materials referred to in para 2.2 above will tend to bio-accumulate in soils, underground aquifers and flow into streams, lakes and river systems.

3.3 Such waste water concentration issues arguably trigger issues of compliance with the purpose and intent of the Resource Management Act 1991. MoH does not seem to have advanced any documentation that shows that it has considered the potential for such third-order adverse effects on the environment when it formulated its fluoridation policy. Yet, there is arguably a statutory duty for MoH to comply with statutory purposes set out in such statutory instruments because they bind the Crown.

3.4 It is submitted that the MoH policy on adding fluoride and its associated toxic substances into public water supplies to the likely inter-generational detriment of peoples' health as well as detriment to the environment should, long ago, have caused MoH to set aside any reasoned pursuit of its idea to advance a policy of fluoridating public water supplies in New Zealand - on the grounds that the risks well out-weighed any possible gains.

3.5 It is not acceptable to administrative law for the MoH to deny evidence of 'a reasonable probability' of significant harm to people and the environment by continuing to claim 'that the present scientific evidence' (I.e. evidence of 95 per cent certainty) has not yet proven that fluoridation of public water supplies in unsafe'. That is arguably a spurious, misleading and unlawful position for the MoH to take.

3.6 It should be clear to the MoH that the available science *does* indicate a reasonable probability of significant inter-generational harm to both people and the environment being caused by its established policy to fluoridate public water supplies.

3.7 Arguably, there is sufficient scientific evidence, for MoH policy formulation purposes, to require the engagement of the precautionary principle and in many instances of the currently available science

engagement of the legal test (greater than a 50 per cent probability) of a reasonable probability of harm. Qualification for either test should, arguably, require MoH to abandon its fluoridation policy.

3.8 For the MoH to further persist with its policy would be against the public interest and therefore illegal.

3.9 Thus, it is arguably an absurdity that the MoH is currently pursuing an 'enabling' amendment to the Medicines Act 1981 so as to advance its grossly-faulted and illegal policy to fluoridate New Zealand public water supplies.

## 4.0 Recommendation

a) That the Ministry of Health should withdraw its policy to pursue fluoridation of public water supplies.

b) That the Ministry of Health should withdraw its application to make an amendment to the Medicines Act 1981 apparently aimed at enabling advancement of its policy to fluoridate public water supplies contrary to safety provisions for medicines that feature in that Act and contrary to the purpose and intent of related health statutes.

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