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Fluoride Free NZ

Fluoride Action Network Incorporated
P O Box 40
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9th January 2015

TO:
Ministry of Health
New Zealand Medicines and Medical Device Safety Authority
P O Box 5013
Wellington

Submission on Medsafe Proposal

"It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies."

Prepared by .
National Coordinator
On behalf of
Fluoride Free New Zealand
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Question 1. Do you support the proposed amendment? If not why not?

Answer to Question 1

No. Fluoride Free New Zealand does not support this proposed new regulation.

Exempting fluoride chemicals from the Medicines Act is an admission that these chemicals are being used as medicines

Only substances that are considered medicines or related products can be exempted from the Medicines Act. Therefore, the Ministry of Health's request to exempt these chemicals is an admission that these chemicals are medicines. The Ministry of Health is then requesting the Government make an unprecedented exception so that these chemicals can be used to medicate communities without applying any of the guidelines, scrutiny and safeguards that is applied to all other medicines.

The Ministry of Health is providing no compelling reason to do this yet there are very good reasons why a Government would not allow this.

When medications are added to the public water supply there is no control of dose, no monitoring of individual reaction and, in this case of fluoridation, there is not even any monitoring of health at the population level. Despite claims by fluoridation proponents that fluoridation has been studied for the past 70 years, these claims are based on endorsements rather than scientific investigation. In fact there is not one study looking at the overall health impact of fluoridation on populations that has found fluoridation to be safe. On the contrary, most Government reviews (e.g. the US National Research

Council's three year, 12 member panel) recommend further research in just about every aspect of human health.

Emails obtained via the Official Information Act, show that Sir Peter Gluckman and Sir David Skegg also relied on other Governmental reviews, rather than doing their own analysis, when producing their report on fluoridation last year. See attached International Critique of that Report.

Reason for proposal is to bypass fluoridation chemicals being subject to normal oversight

Ministry of Health officials claim that the proposal is to provide clarity. Dr Robin Whyman, on TV One News 4th January 2015[1] stated that "It would make it very clear that under the Medicines Act, at the low concentrations we're talking about for community water fluoridation, fluoride in that regard is not a medicine".

Then why add to the water supply? The only claimed reason for adding these chemicals is for the therapeutic purpose of reducing dental decay. But if there is no medicinal effect then there is no reason to add them. The Ministry of Health cannot have it both ways. Fluoride chemicals added to the water supply either provide a therapeutic purpose or they don't. If they do, then they need to come under the Medicines Act, if they don't, there is no need for them and there is no need to exempt them.

It is also misleading and disingenuous for fluoridation promoters to talk about fluoridation in terms of concentration in the water. What is relevant is dose each person is receiving. Attention needs to be given to

[1] http://tvnz.co.nz/national-news/anti-fluoride-campaigners-cry-foul-over-controverisal-legislation-6214457

the huge dose that some people will receive. E.g. a bottle fed baby will receive a dose many times higher than an adult, upwards of 100 times more than a breast fed baby and according to the New Zealand ESR, will often exceed the upper limit.

It also needs to be noted, lowering a dose of medicine does not render it no longer a medicine. If this were true then it would need to be true for all medicines.

Judge Collins decision was patently wrong

Judge Collins found that HFA and SSF satisfied all the key elements of a medicine in that they are used for a therapeutic purpose and they achieve their intended action on the human body by a pharmacological means. He then incorrectly concluded that since they are added at a level less than 10 mg/L (10ppm) that they are not classified as medicines. However, the clause he refers to says "if the medicine is not an injection or eye preparation, only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram" (my emphasis) is in a Section of the Regulations[2] that only refers to Prescription, Restricted and Pharmacy-only medicines and obviously only applies to medicines. If his conclusion was valid, then all the thousands of prescription, restricted and pharmacy-only medicines would no longer be medicines if they were less than 10 mg/L. That would be an absurdity and is not the case. They are still medicines; they are just classified as general sale medicines rather than Prescription, Restricted or Pharmacy-only.

It is patently obvious that Judge Collins decision was wrong. Judge Collins himself must also have been aware that his decision was not

[2] http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM96863.html

robust since he went on to advise the Ministry of Health to apply for an exemption.

New Health New Zealand is appealing this decision. The Ministry of Health officials must realise that no Appeal Court can uphold this decision without the whole judiciary system in New Zealand becoming a kangaroo court. Therefore it appears the real reason for the proposed exemption is so that fluoridation can be continued outside the normal rule of law and public health and safety does not have to be considered in any formal manner.

Proposal in Ambiguous

"..when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies".

Does this mean 1) or 2)?

1) when they are manufactured and supplied for the purpose of fluoridation, or when they are manufactured and distributed for the purpose of fluoridation
2) when they are manufactured and supplied for the purpose of fluoridation, or when they are distributed for the purpose of fluoridation.

If 2) was the correct interpretation then any fluoride containing substance, such as prozac, could be used for fluoridation provided it was distributed for that purpose.

Presumably, the intention is 1). That being the case, only substances manufactured for the purpose of fluoridation would be exempt from the Medicines Act.

Proposal is flawed

Therefore the proposal is flawed. HFA is not manufactured for the purpose of fluoridating community water supplies. HFA is a by-product of the phosphate fertiliser industry. It is not manufactured for the express purpose of fluoridation but happens to end up being used for fluoridation. Therefore, the proposed amendment would not make it legal to add HFA to community water supplies. It possibly could be argued that SSF is manufactured for the purpose of fluoridation since sodium is added to HFA to make it more easily transported to be used for fluoridation.

Even so, the creation of both HFA and SSF is an unintended result of phosphate fertilizer manufacture which industry would have to pay to dispose of if they were not able to sell it to councils for the purpose of fluoridation.

When New Plymouth district council stopped fluoridation in 2011, council spokesman Brent Manning was quoted in the Taranaki Daily News as saying the fluoride could not be returned to the supplier and letting it run out was the cheapest way of disposing of the chemical.[3]

Likewise, when Hamilton city council stopped fluoridation they needed to use up their stocks as they had no other way to dispose of the chemical.

Slippery Slope

The Government embarks on a slippery slope when it amends legislation to overrule laws at the behest of a Government department whenever a department does not like the law.

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[3] http://www.stuff.co.nz/taranaki-daily-news/news/5783079/Beginning-of-the-end-for-fluoridation

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they ?

Answer to Question 2 :

NO. This question is misleading. Fluoride and its compounds are **not** used to **'treat'** community water supplies. The **purpose** of fluoride chemicals added to public water supplies is to **treat people.**

Should medicines or any other substance not used to make the water safe to drink, be added to the public drinking water?

Since issuing an exemption is an admission that these chemicals are medicines, then huge consideration needs to be given to unique practice of adding a medicine to the community water supply.

The Commission of Inquiry in 1957 found that "...the issue concerning rights of individuals has practical importance only after a decision is made:

1. That fluoridation is a desirable process
2. That **the benefits of fluoride cannot effectively be made available by alternative means**
3. That it is **completely safe**

This process (fluoridation) would be **unacceptable if it were ineffective or hazardous**".

All three points can now be disputed:

1. Referenda in fluoridated areas show at least a third of voters are opposed to fluoridation. Referenda in non-fluoridated areas shows two thirds of voters are usually opposed to fluoridation. Only 52% of New Zealanders are receiving fluoridated water.

It is therefore not desirable to a large portion of New Zealand society.

2. Since 1957 there has been the introduction of fluoride toothpaste and fluoride tooth varnishes. According the the Ministry of Health's Oral Health Survey 2009, 93% of New Zealanders use a fluoride toothpaste at least once a day. It is feasible the bulk of the remaining 7% are people who choose to buy a non-fluoride toothpaste.

   Therefore, the benefits of fluoride **can** effectively be made available by alternative means.

3. Since 1957 there have been hundreds, if not thousands of studies, providing evidence of fluoride's toxicity. Some areas of research such as brain development and accumulation of fluoride in soft tissue had not even begun.

   There are now at least 30% of children in fluoridated areas of New Zealand and 15% of children in non-fluoridated areas with some form of dental fluorosis. The only way for a child to get dental fluorosis is if they are over-exposed to fluoride as their teeth are growing. Fluoridation promoters claims that dental fluorosis is "only cosmetic" shows a complete lack of thought and understanding. If a child is over exposed to a heavy metal such as lead they may develop a think blue line on the gum called Burton's Line. Imagine how ignorant it would appear if we were told not to worry about the thin blue line because no one sees your gum. The fact that so many children in New Zealand are displaying this sign of fluoride poisoning should be proof in itself that fluoridation is causing harm.

For more detailed information on fluoride's impact on the brain please see Appendix One *Why Fluoridation should be stopped in New Zealand by Prof Paul Connett*.

Appendix One

Why Fluoridation Should be Ended in New Zealand

A statement by Professor Paul Connett, PhD,

February 2014.

These are my academic credentials:

1) Undergraduate from Cambridge BA (honors) in Natural Sciences 1962.
2) PhD in Chemistry from Dartmouth College, Hanover, NH, USA, 1983

These are the details of my professional experience:

1) I taught chemistry at St. Lawrence University, Canton, NY from 1983 to 2006. My final rank was full professor. My specialty was environmental chemistry and toxicology.

2) From 1985 to 2013 I have been heavily involved in the issue of waste management. This has involved researching the literature on the dangers posed by incinerators and landfills. This research has led to the publication (with my colleague Tom Webster) of six peer-reviewed papers on dioxin; the organizing of three citizens conferences on dioxin; the evaluation of many health risks assessments performed for incinerators; testimony in court cases and public hearings in many states throughout the U.S.; the production over 50 videotapes on the dangers of incinerators and the details of cost-effective and practical alternatives; over 2000 pro bono presentations to communities and local councils in 49 U.S. states, 7 provinces in Canada and 60 other countries, and the publication of several articles on risk assessment and waste management.

This 28-year involvement on the waste issue culminated with the publication in 2013 of the book, *The Zero Waste Solution: Untrashing the Planet One Community at a Time* (Chelsea Green, 2013).

3) From 1996 – 2013 I have been heavily involved with researching fluoride's toxicity and the dangers posed by water fluoridation. This has involved the writing of many articles, editorials and submissions to regulatory authorities,

including an invited 45-minute presentation to the US National Research Council's panel (in 2003) that was reviewing the toxicology of fluoride in water at the invitation of the US Environmental Protection Agency. This panel published its 500-page landmark review in 2006 (NRC, 2006).

A great deal of my research of the literature on the subject of water fluoridation was published with two co-authors in October 2010, *The Case Against Fluoride* (Chelsea Green, 2010).

Since 2000 I have served as the executive director of the Fluoride Action Network (www.AmericanHealthStudies.org).

The Case Against Water Fluoridation in New Zealand

I shall discuss this case under several headings:

1) Fluoridation of the public water supply is a bad medical practice
2) The evidence of harm is growing
3) The evidence for any benefit from swallowing fluoride is very weak.
4) The trial that launched fluoridation in NZ was a fraud.

1) Fluoridation of the public water supply is a bad medical practice

In my view this practice should have never begun in NZ or anywhere else. The use of the public water supply *anywhere* to deliver medical treatment is thwart with problems both practical and ethical. I will list some of these problems below.

a) It is impossible to control the dose people get.

Once a chemical is added to the water to treat people (as opposed to treating the water to make it safe or palatable to drink) it is impossible to control the dose people get. People drink very different amounts of water. In short, engineers at the water works can control the concentration added to the water (mg/liter) but no one can control the total dose (mg/day) individuals receive or the dosage (mg/kg/day) that bottle-fed infants receive, a critical consideration because of their very small bodyweight.

b) It is totally indiscriminate.

It goes to everyone regardless of age, regardless of health or nutritional status.

Of particular concern – as mentioned above - is that it goes to bottle-fed infants, who are more impacted than adults by the *same* dose, because of their small bodyweight.

Also of concern are people with poor kidney function who are unable to clear the fluoride from their bodies via the kidneys as effectively as others. It thus accumulates in their bones more rapidly.

It also goes to people with low or borderline iodine intake, which makes them more vulnerable to fluoride's impact on the thyroid gland (Lin et al., 1991).

In general, according to studies done in India, people with poor diet (low protein, low calcium and low vitamin intake) are more vulnerable to fluoride's toxic effects.

c) It violates the individual's right to informed consent to medical treatment.

Thus water fluoridation is a violation of a very important medical ethic which is fully described on the website of the American Medical Association (www.AMA.org). It is very surprising that so many medical doctors standby while the community does to everyone what they are not allowed to do to a single patient.

The above arguments would apply to any medicine added to the drinking water and that probably explains why since fluoridation has begun the public water supply has not been used for any other medical treatment. But in addition to the general arguments above, there are other aspects to the fluoride ion, which makes it particularly unsuitable for addition to the drinking water.

d) Fluoride is NOT a nutrient.

There is not one single biochemical process in the body that has been shown to require fluoride for normal function (we will see later that fluoride's predominant action on teeth is topical not systemic). However,

e) There are many biochemical processes that are harmed by fluoride (given a sufficient dose).

These include the inhibition of many enzymes. This is the reason that some of the earliest opponents of fluoridation were biochemists like Professor James Sumner from Cornell University, who won the Nobel Prize for his work on enzyme chemistry. More recently fluoride has been shown to activate G-proteins and interfere with the cell's messaging systems. It can also cause oxidative stress. An excellent summary of fluoride's biochemistry can be found in the article "Molecular Mechanisms of Fluoride Toxicity" by Barbier et al, 2010.

f) The levels of fluoride in mothers' milk is extremely low.

This level, on average for a woman in a non-fluoridated community, is 0.004 ppm (NRC, 2006, p.40). This means that a bottle-fed baby in a fluoridated community (at 1 ppm) will get about 250 times more fluoride than a breast fed baby in a non-fluoridated community. Bearing in mind the fact that life emerged from the sea where the average level of fluoride is about 1.4 ppm (in other words there was no impediment for nature to use fluoride in the early evolution of the biochemistry of living creatures) it is remarkable that, other than accumulating in the teeth of sharks, there is little evidence that nature has found any use for this ion in the metabolism of any aquatic or mammalian species, including humans. This is consistent with the low levels in human milk. Nature's verdict appears to be that the baby a) does not need fluoride and b) that it may be harmed by fluoride. In my view, it is more likely that nature knows more about what the baby needs than those who so enthusiastically promote the practice of fluoridation.

g) Fluoridation has always been a trade-off between lowered tooth decay and an increase in the prevalence of dental fluorosis (discoloration and mottling of the enamel) but a key question was never satisfactorily answered.

When the fluoridation trials began in 1945 it was known that the trade off was that approximately 10% of the children would develop dental fluorosis in its

mildest form. While the exact mechanism whereby fluoride caused this effect was not known it was known to be a *systemic* effect. In other words, it was caused by fluoride interfering with biochemistry during the formation of the enamel during the development of the teeth. The question that was not comprehensively answered before the US Public Health Service endorsed fluoridation in 1950, was: "What other tissues in the body may be interfered with at the same time that fluoride was interfering with the laying down of the tooth enamel?"

One would have reasonably anticipated that diligent efforts would have been pursued to answer the following key questions before fluoridation began:

i) Will the baby's bone cells also be impacted?
ii) How about the baby's brain cells?
iii) How about the cells of the glands in the endocrine system?

Sadly, these questions were not pursued in the 1940's and 1950's in any depth in the U.S. and very little has been done in fluoridated countries to answer these questions since fluoridation began.

However, proponents do acknowledge that the appearance of dental fluorosis means that a child has been over-exposed to fluoride before the permanent teeth have erupted. The extent to which this is impacting children today in fluoridated countries is disturbing. In 2000, the review commissioned by the UK government (otherwise referred to as the York Review, estimated that worldwide that the average dental prevalence in communities where the levels of fluoride were about 1 ppm, was 48% with 12.5% at levels of aesthetic concern (McDonagh et al., 2000).

In 2010 the CDC reported that 41% of American children aged 12-15 have dental fluorosis, with 8.6% having the *mild* form (with up to 50% of the enamel impacted) and 3.6% with *moderate* or *severe* dental fluorosis (100% of the enamel impacted). In later arguments in this commentary I will be presenting evidence that fluoride is capable of harming other developing tissues, not just the teeth.

h) Worldwide, fluoridation is not a common practice.

Proponents will often imply that fluoridating the drinking water is a common practice. It is not. Most countries do not fluoridate their water. 97% of the European population is not forced to drink fluoridated water. Four European countries have salt fluoridation (Germany, France, Switzerland and Austria), but the majority of European countries have neither fluoridated water nor fluoridated salt, yet according to World Health Organization (WHO) data available online (measured as DMFT in 12-year-olds) tooth decay rates in 12-year-olds have declined as rapidly over the period 1960 to the present in non-fluoridated countries as fluoridated ones and there is little difference in tooth decay rates today (see Cheng et al, 2007). The reasons that European spokespersons have given for not fluoridating their water are usually twofold: a) they do not want to force fluoride on people who don't want it and b) there are still many unresolved health issues (see a list of statements by country at http://fluoridealert.org/studies/caries01).

i) Typically fluoridation is promoted via endorsements not via sound science.

When the US Public Health Service (PHS) endorsed fluoridation in 1950, before a single trial had been completed and before any meaningful health studies had been published, it clearly was not the result of solid scientific research. However the PHS endorsement set off a flood of endorsements from other health agencies and professional bodies (see Chapters 9 and 10 in *The Case Against Fluoride*). Most of these came between 1950 and 1952. These endorsements were not scientific (there was no solid science that had been established at this point for either effectiveness – none of the trials had been completed –or safety. These endorsements simply reflected a subservience to the public policy interests of the U.S. government by professional bodies. However, promoters of fluoridation for over 60 years have used these endorsements very effectively with the general public as if they were coming from scientific bodies reflecting thorough and comprehensive scientific research. Very seldom is this the case.

2) The evidence of harm is growing

2.1 NZ presents a complicated case

Commenting on the potential adverse health effects of the water fluoridation program in NZ is complicated by the fact that the NZ government has undertaken very few health studies of fluoridated communities since fluoridation was instituted in the 1960s. An independent observer of this practice in NZ like myself is thus forced to gauge the risks of this program in NZ based upon health studies conducted elsewhere.

2.2 Fluoridated countries worldwide have undertaken very few health studies in fluoridated communities.

NZ is not alone in its failure to undertake health studies in fluoridated communities. Most of the fluoridating countries have paid far more attention to promoting the practice of water fluoridation and researching its claimed benefits than investigating any harm it may be causing except for the acknowledged risk of dental fluorosis. Today more effort is going into denying harm than investigating it.

This situation has pertained since 1950 when the US Public Health Service officially endorsed water fluoridation. Since then the wisdom of this practice has been accepted by the Public Health community in the U.S. and other fluoridating countries almost without question (see Chapters 9 and 10, in *The Case Against Fluoride...)*

When assessing harm one is forced to look to studies undertaken in countries, which do not have a fluoridation program to protect. The most important of these are India and China, which have extensive areas with moderate to high levels of fluoride in their drinking water leading to areas, which have made them endemic for both dental and skeletal fluorosis (China News. 2008).

2.3 Studies from countries with endemic fluorosis

In addition to the damage fluoride causes to both the teeth and bone (Li et al., 2001. See also the other bone studies listed in Chapter 17 in *The Case Against Fluoride* ...), it is now becoming clear that fluoride impacts some of the soft tissues

(e.g. the brain) before the damage to teeth in children and bones in adults become obvious and visible.

2.4 The weight of evidence that fluoride damages the brain

Since the early 1990s that have been a large number of studies that fluoride can damage the brain and interfere with neurological development in both animals and children. These include:

> **Over 40 animal studies** that show that prolonged exposure to fluoride can damage the brain (e.g. Varner et al., 1998).
>
> **19 animal studies** that report that mice or rats ingesting fluoride have an impaired capacity to learn and remember.
>
> **12 studies** (7 human, 5 animal) that link fluoride with neurobehavioral deficits (e.g. Mullenix et al., 1995)
>
> **3 human studies that** link fluoride exposure with impaired fetal brain development, and
>
> **37 out of 43 published studies that show that fluoride lowers IQ,** of which 27 were part of a meta-analysis conducted by a team from Harvard (Choi et al. 2012), which included Phillipe Grandjean (www.fluoridealert.org/issues/health/brain)

2.5 A closer look at the IQ studies

After the Harvard University team led by Choi published its meta-analysis of 27 of the IQ studies (most of them conducted in rural China) promoters of fluoridation have claimed that a) there are weaknesses in some of these studies and b) that the concentration of fluoride in the villages where IQ was lowered was too high to be of any significance.

Choi et al., 2012, have acknowledged that there are weaknesses in many of the IQ studies but that nonetheless the results were remarkably consistent with 26 out

of 27 studies with the high-fluoride villages showing a lower IQ than the low-fluoride villages. The average overall lowering was about 7 IQ points, which is quite substantial.

As far as the claim of high concentrations is concerned it is true that in two of the 27 studies reviewed the range of concentration in the well water in the high-fluoride village went as high as 11.5 ppm. However, in 9 of the 27 studies the level of fluoride in the high-fluoride village was lower than 3 ppm (see Table 1 below), which is highly relevant to communities drinking water fluoridated water at about 1 ppm, which we will see below.

TABLE 1

Studies with water F concentration below 3 ppm in "higher F group"

Study	IQ point difference	Statistically significant?	water F concentration "high F group" (mg/L)
Lin et al. 1991	-9.6	Yes	0.88
Xu et al. 1994	-14.0	Yes	1.8
Yang et al. 1994	-7.5	No	2.97
Yao et al. 1997	-6.5	Yes	2
Hong et al. 2001	-6.6	Yes	2.90
Wang SH et al. 2001	-7.5	No	2.97
Seraj et al. 2006	-13.4	Yes	2.5
Li XH et al. 2010	+1.1	No	1.79 *
Poureslami et al. 2011	-6.2	Yes	2.38
Averages	-7.8	Yes	2.24

* NOTE: Probably reporting error in Choi paper. Used value from Li 2009 which appear to be the correct values. Also, used middle of range of high F exposure.

Even though these studies were of an ecological design (i.e. comparison was made based upon exposure at a specific geographical location), several of the studies measured the fluoride in the urine of the children and found an inverse correlation with IQ (e.g. Xiang et al., 2003; Ding et al, 2010). Also Xiang et al.,

2011, reported an inverse correlation between the lowering of IQ and the fluoride levels in the plasma of the children. These measures of *individual exposure* to fluoride strengthen the findings of the ecological studies (exposure gauged by location) for this association between exposure to fluoride and lowered IQ.

2.6 Using the IQ studies to assess the risks posed to the NZ population

Before I get into a detailed risk assessment on this matter, I will briefly go through some of the concepts involved in how regulatory bodies determine safe reference doses and safe drinking water standards.

2.6.1 We must take into account the large range of sensitivity to any toxic substance

In any large population we can anticipate a very large range of sensitivity to any toxic substance. Like other human traits such sensitivity follows a normal distribution curve (the famous bell-shaped curve). The average person will have an average response but at the tails of this curve we will have people who are i) very sensitive at one end and ii) very resistant at the other. Typically we assume some people are going to be at least 10 times more sensitive than others. This is then used to generate a safety factor of 10 (sometimes referred to as the intra-species variation safety factor).

Thus if we find harm in a small human study and wish to determine the level that would protect everyone in a large population from that harm this is what we must do. We take the dose, which has been found to cause no harm (the so-called no observable adverse effect level or NOAEL) and divide that dose by 10 to give a safe dose for the most sensitive individual in the population. Frequently we don't have a NOAEL and so we have to use a LOAEL (the lowest observable adverse effect level) and divide that by 100.

2.6.2 We must estimate doses, not just compare concentrations

Applying these calculations in a real world situation is called a Margin of Safety Analysis and shockingly it is very seldom considered by people who promote fluoridation. They simply use the very crude and highly misleading approach of comparing the *concentration* used in the study group with the *concentration* of the fluoride in the water of the fluoridated population.

For example, the American Dental Association denied the relevance of the National Research Council's groundbreaking review on the toxicology of fluoride in drinking water (NRC, 2006), to water fluoridation because they argued that the NRC panel only found harm in the range of 2 – 4 ppm and in the US we fluoridate in the range of 0.7- 1.2 ppm.

One of several things wrong with this argument is that above-average water drinkers in communities with 0.7 – 1.2 ppm could easily get higher **doses** than some of the below-average water drinkers in the communities studied at 2 ppm and even 4 ppm. **In short, the concentrations maybe different but the doses overlap – and it is the dose that can cause harm.**

So I will now attempt a margin of safety analysis based upon the IQ studies

2.7 A Margin of Safety analysis using the IQ studies

I will use the fact that 9 of 27 studies have found an IQ lowering at less than 3 ppm fluoride. Strictly speaking I should use the lowest concentration where a lowering of IQ occurred and that was 0.9 ppm (Lin et al, 1991) but that is complicated by the iodine levels involved. I could also have used the threshold found by Xiang et al (2003 a,b) of 1.9 ppm as the NOAEL, but I prefer the more conservative approach of using the lowest level found to lower IQ in 5 of the studies listed in Table 2 where the result (lowered IQ) occurred at less than 3 ppm and was statistically significant.

Table 2

IQ studies with water F concentration below 3 mg/L in "higher F group", and with statistically significant results

Study	IQ point difference	Water F concentration "high F group" (mg/L)
Lin et al. 1991	-9.6	0.88
Xu et al. 1994	-14.0	1.8
Yao et al. 1997	-6.5	2
Hong et al. 2001	-6.6	2.90
Seraj et al. 2006	-13.4	2.5
Poureslami et al. 2011	-6.2	2.38
Averages	**-9.4**	**2.08**

2.8 A Margin of Safety analysis –calculations

Step a) As our starting point I will choose the study that found a lowering of IQ at the lowest concentration. That was 1.8 ppm (see Table 2).

Step b) Our next task is to estimate the reasonable dose range this represents for the children in the study group – which of course, will depend on how much water they drink and how much they get from other sources. We believe very few of these rural Chinese children use fluoridated toothpaste and thus their daily dose comes largely from the water.

- If they drank 2 liters of water per day at 1.8 mg/liter (i.e. 1.8 ppm) their daily dose would be (2 L x 1.8 mg/L) = 3.6 mg/day.

- If they drank 1 liter of water per day their daily dose would be 1.8 mg/day

- If they drank 0.5 liters of water per day their daily dose would be approx 0.9 mg/day.

In other words a reasonable estimate of the range of the dose leading to a lowered IQ was approximately 0.9 – 3.6 mg/day.

Step c) Our third task is to determine a safe dose to protect all the infants and children from lowered IQ *in a large population.*

From this range the LOAEL is 0.9 mg/day. We do not have a NOAEL so we have to divide the LOAEL by 10. So the NOAEL = 0.09mg/day.

Now we need to divide this NOAEL by another factor of 10 to protect for the full range of sensitivity in a large population. Thus the safe dose to protect all children for lowered IQ (the safe reference dose is 0.009 mg/day

Thus we would not want any child in a large population drinking more than 9 ml of water fluoridated at 1 ppm to protect against lowered IQ. 9 ml is one or two teaspoonfuls of water!

Here is the calculation. 9 ml = 0.009 Liters. 0.009 L x 1 mg/L = 0.009 mg/day

2.9 A Margin of Safety analysis –conclusion

Based upon the five IQ studies that were statistically significant and found a lowering of IQ at less than 3 ppm a responsible regulatory authority would not allow water fluoridation. There simply is not an adequate margin of safety to protect all of NZ's children from lowered IQ. **This result makes fluoridation an unacceptable risk.** Little wonder then that fluoridation promoters are doing everything they can to criticize these IQ studies.

Recently (Feb 3, 2014) on TV3 Dr. Broadbent announced the results of a, as yet unpublished, IQ study conducted in Dunedin, NZ, which he claims negates the concerns about IQ lowering. Needless to say independent observers will be examining this study to see how sound the methodology and conclusions are.

2.10 Fluoride exposure in babies and the risk of lowered IQ. A Comparison between a breast-fed baby and a bottle-fed baby.

When considering harm to babies we have to take into account the extra problem of the baby's small bodyweight. To take bodyweight into account we use a different measure of exposure: i.e. *dosage* instead of *dose*.

Dose is measured in mg/day, **dosage** is measured in mg/kilogram bodyweight/day.

If we consider that the safe dose we have determined (0.009 mg/day) was protective of a 20 kg child, then we would obtain the safe dosage by dividing this safe dose by the 20 kg bodyweight (0.009 mg/day divided by 20 kg = 0.00045 mg/kg/day). Thus a safe *dosage*, which we can now apply across a range of bodyweights (including a 7 kg baby) is 0.00045 mg/kg/day.

Applying this safe *dosage* to a 7 kg baby we can calculate the safe *dose* by multiplying this dosage by 7 kg. Thus the safe dose for a 7 kg baby would be calculated as follows: 7 kg x 0.00045 mg/kg/day = 0.00315 mg/day.

A breast fed baby (with mothers milk at 0.004 ppm) drinking 800 ml a day would get 0.004 mg/L x 0.8 L = 0.0032 mg/day which is just about what we have determined to be safe for the baby (0.00315 mg/day).

So based on these calculations, the fluoride that naturally occurs in breast milk does not pose a risk of lowering the IQ in babies.

A bottle-fed baby (with water at 0.7 ppm) drinking 800 ml a day would get 0.7 mg/L x 0.8 Liters = 0.56 mg/day. This is 0.56/0.00315 = approx **180 times higher** than the safe level to protect against lower IQ

A bottle-fed baby (with water at 1.2 ppm) drinking 800 ml a day would get 1.2 mg/L x 0.8 Liters = 0.96 mg/day. This is 0.96/0.00315 = approx **300 times higher** than the safe level to protect against lower IQ

So whether by accident or by evolutionary "design" mothers' milk is protective against lowered IQ but formula made up with fluoridated water (0.7-1.2 ppm) is not. **The latter delivers a daily dose of fluoride, which is a factor of 180-300 times larger than a safe dose calculated for a 7 kg baby.**

2.11 Why is a small downward shift in IQ significant for the whole population

Even a small downward shift in IQ for *the whole population* maybe highly significant. As Philippe Grandjean (one of the authors of the Harvard meta-analysis by Choi et al, 2012) in his new book (*Only Once Chance*) explains, a negative shift of 5 IQ points would halve the number of geniuses in our society and double the number of mentally handicapped.

The downward shift caused by fluoride exposure may not be as great as 5 IQ points but nonetheless it is not wise to deliberately add any substance to the water that is known or reasonably anticipated - to cause harm to the neurological development of children.

2.12 The numerous IQ studies underline the recklessness of the fluoridation program

This program was reckless because before it was endorsed by the US Public Health Service there had been no serious attempt to investigate:

> a) short-term health effects of exposing babies to 250 times the level of the fluoride that naturally occurs in mothers' milk at very low levels (1 ppm versus 0.004 ppm, NRC, 2006 p.40)
>
> b) the affect on adults' bones and other tissues with lifetime exposure, even though it was known that fluoride accumulates in the bone

It is even more reckless today now that it is known that there is no adequate margin of safety to protect all citizens, including infants, from the known harm documented in India, China and other countries with high natural levels of fluoride (NRC, 2006).

It is reckless to deliver fluoride in the public water system when it is recognized there is no way we can control the dose people receive. This becomes more serious with such a narrow margin of safety for several end points documented by the NRC (2006).

It is reckless because the NRC (2006) panel reported that certain subsets of the population were exceeding the US EPA's safe reference dosage of 0.06 mg/kg/day (the so-called IRIS level) drinking water at 1 ppm. These subsets included bottle-fed infants, people with poor kidney function and above average water

consumers. Delivery of fluoride to these vulnerable subsets cannot be controlled in any way once fluoride is added to the water.

It is reckless because after 68 years of this practice there are still many unanswered questions about the risks involved. For example the chairman of the NRC (2006) review panel said the following in an interview in Scientific American in January 2008:

> "What the committee found is that we've gone with the status quo regarding fluoride for many years—for too long really—and now we need to take a fresh look . . .In the scientific community people tend to think this is settled. I mean, when the U.S. surgeon general comes out and says this is one of the top 10 greatest achievements of the 20th century, that's a hard hurdle to get over. But when we looked at the studies that have been done, we found that many of these questions are unsettled and we have much less information than we should, considering how long this [fluoridation] has been going on." (Fagin, 2008).

Fluoridation promoters have since circulated a later statement by Doull expressing his support for water fluoridation. However, his own personal opinion of water fluoridation does not diminish in any way his comments on the poor quality of the research on this matter.

It is reckless because even after many research questions were recommended by the NRC (2006) panel, very few, if any, of these research questions have been pursued in the U.S., NZ or any other fluoridated country, in the 7 years since this review was published.

It is reckless because many European countries have demonstrated that there are cost-effective and practical alternatives to fighting tooth decay in children of low-income families (where most of the tooth decay occurs today) which do not involved the unethical practice of forcing fluoride on people that don't want it.

The most recent success story comes from Scotland.

Instead of water fluoridation, the newly devolved Scottish Government opted, in its 2005 dental action plan (their Childsmile program), to pursue:

a) school-based toothbrushing schemes;

b) the offering of healthy snacks and drinks to children;

c) oral health advice to children and families on healthy weaning, diet, teething and toothbrushing;

d) annual dental check-ups and treatment if required, and

e) fluoride varnish applications (The Scottish Government, 2005; Macpherson LMD et al., 2010; Turner S et al., 2010; Chestnutt, 2013; Healthier Scotland, Scottish Government, 2013).

Encouraging results have been reported from this national dental programme with the proportion of children in Primary 1 (aged 4–6 years) without obvious dental decay rising from 42.3% in 1996 to 67% in 2012 (Information Services Division Scotland, 2012).

Similarly, the proportion of children in Primary 7 (aged 10–12 years) without obvious dental decay rose from 52.9% in 2005 to 69.4% in 2011 and 72.8% in 2013 (Information Services Division Scotland, 2013).

The introduction and uptake of nursery school toothbrushing is likely to have contributed to a large extent to the improved oral health in five-year-old Scottish children (Macpherson, 2013).

The BBC reported the success and cost-effectiveness of this program as follows,

"A scheme to encourage nursery children to brush their teeth has saved more than £6m in dental costs, according to a new study.

Childsmile involves staff at all Scottish nurseries offering free supervised toothbrushing every day.

Glasgow researchers found that the scheme had reduced the cost of treating dental disease in five-year-olds by more than half between 2001 and 2010.

The programme was launched in 2001 and costs about £1.8m a year...

An evaluation, funded by the Scottish government and carried out by Glasgow University, found that fewer children needed dental extractions, fillings or general anaesthetics as a result of the programme.

There was also said to be a drop in the number of children needing hospital treatment for dental problems, freeing up operating theatres.

Public Health Minister Michael Matheson said: "This is an amazing achievement and shows just how much can be saved from a very simple health intervention.

"This has seen less tooth decay in children which means less toothache, fewer sleepless nights and less time off school.

"By this simple measure, NHS costs associated with the dental disease of five-year-old children have decreased dramatically.

"More children can just be treated routinely in the dental chair because they need less invasive treatments, so fewer fillings and fewer extractions, and many more children with much better oral health than we have seen in many years." *http://fluoridealert.org/news/nursery-toothbrushing-saves-6m-in-dental-costs/*

2.13 Making matters even worse

The fluoridating chemicals used to fluoridate the water supply are not the pharmaceutical grade chemicals as used in dental products. Most of the chemicals used are obtained from the phosphate fertilizer industry's wet scrubbing systems (see Chapter 3, *The Case Against Fluoride*). One of the problems with this source is that it is contaminated with a number of other toxic chemicals including arsenic and even trace amounts of radioactive elements.

Arsenic is a known human carcinogen and as such for the US Environmental Protection Agency (EPA) there is no safe level. The EPA's maximum contaminant level goal (MCLG) for arsenic in drinking water is thus set at zero. This is the ideal goal based on what is safe i.e. to reduce cancer risk. Fluoridation proponents will argue that after the dilution of these bulk chemicals at the waterworks (by about 200,000 to 1), the level of arsenic is negligible.

They will further argue that this level of arsenic (after dilution) is OK because it is lower than the Maximum Contaminant Level (MCL) set by the US Environmental Protection Agency. The EPA's MCL for arsenic is 10 ppb. But to use this as a

yardstick for what can be ADDED to the water is to confuse the purpose of this standard. As I indicated above the MCLG (the ideal goal) is set at ZERO for HEALTH reasons. The MCL is set at 10 ppb for ECONOMIC reasons. This is to accommodate communities that have naturally occurring arsenic in their water. For them it would be prohibitively expensive to reach the MCLG – thus the MCL is as compromise between what you ideally want and what you can achieve economically.

It is one thing to set a standard (MCL) to accommodate REMOVAL of arsenic but another thing to use this standard to allow the deliberate ADDITION of arsenic and thus exceed the desired MCLG of zero. This especially applies to an unnecessary practice like fluoridation. As there are other delivery systems (for fluoride) which are cost-effective and do not involve the use of these industrial grade chemicals, increasing the cancer rate even by a small amount is not responsible or acceptable.

In addition to the cancer risks posed by the arsenic present in the fluoridating chemicals used are the cancer risks posed by fluoride itself, especially the risk for osteosarcoma.

2.14 Osteosarcoma: politics versus science.

Introduction. There was a discovery made in 2001, which, in my view, should have ended fluoridation once and for all. This finding indicated that fluoridation may actually be killing a few – not many –young men each year with a deadly bone cancer called osteosacoma. But that discovery was hidden for four years. Even after the findings were revealed political efforts have continued to downplay or even dismiss these findings. However, there has been no published scientific study that has refuted them. Let me explain.

a) The discovery in 2001 occurred when Elise Bassin, a dentist completing her doctoral thesis at the Harvard Dental School, found in a carefully conducted matched case-control study, that young boys exposed to fluoridated water at 1 ppm in their 6^{th} to 8^{th} years had an associated 5-7 fold increased risk of succumbing to osteosarcoma. Osteosarcoma is a rare but frequently fatal bone cancer.

b) Bassin's study was first hidden (politics) from the public and scientific community, but was eventually published in 2006. Despite promises from her thesis adviser that his larger study would refute her finding (politics), his study when it was finally published in 2011 failed to do so (Kim et al., 2011).

c) So what we have here is an *unrefuted* study that indicates that a *few* young boys may be losing their lives drinking fluoridated water. I am really amazed that promoters of fluoridation can take this issue so lightly. The small number involved should not justify turning a blind eye to this. As John Colquhoun asked in my videotaped interview with him in 1997 is any saving in tooth decay an adequate exchange for "**one death of a teenage boy from osteosarcoma.**" (http://fluoridealert.org/fan-tv/colquhoun/),

d) I am also disturbed that the Pew Charitable Trusts (a multibillion dollar foundation that is actively campaigning in support of fluoridation) would mischievously claim that the Kim et al (2011) study has put the matter to rest when it clearly has not.

e) The issue of fluoride and osteosarcoma has a long and fascinating history. There is a lot of politics involved, which is not surprising because if this connection was proven it would (or should) end fluoridation immediately. We go into this history in some detail in Chapter 18 of our book, *The Case Against Fluoride*... Below I have provided a timeline (a more elaborate timeline with full references to all the studies cited can be found at http://fluoridealert.org/studies/cancer05/):

> **1955.** The bone specialist who studied the bone X-rays of the children in the Newburgh-Kingston trial, pointed out that the age, gender and anatomical distribution of these cortical bone effects were remarkably similar to the occurrence of osteosarcoma (Caffey, 1955).
>
> **1963.** Harold Hodge referred to Caffey's observations in 1963, when he stated that, "The higher incidence of cortical defects in the Newburgh children's long bones, although these changes are considered by the specialist in children's roentgenology to be 'normal' variants (Coffey (sic) 1955) deserves additional study" (Hodge, 1963).

1977. Donald Taves, in a report written for the National Academy of Science, reiterated Hodge's thoughts but in more detail:

There was an observation in the Kingston-Newburgh (Ast et al., 1956) study that was considered spurious and has never been followed up. There was a 13.5% incidence of cortical defects in bone in the fluoridated community but only 7.5% in the nonfluoridated community. With 474 and 375 children in the respective groups, the t value was 2.85, which is statistically significant (Schlesinger, 1956). Caffey (1955) noted that the age, sex, and anatomical distribution of these bone defects are "strikingly" similar to that of osteogenic sarcoma. **While progression of cortical defects to malignancies has not been observed clinically, it would be important to have direct evidence that osteogenic sarcoma rates in males under 30 have not increased with fluoridation** [emphasis added]. (NAS, 1977).

1990. The long awaited animal cancer study for fluoride, ordered by the US Congress from the National Toxicology Program (NTP) in 1979, was finally published. The NTP reported a higher incidence of osteosarcoma in the fluoride treated ***male*** **rats** compared to controls, but none in the female rats or in male or female mice.

1991. Prompted by findings in the NTP study the National Cancer Institute (NCI) looked at the SEER (Surveillance, Epidemiology, and End Results Program) cancer registries of the US and found an increase in osteosarcoma in young males (but not females) in some of the fluoridated versus non-fluoridated areas (Hoover et al, 1991 a [Appendix E]). The NCI then discounted this finding based upon reanalyses that looked at osteosarcoma rates in relation to duration of fluoridation (Hoover, 1991, b [Appendix F]). However, these reanalyses suffered from low statistical power because they were based on very small numbers per category, as few as a single osteosarcoma. Even more serious, in his reanalysis Hoover mistakenly classified many counties as "non-fluoridated" because he did not realize that amongst these Iowa counties, a majority had high enough natural fluoride levels to meet his criteria for "fluoridated". This misclassification – calling fluoridated areas non-fluoridated – further explains why his reanalysis failed to confirm his initial findings of a connection between osteosarcoma and fluoridation.

1991. A small study from the Harvard Medical and Dental Schools, co-authored by Chester Douglass (see below) did not find a relationship between fluoridation and oesteosarcoma and even suggested that fluoride might protect against fluoridation. This study was given front-page coverage by the *Journal of the American Medical Association* (McGuire et al, 1991).

1992. A small study by Perry Cohn (working for the NJ Department of Health) found a higher incidence of osteosarcoma among **young males** (but not young females) in three fluoridated counties in NJ compared to non-fluoridated areas.

Cohn made an interesting conjecture. He wondered if there was a particular age window that could explain the vulnerability for young boys in this matter. That question lay fallow for a number of years.

1992-2000. Other studies were published did not find a positive association between fluoridation and increased osteosarcoma.

2001. Bassin successfully defended her doctoral thesis at the Harvard Dental School which identified that "age window of vulnerability" that Cohn had suggested (see details above).

2001-2005. Even though Bassin's thesis advisor Professor Chester Douglass had signed off on her thesis, in the three years that elapsed after her research was successfully defended he did not warn his peers, the NRC panel or his funders of this dramatic finding (politics). Instead he kept insisting when asked that his "own" study found no relation between osteosarcoma and fluoridation, without indicating that his own graduate student had found the opposite to be the case.

Douglass knew of course if this connection between fluoridation and osteosarcoma was established that it would end fluoridation and stated as much in a paper he had co-authored ten years earlier (McGuire et al.,1991).

2005. Eventually Bassin's doctoral thesis was found sitting in one of the Harvard libraries in 2005. The Environmental Working Group charged Douglass with academic misconduct for hiding this finding and asked the NIH (which had funded the study) to investigate. The investigation was handed over to Harvard. A committee appointed by the Harvard Dental and Medical Schools investigated the matter and in a short 4-paragraph statement exonerated Douglass suggesting the he did not "deliberately" hide these findings. Harvard refused repeated attempts for tem to provide the basis for this decision but they refused.

2006. Bassin's thesis was subsequently published in the journal *Cancer Causes and Control* (Bassin et al., 2006). In the same issue of the journal a letter was published from Douglass and another graduate student that stated that his larger study would show that Bassin's thesis did not hold (Douglass and Joshipura, 2006). Douglass told the NRC panel that this larger study would be available in the Summer, 2006. But it did not appear for five years.

Meanwhile, Douglass' promise of a study *in a letter* was used by the NHMRC (2007); Health Canada (2011) and health authorities in the UK as if it was an actually peer-reviewed and published study.

2011. Eventually the Douglass paper was published in 2011, but not in the original cancer journal where his claims were made, nor in a medical journal, but in a *dental* journal (Kim et al., 2011). It is a very poor study with many flaws but the key fact is that it did not refute Bassin's findings. Nor could it possibly do so. Because the biometric of exposure was fluoride levels in the bones. There is no way such levels could be used to determine the exposure to fluoride during the critical *age window of vulnerability* found by Bassin (the 6th to 8th years).

f) Conclusion: a well-researched study found a possible and highly plausible relationship between exposure to fluoridated water - at a specific age range in young boys - and a rare but frequently fatal bone cancer. Despite promises to the contrary, which before publication were used by fluoridation promoters inside and outside of government agencies to downplay these findings, this study has never been refuted.

g) As with the lowering of IQ (discussed above) we are talking serious risks here. When even prominent promoters of fluoridation have acknowledged that the *predominant* benefit of fluoride is topical and not systemic (CDC, 1999 and 2001), which means that these benefits can be achieved by other means (e.g. fluoride varnishes in children and fluoridated toothpaste for adults) and when, it is clear that tooth decay is being reduced in the vast majority of countries that neither fluoridate their water, nor their salt, nor their milk, why would anyone today defend putting fluoride into the public drinking water?

3) The evidence for any benefit from swallowing fluoride is very weak.

It comes as a surprise to many that despite claims to the contrary by proponents the evidence that swallowing fluoride reduces tooth decay is very weak. We discuss this weak evidence in chapters 6-8 in our book *The Case Against Fluoride...*

Remarkably in the 68 years of this practice there has not been a single randomized control trial (RCT) to demonstrate the effectiveness of swallowing fluoride to reduce tooth decay. An RCT is the gold standard as far as demonstrating the effectiveness of any medicine or treatment is concerned.

The result is that promoters have had to rely on far weaker studies – usually ecological studies comparing tooth decay between fluoridated and non-fluoridated communities. This is thwart with difficulties because there are so many confounding factors (income levels, diet, other minerals in the water, level of sunshine affecting Vitamin D3 levels, the possible delayed eruption of the teeth caused by fluoride) effecting tooth decay and if these are not all carefully controlled erroneous results and conclusions can be drawn.

Here I would like to draw attention to just two studies. One because it was very large and the other because it was very precise. These were the studies by Brunelle and Carlos (1990) and Warren et al. (2009).

Both these studies were funded by the US taxpayer and both were conducted by pro-fluoridation researchers. So if there were any bias involved it would not have been in favor of the anti-fluoridation position.

Brunelle and Carlos (1990). This was the largest survey of tooth decay ever undertaken in the U.S. The study was administered by the National Institute for Dental Research (NIDR) now called the National Institute for Dental and Cranial Research (NIDCR). The teeth of 39,000 children from 84 communities were examined. In Table 6 of this report the authors compare the Decayed Missing and Filled Surfaces (DMFS) for children (aged 5-17) who had always lived in a fluoridated community with children who had never lived in a fluoridated community. There were about 8000 children in each group. The average DMFS for children in the fluoridated communities was 2.8 and in the non-fluoridated was 3.4. Thus the average saving was 3.4 – 2.8 = 0.6 tooth surfaces. The extraordinary aspect of this report was the authors, even though this was a government-funded study, did not show that the result was statistically significant. Even so, the average saving is remarkably small considering what risks are being taken with this practice.

Warren et al., (2009). This study was part of the U.S. government funded "Iowa Study" where children's tooth decay has been tracked from birth. This enabled the researchers to do something that no other research group has done and that is to examine the relationship between tooth decay and *individual* exposure to fluoride. All the other epidemiological studies have been population based. The authors in this study were attempting to find the so-called "optimal dose" needed by a child to reduce tooth decay. But they couldn't find that dose. In fact, they could not find a clear relationship between tooth decay and the amount of fluoride ingested on a daily base (this included from water, from food and from dental products). In their own words the authors concluded that, **"These findings suggest that achieving a caries-free status may have relatively little to do with fluoride intake..."**

4. The trial that launched fluoridation in NZ was a fraud.

This trial was the Hastings-Napier Fluoridation Trial conducted between 1954 and 1964. The fraud was first discussed by the late Dr. John Colquhoun and his PhD thesis adviser Dr. Robert Mann in an article that appeared in *The Ecologist* in 1986. Further details were presented in Colquhoun's thesis in 1987 (which is now available to a wider audience) and further refined by Colquhoun and Wilson in 1999.

4.1 The bare bones of the case.

The Hastings Napier trial was meant to have Hastings as the fluoridated community and Napier as the control. In other words it was going to be cross-sectional study – comparing tooth decay in two cities at the same point in time after one had been fluoridated and the other had not. Shortly into the experiment the control city was dropped, thus the study became a longitudinal one. In this case comparing the tooth decay in one city (Hastings) at the beginning and end of the trial.

For such a comparison to be valid, there must be no change in *key parameters* during the trial. However, there was a change in one of the key parameters in this trial *and it was a major one* - the method of diagnosing and treating tooth decay. This was more stringent at the end than it was at the beginning.

At the beginning of the trial school dental nurses were filling indentations (as if they were cavities) but the end they were only filling genuine "holes" in the enamel. Thus the drop in tooth decay attributed to fluoridation was part, or all, the result of making the diagnosis and treatment of tooth decay more stringent.

What makes the final report a fraud was that **the authors did not mention the change in diagnosis** when claiming the drop in tooth decay was due to fluoridation.

In other words, the whole of the fluoridation program in NZ has been built on the basis of a fraudulent study.

4.2 The "smoking gun" letter.

This letter was obtained by Colquhoun who used the Official Information Act 1982 to obtain all the files pertaining to the Hastings-Napier trial from Department of Health files (1951-1973) now held in National Archives, Wellington. This letter from GH Leslie, the Director of the Division of Dental health of the NZ government, was found in those files and was reprinted in the paper by Colquhoun and Wilson (1999). The letter was written in 1962, **some eight years into the ten-year Hastings-Napier trial.** Here is the letter:

12, October 1962

Mr. Swann,

I have delayed acknowledging receipt of Dr. Roche's letter to you and replying to your minute in the hope that I would by now be able to give a positive reply to your enquiry. I still cannot.

No one is more conscious than I am of the need for proof of the value of fluoridation in terms of reduced treatment. It is something which has been concerning me for a long time. It is only a matter of time before I will be asked questions and I must have an answer with meaning to a layman or I am going to be embarrassed and so is everyone else connected with fluoridation. But it is not easy to get. On the contrary it is proving extremely difficult. Mr. Espia is conferring with Mr. Bock and Mr. Ludwig and I am hopeful that in due course they will be able to make a practical suggestion.

I will certainly not rest easily until a simple method has been devised to prove the equation fluoridation = less fillings

(G.H. Leslie)
Director
Division of Dental Health

According to Colquhoun and Wilson (1998) what was concerning Leslie in 1962 was that the Hastings tooth decay statistics showed little difference between those exposed to fluoridation in Hastings and the rest of unfluoridated New Zealand. In other words, as he makes clear fluoridation wasn't working and this concerned him greatly as the last sentence indicates, "**I will certainly not rest easily until a simple method has been devised to prove the equation fluoridation = less fillings.**"

In 1962, the chief dental officer in NZ admits that fluoridation isn't working – but two years later in 1964 the Fluoridation Trial report "miraculously" shows that it is a great success! But as Colquhoun and Mann showed this "success" was largely based on an artifact – the change of diagnostic for what teeth needed filling.

Conclusion: The Hastings-Napier trial was a fraud. I can find no evidence of a published rebuttal of that conclusion. Certainly Colquhoun's co-author Professor Robert Mann is not aware of one and I have checked with him.

4.3 Colquhoun one of NZ's heros.

The late John Colquhoun was a remarkable man who did a remarkable thing. As chief dental officer of Auckland and as a city councilor Dr. John Colquhoun had once been a very vigorous and successful promoter of fluoridation. However, once he found out from his research (which included a worldwide tour in 1980-81) that he was wrong, he had the courage and the integrity to change his position publicly and spend the rest of his life trying to undo the damage he believed he had caused. Very few have this kind of integrity.

For those interested I highly recommend that they watch the videotape of my interview with John in 1997. It is titled, "Why I Changed My Mind on Fluoridation." It can be accessed here, http://fluoridealert.org/fan-tv/colquhoun/

This interview was for me the most inspiring moment in all the 17 years of my involvement in this issue. I saw face to face what scientific integrity was. In my view this sorry practice of fluoridation has gone on for such a long time because of the lack of integrity of those in government agencies who know the truth but are determined to keep this practice going at all costs. Maybe one day we will find out why.

Meanwhile, we need many more citizens of NZ to read the literature on this topic with an open mind. If they do so – and if they are able to insist that their government use the best science available on this topic as well as exercise sound ethical judgment - this sorry practice must surely be brought to an end.

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Scientific and Critical Analysis of the 2014 New Zealand Fluoridation Report

International Critique of the Royal Society of New Zealand/Office of the Prime Minister's Chief Science Advisor's Fluoridation Report: *Health effects of water fluoridation: A review of the scientific evidence*

November 2014

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According to the University of York Centre for Reviews and Dissemination:

"Systematic reviews differ from other types of review in that they adhere to a strict scientific design in order to make them more comprehensive, to minimise the chance of bias, and so ensure their reliability. Rather than reflecting the views of the authors or being based on only a (possibly biased) selection of the published literature, they contain a comprehensive summary of the available evidence."

http://www.york.ac.uk/inst/crd/fluofaq.htm#q6

The following critique discusses how the Royal Society of New Zealand / Office of the Prime Minister's Chief Science Advisor's 2014 Fluoridation Report is not a systematic review.

This critique is provided for the benefit of those seeking reliable evidence based scientific information in the fluoridation debate

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Non-Profit
FFNZ Public Health
Education & Advocacy

Co-ordinated by Fluoride Free New Zealand
For further facts about water fluoridation see www.fluoridefree.org.nz

Findings and recommendations

Failure to review health risks and identify harm

Sections of this critique focus on health risks and margin of safety considerations, which the report from the Royal Society of New Zealand and the Office of the Prime Minister's Chief Science Advisor claims are met, but elsewhere in the report identifies that they are not met.

Many examples are given in this critique of the lack of scientific rigor in the NZ report, including several inconsistencies and inaccuracies contained in the report. The report fails to acknowledge that both the safety and efficacy of fluoridation have been questioned for decades by scientists, physicians, dentists, and other professionals, based on the available evidence.

On the questions of risk, specifically those related to dental fluorosis, lead concentrations, IQ, osteosarcoma and kidney function, the NZ report appears unjustifiably complacent. The report identified large sections of the population of NZ who exceed the toxic limits for fluoride ingestion, including:

- Bottle fed infants
- Children under 8 years old
- People with impaired kidney function
- People who drink a lot of fluoridated water
- People who have high fluoride intake from other sources such as diet and toothpaste

Political Bias

The authors of the New Zealand report adopt a noticeably biased approach. The political bias of the fluoridation promoters is demonstrated in the NZ Official Information Act correspondence included.

The "elephant in the room" is that while decay rates have fallen in areas where fluoridation was implemented, it has also fallen in areas that were not fluoridated, often **at a faster rate**. This cannot in good faith be described as a robust and thorough review of fluoridation science by experts, as it fails to address conflicting evidence which is detailed in this critique.

Recommendations

Based on the findings of this critique, it is recommended that local councils suspend water fluoridation until central government conducts thorough safety studies. The burden of proof and guarantee of fluoridation safety lies with officials who enforce, promote and allow fluoridation. **As yet, no fluoridation safety studies have ever been conducted, anywhere in the world.**

Table of Contents

Scientific and Critical Analysis of the Royal Society/Prime Minister's Science Advisor's Office Fluoridation Report: *Health effects of water fluoridation: A review of the scientific evidence*

Introduction

The Report was sent to a selection of independent international experts for peer review. Two of these were members of the US National Research Council (NRC) review panel, whose report was published in 2006 following three years of reviewing the scientific literature. The reviewers were chosen for their particular expertise on the science around fluoridation, and their standing in the scientific community.

The first two reviews in this critique address the toxicity issue.

The first review was prepared by Dr Kathleen Thiessen, PhD, a risk assessment specialist on the NRC panel.

Dr Thiessen's critique has been peer reviewed and endorsed by Dr Hardy Limeback, PhD, the second former NRC panel member, and former Head of Preventive Dentistry, University of Toronto, and Dr James Beck MD, PhD, co-author of *The Case Against Fluoride*, a critically acclaimed contribution to the fluoridation debate.

The second review is by Dr Spedding Micklem, DPhil, co-author of *The Case Against Fluoride*. This critique has been peer reviewed and endorsed by Dr James Beck MD, PhD.

Dr Beck has also authorized publication of the following comment:

> "This report is a clear example of cherry picking, where only select studies that support the 'safe and effective' viewpoint were cited. It is far from a really critical review of the literature."

The third review is regarding tooth decay, and has been prepared by Wellington dentist, Dr Stan Litras, and has been peer reviewed by Dr Hardy Limeback and Dr Bruce Spittle, MB ChB DPM FRANZCP, Managing editor of the international journal *Fluoride*.

Review # 1 Dr Kathleen Thiessen PhD

Oak Ridge Center for Risk Analysis, Inc. NRC Panel member

Peer reviewed and endorsed by: Dr Hardy Limeback, B.Sc., Ph.D., D.D.S. Emeritus Professor, former Head of Preventive Dentistry, University of Toronto. Former president of the Canadian Association for Dental Research. NRC panel member

Dr James Beck MD, PhD co-author of *The Case Against Fluoride*

Comments on the RSNZ/OPMCSA report on "Health effects of water fluoridation: A review of the scientific evidence"

The following comments do not constitute a thorough critique of the RSNZ report. I have primarily tried to give examples of the lack of scientific rigor in the report, including several inconsistencies and inaccuracies contained in the report. Page numbers below refer to the RSNZ report unless otherwise stated.

(1) General comment

This report from the Royal Society of New Zealand and the Office of the Prime Minister's Chief Science Advisor in general falls short of the standards one expects for a "review of the scientific evidence" and instead seems to concentrate on demonstrating a consensus favoring community water fluoridation (CWF). For example, "the scientific consensus confirmed in this review" (p. 5); "Analysis of the peer-reviewed scientific literature reveals a clear consensus on the effectiveness of CWF" (p. 16); "the weight of peer-reviewed evidence supporting the benefits of water fluoridation at the levels used in New Zealand is substantial, and is not considered to be in dispute in the scientific literature" (p. 16); and "while the scientific consensus is that these [cancer, effects on cognitive development of children] are not significant risks" (p. 16).

The review mentions that "the effectiveness of CWF continues to be questioned by a small but vocal minority" (p. 16), but fails to acknowledge that both the safety and efficacy of CWF have been questioned for decades by scientists, physicians, dentists, and other professionals, based on the available evidence. For example, a 1944 editorial in the Journal of the American Dental Association stated that the current "knowledge of the subject certainly does not warrant the introduction of fluorine in community water supplies" and that "the potentialities for harm far outweigh those for good" (JADA 1944). The Director of Laboratories for the utilities department of the City of New York concluded that the "fluoridation of public water supplies is a hazardous procedure, people are bound to get hurt, it remains to find out how many and when" (Nesin 1956). When a former Principal Dental Officer of Auckland, New Zealand, compared decay rates for all children in all communities of the South Island, he found essentially no differences in tooth decay rates with respect to fluoridation status (Colquhoun 1997).

(2) Margin of safety

The report and the cover letter accompanying the report refer in several places to safety or to a margin of safety:

> The "safety margins are such that no subset of the population is at risk because of fluoridation." (Cover letter, p. 2)

> "The fluoride concentrations recommended for CWF have been set based on data from both animal toxicology studies and human epidemiological studies to provide a daily oral exposure that confers maximum benefit without appreciable risk of adverse effects." (pp. 4-5)

> "The amount of fluoride added to water in CWF programmes is set to minimise the risk of this condition [dental fluorosis] while still providing maximum protective benefit against tooth decay." (p. 6)

> "Community water fluoridation (CWF) entails an upward adjustment of the fluoride concentration in fluoride-poor water sources to a level that is considered optimal for dental health, yet broadly safe for the population that drinks the water." (p. 14)

In spite of these mentions of safety or a margin of safety, the report nevertheless indicates that many people exceed the supposedly "safe" levels:

> "In some cases the fluoride intake by these groups [formula-fed infants, young children who are likely to swallow toothpaste] can approach or exceed the currently recommended conservative upper intake level." (p. 6)

> ". . . there is a narrow range between optimal dental health effectiveness and a risk of mild dental fluorosis." (p. 10)

> Reconstituting infant formula with fluoridated water "can provide infants with fluoride at levels approaching or exceeding the recommended upper level for daily intake." (p. 25)

> ". . . infants who are exclusively fed formula made with water fluoridated at 1.0 mg/L will thus regularly exceed the current UL for fluoride." (p. 28)

If identifiable parts of the population predictably exceed the standards for fluoride intake, then the fluoride concentration in drinking water is too high and should be greatly lowered, so that there indeed exists a margin of safety between intake and a level at which health risks occur, and so that all subsets of the population are adequately protected.

(3) Adequacy of the standards for fluoride intake

In principle, the fluoride concentrations are set (in part) with respect to a demonstrated "safe" concentration. For New Zealand, this concentration is referred to as a "tolerable daily intake" (TDI), defined as "a daily oral exposure to the human population (including sensitive groups) that is estimated to be without an appreciable risk of deleterious effects during a lifetime" (p. 18) and which is "determined by applying a safety margin of several orders of magnitude" to a "no observed adverse effect level (NOAEL)" (p. 18).

The TDI appears to be based on the U.S. Environmental Protection Agency's Reference Dose (RfD), defined as "An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime" (EPA 2009). Properly understood, the RfD or TDI should not normally be exceeded by any individual, and any sort of allowable intake or, in this case, concentration in drinking water, should be set so that the RfD or TDI is not exceeded under ordinary circumstances. Individuals, including members of susceptible population subgroups ("sensitive subgroups"), should not normally have exposures in excess of the RfD or TDI.

For fluoride, the U.S. EPA has an existing RfD of 0.06 mg/kg/day (EPA 1989) and has proposed a new RfD of 0.08 mg/kg/day (EPA 2010). Another U.S. government organization, the Agency for Toxic Substances and Disease Registry, has a Minimal Risk Level (MRL, similar in concept to the USEPA's RfD) for fluoride of 0.05 mg/kg/day (ATSDR 2003). New Zealand has an "adequate intake" (AI) value for fluoride of 0.05 mg/kg/day and a "safe upper level of intake" (UL) of 0.1 mg/kg/day (p. 27, Table 2). Thus, New Zealand has set an "adequate" or "optimal" level of fluoride intake at or just below values considered by the U.S. government to be an upper level of "safe," and has set the "safe upper level of intake" above the U.S. values. The UL for older children and adults is based on an intake of 10 mg/day, considered a "NOAEL" for skeletal fluorosis (p. 26). The TDI, which is supposed to be set by "applying a safety margin of several orders of magnitude" to the NOAEL (p. 18), has in fact been set equal to the NOAEL, with no safety factor at all. There is only a factor of 2 between the AI and UL values (0.05 and 0.1 mg/kg/day; p. 27, Table 2). As pointed out above, some identifiable subsets of the population will have fluoride intakes that exceed the UL.

The report ignores entirely the central question of whether EPA's RfD values (old or new) and New Zealand's TDI are adequately protective. EPA's proposed (but not yet official) new RfD of 0.08 mg/kg/day was based on protection of the population from severe dental fluorosis (EPA 2010). However, in order to obtain this value, EPA inappropriately included an assumption of benefit in its risk assessment for fluoride, including the preservation of an intake of 0.05 mg/kg/day as desirable (based on IOM 1997) and exclusion of possible adverse health effects below an intake of 0.07 mg/kg/day (EPA 2010). In other words, EPA had to ignore other, more sensitive, adverse health effects ("known or anticipated adverse health effects"; EPA 2009) and the association of dental fluorosis (all levels) with increased risk of other adverse health effects (e.g., thyroid disease, lowered IQ, and bone fracture; Alarcón-Herrera et al. 2001; Zhao et al. 1996; Li et al. 1995; Lin et al.

1991; Desai et al. 1993; Yang et al. 1994; Jooste et al. 1999; Susheela et al. 2005). A number of adverse health effects can be expected to occur in at least some individuals when estimated average intakes of fluoride are around 0.05 mg/kg/day or higher (NRC 2006; 2009); in other words, a LOAEL for some adverse health effects is lower than EPA's new (or old) RfD, which is supposed to protect the population, including sensitive subgroups, from deleterious effects during a lifetime (EPA 2009; 2011). For persons with iodine deficiency (one example of a sensitive subgroup), average intakes as low as 0.01-0.03 mg/kg/day could produce effects (NRC 2006). Proper derivation of an RfD or TDI would consider these more sensitive endpoints and apply appropriate safety factors to obtain values much lower than those currently considered desirable by the New Zealand government.

(4) Effects of CWF in New Zealand

The RSNZ report states that "No severe form of fluorosis has ever been reported in New Zealand" (p. 6), "The prevalence of fluorosis of aesthetic concern is minimal in New Zealand, and is not different between fluoridated and non-fluoridated communities" (p. 56), and "Water fluoridation in New Zealand has been ongoing since the 1950s, with notable benefits to the oral health of its residents" (p. 55), while offering little documentation. However, the RSNZ has not even mentioned the reports by John Colquhoun, former Principal Dental Officer of Auckland, which report contrary evidence. For example: "When I obtained the decay rates for all children in all the fluoridated and all the nonfluoridated areas in that part of New Zealand [South Island], as well as the decay rates for all children in the recently defluoridated town, they revealed that there are virtually no differences in tooth decay rates related to fluoridation" (italics in the original) and "25 percent of children had dental fluorosis in fluoridated Auckland and around 3 percent had the severer (discolored or pitted) degree of the condition" (Colquhoun 1997).

(5) Carcinogenicity and genotoxicity

The RSNZ report states that "Multiple thorough systematic reviews conducted between 2000 and 2011 all concluded that based on the best available evidence, fluoride (at any level) could *not* be classified as carcinogenic in humans" (pp. 7, 46, italics in the report). The report is inaccurate to say that the U.S. National Research Council "could not" classify fluoride as carcinogenic to humans. While the U.S. National Research Council did not assign fluoride to a specific category of carcinogenicity (i.e., known, probable, or possible), the NRC committee did not consider either "insufficient information" or "clearly not carcinogenic" to be applicable. The committee report (NRC 2006) includes a discussion of how EPA establishes drinking water standards for known, probable, or possible carcinogens; such a discussion would not have been relevant had the committee not considered fluoride to be carcinogenic. The question remains how strongly carcinogenic fluoride is, and under what circumstances. The NRC (2006) specifically discussed the limitations of epidemiologic studies, especially ecologic studies (those in which group, rather than individual, measures of exposure and outcome are used), in detecting small increases in risk—in other words, most of the studies are not sensitive enough to identify small or moderate increases in cancer risk; therefore a

"negative" study does not necessarily mean that there is no risk (see also Cheng et al. 2007). In particular, a "negative" study that does not address a key condition involved in a "positive" finding (e.g., the failure to include age-specific, individual exposure or to separate young and old people in the analysis) cannot be considered evidence of no risk.

The RSNZ report dismisses the Harvard osteosarcoma study (Bassin et al. 2006) on the basis of a letter by Douglass and Joshipura (2006) that contained no actual data. Douglass approved Bassin's dissertation (Bassin 2001), on which her paper was based, and both Douglass and Joshipura were coauthors on an earlier paper by Bassin et al. (2004) describing the exposure analysis used in the study. The dissertation (Bassin 2001) and peer-reviewed paper (Bassin et al. 2006) contain essentially the same results. The key finding reported by Bassin et al. (2006) was an increased risk of osteosarcoma in young males, based on an age-specific analysis of fluoride exposure. Given this finding, studies that do not look at age-specific exposure of young males cannot be said to be negative.

Douglass and Joshipura (2006) mentioned, but did not provide, an analysis of the fluoride content of bone specimens from the osteosarcoma patients and a lack of association between bone fluoride concentration and excess risk of osteosarcoma; however, fluoride concentration in bones of diagnosed patients constitutes a measure of cumulative fluoride exposure which would not necessarily be expected to be correlated with the risk of osteosarcoma. Given that there is a "lag time" of a few years between onset of a cancer and its diagnosis, use of cumulative fluoride exposure until time of diagnosis is potentially misleading, as fluoride exposure during the last several years (during the "lag time" between initiation and diagnosis of a cancer) cannot have contributed to the initiation of a cancer but could have a significant effect on the estimate of cumulative fluoride exposure.

The RSNZ report mentions a later Harvard paper (Kim et al. 2011) which "reported that bone fluoride levels in these samples did not correlate with the occurrence of osteosarcoma" (p. 46). Kim et al. reported no significant difference in bone fluoride levels between cases and controls and no significant association between bone fluoride levels and osteosarcoma risk. The RSNZ report does not mention that Kim et al. (2011) specifically say that "if risk is related to exposures at a specific time in life, rather than total accumulated dose, this metric [bone fluoride content] would not be optimal," thus admitting that they did not address the key finding of Bassin et al. (2006). Comparison of the distributions of bone fluoride concentrations between cases and controls indicates that the ranges are not greatly different; the median was higher for the controls than the cases, which Kim et al. attribute to the older ages of the controls. Given that the median age of the controls is more than twice the median age of the cases (41.3 vs. 17.6), the obvious conclusion is not a lack of association between fluoride exposure and osteosarcoma, but considerably higher average exposure (by about a factor of 2) in cases and controls, in order to reach similar bone fluoride concentrations. Rather than refuting the work of Bassin et al., these findings by Kim et al. support an association between fluoride exposure and osteosarcoma.

In its discussion of animal studies of carcinogenicity (p. 45), the RSNZ report fails to point out that in most, if not all, of these studies, the fluoride exposures started after the age corresponding to the apparent most susceptible age in humans (based on

Bassin et al. 2006), and thus these animal studies may have completely missed the most important exposure period with respect to initiation of the majority of human osteosarcomas.

With respect to genotoxicity (p. 44), the RSNZ should be aware that *in vitro* genotoxic, cytogenetic, or transformational effects (i.e., positive results) have been observed in many studies at fluoride concentrations at or above about 5 mg/L (reviewed by NRC 2009). In addition, a recent paper by Zhang et al. (2009) describes a new testing system for potential carcinogens, based on induction of a DNA-damage response gene in a human cell line. Sodium fluoride tests positive in this system, as do a number of other known carcinogens, representing a variety of genotoxic and nongenotoxic carcinogenic mechanisms. Known noncarcinogens—chemicals not associated with carcinogenicity—did not test positive. For fluoride, a positive effect was seen at a fluoride concentration of about 0.5 mg/L, or a factor of 10 lower than in the other systems. A fluoride concentration of 0.5 mg/L in urine will routinely be exceeded by many people consuming fluoridated water (NRC 2006); for people with substantial fluoride intake, serum fluoride concentrations may also reach or exceed 0.5 mg/L. Acute fluoride exposures (e.g., accidental poisoning, fluoride overfeeds in drinking water systems) have resulted in fluoride concentrations in urine well in excess of 5 mg/L in a number of cases (e.g., Penman et al. 1997; Björnhagen et al. 2003; Vohra et al. 2008). Urine fluoride concentrations can also exceed 5 mg/L if chronic fluoride intake is above about 5-6 mg/day (less than New Zealand's upper level of intake for older children and adults; p. 27, Table 2). At intakes between New Zealand's "adequate" and "upper level" intakes, kidney and bladder cells are probably exposed to fluoride concentrations in the ranges at which genotoxic effects have been reported *in vitro*, especially when the more sensitive system of Zhang et al. (2009) is considered. Based on the results of Zhang et al. (2009), most tissues of the body are potentially at risk if serum fluoride concentrations reach or exceed 0.5 mg/L. In addition, cells in the vicinity of resorption sites in fluoride-containing bone are potentially exposed to very high fluoride concentrations in extracellular fluid (NRC 2006) and thus are also at risk for genotoxic effects.

(6) Neurotoxicity

The RSNZ report is not accurate in its characterization of the Choi et al. (2012) article on effects of fluoride on children's IQ. They indicate that Choi et al. found a "shift of less than one IQ point" (p. 7), and that "the standardised weighted mean difference in IQ scores between "exposed" and reference populations was only -0.45" (p. 49). In fact, the difference is about one- half (-0.45) of a standard deviation, or about 7 IQ points, not one-half of an IQ point. This was clarified in a letter to the journal in March 2013 (Choi et al. 2013); there was also a clarification for nontechnical readers in a September 5, 2012, correction to the original (July 25, 2012) press release from Harvard University.

While many of the articles included in Choi's meta-analysis had reference levels similar to CWF levels, and "high" levels somewhere above that, several studies had "high" levels within the legal limits for fluoride concentrations in drinking water in the U.S. One study had "high" at 0.88 mg/L, quite relevant to CWF. Also, studies

that have "reference" levels similar to or higher than CWF levels can say nothing about the safety of CWF. Rather, for something like neurotoxicity for which there is likely no threshold (the current U.S. assumption for lead exposure, for example), finding that sort of dose response ought to suggest the likelihood of a response at lower (e.g., CWF) levels compared to very low or negligible levels, and the importance of looking for possible effects at lower (CWF) levels is obvious. One extremely important finding by the NRC (2006) and then Choi et al. is the consistency of the effect. Even the one study in Choi's list that did not clearly show lower IQ still showed a tendency in that direction (just not statistically significant), and it certainly did not show clear absence of any effect.

The RSNZ report ignores the fact that Choi et al. (2012) excluded several studies from their meta-analysis because they used individual measures of exposure rather than group exposures-- in other words, some excluded studies might have been of better design than the ones that their meta-analysis could consider. There are also a few studies too recent to have been considered by Choi et al. but that should have been mentioned by the RSNZ report (e.g., Saxena et al. 2012; Seraj et al. 2012; Shivaprakash et al. 2011). While some of the neurotoxicity studies did not address confounders, some did handle them responsibly, a detail not mentioned in the RSNZ report.

The RSNZ report (p. 50) describes as "relatively high quality" a recent paper from New Zealand reporting no evidence for an effect of CWF on IQ (Broadbent et al. 2014). However, the assessment of exposure provided in that paper is inadequate and probably results in comparisons between groups with similar, or at least overlapping, exposures to fluoride. For example, children in the non-CWF group who received fluoride tablets probably had similar exposures to children in the CWF group. Broadbent et al. report that breastfeeding was associated with higher IQs but fail to point out that this effect was larger for CWF areas than non-CWF areas. (Fluoride concentrations in breast milk are quite low, regardless of the mother's fluoride intake.) Broadbent et al. defined breastfeeding as lasting at least 4 weeks, suggesting that further analysis, including duration of breastfeeding, might show a larger effect.

Both Broadbent et al. and the RSNZ report inaccurately state that no plausible mechanism exists for an effect of fluoride on IQ. The fact that no mechanism has been established reflects the absence of research effort, not the absence of a mechanism. One possible mechanism is reduction of maternal and/or infant thyroid function (NRC 2006). Others involve damage to the developing brain or disrupted neurochemistry (e.g., Blaylock and Strunecka 2009). Several studies have shown changes in brain chemistry in fetuses due to maternal fluoride exposures (Dong et al. 1997; Du et al. 2008; He et al. 2008; Yu et al. 2000; 2008).

(7) Significance of animal studies

The RSNZ report dismisses many of the animal studies as involving greatly higher fluoride intakes (or fluoride concentrations in drinking water) than those experienced by people with CWF (pp. 45, 49). However, animals require much higher exposures (5-20 times higher, or more; see NRC 2006; 2009) than

humans to achieve the same effects or similar fluoride concentrations in bone or serum. In other words, humans are considerably more sensitive to fluoride than are most animal species that have been studied. The animal studies cannot so easily be dismissed. This difference in sensitivity should have been discussed in the report.

(8) Endocrine effects

The RSNZ report mentions the extensive review of "potential fluoride effects on endocrine organs and hormones" by the U.S. National Research Council (p. 51), but they fail to mention that the NRC's report concluded that "fluoride affects normal endocrine function or response" and "Fluoride is therefore an endocrine disruptor" (NRC 2006). The RSNZ mentions a paper on childhood goitre in South Africa by Jooste et al. (1999) as included in the York review (p. 52). They have not mentioned the NRC's discussion of the same paper, specifically that the town with the lowest prevalence of goitre also had the lowest prevalence of "undernutrition." When that town is excluded from the analysis, a clear dose response is observed between goitre prevalence and fluoride concentration in drinking water.

(9) Monitoring of fluoride concentrations in water

The RSNZ indicates that "fluoridated drinking water supplies must be sampled at least weekly" (p. 24). It should be mentioned that the American Water Works Association recommends at least once per day (Lauer and Rubel 2004). The AWWA also mention the advantages of continuous monitors, in particular, having one equipped with an alarm to alert operators to a malfunction. Fluoride overfeeds do occur and can cause illness and even death (e.g., Gessner et al. 1994; Penman et al. 1997).

(10) CWF recommendations in the U.S.

The RSNZ report indicates that "optimally fluoridated" drinking water in the U.S. is now 0.7 mg/L (p. 54). However, while the U.S. Department of Health and Human Services proposed a new recommendation of 0.7 mg/L instead of the existing temperature-based recommendation of 0.7-1.2 mg/L (Federal Register 2011), this is not yet anything but a "proposed" new recommendation. As of this date (September 2014), this proposed recommendation has not become an official recommendation, and to the best of my knowledge has not had wide implementation in the U.S.

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NZ Report – Health effects of water fluoridation: A review of the scientific evidence

Critical comments

General

It appears that this report, or at least its summary, is written with a largely lay readership in mind. As such, it calls for particularly high standards of accuracy and integrity, so that readers may not be accidentally misled. The report measures up to these ideals with limited success.

Executive summary

In the executive summary the authors adopt a patronizing tone and a noticeably biased approach. For example, reviews and papers favorable to fluoridation are routinely described as "thorough" or "careful". This sounds more like propaganda than science and suggests that readers should look very critically at the report's conclusions.

Scope

These comments are confined to questions of risk, specifically those related to dental fluorosis, lead concentrations, IQ, osteosarcoma and renal function, where the report appears unjustifiably complacent.

Attitudes to risk

The Report is not alone in exhibiting an attitude to risk that baffles and angers many opponents of fluoridation. Proponents appear, or affect, not to understand the nature of this reaction, denouncing it as ignorant, emotional etc. Proponents tend to take the view that 'credible scientific evidence' does not support the view that fluoride poses any risk to consumers of fluoridated water; to be credible the evidence needs to be direct and incontrovertible. They think this is enough, and it might be enough if they were dealing with a prescription drug, where a sick patient might readily accept some risk of harm, and where considerable energy goes into identifying and recording side-effects. But as soon as something is put into the water supply, the game changes: millions are treated unnecessarily, there is little control over dose, no allowance for individual sensitivity, no individual consent and (despite frequent assertions to the

contrary) little monitoring of safety or attention to claimed ill effects. Opponents of fluoridation recognize this and view fluoridation from a toxicological angle, attaching some weight to animal studies and studies on populations drinking naturally fluoride-rich waters, and evaluating margins of safety. Proponents either do not realize that the game has changed or try to gloss over it. In either case, they adopt a default position that fluoridation is safe and are at pains, as in this report, to downplay any evidence to the contrary.

Dental fluorosis [Section 3.3] – an example of game-change denial

The report's discussion of fluorosis [Section 3.3] provides an example of what we might call game-change denial. The incidence of moderate fluorosis (2%) is described as 'rare' in 8 year olds. But note that side-effects of a drug are often listed as 'common' if they occur in more than 1% of cases. As the report goes on to show, moderate fluorosis is widely considered to be aesthetically unacceptable. That implies some 4-5 thousand aesthetically disadvantaged children and young adults in a largely fluoridated city such as Auckland[1]. A further 8000 must have 'mild' fluorosis, which many, including the York review [report refs 89, 90] and the British Fluoridation Society (BFS)[2] consider to be of aesthetic concern.

The Report's authors are on morally, and also economically, shaky ground here, even if fluorosis is viewed merely as a cosmetic, not a health problem. They do not even mention the cost of veneers (up to $1750 per tooth)[3] and other treatment in their cost-benefit discussion [Section 3.2.5]. Perhaps aware of this, they attempt to exonerate fluoridated water from causing fluorosis by citing the NZ Oral Health Report (2010)[4] to claim that the incidence of moderate fluorosis in 8-30 year olds is no higher in fluoridated than in non-fluoridated areas. However, this was a relatively small survey and, as the 2009 report acknowledges, experience elsewhere has generally been that water fluoridation is associated with an increased incidence of fluorosis, including the grades of aesthetic concern (British Fluoridation Society, op.cit). The BFS suggests that the unusually high reported incidence of fluorosis in non-fluoridated areas of New Zealand may be attributable to supplement use. In other words, the suggestion that water fluoridation does not contribute to fluorosis is probably invalid. Moreover, Kanagaratnam et al[5] reported that 9 year old children who lived continuously in fluoridated areas of Auckland were 4.17 times as likely to have diffuse opacities as children who lived continuously in non-fluoridated areas.

In summary, some thousands of young people in New Zealand are involuntarily paying the price for an excessive load of fluoride that was imposed on them, largely via the public water supply, in early childhood. The NZ Government must surely have done these sums, but the report does not mention them.

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[1] For source and calculations see Appendix

[2] http://www.bfsweb.org/onemillion/05 One in a Million - Dental Fluorosis.pdf] Tables 1-3

[3] See Appendix

[4] https://www.health.govt.nz/system/files/documents/publications/our-oral-health-2010.pdf

[5] Kanagaratnam S1, Schluter P, Durward C, Mahood R, Mackay T Community Dent Oral Epidemiol. 2009 Jun;37(3):250-9. doi: 10.1111/j.1600-0528.2009.00465.x. Epub 2009 Mar 19.

[Section 3.3.5] pg 43. *"...adolescents actually preferred the whiteness associated with mild fluorosis [143]"*. This is deceptive. What the cited paper actually states is that the subjects liked the appearance of a *complete set of artificially white teeth.* They did not like the whiteness associated with fluorosis: even TF1 and TF2 (very mildly fluorosed) teeth were rated lower than natural-coloured normal teeth.

Lead [Section 2.2.1]

Page 23. Reference is made to a report by Jackson et al [27]. Anyone unfamiliar with this contracted report would be hard put to trace it from the inadequate reference details given, even if two spelling mistakes were corrected. It can, however, be downloaded from the British Fluoridation Society's web site. Note that Jackson's 'determination' that "HFA used to fluoridate water is effectively 100% dissociated to form fluoride ion under water treatment conditions" was based on theoretical modeling and took no account of any real life data.

The following paragraph bizarrely suggests that a paper by Urbansky and Schock [33] published in 2000 criticized and fatally discredited papers published by Coplan et al and Maas et al seven years later in 2007.

Urbansky and Schock's paper actually referred to an earlier paper by Masters and Coplan (1999). Coplan et al (2007) [31] was a rebuttal of that with additional data showing that consumers of fluoridated water, particularly from poor communities, had raised concentrations of lead in their blood. The paper by Maas et al (2007) [32] described laboratory experiments showing that fluoride, added as NaF and particularly H2SiF6, enhanced the tendency of chlorine and chloramine to leach lead from brass plumbing components, providing a possible partial explanation for Coplan et al's findings. Urbansky's comments had no relevance to it. A more recent study in rats[6] showed that fluoride enhanced the uptake of lead into blood and bones, another possible factor in Coplan's results.

The studies by Coplan and Maas do not appear to have been challenged. Independent confirmation is needed, but meanwhile lead exposure is an important issue and their conclusions should be taken seriously. The superficial treatment of the subject by SCHER [34], on which the NZ report leans, did not even mention the Maas study. Whatever the truth of the matter, the NZ report is factually misleading here and does not justify its implied conclusion that fluoridation poses no added risk from lead.

Neurotoxicity and IQ [Section 4.4)

This is a superficial and unconvincing attempt to demolish the case that water fluoridation poses a developmental risk to human intelligence. I shall not discuss it in any detail, but make one general point. In most areas of science, the existence of so many studies almost all saying the same (important) thing would be treated with some attention and respect, even if individually most were not strong. The NZ report fails to

[6] Sawan RM, Leite GA, Saraiva MC, Barbosa F Jr, Tanus-Santos JE, Gerlach RF. Toxicology. 2010 Apr 30;271(1-2):21-6. doi: 10.1016/j.tox.2010.02.002. Epub 2010 Feb 25.

do that and even manages to misunderstand and mis-state the conclusions of a systematic review and meta-analysis of many of the studies by Choi et al. The authors made the rather elementary mistake of supposing that a standardized mean difference of 0.45 meant a reduction of less than half an IQ point and was therefore arguably negligible, whereas the actual reduction was almost 7 IQ points, and therefore far from negligible. It is hard to imagine how this mistake could have been made by anyone who had actually read the papers that are disparaged so casually.
Against all these studies the report sets a single inconclusive New Zealand study [176], and concludes (page 7) "that on the available evidence there is no appreciable effect on cognition arising from CWF". We must hope that the authors are right, but the question remains wide open. The issue is hardly trivial and the public is ill-served by such a poorly informed judgement.

Osteosarcoma [Section 4.2.3]

In discussing the paper by Bassin et al 2006 [159], the authors do not appear to understand what they are talking about. They have some excuse since the cited letter from Bassin's director [160] seemed designed to cause uncertainty and confusion and turned out to be factually incorrect. The letter claimed that a larger set of data failed to support Bassin's findings and promised a further paper "currently being prepared for publication". Nothing appeared for 5 years until the paper by Kim et al [161] was published. It did little to contradict Bassin's results, being relatively small, poorly controlled and, crucially, as Kim et al admitted, having no bearing on fluoride exposure during the critical age range identified by Bassin. Since then, as the Report states, Blakey et al [164] studied all (2566) osteosarcoma cases registered in the UK over a 25 year period in relation to the fluoridation status of their closely defined area of residence at the time of diagnosis. A range of potential confounders was taken into account. No association of osteosarcoma with the fluoride content of water was found. Unfortunately, however, no firm conclusions can be drawn from this for reasons that the authors acknowledge: the fluoride connection was only assessed on the place of residence at the time of diagnosis and no residential histories were available, nor any information about fluoride consumption during childhood. In addition, fluoride concentrations in artificially fluoridated waters were based only on information from 2004-06 and varied considerably with many being below 0.7mg/l. Comparable problems beset the other recent ecological studies cited by the Report. The fluoride/osteosarcoma question therefore remains unsettled; nothing has emerged that convincingly contradicts the conclusion of Bassin et al that boys go through a sensitive phase in childhood when exposure to fluoride in drinking water is associated with an increased frequency of osteosarcoma several years later.

Cardiovascular and renal effects [Section 4.5.3]

The Report raises some interesting points related to kidney disease and its cardiovascular consequences. We learn (page 9) that chronic kidney disease (CKD) is relatively common in New Zealand and that sufferers may be at risk of excess fluoride. "However," the Report states, "to date no adverse effects of CWF exposure in people with impaired kidney function have been documented." One meets this kind of statement rather often in reports and reviews. It can have three meanings: 1.

numerous studies have been reported, all considered negative; 2. no studies have been performed; 3. something in between. Critical readers tend to assume the second interpretation. Too often one is left guessing, but later this Report does eliminate interpretation 1, stating "However, the scarcity of data indicates that further studies are required." (page 59). In other words, we don't know.

With this in mind, we may turn to page 52 where the Report summarizes an interesting recent paper by Martin-Pardillos and colleagues [200]. The paper shows that partially nephrectomized rats (a model for human CKD) having 1.5 or 15mg/l fluoride in their drinking water show accelerated medial calcification of vascular smooth muscle. The authors of the paper suggest on the basis of these results that fluoridated water may pose a cardiovascular risk for CKD sufferers. The Report rightly states that the results need to be confirmed. The interesting question is, what should happen meanwhile? I suspect that most opponents of fluoridation would call for CKD sufferers to be warned to avoid tap water. Possibly the NZ health authorities have done so. If not, will they follow the "no adverse effects" message on page 9, or will they adopt a more precautionary approach to protect this group of patients from possible harm? And will further study of the matter be given any degree of priority?

END

Appendix – calculation of dental fluorosis incidence in Auckland (approximate numbers)

Auckland: total population = 1.4 million
- of which >95% fluoridated = 1.3 million
- of which conservatively 20% in 8-30 age group = 272,000
- of which 1.7% have 'moderate' dental fluorosis* = 4600
  and 3.0% have 'mild' fluorosis* = 8100

*Source: Our Oral Health: Key findings of the 2009 New Zealand Oral Health Survey. Ministry of Health, Wellington, 2010. p 171, Table 92.

Cost of veneers $650 - $1750 per tooth according to quality
http://www.clarencetam.co.nz/about_the_practice/standard_pricing.aspx

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NZ Report – Health effects of water fluoridation: A review of the scientific evidence

Introduction

The findings and recommendations in the executive summary in my opinion overstate the benefits of water fluoridation and understate the potential risk to general health of individuals.

No effort was made in the selection of panel members to control for bias (1). The panel apparently simply reviewed a draft report undertaken over just a few months by a single literature researcher, Anne Bardsley, with unspecified previous familiarity of the subject, who was charged with selection and interpretation of papers. (1,2)

A poignant communication from Sir Skegg to Sir Gluckman, lamenting the number of scientists who were approached to be on the review panel, but declined to participate, reads:

"....I can understand why any reputable scientist would be reluctant to put their name to a report if they have not had the time to have a first-hand look." (2)

According to the University of York Centre for Reviews and Dissemination:

"Systematic reviews differ from other types of review in that they adhere to a strict scientific design in order to make them more comprehensive, to minimise the chance of bias, and so ensure their reliability. Rather than reflecting the views of the authors or being based on only a (possibly biased) selection of the published literature, they contain a comprehensive summary of the available evidence."

This cannot in good faith be described as a robust and thorough review of fluoridation science by experts, as it fails to address conflicting evidence as detailed in this critique. In my opinion it fails to meet its requirement of advising local government leaders as to the state of the science on fluoridation.

Similar reviews aimed at advising city councils concerned about the health risks posed to their communities, but which are conducted by a balanced and unbiased review panel, have reached the opposite conclusions and have resulted in rejection of fluoridation in their communities. (3)

Comments on the Understated Health Risks:

This report identified large sections of the population of NZ who exceed the toxic limits for fluoride ingestion, including bottle fed infants, children under 8 years old, people with impaired kidney function, people who drink a lot of water, and people who have high fluoride intake already from other sources such as diet and toothpaste.

Despite this, they conclude that:

"the safety margins are such that no subset of the population is at risk because of fluoridation"

---

a sweeping statement, which is totally unsupported by their own discussion, let alone the science.

The reviewers appear to ignore the risk of fluoride overdose at the individual level of ingestion (dose) as opposed to the fluoride levels in the water at the population level (concentration), despite WHO recommendations stressing that countries who deliberately fluoridate water supplies need to monitor people's total fluoride ingestion at the individual level in case of overdose. (4)

I will leave critiques of the risk to health sections of this review to scientists who are the true experts in the fields.

My comments will focus on the gross over statement of the purported benefits of fluoridation in our society, New Zealand, 2014.

Quotes from the New Zealand report are highlighted in red italics. Quotes from other sources are highlighted in green italics.

Comments on: "Evidence for benefits of water fluoridation"

"Analysis of evidence from a large number of epidemiological studies and thorough systematic reviews has confirmed a beneficial effect of CWF on oral health throughout the lifespan." PAGE 8

The observation in 1906 USA that Italian immigrants from a high fluoride region had discoloured and mottled teeth (subsequently called Dental Fluorosis), but no tooth decay, led to the assumption that fluoride reduces caries.

It was considered useful by public health authorities to put fluoride in the water supplies of populations en masse, based on the erroneous theory that fluoride incorporated into children's developing tooth enamel would make teeth more resistant to decay.

"ingested fluoride is incorporated into the developing enamel, making the teeth more resistant to decay." PAGE 7

It has been widely accepted since the 1990s that any effect on tooth decay from swallowing fluoride is insignificant or non-existent. To quote:

CDC 1999: "the effect of Fluoride is topical " (5)

J Featherstone 1999: "the systemic effect is, unfortunately, insignificant" (6)

Evidence given in support of water fluoridation has generally been weak, often suffering from lack of controls for a variety of confounding factors and research bias. (7)
The "elephant in the room" is that while decay rates fell in areas where fluoridation was implemented, it also fell in areas that weren't, often at a faster rate. (8)
Furthermore, cross sectional studies generally make comparisons on the basis of age and do not identify how long the teeth have actually been present in the mouth for each group.

There is evidence that teeth erupt later in areas exposed to water fluoridation (due to hardening of bone over the erupting tooth and hormonal effects), which of course means less time exposed to plaque acid and less decay at a particular age. (7)

If the actual time teeth have been present in the mouth is accounted for, the minor differences seen in cross sectional studies comparing fluoridated and unfluoridated communities disappear. (9)

Ministry of Health figures recorded every year in 5 year olds and year 8s (12-13 year olds) consistently show minimal or no differences between fluoridated and non-fluoridated areas of NZ. (10)

The highly acclaimed York Review found only 26 studies after 60 years of research which met even the minimum scientific standards to be considered reliable. Most of these were decades old and prior to the widespread use of fluoridated toothpaste.

Nevertheless their conclusion was that water fluoridation during that period did reduce the incidence of tooth decay, but only by about 14%, much less than the 60% quoted publicly by some health agencies and organizations.

Importantly, the York Review noted that the variation of tooth eruption times between fluoridated and unfluoridated areas was not taken into account. (7)

Furthermore, since the widespread use of fluoridated toothpaste from the late 1980s onwards, any perceived benefit from water fluoridation has become minimal at the community level.

This was the conclusion of the European review of fluoridation, Scientific Committee on Health and Environmental Risks 2011 (11):

"In the 1970s, fluoridation of community drinking water, aimed at a particular section of the population, namely children, was a crude but useful public health measure of systemic fluoride treatment. However, the caries preventative effect of systemic fluoride treatment is rather poor (Ismael and Hasson 2008)".

SCHER 2011

"No obvious advantage appears in favour of water fluoridation compared with topical prevention. The effect of continued systemic exposure of fluoride from whatever source is questionable once the permanent teeth have erupted."

SCHER 2011

"This suggests that water fluoridation plays a relatively minor role in the improvement of dental health." SCHER 2011 (11)

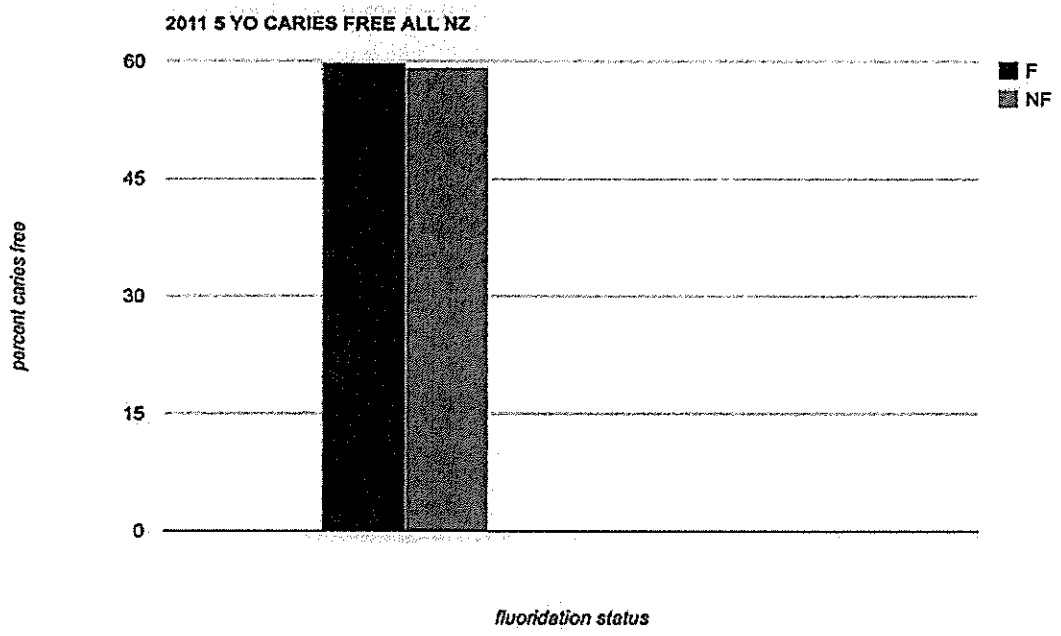
"SCHER agrees that topical application of fluoride is most effective in preventing tooth decay. Topical fluoride sustains the fluoride levels in the oral cavity and helps to prevent caries, with reduced systemic availability. The efficacy of population based policies, e.g. drinking water, milk or salt fluoridation, as regards the reduction of oral health social disparities, remains insufficiently substantiated." (12)

Just how minor a role water fluoridation plays at the community level is evident from the following graphs made from the www.health.govt website. (10)

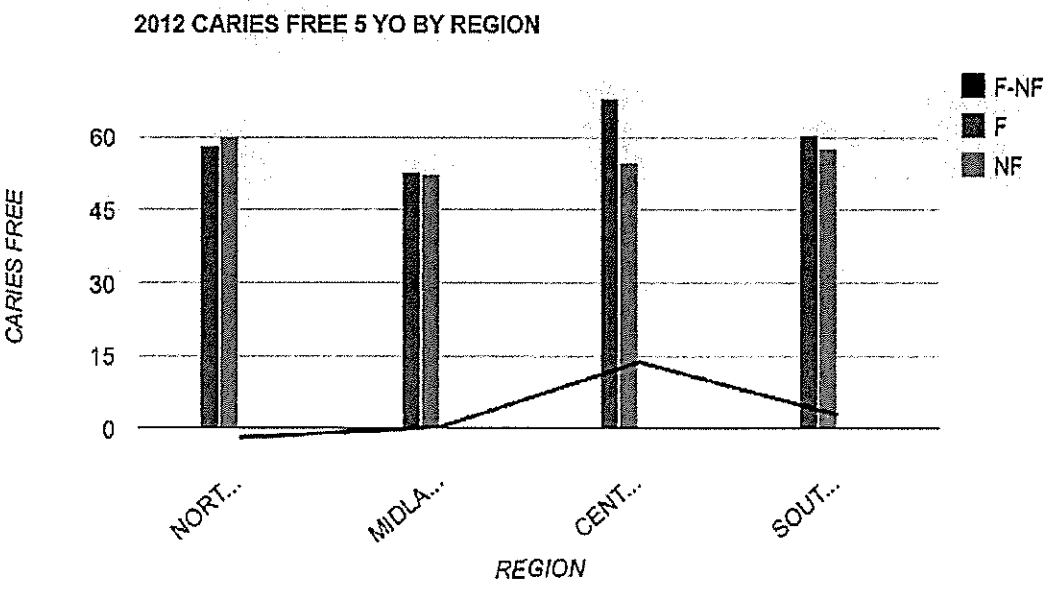
Number 44,653 5YO 44,659 Y8	2011 FLUORIDATED	2011 NOT FLUORIDATED	DIFFERENCE
5YO% CARIES FREE	59.91%	59.18%	0.73%
Y8 % CARIES FREE	55.17%	51.79%	3.38%
5YO dmft	1.77	1.9	0.13
Y8 DMFT	1.14	1.37	0.23

This 2011 real life child data shows that the difference in decay incidence and severity between children living in fluoridated and unfluoridated areas in NZ is insignificant.

Data sourced from: www.health.govt



Small apparent differences could be accounted for by other factors such as delayed eruption of teeth in fluoridated communities, therefore less time in the mouth exposed to plaque acids, ethnic distribution and urban/rural differences.



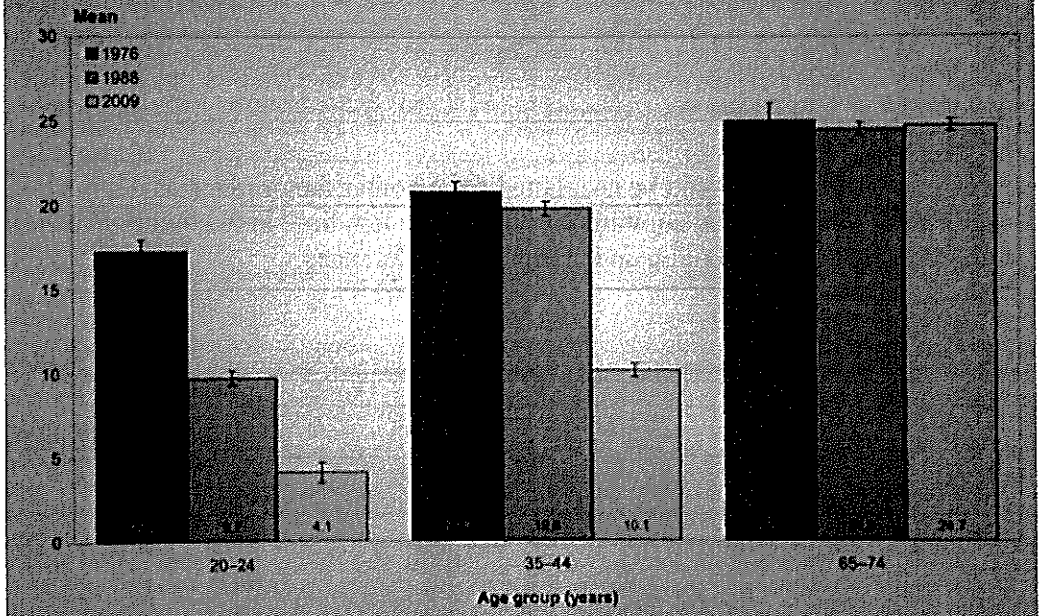
Data from the NZOHS 2010 do not support statements of a lifetime benefit, indicating that the action of fluoride is simply to delay the decay. (13)

The following figures, from the NZOHS, look at the senior adult age group and show that the lifetime decay experience is the same, regardless of the amount of time spent in a fluoridated community.

NZOHS 2010 data indicate that fluoridation only delays tooth decay; the lifetime experience is the same in the older age group irrespective of fluoridation history. No difference was found in DMFT in the 65-74 age group after water fluoridation was implemented in NZ.

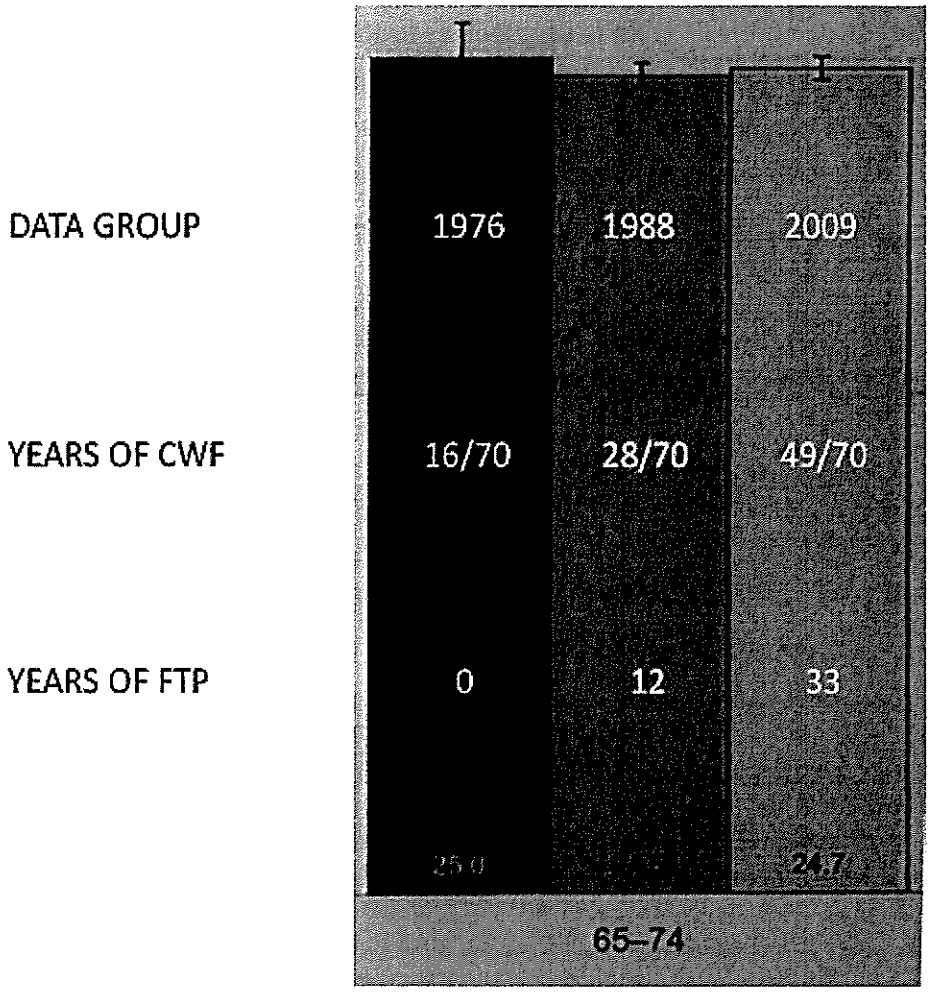
There was no significant change in the mean DMFT score in 65–74-year-old dentate adults from 1976 to 2009.

Figure 53: Mean number of decayed, missing or filled teeth (DMFT) per person, among dentate adults in 1976, 1988 and 2009, by age group (unadjusted mean)



Sources: 1976 Survey of Adult Oral Health, 1988 WHO Study of Oral Health Outcomes (NZ), 2009 New Zealand Oral Health Survey

An analysis of the 65-74 age group by proportion of life since fluoridation (CWF) was introduced and since fluoride toothpaste (FTP) was introduced:



Although we can see apparent benefit in younger age groups, we can see no lifetime benefit from CWF or FTP on this NZOHS data. 65-74 year olds in 2009 had the same lifetime decay experience as they did in 1976, despite having the benefit of fluoridated toothpaste and water fluoridation being available for over 30 years longer for half the population.

The York Review found there was no weight of evidence to support benefit in adults or in low SES groups, or increase of decay in cessation studies. (7)

"In New Zealand, significant differences in decay rates between fluoridated and non-fluoridated communities continue to exist, despite the fact that the majority of people use fluoride toothpastes.
These data come from multiple studies across different regions of the country conducted over the last 15 years, as well as from a national survey of the oral health status of New Zealanders conducted in 2009." PAGE 8

The reliability of NZ studies unfortunately suffers heavily from the weaknesses identified in the York Review in many cases. The studies cited in the review to support the efficacy of fluoridation are no exception.

1. The Hastings Experiment

This was a very questionable pilot study, which launched fluoridation in NZ in the early 1960s.

Designed to compare the decay rates in the communities of Napier (unfluoridated control) and Hastings (artificial fluoride added to water experimentally), it apparently became a case of adjusting the facts to fit the theory.

Decay was dropping faster in Napier and not in Hastings, so the researchers cut Napier out of the study.

It has been accused of being fraudulent, because not only was the methodology changed during the course of the study, the data recording protocols were changed, as were the MoH directives to school dental nurses criteria of when a tooth needed to be filled, and this was not accounted for by the researchers. (14,15)

Fluoridation defenders unsurprisingly no longer refer to this study, yet for decades it was taught in dental schools as the definitive justification for water fluoridation. Full critique attached as appendix 1.

2. Lee & Dennison 2004

These long standing DHB employees cherry picked two cities from the 1996 data to compare. Overall 1998 data show that had other areas been selected, the results would have been the opposite.

Even so, the absolute differences found were minimal, and again the study was seriously flawed by uncontrolled confounding factors and research bias. (16)
Full critique appendix 2.

3. Southland Study: Mackay and Thomson 2005

This review claims it shows children in fluoridated areas had about half the decay rates of those in unfluoridated areas.

In fact this was a very weak study, whose conclusions are not supported by the results presented. Children were examined in a mobile clinic and the teeth were not cleaned or dried for the examination.

Due to the small numbers, results were not statistically significant, and many confounding factors were uncontrolled.

In fact, the authors admit in the discussion that "there were no significant differences in deciduous caries prevalence or severity (or in the permanent caries prevalence) by socio-demographic characteristics or length of residence in fluoridated areas." (17)

4. 2010 NZ Oral Health Survey

This survey was a "snapshot in time" of New Zealander's oral health status in 2009, and was not designed as a scientific study on fluoridation. The writers make a number of disclaimers to this effect; yet still draw conclusions from data which is not statistically significant. (13)
Full critique appendix 3

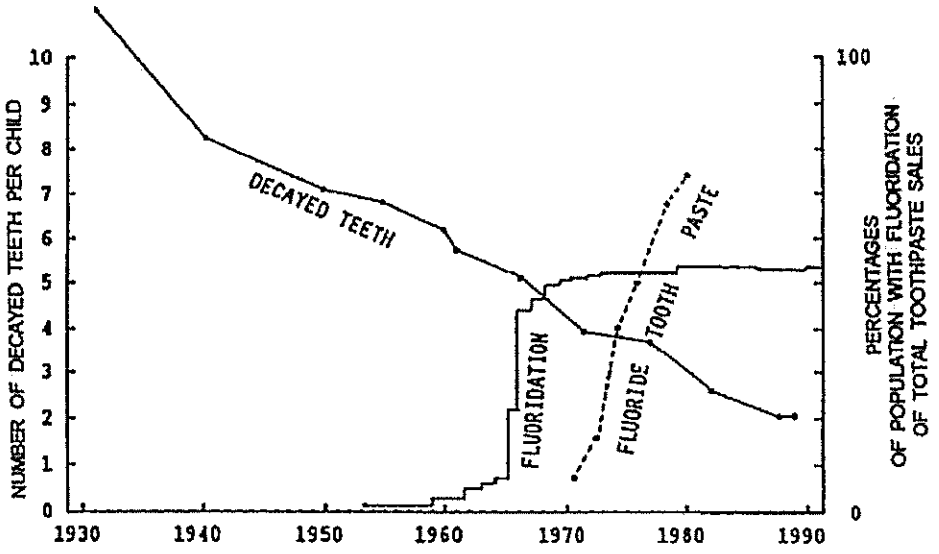
Evidence That Water Fluoridation is Ineffective:

There have been numerous NZ and overseas-published studies which indicate no significant differences in decay rates between fluoridated and unfluoridated areas.

These were overlooked in the present review.

1. New Zealand Studies:

Dr. John Colquhoun, a long serving Principal Dental Officer for the Auckland Health Board, was a leading advocate for water fluoridation for about 20 years.
In 1981 he changed his mind after he realized the data collected by his service proved that water fluoridation had no particular effect on tooth decay in NZ. He showed that the decay rate in NZ was declining before fluoride was introduced, and fluoridation had no apparent impact on this rate.



1. Graph of decline in NZ decay rate prior to fluoridation. Tooth decay was falling in NZ at the same rate even before fluoridation was in widespread use. Colquhoun J, (1984) New evidence on fluoridation. (18)

Dr. Betty de Liefde, who followed John Colquhoun as principal dental officer for the Health Department, made similar observations, and published a report in the NZDJ in 1989 concluding:

"the caries reducing effects of community water fluoridation are clinically insignificant" (19)

In an Auckland study comparing 9-year-old children attending schools in fluoridated and unfluoridated areas, Karaganatnam et al (2009) state:

"no significant relationship was found between residential fluoridation history and dental caries in the permanent dentition" Page 257 (20)

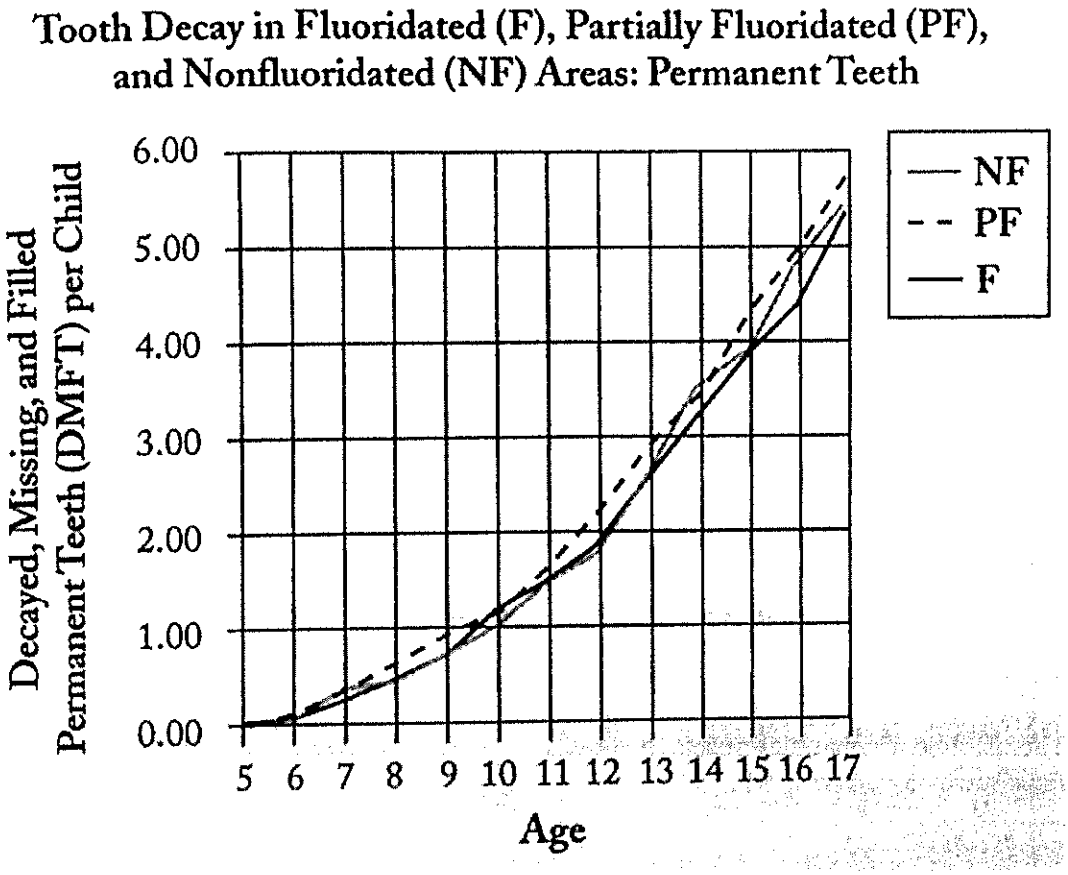
In their 2005 paper "Enamel defects and dental caries among Southland children", Thomson (a panel member of this present review) et al report:

"There were no significant differences in deciduous caries prevalence or severity (or in permanent caries prevalence) by sociodemographic characteristics or length of residence in fluoridated areas" Page 39

This is, in fact, what their research showed, however they oddly concluded that decay rates were halved by CWF. (17)

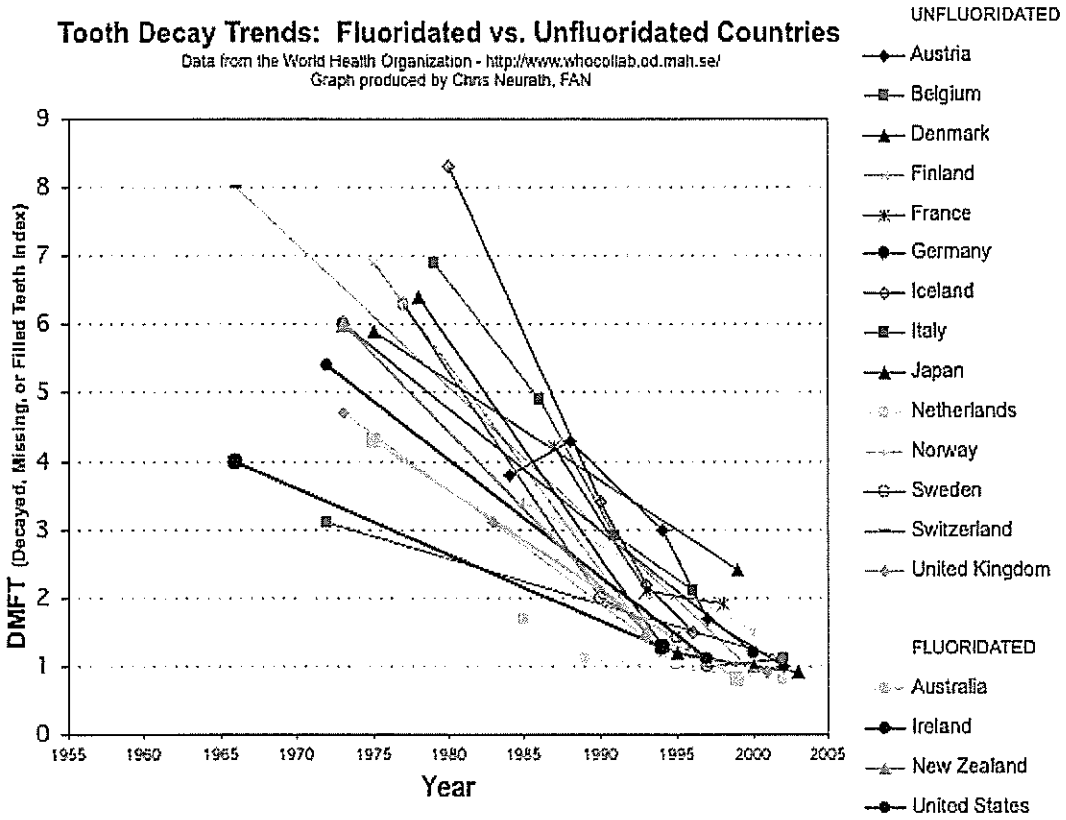
2. Overseas Studies:

The largest USA study also shows no difference in decay rates with or without water fluoridation.

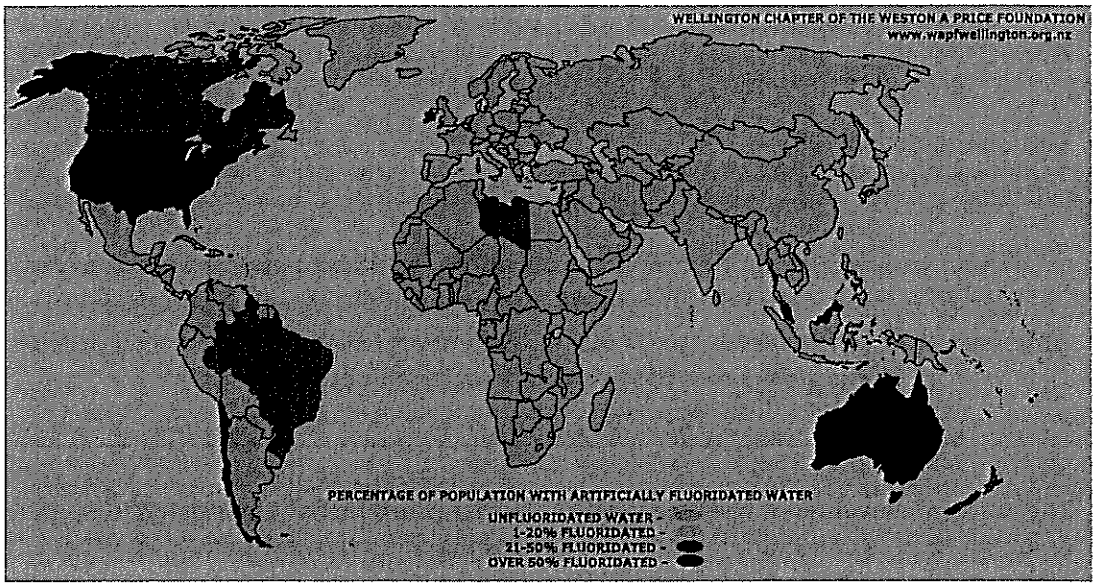


JA Yiamouyiannis water fluoridation and tooth decay: results from the 1986/87 National Survey of US schoolchildren (21)

Globally, fluoridation is seen to make no difference to reduced decay rates, there being no difference between the few countries which use artificial fluoridation, and those that don't. (8,7)



It must be noted that only a handful of countries fluoridate their water supplies, and fewer still fluoridate more than 10% of their population. More than half of all artificially fluoridated people live in the USA.



"Various studies indicate that CWF has an additive effect over and above that of fluoride toothpaste and other sources of fluoride that are now in common use." Page 9

The review appears to be referring to a few weak studies to imply benefit, rather than the weight of evidence. In contrast, the more robust SCHER report states:

"No obvious advantage appears in favour of water fluoridation compared with topical prevention. The effect of continued systemic exposure of fluoridation from whatever source is questionable once the permanent teeth have erupted" SCHER 2011 (11)

An understanding of the mechanism by which fluoride is thought to reduce (or delay) tooth decay is a crucial factor, and the NZ report shows some confusion about this.

"It is now widely accepted that the action of fluoride is topical and that works by helping to slow down the decay process after it has started, that is, its action is in the early stage of decay, not on healthy enamel or established decay." (6)

"To this end, the constant bioavailability of fluoride in the saliva in low doses is desirable. Unfortunately, the increase of salivary fluoride levels from living in a 1ppm fluoridated area is too weak to have any noticeable effect." (22)

The CDC noted in 2001:

"The concentration of fluoride in ductal saliva, as it is secreted from salivary glands, is low – approximately 0.016 parts per million (ppm) in areas where drinking water is fluoridated and 0.006 in nonfluoridated areas. This concentration of fluoride is not likely to affect cariogenic activity." (23)

The required elevation of baseline levels only occurs after using fluoridated toothpaste or mouth rinse, a concentration of 1,000 ppm or more instead of 1 ppm from water. (24)

This elevation of fluoride levels in the saliva is transient and results from fluoride ions bound to oral tissues after using high strength topical agents being slowly released into pooled saliva.

Fluoride recirculated through the salivary ducts is of minimal contribution to pooled salivary levels, even after swallowing large doses as in fluoride toothpaste or tablets. (25)

"The burden of tooth decay is highest among the most deprived socioeconomic groups, and this is the segment of the population for which the benefits of CWF appear to be greatest." Page 9

This statement is clearly not aligned with the findings of the York Review and SCHER Review.

Increased decay rates among low SES groups are more strongly correlated to other factors such as parental education, family income, poor diet and reduced access to dental care. These factors are not improved by fluoridating the water supply, and there is no weight of evidence to support such a claim, which is why the major reviews conclude:

"The efficacy of population based policies, e.g. drinking water, milk or salt fluoridation, as regards the reductions of oral health social disparities, remains insufficiently substantiated." SCHER 2011 (11)

"There appears to be some evidence that water fluoridation reduces the inequalities in dental health across social classes in five and 12 year-olds, using the dmft/DMFT measure. This effect was not seen in the proportion of caries-free children among five year-olds. There was not sufficient data for the effects in children of other ages to investigate fully." York page 33 (7)

The argument that water fluoridation of the entire community is necessary in order to offer at least some benefit in decay reduction to young children in low SES circumstances, who do not brush their teeth, appears very unconvincing.

Aside from the minuscule elevation it contributes to pooled salivary fluoride, too weak to have any effect on caries, plaque growing on the teeth will block the penetration of fluoride to the enamel surface. (26) Furthermore, the caries balance in much of this demographic, with poor high sugar diets, would be heavily in favour of demineralization, so that any effect of fluoride would be further negated. (27)

It would be appropriate to note that tooth decay is caused by consumption of sugar and failure to remove plaque, it is not caused by fluoride deficiency. Efforts to close the gap that exists between SES classes tend to succeed far more when the focus is on diet and oral hygiene rather than on putting fluoride in the drinking water. (28)

NZ data show Maori, who are disproportionately higher represented in the low SES groups, are no closer to Europeans in fluoridated communities than they are in non-fluoridated.

2011 FIVE YEAR OLDS % Caries free	EURO	MAORI	GAP
FLUORIDATED	71.39	42.6	28.79
UNFLUORIDATED	66.26	39.3	26.96

Data sourced from: www.health.govt

On the other hand, Maori are at greater risk of fluoride toxicity due to higher fluoride diets, lower calcium and lower vitamin D. (29)

Research in the USA indicating much higher levels of dental fluorosis and toxicity effects among African American and Latino groups have led to protests and civil unrest. (30)

Furthermore, communities which have stopped water fluoridation have shown no increased decay rate and in most cases, a reduction. (31,32)

In New Zealand, Timaru (ceased CWF in 1985), New Plymouth (2011) and Ashburton (2002), saw reductions in decay after cessation. Disappointingly such information has not been readily advertised by the Ministry of Health and generally is only released after OIA requests. (33)

Comments on: "Known effects of fluoride exposure – dental fluorosis"

"In the common, mild forms it is of minor or no cosmetic significance." Page 9

"No severe form of fluorosis has ever been reported in New Zealand." Page 9

While mild fluorosis is of minor cosmetic significance, it is a biomarker indicating fluoride overdose, and should raise questions of fluoride ingestion levels at the individual level and potential effects on other tissues and organs in the body, such as the thyroid or brain (34)

The review fails to mention the incidence of moderate fluorosis, which is a cosmetic problem requiring expensive treatment. In NZ it is around 5%, or 20,000 people.

The York Review estimated that up to 16% of fluorosis is of cosmetic concern.

"The risk for mild fluorosis that is associated with fluoride exposure is highest for formula-fed infants, and young children who are likely to swallow toothpaste. In some cases the fluoride intake by these groups can approach or exceed the currently recommended conservative upper intake level, but the rarity of cosmetically concerning dental fluorosis in New Zealand indicates that such excess intake is not generally a safety concern." Page 9

The "upper limit" is used in NZ and Australia to indicate how much fluoride you can give at the community level without causing unsightly dental fluorosis to more than 5% to 10% of the community. It addresses the visible (and undeniable) outward signs

of fluoride overdose, but takes no account of the doses at the individual level which can cause increased health risks with chronic ingestion.

Such measures are the Minimal Risk Level (MRL) and Reference Dose (Rf), which are respectively 0.05mg/kg and 0.06mg/kg of body weight/day as the toxic limit, and are generally much less than the UL in most age groups. (34)

"There is strong evidence that CWF is a cost effective use of ratepayer funds"

PAGE 13

One could ask whether funding for public health measures (and indeed liability) should be the responsibility of city councils instead of central government.

Studies on cost effectiveness are flawed and misleading, as they don't consider all the relevant factors and embellish the relevance of factors they do account for.

1. In calculating cost per head, they assume the whole community is gaining a (questionable) benefit, whereas in fact it appears that only a small section of the community are likely to have any significant benefit (young children who don't brush and don't eat much sugar). The cost should be divided by this number, not the entire population.

2. They often include costs for travel, loss of productivity, etc, which are not necessarily applicable.

3. They don't account for cost of PR campaigns, maintenance of equipment, staff payments.

4. They don't account for the cost of repairing fluorosis of aesthetic concern and emotional and social costs of this disfigurement.

5. They don't consider the cost of potential health issues: as fluoridation can increase the risk of conditions such as mental health disorders, diabetes, cardiovascular diseases, bone and joint diseases if they exceed chronic total fluoride intake limits.

6. They overstate the decay saving:
NZOHS & MOH data indicate 0.2 surfaces every 6 years, not 0.6 every year as in 2001 NZ study. (35) Furthermore, the aged population data presented above indicate zero lifetime decay reduction benefit.

7. If one assumes benefit, salt fluoridation is more cost effective as a community fluoridation measure then water fluoridation and has the added advantage that it can be targeted to at-risk groups. (36)

Concluding remarks

Just as individual research studies need to meet certain criteria in order to be considered reliable and relevant, so too do scientific reviews. The York Review 2000, NRC Review 2006 and SCHER Review 2011 do.

This one does not.

This report, far from being the robust definitive review that it repeatedly purports itself to be, falls well short of being a credible review of the conflicting science around fluoridation.

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APPENDIX 1: Critique of the Hastings Experiment
Written by Dr Paul Connett PH.D Chem, B.A. (Hons) Professor Emeritus in Environmental Chemistry at St. Lawrence University in Canton, NY

The Smoking Gun

This NZ fraud begins with a smoking gun letter (dated Oct. 12, 1962) from G. H. Leslie the director of NZ Government dentistry – who EIGHT years into the 10-year Hastings Napier trial (1954-64) complains that they cannot find the evidence to convincingly demonstrate a relationship between fluoridation and lower tooth decay.

12 October, 1962
Mr. Swann,
I have delayed acknowledging receipt of Dr. Roche's letter to you and replying to your minute in the hope that I would by now be able to give a positive reply to your enquiry. I still cannot. No one is more conscious than I am of the need for proof of the value of fluoridation in terms of reduced treatment. It is something which has been concerning me for a long time. It is only a matter of time before I will be asked questions and I must have an answer with meaning to a layman or I am going to be embarrassed and so is everyone else connected with fluoridation. But it is not easy to get. On the contrary it is proving extremely difficult. Mr. Espia is conferring with Mr. Bock and Mr. Ludwig and I am hopeful that in due course they will be able to make a practical suggestion.

I will certainly not rest easily until a simple method has been devised to prove the equation fluoridation = less fillings

(G.H. Leslie)

Director, Division of Dental Health

With this letter we have what amounts to a "smoking gun" as far as the inability of NZ dental officials and researchers to show the effectiveness of fluoridation – some eight years into the ten-year Hastings Napier fluoridation trial. The Mr. Ludwig, who Leslie refers to, is the lead researcher for this trial.

However, miraculously, two years later this trial was proclaimed a great success in demonstrating that fluoridation resulted in a large reduction in tooth decay (over 60%) and the result was used to push for fluoridation throughout the country. So how in the space of two years was this dramatic turnaround achieved?

The answer came from the late Dr. John Colquhoun, the former Chief Dental Officer for Auckland, who after retirement did a PhD thesis on the history of fluoridation in New Zealand (Colquhoun, 1987). As part of his doctoral research he was allowed access to the official files on the Hastings Napier trial (though according to his thesis advisor Professor Robert Mann, it became evident that some were incomplete, especially regarding Napier).
Based on these official files he was able to see how the deception was orchestrated.

In his thesis and in an article published in The Ecologist (Colquhoun and Mann, 1986) he showed that the massive reduction in tooth decay claimed for Hastings was a complete artifice.

According to Colquhoun the Hastings deception was in three parts:

1) After about two years the control city of Napier was dropped for bogus reasons.

2) The reduction in tooth decay claimed was based on comparing tooth decay in Hastings at the beginning and the end of the trial (and not a comparison between tooth decay in Hastings and Napier).

3) The method of diagnosing tooth decay was changed during the trial. Colquhoun describes this third aspect of the deception: "The school dentists in the area of the experiment were instructed to change their method of diagnosing tooth decay... Before the experiment they had filled (and classified as "decayed") teeth with any small catch on the surface, before it had penetrated the outer enamel layer. After the experiment began, they filled (and classified as "decayed") only teeth with cavities, which penetrated the outer enamel layer. It is easy to see why a sudden drop in the numbers of "decayed and filled" teeth occurred.
This change in method of diagnosis was not reported in any of the published accounts of the experiment."

What qualifies these activities as scientific fraud, in my view, is the last sentence: "This change in method of diagnosis was not reported in any of the published accounts of the experiment."

To the best of my knowledge the evidence that Colquhoun and Mann put forward for this rigged trial has never been refuted. In an email I received from Robert Mann (Dec 22, 2013), he wrote:

"I have never been aware of any attempt at rebuttal, let alone a refutation."

References:

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APPENDIX 2: Written by Dr Paul Connett PH.D Chem, B.A. (Hons) Professor Emeritus in Environmental Chemistry at St. Lawrence University in Canton, NY

The Lee Dennison "Study"

This is a study of self-selected data with no blinding and little weight given to confounding factors. Clearly the York team would have rejected it.

Firstly, this study breaks the fundamental rule of scientific enquiry. Both Lee and Dennison are ardent pro fluoridationists, and selected data knowing what outcome they wanted. To avoid unconscious bias data must be selected "blind", unlike this study. Napier and Hastings were chosen for New Zealand's original study because of their demographic similarity, to minimize confounding factors.

Wellington, by contrast, is quite unsuitable for comparison with any other community: It has the highest educational and income levels in New Zealand, both of which correlate to good dental health. It would be extremely difficult to allow for confounding factors using Wellington statistics. We only need to look at statistics from nearby Hutt Valley to see this.

For Form 2 children, Hutt Valley Health records 1.10 DMFT in fluoridated areas and 1.01 DMFT in unfluoridated areas. It shows up in the Maori statistics too: 1.18 DMFT fluoridated, 0.72 DMFT unfluoridated (i.e. the unfluoridated areas have less decay than the fluoridated areas. Obviously something in that area is leading to better teeth (irrespective of fluoridation status).

In fact, Canterbury and Wellington are not a particularly good fit. For example, Wellington is much more urbanized than Canterbury, and there is a well-known correlation between urbanization and lower rates of decay.

Amongst the serious flaws in this study are the following:

The fluoridation history of the subjects was not known, nor whether they used fluoride toothpaste or not;

Two of the communities discontinued fluoridation (i.e. changed their fluoridation status) during the subjects' lifetime;

- There was no blinding;
- Data collection was not standardized;
- Examiner reliability was not ensured;
- Comparability of subjects was not assessed;
- Confounding factors were not eliminated;
- The mineral, particularly calcium and phosphorus, content of the respective water supplies was not determined

- The socio economic evaluations are completely unreliable. They use the 1996 TEFA ratings to assess the 1996 data. But the 1996 TEFAs were derived from 1991 census data. Moreover, TEFAs have been roundly criticized by schools for not accurately reflecting the socio economic status of their students. Not only were the TEFAs based on old data, but that data was derived from just a limited sampling of students (not the entire student population).

But there is an even more fundamental flaw. To adequately correlate socio economic status with decay, you need to do so on a subject-by-subject basis. You need to associate a particular child's DMFS with that child's status, not give every child in the school the same average value (TEFA). As a specific demonstration of the unreliability of the socio economic assessments used in the study, Te Aro School (Wellington) was designated decile 3 in 2002 (lowest group) but decile 8 in 2003 (highest group). (see table below)

The ethnic evaluations are also worthless. Despite the fact that the study was not designed to assess differences based on ethnicity, the authors make broad statements based on inadequate data: "in the non-fluoridated group, the mean DMFSs score of Maori five year olds was double that of the "Other" group, and that for Pacific children, three times greater than the "Others". That non-fluoridated group is Canterbury, which has a low Maori/Pacific population.

Drawing conclusions from such a small sample is worthless. One must also question why South Canterbury was included in the Canterbury sample.

The obvious comparison would be between Wellington and Christchurch. Including South Canterbury makes the unfluoridated sample much larger than the fluoridated sample. Why was that done? It creates a suspicion that the higher decay rates of Timaru were added to pull down the Christchurch figures.

As an indication of the readiness of the authors to [edited], they quote Fergusson (1986), Stockwell (1990), Treasure (1994), Slade (1996), Jones (1999) and Riley (1999) as authorities but neglect to mention that the York Review (2000) said those studies were poor quality and could not be relied on.

But ultimately their conclusions actually showed there was not much difference anyway.

"RESULTS: Caries prevalence and severity was consistently lower for children in the fluoridated area for both age groups, and within all subgroups. Five year olds in the fluoridated area had 2.63 dmfs (sd, 5.88), and those in the non-fluoridated area 3.80 dmfs (sd, 6.79). For 12 year olds the respective figures were 1.39 DMFS (sd, 2.30) and 2.37 DMFS (sd, 3.46). Multivariable analysis confirmed the independent association between water fluoridation and better dental health."
See study.

This results in a saving of 1.17 decayed, missing of filled surfaces in 5 year olds and 1.09 decayed, missing or filled surfaces in 12 year olds. This is hardly any achievement.

Decile ratings of selected schools

	2002	2003
Lumsden School	7	3
Homebush School	5	9
Waihao Downs	6	10
Tapapa School	9	4
Te Moana School	9	5
Te Aro School	3	8
Glendowie School	3	7
Whangara School	3	7
Ngamatea School	4	9
Tahora School	4	8
Waingaro School	4	8
Rissington School	5	9
Glen Oroua School	4	10
Arthurs Pass School	7	1
Aberfeldy School	7	3
Whangaehu School	7	3
Kapuni School	8	3
Putorino School	8	3
Otuni School	9	2
Tiraumea School	9	3
Timaru Christian	9	4
Makarora Primary	10	5
South Wellington	5	8

APPENDIX 3: Critique of NZOHS 2010

This survey describes itself as a "snapshot" of the oral health of New Zealanders at a particular point in time.

It is important to note that it was not one of the objectives of the 2009 NZOHS to compare the oral health status of people by fluoridation status, and therefore the survey cannot be considered a fluoridation study as such. The following results are for a snapshot in time and constitute an ecological analysis based on current place of residence. As such, they do not take into consideration lifetime exposure to fluoridated and nonfluoridated water supplies. Individuals who currently live in fluoridated areas may have spent time in non-fluoridated areas, and the reverse is also true. Furthermore, there may be other confounding facts that have not been taken into consideration.

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While it yielded some useful information, it was not a scientifically designed piece of research into fluoridation, so it is invalid to draw any conclusions from it.
The authors repeatedly warn readers of this fact, for example in addition to a myriad of uncontrolled confounding factors, the sample size studied was statistically insignificant.

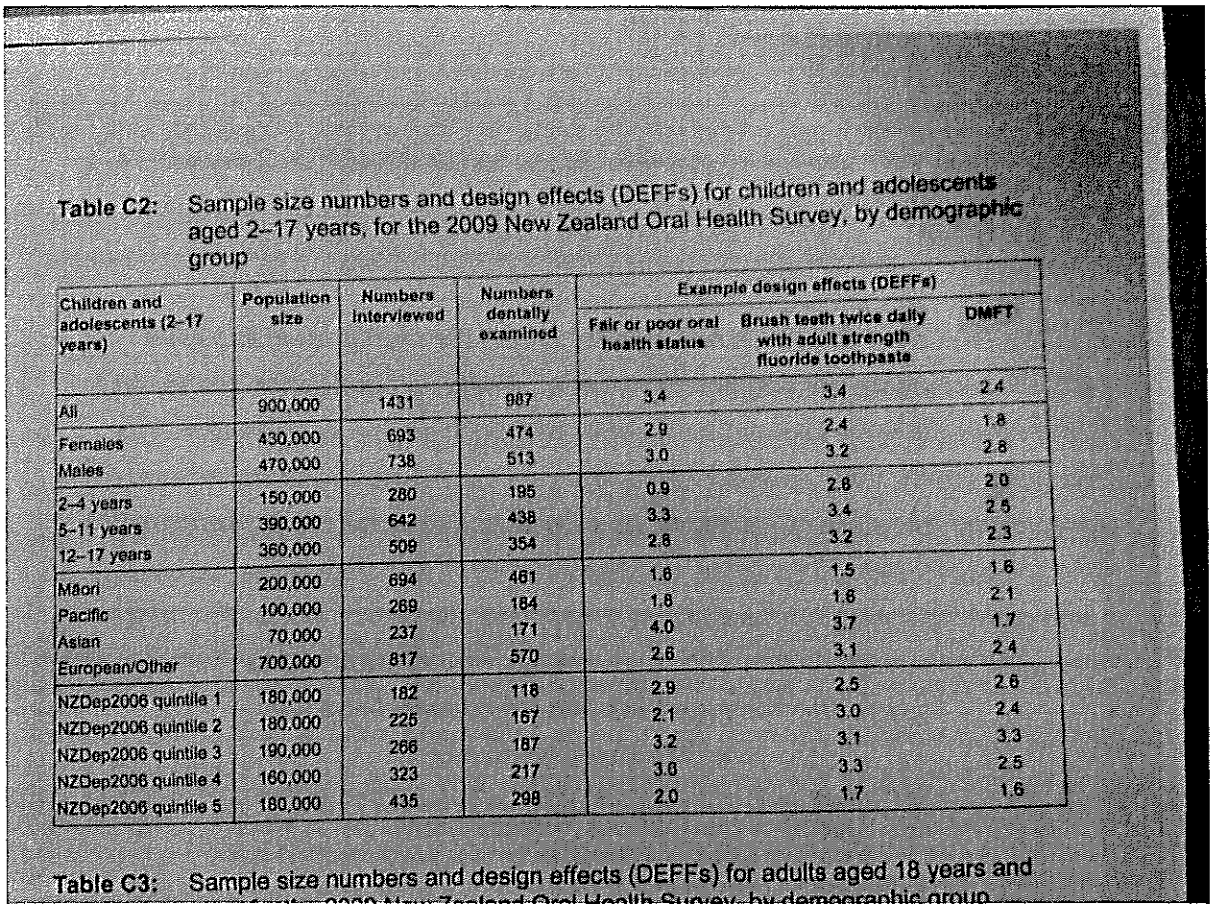


Table C2: Sample size numbers and design effects (DEFFs) for children and adolescents aged 2–17 years, for the 2009 New Zealand Oral Health Survey, by demographic group

Children and adolescents (2–17 years)	Population size	Numbers interviewed	Numbers dentally examined	Example design effects (DEFFs)		
				Fair or poor oral health status	Brush teeth twice daily with adult strength fluoride toothpaste	DMFT
All	900,000	1431	987	3.4	3.4	2.4
Females	430,000	693	474	2.9	2.4	1.8
Males	470,000	738	513	3.0	3.2	2.8
2–4 years	150,000	280	195	0.9	2.6	2.0
5–11 years	390,000	642	438	3.3	3.4	2.5
12–17 years	360,000	509	354	2.8	3.2	2.3
Māori	200,000	694	481	1.6	1.5	1.6
Pacific	100,000	269	184	1.8	1.8	2.1
Asian	70,000	237	171	4.0	3.7	1.7
European/Other	700,000	817	570	2.6	3.1	2.4
NZDep2006 quintile 1	180,000	182	118	2.9	2.5	2.6
NZDep2006 quintile 2	180,000	225	167	2.1	3.0	2.4
NZDep2006 quintile 3	190,000	266	187	3.2	3.1	3.3
NZDep2006 quintile 4	160,000	323	217	3.6	3.3	2.5
NZDep2006 quintile 5	180,000	435	298	2.0	1.7	1.6

Table C3: Sample size numbers and design effects (DEFFs) for adults aged 18 years and

It is profoundly inappropriate to use the NZOHS 2010 for advising policy on water fluoridation.

Analysis of Official Information request responses to: NZ Report – Health effects of water fluoridation: A review of the scientific evidence

Prepared on behalf of Fluoride Free NZ by G Mark Atkin BSc, LLB(Hons)

We have obtained information about the report's development from the Office of the Chief Science Advisor under the Official Information Act. The OIA requests were necessary after the office exhibited reluctance to our requests for transparency of information.

This information is not complete, and in places appears inconsistent. However, it is sufficient to raise serious concerns about the report's reliability, and the political bias observed by some of our reviewers. In all it tends to confirm the view that this is not a robust, objective, scientific report on the current science around water fluoridation, but was prepared to a political timeframe to meet a predetermined political outcome – to endorse water fluoridation as "safe and effective".

The methodology

Contrary to the methodology claimed in the report, (that the academic writer wrote the report which was then peer reviewed by the panel) the actual methodology was as follows:

- A panel of fluoridation advocates was hand-chosen by the pro-fluoridation chairs
- The panel members each prepared a summary of their views on the science in each member's area of claimed expertise.
- These summaries were given to the report author in a single one day session.
- The report author tidied these up, and added some further comments which she had prepared earlier. This was before she had received the bulk of the information.
- The author then gave this back to the panel to "review" their own work. It is therefore hardly surprising that they made few changes, they were only checking that the author had correctly relayed their own summaries.

Timeframes:

- 1 April – writer begins supplementary review (i.e. 6-8 weeks before receiving the bulk of the pre-written papers from the review panel).
- May 15-30 (pro-fluoridation) expert panel gives author 'state-of-the-science' briefing
- First draft complete 15 June (only 2-4 weeks to prepare this.)

Selection of the review panel

The review panel was established by the RSNZ with input from co-chairs. The approach was quoted as:

1. "Project co-chairs and science writer/coordinator to identify high-level headings for the review report and consult with Ministry of Health for their suggestions of issues needing coverage

2. RSNZ to invite experts onto panel in accordance with the identified headings and with the following minimum membership:

    a. Scientist - Public health Epidemiologist
    b. Scientist - Public health (dentistry specialty)
    c. Scientist - Toxicology
    d. Other relevant scientific experts ...
    e. Lay observer - a respected member of the public"

The responses received cannot identify any effort made to ensure the review panel had a balance of positions neutral, for, or against fluoridation on it (as the York and NRC reviews did), and evade the question of whether anyone meeting the expertise criteria, and with views opposing fluoridation, was ever approached.

Some of those approached declined to be involved, as follows:

On 5 April Prof Skegg wrote to Prof Gluckman:

> "As you will see below, however, [withheld] is questioning the feasibility of our approach... I can understand why any reputable scientist would be reluctant to put their name to a report if they have not had time to take a first-hand look at the evidence."

On 2 May Prof Skegg wrote (emphasis added):

> "You will have seen that [withheld] has agreed to join the panel. Unfortunately at the same time as adding a member, we have lost another. Professor [withheld] has just withdrawn: after reading the memorandum again, she felt she had insufficient expertise in the specific area and expressed reservations similar to [withheld]."

Selection of international reviewers

These were selected by the (pro-fluoridation) panel and vetted by the (pro-fluoridation) chairs. They are from fluoridated countries only. More professionals in fluoridated countries are biased in favour of fluoridation. However, thousands of professionals in fluoridated and non fluoridated countries have been very vocally opposed to fluoridation. See the thousands of signatures on the international Professionals Statement Against Fluoridation:
http://fluoridealert.org/researchers/professionals-statement/

Selection of material to review

The following databases were used:

- Pubmed/Medline;
- Web of Science;
- Embase;
- Google Scholar;
- Cochrane library database;
- NFIS scanning was also checked (Reviews of scientific papers – lists new relevant studies up to June 2013).

Pubmed and Medline are known not to carry fluoride-adverse research, as identified by the NZ Public Health Commission in 1994/95.

The NFIS, is a now de-commissioned fluoridation support and co-ordination service, which was called the National Fluoridation Information Service (NFIS). It was a New Zealand Ministry of Health-funded consortium, contracted to "provide a proactive service that helps advance water fluoridation" (clause 2.2, clause 2.4 subclauses 3, 5, 6, 8, 9), and required to "not act in a way that may contradict or be inconsistent with Ministry policy on water fluoridation" (clause 2.3). In fact, the NFIS misrepresented itself, as it never provided objective unbiased information on fluoridation when it was active.

If one wanted the best available research on fluoride, as quickly as possible, the obvious place to look would surely be the only international journal dedicated to this subject. The journal is called *Fluoride* and was referenced heavily by the NRC review. While there is a reference in the Report's citations, the Chief Science Advisor's Office could not identify this as a journal that was identified for reference.

Review of the fluoride toxicity information was deemed too difficult for this panel. On 5 April 2014 Prof Skegg wrote to Prof Gluckman:

> "As you will see below, however, [withheld] is questioning the feasibility of our approach. As you know, I have always had concerns that - whereas the benefits of fluoridation can be summarised succinctly - the literature on potential risks is vast and quite complex. I can understand why any reputable scientist would be reluctant to put their name to a report if they have not had time to take a first-hand look at the evidence... Do you envisage that we could present our report as a synthesis of reviews by reputable evidence-based groups in other countries..." (Note that this refers to politically biased profluoridation organisations such the National Health and Medical Research Council of Australia, as confirmed in another email, rather than the NRC Review, which represents the "state of the science" on fluoride toxicity as at 2006.)

On 10 April Prof Gluckman wrote to Prof Skegg:

> "The reality is that the bulk of these issues have been dealt with by major agencies/academies in recent years and of course a report produced in short order will rely heavily on those."

So the NZ Report is, on the toxicity question, nothing more than a summary of pro-fluoridation international reviews, and therefore does not provide any scientific authority in its own right; nor does it add anything new to the scientific debate on fluoridation.

The types of papers accepted

Papers linked to water fluoridation were assessed for relevance based on the criteria that they were:

- available in English;
- primarily focused on community water fluoridation or concerned with fluoride in levels used for CWF;
- from NZ or comparable context.

Bullet 2 excludes much relevant toxicological research. In particular it excludes all laboratory animal studies on toxicity – exactly the type of study used to test pharmaceuticals. This was the restriction imposed on the York Review, which is why it could not draw any conclusion about safety.

Conversely, these are exactly the studies used by the NRC Review, which is, to date, the definitive review on health risks from fluoridation. This review, conducted under the National Academy of Sciences, sometimes called "The World Court of Science" is ignored by fluoridation promoters because it was not ostensibly about fluoridation at 0.7 to 1ppm, even though many of the studies it included were on communities fluoridated at this level.

Bullet 3 is designed to exclude relevant research such as the Chinese IQ studies used in the Harvard meta-analysis, which is misrepresented in the NZ report.

Validity criteria included:

- robust design;
- adequate sample size;
- systematic data collection to ensure minimal bias;

We note that the Dunedin IQ study, given undue weight in the Report, does not meet these criteria. (This does not reflect on the larger study from which non-fluoride-related data was taken).

Another example where the report fails to meet these criteria is where it relies on a letter to the editor by Douglass and Joshipura to deny the findings of Dr Elize Bassin on osteosarcoma. This unscientific approach was previously taken by the Australian Government NHMRC 2007 Review. (The research promised in that letter did not address Bassin's core finding that the risk is associated with age of exposure at all, let alone disprove it (see below).

Statement on Dental Fluorosis

The two latest scientific studies in NZ show that dental fluorosis rates are twice as high in fluoridated communities as unfluoridated communities (approx. 30% vs approx. 15%). The Report states (emphasis added):

> "...the 2009 New Zealand Oral Health Survey, which showed the overall prevalence of moderate fluorosis to be very low. The survey indicated that fluorosis prevalence is not increasing, and that levels of fluorosis are similar between fluoridated and non-fluoridated areas."

Note: as the survey was a 'snapshot in time" it cannot possibly identify trends.

The Survey report contains the following disclaimer at p167:

> "It is important to note that it was not one of the objectives of the 2009 NZOHS to compare the oral health status of people by fluoridation status, and therefore the survey cannot be considered a fluoridation study as such. The following results are for a snapshot in time, and constitute an ecological analysis based on current place of residence. As such, they do not take into consideration lifetime exposure to fluoridated and non-fluoridated water supplies. Individuals who currently live in fluoridated areas may have spent time in non-fluoridated areas, and the reverse is also true. Furthermore, there may be other confounding factors that have not been taken into account in this analysis, such as the usual reason for visiting a dental professional, and other sources of fluoride such as fluoride toothpaste."

We asked "(a) has the author read the published reports on the Southland (2005) and Auckland (2008) dental fluorosis studies? (b) If so, why does the author cite the 2009 Oral Health Survey on this subject, in light of its disclaimer on page 167, rather than bona fide research?"

The reply was:

> "The NZ Oral Health Survey is the most recent and comprehensive survey of oral health across the whole population of NZ, and is therefore an appropriate reference for a general statement on fluorosis in NZ."

So the Chief Science Advisor's Office has deliberately chosen a survey which itself states "should not be considered a fluoridation study" over *bona fide* science.

Systemic benefit or otherwise

We asked:

> "The author quotes Featherstone 1999 as authority for the claim that fluoride works systemically during tooth formation to harden enamel against decay. Why was there not acknowledgement in the report that the majority view currently is that systemic inclusion in tooth enamel has no significant effect on tooth decay, while a minority still cling to it? Instead the report gives the impression that such benefit is established fact, when the opposite is true. Is the author aware that the quoted paper in fact was the turning point that refuted that belief, in favour of topical effect? If so, why does she falsely quote this paper as endorsing the refuted theory of a systemic pre-eruptive mechanism?"

After acknowledging that the reference to Featherstone was a citation error, the reply went on:

> "The lead writer (and panelists) is aware that this paper is used by some to claim that fluoride has no systemic effect, but notes that this is not the conclusion drawn by the paper's author."

Featherstone actually says:

> "The level of fluoride incorporated into dental mineral by systemic ingestion is insufficient to play a significant role in caries prevention. The effect of systemically ingested fluoride on caries is minimal". (Extract - p31)
>
> "The topical effects of fluoride are over-riding, and the systemic incorporation of fluoride in the tooth mineral is unfortunately not of major benefit" (p37)
>
> "The role of systemically incorporated fluoride is of very limited value." (p37) And in the conclusions "(3) The systemic benefits of fluoride are minimal".

Dr Robin Whyman of the former NFIS states in his affidavit in the Sth Taranaki District Council fluoridation case:

> "Fluoride enhances enamel remineralisation. The effect is "topical". This means it works by the fluoride coming into physical contact with the biofilm [plaque on the teeth] and surface of the tooth enamel."

Featherstone also noted that a minimum of 0.03ppm fluoride is required in saliva. Although study results vary, the CDC's official position is that in a fluoridated community, the fluoride level in saliva is only 0.016ppm – too low to provide topical

benefit. The NZ Report mis-states this, saying that ductal saliva fluoride levels are always above the 0.03ppm required.
So it is NOT that "some [people] claim that fluoride has no systemic effect", but rather that in fact systemic pre-eruptively ingested fluoride has no significant role in caries prevention, but "some people" continue to cling to this now discredited theory of action.

Osteosarcoma

The Chief Science Advisor's Office claims that "All original research articles cited in the report were read in their entirety by Anne Bardsley".
Given that the main papers were processed by Bardsley in a 2 – 4 week window, it is difficult to see how she could have read and digested all the papers as well.
But if she did, Bardsley knows that, in relation to the osteosarcoma issue, the Douglass-Joshipura letter referred to *Kim et al* 2013, which confirms that its methodology does not address Bassin's core thesis of age-related risk in boys. The report refers to fluoride accumulation being shown by bone-fluoride levels, which is not related to osteosarcoma, but fails to state that this is irrelevant to Bassin's core finding. Further, there is also no legitimate scientific reason to cite the letter to the editor now that *Kim et at* has been published. It is worrying that this report continues to mislead the public in its dismissal of Bassin, as fluoridation promoters have done since 2006.

When asked what research addressed age-related exposure, the only specific reference given was to *Kharb et al*, (Kharb, S., Sandhu, R., & Kundu, Z. S. (2012). "Fluoride levels and osteosarcoma" *South Asian J Cancer, 1*(2), 76-77.) which does not address age-related exposure either, but does support a link between fluoridation and osteosarcoma. Oddly, there is no reference to the same authors' early, larger, study (Sandhu R, Lal H, Kundu ZS, Kharb S. "Serum fluoride and sialic acid levels in osteosarcoma" *Biol Trace Elem Res* 2011 Dec;144(1-3):1-5; E-published 2009), which supported a fluoride-osteosarcoma link even more strongly. In fact the researchers stated "this report proves a link between raised fluoride levels in serum and osteosarcoma".

As further evidence of bias in the report, the author refers to Bassin as "a small study", yet does not refer to Kim et al as such, even though it was a significantly smaller study than Bassin. Neither does the author mention that osteosarcoma is such a rare disease that Bassin's study is by far the biggest ever done. The reader is also mislead by the author referring to meaningless NZ statistics on the incidence of a comparatively tiny number of NZ osteosarcoma cases based on place of residence at the time the osteosarcoma was diagnosed, which is irrelevant to the age of exposure, as scientific evidence against Bassin.

Appendix: The stated methodology

Methodology:

1. Project co-chairs and science writer/ coordinator to identify high-level headings for the review report and consult with Ministry of Health for their suggestions of issues needing coverage

2. RSNZ to invite experts onto panel in accordance with the identified headings and with the following minimum membership:

    a. Scientist - Public health Epidemiologist
    b. Scientist - Public health (dentistry specialty)
    c. Scientist - Toxicology
    d. Other relevant scientific experts ...
    e. Lay observer - a respected member of the public

3. Royal Society NZ to convene one-day Expert Panel meeting to be attended by the science writer/ coordinator.

4. Panel members will be expected to present a state-of-the science briefing in their particular areas of expertise. The synthesis should include:
    a. What is known and not known
    b. Areas of consensus and any areas of debate in the literature c. ...

5. Science writer will:
    a. Summarise the Expert Panel briefings
    b. Supplement the briefings with independent review of the literature including any relevant Cochrane Systematic analyses.
    c. Prepare a synthesis report in accordance with the identified headings and/or any emerging headings recommended by the Expert Panel

6. Draft report to be circulated to Expert Panel for review and comment

7. Final draft report will be peer reviewed by two international experts to be identified by the Expert Panel and vetted by co-chairs

8. Peer reviewed report to be submitted to funders (Auckland City Council, Ministry of Health) and made publically accessible online at www.pmcsa.org.nz

Timeframe

April 1:	Project Start ▪ Writer appointed and will start supplementary review of the literature co-chairs to identify key headings ▪ RSNZ to begin Expert Panel recruitment
April 17:	Recruitment and appointment to Expert Panel completed
May 15-30:	RSNZ convene Expert Panel for state-of-the-science briefing
June 15:	first draft report circulated to Expert Panel for feedback
July 6:	Report sent for international peer-review and review by Ministry of Health
July 30:	Report finalized
August 7:	Co-chairs' cover letter completed
August 15:	Report provided to Ministry of Health and Councils
Aug 22:	Report published

Review Comparison

Review	York	US National Research Council	NZ
Timeframe	1 year (1999-2000)	3 years (2003 – 2006)	3 months (April - July 2014)
Budget	£ 1 million	$US 6 million	$ NZ 50 thousand
Chair	Advisory panel: neutral; Review panel: pro-fluoridation	Pro-fluoridation	Two co-chairs, publicly committed to fluoridation
Panel makeup	There were two panels – a fully pro-fluoridation review panel and a mixed advisory panel: pro-, anti- and neutral.	13. Balanced: pro-, anti-, and neutral	5. All pro-fluoridation. Some panellists declined/resigned due to procedural concerns.
Methodology	Systematic review of original published research (approx 3,300). This was established by the UK Health Department "to prove once and for all the safety and effectiveness of fluoridation", as it was intended to launch a renewed push for expanding fluoridation. Excluded animal studies on toxicity, and medical case histories. Parameters were deliberately narrowed to exclude 100 case histories of fluoride-poisoned children received by the review Board.	Systematic review of original published research on adverse health effects of fluoride, from 1ppm upwards. 512 page report. Included animal studies on toxicity, and medical case histories. Focus was solely on health risks from fluoride; not claimed benefits.	Some original research purportedly reviewed. No record of what was rejected. No record of "anti-fluoridation" studies not cited. Pro-fluoridation panel members wrote their own summaries, gave these to the writer to consolidate, and peer-reviewed their own work. Co-chair Skegg admits that the research on toxicity is so 'vast and complex' that they could not possibly review it – second hand pro-fluoridation reviews were adopted instead, contrary to the statements in the public report. Excluded most studies on toxicity, just like York.
Transparency	Review was publicized before being conducted. Information provided openly to the public during the review. Pre-publication peer review included those opposed to fluoridation.	Open, transparent process. The existence and membership of the committee (including a short summary of the project) were all online. Parts of the first meetings were open to the	Conducted in secret, with no external input. Peer reviewers appear to have been selected for pro-fluoridation views. No attempt to have a balanced panel, and evasive when

Review	York	US National Research Council	NZ
		public and some public submissions were heard. Wide canvassing of external community for relevant research. Members of the public also submitted studies/papers for the NRC committee to include, and at least some of those were used.	asked what experts with views against fluoridation were approached.
Outcome	In spite of the bias with which it was established, this review presents a summary of the best available and most reliable evidence on the alleged efficacy of water fluoridation. "Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken." No conclusive evidence on safety, or benefit to the poor. Evidence for general benefit in reducing tooth decay was based on few studies, of mediocre quality, with wide-ranging conclusions (including fluoride increasing tooth decay). "Legitimate scientific controversy will remain until better quality research is done."	The level (of natural fluoride only) allowed in the US of 4ppm is not safe. A promised but disallowed minority report would have recommended a maximum level of 0.4ppm until a truly safe level could be scientifically determined. The Chair stated in an interview for Scientific American "What the committee found is that we've gone with the status quo regarding fluoride for many years—for too long really—and now we need to take a fresh look . . . In the scientific community people tend to think this is settled. But when we looked at the studies that have been done, we found that many of these questions are unsettled and we have much less information than we should, considering how long this [fluoridation] has been going on."	Concluded that there was general consensus that fluoridation is 'safe and effective', as the two co-chairs had publicly proclaimed before the review. This was shortly after the Deputy Director of the National Poisons Centre, Michael Beasley, stated publicly that the "I think the jury is still out regarding the safety of Fluoride." Claimed there was an adequate margin of safety in spite of repeated statements throughout the report identifying there was not.

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer / survivor
Question 1 *Do you support the proposed amendment? If not, why not?*	Do NOT support the amendment or any association with the use of fluoride in public water supplies. There are 50 reasons (see attached) and information on world rejection of fluoride. There are better options without chemicals.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	We don't want fluoride used at all. OZONE water treatment is one better option.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☐ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

50 Reasons to Oppose Fluoridation

By Paul Connett, PhD (updated in September 2012)

Dr. Paul Connett

Introduction

In Europe, only Ireland (73%), Poland (1%), Serbia (3%), Spain (11%), and the U.K. (11%) fluoridate any of their water. Most developed countries, including Japan and 97% of the western European population, do not consume fluoridated water.

In the U.S., about 70% of public water supplies are fluoridated. This equates to approximately 185 million people, which is over half the number of people drinking artificially fluoridated water worldwide. Some countries have areas with high natural fluoride levels in the water. These include India, China and parts of Africa. In these countries measures are being taken to remove the fluoride because of the health problems that fluoride can cause.

Fluoridation is a bad medical practice

1) Fluoride is the only chemical added to water for the purpose of medical treatment. The U.S. Food and Drug Administration (FDA) classifies fluoride as a drug when used to prevent or mitigate disease (FDA 2000). As a matter of basic logic, adding fluoride to water for the sole purpose of preventing tooth decay (a non-waterborne disease) is a form of medical treatment. All other water treatment chemicals are added to improve the water's quality or safety, which fluoride does **not** do.

2) Fluoridation is unethical. Informed consent is standard practice for all medication, and one of the key reasons why most of Western Europe has ruled against fluoridation. With water fluoridation we are allowing governments to do to whole communities (forcing people to take a medicine irrespective of their consent) what individual doctors cannot do to individual patients.

Put another way: Does a voter have the right to require that their neighbor ingest a certain medication (even if it is against that neighbor's will)?

3) The dose cannot be controlled. Once fluoride is put in the water it is impossible to control the dose each individual receives because people drink different amounts of water. Being able to control the dose a patient receives is critical. Some people (e.g., manual laborers, athletes, diabetics, and people with kidney disease) drink substantially more water than others.

4) The fluoride goes to everyone regardless of age, health or vulnerability. According to Dr. Arvid Carlsson, the 2000 Nobel Laureate in Medicine and Physiology and one of the scientists who helped keep fluoridation out of Sweden:

"Water fluoridation goes against leading principles of pharmacotherapy, which is progressing from a stereotyped medication — of the type 1 tablet 3 times a day — to a much more individualized therapy as regards both dosage and selection of drugs. The addition of drugs to the drinking water means exactly the opposite of an individualized therapy" (Carlsson 1978).

5) People now receive fluoride from many other sources besides water. Fluoridated water is not the only way people are exposed to fluoride. Other sources of fluoride include food and beverages processed with fluoridated water (Kiritsy 1996; Heilman 1999), fluoridated dental products (Bentley 1999; Levy 1999), mechanically deboned meat (Fein 2001), tea (Levy 1999), and pesticide residues (e.g., from cryolite) on food (Stannard 1991; Burgstahler 1997). It is now widely acknowledged that exposure to non-water sources of fluoride has significantly increased since the water fluoridation program first began (NRC 2006).

6) Fluoride is not an essential nutrient. No disease, not even tooth decay, is caused by a "fluoride deficiency."(NRC 1993; Institute of Medicine 1997, NRC 2006). Not a single biological process has been shown to require fluoride. On the contrary there is extensive evidence that fluoride can interfere with many important biological processes. Fluoride interferes with numerous enzymes (Waldbott 1978). In combination with aluminum, fluoride interferes with G-proteins (Bigay 1985, 1987). Such interactions give aluminum-fluoride complexes the potential to interfere with signals from growth factors, hormones and neurotransmitters (Strunecka & Patocka 1999; Li 2003). More and more studies indicate that fluoride can interfere with biochemistry in fundamental ways (Barbier 2010).

7) The level in mothers' milk is very low. Considering reason #6 it is perhaps not surprising that the level of fluoride in mother's milk is remarkably low (0.004 ppm, NRC, 2006). This means that a bottle-fed baby consuming fluoridated water (0.6 – 1.2 ppm) can get up to 300 times more fluoride than a breast-fed baby. There are no benefits (see reasons #11-19), only risks (see reasons #21-36), for infants ingesting this heightened level of fluoride at such an early age (an age where susceptibility to environmental toxins is particularly high).

8) Fluoride accumulates in the body. Healthy adult kidneys excrete 50 to 60% of the fluoride ingested each day (Marier & Rose 1971). The remainder accumulates in the body, largely in calcifying tissues such as the bones and pineal gland (Luke 1997, 2001). Infants and children excrete less fluoride from their kidneys and take up to 80% of ingested fluoride into their bones (Ekstrand 1994). The fluoride concentration in bone steadily increases over a lifetime (NRC 2006).

9) No health agency in fluoridated countries is monitoring fluoride exposure or side effects. No regular measurements are being made of the levels of fluoride in urine, blood, bones, hair, or nails of either the general population or sensitive subparts of the population (e.g., individuals with kidney disease).

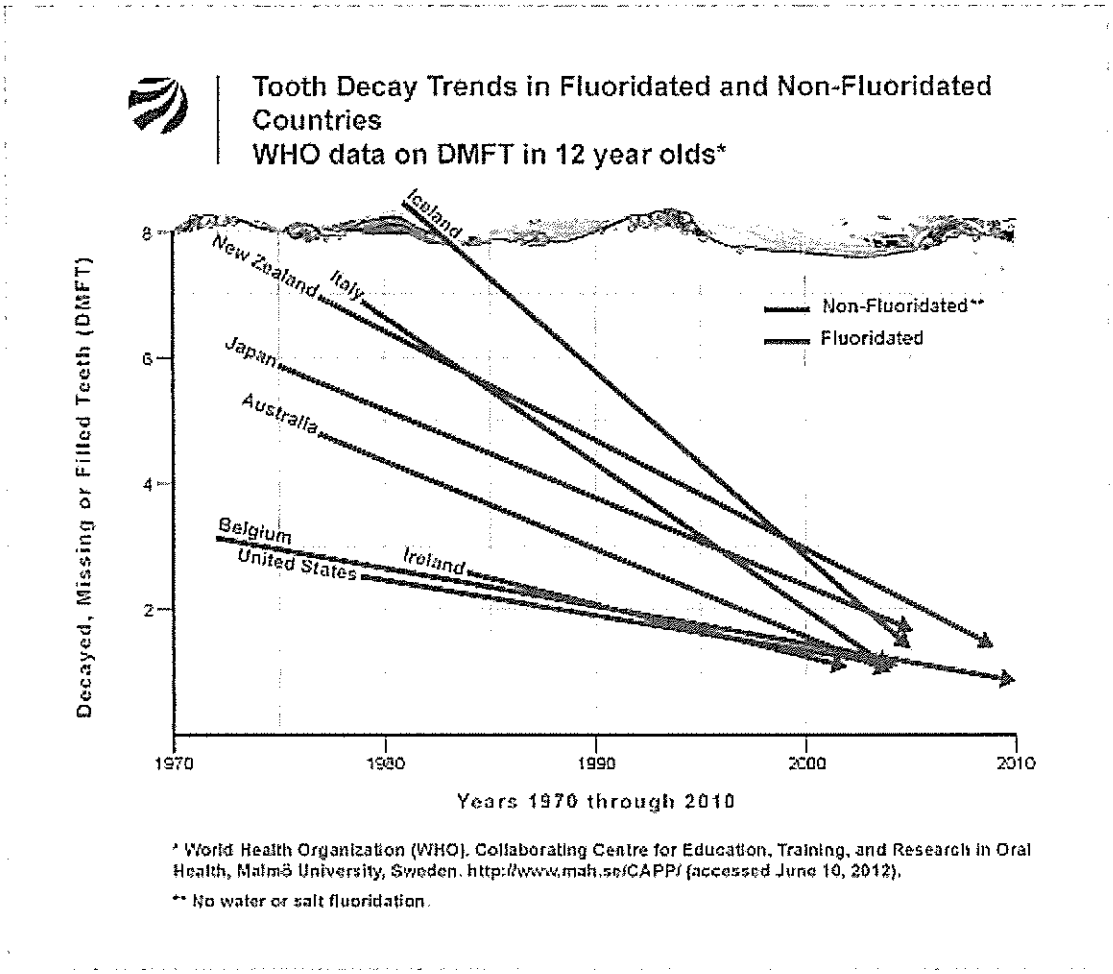
10) There has never been a single randomized controlled trial to demonstrate fluoridation's effectiveness or safety. Despite the fact that fluoride has been added to community water supplies for over 60 years, "there have been no randomized trials of water fluoridation" (Cheng 2007). Randomized trials are the standard method for determining the safety and effectiveness of any purportedly beneficial medical treatment. In 2000, the British Government's "York Review" could not give a single fluoridation trial a Grade A classification – despite 50 years of research (McDonagh 2000). The U.S. Food and Drug Administration (FDA) continues to classify fluoride as an "unapproved new drug."

Swallowing fluoride provides no (or very little) benefit

11) Benefit is topical not systemic. The Centers for Disease Control and Prevention (CDC, 1999, 2001) has now acknowledged that the mechanism of fluoride's benefits are primarily topical, not systemic. There is no need whatsoever, therefore, to swallow fluoride to prote[illegible] Since

the purported benefit of fluoride is topical, and the risks are systemic, it makes more sense to deliver the fluoride directly to the tooth in the form of toothpaste. Since swallowing fluoride is unnecessary, and potentially dangerous, there is no justification for forcing people (against their will) to ingest fluoride through their water supply.

12) Fluoridation is not necessary. Most western, industrialized countries have rejected water fluoridation, but have nevertheless experienced the same decline in childhood dental decay as fluoridated countries. (See data from World Health Organization presented graphically in Figure).



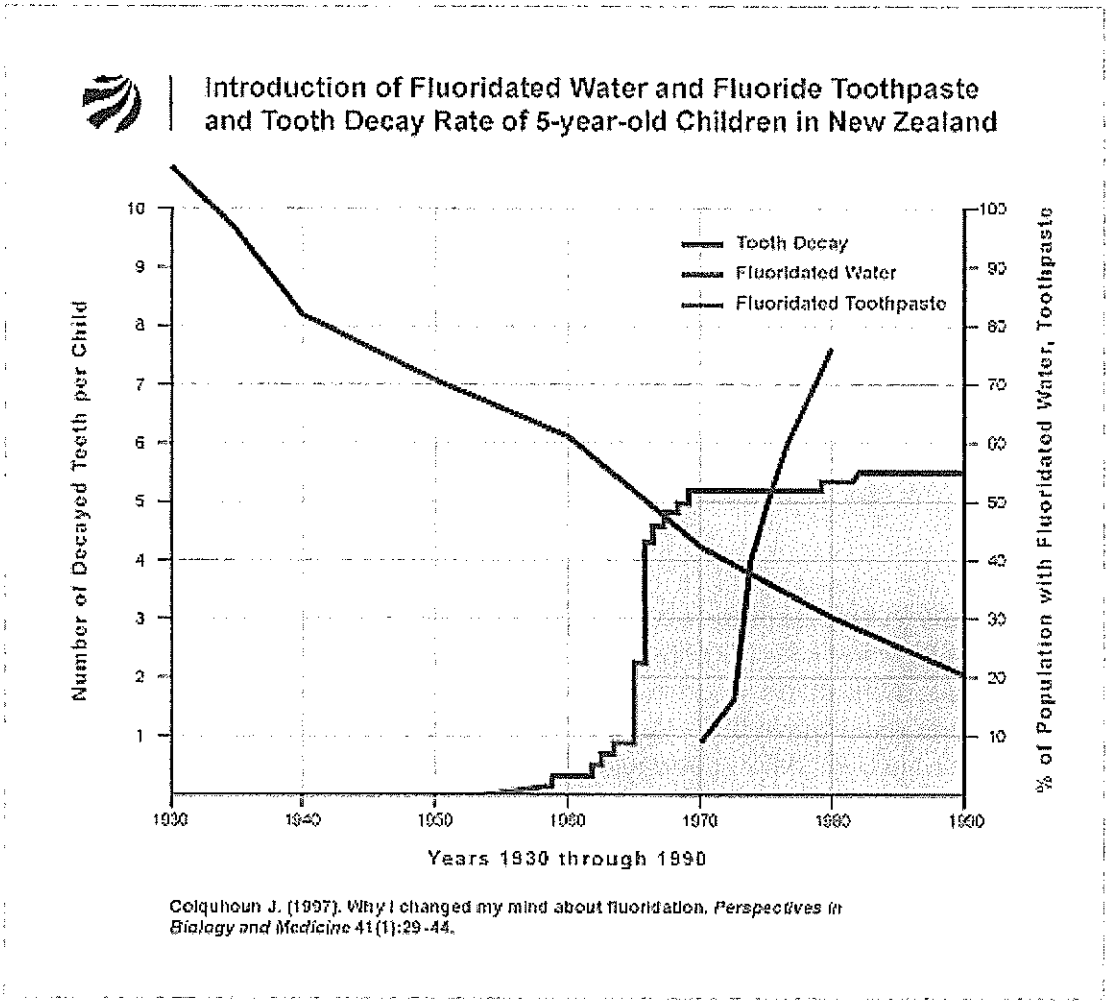
13) Fluoridation's role in the decline of tooth decay is in serious doubt. The largest survey ever conducted in the US (over 39,000 children from 84 communities) by the National Institute of Dental Research showed little difference in tooth decay among children in fluoridated and non-fluoridated communities (Hileman 1989). According to NIDR researchers, the study found an average difference of only 0.6 DMFS (Decayed, Missing, and Filled Surfaces) in the permanent teeth of children aged 5-17 residing their entire lives in either fluoridated or unfluoridated areas (Brunelle & Carlos, 1990). This difference is less than one tooth surface, and less than 1% of the 100+ tooth surfaces available in a child's mouth. Large surveys from three Australian states have found even less of a benefit, with decay reductions ranging from 0 to 0.3 of one permanent tooth surface (Spencer 1996; Armfield & Spencer 2004). None of these studies have allowed for the possible delayed eruption of the teeth that may be caused by exposure to fluoride, for which there is some evidence (Komarek 2005). A one-year delay in eruption of the permanent teeth would eliminate the very small benefit recorded in these modern studies.

14) NIH-funded study on individual fluoride ingestion and tooth decay found no significant correlation. A multi-million dollar, U.S. National Institutes of Health (NIH)-funded study found no significant relationship between tooth decay and fluoride intake among children. (Warren 2009) This is the first time tooth decay has been investigated as a function of individual exposure (as opposed to mere residence in a fluoridated community).

15) Tooth decay is high in low-income communities that have been fluoridated for years. Despite some claims to the contrary, water fluoridation cannot prevent the oral health crises that result from rampant poverty, inadequate nutrition, and lack of access to dental care. There have been numerous reports of severe dental crises in low-income neighborhoods of US cities that have been fluoridated for over 20 years (e.g., Boston, Cincinnati, New York City, and Pittsburgh). In addition, research has repeatedly found fluoridation to be ineffective at preventing the most serious oral health problem facing poor children, namely "baby bottle tooth decay," otherwise known as early childhood caries (Barnes 1992; Shiboski 2003).

16) Tooth decay does not go up when fluoridation is stopped. Where fluoridation has been discontinued in communities from Canada, the former East Germany, Cuba and Finland, dental decay has not increased but has generally continued to decrease (Maupomé 2001; Kunzel & Fischer, 1997, 2000; Kunzel 2000; Seppa 2000).

17) Tooth decay was coming down before fluoridation started. Modern research shows that decay rates were coming down before fluoridation was introduced in Australia and New Zealand and have continued to decline even after its benefits would have been maximized. (Colquhoun 1997; Diesendorf 1986). As the following figure indicates, many other factors are responsible for the decline of tooth decay that has been universally reported throughout the western world.

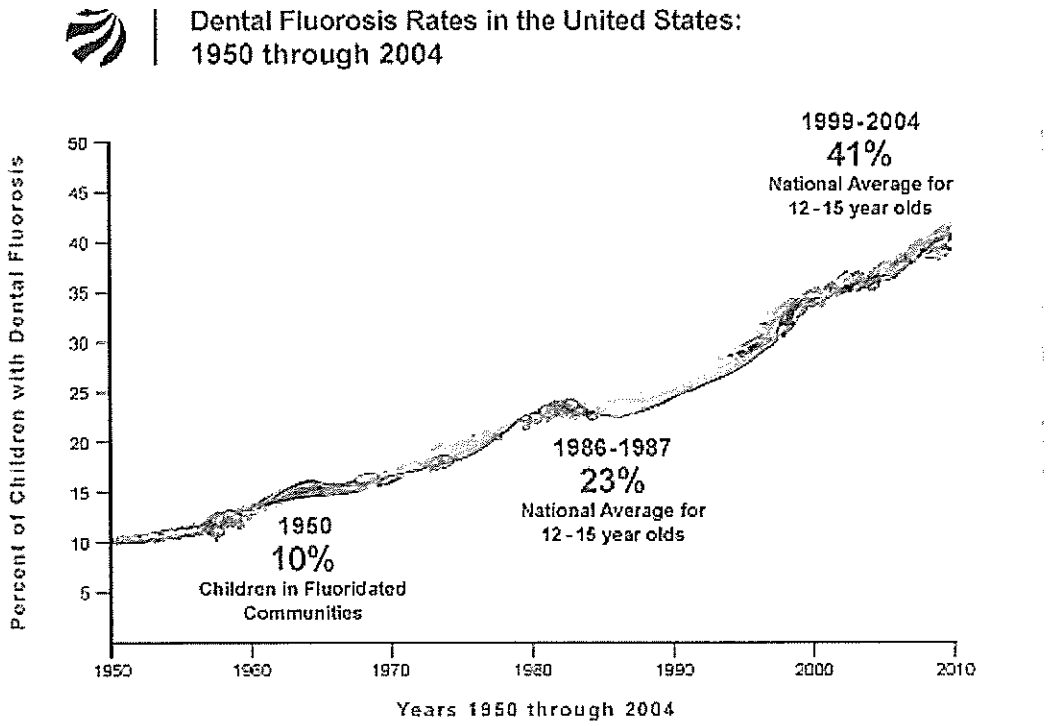


18) The studies that launched fluoridation were methodologically flawed. The early trials conducted between 1945 and 1955 in North America that helped to launch fluoridation, have been heavily criticized for their poor methodology and poor choice of control communities (De Stefano 1954; Sutton 1959, 1960, 1996; Ziegelbecker 1970). According to Dr. Hubert Arnold, a statistician from the University of California at Davis, the early fluoridation trials "are especially rich in fallacies, improper design, invalid use of statistical methods, omissions of contrary data, and just

plain muddleheadedness and hebetude." Serious questions have also been raised about Trendley Dean's (the father of fluoridation) famous 21-city study from 1942 (Ziegelbecker 1981).

Children are being over-exposed to fluoride

19) Children are being over-exposed to fluoride. The fluoridation program has massively failed to achieve one of its key objectives, i.e., to lower dental decay rates while limiting the occurrence of dental fluorosis (a discoloring of tooth enamel caused by too much fluoride. The goal of the early promoters of fluoridation was to limit dental fluorosis (in its very mild form) to10% of children (NRC 1993, pp. 6-7). In 2010, however, the Centers for Disease Control and Prevention (CDC) reported that 41% of American adolescents had dental fluorosis, with 8.6% having mild fluorosis and 3.6% having either moderate or severe dental fluorosis (Beltran-Aguilar 2010). As the 41% prevalence figure is a national average and includes children living in fluoridated and unfluoridated areas, the fluorosis rate in fluoridated communities will obviously be higher. The British Government's York Review estimated that up to 48% of children in fluoridated areas worldwide have dental fluorosis in all forms, with 12.5% having fluorosis of aesthetic concern (McDonagh, 2000).



Beltran ED, et al. (2010). Prevalence and Severity of Dental Fluorosis in the United States, 1999-2004, NCHS Data Brief No. 53. Figure 3.

National Research Council. (1993). Health Effects of Ingested Fluoride. National Academy Press. Washington DC. p. 4-5.

20) The highest doses of fluoride are going to bottle-fed babies. Because of their sole reliance on liquids for their food intake, infants consuming formula made with fluoridated water have the highest exposure to fluoride, by bodyweight, in the population. Because infant exposure to fluoridated water has been repeatedly found to be a major risk factor for developing dental fluorosis later in life (Marshall 2004; Hong 2006; Levy 2010), a number of dental researchers have recommended that parents of newborns not use fluoridated water when reconstituting formula (Ekstrand 1996; Pendrys 1998; Fomon 2000; Brothwell 2003; Marshall 2004). Even the American Dental Association (ADA), the most ardent institutional proponent of fluoridation, distributed a November 6, 2006 email alert to its members recommending that parents be advised that formula should be made with "low or no-fluoride water." Unfortunately, the ADA has done little to get this

information into the hands of parents. As a result, many parents remain unaware of the fluorosis risk from infant exposure to fluoridated water.

Evidence of harm to other tissues

21) Dental fluorosis may be an indicator of wider systemic damage. There have been many suggestions as to the possible biochemical mechanisms underlying the development of dental fluorosis (Matsuo 1998; Den Besten 1999; Sharma 2008; Duan 2011; Tye 2011) and they are complicated for a lay reader. While promoters of fluoridation are content to dismiss dental fluorosis (in its milder forms) as merely a cosmetic effect, it is rash to assume that fluoride is not impacting other developing tissues when it is visibly damaging the teeth by some biochemical mechanism (Groth 1973; Colquhoun 1997). Moreover, ingested fluoride can only cause dental fluorosis during the period before the permanent teeth have erupted (6-8 years), other tissues are potentially susceptible to damage throughout life. For example, in areas of naturally high levels of fluoride the first indicator of harm is dental fluorosis in children. In the same communities many older people develop skeletal fluorosis.

22) Fluoride may damage the brain. According to the National Research Council (2006), "it is apparent that fluorides have the ability to interfere with the functions of the brain." In a review of the literature commissioned by the US Environmental Protection Agency (EPA), fluoride has been listed among about 100 chemicals for which there is "substantial evidence of developmental neurotoxicity." Animal experiments show that fluoride accumulates in the brain and alters mental behavior in a manner consistent with a neurotoxic agent (Mullenix 1995). In total, there have now been over 100 animal experiments showing that fluoride can damage the brain and impact learning and behavior. According to fluoridation proponents, these animal studies can be ignored because high doses were used. However, it is important to note that rats generally require five times more fluoride to reach the same plasma levels in humans (Sawan 2010). Further, one animal experiment found effects at remarkably low doses (Varner 1998). In this study, rats fed for one year with 1 ppm fluoride in their water (the same level used in fluoridation programs), using either sodium fluoride or aluminum fluoride, had morphological changes to their kidneys and brains, an increased uptake of aluminum in the brain, and the formation of beta-amyloid deposits which are associated with Alzheimer's disease. Other animal studies have found effects on the brain at water fluoride levels as low as 5 ppm (Liu 2010).

23) Fluoride may lower IQ. There have now been 33 studies from China, Iran, India and Mexico that have reported an association between fluoride exposure and reduced IQ. One of these studies (Lin 1991) indicates that even just moderate levels of fluoride exposure (e.g., 0.9 ppm in the water) can exacerbate the neurological defects of iodine deficiency. Other studies have found IQ reductions at 1.9 ppm (Xiang 2003a,b); 0.3-3.0 ppm (Ding 2011); 1.8-3.9 ppm (Xu 1994); 2.0 ppm (Yao 1996, 1997); 2.1-3.2 ppm (An 1992); 2.38 ppm (Poureslami 2011); 2.45 ppm (Eswar 2011); 2.5 ppm (Seraj 2006); 2.85 ppm (Hong 2001); 2.97 ppm (Wang 2001, Yang 1994); 3.15 ppm (Lu 2000); 4.12 ppm (Zhao 1996). In the Ding study, each 1 ppm increase of fluoride in urine was associated with a loss of 0.59 IQ points. None of these studies indicate an adequate margin of safety to protect all children drinking artificially fluoridated water from this affect. According to the National Research Council (2006), "the consistency of the results [in fluoride/IQ studies] appears significant enough to warrant additional research on the effects of fluoride on intelligence." The NRC's conclusion has recently been amplified by a team of Harvard scientists whose fluoride/IQ meta-review concludes that fluoride's impact on the developing brain should be a "high research priority." (Choi et al., 2012). Except for one small IQ study from New Zealand (Spittle 1998) no fluoridating country has yet investigated the matter.

24) Fluoride may cause non-IQ neurotoxic effects. Reduced IQ is not the only neurotoxic effect that may result from fluoride exposure. At least three human studies have reported an association between fluoride exposure and impaired visual-spatial organization (Calderon 2000; Li 2004;

Rocha-Amador 2009); while four other studies have found an association between prenatal fluoride exposure and fetal brain damage (Han 1989; Du 1992; Dong 1993; Yu 1996).

25) Fluoride affects the pineal gland. Studies by Jennifer Luke (2001) show that fluoride accumulates in the human pineal gland to very high levels. In her Ph.D. thesis, Luke has also shown in animal studies that fluoride reduces melatonin production and leads to an earlier onset of puberty (Luke 1997). Consistent with Luke's findings, one of the earliest fluoridation trials in the U.S. (Schlesinger 1956) reported that on average young girls in the fluoridated community reached menstruation 5 months earlier than girls in the non-fluoridated community. Inexplicably, no fluoridating country has attempted to reproduce either Luke's or Schlesinger's findings or examine the issue any further.

26) Fluoride affects thyroid function. According to the U.S. National Research Council (2006), "several lines of information indicate an effect of fluoride exposure on thyroid function." In the Ukraine, Bachinskii (1985) found a lowering of thyroid function, among otherwise healthy people, at 2.3 ppm fluoride in water. In the middle of the 20th century, fluoride was prescribed by a number of European doctors to reduce the activity of the thyroid gland for those suffering from hyperthyroidism (overactive thyroid) (Stecher 1960; Waldbott 1978). According to a clinical study by Galletti and Joyet (1958), the thyroid function of hyperthyroid patients was effectively reduced at just 2.3 to 4.5 mg/day of fluoride ion. To put this finding in perspective, the Department of Health and Human Services (DHHS, 1991) has estimated that total fluoride exposure in fluoridated communities ranges from 1.6 to 6.6 mg/day. This is a remarkable fact, particularly considering the rampant and increasing problem of hypothyroidism (underactive thyroid) in the United States and other fluoridated countries. Symptoms of hypothyroidism include depression, fatigue, weight gain, muscle and joint pains, increased cholesterol levels, and heart disease. In 2010, the second most prescribed drug of the year was Synthroid (sodium levothyroxine) which is a hormone replacement drug used to treat an underactive thyroid.

27) Fluoride causes arthritic symptoms. Some of the early symptoms of skeletal fluorosis (a fluoride-induced bone and joint disease that impacts millions of people in India, China, and Africa), mimic the symptoms of arthritis (Singh 1963; Franke 1975; Teotia 1976; Carnow 1981; Czerwinski 1988; DHHS 1991). According to a review on fluoridation published in Chemical & Engineering News, "Because some of the clinical symptoms mimic arthritis, the first two clinical phases of skeletal fluorosis could be easily misdiagnosed" (Hileman 1988). Few, if any, studies have been done to determine the extent of this misdiagnosis, and whether the high prevalence of arthritis in America (1 in 3 Americans have some form of arthritis – CDC, 2002) and other fluoridated countries is related to growing fluoride exposure, which is highly plausible. Even when individuals in the U.S. suffer advanced forms of skeletal fluorosis (from drinking large amounts of tea), it has taken years of misdiagnoses before doctors finally correctly diagnosed the condition as fluorosis.

28) Fluoride damages bone. An early fluoridation trial (Newburgh-Kingston 1945-55) found a significant two-fold increase in cortical bone defects among children in the fluoridated community (Schlesinger 1956). The cortical bone is the outside layer of the bone and is important to protect against fracture. While this result was not considered important at the time with respect to bone fractures, it did prompt questions about a possible link to osteosarcoma (Caffey, 1955; NAS, 1977). In 2001, Alarcon-Herrera and co-workers reported a linear correlation between the severity of dental fluorosis and the frequency of bone fractures in both children and adults in a high fluoride area in Mexico.

29) Fluoride may increase hip fractures in the elderly. When high doses of fluoride (average 26 mg per day) were used in trials to treat patients with osteoporosis in an effort to harden their bones and reduce fracture rates, it actually led to a higher number of fractures, particularly hip fractures (Inkovaara 1975; Gerster 1983; Dambacher 1986; O'Duffy 1986; Hedlund 1989; Bayley 1990; Gutteridge 1990. 2002; Orcel 1990; Riggs 1990 and Schnitzler 1990). Hip fracture is a very serious issue for the elderly, often leading to a loss of independence or a shortened life. There

have been over a dozen studies published since 1990 that have investigated a possible relationship between hip fractures and long term consumption of artificially fluoridated water or water with high natural levels. The results have been mixed – some have found an association and others have not. Some have even claimed a protective effect. One very important study in China, which examined hip fractures in six Chinese villages, found what appears to be a dose-related increase in hip fracture as the concentration of fluoride rose from 1 ppm to 8 ppm (Li 2001) offering little comfort to those who drink a lot of fluoridated water. Moreover, in the only human epidemiological study to assess bone strength as a function of bone fluoride concentration, researchers from the University of Toronto found that (as with animal studies) the strength of bone declined with increasing fluoride content (Chachra 2010). Finally, a recent study from Iowa (Levy 2009), published data suggesting that low-level fluoride exposure may have a detrimental effect on cortical bone density in girls (an effect that has been repeatedly documented in clinical trials and which has been posited as an important mechanism by which fluoride may increase bone fracture rates).

30) People with impaired kidney function are particularly vulnerable to bone damage. Because of their inability to effectively excrete fluoride, people with kidney disease are prone to accumulating high levels of fluoride in their bone and blood. As a result of this high fluoride body burden, kidney patients have an elevated risk for developing skeletal fluorosis. In one of the few U.S. studies investigating the matter, crippling skeletal fluorosis was documented among patients with severe kidney disease drinking water with just 1.7 ppm fluoride (Johnson 1979). Since severe skeletal fluorosis in kidney patients has been detected in small case studies, it is likely that larger, systematic studies would detect skeletal fluorosis at even lower fluoride levels.

31) Fluoride may cause bone cancer (osteosarcoma). A U.S. government-funded animal study found a dose-dependent increase in bone cancer (osteosarcoma) in fluoride-treated, male rats (NTP 1990). Following the results of this study, the National Cancer Institute (NCI) reviewed national cancer data in the U.S. and found a significantly higher rate of osteosarcoma (a bone cancer) in young men in fluoridated versus unfluoridated areas (Hoover et al 1991a). While the NCI concluded (based on an analysis lacking statistical power) that fluoridation was not the cause (Hoover et al 1991b), no explanation was provided to explain the higher rates in the fluoridated areas. A smaller study from New Jersey (Cohn 1992) found osteosarcoma rates to be up to 6 times higher in young men living in fluoridated versus unfluoridated areas. Other epidemiological studies of varying size and quality have failed to find this relationship (a summary of these can be found in Bassin, 2001 and Connett & Neurath, 2005). There are three reasons why a fluoride-osteosarcoma connection is plausible: First, fluoride accumulates to a high level in bone. Second, fluoride stimulates bone growth. And, third, fluoride can interfere with the genetic apparatus of bone cells in several ways; it has been shown to be mutagenic, cause chromosome damage, and interfere with the enzymes involved with DNA repair in both cell and tissue studies (Tsutsui 1984; Caspary 1987; Kishi 1993; Mihashi 1996; Zhang 2009). In addition to cell and tissue studies, a correlation between fluoride exposure and chromosome damage in humans has also been reported (Sheth 1994; Wu 1995; Meng 1997; Joseph 2000).

32) Proponents have failed to refute the Bassin-Osteosarcoma study. In 2001, Elise Bassin, a dentist, successfully defended her doctoral thesis at Harvard in which she found that young boys had a five-to-seven fold increased risk of getting osteosarcoma by the age of 20 if they drank fluoridated water during their mid-childhood growth spurt (age 6 to 8). The study was published in 2006 (Bassin 2006) but has been largely discounted by fluoridating countries because her thesis adviser Professor Chester Douglass (a promoter of fluoridation and a consultant for Colgate) promised a larger study that he claimed would discount her thesis (Douglass and Joshipura, 2006). Now, after 5 years of waiting the Douglass study has finally been published (Kim 2011) but in no way does this study discount Bassin's findings. The study, which used far fewer controls than Bassin's analysis, did not even attempt to assess the age-specific window of risk that Bassin identified. Indeed, by the authors' own admission, the study had no capacity to assess the risk of

osteosarcoma among children and adolescents (the precise population of concern). For a critique of the Douglass study, click here.

33) Fluoride may cause reproductive problems. Fluoride administered to animals at high doses wreaks havoc on the male reproductive system – it damages sperm and increases the rate of infertility in a number of different species (Kour 1980; Chinoy 1989; Chinoy 1991; Susheela 1991; Chinoy 1994; Kumar 1994; Narayana 1994a,b; Zhao 1995; Elbetieha 2000; Ghosh 2002; Zakrzewska 2002). In addition, an epidemiological study from the US found increased rates of infertility among couples living in areas with 3 ppm or more fluoride in the water (Freni 1994), two studies have found increased fertility among men living in high-fluoride areas of China and India (Liu 1988; Neelam 1987); four studies have found reduced level of circulating testosterone in males living in high fluoride areas (Hao 2010; Chen P 1997; Susheela 1996; Barot 1998), and a study of fluoride-exposed workers reported a "subclinical reproductive effect" (Ortiz-Perez 2003). While animal studies by FDA researchers have failed to find evidence of reproductive toxicity in fluoride-exposed rats (Sprando 1996, 1997, 1998), the National Research Council (2006) has recommended that, "the relationship between fluoride and fertility requires additional study."

34) Some individuals are highly sensitive to low levels of fluoride as shown by case studies and double blind studies. In one study, which lasted 13 years, Feltman and Kosel (1961) showed that about 1% of patients given 1 mg of fluoride each day developed negative reactions. Many individuals have reported suffering from symptoms such as fatigue, headaches, rashes and stomach and gastro intestinal tract problems, which disappear when they avoid fluoride in their water and diet. (Shea 1967; Waldbott 1978; Moolenburgh 1987) Frequently the symptoms reappear when they are unwittingly exposed to fluoride again (Spittle, 2008). No fluoridating government has conducted scientific studies to take this issue beyond these anecdotal reports. Without the willingness of governments to investigate these reports scientifically, should we as a society be forcing these people to ingest fluoride?

35) Other subsets of population are more vulnerable to fluoride's toxicity. In addition to people suffering from impaired kidney function discussed in reason #30 other subsets of the population are more vulnerable to fluoride's toxic effects. According to the Agency for Toxic Substances and Disease Registry (ATSDR 1993) these include: infants, the elderly, and those with diabetes mellitus. Also vulnerable are those who suffer from malnutrition (e.g., calcium, magnesium, vitamin C, vitamin D and iodine deficiencies and protein-poor diets) and those who have diabetes insipidus. See: Greenberg 1974; Klein 1975; Massler & Schour 1952; Marier & Rose 1977; Lin 1991; Chen 1997; Seow 1994; Teotia 1998.

No Margin of Safety

36) There is no margin of safety for several health effects. No one can deny that high natural levels of fluoride damage health. Millions of people in India and China have had their health compromised by fluoride. The real question is whether there is an adequate margin of safety between the doses shown to cause harm in published studies and the total dose people receive consuming uncontrolled amounts of fluoridated water and non-water sources of fluoride. This margin of safety has to take into account the wide range of individual sensitivity expected in a large population (a safety factor of 10 is usually applied to the lowest level causing harm). Another safety factor is also needed to take into account the wide range of doses to which people are exposed. There is clearly no margin of safety for dental fluorosis (CDC, 2010) and based on the following studies nowhere near an adequate margin of safety for lowered IQ (Xiang 2003a,b; Ding 2011; Choi 2012); lowered thyroid function (Galletti & Joyet 1958; Bachinskii 1985; Lin 1991); bone fractures in children (Alarcon-Herrera 2001) or hip fractures in the elderly (Kurttio 1999; Li 2001). All of these harmful effects are discussed in the NRC (2006) review.

Environmental Justice

37) Low-income families penalized by fluoridation. Those most likely to suffer from poor nutrition, and thus more likely to be more vulnerable to fluoride's toxic effects, are the poor, who unfortunately, are the very people being targeted by new fluoridation programs. While at heightened risk, poor families are least able to afford avoiding fluoride once it is added to the water supply. No financial support is being offered to these families to help them get alternative water supplies or to help pay the costs of treating unsightly cases of dental fluorosis.

38) Black and Hispanic children are more vulnerable to fluoride's toxicity. According to the CDC's national survey of dental fluorosis, black and Mexican-American children have significantly higher rates of dental fluorosis than white children (Beltran-Aguilar 2005, Table 23). The recognition that minority children appear to be more vulnerable to toxic effects of fluoride, combined with the fact that low-income families are less able to avoid drinking fluoridated water, has prompted prominent leaders in the environmental-justice movement to oppose mandatory fluoridation in Georgia. In a statement issued in May 2011, Andrew Young, a colleague of Martin Luther King, Jr., and former Mayor of Atlanta and former US Ambassador to the United Nations, stated:

"I am most deeply concerned for poor families who have babies: if they cannot afford unfluoridated water for their babies' milk formula, do their babies not count? Of course they do. This is an issue of fairness, civil rights, and compassion. We must find better ways to prevent cavities, such as helping those most at risk for cavities obtain access to the services of a dentist...My father was a dentist. I formerly was a strong believer in the benefits of water fluoridation for preventing cavities. But many things that we began to do 50 or more years ago we now no longer do, because we have learned further information that changes our practices and policies. So it is with fluoridation."

39) Minorities are not being warned about their vulnerabilities to fluoride. The CDC is not warning black and Mexican-American children that they have higher rates of dental fluorosis than Caucasian children (see #38). This extra vulnerability may extend to other toxic effects of fluoride. Black Americans have higher rates of lactose intolerance, kidney problems and diabetes, all of which may exacerbate fluoride's toxicity.

40) Tooth decay reflects low-income not low-fluoride intake. Since dental decay is most concentrated in poor communities, we should be spending our efforts trying to increase the access to dental care for low-income families. The highest rates of tooth decay today can be found in low-income areas that have been fluoridated for many years. The real "Oral Health Crisis" that exists today in the United States, is not a lack of fluoride but poverty and lack of dental insurance. The Surgeon General has estimated that 80% of dentists in the US do not treat children on Medicaid.

The largely untested chemicals used in fluoridation programs

41) The chemicals used to fluoridate water are not pharmaceutical grade. Instead, they largely come from the wet scrubbing systems of the phosphate fertilizer industry. These chemicals (90% of which are sodium fluorosilicate and fluorosilicic acid), are classified hazardous wastes contaminated with various impurities. Recent testing by the National Sanitation Foundation suggest that the levels of arsenic in these silicon fluorides are relatively high (up to 1.6 ppb after dilution into public water) and of potential concern (NSF 2000 and Wang 2000). Arsenic is a known human carcinogen for which there is no safe level. This one contaminant alone could be increasing cancer rates – and unnecessarily so.

42) The silicon fluorides have not been tested comprehensively. The chemical usually tested in animal studies is pharmaceutical grade sodium fluoride, not industrial grade fluorosilicic acid. Proponents claim that once the silicon fluorides have been diluted at the public water works they are completely dissociated to free fluoride ions and hydrated silica and thus there is no need to

examine the toxicology of these compounds. However, while a study from the University of Michigan (Finney et al., 2006) showed complete dissociation at neutral pH, in acidic conditions (pH 3) there was a stable complex containing five fluoride ions. Thus the possibility arises that such a complex may be regenerated in the stomach where the pH lies between 1 and 2.

43) The silicon fluorides may increase lead uptake into children's blood. Studies by Masters and Coplan (1999, 2000, 2007), and to a lesser extent Macek (2006), show an association between the use of fluorosilicic acid (and its sodium salt) to fluoridate water and an increased uptake of lead into children's blood. Because of lead's acknowledged ability to damage the developing brain, this is a very serious finding. Nevertheless, it is being largely ignored by fluoridating countries. This association received some strong biochemical support from an animal study by Sawan et al. (2010) who found that exposure of rats to a combination of fluorosilicic acid and lead in their drinking water increased the uptake of lead into blood some threefold over exposure to lead alone.

44) Fluoride may leach lead from pipes, brass fittings and soldered joints. In tightly controlled laboratory experiments, Maas et al (2007) have shown that fluoridating agents in combination with chlorinating agents such as chloroamine increase the leaching of lead from brass fittings used in plumbing. While proponents may argue about the neurotoxic effects of low levels of fluoride there is no argument that lead at very low levels lowers IQ in children.

Continued promotion of fluoridation is unscientific

45) Key health studies have not been done. In the January 2008 issue of Scientific American, Professor John Doull, the chairman of the important 2006 National Research Council review, Fluoride in Drinking Water: A Review of EPA's Standards, is quoted as saying:

What the committee found is that we've gone with the status quo regarding fluoride for many years—for too long really—and now we need to take a fresh look . . . In the scientific community people tend to think this is settled. I mean, when the U.S. surgeon general comes out and says this is one of the top 10 greatest achievements of the 20th century, that's a hard hurdle to get over. But when we looked at the studies that have been done, we found that many of these questions are unsettled and we have much less information than we should, considering how long this [fluoridation] has been going on.

The absence of studies is being used by promoters as meaning the absence of harm. This is an irresponsible position.

46) Endorsements do not represent scientific evidence. Many of those promoting fluoridation rely heavily on a list of endorsements. However, the U.S. PHS first endorsed fluoridation in 1950, before one single trial had been completed and before any significant health studies had been published (see chapters 9 and 10 in *The Case Against Fluoride* for the significance of this PHS endorsement for the future promotion of fluoridation). Many other endorsements swiftly followed with little evidence of any scientific rational for doing so. The continued use of these endorsements has more to do with political science than medical science.

47) Review panels hand-picked to deliver a pro-fluoridation result. Every so often, particularly when their fluoridation program is under threat, governments of fluoridating countries hand-pick panels to deliver reports that provide the necessary re-endorsement of the practice. In their recent book Fluoride Wars (2009), which is otherwise slanted toward fluoridation, Alan Freeze and Jay Lehr concede this point when they write:

There is one anti-fluoridationist charge that does have some truth to it. Anti-fluoride forces have always claimed that the many government-sponsored review panels set up over the years to assess the costs and benefits of fluoridation were stacked in favor of fluoridation. A review of the

membership of the various panels confirms this charge. The expert committees that put together reports by the American Association for the Advancement of Science in 1941, 1944 and 1954; the National Academy of Sciences in 1951, 1971, 1977 and 1993; the World Health Organization in 1958 and 1970; and the U.S. Public Health Service in 1991 are rife with the names of well-known medical and dental researchers who actively campaigned on behalf of fluoridation or whose research was held in high regard in the pro-fluoridation movement. Membership was interlocking and incestuous.

The most recent examples of these self-fulfilling prophecies have come from the Irish Fluoridation Forum (2002); the National Health and Medical Research Council (NHMRC, 2007) and Health Canada (2008, 2010). The latter used a panel of six experts to review the health literature. Four of the six were pro-fluoridation dentists and the other two had no demonstrated expertise on fluoride. A notable exception to this trend was the appointment by the U.S. National Research Council of the first balanced panel of experts ever selected to look at fluoride's toxicity in the U.S. This panel of twelve reviewed the US EPA's safe drinking water standards for fluoride. After three and half years the panel concluded in a 507- page report that the safe drinking water standard was not protective of health and a new maximum contaminant level goal (MCLG) should be determined (NRC, 2006). If normal toxicological procedures and appropriate margins of safety were applied to their findings this report should spell an end to water fluoridation. Unfortunately in January of 2011 the US EPA Office of Water made it clear that they would not determine a value for the MCLG that would jeopardize the water fluoridation program (EPA press release, Jan 7, 2011. Once again politics was allowed to trump science.

More and more independent scientists oppose fluoridation

48) Many scientists oppose fluoridation. Proponents of fluoridation have maintained for many years— despite the fact that the earliest opponents of fluoridation were biochemists—that the only people opposed to fluoridation are not bona fide scientists. Today, as more and more scientists, doctors, dentists and other professionals, read the primary literature for themselves, rather than relying on self-serving statements from the ADA and the CDC, they are realizing that they and the general public have not been diligently informed by their professional bodies on this subject. As of January 2012, over 4,000 professionals have signed a statement calling for an end to water fluoridation worldwide. This statement and a list of signatories can be found on the website of the Fluoride Action Network. A glimpse of the caliber of those opposing fluoridation can be gleaned by watching the 28-minute video "Professional Perspectives on Water fluoridation" which can be viewed online at the same FAN site.

Proponents' dubious tactics

49) Proponents usually refuse to defend fluoridation in open debate. While pro-fluoridation officials continue to promote fluoridation with undiminished fervor, they usually refuse to defend the practice in open public debate – even when challenged to do so by organizations such as the Association for Science in the Public Interest, the American College of Toxicology, or the U.S. EPA (Bryson 2004). According to Dr. Michael Easley, a prominent lobbyist for fluoridation in the US, "Debates give the illusion that a scientific controversy exists when no credible people support the fluorophobics' view" (Easley, 1999). In light of proponents' refusal to debate this issue, Dr. Edward Groth, a Senior Scientist at Consumers Union, observed that, "the political profluoridation stance has evolved into a dogmatic, authoritarian, essentially antiscientific posture, one that discourages open debate of scientific issues" (Martin 1991).

50) Proponents use very dubious tactics to promote fluoridation. Many scientists, doctors and dentists who have spoken out publicly on this issue have been subjected to censorship and intimidation (Martin 1991). Dr. Phyllis Mullenix was fired from her position as Chair of Toxicology at Forsythe Dental Center for publishing her findings on fluoride and the brain (Mullenix 1995); and

- Dr. William Marcus was fired from the EPA for questioning the government's handling of the NTP's fluoride-cancer study (Bryson 2004). Many dentists and even doctors tell opponents in private that they are opposed to this practice but dare not speak out in public because of peer pressure and the fear of recriminations. Tactics like this would not be necessary if those promoting fluoridation were on secure scientific and ethical grounds.

Conclusion

When it comes to controversies surrounding toxic chemicals, vested interests traditionally do their very best to discount animal studies and quibble with epidemiological findings. In the past, political pressures have led government agencies to drag their feet on regulating asbestos, benzene, DDT, PCBs, tetraethyl lead, tobacco and dioxins. With fluoridation we have had a sixty-year delay. Unfortunately, because government officials and dental leaders have put so much of their credibility on the line defending fluoridation, and because of the huge liabilities waiting in the wings if they admit that fluoridation has caused an increase in hip fracture, arthritis, bone cancer, brain disorders or thyroid problems, it will be very difficult for them to speak honestly and openly about the issue. But they must, not only to protect millions of people from unnecessary harm, but to protect the notion that, at its core, public health policy must be based on sound science, not political expediency. They have a tool with which to do this: it's called the Precautionary Principle. Simply put, this says: if in doubt leave it out. This is what most European countries have done and their children's teeth have not suffered, while their public's trust has been strengthened.

Just how much doubt is needed on just one of the health concerns identified above, to override a benefit, which when quantified in the largest survey ever conducted in the US, amounts to less than one tooth surface (out of 128) in a child's mouth?

While fluoridation may not be the greatest environmental health threat, it is one of the easiest to end. It is as easy as turning off a spigot in the public water works. But to turn off that spigot takes political will and to get that we need masses more people informed and organized. Please get these 50 reasons to all your friends and encourage them to get fluoride out of their community and to help ban this practice worldwide.

Postscript

Further arguments against fluoridation, can be viewed at http://www.fluoridealert.org and in the book The Case Against Fluoridation (Chelsea Green, 2010).

Fluoridation status of some countries

Despite dental pressure, 99% of western continental Europe **has rejected, banned, or stopped fluoridation** due to environmental, health, legal, or ethical concerns

Only about 5% of the world population is fluoridated and more than 50% of these people live in North America. The Danish Minister of Environment recommended against fluoridation in 1977 because "no adequate studies had been carried out on its long-term effects on human organ systems other than teeth and because not enough studies had been done on the effects of fluoride discharges on freshwater ecosystems."

"In 1978, the West German Association of Gas & Water Experts rejected fluoridation for legal reasons and because 'the so-called optimal fluoride concentration of 1 mg per L is close to the dose at which long-term damage [to the human body] is to be expected.' "

Quotes from: Hilleman B, "FLUORIDATION: Contention won't go away," *Chemical and Engineering News*,

Country	Fluoridation Status
China	BANNED: "not allowed"
Austria	REJECTED: "toxic fluorides" NOT added
Belgium	REJECTED: encourages self-determination – those who want fluoride should get it themselves.
Finland	STOPPED: "...do not favor or recommend fluoridation of drinking water. There are better ways of providing the fluoride our teeth need."
Germany	STOPPED: A recent study found no evidence of an increasing trend of caries
Denmark	REJECTED: "...toxic fluorides have never been added to the public water supplies in Denmark."
Norway	REJECTED: "...drinking water should not be fluoridated"
Sweden	BANNED: "not allowed". No safety data available!
The Netherlands	Inevitably, whenever there is a court decision against fluoridation, the dental lobby pushes to have the judgement overturned on a technicality or they try to get the laws changed to legalize it. Their tactics didn't work in the vast majority of Europe.
Hungary	STOPPED: for technical reasons in the '60s. However, despite technological advances, Hungary remains unfluoridated.
Japan	REJECTED: "...may cause health problems.... the hazardous waste by-product which is added with artificial fluoridation.

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Concerned citizen and voter, former North Shore City Councillor, unwilling consumer of artificial fluoride and all of its contaminants whenever I am not able to filter them from what is supposed to be safe potable water supplied by public authorities, and used in production of what are supposed to be safe foods and drinks by whatever manufacturer may be obliged to use what is supposed to be safe potable water supplied by public authorities.
Question 1 *Do you support the proposed amendment? If not, why not?*	NO Fluoride is not a water treatment like chlorine. So why is it being put in water supplies when there is no universal acceptance of any positive health effects of the addition of fluoride to drinking water supplies? Does that not have to be because some people have followed the USA-originated

	doctrine that it was supposed to be of some benefit to the health of the consumer's teeth. That makes it a medicine! You can't manipulate your way around that position. Not even at the misguided suggestion of a Justice David Collins in his judgement in New Health New Zealand v Attorney-General [2014] NZHC2487. It's plain English. Fluoride is being used as a medicine and the intention is that it is a medicine! A medicine to treat teeth! Why do I say misguided? Had he ever looked into how fluoridation of public water supplies came about in the first place? Have you? Fluoride has never been proven to be safe for humans. Its origins scream a warning to all. Fluoridation is a relic of the US A-bomb development with research papers and toxicology evidence suppressed for reasons of national security. Fluoride was a key chemical for atomic bomb production but pollution from this production caused significant damage to crops, animals and people. So Manhattan Project research was originally designed to prove fluoride was "safe" and so avoid legal suits arising from this. Suppressed for many years were research papers that showed an adverse effect on the central nervous system, although authorities denied this. Other papers are still not unclassified. To counteract public fears about fluoride pollution and provide evidence to against legal action an experiment with human use was needed. Planning began in 1943 with the appointment of a special New York State Health Department committee to study the advisability of adding fluoride to Newburgh's drinking water. The

	chairman of the committee was Dr. Hodge, then chief of fluoride toxicity studies for the Manhattan Project. There were other scientists, doctors and dentists involved. They could give credibility to the promotion. Dental fluorosis, discolouring of teeth by fluoride, was known about but this adverse health effect had to be concealed. There is more to the outrageous story but it involves significant manipulation of information to achieve a mindless target of disposal of fluoride that was needed for production of an atom bomb to defeat American enemies in World War II that had gone on too long and cost too many lives. That proved to be great for American prestige for decades to come. So a chemical that was once avoided as being toxic to living beings, ends up being promoted as "safe". With ensuing adoption in the US the US-influenced World Health Organisation eventually says it's OK. Once this is done what other doctor or dentist or health authority is going to say otherwise. It becomes a mantra that is repeated by those choosing to side with the orthodox. Critics are dismissed as being unknowledgeable. But they are often the ones who have looked more seriously into the background and taken account information that shows converse information and broader adverse effects with a sufficiently open mind. Do you have such a mind or are you just following the conventional opinion? Of course the people wouldn't become unsettled while the Ministry of Health and others following the orthodox view continue to repeat their mantra, that is until they found out about things more. Well avenues for this need to be left open. And opportunities for allowing other opinion-makers with sufficiently open minds to hear more and look into

	its credibility, so far as they and their community are concerned. Your attempt to deny this by sweeping aside any chance for that by a wrongful manipulation of this one regulation is improper. Do not do it, please!
	More has to be said. There is the significant question of the individual having the right to decide what they choose to consume or imbibe or take as a medicine. This opportunity to choose is a significant element of freedom in a democratic society or community. But your cute manipulation of one regulation is going to deny more people in New Zealand the right of choice. They won't get the opportunity to persuade their local decision-makers that they don't want the toxin in their public water. **People should have a right to choose and they should NOT be compulsorily medicated!** I know that's what you're trying do – make the process of fluoridation unchallengeable throughout the country and the New Zealand judicial system. But I submit that it is very wrong to do that. The current view of the NZ Ministry of Health should not be absolute! It is a wrongful act so don't continue with it, please. Only about 5% of the world's population have to endure this addition of fluoride to their water. Most countries in the EU don't and some have laws against doing so. I don't wish to consume fluoride and associated toxic chemicals in any way because I know about the significant

	safety issues for humans involved with the stuff. I have to go to some expense to avoid doing so because I live in Auckland where, unfortunately, fluoridation is carried out as a consequence of Ministry of Health promotion of the practice to former councils. Is the Ministry going to provide portable water filter equipment should they choose to travel to other places in New Zealand currently not putting fluoride in their water now, but being obliged to do so in the future when their open-minded, concerned residents willing to question the practice of fluoridation if it is proposed, won't be able to have it rejected because of your present move to slip through a regulation change to block the possible any challenge by making your present policy mantra unchallengeable? This will be a wrong! Don't do it. There are many other issues such as fluoride toxicity, the latter-day finding that fluoride is more effective if it topically applies to teeth and many toothpastes now have fluoride in them so putting more of the stuff in public water supplies as a medicine where there is no control on dose, and more. I request very strongly that you do not proceed with your plan to change a regulation in the attempt to make something that is a medicine, and is being used for medicine purpose, not seem to be so. It is wrong to do so, so don't continue with it, please.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named*	**NO** You have this quite wrong. Fluoride and its compounds are **not** used to **"treat"** community water supplies.

in the regulation? If so, what are they?	Chlorine is used for that purpose – to kill the bugs and germs. Putting fluoride in community water supplies is ONLY to **treat people** and their teeth. That is why it is being put in, isn't it. To say it is to "treat community water supplies" is patently wrong.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☐ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Submission on flouride
: askmedsafe 09/01/2015 03:52 p.m.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people.

I do not wish to speak to my submission.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Nam
Email
Address. [redacted] Australia

Submission to Consulation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluroide (2014)
kmedsafe 09/01/2015 03:52 p.m.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Na

Email

Address:

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
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2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
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Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

to: askmedsafe 09/01/2015 03:54 p.m.

Attention:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145
New Zealand

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name
Occupation Civil Engineer
Qualifications:
Email
Address

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as a (supposed) treatment for the disease of dental caries therefore it is (supposed) a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community

water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

fluoride

Please respond t

askmedsafe@moh.govt.nz 09/01/2015 03:56 p.m.

Question 1. *Do you support the proposed amendment? If not why not?*
NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*
NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

i do not wish to speak

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	-
If this submission is made on behalf of an organisation, please name that organisation here:	NA
Please provide a brief description of the organisation if applicable:	NA
Address/email:	London, Ontario, Canada N6H 2Y1
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer and a frequent visitor to NZ.
Question 1 *Do you support the proposed amendment? If not, why not?*	No. This has to be the strangest amendment! The pretence of legal clarity is all too transparent. The existing definition is valid and sound in that Fluoride is added specifically to prevent *Caries* regardless of the level utilized, this is a pharmacological effect. So why is it now not a medicine? Further, HFA & SSF do not meet good manufacturing practices and yet are still allowed to be added to the water?
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	Any fluoride compound used for the tooth disease management should meet all the requirements of a medicine. And therefore is medicine by definition There is simply no reason to have exceptions unless there are ulterior motives.

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If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☐ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

fluoride

to: askmedsafe 09/01/2015 04:21 p.m.

To whom it may concern.

I do NOT support the amendment. The reason I have listed below.

Unlike Chlorine which is added to the water to purify it, fluoride is added to supposedly reduce dental caries, therefore if it is added to prevent something negative occurring in a human body then it is a medicine. I'd therefore have to ask the question that the fact as a medicine I ought to have a human right to reject it but adding it to my water supply I have no choice but to bathe in it and drink it.

Fluoride is known to block iodine receptors as is bromide and chlorine. Lack of iodine is now implicated with a dramatic rise in breast cancer and thyroid cancer over the last 30 years. I have a certain conditions and have a right to choose what medicine's I wish to absorb/consume...fluoride is not one of them. Therefore it should be my choice to take fluoride tablets or have fluoride painted on my teeth voluntarily not be forced to consume/absorb a medicine that is not healthy to my body.

As I shower daily and drink 2 to 2.5 litres of water a day how you be certain I am not absorbing/consuming more than the recommended dosage when I also drink tea that contains fluoride naturally.

Regards

Fluoridation

o: askmedsafe@moh.govt.nz 09/01/2015 04:22 p.m.

Nam
Emə

Question 1. Do you support the proposed amendment? If not why not?
NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine

2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines
Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?
NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

kmedsafe@moh.govt.nz 09/01/2015 04:25 p.m.

Dear concerned,

Please see my submission form below:

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

Nam
Email
Address as, tx 75211

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. **A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.**

**** In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered**

If one looks up the word "medicine" in any major dictionary in the English language the definition is very simple and clear. A medicine is "a substance that is used to treat, prevent or mitigate a disease." In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,
Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications,
The physiology and biochemistry of the mouth (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. **At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.**

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community*

water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission

Thank you,

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

To: askmedsafe 09/01/2015 04:26 p.m.

SUBMISSION FORM

I do give permission for my personal details to be released to persons under the Official Information Act 1982.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe.

Name:

Email:

Address:

Question 1. *Do you support the proposed amendment ? If not why not ?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine.
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine.
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm".
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation ? If so, what are they ?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people.**

I do not wish to speak to my submission.

Yours sincerely,

Classical Homeopath *dip.hom.*

Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

to: askmedsafe@moh.govt.nz 09/01/2015 04:28 p.m.

Dear concerned,
Please see my submission form below:

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

Nam
Email
Address: , dallas, tx 75211

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:

1. A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.

**** In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself< http://org.salsalabs.com/dia/track.jsp?v=2&c=I1edSzfDtF22ds2hYwZWA5fTVv0uSKf%2F>. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. A medicine is not defined by the dose used, but by the purpose for which it is administered

If one looks up the word "medicine" in any major dictionary in the English language the definition is very simple and clear. A medicine is "a substance that is used to treat, prevent or mitigate a disease." In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply - in the few countries that practice water fluoridation - in order to fight tooth decay, which is a disease.

See,
Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, The physiology and biochemistry of the mouth (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0

ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.

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3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission

Thank you

Please excuse both brevity and typos as this email was sent from my iPhone.

fluoridation

askmedsafe@moh.govt.nz 09/01/2015 04:29 p.m.

Nam
Ema

Question 1. Do you support the proposed amendment? If not why not?
NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine

2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines
Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?
NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

No exemption for Flouride!
to: askmedsafe
Cc:
09/01/2015 04:32 p.m.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people.

I do / do not (delete whichever does not apply) wish to speak to my submission.

I do / do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

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Em .....
Addres ustralia.....

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:
Email:
Address:

Qualifications: **Registered General Nurse**
Registered Midwife
Plunket Nurse

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a treatment to make water safe for drinking.

2. **The intention behind adding fluoride to a community water supply is the key issue. The intention is that it should be a medical treatment to treat dental caries in the entire population. Therefore it is a medicine.**

3. Treatment of whole populations needs to be under a Medicines Act.

3 The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4 The individual's choice of medicine is overridden

5 Babies have immature kidney function and fluoride cannot be eliminated adequately and could build up with the risk of damaging enzyme functions throughout all systems in the baby's body.
Weakened kidney function can occur in the elderly. Allergies in people are rife at the present time.

5. To remove fluoride from a water supply requires a reverse osmosis system, which is expensive and mothers/families with young babies may not be able to afford it if they wish to remove fluoride from their water to feed their baby.

6 There are other options for medicating oneself with fluoride.

7 There are other options for treating dental caries

I do not wish to speak to my submission.

Submission on Fluoride Containing Substances - Proposed Amendment to Regulations under the Medicines Act 1981

:o: askmedsafe 09/01/2015 04:44 p.m.

Dear Sir/Madam

Submission on Fluoride Containing Substances - Proposed Amendment to Regulations under the Medicines Act 1981

"It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies."

Source: Medsafe website, http://www.medsafe.govt.nz/consultations/medicine-regulations-fluoride-in-drinking-water.asp

Question 1: Do you support the proposed amendment? If not why not?

Answer 1: No, I DO NOT support the proposed amendment.

I DO NOT support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine;
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine;
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm";
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.

Question 2: Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

Answer 2: No.

Fluoride and its compounds are not used to "treat" community water supplies. The purpose of fluoride and its compounds in community water supplies is to treat people.

I do give permission for my personal details to be released to persons under the Official Information Act 1982.

I do not wish to speak to my submission.

SUBMISSION FORM

I **DO NOT** give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:
Email:
Address:

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. I experience side effects from drinking fluoridated water. I get headaches, brain fog and confusion when drinking optimally fluoridated water. For this reason fluoride needs to be regulated so that people can be warned of possible side effects. Doctors and dentists need to be educated as well, because a patient may present with side-effects and neither the doctor nor patient will suspect fluoride. The patient may be treated for side effects with medication when all that is needed, is for the patient to be counselled to avoid fluoridated water and other sources of fluoride as much as possible. Side effects from fluoride even at low levels are well documented in the scientific and medical literature. Case histories and peer reviewed research shows that fluoride can cause harm in some people. Symptoms include neurological problems, headaches, skin irritation, gastrointestinal pain and symptoms (Waldbott 1956, 1958, Feltman 1956, Feltman and Kosel 1961, Grimbergen 1974, Petraborg 1977, Spittle 2008). Patients were often unaware that their drinking water contained fluoride. Symptoms improved with avoidance of fluoridated water and returned with consumption of fluoridated water or with experimental challenge with fluoride and confirmed by double blind testing. Doctors aren't trained to suspect fluoride, so patients may be treated for side effects when all that is needed, is avoidance of fluoridated water.
Based on the scientific evidence, 1 to 2 % of the population will benefit from a low fluoride intake. This equates to 45,000 to 90,000 New Zealanders. Fluoride needs to be regulated so that people in this category aren't harmed.

2. Because fluoride is used as a therapeutic product it should be manufactured according to cGMP (current Good Manufacturing Practice). This is not being done at the moment and introduces risk to the public. Currently the supplier could use different raw materials, different processes, unqualified equipment to produce the fluoride product and not have to undergo rigorous audits which could result in potential harm to the public.

3. Because fluoride is used as therapeutic product it should be subject to rigorous control trials, confirming safety and efficacy for people of all ages and medical conditions.

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds play no role in water treatment. They are not required to make the water safe and to meet drinking water standards. Fluoride compounds actually introduce contamimnats to the public water supply. In community water fluoridation (CWF) the public water supply is used as a vehicle to deliver fluoride to people for ingestion ie it **treats people.**

*I **DO** wish to speak to my submission.*

Thank you for the opportunity to make this submission.

Submission re Proposed amendment to regulations concerning Flouride
: askmedsafe 09/01/2015 04:55 p.m.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

Please accept my submission regarding the two questions in relation to the proposed amendment that states "It is proposed that a new regulation be made under section 105(1)(i) that: Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies". Medsafe

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
2. Fluoride is not a water treatment like chlorine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission and I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submitted by:

Name:
Email:
Address Australia

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

.o: askmedsafe 09/01/2015 04:58 p.m.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name:

Email:

Address:

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

: askmedsafe 09/01/2015 05:06 p.m.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Nam

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Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

Thank You

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Dentist
Question 1 *Do you support the proposed amendment? If not, why not?*	Yes

Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	Sodium Fluoride

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☑ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Vote NO

askmedsafe 09/01/2015 05:12 p.m.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

Name
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Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. **A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.**

Fluoridation by any municipality is a gross mistake in ethics and morality. Medicating without consent is not just wrong an immoral it is illegal in every country! Practicing medicine without a license is what is occurring but instead of using an approved drug with informed consent of the patient you are using a toxic substance, treating it as a drug to treat a condition without informed consent of the populace without any concern for the health and well being of the people. Treating cavities this way is equivalent to swallowing bleach to whiten your teeth!

In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered**

If one looks up the word "medicine" in any major dictionary in the English language the definition is very simple and clear. A medicine is "a substance that is used to treat, prevent or mitigate a disease." In other words it is defined by its

purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See,
Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. **At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.**

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat*

community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission

Submission regarding fluoride in the Medicines Act 1981
to: askmedsafe@moh.govt.nz 09/01/2015 05:13 p.m.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)
"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

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Email:
Address:

Question 1. *Do you support the proposed amendment? If not why not?*
NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*
NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	N/A
Please provide a brief description of the organisation if applicable:	N/A
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
Question 1 *Do you support the proposed amendment? If not, why not?*	**NO.** I do not support the proposed amendment because: 1. Fluoride is not a water treatment like chlorine 2. Fluoride is added to the water as a supposed treatment for the disease of dental caries therefore it is a medicine. 3. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	**NO.** Fluoride-containing compounds are **not** used to **'treat'** community water supplies. In community water fluoridation the **purpose** of fluoride-containing compounds is to **treat people.**

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X I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Fluoride legislation

: askmedsafe 09/01/2015 06:21 p.m.

Dear Sir/Madam. I herewith voice my opposition to the proposed Legilation.
Fluoride is not a Medical Substance and should therefore not be an a substance to be added to a basic element such as water which by the addition to water will be ingested by every member of the population regardless of age, gender, medical condition or need. I consider it un-ethical that a substance is administered to an individual without their approval. As an Engineer I am aware and know for a fact that Fluoride in its many forms (please note the distinction) is a By-product of 2(two) manufacturing processes, these are (1) the Aliminium Industry, where Beauxite is refined into Aliminium and (2) the Fetilizer Industry. In addition to the two industries, it has recently come to light that Fluoride is produced as a by-product in the refining of Uranium into nuclear fuel. In the light of my knowledge I ( ) Do Not Support and furthermore Object to the Proposed Legilation. Signed by
Email.
Address.

Fluoride consultation
ıskmedsafe 09/01/2015 06:59 p.m.

I

Regarding the Ministry of Health's request for feedback on the proposed exemption of the chemicals used as water fluoridation agents from the NZ water supply:

Question 1. *Do you support the proposed amendment? If not why not?*

NO . I do not support the proposed amendment because:

1. Fluoride is not a water treatment agent like chlorine (which is necessary in many situations to kill pathogenic organisms which have entered raw water supplies).
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine.
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm".
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people.**
It is highly unethical to add any unnecessary chemical to public water supplies thereby using the water people use for drinking and bathing as medium for mass medication of the population. The addition of any medication to public water supplies violates people's right to give informed consent prior to taking a medication.
It is also inherently unsafe because it exposes the entire population to the medication (including those who have allergies to fluoride compounds) and the dose of fluoridation chemicals that are added to the water supplies cannot be tailored to the individual but is instead dependent on how much fluoridated water (and/or foods prepared using fluoridated water) an individual may consume.
For these reasons alone, water fluoridation is a practice that has been abandoned in much of the rest of the world and should also cease in NZ.
I know that the considerable evidence that fluoride poses health risks has been previously presented to MoH representatives who, unfortunately, chose to ignore it.
If the Ministry of Health believes that supplementary fluoride is essential for health (a highly debateable assertion, but I had no time to present all the evidence against fluoridation here) **here is a simple solution:**
Pass legislation to allow for some cooking and/or table salt products on the NZ market to be fluoridated - as is done in some countries in Europe.
Obviously, any policy of fluoridating salt would need to be done with appropriate labelling so that consumers know that the product contained added fluoride and how much fluoride is contained in, for example, one quarter of a teaspoon.
Allowing the option of fluoridated salt on the supermarket shelves would allow people who want extra fluoride the option of using fluoridated salt. It would be similar to how people in NZ currently can choose between purchasing salt with added iodine ("iodised salt") and/or other varieties of salt such as natural sea salt, rock salt etc. according to their personal preference and/or health needs. The policy of having iodised salt available (rather than adding iodine to drinking water) accommodates the needs of people who need to avoid supplementary iodine due to their suffering from medical conditions such as hyperthyroidism.

A policy of fluoridating some salt products does not violate anyone's freedom of choice. Moreover, adding fluoride to some cooking and/or table salts means that individuals can control the dose of supplementary fluoride that they choose to consume by measuring the amount of salt that they use in cooking (and making enquiries of anyone else who prepares food that they consume about the amount and type of salt added during or after cooking.)

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	consumer
Question 1 *Do you support the proposed amendment? If not, why not?*	No I don't. I don't think that a blanket solution should be used for the dental health of neglectful people. I also don't want it in the water because I have an autoimmune disease and I have to avoid all toxins which include fluoride.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	There shouldn't be anything added to anyone's water without consent – full stop. There should be full disclosure of anything that isn't 100% H2O.

Please note that all correspondence may be requested by any member of the public under

the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☒ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

to: askmedsafe@moh.govt.nz 09/01/2015 07:12 p.m.

I do give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Nam
Email:
Address:

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people.

I do not wish to speak to my submission.

Submission on Fluoride
askmedsafe
Cc: j.coleman
09/01/2015 07:14 p.m.

Dear Medsafe

SUBMISSION ON PROPOSAL THAT HFA AND SSF ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

ANSWER TO QUESTION 1

I oppose the proposed amendment for the following reasons:

1 = No Regulation should be made exempting HFA and SSF from being medicines until the Court of Appeal has determined whether or not HFA and SSF are medicines under the Medicines Act.

2 = If HFA and SSF are medicines they should not be exempt from the Medicines Act.

3 = If HFA and SSF are not medicines there is no need for the exemption.

4 = The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls. Fluoride is a known neurotoxin

5 = These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance. Fluoride is a known neurotoxin

6 = If fluoride tablets are not recommended for babies, toddlers and pregnant women, these sub-populations should not be ingesting fluoridated water. Fluoride is a known neurotoxin

7 = No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed. Fluoride is a known neurotoxin. Topical Administration only.

8 = Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2:

I do not give permission for my personal details to be released to persons under the Official Information Act 1982.

Yours sincerely

to: askmedsafe 09/01/2015 07:44 p.m.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982
Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)
"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe
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Question 1. *Do you support the proposed amendment? If not why not?*
NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines
Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*
NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people
Let democracy prevail and let the New Zealand Individuals Choose to add Fluoride to their own water or not. Do not force it upon everyone against our will.

I do not wish to speak to my submission.

Thank you for your time.

Fluoride IS a medicine
to: askmedsafe@moh.govt.nz 09/01/2015 08:13 p.m.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

Name:
Email:
Address ___, USA

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. **A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.**

In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered.**

By definition, a medicine is "a substance that is used to treat, prevent or mitigate a disease." In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.
Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

See:
Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins)

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. **At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose**

remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

.o: askmedsafe 09/01/2015 08:17 p.m.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

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Question 1. Do you support the proposed amendment? If not why not?

NO. I do not support the proposed amendment because:
1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

Kind Regards

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	I would like to be heard on my submission.
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer and health professional
Question 1 *Do you support the proposed amendment? If not, why not?*	No, fluoride is a medicine and should not be used as a mass inoculant in the water supply. The over use of fluoride in toothpaste, medicines as well as water could lead to ill heath in children and adults who use all these products. The term "fluoride" is misleading, as there are many forms of it, the terminology regarding the lifting of the term from a medicine is not scientific and does not specify what type of fluoride you are exempting.

	Are you meaning all fluorides like Sodium mono fluoroacetate or Sodium mono fluorophosphates? Or Calcium fluoride? The dangers of sodium mono fluoroacetate (1080) should not be given any exemption. The public have not been given any science to consider this amendment and it is so arbitrary that proper evaluation should be given. Clean Drinking water in itself is considered a life supporting necessity and therefore should have no "treatments" added to it on the whim of a current trend that is unproven and dangerous for a section of the community. The Health department used to dispense fluoride tablets to families who needed it this should be considered again. If fluoride is mandated for the water then a separate supply should be set-aside for those who do not want it. No this amendment should not go ahead.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	Community water supplies should be free of any additives. Treatments should be targeted to individual populations. This is a dangerous mass medication of a toxic compound that has the potential to cause extreme harm to vulnerable individuals.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual,

rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

☐ I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

All About Health Your Complete Holistic Healthcare Center to: askmed 09/01/2015 08:23 p.m.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name: Dr.

Email:

Address: , AZ 85297

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

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Sincerely yours

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

to: askmedsafe@moh.govt.nz 09/01/2015 08:25 p.m.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Nam
Email:
Addres

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people

I do not wish to speak to my submission.

SUBMISSION FORM

I do not (delete whichever does not apply) give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Nar
Email
Address

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not (delete whichever does not apply) wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145

Email to: askmedsafe@moh.govt.nz

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Consumer
Question 1 *Do you support the proposed amendment? If not, why not?*	Yes.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	The practice of water fluoridation should not be subject to the Medicines Act. Fluoride is beneficial and safe.

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consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

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X I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

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Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

o: askmedsafe 09/01/2015 09:38 p.m.

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name
Email:
Address

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. Ingesting hydrofluorosilicic acid (HFA) and/or sodium silico fluoride (SSF) has never been subject of a Randomised, Double Blind, Placebo controlled Trial, consequently has no reliable data
4. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
5. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people.**

Yours Sincerely.

Fluoride is a Medicine

skmedsafe 09/01/2015 09:44 p.m.

SUBMISSION FORM

I do not give permission for my personal details to be released to persons under the Official Information Act 1982

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

Nan
Emai
Address: **Australia**

Question 1. *Do you support the proposed amendment? If not why not?*

NO. I do not support the proposed amendment because:

1. **A medicine is not defined by the dose used, but by the purpose for which it is administered -in this case these chemicals are added to the public water supply to treat dental disease. That makes fluoridating chemicals medicines.**

A medicine is not defined by the dose used, but by the purpose for which it is administered

If one looks up the word "medicine" in any major dictionary in the English language the definition is very simple and clear. A medicine is "a substance that is used to treat, prevent or mitigate a disease." In other words it is defined by its purpose. It is not defined by the dose used or even by whether it works or not.

Fluoride chemicals (HFA, SFA, NaF) are added to the water supply – in the few countries that practice water fluoridation – in order to fight tooth decay, which is a disease.

Caries as a Disease of Civilization (Chapter XI, Blackwell Scientific Publications, *The physiology and biochemistry of the mouth* (4th Ed) by G Neil Jenkins).

Also Fluoride works topically: see Scher opinion

"The cariostatic effect of topical fluoride application, e.g. fluoridated toothpaste, is to maintain a continuous level of fluoride in the oral cavity. Scientific evidence for the protective effect of topical fluoride application is strong, while the respective data for systemic application via drinking water is less convincing. No obvious advantage appears
in favour of water fluoridation as compared with topical application of fluoride. In several environmental scenarios it was found that exposure of environmental organisms to levels of fluoride used for fluoridation of drinking water is not expected to lead to unacceptable risks to the environment. The opinion is available at: http://ec.europa.eu/health/scientif ic_committees/environmental_risks/docs/scher_o_139.pdf

Fluoride compounds are medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. **At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.**

For the NZ Ministry of Health to attempt to change the definition of fluoride as used in water fluoridation from anything else but a medicine would make its support of this unscientific and unethical practice even more embarrassing than it already is. The effort to change the language itself represents the last desperate exercise in the application of arbitrary governmental power in support of a bankrupt policy. Clearly reason and scientific argument have failed. It is consistent with a series of steps taken recently in NZ to keep the practice of water fluoridation going at all costs.

2. Fluoride is not a water treatment chemical to treat the water (like chlorine) but simply to use the water supply to deliver medical treatment.

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission
Yours Sincerely

SUBMISSION FORM

Please provide your contact details below. You may also wish to use this form to comment on the proposed amendment.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	Not applicable
Please provide a brief description of the organisation if applicable:	Not applicable
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Concerned New Zealand citizen
Question 1 *Do you support the proposed amendment? If not, why not?*	No I don't support the proposed amendment because this amendment would allow it to bypass the law and not be treated as a medicine whereas in fact fluoride is put in the public water supply to treat dental cavities as medicine. This amendment would remove a precautionary measure aimed at protect people from negative effects of fluoride and its compounds. Fluoride is not like chlorine which is used to effectively clean the water of impurities. Fluoride is put in the water on a purely mass-medication basis to improve oral health care. Mass-fluoridation of water supplies also infringes upon medical ethics by indiscriminatelymedicating New Zealanders.

Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	All fluoride and its compounds used in our public water supplies are not used to treat the water per say but the people drinking it.

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Submission form: Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)

askmedsafe 09/01/2015 10:48 p.m.

SUBMISSION FORM
I do not give permission for my personal details to be released to persons under the Official Information Act 1982
Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014)
"It is proposed that a new regulation be made under section 105(1)(i) that:

Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe
Name
Email:
Address

Question 1. Do you support the proposed amendment? If not why not?
NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine

2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine

3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"

4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines

Question 2. Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?
NO. Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of fluoride and its compounds is to treat people
I do not wish to speak to my submission.

Post to:

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145