IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY CIV 2014-485-4138

UNDER	the Judicature Amendment Act 1972 and the Declaratory Judgments Act 1908
IN THE MATTER	of an application for judicial review and an application for a declaration
BETWEEN	NEW HEALTH NEW ZEALAND INC
	Plaintiff
AND	ATTORNEY-GENERAL for and on behalf of the Minister of Health
	Defendant

THIRD AFFIDAVIT OF PATRICK DAVID SLOAN

Dated 28 July 2014

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I, Patrick David Sloan, director of Christchurch solemnly and sincerely affirm:

1. This is my third affidavit.

2. Its purpose is to respond to some matters raised in the affidavits of Stewart Jessamine and Paul Prendergast.

"Pragmatic filter"

3. Dr Jessamine suggests at paragraph 18 that a "pragmatic filter" ought to be applied to the definition of medicine because a rigid interpretation would be impractical and make many things, including water, a medicine.

4. This response is surprising to me for two reasons.

5. First, I don't know how anyone could sensibly suggest water is a medicine per se. It is essential for normal functioning, and there is no therapeutic claim involved.

6. Secondly, it has always been my understanding that if a product makes a therapeutic claim or contains an ingredient which is classified as a medicine, Medsafe will treat it as a medicine.

7. I refer to a slide presentation Derek Fitzgerald of Medsafe gave to the New Zealand Register of Acupuncturists conference in June 2011 entitled "How the NZ medicines legislation applies to the sale and supply of Chinese medicines".

8. This is attached and marked "A". One of the slides states that:

> A product is a medicine if a therapeutic purpose is claimed for it **or** if it contains a medicinal (scheduled) substance. The product need not contain a therapeutic substance to be regarded as a medicine, a therapeutic claim is sufficient.

9. As I have shown my second affidavit at paragraph 55 and exhibit B that is the approach Medsafe takes when considering whether dietary supplements comply with the Medicines Act.

10. To further illustrate this point I attach a transcript of an interview aired on the Nine to Noon show on National Radio on 5 March 2008. This is attached and marked "B".

11. The interview was entitled "Natural Health Practitioners Under Fire from Medsafe". Katherine Ryan was interviewing aromatherapist Marilyn Johnston who was selling lavender oil. On her website she claimed that it healed burns. Medsafe sent her a letter advising that she wasn't allowed to make therapeutic claims for her lavender oil.

12. Stewart Jessamine was also being interviewed and explained that products cannot make therapeutic claims, otherwise they will be medicines.

13. A further example of Medsafe's approach is provided in a letter dated 30 October 2013 from Medsafe to High Performance Health Ltd. This letter is attached and marked with the letter "C".

14. Medsafe entered the premises of High Performance Health Limited and seized various items including containers of dimethyl sulphoxide (DMSO) (an industry solvent). The DMSO was seized because it is a prescription medicine listed in the first schedule of the Medicines Regulations 1984.

15. I cannot understand how HFA and SSF which are used for the treatment of dental decay are not considered by Medsafe to be medicines. Not only do they have a therapeutic claim/purpose they contain an ingredient which is classified as a medicine.

16. In my second affidavit I noted that fluoride is classified as pharmacy-only, prescription and restricted medicine. It is also a general medicine. An extract from the Medsafe Medicine Classification is attached and marked "D".

Safety and efficacy not accepted

17. Dr Jessamine claims fluoridation is safe and effective and at paragraph 14 refers to a list comprising major international reviews and meta-analyses on water fluoridation published between 1951 and 2011.

18. This list comprises principally (but not exclusively) publications from pro-fluoridation organisations.

19. I wish to comment on three of these reports as a careful reading shows that they seriously question the efficacy and/or safety of water fluoridation. These are the York Report (2000), NRC Report (2006) and SCHER report (2011).

York Report

20. In 2000 the NHS Centre for Reviews and Dissemination at the University of York carried out the first full systematic review of water fluoridation (the York review). It identified 5 objectives:

    20.1. What are the effects of fluoridation of drinking water supplies on the incidence of dental caries?

    20.2. If water fluoridation is shown to have beneficial effects, what is the effect over and above that offered by the use of alternative interventions and strategies?

    20.3. Does water fluoridation result in a reduction of caries across social groups and between geographical locations, bringing equity?

    20.4. Does water fluoridation have negative effects?

    20.5. Are there differences in the effects of natural and artificial water fluoridation?

21. After nearly 50 years of study into water fluoridation it found that there was a surprising lack of high quality studies demonstrating benefits. In

respect of objective 1 its conclusions were based on a limited number (26) of moderate quality studies, many of which lacked appropriate analysis. From these data the executive summary recorded:

> The best available evidence suggests that fluoridation of drinking water supplies does reduce caries prevalence, both as measured by the proportion of children who are caries free and by the mean change in dmft/DMFT score. The studies were of moderate quality (level B), but of limited quantity. The degree to which caries is reduced, however, is not clear from the data available. The range of the mean difference in the proportion (%) of caries-free children is -5.0 to 64% with a median of 14.6% (interquartile range 5.05, 22.1%). The range of mean change in dmft/DMFT score was from 0.5 to 4.4 median teeth (interquartile range 1.23, 3.63 teeth). It is estimated that a median of six people need to receive fluoridate water for one extra person to be caries-free (interquartile range of study NNTs 4,9). The best available evidence from studies following withdrawal of water fluoridation indicates that caries prevalence increases, approaching the level of the low fluoride group. Again, however, the studies were of moderate quality (level B), and limited quantity. The estimates of effect could be biased due to poor adjustment for the effects of potential confounding factors.

22. In respect of objective 3 it found that there were no level A or B studies examining the effect of water fluoridation on the inequalities of dental health. Relying on level C (poor quality) studies:

> [t]here appears to be some evidence that water fluoridation reduces the inequalities in dental health across social classes in 5 and 12 year-olds, using the dmft/DMFT measure. This effect was not seen in the proportion of caries-free children among 5 year-olds. The data for the effects in children of other ages did not show an effect. The small quantity of studies, differences between these studies, and their low quality rating, suggest *caution* interpreting these results.

23. In respect of objective 4 it found:

23.1. That the prevalence of fluorosis at a level of 1 ppm was estimated to be 48% and for fluorosis of aesthetic concern predicted to be 12%.

23.2. Studies into bone fracture and cancer were of low quality with a high risk of bias. No clear association was found between the incidence of hip fracture and cancer and water fluoridation.

24. The executive summary concluded:

> This review presents a summary of the best available and most reliable evidence on the safety and 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. As such, this review should provide both researchers and commissioners of research with an overview of the methodological limitation of previous research conducted in this area.
>
> The evidence of a benefit of a reduction in caries should be considered together with the increased prevalence of dental fluorosis. The research evidence is of insufficient quality to allow confident statements about other potential harms or whether there is an impact on social inequalities. This evidence on benefits and harms needs to be considered along with the ethical, environmental, ecological, costs and legal issues that surround any decisions about water fluoridation. All of these issues fell outside the scope of this review.
>
> Any future research into the safety and efficacy of water fluoridation should be carried out with the appropriate methodology to improve the quality of the existing evidence base.

25. This report is hardly an endorsement of the efficacy and safety of fluoridation. Despite the expressed lack of certitude about these, the report was used by those promoting fluoridation (eg the British Dental Association and British Medical Association) to support claims of safety and efficacy. This prompted the York Reviewers to express concern about such misrepresentations in a statement dated 28 October 2003.

> We are concerned about the continuing misinterpretations of the evidence and think it is important that decision makers are aware of what the review really found. As such, we urge interested parties to read the review conclusions in full.
>
> We were unable to discover any reliable good-quality evidence in the fluoridation literature world-wide.

What evidence we found suggested that water fluoridation was likely to have a beneficial effect, but that the range could be anywhere from a substantial benefit to a slight disbenefit to children's teeth.

This beneficial effect comes at the expense of an increase in the prevalence of fluorosis (mottled teeth). The quality of this evidence was poor.

As association with water fluoride and other adverse effects such as cancer, bone fracture and Down's syndrome was not found. However, we felt that not enough was known because the quality of the evidence was poor.

The evidence about reducing inequalities in dental health was of poor quality, contradictory and unreliable.

Since the report was published in October 2000 there has been no other scientifically defensible review that would alter the findings of the York review. As emphasised in the report, only high-quality studies can fill in the gaps in knowledge about these and other aspect of fluoridation. Recourse to other evidence of a similar or lower level than that included in the York review, no matter how copious, cannot do this.

26. Attached and marked "E" is a copy of that letter

27. In 2001 Professor Trevor Sheldon who chaired the Advisory Group for the York review published the following open letter

3/1/2001

In my capacity of chair of the Advisory Group for the systematic review on the effects of water fluoridation recently conducted by the NHS Centre for Reviews and Dissemination the University of York and as its founding director, I am concerned that the results of this review have been widely misrepresented. The review was exceptional in this field in that it was conducted by an independent group to the highest international scientific standards and a summary has been published in the British Medical Journal. It is particularly worrying then that statements which mislead the public about the review's findings have been made in press releases and briefings by the British Dental Association, British Medical Association, the National Alliance for Equity in Dental Health and the British Fluoridation Society. I should like to correct some of these errors:

1. Whilst there is evidence that water fluoridation is effective at reducing caries, the quality of the studies was generally moderate and the size of the estimated benefit, only of the order of 15%, is far from "massive".

2. The review found water fluoridation to be significantly associated with high levels of dental fluorosis which was not characterised as "just a cosmetic issue".

3. The review did not show water fluoridation to be safe. The quality of the research was too poor to establish with confidence whether or not there are potentially important adverse effects in addition to the high levels of fluorosis. The report recommended that more research was needed.

4. There was little evidence to show that water fluoridation has reduced social inequalities in dental health.

5. The review could come to no conclusion as to the cost-effectiveness of water fluoridation or whether there are different effects between natural or artificial fluoridation.

6. Probably because of the rigour with which this review was conducted, these findings are more cautious and less conclusive than in most previous reviews.

7. The review team was surprised that in spite of the large number of studies carried out over several decades there is a dearth of **reliable** evidence with which to inform policy. Until high quality studies are undertaken providing more definitive evidence, there will continue to be legitimate scientific controversy over the likely effects and costs of water fluoridation.

SIGNED,
Professor Trevor Sheldon MSc MSc DSc FMedSci

28. Attached and marked "F" is a copy of that letter.

NRC Report

29. A 2006 report by the NRC found that fluoridation at 4 ppm (4 times higher than the current maximum fluoridation concentration) did not protect human health and posed real risks in terms of skeletal fluorosis and risk of bone fractures. Other possible risks such as neurotoxicity and endocrine effects were also identified.

30. In its claim against the South Taranaki District Council New Health obtained an affidavit from a member of the NRC review team, Dr Kathleen Thiessen.

31. A copy of her affidavit is attached and marked "G".

SCHER Report

32. The 2011 SCHER Report concludes that topical application of fluorides is the most effective means of protecting against decay. It says that swallowing fluoride has no benefit for permanent teeth and concludes that water fluoridation has not been sufficiently proven to reduce health inequalities.

> Water fluoridation as well as topical applications (eg fluoridated toothpaste or varnish) appear to prevent caries, primarily on permanent dentition. 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 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, eg drinking water, milk or salt fluoridation, as regards the reduction of oral-health social disparities, remains insufficiently substantiated.

33. In my experience of reading pro-fluoridation material, this comes as close to an admission that water fluoridation is ineffectual as any I have read.

34. It affirms that topical application of fluoride is best, that swallowing fluoride is ineffective and that fluoridation has not been proven to reduce health inequalities. This latter admission is significant as a major reason why the Ministry of Health promotes fluoridation is that it claims it reduces health inequalities and will benefit those who don't brush their teeth regularly. According to SCHER such a claim appears to be false.

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NFIS

35. Dr Jessamine refers in his schedule to information from the NFIS.

36. New Health is sceptical that the NFIS is able to critically evaluate evidence which questions the efficacy and safety of fluoridation.

37. New Health attempted to engage in a dialogue with the NFIS but was effectively "fobbed off". As a consequence New Health made a complaint to the Ombudsman. The relevant documents are attached and marked "H" and are self explanatory.

No safety testing of HFA and SSF

38. It is very surprising to me how Dr Jessamine can claim fluoridation is safe when the product being used to fluoridate the water is a hazardous substance containing heavy metal contaminants, including arsenic, a known human carcinogen.

39. I am not aware of any specific human health safety testing that has been done on HFA or SSF. I am aware that the US EPA considers there is a need for human health safety studies to be conducted on silicofluorides as distinct from sodium fluoride or calcium fluoride and requested such research in 2002. However, to reiterate I am not aware that any such research has been undertaken.

Neurotoxic effects of fluoride

40. I referred in my second affidavit to the neurotoxic effects of fluoride and reiterate that point in this affidavit. There is a wealth of significant and compelling data suggesting that fluoride adversely affects the developing brain. A recent Harvard University Funded study published in Environmental Health Perspectives, a highly respected peer-review journal published reviewed 27 studies that examined the effects of fluoride exposure on IQ in children. It found that in 26 of the 27 studies children with increased exposure to higher levels of fluoride tested lower

for IQ: Choi et al, Developmental Fluoride Neurotoxicity: a systematic review and meta-analysis, Environmental Health Perspect. 120(1); 1362 (2012).

41. A non-exhaustive list of publications that show fluoride impacts negatively on animal and human brain is attached and marked "I".

Ministry's explanations about why HFA/SSF not a medicine are inconsistent

42. At paragraph 30 of his affidavit Mr Prendergast says that "fluoridation of drinking water is not a treatment process, but has been and continues to be effective in reducing the incidence of dental caries".

43. New Health agrees that fluoridation is not a water treatment process.

44. However, when New Health first raised its concerns about HFA/SSF being medicines with Dr Jessamine, he advised that they were not medicines because they were sold for the purpose of water treatment.

45. The relevant correspondence comprising letters dated 17, 19 and 20 March 2014 are attached and marked "J".

Paragraph 15 of Dr Jessamine's affidavit

46. At paragraph 15 of his affidavit Dr Jessamine refers to an expert panel that has been commissioned by the Royal Society and the Prime Minister's Chief Science Advisor to review water fluoridation. According to Dr Jessamine it is to report in August 2014.

47. New Health was unaware such a review was underway and was surprised to read this in Dr Jessamine's affidavit, particularly because last year Professor David Skegg from the Royal Society said a review would not be undertaken.

48. New Health has attempted to obtain information about this review, for example, who is on it, why it was considered necessary to do it now and

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without public knowledge. The only document the Ministry of Health has released to date is attached and marked "K".

49. The review is concerning for two reasons. Both Professor Skegg and Professor Sir Peter Gluckman who are chairing the review have expressed publicly very strong pro-fluoride views. Secondly, it is being carried out in secret.

Mr Prendergast's affidavit

50. At paragraph 47 Mr Prendergast says that the reason the US has an MCL at 4 mg/L is because the US has large areas dependant on groundwater supplies which have naturally occurring higher fluoride content.

51. I do not believe that statement is correct. It is my understanding that the proportion of the US population which has groundwater between 2 and 3ppm and 3 and 4 ppm respectively is less than 0.5%.

AFFIRMED at Christchurch this 28th)

day of July 2014

Patrick David Sloan

before me:

A Barrister and Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

How the NZ medicines legislation applies to the sale and supply of Chinese medicines

A presentation to the New Zealand Register of Acupuncturists conference

Derek Fitzgerald
Manager, Compliance Management, Medsafe
25 June 2011

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY

The NZ medicines legislation

- Aim is to protect public health by ensuring that medicines and other therapeutic products are available that are safe and effective

This is achieved through:

- General requirement for medicines to be assessed by Medsafe before they can be advertised and sold
- Medicines are classified according to the risks they pose so that medicines posing greatest risk can only be supplied on a prescription from a medical doctor and obtained from a pharmacy
- In general the distribution chain is controlled from manufacturer to pharmacy

What is a medicine?

Sections 3 and 4 of the Medicines Act

A medicine is any substance used in humans for a therapeutic purpose

The term 'therapeutic purpose' has a wide definition and includes: treating, preventing and diagnosing disease; changing the size and shape of the body; changing a normal physiological process

A disease includes any disorder or adverse condition whether of body or mind

A therapeutic claim is a claim (label, advertisement etc) that a product has a therapeutic purpose

Classification of medicines

Medicines are classified in schedule 1 of the Medicines Regulations 1984 (available on the Medsafe website). If a substance is classified as:

- A prescription medicine, it may only be prescribed by a NZ-registered medical practitioner (or other person authorised under the legislation) and can only be supplied from a pharmacy
- A restricted (pharmacist-only medicine) may only be supplied by pharmacist in a pharmacy
- A pharmacy-only medicine may only be supplied by a pharmacy
- A medicine that is not classified is a general sales medicine

There are some minor exceptions relating to supply by certain healthcare professionals

What is a dietary supplement?

Dietary Supplements Regulations 1985

- Contains an amino acid, edible substance, herb, mineral, synthetic nutrient or vitamin
- Is in a 'controlled' dose form
- Is for oral use
- Is intended to supplement the amount of the substance normally derived from food
- Is not recommended for a therapeutic purpose

It is important to note that:

A product is a medicine if a therapeutic purpose is claimed for it **or** if it contains a medicinal (scheduled) substance.

The product need not contain a therapeutic substance to be regarded as a medicine, a therapeutic claim is sufficient.

What does all this mean?

A medicine cannot be manufactured, advertised, sold or supplied unless it has been assessed by Medsafe and the Minister of Health has given consent to its distribution

Unless an exemption applies

The exemptions are strictly controlled and are described in sections 25 to 34 of the Medicines Act

Exemption for natural therapists

Natural therapists (including practitioners of Chinese medicine) may provide unapproved medicines under certain circumstances

Section 32

A natural therapist may manufacture, pack, label and sell by retail certain medicines provided:

- The medicines are supplied to an individual for the treatment needs of that individual following a consultation with the practitioner
- The medicine does not contain a scheduled (classified) medicine or controlled drug
- The medicine is not advertised in any way

A therapeutic claim

Section 4

Includes any reference to:

- a disease or other adverse condition and how a product may help with this
- improving a bodily or mental function
- ancient or traditional use as a remedy or medicine
- someone who has benefited from its use
- weight loss

Assessment by Medsafe – the legal route to 'market' a product

If you want to operate outside the exemption:

Medsafe assesses medicines for New Zealand against international guidelines that ensure a product will be safe, effective and of an acceptable quality.

Information is available on the website giving guidance on the application process, costs and data required.

Medsafe staff are happy to provide guidance on the application process.

In summary

A product may not be sold for a therapeutic purpose unless it has been approved by Medsafe or unless it is being sold by a natural therapist in strict compliance with the exemption for natural therapists

A product that is scheduled as prescription, restricted (pharmacist-only) or pharmacy may not be sold under any circumstance by a retailer that is not a pharmacy

A product that has not been approved by Medsafe cannot be advertised under any circumstance

Information sources

Medsafe website – www.medsafe.govt.nz

- Making an application to distribute a medicine
- Previous safety warnings, including photographs
- Media releases – Prosecution information
- Classifications – look up ingredients and herbs that are classified as medicines
- List of regulatory consultants that can offer advice

Legislation – www.legislation.govt.nz

- Complete copies of the Medicines Act 1981, Medicines Regulations 1984, Dietary Supplements Regulations 1985 and other significant legislation

Medsafe staff

Legal advice

Therapeutic Advertising Pre-vetting Service – TAPS – www.anza.co.nz

'B'

Radio NZ – Nine to Noon (Katherine Ryan) interview with Marilyn Johnston on 5 March 2008

Well first this morning is this bureaucracy gone mad. An aromatherapist is angry she's been told that she is not allowed to extol the sleep enhancing properties of lavender oil or recommend eucalyptus for congested sinuses. Marilyn Johnston has a small business, Celestial Essentials. She's built it up over the last six years. She says now she has had a letter from the government agency Medsafe saying material on her website about the healing properties of her oils is in breach of the 1981 Medicines Act and she has to remove it. She says many natural practitioners have had the same letter and the industry is reeling at the heavy handed tactics, which she believes is a reaction to the government failing to pass a controversial bill last year. If it had been passed it would have regulated natural medicines. The Therapeutic Products and Medicines Bill, which would've set up a Trans-Tasman regulatory agency was defeated last year. Marilyn Johnston says enforcing the old legislation this way will take NZ back to the dark ages and will have wide ranging implications for all alternative medicine practitioners and consumers. Marilyn Johnston joins us now on the line from Auckland. Good morning to you.

Marilyn Johnston: Good morning.

And also with us is Stewart Jesimine the interim Manager of Medsafe, good morning to you Stewart.

Stewart: Good morning.

Marilyn first of all what kind of business is yours?

Marilyn Johnston: I am just a small sole trader. I actually really do focus more on the spiritual and emotional aspects in the work that I do. However I do have a website, and I set this up primarily for getting people free information about natural health products and promoting other natural health practitioners. So to me this is really come out of left field

THIS is the Exhibit marked with the letter. B
referred to in the annexed affidavit of PATRICK DAVID SLOAN
AFFIRMED/~~SWORN~~ at ...CHRISTCHURCH
this 28th day of ...July.....2014 before me:

MEMorrison
A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

or blistering. And he was the first person in the last century who then decided to investigate more what the therapeutic aspects of essential oils were. And how they could be used on the human body. And this is a recorded fact. And I have personally have had symptoms and similar instances myself and I know that lavender oil heals burns. People have been doing this for a long time. It is like essential oils have been around for 2,000 years. They have been in clinical trials for that long. This is anecdotal and traditional evidence.

Yeah, and what other claims do you make for lavender oil?

Marilyn Johnston: It helps bruising. I actually put very little information on my site. I put just enough to make, to give the person a little bit of an idea. I then recommend that they go to an aromatherapy book and find out if there are any contra indications that may affect them. And that offers them a far broader range of information than I offer on my website.

When you say contra indications you are talking about what?

Marilyn Johnston: Well for instance, and I do put this on my website, the major indication that lavender lowers blood pressure. So if a person has low blood pressure they should not use lavender oil.

It is borderline is it not to tendering some kind of professional advice?

Marilyn Johnston: I suppose borderline, I don't know. I find, the way that I feel is, these are natural health therapies not just me as an aromatherapist, but many other types of therapies. And therapies that mankind has used in the beginning, medicines are only say a few hundred years old. Where as natural therapies are what have sustained mankind since mankind began to evolve. So how can that be a bad thing?

How long has the website information been up?

Marilyn Johnston: My website is about a year, 18 months old I suppose.

And so what happens to alert you that Medsafe was on to you – they'd wrote to you?

Marilyn Johnston: They wrote me a letter. And they sent me a copy of a guidance to comply with the Medicines Act – at this point I think what everyone was what everyone was wanting or why they weren't happy with the bill last year. Well it seemed to be that the Australians were really going to dictate to NZ how NZ natural therapies and products were to be regulated. What natural therapy industry in NZ now wants, is a new Act or legislation that is written by New Zealanders, for New Zealanders and that covers us and takes us out of the Medicines Act but still regulates us.

Alright, so you are not averse to the idea of some regulation? You just don't think the Medicines Act is the right bit here. Stay with us Marilyn, Okay, I want to bring in Stewart from Medsafe now. Now I am looking at this stuff, part of plant extraction, supports the respiratory system. It is not telling me to stop taking the pills is is? Or not to go to the doctor if I have pain down my left arm?

Stewart: I think what we are trying to do with this, and we have been enforcing. In New Zealand the legislation is based on stuff that was written in the 1970s and early 1980s. So there are really only two things. There are medicines and there are dietary supplements and an aromatherapy product

cannot be a dietary supplement because it is not something that you eat or consume. So anything that you put on the skin, any eye, nose, ear drops, suppositories cannot be dietary supplements. They automatically come under medicines. And then the Medicines Act says that you can't sell a medicine unless its got consent of the Minister. Then it also says what's more you cannot advertise certain things. And it so happens that things that aids to sleep are actually prohibited adverts unless the product is approved by the Ministry of Health. Now, the next step is we are not saying, there's lots of textbooks that say these. So we are not interested in those –

Why aren't you interested in those?

Stewart: Well because people have the right to have access to information. The link for us is if people then start making claims for their product because then they are selling a medicine at that point. So yes we all have access to information, yes we all have access to, freedom of access about essential oils and natural therapies. The issue for us is when they start to be linked to certain products.

How did you, Medsafe, come to be targeting a small business like Celestial Oils with a website saying Tea Tree oil is an antibacterial for cuts, sores, coughs and sinuses?

Stewart: Okay, well what we have been doing for a long time now is policing this interface between the two bits of legislation at the very highest level of claims. And people were making cancer claims or cure heart disease or cure psoriasis.

Lyprinol is the classic example

Exactly where we come in with the full weight of the law. We have then set up a system of co-regulation or almost self-regulation, where companies who are printing advertising have agreed that their printed adverts will comply with the Advertising Standard Authority's codes of advertising. And that then tends to put the adverts into supportive type claims-

What do you mean by that, I don't understand?

Stewart: Well what we mean is that if someone wishes to advertise a dietary supplement in the newspaper or on television or on the radio their claims that they make for the product must comply with the Advertising Standard Authority's code, which prohibits them from saying it cures cancer or it treats burnings.

But no one, this is the point Stewart – no one is claiming a cure for cancer with lavender oil.

Stewart: No, what actually happens then is that when you control those two areas, the last area is that people start then making their outrageous claims on the internet.

Do you think is outrageous?

Stewart: I don't necessarily think is outrageous, but the point is that when you go auditing the internet sites you find things that are in -

So what is happening? Is there a big campaign at the moment going right through internet sites in New Zealand?

Stewart: There is, we have a team of people who are looking at internet sites in New Zealand to remind people that they need to have them in compliance with the legislation.

And who instigated that?

Stewart: It was instigated from within Medsafe, as we move forward into, people have for a long time said that the dietary supplements rates are fantastic. Well yeah, but that is because they have not actually been applied properly. A lot of people thought that the dietary supplements regulations allowed them to have crèmes and ointment and eyedrops and this is part of a campaign to educate people that the legislation isn't perfect. And that we agree that there is need for new legislation in this area and that is what we are working on.

Was that decision to go through the internet and track down every little business made before or after the Therapeutics Bill failed because it couldn't get its numbers in Parliament ?

Stewart: A series of things happened. We started to employ people whose aim was around enforcement for the first time in 2007.

So you hired an enforcement arm?

Stewart: We hired enforcement, we had to have an enforcement arm because we never ever had one. And that, did we go out and say we are going to penalise this industry because we didn't get legislation? No. What we are really saying is that we were proposing new legislation, that has gone on hold, it has not been thrown out. It is still on the order paper. But that we've decided in effect that this interface needs policing because we have got a lot of people complying with the legislation and some people who are not. And that is not an equitable position either.

Let's bring Marilyn back in again. Marilyn, the legislation as we said dates back to 1981. And in your six years you've had no experience like this before? But not there is as Stewart is describing, an enforcement arm being brought in.

Marilyn Johnston: Yes, the other thing that I would like to ask Stewart about if I may is this guidance on compliance it does say that there is to be no promotional material, any written or spoken word. Nothing on product labels, product leaflets, instructions, in-store sales material, nothing on websites, nothing on newsletters, nothing in any direct promotion. That basically, for me, shuts down any method I have of speaking to anybody about any properties to do with my –

Well you can publish a book apparently?

Stewart: No you could also publish the information about lavender oil on your website.

Marilyn Johnston: You've just told me I am not allowed to.

Stewart: No, no, no, but you can't publish, what compliance with the legislation is all about your brand of lavender oil. So your brand can't have on the label that it treats burns because that is a therapeutic claim –

I'm sorry. She can have on her website a comment that says lavender oil aids burns. But she can't say it is her lavender oil?

Stewart: That is correct, yes.

That just sounds completely barking mad?

Stewart: Welcome to the wonderful world of

Bureaucracy?

Stewart: Legislation.

Marilyn Johnston: So I could have a website that is not my website that says that, that doesn't even make sense.

Stewart: No, the point is that we have got to separate out what is people's rights to have access to information. And then what is allowed under the legislation.

Surely the point of the legislation is to protect people from being told things that can harm them like lypranol is a huge breakthrough of cancer. What is the point of the legislation?

Stewart: The point of the legislation is the protection of public health.

So if that's the case why can you make a claim for lavender oil generically but not mention your own product?

Stewart: Because the legislation is based on products, not on –

Well the legislation is an ass

The problem is if you want to go down that path and say let's control what anyone can say about any substance that's a whole lot more draconian.

I know, but I don't see anyone's problem is solved, I don't see how the public health is being protected?

Stewart: Well it is partly because where do most people get their information? They actually get their information off the label in the shop. They don't see a practitioner like the person that is speaking here, they don't see an aroma therapist. They actually, as things currently stand, can buy products containing these oils anywhere with whatever claim that the person who sells it wishes to make on the label.

Marilyn Johnston: Have you ever looked at a product label of an essential oil? Nobody who sells a bottle of essential oil has any room on that – we don't list any therapeutic properties. All we do is list the botanical name, the method of distillation, the part of the plant that it is derived from, its common name.

Is this in the same league Stewart Jessamine as some of the Chinese medicines that we've discussed that might be claiming we can improve your virility or indeed provide you with some kind of protection? Is this really in the league, of what this Act was intended to do for consumers?

Stewart: Well let's take a hypothetical example around an essential oil that is made from the wrong plant, is made in the wrong way, is contaminated with something else, is bacterially contaminated so

that you put it on your burn and you get an infection. Those are all real risks. Now the person who we are talking to has obviously taken great care to make that doesn't happen, but the problem is that under the current scheme there is no way of differentiating between those people who are dedicated and passionate about the product and those who are out to say we'll stack them high and sell them cheap at a risk to public health.

We'll stay with this. Let's bring in Janice Priest now from Healthy Options magazine. Good morning to you Janice. Janice, is this happening to a lot of small businesses in this field?

Janice: This is happening right through the country in an unprecedented move. In the 40 years that I've been a naturopath and now a naturopathic doctor and a publisher I have never seen a wave of this type of restriction to our natural health field before.

What are you being told? Every business associated with your association is getting this letter?

Janice: Not everyone as yet. They are progressing through the websites. They have already been through the mainstream natural health industry, from the medicine perspective, and the drive is to try and make natural remedies medicines.

You have described this as something akin to bullying. Having heard Stewart explain the logic, explain the fact that they have just brought in an enforcement arm, is that really a fair claim or is it simply that the law is being enforced?

Janice: Well you must realise that Medsafe are acting under a directive from the Labour Party and Ministry of Health. And this directive has come about since the Trans-Tasman deal has closed and the directive and we must appreciate that they are being put under this pressure. So it's really about why they are doing this. We have had 30 odd years of negotiations, especially the last 12 years in which the industry has come up with solutions, we have been working with Medsafe, Ministry of Health we're talking about the whole industry. We have had meetings, associations, we have had an agreement. And that was all put on hold, just at the point where everybody was moving on with our legislation. And then we were just simply told that we were going to go over to the Australian model. And the Australian model is under a medicine directive. In fact they have just been recently informed that the ham industry, which the Australian TGA, which we would have come under the legislation, have just been fined by the court for closing down the industry. And they are going to be fined millions for doing so. So this was the regulatory body that we were going to have. But now that that's over we've come back to look at what New Zealand needs instead of sitting down with the negotiation and moving forward they have basically said carte blanche no we are going to go back to 1981, back to the beginning. Millions of dollars have been spent in negotiations to move forward and we've basically been told "stuff that" we are taking you back to the 1981 Medicines Act and regulations and tough, that is all there is to it.

See it just seems, Stewar Jessamine, we've covered many times on the programme a long running issue, and it does seem like classic sledgehammer to nuts going on at the moment, can't you just exercise a bit of common sense until whatever's going to replace the Therapeutics Bill is ready?

Stewart: Yep, absolutely, there is work that is being developed in the background around what might a future regulation look like. And when and if that is ready to go we will be out consulting again, that

is what we have to do. But I guess what we are also saying in the interim period is that people have to realise that this is the law.

Well why has it not been enforced this way since 1981?

Stewart: Well we have enforced it, due to resources. We have only gone for the biggest risk –

So you have hired too many staff now Stewart?

Stewart: No. And in fact the enforcement staff are actually not doing this alone, they are actually doing a lot of stuff around Chinese medicines adulterated with a prescription medicine –

Which people might be really concerned about, people in the lavender –

Stewart: In terms of risk to public health, absolutely. The problem is you can't sort out one without the other.

And meanwhile Marilyn what's the impact going to be? You have got to pull this website from the first week of April, and you'll be doing that?

Marilyn Johnston: No what I am doing is going through and just trying to modify all my statements on my website. And just basically I am allowed to say certain things eg aids the respiratory system.

Smells nice?

Stewart: Yep.

Marilyn Johnston: Thank you.

Marilyn Johnston of Celestial Oils. Also speaking there with Stewart Jessamine of Medsafe and Janice Priest from Healthy Options Magazine.

C7

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

30 October 2013

Hugh Robinson
Director
High Performance Health Ltd
45B Carlyle St
Sydenham
CHRISTCHURCH 8023

THIS is the Exhibit marked with the letter "C" referred to in the annexed affidavit of PATRICK DAVID SLOAN AFFIRMED/~~SWORN~~ at CHRISTCHURCH this 28 day of July 2014 before me:

MEMorrison

A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

By email : jplus@ihug.co.nz

Dear Hugh Robinson,

As you are aware, on 23 and 24 October 2013 I entered the premises of High Performance Health Ltd and seized items pursuant to s63(2)(i) and (j) of the Medicines Act 1981 ("The Act") from the premise as I have reasonable grounds to believe that offences against s17, s20 and s43 have been committed. A list of items seized is attached.

Dimethyl sulphoxide (DMSO) is a prescription medicine listed in the first schedule to the Medicines Regulations 1984. The Muscle Joint and Liniment product that you manufacture and sell is also a new medicine, in that it does not have the consent of the Minister for distribution.

GHRP-6 and CJC 1295 are prescription medicines as they fall within the group listing of hypothalamic releasing factors. They are also new medicines.

Ostarine, Mechano Growth Factor and Melanotan II (bremelanotide) are not yet scheduled prescription medicines. However, as they are for administering to human beings and they have a therapeutic purpose they are defined as medicines under the Act. As they do not have the consent of the Minister for distribution they are new medicines.

Section 43 of the Act provides that it is unlawful to import or possess prescription medicines without a reasonable excuse.

Section 20 of the Act provides that it is unlawful to sell, distribute or advertise a new medicine. Possession for sale is included in the definition of the word sell.

In addition to this s17 of the Act provides that it is unlawful to manufacture, pack and label any medicine unless authorised under the Act to do so. Neither you nor High Performance Health Ltd are licensed under the Act to deal in medicines.

Based on what I saw at the premise and what you told me I have reasonable grounds to believe that the medicine in vials and bottles were in your possession for sale and that the raw ingredients in plastic containers were for the manufacture or packing of a medicine that you intended to sell.

I also have reasonable grounds to believe that the labels seized were to be used for the labelling of medicines contrary to s17 of the Act.

I advise that section 65(1) of The Act provides that any person who has an interest in the items seized may, within seven days of notification of seizure, make application to the District Court to apply for an order -

(a) that the seizure be disallowed and that the article be returned or otherwise be made available to him.

(b) that the Crown shall pay to him such sum by way of value of the substance or article resulting from its seizure, detention, or removal as the Crown thinks fit.

I further advise that if no application for disallowance is received within seven days then the articles become property of the Crown.

On 29 October 2013 we spoke by telephone. You advised that:

- You sold the GHRP-6 and other peptides for $60 per vial.
- That details of their sale were recorded in the day book as peptides
- You thought that you have imported the raw ingredients for the peptides on two or three occasions.
- You thought they were legal as you had a biochemist look into the situation and also the importations had been inspected, tested and cleared by Customs.
- You had emails from Customs about the clearance of the peptides. (It would be useful for me to see those emails and I would be grateful if you would forward them to me).
- That there is half a drum of DMSO (approximately 10 litres) at High Performance Health Ltd.

This letter also covers the seizure of the half drum of DMSO currently at your premise. I will arrange for this to be uplifted. In the interim I advise that this item is to be detained at your premise pursuant to s64(2) of the Act. The provisions of section 65(1) of the Act also apply to this item.

At this stage Medsafe has not made any decision as to what (if any) action in addition to seizure that we will be taking. Any records you have of steps you took to enquire as to the legality of manufacturing and supplying the peptides will be extremely useful to us in making our decision. I would be grateful if you would forward those details to me, along with the emails from Customs.

Yours faithfully

Nicola Squire
Senior Investigator
Investigation and Enforcement Team
09 580 9133

Item Seized from High Performance Health Ltd 23 & 24 October 2013
Seven bottles Muscle and Joint Liniment containing dimethyl sulphoxide (DMSO)
Two blue drums labelled dimethyl sulphoxide (DMSO)
One white container labelled DMSO
Six bottles Ostarine 12.5mg, 60 tablets
Seven 10ml vials labelled MGF Mechano Growth Factor
Mechano Growth Factor Labels
Seven 10ml vials labelled MGF Mechano Growth Factor Carrier Solution (approx 5ml)
Eight 20ml vials labelled CJC1295 .8mcg
One 10ml vial labelled CJC1295 .8mcg
Eight 20ml vials labelled CJC1295 Carrier Solution (2ml)
One 10ml vial labelled CJC1295 Carrier Solution (2ml)
CJC 1295 Carrier Solution Labels
Seven 20ml vials labelled GHRP6
Two 10ml vials labelled GHRP6
Seven 20ml vials labelled GHRP6 Carrier solution (4ml)
One 10ml vial labelled GHRP6 Carrier Solution (2ml)
GHRP 6 Labels
GHRP 6 Carrier Solution labels
Fourteen 10ml vials labelled MT-2 Melanotan
Twently-two 10ml vials labelled Melanotan Carrier Solution 1.6mg
Four dropper bottles labelled Melanotan (approx 10ml liquid). Dosage not specified
Melanotan labels
Melanotan Carrier Solution Labels
Two 10ml vials labelled metanotan "Muzz"
One 10ml vial with handwritten D on bottom
Plastic container labelled "Mechano MGF" containing white powder
Plastic container labelled "CJC1295 premixed 5gm L-Carn" containing white powder
Plastic container labelled "GHRP 6" containing white powder
Plastic container labelled "Melanotan" containing white powder

D

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

THIS is the Exhibit marked with the letter D referred to in the annexed affidavit of PATRICK DAVID SLOAN AFFIRMED ~~SWORN~~ at CHRISTCHURCH this 28 day of July 2014 before me:
M G Marroon
A Solicitor of the High Court of New Zealand

Committees

Database of Medicine Classifications

Revised: 17 April 2012

Solicitor
Christchurch

Show introductory statements

Enter a substance name:
(use the underscore character "_"
to produce a full listing)

OR select a classification: Any classification

Search

Ingredient	Conditions (if any)	Classification
2,4-dinitrochlorobenzene		General Sale
Acetomenaphthone		General Sale
Acetrizoate sodium		General Sale
Acetylcholine	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Acetylcysteine	for external use; for oral use in medicines containing 1 gram or less per recommended daily dose	General Sale
Aciclovir	for external use for the treatment of herpes labialis in medicines containing 5% or less and in tubes containing 10 grams or less	General Sale
Aconitum spp.	for oral use in packs containing 0.02 milligrams or less of total alkaloids; for dermal use in concentrations 0.02% or less and in packs containing 0.02 milligrams or less of total alkaloids	General Sale
Acriflavine		General Sale
Adrenal extract	for dermal use in medicines containing 0.02% or less of ketosteroids	General Sale
Adrenaline	in medicines for injection containing 0.02% or less	General Sale
Aescin		General Sale

Alcohol	except for injection in medicines containing more than 20%	General Sale
Aldosterone	in medicines containing 10 micrograms or less per litre or per kilogram	General Sale
Allantoin		General Sale
Aloes	for external use; for internal use when obtained solely from the mucilaginous gel of the leaf	General Sale
Aluminium		General Sale
Amethocaine	for external use in medicines containing 2% or less	General Sale
Amidotrizoic acid		General Sale
Aminacrine		General Sale
Amorolfine	in preparations for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Anorexients, bulk		General Sale
Antimony	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Antithrombin III		General Sale
Apomorphine	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Arsenic	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Aspirin	except when specified in the First Schedule to the Medicines Regulations 1984	General Sale
Barium		General Sale
Bentiromide		General Sale
Benzocaine	in dermal preparations containing 2% or less of total anaesthetic substances; in lozenges containing 30 milligrams or less of total anaesthetic substances per dosage unit	General Sale
Benzoic acid		General Sale
Benzoyl peroxide	for external use in medicines containing 5% or less	General Sale
Benzydamine	for dermal use	General Sale
Benzyl benzoate		General Sale
Berberine		General Sale
Beta carotene	in medicines containing 18 milligrams or less per recommended daily dose	General Sale
Bifonazole	for dermal use in medicines for tinea pedis only or in shampoos containing 1% or less	General Sale

Bioallethrin		General Sale
Bismuth	for external use in medicines containing 3% or less	General Sale
Blood clotting factors		General Sale
Blood corpuscles		General Sale
Blood, whole		General Sale
Borax (see Boron)	in medicines for internal use containing 6 milligrams or less per recommended daily dose; for dermal use other than paediatric use in medicines containing 0.35% or less; when present as an excipient	General Sale
Boric acid (see Boron)	in medicines for internal use containing 6 milligrams or less per recommended daily dose; for dermal use other than paediatric use in medicines containing 0.35% or less; when present as an excipient	General Sale
Boron including borax and boric acid	in medicines for internal use containing 6 milligrams or less per recommended daily dose; for dermal use other than paediatric use in medicines containing 0.35% or less; when present as an excipient	General Sale
Bromelains		General Sale
Broxyquinoline		General Sale
Bufexamac	in suppositories; for dermal use in medicines containing 5% or less	General Sale
Butoxyethyl nicotinate		General Sale
Butyl aminobenzoate	for dermal use in medicines containing 2% or less	General Sale
C1 esterase inhibitors		General Sale
Calcium glucono-galacto-gluconate		General Sale
Calcium hypochlorite		General Sale
Calcium salicylate		General Sale
Camphor, ammoniated		General Sale
Capsicum oleo-resin		General Sale
Carbaryl	for external use in medicines containing 2% or less	General Sale
Carbenoxolone	for external use	General Sale
Carbetapentane	in medicines containing 0.5% or less	General Sale
Cardamom compound		General Sale
Catechu		General Sale

Cephaelis acuminata	in medicines containing less than 0.2% of emetine	General Sale
Cephaelis ipecacuanha	in medicines containing less than 0.2% of emetine	General Sale
Cetirizine	in divided solid dosage forms for oral use containing 10 milligrams or less of cetirizine hydrochloride per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply	General Sale
Chloral hydrate	for dermal use in medicines containing 2% or less	General Sale
Chlorbutol	in medicines containing 0.5% or less	General Sale
Chlorhexidine		General Sale
Chloroform	in medicines containing 0.5% or less	General Sale
Chlorphenesin		General Sale
Choline salicylate	in medicines containing 10% or less and in packs sizes of 15 grams or less	General Sale
Chorionic gonadotrophin	in pregnancy test kits	General Sale
Chromium		General Sale
Chymotrypsin		General Sale
Ciclopirox	for external use in medicines containing 2% or less when for the treatment of tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Clotrimazole	for external use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Colecalciferol	in medicines containing 25 micrograms or less per recommended daily dose; in parenteral nutrition replacement preparations	General Sale
Collagen	except in injections or implants for tissue augmentation or cosmetic use	General Sale
Contact lens preparations		General Sale
Copaiba balsam		General Sale
Copper		General Sale
Creosote	in medicines containing 10% or less	General Sale
Cresols	in medicines containing 3% or less	General Sale
Crocus sativus		General Sale
Croton tiglium	in medicines containing 1 milligram or less per litre or per kilogram	General Sale

Cyanocobalamin		General Sale
Delphinium staphisagria	in medicines containing 0.2% or less	General Sale
Deoxyribonuclease	for external use	General Sale
Dequalinium		General Sale
Dextranomer		General Sale
Dextrans		General Sale
Dextromethorphan	in liquid form containing 0.25% or less or in solid dose form containing 15 milligrams or less per dose form when in packs containing not more than 600 milligrams and with a recommended daily dose of not more than 120 milligrams; except in medicines for the treatment of the symptoms of cough and cold in children aged 6-12 years	General Sale
Diamthazole		General Sale
Diatrizoic acid		General Sale
Dichlorobenzyl alcohol		General Sale
Diclofenac	in preparations for external use other than for the treatment of solar keratosis	General Sale
Diethylamine salicylate		General Sale
Dioctyl sodium sulphosuccinate		General Sale
Diphemanil	for dermal use	General Sale
Econazole	for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Edetic acid	in medicines containing 0.25% or less; in contact lens preparations; in preparations containing dicobalt edetate for the treatment of cyanide poisoning	General Sale
Emetine	in medicines containing 0.2% or less	General Sale
Ephedra navadensis		General Sale
Ergocalciferol	in medicines containing 25 micrograms or less per recommended daily dose	General Sale
Erysimum spp.	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Ether	in medicines containing 10% or less	General Sale
Ethyl nicotinate		General Sale
Ethyl salicylate		General Sale
Etidronic acid	in medicines for external use containing 1% or less	General Sale

Factor VIII		General Sale
Factor VIII inhibitor bypassing fraction		General Sale
Fenticlor		**General Sale**
Fexofenadine	for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when in capsules containing 60 milligrams or less of fexofenadine hydrochloride or in tablets containing 120 milligrams or less of fexofenadine hydrochloride with a maximum daily dose of 120 milligrams when sold in the manufacturer's original pack containing 10 dosage units or less and not more than 5 days' supply	General Sale
Fibrinogen		General Sale
Fibrinolysin	for external use	General Sale
Fluorescein	except for injection	General Sale
Fluorides	for external use in liquid form in medicines containing 220 milligrams or less per litre or per kilogram and in packs containing not more than 120 milligrams of total fluoride which have been approved by the Minister or the Director-General for distribution as general sale medicines; for external use in non-liquid form in medicines containing 1.5 grams or less per litre or per kilogram and, when containing more than 1 gram per litre or per kilogram, sold in packs approved by the Minister or the Director-General for distribution as general sale medicines; in medicines containing 15 milligrams or less per litre or per kilogram; in parenteral nutrition replacement preparations	General Sale
Folic acid	for oral use in medicines containing 500 micrograms or less per recommended daily dose; in parenteral nutrition replacement preparations	General Sale
Folinic acid	for oral use in medicines containing 500 micrograms or less per recommended daily dose	General Sale
Follicle-stimulating hormone	in medicines containing 100 micrograms or less per litre or per kilogram	General Sale
Formaldehyde	in medicines containing 5% or less	General Sale
Formic acid		General Sale
Gadobenic acid		General Sale
Gadobutrol		General Sale

Gadodiamide		General Sale
Gadopentetic acid		General Sale
Gadoteric acid		General Sale
Galactose		General Sale
Gamolenic acid		General Sale
Gelsemium sempervirens	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Gentian compound		General Sale
Glutathione	except for injection	General Sale
Glycol salicylate		General Sale
Guaiphenesin	for oral use in medicines containing 2% or less or 200 milligrams or less per dose form; for oral use in modified release form with a maximum recommended daily dose of not more than 2.4 grams when sold in the manufacturer's original pack containing not more than 10 days' supply	General Sale
Guar gum		General Sale
Haloperidol	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Haloprogin		General Sale
Halquinol	for external use	General Sale
Heparins	for external use; when present as an excipient	General Sale
Hetastarch		General Sale
Hexachlorophane	in medicines containing 0.75% or less	General Sale
Hexamidine		General Sale
Hexetidine	for external use	General Sale
Hexyl nicotinate		General Sale
Hippuric acid		General Sale
Histamine	in medicines containing 0.5% or less	General Sale
Human chorionic gonadotrophin	in pregnancy test kits	General Sale
Human protein C		General Sale
Hyaluronic acid	except in injections or implants for tissue augmentation or cosmetic use	General Sale
Hyaluronidase		General Sale
Hydrocyanic acid	for oral use in packs containing 0.5 milligrams or less; in medicines containing 1microgram or less per litre or per kilogram	General Sale
Hydrogen peroxide		General Sale

Hydroiodic acid		General Sale
Hydroquinone	for external use in hair preparations containing 1% or less	General Sale
Hydroxocobalamin		General Sale
Hydroxyquinoline sulphate	for external use	General Sale
Hylan polymer	except in injections or implants for tissue augmentation or cosmetic use	General Sale
Hyoscyamus niger	in packs containing 30 micrograms or less of total solanaceous alkaloids	General Sale
Ibuprofen	for external use; in divided solid dosage forms for oral use containing 200 milligrams or less per dose form with a recommended daily dose of not more than 1.2 grams and when sold in the manufacturer's original pack containing not more than 25 dose units per pack	General Sale
Ichthammol		General Sale
Icodextrin		General Sale
Idoxuridine	for dermal use in medicines containing 0.5% or less	General Sale
Indomethacin	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Intrinsic factor		General Sale
Iodamide		General Sale
Iodine	for external use in medicines containing 2.5% or less; for internal use in medicines containing less than 300 micrograms per recommended daily dose	General Sale
Iodised oil		General Sale
Iodixanol		General Sale
Iodoform		General Sale
Iodoxamic acid		General Sale
Iohexol		General Sale
Iomeprol		General Sale
Iopamidol		General Sale
Iopromide		General Sale
Iopronic acid		General Sale
Iothalamic acid		General Sale
Iotrolan		General Sale
Iotroxic acid		General Sale

Ioversol		General Sale
Ioxaglic acid		General Sale
Ipecacuanha	in medicines containing less than 40 micrograms of ipecacuanha alkaloids per recommended dose for the treatment of the symptoms of cough and cold in children aged 6-12 years	General Sale
Ipodate		General Sale
Iron	for oral use in medicines containing 24 milligrams or less per recommended daily dose either in medicines containing not more than 5 milligrams per dose unit or in medicines containing more than 5 milligrams per dose unit and in packs containing not more than 750 milligrams of iron; in parenteral nutrition replacement preparations	General Sale
Isoconazole	for dermal use when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Isopropyl myristate		General Sale
Jaborandi		General Sale
Ketoconazole	for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board; in medicines for treatment of the scalp containing 1% or less	General Sale
Ketoprofen	for dermal use	General Sale
Krameria		General Sale
Lauromacrogols	except for injection	General Sale
Laxatives	except when specified in the First Schedule of the Medicines Regulations 1984	General Sale
Lidocaine	see lignocaine	General Sale
Lignocaine	for external use in medicines containing 2% or less; in throat lozenges containing 30 milligrams or less per dose form	General Sale
Liquorice deglycyrrhizinised		General Sale
Lithium	for dermal use in medicines containing 0.01% or less; when present as an excipient in medicines for dermal use containing 0.25% or less	General Sale
Lobelia inflata	in medicines for smoking or burning	General Sale
Lobeline	in medicines for smoking or burning	General Sale

Loperamide	in divided solid dosage forms for oral use containing 2 milligrams or less of loperamide per dosage form when sold in a pack containing not more than 8 dosage forms approved by the Minister or the Director-General for distribution as a general sales medicine for the symptomatic treatment of acute non-specific diarrhoea	General Sale
Loratadine	in divided solid dosage forms for oral use containing 10 milligrams or less per dose form for the treatment of seasonal allergic rhinitis when sold in the manufacturer's original pack containing not more than 5 days' supply	General Sale
Magenta		General Sale
Malathion	for external use in medicines containing 2% or less	General Sale
Mangafodipir		General Sale
Menadiol		General Sale
Menthyl valerate		General Sale
Mepyramine	for external use in medicines containing 2% or less in packs not exceeding 25 grams.	General Sale
Mercury	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Methoxamine	for external use in mediicnes containing 1% or less	General Sale
Methyl mercury	in medicines containing 300 micrograms or less per litre or per kilogram	General Sale
Methyl nicotinate		General Sale
Methyl salicylate	for external use; for internal use when present as an excipient in medicines containing 1.04% or less per dose form	General Sale
Methylene blue	except for injection	General Sale
Metrizamide		General Sale
Metrizoic acid		General Sale
Miconazole	for external use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Monoacetin		General Sale
Monoclonal antibodies	in pregnancy test kits	General Sale
Nicotinamide		General Sale
Nicotine	in preparations for oromucosal or transdermal absorption	General Sale

Nicotinic acid except nicotinamide	in medicines containing 100 milligrams or less per dose form	General Sale
Nicotinyl alcohol	in medicines containing 100 milligrams or less per dose form	General Sale
Nitrous ether spirit		General Sale
Nonylic acid		General Sale
Nux vomica	in medicines containing 1 milligram or less per litre or per kilogram of strychnine	General Sale
Nystatin	for dermal use when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Octocog alfa		General Sale
Oestradiol	in medicines containing 10 micrograms or less per litre or per kilogram	General Sale
Oestrone	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Oxedrine	in medicines containing 30 milligrams or less per recommended daily dose	General Sale
Oxerutins		General Sale
Oxiconazole	for dermal use in medicines for tinea pedis only	General Sale
Oxymetazoline	for nasal use, when sold in the manufacturer□s original pack containing not more than 20 millilitres	General Sale
Oxytocin	in medicines containing 1 microgram or less per litre or per kilogram	General Sale
Pancreatic enzymes	in medicines containing 20 000 BP units or less of lipase activity	General Sale
Paracetamol	in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; in powder form in sachets containing 1 gram or less and not more than 10 grams	General Sale
Paraformaldehyde	in medicines containing 5% or less	General Sale
Pentastarch		General Sale
Pepsin		General Sale
Perflutren		General Sale
Permethrin	in medicines containing 5% or less	General Sale
Phenacetin	when present as an excipient	General Sale
Phenol	in medicines other than for injection containing 3% or less	General Sale
Phenothrin		General Sale
Phenoxyethanol		General Sale

Phenylephrine	for nasal or ophthalmic use in medicines containing 1% or less; for oral use in medicines containing 50 milligrams or less per recommended daily dose and in packs containing 250 milligrams or less of phenylephrine per pack; except in medicines for the treatment of the symptoms of cough and cold in children aged 6-12 years	General Sale
Phytomenadione		General Sale
Pilocarpine	in medicines containing 0.025% or less	General Sale
Piperonyl butoxide		General Sale
Piroctone		General Sale
Piroxicam	for external use	General Sale
Plasma		General Sale
Plasma protein fraction		General Sale
Plasmin		General Sale
Plasminogen activator		General Sale
Platelets		General Sale
Polygeline		General Sale
Polynoxylin		General Sale
Polysulfated glycosaminoglycans	except in injections other than intraocular viscoelastic products	General Sale
Pomegranate		General Sale
Potassium	for external use; for internal use: in medicines containing 100 milligrams or less per recommended dose; in medicines for oral rehydration therapy, parenteral nutrition replacement, or dialysis; in glucosamine sulphate complexed products containing 600 milligrams or less of potassium chloride per recommended dose	General Sale
Potassium chlorate	in medicines containing 10% or less	General Sale
Pregnancy test kits		General Sale
Progesterone	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Pronase		General Sale
Propranolol	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Propyl undecylenate		General Sale
Propylene glycol		General Sale
Propyliodone		General Sale

Pumilio pine oil		General Sale
Pyrethrins	in medicines containing 10% or less	General Sale
Pyridoxal	in medicines containing 200 milligrams or less per recommended daily dose	General Sale
Pyridoxamine	in medicines containing 200 milligrams or less per recommended daily dose	General Sale
Pyridoxine	in medicines containing 200 milligrams or less per recommended daily dose	General Sale
Pyrithione zinc	for treatment of the scalp in medicines containing 2% or less	General Sale
Quassia		General Sale
Quinine	in medicines containing 50 milligrams or less per recommended daily dose	General Sale
Ranitidine	in medicines containing 150 milligrams or less per dose unit when sold in the manufacturer's original pack containing not more than 7 days' supply	General Sale
Ribonuclease		General Sale
Sabadilla	in preparations containing 10 milligrams or less of total alkaloids of Schoenocaulon officinale per litre or per kilogram	General Sale
Safrole	for internal use in medicines containing 0.1% or less	General Sale
Salicylic acid	in medicines for dermal use containing 40% or less	General Sale
Salsalate		General Sale
Schoenocaulon offincinale	in preparations containing 10 milligrams or less of total alkaloids of Schoenocaulon officinale per litre or per kilogram	General Sale
Scillarens		General Sale
Selenium	for oral use in medicines containing 150 micrograms or less per recommended daily dose; for external use in medicines containing 3.5% or less of selenium sulfide	General Sale
Senega		General Sale
Silicones	except for injection	General Sale
Silver	in oral solutions containing 0.3% or less or other medicines containing 1% or less	General Sale
Sodium bitartrate		General Sale
Sodium dichloroisocyanurate		General Sale
Sodium hydroxide		General Sale

Sodium iodide		General Sale
Sodium ipodate		General Sale
Sodium lauryl sulphoacetate		General Sale
Sodium nitrite	for use as an excipient	General Sale
Sodium phosphate	except where specified in the First Schedule to the Medicines Regulations 1984	General Sale
Sodium salicylate		General Sale
Sodium sulphide		General Sale
Sodium tetradecyl sulphate	except for injection	General Sale
Solcoseryl		General Sale
Squill	in medicines containing 1% or less	General Sale
Stannous chloride		General Sale
Stannous oxide		General Sale
Strontium		General Sale
Strychnos spp.	in medicines containing 1 milligram or less per litre or per kilogram of strychnine	General Sale
Subtilisin		General Sale
Sucralfate		General Sale
Sulfurated potash		General Sale
Tanacetum vulgare	in medicines containing 0.8% or less of oil of tansy	General Sale
Tannic acid		General Sale
Tar		General Sale
Terbinafine	for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Terpin hydrate		General Sale
Testosterone	in medicines containing 1 milligram or less per litre or per kilogram	General Sale
Tetrastarch		General Sale
Theobromine		General Sale
Thiourea	in medicines containing 0.1% or less	General Sale
Thioxolone		General Sale
Thrombin		General Sale
Thurfyl salicylate		General Sale
Thyroxine	in medicines containing 10 micrograms or less per litre or per kilogram	General Sale

Tioconazole	for dermal use in medicines for tinea pedis only or when sold in practice by a podiatrist registered with the Podiatrists Board	General Sale
Tolciclate		General Sale
Tolnaftate		General Sale
Trichloroacetic acid	for external use in medicines containing 12.5% or less for the treatment of warts other than anogenital warts	General Sale
Triclosan		General Sale
Trometamol	except for injection in medicines containing more than 3%	General Sale
Trypsin		General Sale
Tryptophan	in medicines containing 100 milligrams or less per recommended daily dose; in parenteral nutrition replacement preparations	General Sale
Tyloxapol		General Sale
Undecenoic acid		General Sale
Vitamin A	for internal use in medicines containing 3 milligrams or less of retinol equivalents per recommended daily dose; in parenteral nutrition replacement preparations; for external use in medicines containing 1% or less	General Sale
Vitamin D	for external use; for internal use in medicines containing 25 micrograms or less per recommended daily dose; in parenteral nutrition replacement preparations	General Sale
Xylenols	in medicines containing 3% or less	General Sale
Zinc	for external use except zinc chloride in medicines containing more than 5%; for internal use in medicines containing 25 milligrams or less per recommended daily dose; for internal use in medicines containing 50 milligrams or less and more than 25 milligrams per recommended daily dose and in packs which have received the consent of the Minister or the Director-General to their distribution as general sale medicines and that are sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods; except in parenteral nutrition replacement preparations	General Sale

'E'

Search

UNIVERSITY of York
Centre for Reviews and Dissemination

What the "York Review" on the fluoridation of drinking water really found

Originally released : 28 October 2003

A statement from the Centre for Reviews and Dissemination (CRD).

In 1999, the Department of Health commissioned CRD to conduct a systematic review into the efficacy and safety of the fluoridation of drinking water. The review specifically looked at the effects on dental caries/decay, social inequalities and any harmful effects. The review was published on the CRD Fluoridation Review website and in the BMJ in October 2000.

We are concerned about the continuing misinterpretations of the evidence and think it is important that decision makers are aware of what the review really found. As such, we urge interested parties to read the review conclusions in full.

We were unable to discover any reliable good-quality evidence in the fluoridation literature world-wide.

What evidence we found suggested that water fluoridation was likely to have a beneficial effect, but that the range could be anywhere from a substantial benefit to a slight disbenefit to children's teeth.

This beneficial effect comes at the expense of an increase in the prevalence of fluorosis (mottled teeth). The quality of this evidence was poor.

An association with water fluoride and other adverse effects such as cancer, bone fracture and Down's syndrome was not found. However, we felt that not enough was known because the quality of the evidence was poor.

The evidence about reducing inequalities in dental health was of poor quality, contradictory and unreliable.

Since the report was published in October 2000 there has been no other scientifically defensible review that would alter the findings of the York review. As emphasised in the report, only high-quality studies can fill in the gaps in knowledge about these and other aspects of fluoridation. Recourse to other evidence of a similar or lower level than that included in the York review, no matter how copious, cannot do this.

The full report is available via the **CRD Fluoridation Review website**. For more information, please contact **Paul Wilson**.

AFFIRMED

THIS is the Exhibit marked with the letter... E ...
referred to in the annexed affidavit of
PATRICK DAVID SLOAN
~~SWORN~~ at CHRISTCHURCH
this 25th day of July 2014 before me:
M Harrod
A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

6 F 7

Professor Trevor Sheldon's open letter

Department of Health Studies
Innovation Centre
York Science Park
University Road
York YO10 5DG

THIS is the Exhibit marked with the letter ... F ...
referred to in the annexed affidavit of
PATRICK DAVID SLOAN
AFFIRMED SWORN at ... CHRISTCHURCH
this ... 28th ... day of ... JULY ... 2014 before me:
M Morrison
A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

3/1/2001

In my capacity of chair of the Advisory Group for the systematic review on the effects of water fluoridation recently conducted by the NHS Centre for Reviews and Dissemination the University of York and as its founding director, I am concerned that the results of this review have been widely misrepresented. The review was exceptional in this field in that it was conducted by an independent group to the highest international scientific standards and a summary has been published in the British Medical Journal. It is particularly worrying then that statements which mislead the public about the review's findings have been made in press releases and briefings by the British Dental Association, British Medical Association, the National Alliance for Equity in Dental Health and the British Fluoridation Society. I should like to correct some of these errors:

1. Whilst there is evidence that water fluoridation is effective at reducing caries, the quality of the studies was generally moderate and the size of the estimated benefit, only of the order of 15%, is far from "massive".

2. The review found water fluoridation to be significantly associated with high levels of dental fluorosis which was not characterised as "just a cosmetic issue".

3. The review did not show water fluoridation to be safe. The quality of the research was too poor to establish with confidence whether or not there are potentially important adverse effects in addition to the high levels of fluorosis. The report recommended that more research was needed.

4. There was little evidence to show that water fluoridation has reduced social inequalities in dental health.

5. The review could come to no conclusion as to the cost-effectiveness of water fluoridation or whether there are different effects between natural or artificial fluoridation.

6. Probably because of the rigour with which this review was conducted, these findings are more cautious and less conclusive than in most previous reviews.

7. The review team was surprised that in spite of the large number of studies carried out over several decades there is a dearth of **reliable** evidence with which to inform policy. Until high quality studies are undertaken providing more definitive evidence, there will continue to be legitimate scientific controversy over the likely effects and costs of water fluoridation.

SIGNED,
Professor Trevor Sheldon MSc MSc DSc FMedSci

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THIS is the Exhibit marked with the letter G referred to in the annexed affidavit of PATRICK DAVID SLOAN AFFIRMED at CHRISTCHURCH this 28th day of July 2014 before me:

MEMorrison

A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

G

IN THE HIGH COURT OF NEW ZEALAND
NEW PLYMOUTH REGISTRY **CIV 2013-443-107**

UNDER	**the Judicature Amendment Act 1972 and the Declaratory Judgments Act 1908**
IN THE MATTER	**of an application for judicial review and an application for a declaration**
BETWEEN	**NEW HEALTH NEW ZEALAND INC**
	Plaintiff
AND	**SOUTH TARANAKI DISTRICT COUNCIL**
	Defendant

AFFIDAVIT OF KATHLEEN MOORE THIESSEN

Dated October 29, 2013

Solicitor
Wynn Williams Lawyers
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KMT

I, Kathleen Moore Thiessen, scientist of Tennessee, affirm:

Introduction

1. I am a Senior Scientist with Oak Ridge Center for Risk Analysis, Inc. Oak Ridge Center for Risk Analysis investigates the environmental fate of radiological and chemical contaminants and evaluates human doses and health risks resulting from exposures to those contaminants.

2. My projects have involved a variety of assessments of contaminant transport, human exposures, toxicity, and health risks for both radiological and chemical contaminants.

3. I have read the statement of claim, statement of defence and the affidavits of: David Menkes, Martin Ferguson, David Sloan, Paul Connett, Stewart Jesamine, Gregory Simmons, John McMillan, Howard Wilkinson, Robyn Haisman-Welsh, Robin Wyman and Sandra Pryor.

4. I have also read, understood, and agree to comply with the Code of Conduct for expert witnesses.

Background and experience on fluoridation

5. I hold a Ph.D. degree in Biomedical Sciences (concentration, genetics) from the University of Tennessee-Oak Ridge Graduate School of Biomedical Sciences (1986) and a B.A. degree in Biology and Chemistry from Covenant College (1981).

6. While a member of the Chemical Hazard Evaluation Program of the Health and Safety Research Division of Oak Ridge National Laboratory, I authored a *Summary Review of Health Effects Associated with Hydrogen Fluoride*

KMT

and Related Compounds: Health Issue Assessment for the Environmental Protection Agency (1988), as well as health effects assessments for other chemicals. I have served on two National Research Council subcommittees, one dealing with fluoride exposure and toxicology (*Fluoride in Drinking Water: A Scientific Review of EPA's Standards*) (2006) and one dealing with guidance levels for air contaminants, including hydrogen fluoride (*Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants: Volume 3*) (2009).

7. I have given presentations on fluoride exposure, toxicology, and health risks to a variety of audiences, including technical (International Society for Fluoride Research, American Scientific Affiliation, International Academy of Oral Medicine and Toxicology, American Chemical Society), academic (Binghamton University, Covenant College), and lay (Metropolitan Water District of Southern California; 2nd Citizens' Conference on Fluoride; the Tennessee legislature; the town of Yellow Springs, Ohio; a citizens' group in Maryville, Tennessee). I have provided comments on fluoride-related technical reports to the U.S. Environmental Protection Agency, the U.S. Department of Health and Human Services, the California Environmental Protection Agency, the Food and Drug Administration, and the Agency for Toxic Substances and Disease Registry. I have also provided comments to a variety of state and local authorities and responded to interview requests from various news media.

Kurt

8. I first became acquainted with the scientific and medical literature on fluoride exposure and toxicology in the mid-1980s, when I prepared a health issue assessment on airborne fluoride for the Environmental Protection Agency (EPA). This assessment was published in 1988 as *Summary Review of Health Effects Associated with Hydrogen Fluoride and Related Compounds: Health Issue Assessment*, Report No. EPA/600/8-89/002F (EPA 1988) and included a review of available scientific literature through January 1987. The EPA's main concern initially was hydrogen fluoride (HF). At my request, the scope of the report was expanded to include other fluoride-containing compounds. In many situations, intake of airborne fluoride is small in comparison to total intake of fluoride, but most of the toxicological effects depend on total intake of fluoride from all sources. I pointed out in this report that (1) health effects from chronic fluoride exposure are dependent on total fluoride intake from all sources; (2) people with kidney disease (renal dysfunction) are at higher risk for toxic effects due to slower clearance of fluoride from the body; (3) at least some of the decline in tooth decay attributed to fluoridated water may be due to other causes (e.g., changes in dietary patterns, changes in immune status, use of topical fluorides); and (4) the beneficial effects and adverse effects of fluoride must be weighed in determining the optimal dose for humans, and in particular, the optimal fluoride level to be maintained in public water supplies.

9. In 1998, at the request of my father, I reviewed some materials on fluoridation sent to the county school board on which he served (Lee

KMT

County, Florida) by one of the science teachers in the school system. At this time I began to be more aware of information calling into question the wisdom of water fluoridation. Some of this information was new since I had reviewed fluoride toxicity in the 1980s, and some of it was material that I had not found or had not fully appreciated in the 1980s. In particular, I learned that (1) few if any studies had examined the chemicals actually used in water fluoridation or the fluoridated water as it is consumed; (2) many human studies considered only the fluoride level in the local water supply, rather than the actual fluoride intakes experienced by individuals; (3) there was evidence for an association between water fluoridation and increased lead levels in tap water and in children's blood; (4) other countries were moving away from fluoridation of drinking water; and (5) people's fluoride intake was likely higher than had been assumed, especially for people with high water intake (e.g., athletes, outdoor workers, diabetics). I found the association between fluoridation and lead exposure especially troubling, as the connection between lead exposure and subsequent neurological and behavioral problems in children was becoming established. It also was becoming apparent to me that an association between fluoride exposure and a number of previously unacknowledged adverse health effects was plausible, but inadequately studied.

10. In 2003, I was asked to serve on a National Research Council (NRC) subcommittee charged with reviewing fluoride exposure and toxicology, and specifically with evaluating whether the EPA's drinking water

standard was sufficiently protective. As is customary for the NRC, the committee was composed of experts in several relevant disciplines and representing a variety of viewpoints. In particular, the commitee included people who had expressed opinions for or against the practice of fluoridation as well as people who had expressed no opinion on fluoridation. As described in our 2006 report (*Fluoride in Drinking Water: A Scientific Review of EPA's Standards*; NRC 2006), the committee unanimously concluded that the EPA's maximum contaminant level goal (MCLG, a nonenforceable, health-based standard) which is set at 4 mg/L was not protective, and hence its maximum contaminant level (MCL, the enforceable standard, in this case equal to the MCLG) was not protective. This conclusion was based on severe dental fluorosis, stage II skeletal fluorosis, and increased risk of bone fracture, adverse effects for which sufficient information is available in the literature to consider them to be "known" adverse health effects. EPA's MCLG is supposed to be set "at a level at which no known or anticipated adverse effect on the health of persons occurs and which allows an adequate margin of safety" (EPA 2009). The NRC subcommittee also reviewed a number of other adverse health effects which can reasonably be anticipated from fluoride exposure, at the exposure levels experienced by people served with fluoridated water. The NRC subcommittee did not review the assumed benefits of fluoride exposure or of water fluoridation or make any finding that the practice of fluoridation is safe or that typical fluoride concentrations in water (concentrations corresponding to water

fluoridation) are safe. We did not evaluate the safety or benefits or efficacy of fluoridation.

11. In 2008 I was asked to serve on another NRC subcommittee, this one looking at guidance levels for air contaminants on submarines, for both acute and chronic exposures. One of the chemicals on the list was hydrogen fluoride (NRC 2009). For chronic toxicity of hydrogen fluoride, the total fluoride exposure from all sources has to be considered, as I had pointed out in 1988. The population of interest for this subcommittee was limited to healthy young men (submarine crews include no women, children, older men, or men with certain known health problems). This report provides a list of average exposure levels at which fluoride-related health effects have been reported and an estimate of the average exposure levels experienced by submarine crews on and off the submarines. The proposed 90-day Continuous Exposure Guidance Level for airborne hydrogen fluoride corresponds to a fluoride intake of 0.023-0.026 mg/kg-day, about a factor of 2 lower than a dose associated with the potential for fluoride-induced systemic toxicity (0.05 mg/kg-day), a value which is exceeded by many persons consuming fluoridated water.

12. From working on the NRC reports (2003 on), I became well acquainted with the literature on fluoride exposure and on adverse health effects from fluoride exposure. Following publication of the NRC report in 2006, I also began reviewing material on the assumed benefits of fluoridation. I have also reviewed both recent and not-so-recent

Kurt

documents from the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS), EPA, NRC, the American Dental Association (ADA), and others. From my extensive review of the scientific and medical literature, agency reports, and other publicly available information, I have identified three major areas of concern:

12.1 Available data do not support a role of community water fluoridation in improving dental health.

12.2 A variety of adverse health effects are associated with fluoride exposures in the range experienced by people with fluoridated water.

12.3 By fluoridation of drinking water, governments and water suppliers are indiscriminately administering a drug to the population, without individual evaluation of need, appropriate dose, efficacy, or side effects.

13. The following sections of this affidavit address these three areas of concern.

Available data do not support a role of community water fluoridation in improving dental health.

14. The U.S. Department of Health and Human Services (HHS) considers community water fluoridation to be important in the prevention of dental

caries (Federal Register 2011), as do governments and health agencies in a few other countries including, I understand, New Zealand. However, the question of whether water fluoridation actually produces a benefit requires further attention.

15. The University of York has carried out perhaps the most thorough review to date of human studies on effects of fluoridation. Their work (McDonagh et al. 2000) is often cited as showing the safety and efficacy of water fluoridation, but it actually does neither (Wilson and Sheldon 2006; Cheng et al. 2007). The report mentions a surprising lack of high quality studies demonstrating benefits, and also finds little evidence that water fluoridation reduces socioeconomic disparities:

    15.1. 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. (McDonagh et al. 2000)

    15.2. Water fluoridation aims to reduce social inequalities in dental health, but few relevant studies exist. The quality of research was even lower than that assessing overall effects of fluoridation. (Cheng et al. 2007)

    15.3. Evidence relating to reducing inequalities in dental health was both scanty and unreliable. (Wilson and Sheldon 2006)

16. The apparent benefit is modest, about a 15% difference in the proportion of caries-free children (McDonagh et al. 2000). The American Dental Association (2005) states that "water fluoridation continues to be effective in reducing dental decay by 20-40%," which would translate to

less than 1 decayed, missing, or filled permanent tooth (DMFT) in older children and adolescents (based on U.S. data from CDC 2005).

17. Neither McDonagh et al. (2000) nor the ADA (2005) mentions that fluoride exposure appears to delay the eruption of permanent teeth, although this has been known since the 1940s (Short 1944; Weaver 1948; NRC 2006; Limeback and Robinson 2012). A delay in tooth eruption alters the curve of caries rates with respect to age and complicates the analysis of age-specific caries rates (Psoter et al. 2005; Alvarez 1995; Alvarez and Navia 1989). Specifically, "the longer the length of exposure to the oral environment the greater is the risk of the tooth becoming carious" (Finn and Caldwell 1963; citing Finn 1952). Komárek et al. (2005) have calculated that the delay in tooth eruption due to fluoride intake may explain the apparent reduction in caries rates observed when comparisons are made at a given age, as is usually done.

18. Most studies of benefits of fluoride intake or fluoridation have failed to account for a number of important variables, including individual fluoride intakes (as opposed to fluoride concentrations in the local water supplies), sugar intake, socioeconomic variables, local variations in caries rates, and the general decline in caries rates over the last several decades, independent of water fluoridation status. When World Health Organization data on oral health of children in various countries are compared, similar declines in caries over time are seen in all developed countries, regardless of fluoridation status (Cheng et al. 2007; Neurath 2005). The only peer-reviewed paper to be published from California's

major oral health survey in the 1990s reported no association between fluoridation status and risk of early childhood caries (Shiboski et al. 2003). Several studies show differences in caries rates with socioeconomic status or dietary factors but not with fluoridation status (e.g., Adair et al. 1999; Hamasha et al. 2006). Hagan (1947) reported a wide rangeof caries rates (DMFT = 1.41-10.64 at age 16) in children in various nonfluoridated communities in the state of Georgia.

19. In general, the role of diet and nutrition in good dental health seems to be underappreciated. For example, Cote et al. (2004) have documented a much lower rate of caries experience in refugee children from Africa than in U.S. children or refugee children from Eastern Europe, a situation that the authors attribute more to the amount of sugar in the diet than the presence of fluoride in the water. Finn (1952) provides an extensive review of dental caries in "modern primitive peoples," concluding that they "show less dental caries than do most civilized peoples. . . . Evidence indicates, however, that primitive peoples have an increased caries attack rate when brought into contact with modern civilization and a civilized diet."

20. A number of sources (reviewed by NRC 2006), including the Centers for Disease Control and Prevention (CDC 2001), indicate that any beneficial effect of fluoride on teeth is topical (e.g., from toothpaste), not from ingestion. Featherstone (2000) describes mechanisms by which topical fluoride has an anti-caries effect and states that "[f]luoride incorporated

during tooth development [i.e., from ingested fluoride] is insufficient to play a significant role in caries protection." Also:

20.1. The fluoride incorporated developmentally—that is, systemically into the normal tooth mineral—is insufficient to have a measureable effect on acid solubility. (Featherstone 2000)

20.2. The prevalence of dental caries in a population is not inversely related to the concentration of fluoride in enamel, and a higher concentration of enamel fluoride is not necessarily more efficacious in preventing dental caries. (CDC 2001)

21. Fluoride concentrations in drinking water or saliva are too low to be contributing significantly to a topical anti-caries effect, especially since most drinking water is not "swished" around the teeth before being swallowed. CDC (2001) states that "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 ppm in nonfluoridated areas. This concentration of fluoride is not likely to affect cariogenic activity."

22. The single study that has examined caries experience in relation to individual fluoride intakes at various ages during childhood (the Iowa study) has found no association between fluoride intake and caries experience; caries rates (% of children with or without caries) at ages 5 and 9 were similar for all levels of fluoride intake (Warren et al. 2009).

The authors state that "the benefits of fluoride are mostly topical" and that their "findings suggest that achieving a caries-free status may have relatively little to do with fluoride *intake*" (emphasis in the original). Most of the children with caries had "relatively few decayed or filled surfaces" (Warren et al. 2009). The authors' main conclusion:

> Given the overlap among caries/fluorosis groups in mean fluoride intake and extreme variability in individual fluoride intakes, firmly recommending an "optimal" fluoride intake is problematic. (Warren et al. 2009).

23. The national data set collected in the U.S. in 1986-1987 (more than 16,000 children, ages 7-17, with a history of a single continuous residence) shows essentially no difference in caries rates in the permanent teeth of children with different water fluoride levels (Table 1; Fig. 1; data obtained from Heller et al. 1997; similar data can be obtained from Iida and Kumar 2009). Analysis in terms of mean DMFS (decayed, missing, or filled tooth surfaces) for the group (Fig. 2), as opposed to caries prevalence, shows an apparent 18% decrease between the low-fluoride (< 0.3 mg/L) and fluoridated (0.7-1.2 mg/L) groups. In absolute terms, this is a decrease of about one-half (0.55) of one tooth surface per child. One possible explanation is delayed tooth eruption, which was not considered in the study. Note that the mean DMFS for the highest fluoride group is higher than for either of the two intermediate groups, also indicating that DMFS scores are not solely a function of water fluoride concentration. When the data are examined by the distribution of DMFS scores (Fig. 3),

no real difference in caries experience with respect to water fluoride concentration is observed.

24. In my opinion as a scientist with particular expertise in reviewing toxicological and epidemiological literature and in assessing exposures and health risks, the available data, responsibly interpreted, indicate little or no beneficial effect of water fluoridation on oral health.

A variety of adverse health effects are associated with fluoride exposures.

25. For most of the U.S. population, the single largest source of fluoride exposure is municipal tap water, including tap water used directly, beverages and foods prepared with municipal tap water either at home or in restaurants, and commercial beverages and processed foods prepared with municipal tap water. For a water fluoride level of 1 mg/L (1 ppm), which is the level still used in most fluoridated U.S. cities, estimated average exposures to fluoride from all sources range from about 0.03 mg/kg/day (mg of fluoride per kg of body weight per day) for adults and nursing infants to 0.09 mg/kg/day for non-nursing infants (especially infants fed formula prepared with fluoridated tap water). Note that these are estimated *average* exposures. For individuals with high tap water consumption (discussed by NRC 2006), total fluoride exposures can exceed 0.1 mg/kg/day for some adults and may reach 0.2 mg/kg/day for some infants. In one of the few studies to evaluate individual intake of fluoride from all sources, Warren et al. (2009) report individual fluoride intakes (from all sources) in excess of 0.2 mg/kg/day for some infants.

26. The NRC (2006) identified several sizeable subgroups of the U.S. population that require special consideration due to above-average fluoride exposures, increased fluoride retention, or greater susceptibility to effects from fluoride exposures. Groups known to be at risk of high fluoride intake include those with high water intake (e.g., outdoor workers, athletes, and individuals with diabetes insipidus or other medical conditions) or exposure to other sources of fluoride intake (NRC 2006). In addition, people with impaired renal function are at higher risk of adverse effects per unit intake of fluoride, due to impaired excretion of fluoride and consequent higher fluoride concentrations in the body. Tap water consumption varies among individuals by more than a factor of 10, depending on age, activity level, and the presence of certain health conditions such as diabetes insipidus (NRC 2006; see also Warren et al. 2009 for an example of estimated fluoride intakes for individual children at different ages). A substantial number of infants have water consumption rates in excess of 0.1 L/kg/day (100 mL per kg body weight per day; NRC 2006; EPA 2004a).

27. The U.S. Department of Health and Human Services (HHS) recently proposed a new recommendation regarding fluoride concentrations in drinking water (Federal Register 2011), the primary change being from a recommended range of 0.7-1.2 mg/L fluoride in drinking water (0.7-1.2 ppm) based on ambient local temperatures, to a single value of 0.7 mg/L (0.7 ppm), regardless of temperature. At the proposed fluoride concentration of 0.7 mg/L in drinking water, infants consuming at least

0.1 L/kg/day of tap water will have fluoride intakes at and above 0.07 mg/kg/day, and some will exceed 0.15 mg/kg/day (NRC 2006).

28. The HHS recommendation addresses only dental fluorosis (discussed below), while ignoring a long list of other health concerns for the U.S. population. Dental fluorosis itself has been associated with increased risks of various adverse health effects, including 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; Li et al. 2003; Susheela et al. 2005; Rocha-Amador et al. 2009). To the best of my knowledge, no studies in the U.S. or Canada have looked for associations between dental fluorosis and risk of other adverse effects. However, the failure to look for adverse health effects does not demonstrate the absence of adverse health effects.

29. The NRC (2006) indicated that the Environmental Protection Agency's (EPA's) present drinking water standards for fluoride (maximum contaminant level goal [MCLG] and maximum contaminant level [MCL], both at 4 mg/L) are not protective of human health, based on preventing severe dental fluorosis, stage II skeletal fluorosis, and increased risk of bone fractures. Given the wide range of water intake within the American population and the presence of other sources of fluoride intake, one can reasonably expect that a "safe" level of fluoride in drinking water would be at least a factor of 10 below the "unsafe" level of 4 mg/L. EPA's MCLG is defined as a "non-enforceable health goal which is set at a level at which no known or anticipated adverse effect on

the health of persons occurs and which allows an adequate margin of safety" (EPA 2009). Dental fluorosis, skeletal fluorosis, and increased risk of bone fracture are all reasonably well known and acknowledged adverse health effects from fluoride exposure. However, EPA is also required to consider the "anticipated" adverse effects (which may occur at lower levels of fluoride exposure than the "known" effects) and allow for an adequate margin of safety. The proposed HHS recommendation for water fluoridation at 0.7 mg/L is not adequate to protect against known or anticipated adverse effects and does not allow an adequate margin of safety to protect young children, people with high water consumption, people with kidney disease (resulting in reduced excretion of fluoride), and other potentially sensitive population subgroups.

30. In addition to the "known" adverse health effects of dental fluorosis, skeletal fluorosis, and increased risk of bone fracture, "anticipated" adverse health effects from fluoride exposure or community water fluoridation include (but are not limited to) carcinogenicity, genotoxicity, endocrine effects, increased blood lead levels, and hypersensitivity (reduced tolerance) to fluoride. These effects (described in more detail below) are not as well studied as the dental and skeletal effects, which should indicate that a greater margin of safety is necessary to ensure protection of the population—"in the face of uncertain evidence it is important to act in a manner that protects public health" (Tickner and Coffin 2006). In addition, it should be noted that some of these effects may occur at lower fluoride exposures than those typically associated with dental or skeletal effects, such that protection against the dental or

skeletal effects does not necessarily ensure protection against other anticipated adverse health effects. Elimination of community water fluoridation is in my opinion the best way to reduce fluoride exposures for most individuals to a level at which adverse health effects are unlikely.

31. A few comments regarding the interpretation of the available fluoride studies may be helpful. As Cheng et al. (2007) have described, a "negative" study may simply mean that the study was not sufficiently sensitive to demonstrate a moderate (as opposed to large) effect. This is often due to use of too small a sample size. In addition, study populations are often grouped by community, water source, or fluoride concentration in the water, rather than by individual intake. Due to the wide variation in drinking water intake, this approach results in study groups with overlapping intakes and makes it difficult to detect dose response relationships that do in fact exist.

32. The few studies that have looked at age-dependent exposure to fluoride have found increased risks of adverse effects (e.g., Bassin et al. 2006 for osteosarcoma; Danielson et al. 1992 for hip fracture risk); studies that have not looked at age-dependent exposure cannot be assumed to provide evidence of no effect. Similarly, studies that have used a measure of current exposure where a cumulative measure would be more appropriate, or vice versa, cannot be assumed to demonstrate lack of an effect.

33. Studies of fluoride toxicity in laboratory animals are sometimes dismissed as irrelevant because the exposures or fluoride concentrations used were

higher than those expected for humans drinking fluoridated tap water. It is important to know that 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.

34. 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). For persons with iodine deficiency, average intakes as low as 0.01-0.03 mg/kg/day could produce effects (NRC 2006). The next few sections briefly summarize some (not all) of the adverse health effects, known and anticipated, that should be considered in any reevaluation of the drinking water standards for fluoride. Most of these effects have been reviewed in detail by the NRC (2006), although the NRC did not specifically evaluate health risks over the whole range of fluoride intakes or attempt to identify a "safe" level of fluoride exposure.

Dental fluorosis

35. The main reason for the change in fluoridation levels proposed by HHS is the prevention of dental fluorosis, a condition ranging from mild spotting of the teeth to severe pitting and staining. Dental fluorosis is caused by excessive fluoride ingestion during the early years of childhood, before the permanent teeth erupt. The HHS recommendation is

intended to limit the risk of dental fluorosis while maintaining caries protection (Federal Register 2011). The most recent data indicate a fluorosis prevalence in the U.S. (all levels of severity) of 40.7% in 1999-2004 vs. 22.6% in 1986-1987 for children ages 12-15 (Beltrán-Aguilar et al. 2010). The proposed change in water fluoridation level will put the U.S. in agreement with Canada, which in 2009 recommended a fluoride concentration of 0.7 mg/L for all parts of the country (Health Canada 2009).

36. Based on the 1986-1987 data set (as reported by Heller et al. 1997), which included water fluoride concentrations, fluoridating at 0.7 mg/L can be expected to bring the fluorosis prevalence in the U.S. down to about 27%. Elimination of fluoridation entirely, for the whole population, would be expected to bring the fluorosis prevalence down to that of the current low-fluoride population (to around 13% based on Heller et al. 1997; Fig. 4).

37. The only U.S. study to have looked at dental fluorosis and individual fluoride intake at various ages (the Iowa study) reported that for children with fluoride intakes above 0.06 mg/kg/day during the first 3 years of life, fluorosis rates were as high as 50% (Hong et al. 2006b). As mentioned above, at a fluoride concentration of 0.7 mg/L in drinking water, many infants will have fluoride intakes at and above 0.07 mg/kg/day, and some will exceed 0.15 mg/kg/day (NRC 2006). Thus a large fraction of infants and young children fed formula made with

fluoridated tap water can be expected to develop dental fluorosis even at a water fluoride concentration of 0.7 mg/L.

38. The National Research Council considers severe dental fluorosis to be an adverse health effect and reports the general consensus in the literature that both severe and moderate dental fluorosis should be prevented (NRC 2006). Health Canada (2009) considers moderate dental fluorosis to be an adverse effect. The Iowa study indicates that high fluoride intake during the first 2 years of life is most important with respect to development of dental fluorosis of the permanent maxillary central incisors (the "top front teeth")—the teeth that most affect a person's appearance—although fluoride intake up to at least 4 years old was also important (Hong et al. 2006a). The American Dental Association has issued a brief statement to the effect that parents should not prepare infant formula with fluoridated water if they are concerned about the possibility of their child developing dental fluorosis (ADA 2007). This is an admission that dental fluorosis is undesirable, and that fluoridated tap water is not "safe" for all individuals. The CDC (2005) reports a higher likelihood of moderate and severe fluorosis for minority and low-income children. While for a variety of reasons it is appropriate for governments and health agencies to encourage breastfeeding of infants, in many family situations breastfeeding is not possible (e.g., in cases of adoption or of ill-health or death of the mother). It is therefore essential that tap water be safe for use in infant formula, without putting infants at increased risk of dental fluorosis.

Skeletal fluorosis

39. Bone fluoride concentrations in the ranges reported for stage II and III skeletal fluorosis will be reached by long-term fluoride exposures of 0.05 mg/kg/day or higher (estimated from NRC 2006). Bone fluoride concentrations, radiologic changes, and symptoms are not clearly correlated (Franke et al. 1975), and most U.S. studies do not categorize cases by stage. Recent case reports include fluorosis attributed to excessive ingestion of tea or toothpaste (Whyte et al. 2005; Hallanger Johnson et al. 2007; Kurland et al. 2007). Most of the literature addresses high fluoride exposures over a few years; there has been essentially no investigation of effects of low exposures over many years and no effort to identify fluorosis of any stage in the U.S. "Arthritis" (defined as painful inflammation and stiffness of the joints) is the leading cause of disability in the U.S., currently affects at least 46 million adults in the U.S. (including 50% of the population > 65 years old), and is expected to affect 67 million adults in the U.S. by 2030 (CDC 2006). The possibility that a sizeable fraction of "bone and joint pain" or "arthritis" in U.S. adults is attributable to fluoride exposure has not been addressed, although it is plausible, given what is known about fluoride intakes.

Increased risk of bone fractures

40. The NRC (2006) concluded that lifetime exposure to fluoride at an estimated average daily intake of 0.08 mg/kg/day (average adult fluoride

intake with water at 4 mg/L) is likely to result in higher bone fracture rates, and the available information suggests an increased likelihood of bone fracture for daily fluoride intakes of 0.05 mg/kg/day (average adult fluoride intake at 2 mg/L). The Agency for Toxic Substances and Disease Registry (ATSDR) has identified a chronic-duration Minimal Risk Level (MRL) for oral exposure to fluoride of 0.05 mg/kg/day, based on an increased risk of bone fracture (ATSDR 2003). The NRC's findings (NRC 2006) indicate that the ATSDR's MRL is not protective enough. The available studies consider fluoride intake only in terms of the concentration in the local drinking water, and most use fluoridated water (1 mg/L, corresponding to an average daily intake of 0.03 mg/kg/day for adults) as a control. Thus there is probably considerable overlap in exposures between groups, making effects more difficult to distinguish, and the entire dose response range of interest has not been well studied. The findings in humans are consistent with animal studies that have found increased brittleness of bones with increased fluoride exposure (Clark and Mann 1938; Turner et al. 1997; 2001).

41. Danielson et al. (1992) reported an increased relative risk for hip fracture in a fluoridated area of 1.27 (95% CI 1.08-1.46) for women and 1.41 (95% CI 1.00-1.81) for men. These authors reported a difference between women exposed to fluoride prior to menopause and those exposed afterwards. For women exposed prior to menopause, the fracture risk was considerably higher than for those not exposed to fluoride. Many studies of fracture risk have not looked at age-specific

exposure, or have involved women exposed only after menopause, when fluoride uptake into bone is probably substantially lower.

42. The Iowa study reported effects on bone mineral concentration and bone mineral density with average childhood fluoride intakes of 0.02-0.05 mg/kg/day (Levy et al. 2009). Linear correlation between dental fluorosis and risk of bone fracture has been reported for children and adults (Alarcón-Herrera et al. 2001; Fig. 5). Bone fracture rates in children in the U.S. may be increasing (e.g., Khosla et al. 2003), but fluoride exposure has not been examined as a possible cause or contributor.

Carcinogenicity

43. Three U.S. courts have found water fluoridation to be injurious to human health, specifically that it may cause or contribute to the cause of cancer and genetic damage (described in detail by Graham and Morin 1999). The NRC's committee on fluoride toxicology unanimously concluded that "Fluoride appears to have the potential to initiate or promote cancers," even though the overall evidence is "mixed" (NRC 2006). Referring to the animal studies, the committee also said that "the nature of uncertainties in the existing data could also be viewed as supporting a greater precaution regarding the potential risk to humans." The committee 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, 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).

44. While the NRC did not assign fluoride to a specific category of carcinogenicity (i.e., known, probable, or possible), the 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 becomes one of how strongly carcinogenic fluoride is, and under what circumstances.

45. The case-control study by Bassin et al. (2006) is the only published study thus far to have looked at age-dependent exposure to fluoride. This study reported a significantly elevated risk of osteosarcoma in boys as a function of estimated age-specific fluoride intake. Osteosarcoma is a bone cancer that commonly results in amputation of an affected limb and may result in death. At the very least, this study indicates that similar studies of pediatric osteosarcoma that have not looked at age-dependent intake cannot be considered to show "no effect." A recent review of osteosarcoma risk factors (Eyre et al. 2009) lists fluoride among "a number of risk factors that emerge with some consistency" and considers fluoride exposure to have a "plausible" role in etiology of osteosarcoma.

46. While a few other studies (e.g., Gelberg et al. 1995; Kim et al. 2011) have looked at individual fluoride exposure (as opposed to group or ecologic measures of exposure), these have looked at total fluoride exposure until time of diagnosis or treatment. 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") cannot have contributed to the initiation of a cancer but could have a significant effect on the estimate of cumulative fluoride exposure.

47. The 1990 National Toxicology Program (NTP) study on sodium fluoride officially concluded that "there was *equivocal evidence of carcinogenic activity* of sodium fluoride in male F344/N rats, based on the occurrence of a small number of osteosarcomas in dosed animals" (NTP 1990; italics in the original). According to the published report, a "small number of osteosarcomas occurred in mid- and high-dose male rats. These neoplasms occurred with a significant dose response trend, but at a rate within the upper range of incidences previously seen in control male rats in NTP studies" (NTP 1990). It is important to realize that the historic controls from previous studies had not had the special low-fluoride diet used for this study, and therefore more properly constitute a low- to mid-range exposed group rather than a control group. This and other concerns were described in a memo within the Environmental Protection Agency (Marcus 1990) and reported in the press (Hileman 1990). These concerns and the testimony before the U.S. Senate of the union representing EPA scientists (Hirzy 2000) should be taken seriously.

48. In humans, osteosarcomas tend to occur most commonly in young people (pediatric cases) or the very old (adult or geriatric cases), with a higher incidence in males than in females (Bassin et al. 2006). Sergi and Zwerschke (2008) indicate that 60-75% of cases are in patients between 15 and 25 years old. In the NTP 2-year study, fluoride exposure was begun when the animals were 6 weeks old, as is typical for NTP and similar studies (Hattis et al. 2004). Puberty in the rat typically occurs at about 32 days of age in females and 42 days in males (e.g., Gray et al., 2004; Evans 1986). Thus, the age of 6 weeks in the NTP study probably corresponds to pubertal or post-pubertal animals. The cases of osteosarcoma in the rats were reported in the late stages of the test, and probably corresponded to geriatric osteosarcomas in humans. In Bassin's study, the age range for which the fluoride-osteosarcoma association was most apparent was for exposures at ages 4-12 years, with a peak for exposures at age 6-8 years (Bassin et al. 2006). Very likely, the fluoride exposures in most of the animal studies have started after the age corresponding to the apparent most susceptible age in humans, and thus these animal studies may have completely missed the most important exposure period with respect to initiation of the majority of human osteosarcomas. Therefore, this animal study cannot be interpreted as showing no evidence of causation for pediatric osteosarcoma, although, properly interpreted, it does show evidence for causation of geriatric osteosarcoma.

Genotoxicity

49. Genotoxicity, or the ability to damage the genetic material (genes and chromosomes) of cells, is considered indicative of potential carcinogenicity. A number of mammalian *in vitro* systems have shown dose-dependent cytogenetic or cell transformational effects from fluoride exposure (reviewed by NRC 2009). Several reports suggest an indirect or promotional mechanism, e.g., inhibition of DNA synthesis or repair enzymes, rather than a direct mutagenic effect (Lasne et al. 1988; Aardema et al. 1989; Aardema and Tsutsui 1995; Meng and Zhang 1997). Human cells seem to be much more susceptible to chromosome damage from fluoride than are rodent cells (Kishi and Ishida 1993).

50. 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. The system described by Zhang et al. (2009) is considerably more sensitive than the older systems for most chemicals examined; a positive effect was seen at a fluoride concentration of about 0.5 mg/L, or a factor of 10 lower than in other systems.

51. 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., Gessner et al. 1994; 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 (0.07-0.09 mg/kg/day for an adult; based on NRC 2006). Thus, 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.

Endocrine effects

52. The NRC (2006) concluded that fluoride is an endocrine disruptor. Endocrine effects include altered thyroid function or increased goiter prevalence (at fluoride intakes of 0.05-0.1 mg/kg/day, or 0.01-0.03 mg/kg/day with iodine deficiency), impaired glucose tolerance (at fluoride intakes above 0.07 mg/kg/day), a decrease in age at menarche in girls in fluoridated towns, and disruptions in calcium metabolism

(calcitonin and parathyroid function, at fluoride intakes of 0.06-0.15 mg/kg/day or higher). ATSDR's toxicological profile for fluoride (ATSDR 2003) refers to an animal study of thyroid function that would give a lower MRL (value not given) than the MRL derived for bone fracture risk (0.05 mg/kg/day).

53. Thyroid dysfunction and Type II diabetes presently pose substantial health concerns in the U.S. (NRC 2006). Of particular concern is an inverse correlation between subclinical maternal hypothyroidism and the IQ of the offspring. In addition, maternal subclinical hypothyroidism has been proposed as a cause of or contributor to development of autism in the child (Román 2007; Sullivan 2009). Steingraber (2007) has described the decrease in age at puberty of U.S. girls and the associated increased risk of breast cancer. Calcium deficiency induced or exacerbated by fluoride exposure may contribute to other health effects (NRC 2006).

Increased blood lead levels

54. An increased likelihood of elevated blood lead levels is associated with use of silicofluorides (usually H_2SiF_6 or Na_2SiF_6) as the fluoridating agent (NRC 2006; Coplan et al. 2007). Approximately 90% of people on fluoridated water are on systems using silicofluorides (NRC 2006). The chemistry and toxicology of these agents, especially at low pH (e.g., use of fluoridated water in beverages such as tea, soft drinks, or reconstituted fruit juices), have not been adequately studied (NRC 2006). Associations between silicofluoride use and biological effects in humans have been reported, in particular, elevated levels of blood lead in children **and**

inhibition of acetylcholinesterase activity (reviewed by Coplan et al. 2007). A recent study in rats found significantly higher concentrations of lead in both blood and calcified tissues of animals exposed to both silicofluorides and lead (Sawan et al. 2010).

55. In addition to biological effects of silicofluorides, the interaction of silicofluorides (as the fluoridating agent) and disinfection agents (specifically, chloramines) also increases the leaching of lead from plumbing fixtures into drinking water (Maas et al. 2005; 2007). For example, the interaction of silicofluorides and chloramines is the probable explanation for the high lead levels in drinking water and children's blood in Washington, D.C. a few years ago (Maas et al. 2005; 2007; Leonnig 2010). EPA considers lead to be a probable human carcinogen and to have no practical threshold with respect to neurotoxicity (EPA 2004b)—in other words, there is considered to be no safe level of lead exposure, and the MCLG for lead is zero (EPA 2009).

Neurotoxicity

56. Grandjean and Landrigan (2006) list fluoride as an "emerging neurotoxic substance" that needs further in-depth studies. The major concern is neurotoxic effects during human development. The NRC (2006) concluded that "it is apparent that fluorides have the ability to interfere with the functions of the brain and the body by direct and indirect means." A number of studies indicate an association of fluoride exposure with lower IQ in children and with other measures of neuropsychological

development (reviewed by NRC 2006; Connett et al. 2010; Choi et al. 2012; see also Zhao et al. 1996; Lu et al. 2000; Xiang et al. 2003; Rocha-Amador et al. 2007; 2009; Saxena et al. 2012; Seraj et al. 2012).

Additional adverse health effects

57. Fluoride intake is likely to affect the male reproductive-hormone environment, beginning at intakes of around 0.05 mg/kg/day (reviewed by NRC 2009). A "safe" intake with respect to male reproductive effects is probably somewhere below 0.03 mg/kg/day.

58. The NRC has reviewed the possible association between exposure to fluoridated water (approximately 0.02 mg/kg/day for adults) and increased risk of Down syndrome (trisomy 21) in children of young mothers, discussed a possible mechanism, and recommended further study (NRC 2006). Fetuses with Down syndrome are less likely to survive to birth, due both to higher natural fetal loss and to a high rate of pregnancy termination (Buckley and Buckley 2008; Forrester and Merz 1999; Siffel et al. 2004; Biggio et al. 2004).

59. Hypersensitivity or reduced tolerance to fluoride has been reported for exposure to fluoridated water (approximately 0.02 mg/kg/day for adults) or use of fluoride tablets (approximately 1 mg/day). Symptoms include skin irritation, gastrointestinal pain and symptoms (nausea, vomiting, diarrhea, constipation), urticaria, pruritus, stomatitis, chronic fatigue, joint pains, polydipsia, headaches, and other complaints (Waldbott 1956; 1958; Feltman and Kosel 1961; Grimbergen 1974; Petraborg 1977; Spittle 2008;

reviewed by NRC 2006). Patients were often unaware that their drinking water contained fluoride. Symptoms improved with avoidance of fluoridated water and recurred with consumption of fluoridated water or with experimental challenge with sodium fluoride. Double-blind tests of patients have confirmed hypersensitivity to fluoride (Grimbergen 1974; Waldbott 1956; 1958). Many of the observed symptoms represent true allergic phenomena, while others (e.g., gastrointestinal symptoms) could be due to a lower level of tolerance for fluoride (intoxication at lower exposure; Waldbott 1956; 1958).

By fluoridation of drinking water, governments and water suppliers are indiscriminately administering a drug to the population, without individual evaluation of need, appropriate dose, efficacy, or side effects.

60. The U.S. Food and Drug Administration (FDA) considers fluoride in toothpaste to be a non-prescription drug (e.g., FDA undated-a; undated-b) and fluoride "supplements" (usually tablets or lozenges) to be prescription drugs (e.g., Medline Plus 2008). Most prescription fluoride supplements are considered unapproved drugs (for example, see DailyMed 2011a,b,c), meaning that they "may not meet modern standards of safety, effectiveness, quality, and labeling" (FDA 2011). The goal of community water fluoridation is to provide a dental health benefit to individuals and to the population generally (Federal Register 2010), and EPA's recent reference (Federal Register 2010) to a "treated population"

acknowledges this use of drinking water systems to deliver a drug to entire populations. This in effect puts local governments and water treatment personnel in charge of administering a chemical (i.e., a drug) to the population in an effort to improve individual and population health (Cross and Carton 2003; Cheng et al. 2007). Many people consume more fluoride from tap water than from either non-prescription (toothpaste) or prescription (tablets or lozenges) fluoride sources, without any monitoring for either efficacy or side effects, without the "drug information" or warning labels generally provided for drugs, and without any semblance of informed consent.

61. In addition, most fluoridation operations use fluorosilicates (usually H_2SiF_6 or Na_2SiF_6) rather than sodium fluoride (NaF). The chemistry and toxicology of these compounds have not been adequately studied, although important differences in biological effects between silicofluorides and simple fluorides (e.g., NaF) have been reported (Coplan et al. 2007; NRC 2006; Masters et al. 2000; Masters and Coplan 1999). The NRC (2006) discussed the increased toxicity of aluminofluorides and beryllofluorides vs. fluoride alone, as well as the different mechanisms of action of the different chemical combinations. In my opinion it is irresponsible to recommend addition of fluoride, or a particular concentration of fluoride to be added, without a comprehensive review of the substances (H_2SiF_6 or Na_2SiF_6) that are actually added. In addition, fluoridation chemicals often contain impurities such as lead and arsenic (e.g., Weng et al. 2000; Brown et al. 2004), for which EPA has set MCLGs of zero (EPA 2009), such that a

water supplier is actually adding contaminants for which the ideal maximum amount in drinking water is zero.

62. In summary, in my opinion it is irresponsible to promote or encourage uncontrolled exposure of any population to a drug that, at best, is not appropriate for many individuals (e.g., those who do not want it, those whose water consumption is high, formula-fed infants, people with impaired renal function) and for which the risks are inadequately characterized and inadequately disclosed to the public. Elimination of community water fluoridation at the earliest possible date would be in the best interest of public health.

Table 1. Caries prevalence and fluorosis prevalence with water fluoride concentration.[a]

Water fluoride concentration mg/L	Children with no caries %	Mean DMFS score[b]	Children with fluorosis[c] %	Mean severity of fluorosis[d]
< 0.3	53.2	3.08	13.5	0.30
0.3 - < 0.7	57.1	2.71	21.7	0.43
0.7 - 1.2	55.2	2.53	29.9	0.58
> 1.2	52.5	2.80	41.4	0.80

[a] Data for permanent teeth of children ages 5-17 (caries experience and DMFS score) or 7-17 (dental fluorosis), with a history of a single residence, from Tables 2 and 5 of Heller et al. (1997).

[b] Decayed, missing, or filled tooth surfaces (permanent teeth).

[c] Includes very mild, mild, moderate, and severe fluorosis, but not "questionable."

[d] Dean's Community Fluorosis Index.

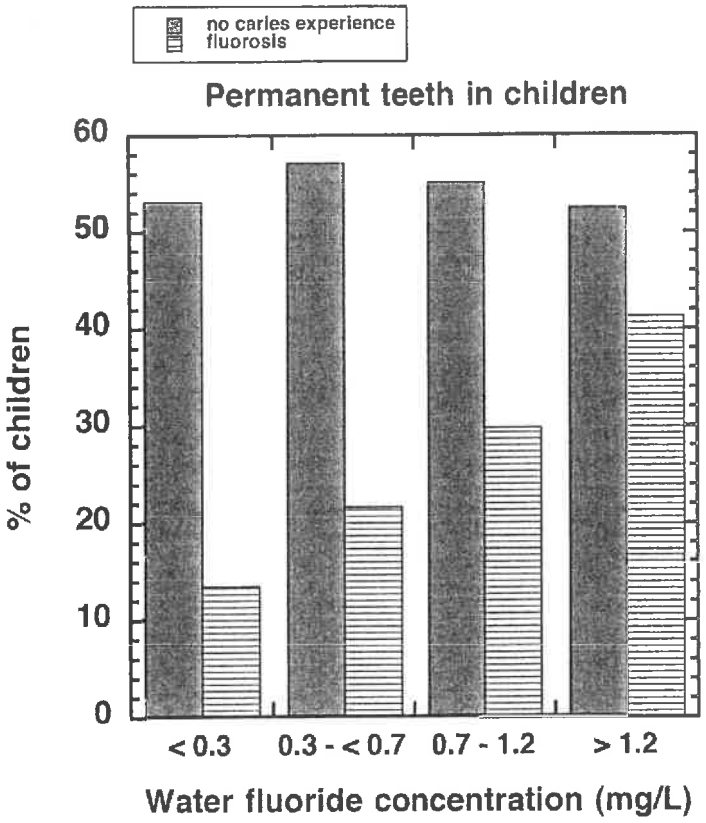

Fig. 1. Percent of children with no caries experience in the permanent teeth (DMFS = 0) and with fluorosis, with respect to water fluoride concentration. Data are shown as % of total children having no caries experience (blue) or having fluorosis (very mild, mild, moderate, or severe, but not questionable; red). Numerical values are provided in Table 1 and were obtained from Tables 2 and 5 of Heller et al. (1997).

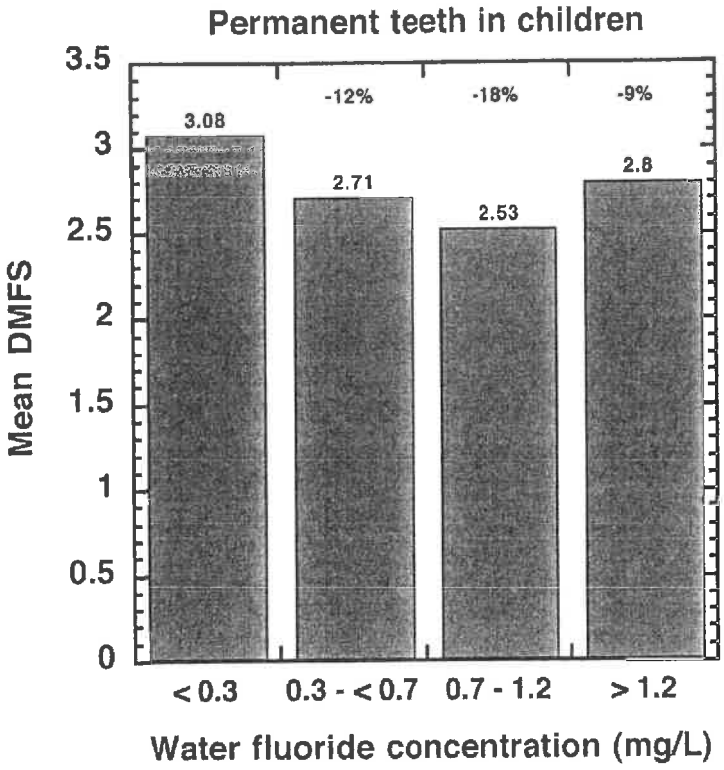

Fig. 2. Mean DMFS score (decayed, missing, or filled permanent tooth surfaces in permanent teeth), with respect to water fluoride concentration. Numerical values are provided in Table 1 and were obtained from Table 2 of Heller et al. (1997). The percent difference with respect to the lowest fluoride group is also provided.

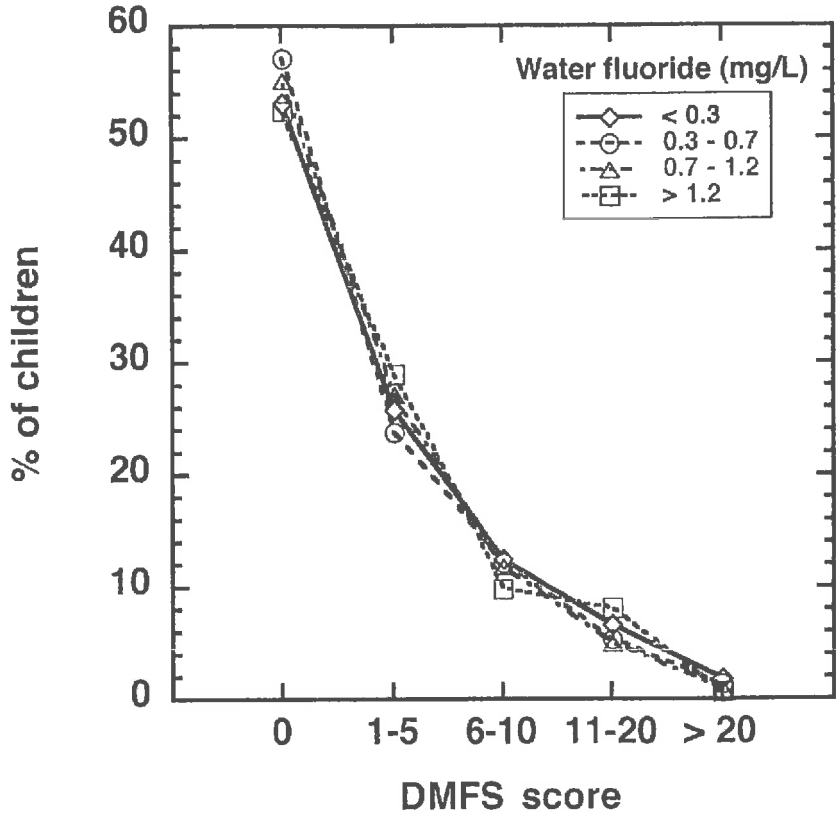

Fig. 3. Percent of children by DMFS score, with respect to water fluoride concentration. Data are shown as % of total children in a given group according to the number of decayed, missing, or filled tooth surfaces in the permanent teeth (DMFS). Data were obtained from Table 2 of Heller et al. (1997).

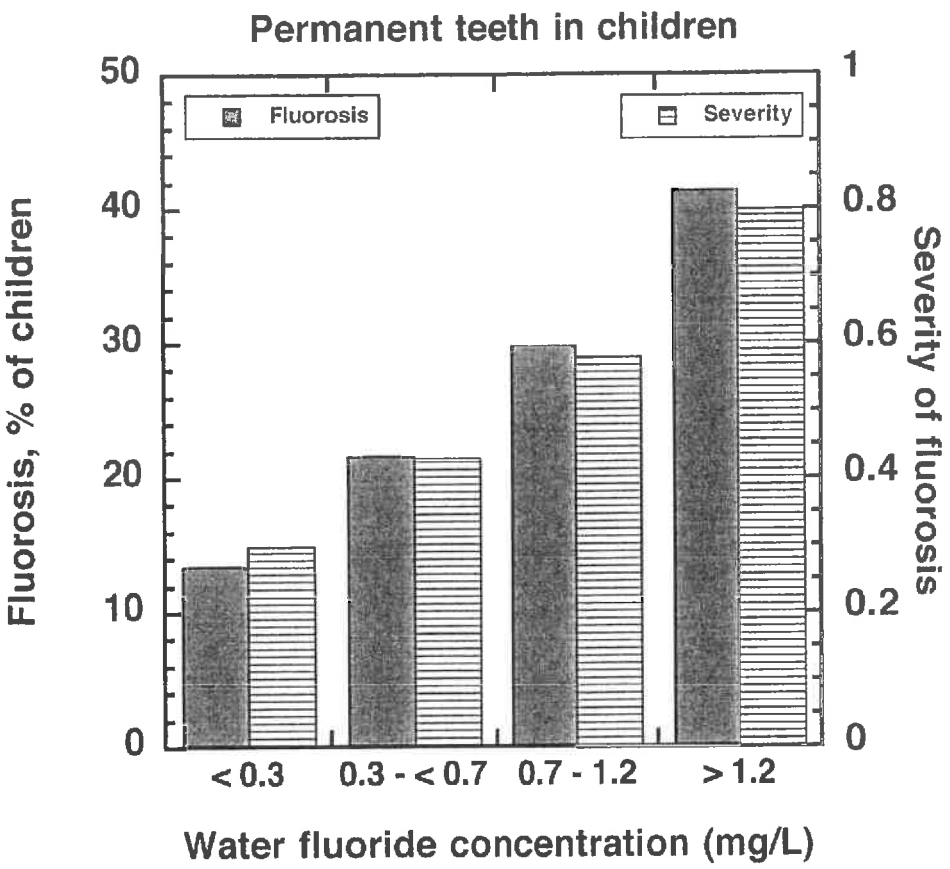

Fig. 4. Fluorosis prevalence and severity with water fluoride concentration for children ages 7-17 with a history of a single continuous residence. Data are shown as (left) % of total children having fluorosis (very mild, mild, moderate, or severe, but not questionable) or (right) severity of fluorosis by Dean's Community Fluorosis Index. Numerical values are provided in Table 1 and were obtained from Table 5 of Heller et al. (1997).

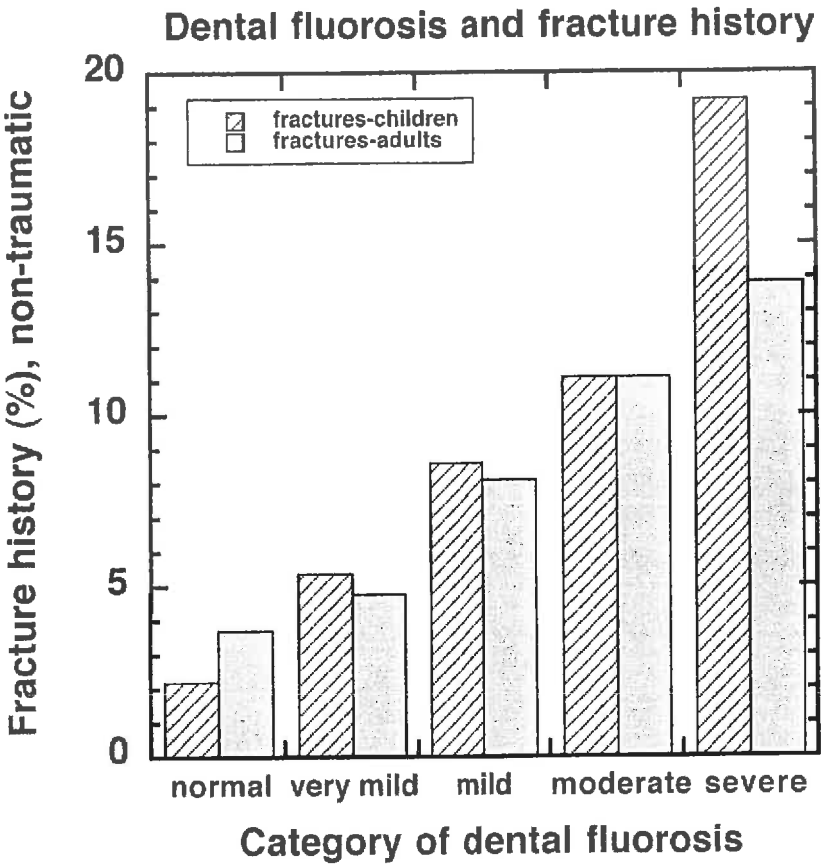

Fig. 5. Fracture history with category of dental fluorosis for children (ages 6-12) and adults (ages 13-60). Numerical values were obtained from information in Tables 5 and 6 of Alarcón-Herrera et al. (2001).

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Kathleen M Thiessen

AFFIRMED at Oak Ridge, TN this 29th

day of Oct 2013

before me:

KIMBERLY H. DISNEY
STATE OF TENNESSEE
NOTARY PUBLIC
ANDERSON COUNTY
My Commission Expires 04/26/2014

Kimberly H. Disney

A person who is authorised to administer oaths by the law of the state of Tennessee

Commission Expires 4/26/14

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6 H 9

LISA HANSEN
BA(Hons)LLB(Hons) Otago
BARRISTER

29 May 2014

AFFIRMED

THIS is the Exhibit marked with the letter "H" referred to in the annexed affidavit of PATRICK DAVID SLOAN ~~sworn~~ at CHRISTCHURCH this 28 day of July 2014 before me:

MEMorrison

A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

Office of the Obmudsman
P O Box 10152
WELLINGTON

Dear Sir

Complaint about response by the National Fluoridation Information Service

1. I write on behalf of New Health New Zealand Inc.

2. I **enclose** documents relating to a request for information from the National Fluoridation Information Service (which is part of the Hutt Valley DHB).

3. The documents consist of the following:

   a. Letter dated 19 December 2013 (wrongly dated 2012) from Lisa Hansen to NFIS;
   b. Email dated 27 January 2014 from NFIS to Lisa Hansen;
   c. Letter dated 6 March 2014 from NFIS to Lisa Hansen;
   d. Letter dated 12 March 2014 from Lisa Hansen to NFIS;
   e. Email chain dated 13 March 2014 (2 pages);
   f. Email chain dated 14 March 2014 (2 pages);
   g. Email dated 6 May 2014 from Lisa Hansen to NFIS;
   h. Email dated 6 May 2014 from HVDHB to Lisa Hansen;
   i. Letter dated 6 May 2014 from Regional Public Health to Lisa Hansen;
   j. Letter and email dated 9 May 2014 from Lisa Hansen to Regional Public Health.

4. For completeness I note that no response has been received to the letter of 9 May 2014.

5. New Health wishes to complain that its request for information from NFIS has not been dealt with in accordance with requirements of the Official Information Act.

6. The substance of its inquiry has been ignored, the timeframes for providing a response have not been observed, and NFIS has failed to even acknowledge at any time in the process that it is bound by the OIA requirements.

7. New Health requests that this complaint is investigated as soon as possible.

8. You should be aware that I previously made a complaint about fluoridation on behalf of the NZ Health Trust on 12 February 2013 that has only just now been notified (some fifteen and a half months after the complaint was made). New Health does not want a similar period of time to pass before this complaint is actioned.

9. In addition I am aware that NZ Health Trust has another current complaint with your office (H201303977) that has some similarity to this new complaint.

10. It is not uncommon for requests for information about fluoridation to officials to be fobbed off by general references to information contained on websites. That is a feature of H201303977 and also arises in this complaint.

11. Please advise if your require any further information.

Yours sincerely

Lisa Hansen

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LISA HANSEN
BA(Hons)LLB(Hons) Otago
BARRISTER

19 December 2012

COPY

Emmeline Haymes
NFIS
Regional Public Health
Private Bag 31907
LOWER HUTT 5040

Dear Emmeline

Invitation to meet

I write on behalf of New Health New Zealand Inc.

You may be aware that New Health recently challenged a decision of the South Taranaki District Council to add fluoride to its Waverley and Patea water supplies in the New Plymouth High Court.

New Health argued that fluoridation is a breach of the right to refuse to undergo medical treatment in s 11 of the New Zealand Bill of Rights Act 1990 and is neither prescribed by law nor justified in a free and democratic society.

A decision is expected in the New Year.

Putting the legal issues to one side, it is apparent that the scientific evidence both for and against fluoridation is unclear.

As part of its case, New Health provided scientific evidence to the court querying the efficacy and safety of fluoridation. In particular:

1. It referred to Featherstone's 1999 paper[1] which conclusively established that fluoride works topically rather than systemically. This calls into question why there is a need to swallow fluoridated water, particularly when there is no dietary need for fluoride.

2. It noted the findings of the York Report 2000 to the effect that the quality of evidence used to justify fluoridation in the past was low and that any benefit was modest. That report also established that harms also could not be excluded due to the poor quality of the evidence.

[1] Prevention and reversal of dental caries: role of low level fluoride Community Dent Oral Epidemiol 1999: 27/31-40

3. It identified that fluorosis is a known and accepted harm and the York Report said this cannot be dismissed as simply cosmetic.

4. It referred to the 2006 NRC report which identified real risks of harm at 4 ppm and evidence of harm in some end point at 1 ppm, and to the 2011 SCHER report which identified benefits of fluoride toothpaste but queried the benefits of fluoridation.

You should be aware that at the hearing the judge Rodney Hansen J, observed that in light of the scientific evidence provided by behalf of the plaintiff it was "surprising there's anybody left to advocate fluoridation [of] water". The judge also observed that there are plainly "two schools of thought in which well intentioned, well informed people, including highly qualified experts, have reached different conclusions on this issue".

In circumstances where the science is so strongly contested, New Health finds it surprising that fluoridation continues to be supported at the highest levels of the health bureaucracy.

New Health considers that one explanation is that fluoridation is a sacred cow that cannot be questioned. There is no ability for health officials to look at the matter objectively and to actually consider changing their minds in light of credible scientific evidence to the contrary. Further, it is New Health's experience that those opposed to fluoridation are ridiculed, branded as "nutters" and casually and contemptuously dismissed as being anti-scientific, and that this is a view held by health officials.

Your assurance that minds are indeed open on the issue at NFIS would be welcome because to date it is not apparent that the health bureaucracy is receptive to reasoned and informed debate. This is particularly so as New Health understands that NFIS has previously stated that it could viably recommend a change in fluoride-use policy.

New Health would like to meet with you in the New Year to discuss its concerns.

There are three main topics it would like to raise.

First, it would like to understand how NFIS evaluates one scientific paper over another. For every paper that is provided to you in support of fluoridation, there is equally one that is against. What criteria does NFIS apply to accepting or rejecting scientific papers? To take just two examples:

1. Has NFIS accepted Komarek's 2005 study[2] that there is an approximately one year delay in tooth eruption due to fluoridation, and that this varies between individuals, possibly on a genetic basis. Further once the delay in eruption is adjusted for, there is no difference in tooth decay rates. What other scientific studies for and against the proposition of delayed tooth eruption has the NFIS considered, and either accepted or rejected? Does the NFIS consider the Komarek study to be as good, better, or worse than those studies?

2. Does NFIS accept the recent analysis done by the National Institute of Environmental Health Sciences which showed that children in high fluoride areas had significantly lower

[2] *A Bayesian analysis of multivariate doubly-interval-censored dental data* Biostatistics (2005) 6 1 pp 145-155

IQ scores that those who lived in low fluoride areas.[3] How does NFIS believe the doses in those studies compare with the 3 mg/day accepted by the Ministry of health as applying in fluoridated communities in NZ.

Secondly, it would like to identify issues on which there is a consensus. For example, the Ministry of Health says (presumably based on Featherstone's research), and New Health accepts, that fluoride works topically. If that is the case, it is useful to understand what benefit swallowing fluoridated water confers. New Health's view is that there is no benefit, and relies on the statement by the CDC to the effect that the concentration of fluoride returning in ductal saliva is too low to be of any benefit.[4] However, it would appreciate an explanation.

Thirdly, and this is an aspect of the mechanism of action, New Health would like NFIS to explain how fluoridation actually provides benefit against tooth decay and how it operates to reduce health inequalities.

New Health understands that in order to provide protection against tooth decay there needs to be a sufficient concentration of fluoride in the oral cavity to have a topical effect. New Health understands that the concentration of fluoride in water fluoridation is too low to provide any cariostatic effect. Is that correct? If not please provide evidence of studies you rely on to assert the contrary.

Further, fluoridation is aimed at assisting those people who have a poor diet and who do not regularly use a toothbrush. Can you please explain just how the fluoride in water fluoridation is able to be effective for a person who does not clean their teeth. It is New Health's understanding that the fluoride in water fluoridation cannot penetrate a plaque layer of more than 50 microns and that such a thickness is formed quite soon after toothbrushing. Is this correct? If not please provide evidence of studies you rely on to show just how fluoridation is effective for those populations with poor diet and poor oral hygiene.

A meeting is proposed on either **Thursday 20 or Friday 21 February 2014** at a time and place convenient to you.

I look forward to hearing from you.

Yours sincerely

Lisa Hansen

---

[3] *Developmental Fluroide Neurotoxicity: A Systematic Review and Meta-Analysis*, Environmental Health Perspectives

[4] MMWR Recommendations for using fluoride to prevent and control dental caries in the United States

Lisa Hansen

From: Emmeline Haymes [HVDHB]
Sent: Monday, 27 January 2014 12:46 p.m.
To: 'l.hansen@barristerscomm.com'
Subject: Invitation to meet on behalf of New Health New Zealand Inc.

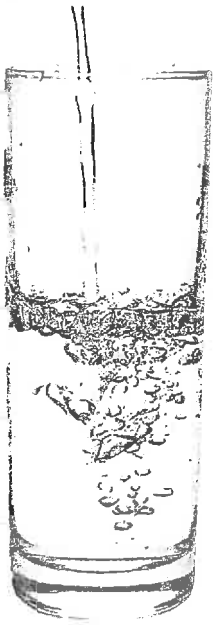
Dear Lisa,

Thank you for your letter dated the 19th of December. I am preparing a response and will get back to you as soon as possible.

Regards,
Emmeline.

Emmeline Haymes | National Coordinator | National Fluoridation Information Service | Systems Quality and Information Team | Regional Public Health

Phone (04) 587 2815
Mobile (0)27 487 5716
www.NFIS.org.nz



NFIS
National Fluoridation Information Service

c/ Regional Public Health
Private Bag 31907
Lower Hutt 5040
04 570 9002
nfis@huttvalleydhb.org.nz
www.nfis.org.nz

NFIS Consortium Partners:
Regional Public Health
Hutt Valley District Health Board
Massey University Wellington
Environmental Science & Research
NZ National Poisons Centre

6 March 2014

Lisa Hansen
Barristers. Comm
PO Box 8045
Wellington 6143

Dear Lisa

Response to letter 'Invitation to meet' dated 19 December 2013.

I am writing to respond to your letter written on behalf of New Health New Zealand Inc.

Regarding your request of, *"Your assurance that minds are indeed open on the issue at NFIS would be welcome because to date it is not apparent that the health bureaucracy is receptive to reasoned and informed debate. This is particularly so as New Health understands that NFIS has previously stated that it could viably recommend a change in fluoride-use policy"*

Please see the section in each of our six monthly reviews of scientific papers (links provdided below) entitled Implications for the Ministry of Health's Fluoridation Policy

1. http://www.rph.org.nz/content/694bf160-de86-432e-abf5-f409b276277c.cmr Review of Scientific Reviews Relating to Water Fluoridation Published between January 2000 and July 2010.
2. http://www.rph.org.nz/content/97848c01-6c32-4724-94d9-ea5793f465c2.cmr Review of Scientific Papers Relating to Water Fluoridation published between January and November 2010.
3. http://www.rph.org.nz/content/c196653e-14e4-4ec7-a901-5f4e60445c63.cmr Review of Scientific Papers Relating to Water Fluoridation published between December 2010 and August 2011.
4. http://www.rph.org.nz/content/d5039490-777b-416b-b505-98044eecd3f2.cmr Review of Scientific Papers Relating to Water Fluoridation published between September 2011 and January 2012.
5. http://www.rph.org.nz/content/c59cda64-998f-4536-a389-fad9bd3df918.cmr Review of Scientific Papers Relating to Water Fluoridation published between February and July 2012
6. http://www.rph.org.nz/content/32de6c27-1d74-4566-8b7f-1b3d07ccfff7.cmr Review of Scientifc Papers Relating to Water Fluoridation published between August and December 2012

Regional Public Health
Hutt Valley DHB
MASSEY UNIVERSITY WELLINGTON
ESR

7. http://www.rph.org.nz/content/dea6f769-1248-4039-819a-e59a7b43df82.cmr Review of Scientific Papers Relating to Water Fluoridation published between January and June 2013.

In each of these reports please note the tables in the appendices and the criteria each paper is assessed against:

- The aim/hypothesis of the study are clearly stated?
- The study method is appropriate?
- Data collection quality?
- Sound logic is used in the conclusions reached?
- The study reaches valid conclusions with respect to the initial hypothesis/aim?

Each paper is also assesed for its strengths and limitations; whether or not the findings can be generalised beyond the study participants/population; the applicability of the findings to community water fluoridation in New Zealand and; implications of the findings for the Ministry of Health's community water fluoridation policy. To understand how NFIS informs the Ministry of its review findings please see Appendix one to this letter.

In response to the section *"There are three main topics it would like to raise"*. Regarding *"First it would like to understand how NFIS evaluates one scientific paper over another"* please see:

- this link on our website to the NFIS Inclusion criteria

http://www.rph.org.nz/content/48137e7a-4f54-428d-94b8-2cd227c59c11.cmr

- this link on our website to our grey literature guideline

http://www.rph.org.nz/content/a3325f48-7fd4-4edf-bb8d-55303e46d1e1.cmr

- this link for links to lists for the citations of all our searched literature

http://www.rph.org.nz/content/2702c4c2-b679-4d96-ac08-8249f7025a63.html

- see also Appendix two to this letter - National Fluoridation Information Service Six Month Review Peer Review & Editing Process

To understand how these processes fit together please read this article (also available on our website), "What do we mean by evidence"
http://www.rph.org.nz/content/95c292c5-c60f-443e-8924-1f550606dc20.cmr

Regarding *"Secondly it would like to identify issues on which there is a consensus"*. We are taking this to mean scientific consensus and refer you to our CWF activity hub section of our website. Please see the evidence based organisations link and also please follow the international link here http://www.rph.org.nz/content/40bbc769-c358-4abe-bd3f-c3d02c25b782.html to the link 'fluoride in drinking water" http://www.who.int/water_sanitation_health/publications/fluoride_drinking_water/en/ a comprehensive WHO discussion on the pros and cons of fluoride in water around the world. You may also find the brief outline at the 'Inadequate or excess fluoride' http://www.who.int/ipcs/assessment/public_health/fluoride/en/ very informative.

Regarding *"Thirdly, and this is an aspect of the mechanism of action, New Health would like NFIS to explain how fluoridation actually provides benefit against tooth decay and how it operates to reduce health inqualities"*.

NFIS are not the expert body for discussing the mechanisms of fluoride action and New Health New Zealand may well find it useful to refer this question to the Faculty of Dentistry at the University of Otago. However this brief article on our website may be of use regarding the basics of the mechanisms of fluroride for dental health http://www.rph.org.nz/content/f69b09b6-47f0-4b40-9a78-3e5284906966.cmr.

Regarding *"how it operates to reduce health inequalities"* we are also not the experts in the broader field of public health dentistry and would again refer New Health New Zealand to the Faculty of Dentistry. However you may find our advisory 'A review of the current cost benefit of community water fluoridation interventions' http://www.rph.org.nz/content/d49e7586-71fe-4503-97d3-1a352f266aaf.cmr a useful starting point in this regards.

Regarding *"It is New Health's understanding that the fluoride in water fluoridation cannot penetrate a plaque layer of more that 50 microns and that such a thickness is formed quite soon after toothbrushing. Is this correct?"* We would again recommend that you follow up with our colleagues at the Faculty of Dentistry as our core business is to provide information based on our reviews of the ongoing science relevant to water fluoridation in New Zealand (please refer to links provided above) not to provide information on all of the biochemical and physiological mechanims of fluoride in the oral environment. However please see this link to our our letter to the editor http://www.rph.org.nz/content/780d0e61-3cc2-4f50-8cce-2b474f2e3b01.cmr on our Media page under NFIS Letters to the Editor Waikato Times 29 October 2013, for a brief discussion on this topic.

Regarding *"A meeting is proposed either on Thursday 20 or Friday 21 February 2014 at a time and place convenient to you"*. Having provided answers to all of the specific questions in your letter we are satisfied that there is no need for us to meet with you and your clients personally. However if you have further scientific queries relating to our ongoing review of the science relevant to community water fluoridation in New Zealand we are happy to help you. Please note that we publish all of work on our website www.NFIS.org.nz . As well as the specific links provided above you will find much there to read which will be of interest to you and your clients.

Warm Regards,
Emmeline Haymes

Coordinator
National Fluoridation Information Service
Regional Public Health
Hutt Valley DHB

Appendix one

National Fluoridation Information Service
Draft Terms of Reference
Working with the Ministry of Health

These draft TOR set out how the National Fluoridation Information Service will interact with the Ministry of Health in providing independent robust critical review of the science and safety of water fluoridation relevant to the New Zealand fluoridation environment.

1. All communications will be made via the NFIS co-ordinator/ through the NFIS email address nfis@huttvalleydhb.org.nz .

2. Feedback on NFIS documents from the MoH will be face to face, whenever possible, with initial communication re receipt no more than one week after submission. Final feedback dates will be negotiated dependent on the length and complexity of the document.

3. Acknowledgement – in writing – of areas identified by the consortium for new research and implications for the Ministry's fluoridation policy (identified via the scientific review of papers for the six month review and in the preparation of advisory documents or statements), will be given to NFIS by the Ministry alongside final feedback on document content.

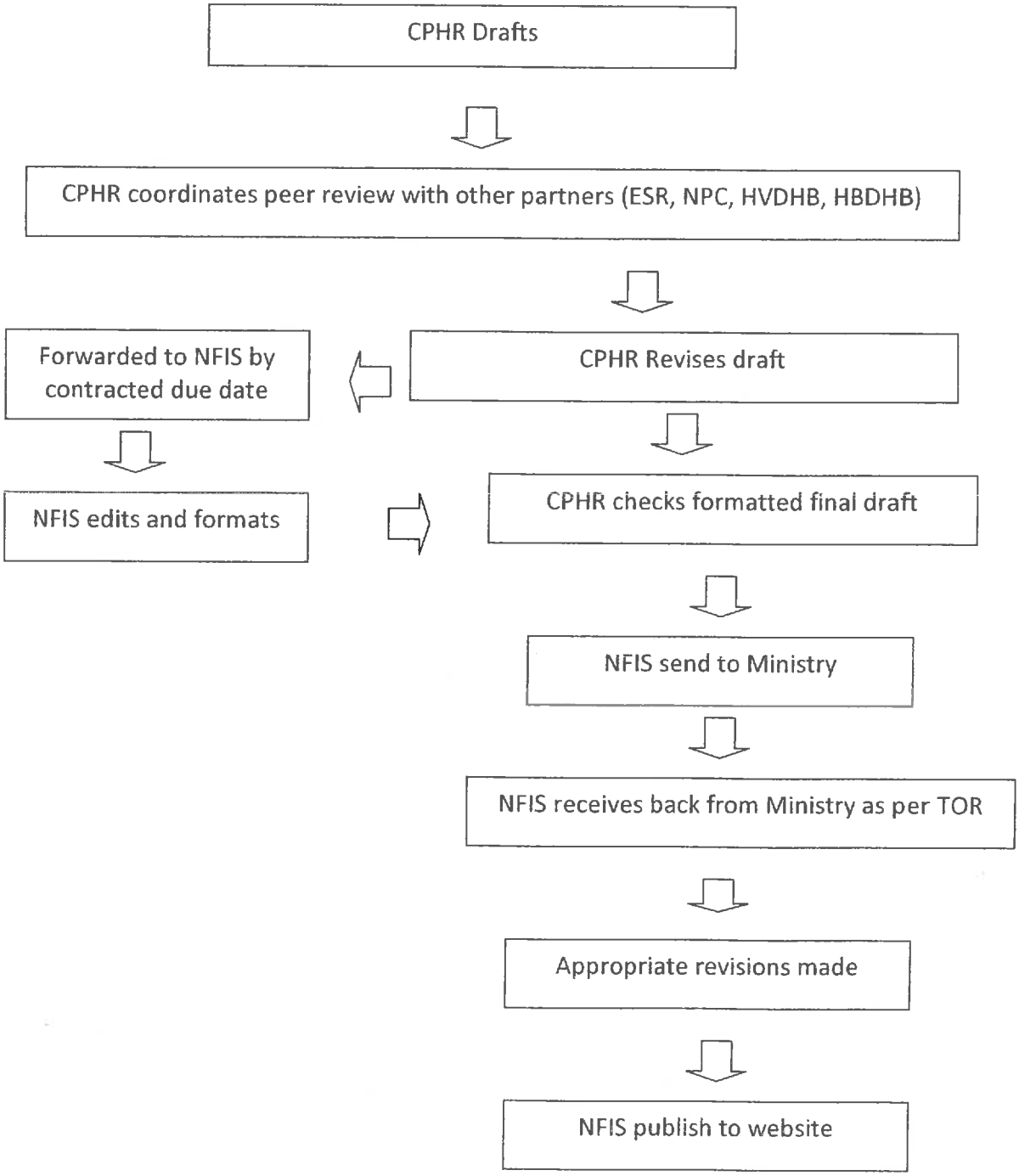
4. In general the Steering Group shall decide the priority and order of tasks required to fulfil contract obligations (clarified as per the service Annual Plan), however the MoH may from time to time elect for new pieces of work to be given top priority if or when needed. This will be negotiated with the consortium considering timeframes and budget available for completion of the tasks identified. The annual plan will adjusted accordingly including the removal of tasks to accommodate new priorities and/or the re-allocation of tasks to the following financial year.

5. Acknowledgement and response from the Ministry regarding relevant identified areas of research and policy implications will be made public via its own website as considered appropriate by the Ministry.

6. Promotion of the Ministry's water fluoridation policy will be carried out by the Ministry and/or DHBs.

Appendix two

National Fluoridation Information Service
Six Month Review Peer Review & Editing Process



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LISA HANSEN
BA(Hons)LLB(Hons) Otago
BARRISTER

12 March 2014

COPY

Emmeline Haymes
NFIS
Regional Public Health
Private Bag 31907
LOWER HUTT 5040

By email: emmeline.haymes@huttvalleydhb.org.nz

Dear Emmeline

Your letter of 6 March 2014

1. Thank you for your letter. The information you referred me to by way of weblinks was helpful (albeit comprising approximately 900 pages which I have now reviewed).

2. However, your response did not really sufficiently address the issues I raised.

3. My request regarding an assurance that minds are indeed open was met with a list of NFIS Reviews from 2000. **Is there some reason you declined to expressly reassure my client about NFIS's objectivity?**

4. In my letter of 19 December 2013 (incorrectly dated 2012) I asked the following questions, neither of which you have addressed.

    1. **Has NFIS accepted Komarek's 2005 study[1] that there is an approximately one year delay in tooth eruption due to fluoridation, and that this varies between individuals, possibly on a genetic basis. Further once the delay in eruption is adjusted for, there is no difference in tooth decay rates. What other scientific studies for and against the proposition of delayed tooth eruption has the NFIS considered, and either accepted or rejected? Does the NFIS consider the Komarek study to be as good, better, or worse than those studies?**

[1] *A Bayesian analysis of multivariate doubly-interval-censored dental data* Biostatistics (2005) 6 1 pp 145-155

2. **Does NFIS accept the recent analysis done by the National Institute of Environmental Health Sciences which showed that children in high fluoride areas had significantly lower IQ scores that those who lived in low fluoride areas.[2] How does NFIS believe the doses in those studies compare with the 3 mg/day accepted by the Ministry of Health as applying in fluoridated communities in NZ.**

5. The NFIS Review of Scientific Studies from January 2000 to July 2010 does not appear to have considered Komarek. That seems surprising because the study would qualify for inclusion under the NFIS criteria that you have referred me to. **Can you please explain why it wasn't considered.**

6. By way of contrast the IQ study is considered in the Review of Scientific Papers published between January and June 2013.

7. **Can you please provide a substantive response to my questions**. It would be helpful when addressing the second issue if consideration could be given to the largely ignored concern that fluoridation does not control for dose. It seems surprising that studies where the concentration of fluoride is higher are simply dismissed as irrelevant on the basis of a higher concentration. Many people who consume high amounts of water may be getting similar amounts of fluoride to those in higher concentration areas as identified by the US NRC Review.

8. NFIS, to its credit ,seems to be very cognisant of the issue of infants and babies overdosing on fluoride and being exposed to a high risk of fluorosis. **Why isn't this concern extrapolated into adults who may consume high amounts of water?**

9. Your response to the issue I raised about mechanism of action is perturbing. You say that NFIS is not the expert body for discussing the mechanisms of fluoride action and you refer my client to the Faculty of Dentistry at Otago University.

10. New Health struggles to understand how NFIS can properly perform its role without an understanding of the mechanism of action. Unless NFIS is satisfied that there is cogent evidence to support the biochemical and physiological mechanisms of fluoride then it is really accepting on blind faith studies that purport to show a link between fluoridation and dental caries reduction.

11. Your statement is also at odds with the fact that in each of the Reviews there is a section dealing with the mechanism of action. The latest statement which appears to have been in all Reviews says this:

> *It is now generally accepted that the main actions by which fluoride acts to protect dental enamel are through remineralisation and the inhibition of demineralisation. Exposure of the enamel surface of the post-eruptive tooth (a tooth exposed through the gum) to fluoride is of greatest importance in creating a surface resistant to acids formed by bacteria. The beneficial effects of the*

[2] *Developmental Fluroide Neurotoxicity: A Systematic Review and Meta-Analysis*, Environmental Health Perspectives

post-eruptive interaction of fluoride with teeth have been well demonstrated by epidemiological studies. A constant low level of fluoride in the oral cavity assists the post-eruptive protective mechanism. The application of fluoride to the surface of the tooth to improve its resistance to caries, by using toothpaste or fluoride varnish, is termed topical application.

The ingestion of fluoride is a means by which fluoride can gain access to the pre-eruptive tooth (ie prior to the tooth being exposed through the gum). This is termed systemic application. Although the post-eruptive effect of fluoride is well accepted, the pre-eruptive effects of fluoride on the tooth, and the extent to which this influences resistance to caries is still under debate.

Community Water fluoridation (CWF) provides a mechanism by which fluoride can reach the tooth both topically and systemically. In particular it provides a means by which a constant low level of fluoride can be sustained in the oral cavity.

Evaluating the relative contributions of the pre- and post-eruptive action of fluoride is extremely difficult, but irrespective of their relative importance, fluoridated water helps to ensure constant exposure to low concentrations of fluoride.

Excessive exposure of the tooth to fluoride during the pre-eruptive stage of enamel formation causes hypomineralisation of the enamel, known as enamel fluorosis.

12. This statement is interesting as I am not aware of what debate exists about systemic pre-eruptive benefit. **Can you please elaborate and explain what the current research is?** My understanding was that the Ministry accepted that fluoride works exclusively topically.

13. Also New Health's understanding is that fluoridation does not make tooth enamel more resistant to decay, as confirmed by the CDC and research on shark's teeth.

14. Rather than referring me to the Otago Dental School, can you please address the following two paragraphs:

    a. **New Health understands that in order to provide protection against tooth decay there needs to be a sufficient concentration of fluoride in the oral cavity to have a topical effect. New Health understands that the concentration of fluoride in water fluoridation is too low to provide any cariostatic effect. Is that correct? If not please provide evidence of studies you rely on to assert the contrary.**

    b. **Further, fluoridation is aimed at assisting those people who have a poor diet and who do not regularly use a toothbrush. Can you please explain just how the fluoride in water fluoridation is able to be effective for a person who does not clean their teeth. It is New Health's understanding that the fluoride in water fluoridation cannot penetrate a plaque layer for more than a short time after brushing, and could never penetrate the plaque layer of the teeth of individuals who do not brush. Is this correct? If not please provide evidence of studies you rely on to show just how fluoridation is effective for those populations with poor diet and poor oral hygiene.**

15. There is one final question New Health would like a response to.

16. **Under what circumstances would NFIS consider recommending that fluoridation cease?**

17. I have highlighted the specific questions in bold to ensure they are clear.

18. When replying can you please not answer by referring me to weblinks. While these may be referred to in order to support a response, please provide a substantive response in the text of the letter.

19. I look forward to a reasonably prompt response.

Yours sincerely

Lisa Hansen

Lisa Hansen

From: Emmeline Haymes [HVDHB]
Sent: Thursday, 13 March 2014 12:59 p.m.
To: 'Lisa Hansen'
Cc: Richard Schmidt [HVDHB]; Peter Gush [HVDHB]; Toby Regan [HVDHB]
Subject: RE: Response to your letter of 6 March 2014
Attachments: ResponsefromLHansen2014pdf.pdf

I would appreciate meeting with you Richard and Peter before beginning to draft a response. I note that these queries are all addressed as coming from Lisa herself rather than on behalf of her client. As such I think any response should be considered to be of similar priority to any response to a private individual as per our contract.

Emmeline Haymes | National Coordinator | National Fluoridation Information Service |Systems Quality and Information Team| Regional Public Health

Phone (04) 587 2815
Mobile (0)27 487 5716
.vw.NFIS.org.nz

From: Lisa Hansen [mailto:l.hansen@barristerscomm.com]
Sent: Wednesday, 12 March 2014 12:01 p.m.
To: Emmeline Haymes [HVDHB]
Cc: Richard Schmidt [HVDHB]; Peter Gush [HVDHB]; Toby Regan [HVDHB]
Subject: Response to your letter of 6 March 2014

Dear Emmeline

Thank you for your letter. A response is attached.

Kind regards
Lisa

Lisa Hansen
Barrister
Phone 64-4-914 1052
Fax 64-4-473 3179
Mobile 021 024 13822
Email l.hansen@barristerscomm.com
Website www.barristerscomm.com
L.8, Wakefield House, 90 The Terrace
PO Box 8045, Wellington 6143

BARRISTERS@COMM

From: Emmeline Haymes [HVDHB] [mailto:Emmeline.Haymes@huttvalleydhb.org.nz]
Sent: Friday, 7 March 2014 12:45 p.m.

Lisa Hansen

From: Lisa Hansen
Sent: Thursday, 13 March 2014 2:05 p.m.
To: 'Emmeline Haymes [HVDHB]'
Cc: 'Richard Schmidt [HVDHB]'; 'Peter Gush [HVDHB]'; 'Toby Regan [HVDHB]'
Subject: RE: Response to your letter of 6 March 2014

Dear Emmeline

I am astonished and somewhat disconcerted by your email. It should be abundantly clear that I am writing to you on behalf of New Health as their lawyer. I am not writing as a private individual – although why it should make any difference to the priority you give to providing a response is surprising.

Kind regards
Lisa

From: Emmeline Haymes [HVDHB] [mailto:Emmeline.Haymes@huttvalleydhb.org.nz]
Sent: Thursday, 13 March 2014 12:59 p.m.
To: 'Lisa Hansen'
Cc: Richard Schmidt [HVDHB]; Peter Gush [HVDHB]; Toby Regan [HVDHB]
Subject: RE: Response to your letter of 6 March 2014

I would appreciate meeting with you Richard and Peter before beginning to draft a response. I note that these queries are all addressed as coming from Lisa herself rather than on behalf of her client. As such I think any response should be considered to be of similar priority to any response to a private individual as per our contract.

Emmeline Haymes | National Coordinator | National Fluoridation Information Service | Systems Quality and Information Team | Regional Public Health

Phone (04) 587 2815
Mobile (0)27 487 5716
www.NFIS.org.nz

From: Lisa Hansen [mailto:l.hansen@barristerscomm.com]
Sent: Wednesday, 12 March 2014 12:01 p.m.
To: Emmeline Haymes [HVDHB]
Cc: Richard Schmidt [HVDHB]; Peter Gush [HVDHB]; Toby Regan [HVDHB]
Subject: Response to your letter of 6 March 2014

Dear Emmeline

Thank you for your letter. A response is attached.

Kind regards
Lisa

Lisa Hansen
Barrister
Phone 64-4-914 1052
Fax 64-4-473 3179
Mobile 021 024 13822

Lisa Hansen

From: Peter Gush [HVDHB]
Sent: Friday, 14 March 2014 12:30 p.m.
To: Lisa Hansen
Cc: Richard Schmidt [HVDHB]; Toby Regan [HVDHB]; Emmeline Haymes [HVDHB]
Subject: RE: Response to your letter of 6 March 2014

Dear Lisa

Thank you for your emails yesterday and today following on from Emmeline's honest mistake in including you in an email which she had intended for internal distribution only.

Emmeline's intention had been to seek advice regarding her preparation of our response, it is indeed regrettable that you were included in the email, and for that I apologise. Personally I do not see this mistake as something which should in any way cause you or your client any concern regarding NFIS's ability to respond to enquiries in a professional and timely way.

ıd regards
Peter

Peter Gush | Service Manager | Regional Public Health

Phone (04) 570 9499
Mobile (0)274 416 258
www.rph.org.nz

From: Lisa Hansen [mailto:l.hansen@barristerscomm.com]
Sent: Friday, 14 March 2014 9:42 a.m.
To: Emmeline Haymes [HVDHB]
Cc: Richard Schmidt [HVDHB]; Peter Gush [HVDHB]; Toby Regan [HVDHB]
Subject: Re: Response to your letter of 6 March 2014

ɔear Emmeline

ıy client wishes to put on the record its concern that your email yesterday puts in issue whether NFIS is capable of responding to its enquiries in a professional and timely way.

It hopes, however, that its misgivings are not borne out.

Kind regards

Lisa Hansen

Sent from my iPhone

Lisa Hansen

From: Lisa Hansen
Sent: Friday, 14 March 2014 12:44 p.m.
To: Peter Gush [HVDHB]
Cc: Richard Schmidt [HVDHB]; Toby Regan [HVDHB]; Emmeline Haymes [HVDHB]
Subject: Re: Response to your letter of 6 March 2014

Dear Peter

Thank you for your response and reassurance.

Kind regards
Lisa Hansen

Sent from my iPhone

On 14/03/2014, at 12:29 PM, "Peter Gush [HVDHB]" <Peter.Gush@huttvalleydhb.org.nz> wrote:

> Dear Lisa
>
> Thank you for your emails yesterday and today following on from Emmeline's honest mistake in including you in an email which she had intended for internal distribution only.
>
> Emmeline's intention had been to seek advice regarding her preparation of our response, it is indeed regrettable that you were included in the email, and for that I apologise. Personally I do not see this mistake as something which should in any way cause you or your client any concern regarding NFIS's ability to respond to enquiries in a professional and timely way.
>
> Kind regards
> Peter
>
> **Peter Gush | Service Manager | Regional Public Health**
>
> Phone (04) 570 9499
> Mobile (0)274 416 258
> www.rph.org.nz
>
>
>
> ---
>
> **From:** Lisa Hansen [mailto:l.hansen@barristerscomm.com]
> **Sent:** Friday, 14 March 2014 9:42 a.m.
> **To:** Emmeline Haymes [HVDHB]
> **Cc:** Richard Schmidt [HVDHB]; Peter Gush [HVDHB]; Toby Regan [HVDHB]
> **Subject:** Re: Response to your letter of 6 March 2014
>
> Dear Emmeline
>
> My client wishes to put on the record its concern that your email yesterday puts in issue whether NFIS is capable of responding to its enquiries in a professional and timely way.
>
> It hopes, however, that its misgivings are not borne out.
>
> Kind regards

Lisa Hansen

From: Lisa Hansen
Sent: Tuesday, 6 May 2014 2:56 p.m.
To: 'emmeline.haymes@huttvalleydhb.org.nz'
Cc: 'Richard Schmidt'
Subject: Query

Dear Emmeline

I refer to my letter of 12 March 2014 on behalf of New Health NZ Inc.

A response appears to be overdue.

Can you please provide a full reply to all of the issues raised by no later than **Friday 9 May 2014**.

Many thanks

Kind regards
Lisa

Lisa Hansen
Barrister
Phone 64-4-914 1052
Fax 64-4-473 3179
Mobile 021 024 13822
Email l.hansen@barristerscomm.com
Website www.barristerscomm.com
L.8, Wakefield House, 90 The Terrace
PO Box 8045, Wellington 6143

Lisa Hansen

From: Emmeline Haymes [HVDHB]
Sent: Tuesday, 6 May 2014 3:06 p.m.
To: 'Lisa Hansen'
Cc: Toby Regan [HVDHB]; Peter Gush [HVDHB]
Subject: RE: Query

Hi Lisa, I no longer work for NFIS, I have forwarded your email to the appropriate people and trust you will hear from them shortly.

Regards,
Emmeline

Emmeline Haymes Nutritionist (Reg.) | Public Health Advisor| Healthy Communities | Regional Public Health

Phone (04) 570 9193
www.rph.org.nz

From: Lisa Hansen [mailto:l.hansen@barristerscomm.com]
Sent: Tuesday, 6 May 2014 2:56 p.m.
To: Emmeline Haymes [HVDHB]
Cc: Richard Schmidt [HVDHB]
Subject: Query

Dear Emmeline

I refer to my letter of 12 March 2014 on behalf of New Health NZ Inc.

A response appears to be overdue.

Can you please provide a full reply to all of the issues raised by no later than **Friday 9 May 2014**.

Many thanks

Kind regards
Lisa

Lisa Hansen
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BARRISTERS@COMM

6 May 2014

Lisa Hansen
Barristers.Comm
PO Box 8045
Wellington 6143

Dear Lisa

Response to letter 'Your letter of 6 March 2014' dated 12 March 2014.

I am responding to your second letter to Emmeline Haymes written on behalf of New Health New Zealand Inc.

A description of the role of NFIS is provided on the NFIS website (www.NFIS.org.nz):

- Provide a central authoritative, accurate and up-to-date source of information and critical commentary on research pertaining to water fluoridation
- Provide coordinated clinical and technical support and advice to district health boards, territorial local authorities and the Ministry of Health
- Ensure district health boards and the Ministry of Health are able to communicate consistent, accurate and up to date information on water fluoridation
- Follow public discussion and decision making on water fluoridation.

NFIS fulfils this role by:

- Providing a centralised website portal to data and research on dental health and water fluoridation in New Zealand
- Providing up to date critical review of emerging research related to water fluoridation
- Sharing information via quarterly e-newsletters and e-briefings
- Supporting and providing clinical and technical advice to district health boards and territorial local authorities around water fluoridation.

NFIS endeavours to respond to members of the public's requests for information as time permits though this is not their core business. However they make every effort to ensure that all of their work is freely available on the NFIS website, hence the links included for you in the previous reply.

Regarding your request for assurance of the open mindedness of NFIS, the links were included to the sections of the six monthly reviews where NFIS have previously made recommendations to the Ministry of Health in relation to their policy on community water fluoridation. NFIS will continue to make recommendations based on the scientific evidence reviewed in each six monthly period.

Yours sincerely,

Peter Gush
Service Manager

Lisa Hansen

From: Lisa Hansen
Sent: Friday, 9 May 2014 8:25 a.m.
To: 'peter.gush@huttvalleydhb.org.nz'
Subject: Letter attached
Attachments: SKMBT_C36014050818321.pdf

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LISA HANSEN
BA(Hons)LLB(Hons) Otago
BARRISTER

9 May 2014

Peter Gush
Service Manager
Regional Public Health
Private Bag 31907
LOWER HUTT 5040

By email: peter.gush@huttvalleydhb.org.nz

Dear Peter

Your letter of 6 May 2014

1. Thank you for your letter.

2. It is clearly not a response to the questions I raised (on behalf of New Health NZ Inc) in my letters of 12 March 2014 and 19 December 2013.

3. NFIS's role is to provide an authoritative, accurate, and up-to-date source of information and critical commentary on research relating to water fluoridation.

4. If NFIS was fulfilling its role, responding substantively to my questions should be relatively straightforward.

5. Because NFIS is part of the Hutt Valley DHB it is subject to the Official Information Act 1982. New Health's enquiries ought to have been dealt with under this Act and responded to within 20 working days.

6. This timeframe has been significantly exceeded and to date incomplete responses have been provided.

7. Please fully respond to each of the questions I raised in my letter of 12 March by no later than **Friday 23 May 2014**.

Yours sincerely

Lisa Hansen

Lisa Hansen

6 I 7

THIS is the Exhibit marked with the letter. I
referred to in the annexed affidavit of
PATRICK DAVID SLOAN
AFFIRMED ~~SWORN~~ at CHRISTCHURCH
this 28 day of July 2014 before me:

A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

In addition to the Choi et al (2010) there are many other studies indicating that fluoride impacts both animal and human brain. Here is a sampling organized by category:

Set 1: Animal Studies – Adverse Effects on Brain (a non-exhaustive list)

Sarkar C, et al. (2014). Ameliorative effects of oleanolic acid on fluoride induced metabolic and oxidative dysfunctions in rat brain: Experimental and biochemical studies. Food Chem Toxicol. 66:224-36.

Qian W, et al. (2013). Effect of selenium on fluoride-induced changes in synaptic plasticity in rat hippocampus. Biol Trace Elem Res. 2013 Aug 21. [Epub ahead of print]

Lou DD, et al. (2013). The influence of chronic fluorosis on mitochondrial dynamics morphology and distribution in cortical neurons of the rat brain. Arch Toxicol. 87(3):449-57.

Zhu W, et al. (2011). Effects of fluoride on synaptic membrane fluidity and PSD-95 expression level in rat hippocampus. Biol Trace Elem Res. 139(2):197-203.

Liu YJ, et al. (2011). Increased level of apoptosis in rat brains and SH-SY5Y cells exposed to excessive fluoride–a mechanism connected with activating JNK phosphorylation. Toxicol Lett. 204(2-3):183-9.

Ge Y, et al. (2011). Proteomic analysis of brain proteins of rats exposed to high fluoride and low iodine. Arch. Toxicol. 85:27-33.

Liu YJ, et al. (2010). Alterations of nAChRs and ERK1/2 in the brains of rats with chronic fluorosis and their connections with the decreased capacity of learning and memory. Toxicol Lett. 192(3):324-9.

Shan KR, Qi XL, Long YG, Wang YN, Nordberg A, Guan ZZ. (2004). Decreased nicotinic receptors in PC12 cells and rat brains influenced by fluoride toxicity—a mechanism relating to a damage at the level in post-transcription of the receptor genes. Toxicology 200: 169–177.

Chen J, Shan KR, Long YG, Wang YN, Nordberg A, Guan ZZ. (2003). Selective decreases of nicotinic acetylcholine receptors in PC12 cells exposed to fluoride. Toxicology 183: 235-42.

Shashi A. (2003). Histopathological investigation of fluoride-induced neurotoxicity in rabbits. Fluoride 36: 95-105.

Long YG, Wang YN, Chen J, Jiang SF, Nordberg A, Guan ZZ. (2002). Chronic fluoride toxicity decreases the number of nicotinic acetylcholine receptors in rat brain. Neurotoxicology and Teratology 24:751-7.

Bhatnagar M, et al. (2002). Neurotoxicity of fluoride: neurodegeneration in hippocampus of female mice. Indian Journal of Experimental Biology 40: 546-54.

Shivarajashankara YM , et al. (2002). Brain lipid peroxidation and antioxidant systems of young rats in chronic fluoride intoxication. Fluoride 35: 197-203.

Guan ZZ, Wang YN, Xiao KQ, Dai DY, Chen YH, Liu JL, Sindelar P, Dallner G. (1998). Influence of chronic fluorosis on membrane lipids in rat brain. Neurotoxicology and Teratology 20: 537-542.

Varner JA, et al. (1998). Chronic administration of aluminum-fluoride and sodium-fluoride to rats in drinking water: Alterations in neuronal and cerebrovascular integrity. Brain Research 784: 284-298.

Issacson R, et al. (1997). Toxin-induced blood vessel inclusions caused by the chronic administration of aluminum and sodium fluoride and their implications for dementia. Annals of the New York Academy of Science 825: 152-166.

Set 2: Animal Studies – Learning/Memory

Han H, et al. (2014). Effects of chronic fluoride exposure on object recognition memory and mRNA expression of SNARE complex in hippocampus of male mice. Biological Trace Element Research [Epub ahead of print]

Liu F, et al. (2014). Fluoride exposure during development affects both cognition and emotion in mice. Physiology & Behavior 124:1-7.

Jiang C, et al. (2014). Low Glucose Utilization and Neurodegenerative Changes Caused by Sodium Fluoride Exposure in Rat's Developmental Brain. Neuromolecular Medicine 16(1):94-105.

Jetti R, et al. (2013). Protective effect of ascorbic acid and Ginkgo biloba against learning and memory deficits caused by fluoride. Toxicology and Industrial Health. 2013 Sep 30. [Epub ahead of print]

Zhang C, et al. (2013). The analog of ginkgo biloba extract 761 is a protective factor of cognitive impairment induced by chronic fluorosis. Biological Trace Element Research 153:229-36.

Liu CB, et al. (2013). [Effect of lycopene on oxidative stress and neurobehavior in mouse exposed to drinking water fluorosis]. [Chinese]. Chinese Public Health.

Chen H, Deng G. (2012). [The establishment and assessment of animal model of chronic fluorosis-induced cognitive dysfunction in rats]. Acta Academiae Medicinae Xuzhou 31(5):319-22.

Basha PM, Sujitha NS (2012). Combined impact of exercise and temperature in learning and memory performance of fluoride toxicated rats. Biological Trace Element Research 150:306-13.

Balaji B, et al. (2012). Evaluation of standardized Bacopa monniera extract in sodium fluoride induced behavioural, biochemical, and histopathological alterations in mice. Toxicology and Industrial Health. 2012 Dec 6. [Epub ahead of print]

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Pereira M, et al. (2011). Memory impairment induced by sodium fluoride is associated with changes in brain monoamine levels. Neurotox Res. 19(1):55-62.

Basha PM, et al. (2011). Fluoride toxicity and status of serum thyroid hormones, brain histopathology, and learning memory in rats: a multigenerational assessment. Biol Trace Elem Res. 144(1-3):1083-94.

Gui CZ, et al. (2010). Changes of learning and memory ability and brain nicotinic receptors of rat offspring with coal burning fluorosis. Neurotoxicol Teratol. 32(5):536-41.

El-Lethey H, et al. (2010). Neurobehavioral toxicity produced by sodium fluoride in drinking water of laboratory rats. Journal of American Science 6:54-63

Liu YJ, et al. (2010). Alterations of nAChRs and ERK1/2 in the brains of rats with chronic fluorosis and their connections with the decreased capacity of learning and memory. Toxicol Lett. 192(3):324-9.

Bai J, et al. (2010). [Learning and memory obstacles and changes in brain tissue growth inhibitors from brick tea fluoride and aluminum poisoning of rats]. [Chinese]. Chinese Journal of Control of Endemic Diseases 25(3):161-63.

Gao Q, et al. (2009). Decreased learning and memory ability in rats with fluorosis: increased oxidative stress and reduced cholinesterase activity in the brain. Fluoride 42(4):277-85.

Gao Y, et al. (2009). [Effects of learning and memory of fluoride and the antagonism of selenium in rat]. [Chinese]. Studies of Trace Elements and Health 26(2).

Zhang J, et al. (2009). The effect of fluorine exposure of pregnant rats on the learning and memory capabilities of baby rats. Chinese Journal of Public Health 25(11):1347-48.

Niu R, et al. (2009). Decreased learning ability and low hippocampus glutamate in offspring rats exposed to fluoride and lead. Environ Toxicol Pharmacol. 28(2):254-8.

Chioca LR, et al. (2008). Subchronic fluoride intake induces impairment in habituation and active avoidance tasks in rats. European Journal of Pharmacology 579(1-3):196-201.

Wang G, et al. (2006). [Effect of different doses of chronic exposure of fluoride on rat learning and memory behavior]. [Chinese]. Studies of Trace Elements & Health 23(2):1-2.

Hong J, et al. (2005). [Effects of high fluoride and low iodine on learning-memory and TchE of brain in offspring rats.] [Chinese]. China Preventive Medicine (6):489-91.

Wang J, et al. (2004). Effects of high fluoride and low iodine on biochemical indexes of the brain and learning-memory of offspring rats. Fluoride 37: 201-208.

Shen X, et al. (2004). [Effect of iodine and selenium on learning memory impairment induced by fluorosis and blood biochemical criterion of rats]. [Chinese]. Occupation & Health 20(1):6-8.

Bhatnagar M, et al. (2002). Neurotoxicity of fluoride: neurodegeneration in hippocampus of female mice. Indian Journal of Experimental Biology 40: 546-54.

Xu X, et al. (2001). [Effect of fluorosis on mice learning and memory behaviors and brain SOD activity and MDA content]. [Chinese]. China Public Health 17(1):8-10.

Zhang Z, et al. (2001). Effects of selenium on the damage of learning-memory ability of mice

Sun ZR, et al. (2000). Effects of high fluoride drinking water on the cerebral functions of mice. Chinese Journal of Epidemiology 19: 262-263.

Zhang Z, et al. (1999). Effect of fluoride exposure on synaptic structure of brain areas related to learning-memory in mice. Journal of Hygiene Research 28(4):210-2. (Republished in Fluoride 2008; 41:139-43.

Set #4: Human Studies – IQ Loss

Trivedi MH, et al. (2012). Assessment of groundwater quality with special reference to fluoride and its impact on IQ of schoolchildren in six villages of the Mundra Region, Kachchh, Gujurat, India. Fluoride 45(4):377-83.

Zhang X. (2012). Studies of relationships between the polymorphism of COMT gene and plasma proteomic profiling and children's intelligence in high fluoride areas. Master's Dissertation, Huazhong University of Science & Technology, May 2012.

Seraj B, et al. (2012). Effect of high water fluoride concentration on the intellectual development of children in Makoo/Iran. Journal of Dentistry, Tehran University of Medical Sciences. 9(3): 221-29.

Saxena S, et al. (2012). Effect of fluoride exposure on the intelligence of school children in Madhya Pradesh, India. *Journal of Neurosciences in Rural Practice* 3(2):144-49.

Ding Y, et al. (2011). The relationships between low levels of urine fluoride on children's intelligence, dental fluorosis in endemic fluorosis areas in Hulunbuir, Inner Mongolia, China. *Journal of Hazardous Materials* 186(2-3):1942-46.

Poureslami HR, et al. (2011). Intelligence quotient of 7 to 9 year-old children from an area with high fluoride in drinking water. *Journal of Dentistry and Oral Hygiene* 3(4):61-64.

Eswar P, et al. (2011). Intelligent quotients of 12-14 year old school children in a high and low fluoride village in India. *Fluoride* 44:168-72.

Shivaprakash PK, et al. (2011). Relation between dental fluorosis and intelligence quotient in school children of Bagalkot district. *J Indian Soc Pedod Prev Dent.* 29(2):117-20.

Li F, et al. (2009). The impact of endemic fluorosis caused by the burning of coal on the development of intelligence in children. *Journal of Environmental Health* 26(4):838-40.

Rocha-Amador D, et al. (2007). Decreased intelligence in children and exposure to fluoride and arsenic in drinking water. *Cadernos de Saude Publica* 23(Suppl 4):S579-87.

Wang SX, et al. (2007). Arsenic and fluoride exposure in drinking water: children's IQ and growth in Shanyin county, Shanxi province, China. *Environmental Health Perspectives* 115(4):643-7.

Trivedi MH, et al. (2007). Effect of high fluoride water on intelligence of school children in India. *Fluoride* 40(3):178-183.

Fan Z, et al. (2007). The effect of high fluoride exposure on the level of intelligence in children. *Journal of Environmental Health* 24(10):802-03.

Seraj B, et al. (2006). [Effect of high fluoride concentration in drinking water on children's intelligence]. [Study in Persian] *Journal of Dental Medicine* 19(2):80-86.

Wang S, et al. (2005). The effects of endemic fluoride poisoning caused by coal burning on the physical development and intelligence of children. *Journal of Applied Clinical Pediatrics* 20(9):897-898 (republished in *Fluoride* 2008; 41:344-348).

Xiang Q, et al. (2003a). Effect of fluoride in drinking water on children's intelligence. *Fluoride* 36: 84-94.

Li Y, et al. (2003). Effects of endemic fluoride poisoning on the intellectual development of children in Baotou. *Chinese Journal of Public Health Management* 19(4):337-338 (republished in *Fluoride* 2008; 41:161-64).

Shao Q, et al. (2003). Study of cognitive function impairment caused by chronic fluorosis. *Chinese Journal of Endemiology* 22(4):336-38.

Wang X, et al. (2001). Effects of high iodine and high fluorine on children's intelligence and thyroid function. *Chinese Journal of Endemiology* 20(4):288-90.

Hong F, et al. (2001). Research on the effects of fluoride on child intellectual development under different environments. *Chinese Primary Health Care* 15(3):56-57 (republished in *Fluoride* 2008; 41(2):156–60).

Lu Y, et al (2000). Effect of high-fluoride water on intelligence of children. *Fluoride* 33:74-78.

Zhang J, et al. (1998). The effect of high levels of arsenic and fluoride on the development of children's intelligence. *Chinese Journal of Public Health* 17(2):119.

Yao Y, et al. (1997). Comparative assessment of the physical and mental development of children in endemic fluorosis area with water improvement and without water improvement. *Literature and Information on Preventive Medicine* 3(1):42-43.

Yao Y, et al. (1996). Analysis on TSH and intelligence level of children with dental Fluorosis in a high fluoride area. *Literature and Information on Preventive Medicine* 2(1):26-27.

Zhao LB, et al. (1996). Effect of high-fluoride water supply on children's intelligence. *Fluoride* 29: 190-192.

Wang G, et al. (1996). A study of the IQ levels of four- to seven-year-old children in high fluoride areas. *Endemic Diseases Bulletin* 11(1):60-6 (republished in *Fluoride* 2008; 41:340–43).

Li XS, et al. (1995). Effect of fluoride exposure on intelligence in children. *Fluoride* 28:189-192.

Duan J, et al. (1995). A comparative analysis of the results of multiple tests in patients with chronic industrial fluorosis. Guizhou Medical Journal 18(3):179-80.

Xu Y, et al. (1994). The effect of fluorine on the level of intelligence in children. *Endemic Diseases Bulletin* 9(2):83-84.

Li Y, et al. (1994). Effects of high fluoride intake on child mental work capacity: Preliminary investigation into the mechanisms involved. *Journal of West China University of Medical Sciences* 25(2):188-91 (republished in *Fluoride* 2008; 41:331-35).

Yang Y, et al. (1994). The effects of high levels of fluoride and iodine on intellectual ability and the metabolism of fluoride and iodine. *Chinese Journal of Epidemiology* 15(4):296-98 (republished in *Fluoride* 2008; 41:336-339).

An J, et al. (1992). The effects of high fluoride on the level of intelligence of primary and secondary students. *Chinese Journal of Control of Endemic Diseases* 7(2):93-94.

Lin Fa-Fu; et al (1991). The relationship of a low-iodine and high-fluoride environment to subclinical cretinism in Xinjiang. *Endemic Disease Bulletin* 6(2):62-67 (republished in *Iodine Deficiency Disorder Newsletter* Vol. 7(3):24-25).

Guo X, et al. (1991). A preliminary investigation of the IQs of 7-13 year old children from an area with coal burning-related fluoride poisoning. *Chinese Journal of Endemiology* 10(2):98-100 (republished in *Fluoride* 2008; 41(2):125–28).

Chen YX, et al. (1991). Research on the intellectual development of children in high fluoride areas. *Chinese Journal of Control of Endemic Diseases* 6(Suppl):99-100 (republished in *Fluoride* 2008; 41:120–24).

Sun M, et al. (1991). Measurement of intelligence by drawing test among the children in the endemic area of Al-F combined toxicosis. *Journal of Guiyang Medical College* 16(3):204-06.

Qin LS, Cui SY. (1990). Using the Raven's standard progressive matrices to determine the effects of the level of fluoride in drinking water on the intellectual ability of school-age children. *Chinese Journal of the Control of Endemic Diseases* 5(4):203-04 (republished in *Fluoride* 2008; 41:115–19).

Ren D, et al. (1989). A study of the intellectual ability of 8-14 year-old children in high fluoride, low iodine areas. *Chinese Journal of Control of Endemic Diseases* 4(4):251 (republished in *Fluoride* 2008; 41:319-20).

Set #4: Human Studies - Other Cognitive Impairments

Yazdi SM, et al. (2011). Effects of fluoride on psychomotor performance and memory of aluminum potroom workers. Fluoride 44:158-62.

Rocha-Amador, D. et al (2009). Use of the Rey-Osterrieth Complex Figure Test for neurotoxicity evaluation of mixtures in children. Neurotoxicology 30(6):1149-54.

Li J, Yao L, Shao Q-L. (2004). Effects of high-fluoride on neonatal neurobehavioural development. Chinese Journal of Endemiology 23:464-465. (Republished in Fluoride 2008; 41:165-70).

Guo Z, et al. (2001). Study on neurobehavioral function of workers occupationally exposed to fluoride. Industrial Health and Occupational Disease 27:346-348. (Republished in Fluoride 2008; 41:152-55).

Calderon J, et al. (2000). Influence of fluoride exposure on reaction time and visuospatial organization in children. Epidemiology 11(4): S153.

Calvert GM, et al. (1990). Health effects associated with sulfuryl fluoride and methyl bromide exposure among structural fumigation workers. Am J Public Health. 88(12):1774-80.

Rotton J, et al. (1983). Behavioral Effects of Chemicals in Drinking Water. Journal of Applied Psychology 67:230-38.

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J

LISA HANSEN
BARRISTER

17 March 2014

THIS is the Exhibit marked with the letter J referred to in the annexed affidavit of PATRICK DAVID SLOAN
AFFIRMED ~~sworn~~ at CHRISTCHURCH this 28 day of July 2014 before me:

MEMorrison
A Solicitor of the High Court of New Zealand

Margaret Elizabeth Morrison
Solicitor
Christchurch

Dr Stewart Jessamine
Ministry of Health

By email: stewart_jessamine@moh.govt.nz

Dear Dr Jessamine

New Health NZ Inc v South Taranaki District Council
High Court Judgment dated 7 March 2014

1. I write on behalf of New Health NZ Inc.

2. You will be undoubtedly aware of the above judgement.

3. There are two aspects of the judgment that are directly relevant to the Medicines Act 1981.

4. First, the judge has held that fluoridation has a therapeutic medical purpose, namely preventing tooth decay (eg paragraph [58] of the decision).

5. On that basis it must follow that the fluoride which is supplied to councils for water fluoridation is a "medicine" under the Medicines Act.

6. A medicine is a substance that is manufactured, imported, sold, or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose. A therapeutic purpose means treating or preventing disease.

7. The fluoride used in water fluoridation (hydrofluorosilicic acid (eg HFA) and sodium silicofluoride (SSF) – both by-products of the superphosphate industry) is sold to and then supplied by Councils to administer to human beings to treat the disease of dental caries.

8. The principal purpose of the sale to and supply by councils of HFA and SSF is to introduce it into the human body through being mixed with the water supply in order to provide protection against dental decay.

9. As a medicine HFA/SSF and any other fluoridating chemicals need to be approved as new medicines under ss 20 to 22 of the Medicines Act and cannot be sold or distributed before that consent is granted.

10. Further the manufacturer of the medicine (the superphosphate industry supplier) requires a licence under Medicines Act: refer s 17.

11. Can you please urgently confirm that unless and until appropriate authorisation is granted under the Medicines Act you will be taking immediate steps to:

    11.1. stop the further sale and supply of these unapproved medicines;

    11.2. ensure that any stocks of these substances held by Councils are recalled.

12. The second aspect of the decision concerns paragraphs [44] to [46].

13. New Health had argued that fluoridated water was a "related product" for the purposes of s 94(1) of the Medicines Act 1981.

14. As you know a "related product" means any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose. There are certain exclusions including medicines.

15. The judge held that water does not constitute a food. In doing so he relied on the decision of *Diet Tea Company Ltd v Attorney-General* that decided that food did not include a beverage such as tea.

16. On its face this finding appears to have implication for the natural medicine industry and the sale of unapproved general sale medicines.

17. For example there appears to be no impediment (at least under the Medicines Act) to the sale of "therapeutic" water, nor to the sale of any other beverage such as coke or tea, which claims to have a therapeutic purpose.

18. On the MedSafe website providing guidance for Natural Health Practitioners in respect of dietary supplements it has a section explaining "What Natural Therapists can't do". In that is says that they can't do things including the following:

    18.1. Display products that are labelled so as to state or imply a therapeutic purpose unless those products have been approved as medicine;

    18.2. Advertise or display product advertising that implies the product has a therapeutic purpose;

    18.3. Supply unapproved medicines to the consumer.

19. Can you please confirm that the "products" which are referred to in the above subparagraphs exclude water and other beverages.

20. I look forward to hearing from you.

Yours sincerely

Lisa Hansen

MEDSAFE
NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY
A BUSINESS UNIT OF
THE MINISTRY OF HEALTH
www.medsafe.govt.nz

19 March 2014

Lisa Hansen
Barristers.Comm
PO Box 8045
WELLINGTON 6143

Dear Lisa

High Court Judgment (7 March 2014) – New Health NZ Inc v South Taranaki District Council

Thank you for your letter dated 17 March 2014 sent by email on behalf of New Health NZ Inc. in relation to the High Court decision in *New Health New Zealand Inc v South Taranaki District Council* (the High Court decision).

At [58], the judgment states that fluoridation has a therapeutic medical objective, but it confirms at [90] and [91] that fluoridation does not come within the purview of medical treatment.

The judge concluded that there is an implied power to fluoridate in the Local Government Act 2002 and that fluoride may be added to drinking water in accordance with the water standards under the Health Act 1956.

Given this conclusion, fluoride sold by the manufacturer to the Council for the purpose of water treatment (being a lawful purpose) is therefore not a medicine under the Medicines Act. That being the case, I am not in a position to require manufacturers of fluoride for water treatment purposes to obtain a licence under that Act.

I do not intend to set out in this letter, the rationale for the Judge's decision on the fluoridation of water as challenged by New Health, as this is adequately set out in that decision.

I am satisfied that the content on the Medsafe website regarding guidance for natural health practitioners in respect of dietary supplements is accurate.

Yours sincerely

Stewart Jessamine
Group Manager
Medsafe

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LISA
BA(Hons)LLB(Hons) Otago HANSEN
BARRISTER

20 March 2014

Dr Stewart Jessamine
Ministry of Health

By email: stewart_jessamine@moh.govt.nz

Dear Dr Jessamine

New Health NZ Inc v South Taranaki District Council
High Court Judgment dated 7 March 2014

1. Thank you for your letter of 19 March 2014.

2. I interpret your response to mean that fluoride is sold "for the purpose of water treatment", that this is not a therapeutic purpose, and therefore the fluoride is not a medicine.

3. With respect, that answer misses the point entirely because it fails to acknowledge why fluoride is being used in the water treatment process.

4. The Standard for the Supply of Fluoride for Use in Water Treatment 1997 put out by the New Zealand Water Supply and Disposal Association (**enclosed**) makes it absolutely clear why the fluoride is being used in water treatment.

5. It says at paragraph 1.4:

> *Fluoride is added to the water supply to reduce the incidence of dental caries.*
> Hydrofluosicilic acid, sodium, fluoride and sodium silicofluoride are the fluoride compounds that are commonly used for this purpose. (emphasis added)

6. As the judge has held, reducing dental decay is a therapeutic purpose.

7. Although the judge held fluoridation wasn't medical treatment for the purpose of s 11 NZ Bill of Rights Act 1990 that does not mean that the fluoridating chemicals are not a medicine. The judge didn't decide that question.

8. Further, even if under the judgment the council is permitted under the Local Government Act and Health Act to add fluoride to the water supply this does not mean that the fluoride compounds are ipso facto exempt from the Medicines Act.

9. If you haven't already seen the Standard I draw it to your attention in its entirety.

10. It explains that the compounds used in fluoridation are by-products of the phosphate industry (paragraph 1.5). It describes hydrofluosicilic acid is described as a "strong, corrosive, pale yellow liquid with a characteristic sour odour" (paragraph 1.6.1). The Standard also notes that the fluoride compounds may contain heavy metals (section 2.3.3) and that fluoride compounds are toxic and should be handled with care (section 3).

11. It is New Health's opinion that when it comes to fluoride, the Ministry of Health suffers from double standards.

12. If MedSafe continues to fail to act, then that must mean that anything used in the water treatment process or added to water generally can never be a medicine. That would appear to give councils and others carte blanche to use unapproved medicines in water.

13. In respect of the second point I raised in my letter of 17 March your answer again, with respect, misses the point. I didn't ask whether the instructions on the website were accurate. I asked whether the instructions applied to water and other beverages.

14. New Health challenges the Ministry of Health to start doing its job. The fluoridation chemicals are sold and supplied wholly and principally for administering to human beings for a therapeutic purpose. They are unquestionably a "medicine" as defined in the Medicines Act 1981 and must be regulated as such.

Yours sincerely

Lisa Hansen

Encl

   d. Other relevant scientific experts...
   e. Lay observer – a respected member of the public
3) Royal Society NZ to convene 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. Identification of issues which cause controversy
   d. Consideration of broader concerns/claims

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 and Sir Peter and Sir David for review and comment
7) The Ministry of Health will also be invited to comment at this stage
8) Final draft report will be peer reviewed by two international experts to be identified by the Expert Panel and vetted by co-Chairs .
9) Peer reviewed report to be submitted to funders (Auckland City Council, Ministry of Health) and made publically accessible online at www.pmcsa.org.nz and www.royalsociety.org.nz

Timeframe

March 18: Project Start
- writer will start supplementary review of the literature
- co-Chairs to agree 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, project chairs and review by Ministry of Health
July 30: Report finalized
August 7: Co-Chairs' cover letter completed
August 15th: Report provided to Ministry of Health and Councils
Aug 22: Report published