1301

Fluoride

askmedsafe 09/01/2015 12:02 p.m.

Cc: j.coleman

History: This message has been replied to.

Dear Medsafe

SUBMISSION ON PROPOSAL THAT HFA AND SSF ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

ANSWER TO QUESTION 1

I oppose the proposed amendment for the following reasons:

1 = No Regulation should be made exempting HFA and SSF from being medicines until the Court of Appeal has determined whether or not HFA and SSF are medicines under the Medicines Act.

2 = If HFA and SSF are medicines they should not be exempt from the Medicines Act.

3 = If HFA and SSF are not medicines there is no need for the exemption.

4 = The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls.

5 = These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance.

6 = If fluoride tablets are not recommended for babies, toddlers and pregnant women, these sub-populations should not be ingesting fluoridated water.

7 = No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed.

8 = Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2: NO.

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

Yours sincerely

SUBMISSION FORM

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

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Dentist
Question 1 *Do you support the proposed amendment? If not, why not?*	Yes, I support the proposed amendment to reclassify Fluoride, when used to adjust the fluoride level in water supplies, as not being a medicine. The use of fluoride in this way, at the quantities used, in my opinion, is a public health measure, not a medicine as meant in the Medicines Act. This conclusion was also reached by Justice Collins last year.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	

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

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

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

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

SUBMISSION

; to: askmedsafe 09/01/2015 12:08 p.m.

History: This message has been replied to.

SUBMISSION FORM

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

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

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

Name:
Email:
Addre:

Question 1. *Do you support the proposed amendment? If not why not? NO*

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

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

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

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

Fluoride

nedsafe

09/01/2015 12:15 p.m.

Cc: j.coleman

Dear Medsafe

SUBMISSION ON PROPOSAL THAT HFA AND SSF ARE NOT MEDICINES FOR THE PURPOSES OF THE MEDICINES ACT WHEN THEY ARE MANUFACTURED AND SUPPLIED OR DISTRIBUTED FOR THE PURPOSE OF FLUORIDATING COMMUNITY WATER SUPPLIES

QUESTION 1: DO YOU SUPPORT THE PROPOSED AMENDMENT? IF NOT, WHY NOT?

ANSWER TO QUESTION 1

I oppose the proposed amendment for the following reasons:

1 = No Regulation should be made exempting HFA and SSF from being medicines until the Court of Appeal has determined whether or not HFA and SSF are medicines under the Medicines Act.

2 = If HFA and SSF are medicines they should not be exempt from the Medicines Act.

3 = If HFA and SSF are not medicines there is no need for the exemption.

4 = The Medicines Act is designed to ensure the safety, quality and efficacy of medicines. HFA and SSF should be subject to these controls.

5 = These controls will ensure that people are not exposed to uncontrolled doses of fluoride from an industrial grade and heavy-metal contaminated fluoride substance.

6 = If fluoride tablets are not recommended for babies, toddlers and pregnant women, these sub-populations should not be ingesting fluoridated water.

7 = No protection against dental decay is provided by swallowing fluoride; consequently HFA and SSF should not be swallowed.

8 = Those people who believe there is a benefit in ingesting fluoride can buy sodium fluoride tablets from a pharmacy.

QUESTION 2: ARE THERE ANY OTHER FLUORIDE-CONTAINING COMPOUNDS USED TO TREAT COMMUNITY WATER SUPPLIES THAT SHOULD BE SPECIFICALLY IN THE REGULATION? IF SO, WHAT ARE THEY?

ANSWER TO QUESTION 2:

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

Yours sincerely

Submission - Proposed Amendment to Regulations under the Medicines Act 1981 - Fluoride (2014) :: I do NOT support amendment

skmedsafe 09/01/2015 12:18 p.m.

Cc: "

Below is my personal submission on the Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)

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

I give permission for my submission (including my name, but not my personal contact details) to be released to persons under the Official Information Act 1982

Name
Emai
Address

Firstly, I wish to refer Medsafe and the New Zealand Health Ministry to Statements from European Health, Water, & Environment Authorities on Water Fluoridation – specifically from Belgium, Finland, France , Germany and the Czech Republic . These official statements can be found since 2007 on the Fluoride Action Network at listed at
http://www.fluoridealert.org/content/europe-statements/
Each of these statements from European countries variously acknowledge that the water fluoridation is a " medicinal treatment " or a " medication "; that water fluoridation is not done in France for ethical and medical reasons, water fluoridation is not done in Germany because it would be compulsory medication and water fluoridation is not done in the Czech Republic because it would be unethical ("forced medication")
These 5 European countries have formally recognized that water fluoridation is either the addition of a medicine/ medication to drinking water, or that it is a medical treatment (by adding a medicine/ medication to drinking water) that is done with the intention of treating people.

Belgium:

"This water treatment has never been of use in Belgium and will never be (we hope so) into the future. The main reason for that is the fundamental position of the drinking water sector that it is not its task to deliver **medicinal treatment** to people. This is the sole responsibility of health services."
SOURCE: Chr. Legros, Directeur, Belgaqua, Brussels, Belgium, February 28, 2000.

Finland:

"We do not favor or recommend fluoridation of drinking water. There are better ways of providing the fluoride our teeth need."

SOURCE: Paavo Poteri, Acting Managing Director, Helsinki Water, Finland, February 7, 2000.

"Artificial fluoridation of drinking water supplies has been practiced in Finland only in one town, Kuopio, situated in eastern Finland and with a population of about 80,000 people (1.6% of the Finnish population). Fluoridation started in 1959 and finished in 1992 as a result of the resistance of local population. The most usual grounds for the resistance presented in this context were an individual's right to drinking water without additional chemicals used for the **medication** of limited population groups. A concept of "force-feeding" was also mentioned.

Drinking water fluoridation is not prohibited in Finland but no municipalities have turned out to be willing to practice it. Water suppliers, naturally, have always been against dosing of fluoride chemicals into water."
SOURCE: Leena Hiisvirta, M.Sc., Chief Engineer, Ministry of Social Affairs and Health, Finland, January 12, 1996.

France:

"Fluoride chemicals are not included in the list [of 'chemicals for drinking water treatment']. **This is due to ethical as well as medical considerations.**"
SOURCE: Louis Sanchez, Directeur de la Protection de l'Environment, August 25, 2000.

Germany:

"Generally, in Germany fluoridation of drinking water is forbidden. The relevant German law allows exceptions to the fluoridation ban on application. The argumentation of the Federal Ministry of Health against a general permission of fluoridation of drinking water is the problematic nature of **compuls[ory] medication**."
SOURCE: Gerda Hankel-Khan, Embassy of Federal Republic of Germany, September 16, 1999.

Czech Republic:

"Since 1993, drinking water has not been treated with fluoride in public water supplies throughout the Czech Republic. Although fluoridation of drinking water has not actually been proscribed it is not under consideration because this form of supplementation is considered:

- uneconomical (only 0.54% of water suitable for drinking is used as such; the remainder is employed for hygiene etc. Furthermore, an increasing amount of consumers (particularly children) are using bottled water for drinking (underground water usually with fluor)
- unecological (environmental load by a foreign substance)
- **unethical ("forced medication")**
- toxicologically and phyiologically debateable (fluoridation represents an **untargeted form of supplementation which disregards actual individual intake and requirements and may lead to excessive health-threatening intake** in certain population groups; [and] complexation of fluor in water into non biological active forms of fluor."

SOURCE: Dr. B. Havlik, Ministerstvo Zdravotnictvi Ceske Republiky, October 14, 1999.

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

NO. **I do NOT support the proposed amendment because:**

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

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

NO. Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people. Similarly Sodium Fluoride is not added to drinking water to treat water – Sodium Fluoride as well as the other two fluoride compounds listed are added to water deliberately in the attempt to treat people**

I do not wish to speak to my submission.

Kindly acknowledge receipt of my submission.

1306

SUBMISSION FORM

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

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Chemistry researcher and educator
Question 1 *Do you support the proposed amendment? If not, why not?*	Yes. Adjustment of drinking water to a minimum standard cannot be regarded as medication.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	Sodium fluoride (NaF)

Please note that all correspondence may be requested by any member of the public under

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

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

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

1307

SUBMISSION FORM

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

Name:	[redacted]
If this submission is made on behalf of an organisation, please name that organisation here:	n/a
Please provide a brief description of the organisation if applicable:	n/a
Address/email:	[redacted]
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Although I am making this submission as a private citizen, my background and occupation may be of some relevance. I am an academic psychiatrist, with specific training in pharmacology (PhD, 1983, Yale University). I have researched and taught pharmacological topics, both clinical and preclinical, for most of my career. I attach a brief CV to illustrate this.
Question 1 *Do you support the proposed amendment? If not, why not?*	No (see attached document)
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	While I contend that fluoride-releasing chemicals used in community water fluoridation should be regarded as medicines, it would make pharmacological sense that sodium fluoride (NaF), sometimes used for this purpose, should be considered in the same category as HFA and SSF.

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

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

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

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

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

Reasons why fluoride releasing chemicals used in community water fluoridation should be regarded as medicines under the Act

Do HFA and SSF function as medicines when used in CWF?

1. Section 3 of the Medicines Act 1981 defines "medicine" as any substance or article, other than a medical device that is manufactured, imported, sold, or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose.

2. "Therapeutic purpose" includes treating or preventing disease (Section 4 of the Medicines Act).

3. Dental caries is a disease and clearly HFA and SSA when used in water fluoridation have a 'therapeutic purpose' as defined in the Medicines Act.

4. Section 2 of the Medicines Act defines "administer" to include administering a medicine to people, either orally, by injection or by introduction into the body in any other way, either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some substance in which it is to be administered.

5. In my opinion these characteristics of drug administration apply to HFA and SSF when used in CWF to increase the concentration of fluoride and thereby promote its delivery to and ingestion by human beings. It is thus my view that HFA and SSF function as medicines when used in CWF.

6. This view accords with the definition of a "medicine" in Section 3 of the Act (see above) as well as its standard dictionary definition: *a drug or other preparation for the treatment or prevention of disease* (http://oxforddictionaries.com/definition/english).

7. The definitions of "medicine" and "therapeutic purpose" were slightly amended in 2014. The definition of medicine now reads:

> (1) In this Act, unless the context otherwise requires, **medicine**—

(a) means any substance or article that—

(i) is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and

(ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means; and

(b) includes any substance or article—

(i) that is manufactured, imported, sold, or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or

(ii) of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of this Act; but

(c) does not include—

(i) a medical device; or

(ii) any food within the meaning of section 2 of the Food Act 1981; or

iii) any radioactive material within the meaning of section 2(1) of the Radiation Protection Act 1965; or

(iv) any animal food in which a medicine (within the meaning of paragraph (a) or (b)) is incorporated; or

(v) any animal remedy; or

(vi) any substance or article of a kind or belonging to a class that is declared by regulations not to be a medicine for the purposes of this Act."

8. The definition of "therapeutic purpose" now reads:

In this Act, unless the context otherwise requires, **therapeutic purpose** means any of the following purposes, or a purpose in connection with any of the following purposes:

(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or

(b) influencing, inhibiting, or modifying a physiological process; or

(c) testing the susceptibility of persons to a disease or ailment; or

(d) influencing, controlling, or preventing conception; or

(e) testing for pregnancy; or

(f) investigating, replacing, or modifying parts of the human anatomy.

9. It is my opinion that HFA or SSF are used to achieve their principal intended action by increasing the concentration of fluoride ions, thus affecting mineralisation of tooth enamel and thereby preventing dental caries. This action on the human body is achieved by pharmacological means and thus satisfies the requirements of the revised definition of "medicine" described above.

10. The caries-preventive action of fluoride is mainly topical in that fluoride ions in sufficient concentration interact with the surface of the tooth enamel and can thereby inhibit demineralisation and promote remineralisation.

11. As well as intended to prevent disease, the fluoride-releasing compounds HFA and SSF when used in CWF could also be said to come within subparagraph (b) of the definition of "therapeutic purpose", in that they are used for the purpose of influencing, inhibiting, or modifying a physiological process (see above).

12. As used in New Zealand, CWF also can be seen to have a further characteristic of the use of medicines, namely the dose-response relationship. The current target range of 0.7 – 1.0 ppm fluoride in tap water, achieved by the careful addition of HFA or SSF to communal water supplies, is based on the Ministry's view that this range offers the optimum balance between desired effects and unintended adverse or toxic side-effects. Regular monitoring is required to ensure that the concentration of fluoride ions in tap water stays within this target range. Lower levels are less likely to be effective, while higher levels are more prone to produce adverse effects. In other words, the 0.7 to 1.0 ppm concentration range has been specifically chosen to achieve an optimum dose-response for this intervention.

13. To date Medsafe has not described HFA and SSF as medicines, even though a variety of other fluoride-releasing products are so classified. For example, the NZ Formulary lists sodium fluoride tablets as a pharmacy-only medicine indicated for the prophylaxis of dental caries.[1]

14. Ingesting two 1.1 mg sodium fluoride tablets supplies a person with approximately 1.0 mg of elemental fluoride, the same dose as obtained by consuming 1 litre of fluoridated water (at the upper target concentration of 1.0 ppm) or 1.43 litres of water fluoridated with HFA or SSF to the lower target of 0.7 ppm.

[1] http://www.nzf.org.nz/nzf_5320.html

15. In my opinion there is no valid medical or pharmacological reason why the delivery of the same dose of the active principle fluoride should be considered to reflect use of a medicine in one form (sodium fluoride tablets) and not in the other (water fluoridated with HFA or SSF), particularly when, as in the example given above, both reflect a typical daily dose and are supplied by a fluoride-releasing salt with the same therapeutic purpose.

16. There is thus no essential difference, in therapeutic intent or pharmacological mechanism, between ingesting the same dose of fluoride by tablet or by artificially fluoridated water. Both can be said to reflect the use of a medicine, particularly in light of the fact sodium fluoride tablets should, according to Ministry guidelines, be "chewed or sucked, or dissolved in drinking liquid".[2]

17. To reiterate, HFA and SSF, when used for CWF, have the characteristics of medicines namely because their use is intended to cause "a pharmacological effect" (mineralisation of tooth enamel via the release of fluoride ions), and they are "used in one or more humans primarily for a therapeutic purpose" (prevention of dental caries).

18. While HFA and SSF are, for all intents and purposes, used as medicines in CWF, they are not pharmaceutical grade. Rather they are of a less pure and cheaper 'water treatment grade' (www.waternz.org.nz/).

19. CWF can be distinguished from the practice of fortifying foodstuffs with essential nutrients, such as iodine or folic acid in bread, due to the fact that fluoride is not a dietary nutrient. Both fluoride-releasers (such as HFA and SSF) and essential nutrients may be used to prevent disease, but the former are used as medicines in CWF whereas the latter are considered dietary supplements. Many essential nutrients, such as folic acid, iodine, iron or zinc, can also be used as medicines, depending on the dose and the route of administration.

[2] www.health.govt.nz/system/files/documents/publications/guidelines-for-the-use-of-fluoride-nov09.pdf

20. As with certain other atomic elements (notably lithium, but also antimony, bromide, gold, mercury, strontium) the salts of which have been used as medicines, there is no physiological reaction in the human body that requires fluoride. Nor is fluoride required for any aspect of human growth, development, or reproduction. Accordingly, fluoride-releasing salts cannot be considered nutrients or dietary supplements.

21. According to international guidelines, levels of fluoride in drinking water that are said to help prevent tooth decay are in the range of 0.7 – 1.0 ppm.[3] Because the natural levels of fluoride in fresh water in most parts of NZ are considered too low to have a measurable effect on tooth mineralisation, the Ministry of Health recommends that the levels of fluoride in community water supplies be 'adjusted' to 0.7 - 1.0 ppm. In NZ and in the European Community, the Maximum Acceptable Level of fluoride in drinking water is set at 1.5 ppm, in order to prevent the toxicity associated with exposure to higher concentrations.

22. Some have argued that because fluoride exists in the environment, and is found naturally in groundwater, that compounds that release it into drinking water could not be considered medicines. In my opinion this is incorrect. First, as noted above, various fluoride-releasing compounds are scheduled as medicines and, in the case of sodium fluoride tablets, can be taken dissolved in water. Second, salts that release certain other atomic elements, which in their ionized form are found naturally in water, have also been used as medicines (see above) and, in sufficient concentration, are known to be toxic. Fluoride, like other elemental ions that are released by medicinal salts, can be considered therapeutic or toxic, depending on the dose.

23. Some have also argued that fluoridated water should not be considered a medicine because it's delivered in water which is supplied for another primary purpose. However, medicines are often delivered through an aqueous solution. For example, acutely dehydrated or hypotensive patients treated with intravenous saline in emergency settings often also receive specific medicines dissolved in the saline (such as chlorpromazine for severe migraine with vomiting, or adrenaline for anaphylactic shock). In these cases the principal purpose of the saline infusion is hydration, but the added medicines also have

[3] http://www.who.int/water_sanitation_health/dwq/nutfluoride/en/

specific therapeutic purposes, and their classification and use as medicines is in no way diminished by the fact that they are administered in an aqueous solution given for another primary purpose.

24. It has also been argued that a substance with medicinal qualities is not necessarily a medicine in all its forms, for example lithium is often found in paint or batteries.

25. This principle undoubtedly also applies to fluoride which, like lithium, occurs in many different forms. However, the key point again is that when used to fluoridate drinking water, fluoride is for all intents and purposes being used as a medicine with a specific therapeutic purpose for those consuming the water.

26. Batteries or paint containing lithium indeed do not have a therapeutic purpose or a therapeutic claim; the same can be said of many fluoride-containing compounds. However, certain lithium-releasing salts (e.g. lithium carbonate) have a therapeutic purpose and are used as medicines, and the same can reasonably be said of the fluoride releasing salts HFA and SSF (see above).

27. HFA and SSF are used for the same purpose (prevention of dental caries) and exert the same pharmacological effect as sodium fluoride, another fluoride-releasing salt.

28. Sodium fluoride tablets (1.1 mg, each containing 0.5 mg elemental fluoride) are classified as a pharmacy-only medicine in New Zealand and are recommended as a substitute fluoride source for people in areas without artificial water fluoridation.

29. Based on an average consumption of 2 litres of water a day, a person in a fluoridated community ingests through the water supply a daily dose of fluoride equivalent to 3 to 4 fluoride tablets (1.5 – 2.0 mg of elemental fluoride). As indicated in the product information sheet, these tablets can be taken dissolved in water, making their administration (as well as their therapeutic purpose and pharmacological mechanism) essentially identical to consuming water in fluoridated areas at concentrations currently recommended in New Zealand (0.7 – 1.0 mg/litre).

30. It may be argued that fluoride-releasing compounds such as HFA or SSF cannot be considered medicines since they are supplied in industrial size containers.

31. I disagree with this argument. For example, a New Zealand registered prescription medicine, the anaesthetic gas nitrous oxide, is supplied in industrial size containers, in this case ranging from 1.09 – 18.14 cubic metres.

32. Likewise, it has been argued that such industrial size containers are not "recognisable medicinal dose forms". This characteristic also applies to nitrous oxide, but this in no way diminishes its use or status as a medicine.

33. The size or shape of the container supplying a medicine thus does not determine its classification. What matters is how it is used, for what purpose, and whether it has a recognised pharmacological mechanism of action.

34. An essential characteristic of the use of medicines is dose control, in order to optimise the balance between intended and adverse effects.[4]

35. Consistent with this principle, artificial water fluoridation requires concentrations in the target range (0.7 – 1.0 ppm) in order to provide what is thought to be an adequate dose of fluoride to prevent tooth decay while minimising risks of harm. Dose control also explains why sodium fluoride tablets are contraindicated for those living in areas with artificial water fluoridation.

36. It has also been pointed out that because concentrated fluoride compounds are never directly consumed in an undiluted form by human beings they are not supplied wholly or principally for administration to a human being for a therapeutic purpose.

37. This is incorrect in my view. Many medicines require dilution before they are administered and act upon the human body. To avoid cardiac arrest, for example, potassium chloride solution (0.75 g/10 mL) **must** be diluted in an aqueous solution before intravenous injection.

38. Similarly, many chemotherapeutic drugs or volatile anaesthetics require dilution in water or air, respectively, before they can be administered safely. In each of these cases, dilution is part of normal therapeutic practice and the fact that these agents are supplied in a concentrated form in no way challenges their classification or use as medicines.

[redacted]

[4] Richards D, Aronson J. *Oxford Handbook of Practical Drug Therapy*. Oxford University Press, 2005

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

skmedsafe 09/01/2015 12:33 p.m.

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

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

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

Nam
Email:
Addre

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

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

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

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

I do wish to speak to my submission.

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

: askmedsafe 09/01/2015 12:37 p.m.

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

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

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

Nam
Email:
Addre

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

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

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

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

I do wish to speak to my submission.

Name:
Email:
Address:

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

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

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

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

I do not wish to speak to my submission.

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

askmedsafe@moh.govt.nz 09/01/2015 12:45 p.m.

SUBMISSION FORM

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

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

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

Nam
Emai

1

Address:

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

NO. I do not support the proposed amendment because:

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

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

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

I do not wish to speak to my submission.

Kind regards,

SUBMISSION FORM

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

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	I am a health professional (RN, PGDipPH)
Question 1 *Do you support the proposed amendment? If not, why not?*	Yes, I do support the proposed amendment because: 1. Fluoride is the most simple, most cost effective way of reducing dental caries. 2. Fluoride is a harmless element when added to community drinking water. 3. Not everyone in New Zealand has equitable access to oral health. By increasing access to fluoridated community drinking water, those most at risk of poor oral health, health equity will increase, and harm to these at risk populations will be decreased. 4. Fluoride is harmless when added to community drinking water.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	Not that I am aware of.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you

consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

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

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

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

Submission on proposed amendment

to: askmedsafe@moh.govt.nz 09/01/2015 01:00 p.m.

Sent by:

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

NO. **I do not support the proposed amendment because:**

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

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

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

I visit New Zealand and have friends and relatives there.

I have severe concerns about the NZ legal system potentially being used to validate unethical mass medication of the NZ population. This is an abuse a perversion of justice.

Regards

Regulations under the Medicines Act 1981 Consultation
to: askmedsafe 09/01/2015 01:02 p.m.

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

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

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

Name
Email
Address

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

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

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

TOURISM: Many people would not be able to travel to NZ. due to their sensitivity to chemicals.

I do not wish to speak to my submission.

1378
1315

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

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

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

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

Name:

Email:

Address:

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

NO. I do not support the proposed amendment because:

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

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

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

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

Email to: askmedsafe@moh.govt.nz

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

askmedsafe 09/01/2015 01:07 p.m.

Dear Sir/Madam

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

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

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

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

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

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

I DO NOT support the proposed amendment because:

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

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

Answer 2: No.

Fluoride and its compounds are not used to "treat" community water supplies. The

purpose of fluoride and its compounds in community water supplies is to treat people.

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

I do not wish to speak to my submission.

Sincerely,

On the subject of water fluoridation
to: askmedsafe 09/01/2015 01:12 p.m.
cc.

SUBMISSION FORM

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

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

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

Nam
Em
Addres , Dublin 6W, Ireland

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

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine, moreover it interacts and binds with aluminium and lead in the water system to carry this ultimately to the brain of users.
2. Fluoride is added to the water as treatment for the disease of dental caries and for no other reason, therefore it is a medicine.
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm". Ongoing scientific debate around the world together with almost weekly findings of neurotoxic, IQ, bone and other bodily harm from fluoride should require the Precautionary Principle is used.
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines.

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

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

I do not wish to speak to my submission.

please include this comment-Medicines act 1981(2014)
uskmedsafe 09/01/2015 01:15 p.m.

SUBMISSION FORM

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

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

Name:
Email:
Address: Waiheke

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

NO. I do not support the proposed amendment because I am a medical professional and know this is unethical. Water Fluoridation is bad policy supported by the Dental Chambers of Commerce and it is ONLY about money-Not about health.

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

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

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

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

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

This makes these fluoride compounds medicines by universal definition. To claim that somehow these are no longer medicines in the doses delivered via water fluoridation is nonsense. Assuming that fluoride at some higher dose was considered by NZ's Medicines' Act was a medicine, lowering the dose to a level of approximately 1 ppm used in water

fluoridation could do two possible things: a) it could lower its effectiveness and b) it could reduce its toxic side effects, but it would not change the purpose for which these substances were added to the water supply. At whatever dose used in tablet form, or whatever the concentration added to water (0.6 ppm, 0.7ppm, 1.0 ppm or 1.2 ppm) the purpose remains the same: to fight tooth decay. Therefore they remain medicines and water fluoridation remains medical treatment.

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

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

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

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

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

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

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Submission Form

: askmedsafe 09/01/2015 01:29 p.m.

SUBMISSION FORM
I do

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

Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)
"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name

Email
Address

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

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

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

I do not wish to speak to my submission

--

Fwd: Submission Form

: askmedsafe 09/01/2015 01:36 p.m.

History: This message has been replied to.

SUBMISSION FORM
I do not give permission for my personal details to be released to persons under the Official Information Act 1982
Submission to Consultation on Proposed Amendment to Regulations under the Medicines Act 1981 – Fluoride (2014)
"It is proposed that a new regulation be made under section 105(1)(i) that:
Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purpose of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water supplies." Medsafe

Name
Email
Address:

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

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

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

I do not wish to speak to my submission

--

FLUORIDE
to: askmedsafe 09/01/2015 01:37 p.m.

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

I very strongly object to any attempt to amend regulations so that Fluoride containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) would not be regulated as medicines when added to our water supply.

One can access a number of definitions in dictionaries but it is clear that - **A medicine is defined as a drug or other preparation for the treatment or prevention of disease**.

As stated in the online document (titled as above) ***"In New Zealand, the addition of fluoride compounds to community drinking water supplies for the purpose of preventing and reducing tooth decay is a common practice*** ". Any sage observer would conclude that the Fluoride is used because it is believed to have medicinal properties. I don't believe anyone could argue otherwise.

I imagine many submissions received will provide evidence of the dangers of mass medication with a highly toxic substance such as Fluoride.

It seems to me however that the science is being conveniently overlooked and the objective is simply to maintain the status quo by changing regulations in order to avoid any legal challenge.

"The benefit of the proposed amendment is that it would preserve the status quo and provide legal clarity about the regulatory status of fluoride compounds used to treat community water supplies".

When Fluoridation is referred to in the media the term **Fluoride debate** is often used. The reality is that there has never been any real debate on the issue. Any attempt at this is immediately 'shut down'.
To maintain the status quo by simply changing the regulations is underhand and it demonstrates that the issue with Fluoride has more to do with politics than it does with science and public health.

"There is no universal acceptance of the positive health effects of the addition of fluoride to drinking water supplies"

My submission is that any proposed amendment to the regulations under the Medicines Act 1981 is put on hold until such time as the matter of Fluoridation is properly and publicly debated with experts from both sides being called.

The public have a right to be informed and so far this has not happened.

1322

water NEW ZEALAND

The New Zealand Water & Wastes Association Wairra Aotearoa

Submission to the Ministry of Health

on

Proposed Amendment to Regulations under the Medicines Act 1981

9 January 2015

INTRODUCTION

1. A not for profit incorporated society, Water New Zealand promotes and enables the sustainable management and development of the water environment. With 1500 members Water New Zealand's membership is large and diverse, including Territorial Local Authorities, Council Controlled Organisations, water and wastes services providers, the major consultancies involved in providing engineering, planning and research services to the industry, Crown and other research institutes involved in the water and wastes environment, academia, members of the legal fraternity and training providers.
2. The Association supports the development of regulations under the Medicines Act 1981 that would have the effect of determining that fluoride substances used to treat drinking water are not medicines.

SUBMISSION

3. Water New Zealand has recently been involved with the Ministry of Health in the development of a *Code of Practice – Fluoridation of Drinking Water Supplies in New Zealand.*
4. There is ample scientific evidence that the addition of fluoride is concentrations between 0.7 and 1.0 ppm has significant dental health benefits.
5. Water New Zealand recognises that there is likely to be continued opposition to fluoridation by some sectors of the community. From our perspective it is important decisions made by communities have a sound scientific basis. The most recent attempt to prevent fluoridation by arguing that fluoride is a medicine under the Medicines Act does not appear to have a sound basis in science and undermines efforts being taken by regulatory authorities to improve dental care in New Zealand.
6. Water New Zealand supports the use of regulation making powers under the Medicines Act to specify that the following substances are not medicines for the purposes of the Act:

    a. Fluorosilicic acid (H_2SiF_6)
    b. Sodium fluoride (NaF)
    c. Sodium fluorosilicate (Na_2SiF_6)

7. In our view these compounds should be specifically named in the regulations. We suggest the proposed new regulation to be made under section 105(1)(i) read as follows:

    'The substances fluorosilicic acid (H_2SiF_6), sodium fluoride (NaF) and sodium fluorosilicate (Na_2SiF_6) are not medicines for the purposes of the Act when they are used for the purpose of fluoridating community water supplies.'

Sincerely

John Pfahlert

Chief Executive

SUBMISSION FORM

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

Name: (	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc): Human being	
Question 1 *Do you support the proposed amendment? If not, why not?* *NO, where is the freedom of choice? I would not drink this water at all, ridiculous.*	
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?* Everything what's not natural.	

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

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

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

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

1324

Fluoride

to: askmedsafe 09/01/2015 01:47 p.m.

SUBMISSION FORM

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

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	Individual
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	consumer
Question 1 *Do you support the proposed amendment? If not, why not?*	No. Fluoride is not a water treatment. It is a neuro-toxin used by local authorities in the mistaken belief that it will improve the health of our teeth. As such it must be construed to be a medicine. The fact that you are trying to have it removed from the list is proof that it has no positive effect on the health of our teeth, a fact well-known

	throughout the rest of the world most of whom now refuse to have it added to the water supply. Setting a precedent in this way opens the door to justify all manners of chemicals be added to the water supply with alleged health advantages.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	No. Fluoride is not a water treatment. The fact that you present it in this way brings into question your ability to manage this consultation. I repeat that fluoride is a neuro-toxin now known to reduce the IQ in children by around 8 points. The lack of reason shown in your presentation might suggest that there is already evidence of this dulling of our minds widespread in the communities who have to ingest this toxin.

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under this legislation, please make this clear in your submission, noting the reasons why you would like the information to be withheld.
If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

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

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

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

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

Please respond to

Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health

-

SUBMISSION FORM

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

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

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

Nam
Emai
Address

I do not support the proposed amendment because:

Fluoride is only applied to water to help prevent tooth decay therefore it is a medicine and should always remain so under the health act.

In October last year, Judge Collins found that HFA and SSF satisfied all the key elements of a medicine in that they are used for a therapeutic purpose and they achieve their intended action on the human body by a pharmacological means.

He then incorrectly concluded that since they are added at a level less than 10 mg/L (10ppm) that they are not classified as medicines.

However, the clause he refers to says if the medicine is not an injection or eye preparation, only if the concentration of the medicine is greater than 10 milligrams per litre or per kilogram; is in a Section of the Regulations http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM96863.html) that only refers to prescription, restricted and pharmacy-only medicines and obviously only applies to medicines.

If his conclusion was valid, then all the thousands of prescription, restricted and pharmacy-only medicines would no longer be medicines if they were less than 10 mg/L.

That would be an absurdity and is not the case. They are still medicines; they are just classified as general sale medicines rather than prescription, restricted or pharmacy-only.

Dr Robin Whyman, consultant to the now defunct National Fluoridation Information Service, stated on TV One News 4th January 2015 (http://tvnz.co.nz/national-news/anti-fluoride-campaigners-cry-foul-over-controverisal-legislation-6214457), that It would make it very clear that under the Medicines Act, at the low concentrations were talking about for community water fluoridation, fluoride in that regard is not a medicine.

Then why add to the water supply?

If the concentrations that are used to fluoridate the water are not enough to provide a therapeutic purpose then there is no need to add them?
There is ample peer reviewed data to show that fluoride is harmful to health and has minimal benefits to teeth and is used as a medicine for teeth decay.

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

Fluoride and its compounds are **not** used to **'treat'** community water supplies. In community water fluoridation (CWF) the **purpose** of fluoride and its compounds is to **treat people**

I do not wish to speak to my submission.

Please read out my submission in full and confirm that it has been received and will be acted on according to my request.

Signed

Submission re fluoridation chemicals - pasted below AND attached

askmedsafe 09/01/2015 03:35 p.m.

Please respond

SUBMISSION FORM

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

If this submission is made on behalf of an organisation, please name that organisation here:
Please provide a brief description of the organisation if applicable:

Address/email:

Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):
Consumer, Citizen, Parent, Scientist, Health Advocate, Trainee Health Professional

Question 1
Do you support the proposed amendment? If not, why not?
NO.

I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is intended as a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to ¡Sfirst do no harm¡¨
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines
5. It would be inconsistent with other compounds/chemicals that are permitted to be DELIBERATELY added to the public food supply where there are restrictions on safety and quality of those additives and where public intakes are known (eg National Nutrition Survey, or Total Diet Survey which assesses intakes under the headings Nutrients and Contaminants ¡V even though the MoH has for many years claimed that NZers are ¡¥suffering¡¦ from a ¡¥deficiency¡¦ of fluoride, they have collected no evidence to support this claim ¡V not via the Total Diet Survey*, or by other means), AND where there is biomonitoring of the community¡¦s levels of those additions are quantified (ie through regularly blood/tissue testing performed by the DHBs labs and where tests are routinely performed and routinely available to requesting clinicians. Even though the MoH states/knows that fluoride

accumulates in bones, teeth and other calcium-accumulating tissue they make NO EFFORT to comprehensively test such tissues.
NB compared with iodine added to salt, folic acid added to bread, and actual nutrients added to foods/drinks generally.
*Note that MoH is faced with a further quandary wrt the Total Diet Survey in that they are unable to classify fluoride as a ¡¥nutrient¡¦ (because it¡¦s not ¡V the accepted definition being that prolonged absence of such causes a ¡¥deficiency disease¡¦), and they have not wanted to admit that it is in fact a ¡¥contaminant¡¦ of the food supply as this does not fit with their pro-fluoridation agenda.

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

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„©X I do not give permission for my personal details to be released to persons under the Official Information Act 1982.
All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

I would like to be given opportunity to further speak on this submission in person ¡V Thank You

CMM SUBMISSION FORM.docx

SUBMISSION FORM

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

Name:

If this submission is made on behalf of an organisation, please name that organisation here:

Please provide a brief description of the organisation if applicable:

Address/email:

Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):

Consumer, Citizen, Parent, Health Advocate

Question 1

Do you support the proposed amendment? If not, why not?

NO.

I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine

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

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

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

5. It would be inconsistent with other compounds/chemicals that are permitted to be DELIBERATELY added to the public food supply where there are restrictions on safety and quality of those additives and where public intakes are known (eg National Nutrition Survey, or Total Diet Survey which assesses intakes under the headings Nutrients and Contaminants – even though the MoH has for many years claimed that NZers are 'suffering' from a 'deficiency' of fluoride, they have collected no evidence to support this claim – not via the Total Diet Survey*, or by other means), AND where there is biomonitoring of the community's levels of those additions are quantified (ie through regularly blood/tissue testing performed by the DHBs labs and where tests are routinely performed and routinely available to requesting clinicians. Even though the MoH states/knows that fluoride accumulates in bones, teeth and other calcium-accumulating tissue they make NO EFFORT to comprehensively test such tissues.

NB compared with iodine added to salt, folic acid added to bread, and actual nutrients added to foods/drinks generally.

*Note that MoH is faced with a further quandary wrt the Total Diet Survey in that they are unable to classify fluoride as a 'nutrient' (because it's not – the accepted definition being that prolonged absence of such causes a 'deficiency disease'), and they have not wanted to admit that it is in fact a 'contaminant' of the food supply as this does not fit with their pro-fluoridation agenda.

Question 2

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

NO.

Fluoride and its compounds are not used to 'treat' community water supplies. In community water fluoridation (CWF) the purpose of adding fluoride and its compounds is to treat/medicate people.

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

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I would like to be given opportunity to further speak on this submission in person – Thank You

~~1393~~
1327

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

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

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

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

Name:

Email:

Address

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

NO I do not support the proposed amendment because:

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

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

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

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

Email to: askmedsafe@moh.govt.nz

OBJECTION FORM

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

Name: Tricia Cheel	
If this submission is made on behalf of an organisation, please name that organisation here:	Fluoridation Information Network – F.I.N.
Please provide a brief description of the organisation if applicable:	F.I.N. formed in 1996 in an attempt to counter all the propaganda coming out promoting fluoride in the face of a referendum for North Shore City, and give people a fuller picture on which to base their decision.
Address/email :	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	My whole life has been blighted by this poison since it was first added to the Auckland supply in 1967 the year I came down from Dargaville to do my Upper 6th form year and going on to the first intake of the Auckland School of Medicine in 1968. People wondered why I struggled with the academic challenge which had never bothered me before, and shrugged it off saying "Big fish in small pond now small fish in big pond": not realising how much life had become a nightmare all round as I felt everyday was like walking through treacle whilst in Auckland, and yet back in Dargaville for the holidays I felt re-energised – dismissed by "That's what holidays do!" I have always opposed fluoridation on the basis of it should be my right to choose what I put into my body and struggle to see what the difference is between forced medication and human experimentation of the Nazi regime

	and others, and even criminal rape as prosecuted here in NZ to this day and the addition of highly toxic fluorides to the public water supply sanctioned by the state. Over the next 35 years I struggled to find out what was wrong with me and enjoyed periods of feeling great as I avoided tap water as part of various programmes such as a raw food diet or 'de-tox' etc and believing also that the major damage from ingesting fluoride came from accumulating 40%+ of it leading to increased rate of hip fractures, brittle bones, cancer etc: so I just avoided it whenever I could to reduce that accumulation. However in 2007 I moved house to look after my mother, without being able to secure a non-fluoridated supply, and was soon too tired to bother doing anything more than just the basics for survival – indeed believing that I must be dying on the days I felt really bad. My mother had never been on fluoridated water but was taking fluorinated medicines and died less than 2 years later with my following her just 3 weeks later – he was also on fluorinated medications. It wasn't until 20th October 1012 that I suddenly stopped drinking the tap water when I bought 4 bottles of Tongariro water from Eric Rush's New World here in Browns Bay, because he was offering a free stand . . . and the rest is history! In less than a day I felt the inertia lift and I no longer had to sit in front of the Television blobbed out for hours on end trying to recover from the day's activities. As the days and weeks went by I found: I could bend down and pick things up without feeling uncomfortable as it had become – so that I had even stopped stooping to pick up litter in the park as I was accustomed to do: I no longer felt 'waterlogged' after drinking a small glass of water and can now drink as much as I like without feeling so; My big toes stopped tingling painfully when I stretch them; I no longer have to hang on to the banister whilst coming down stairs, nor cling on to something in the shower when I close my eyes to wash my face; Best of all I have found my intellect is returning and I have more clarity and decisiveness with less confusion and vagueness: I can think things through better and comprehend more of what I read . . . maybe not as well as in 1967 yet but it is improving stlll. I have described the difference in the way I feel on the Fluoridation Information Network's FB page as follow: It's hard to describe but I feel more 'connected' and the analogy that came to mind is that I feel now like a sleek well maintained pocket battleship with a relaxed and happy but highly efficient and well presented crew that can man the battle stations at a moments notice. This is compared to the rusty, leaky old hulk with a crew of drunken sailors that I had to round up every morning simply

to fire up the boilers and lurch around in the ocean hoping we were going in the right direction but never sure because the instruments were all steamed up and no one seemed to be taking their job seriously.
I noticed in the bank while waiting in the queue that I was no longer just wishing that they would hurry up so I could go and lie down which is how I felt whenever just standing around.

I wouldn't invite people inside for a cup of tea unless absolutely necessary because as soon as I sat down I would just be wishing they would go so I could go and lie down: so I never invited people around or went anywhere unnecessary either . . . life had shrunk to just the bare necessities.

A fuller account may be read here:

https://www.facebook.com/598111543549295/photos/pb.598111543549295.-2207520000.1420750439./629583923735390/?type=1&theater

In 1984, as part of my quest to feel better, I enrolled at the Auckland College of Homoeopathy and as I began to set up practice after 1987 I noticed that the same people would come with the same complaints every time the council sprayed their area: and since June 1990 I have been co-ordinator for Friends of Sherwood, a community group working hard to enhance the neighbourhood and keep it as free as possible of toxic chemicals waste and other pollution, since it made no sense to me to continue to treat people whilst ignoring the cause.

We have had fluoridation in New Zealand now for 60 years and to my knowledge none of these bodies promoting it have bothered to find out what effect it may be having on parts of the body other than teeth:

The Auckland School of Medicine:

The Auckland Council:

The DHBs;

The Ministry of Health:

Should all have been researching this tragedy on their doorstep:

The statistics are on the Ministry of Health's own web site to show that teeth in non-fluoridated areas have improved more than those in the fluoridated ones - from their own data between 1999 and 2011!

The same motivation that propelled me to study medicine still drives me now, to alleviate suffering wherever I can, and it distresses me that thousands of people may be feeling the way I did and not only are they being ignored, but may be being treated with ever more drugs that may be adding to their misery and even worse, an untimely death, as has happened for both my mother and son.

Furthermore, I have a niece and nephew, and their children of Ngapuhi descent, and if alarms me greatly to learn that black Americans and Hispanics are damaged even more by fluoride than those of European

	origin . . . for instance, a recent study of Samoans and Tongans? in USA suggests that those living in fluoridated regions have a far greater incidence of asthma. The misplaced certitude of Professor Gluckman et al, that fluroidation is 'safe' and can do no harm, and the arrogance that goes with it has obviously carried over to the people they advise, including this 'Consultation'. It no doubt gave my GP the misplaced confidence to assert that the tap water couldn't possibly make me sick since 'they' all drank it and none of them were affected by it – how 'scientific' is that? Medsafe needs to take a hard look at these matters considering it has just been found that their medications make it more likely for 40% of sufferers to die from a heart attack – again affecting Maori and Pacific Islanders more, and those trying to find answers may well benefit from delving into homoeopathy where individualisation of prescriptions is central to that modality, rather than trying to re-invent the wheel – it's been known for 200 years! Not only am I offended as a Classical Homoepath to have my profession denigrated by both the Prime Minister, John Key, and Minister of Health, Jonathon Coleman who have inferred both myself are 'barking mad' and 'whacko' - and presumably the Royal Family as well since their head is said to travel with 60–80 homoeopathic remedies: But also by this supposed 'consultation' pantomine, held over the Christmas period; On the instigation by a member of the judiciary – to make their job easier? – should I take my next headache to this judge for him to rule whether it is a migraine or brain tumour?: Describing it as a 'benefit' in preserving the status quo!!! All without even having the courtesy to inform those of us who have expressed concern about this topic for over 30 years! As a keen gardener and project manager for revegetation of 2km of stream bank here in the Taiaotea, on behalf of Friends of Sherwood, I also have concerns about the effects it is having on the whole ecosystem, the stream, the Hauraki Gulf and beyond. We have lost 50% of wildlife in the past 40 years (or the other way around . . . either way still tragic . . .:} and it is the same fluorine element involved in inhibiting the Krebb's cycle in these fluoride compounds, be they from fluoridation or 1080 poison, neither of which have any excuse for being released into general circulation. I believe that this disruption of the main pathway by which we produce energy in our bodies is not only responsible for my lethargy but also the cruel death inflicted on animals who suffer hours and days of agony after ingesting mono-fluoroacetate or 1080 poison. Rather than looking at how they can get away with disposing of this highly toxic industrial waste via the public kidney, Medsafe would be better employed investigating safer, less toxic substances to replace those drugs already adversely affecting at least 40% of the population (the incidence of iatrogenic illnesses I believe?) and polluting ecosystems around the world. If I was still a Vice-president of the Soil & Health Association, or similar, I would also be calling for a halt to tipping this poison into public water

	supplies or being released into the environment in any other manner at all: and all the other poisons, masquerading as medicine, ending up in the same place – our increasingly overburdened oceans.
Question 1 *Do you support the proposed amendment? If not, why not?*	I do not support this amendment. It is an obvious attempt by the judiciary to dig them selves out of a big hole that is looming up where they will be called upon to administer the law even handedly and ban the disposal of this poison into the public water supply. This may well put them at odds with the 'powers that be' that pay their remuneration, and make life very uncomfortable for them – I have no sympathy for this considering what effect fluoride has had on my family. Fluoride, as HFA or SSFs, is not used to treat water; They are not used to make water safer to drink: They are added to water for the purpose of treating tooth decay; And therefore must be considered medicines for the purposes of the Medicines Act 1981 Furthermore, if Judge Collins has found in October 22014, that HF and SSFs are not classified as medicines since they are administered at a level less than 10mg/L or 10ppm, then all homoeopathic remedies must become exempt also.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	

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

Fluoride in the water.

): askmedsafe 09/01/2015 03:07 p.m.

...ai and ... y do not agree with the idea of keeping or adding more fluoride to our drinking water supply. It is un healthy and has long term effects that are not worth having...
Thank you.

Regulations under the Medicines Act 1981 Consultation
to: askmedsafe 09/01/2015 03:08 p.m.

SUBMISSION FORM

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

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

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

Name:
Email:
Address: ;

Question 1. *Do you support the proposed amendment? If not why not?*
I do NOT support the proposed amendment because:
Fluoride is added to community water supplies not to treat the water to make it safe to drink. It's added to address tooth decay. It has a medicinal purpose, therefore it should be classified as a medicine. The concentration is irrelevant. It's the purpose that matters.

Question 2. *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*
No, I don't see why any fluoride-containing compounds should be specifically named. The ingredients of a substance is irrelevant. If it is added for a medicinal purpose it should be classified as a medicine.

I do do not wish to speak to my submission.

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

): askmedsafe 09/01/2015 03:16 p.m.

C

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

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

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

Name
Emai
Address:

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

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

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

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

I do wish to speak to my submission.

SUBMISSION FORM

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

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	Not submitting on behalf of an organisation
Please provide a brief description of the organisation if applicable:	
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	Dental professional
Question 1 *Do you support the proposed amendment? If not, why not?*	NO Due to he availability of Tpharmicutical level topical fluoride compounds in toothpastes, have been shown to be effective in the reduction of dental decay. HFA and SSF are bi products of fertiliser production and consumers should not be subjected to being forced to swallow them in their drinking water. There are studies showing long term detrimental effects and could prove detrimental/harmful to overall systemic health. These compounds should be classified as POISONS if anything, and certainly not deregulated
Question 2	NO. All fluoride compounds should remain

Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?	classified as medicines. Please refer to this website. http://fluoridealert.org/articles/50-reasons/ Even the US FDA classifies fluoride as a DRUG!!!! Declassifying this element is madness!!

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

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FLUORIDE IS A MEDICAL TREATMENT OF WATER SUPPLIES
to: askmedsafe 09/01/2015 02:43 p.m.

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

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

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

Name:

Email

Address:

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

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

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

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

Consultation on Proposed Amendment to Regulations under the Medicines Act 1981

o: askmedsafe@moh.govt.nz 09/01/2015 02:50 p.m.

Tena koe

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

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

Name
Email
Address:

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

NO. I do not support the proposed amendment because:

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm"
4. The proposed amendment would effectively remove the safety precaution protecting people from harm thereby undermining the right of every New Zealander to be safe from the indiscriminate use of medicines
5. It seems to be a profit protection scheme so the companies dumping their toxic waste wont have to abide by pharmaceutical standards, which they will never obtain
6. I also have concerns that the MOH allows other known toxic chemicals including arsenic, lead, mercury and uranium as part of the fluoridation contamination.

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

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

I do wish to speak to my submission.

Mauri ora

Submission to Medsafe Consultation on Fluoride 2014 (continued)
Note : I would like to speak to this submission and i do not give permision for my personal details to be.....

Thursday 8th January 2015

I think it's foolish to try and shut and bolt the door on considering the adverse health effects of fluoridating the public water supply

- The proposal that fluoride (and the associated heavy metals in the products used) should be exempt from the medicines act because of low concentrations seems quite ignorant of how some medicines work. eg homeopathic medicines are effective at extremely low or trace amounts. (question 1 and by implication question 2))
- I gather those on kidney dialysis must not use a fluoridated water supply during their treatment.
- Dioxins are a class I carcinogen widespread in our community and take effect at very low concentrations .They can be measured these days to ppt (parts per trillion). I gather dioxins are excluded from consideration when monitoring the chimney output from cremators. Its really poor policy to turn a blind eye to any harmful substances whether deliberately added or inadvertently produced as by product from another process.
- The synergistic effects of combining small amounts of chemicals (not deemed to be harmful on their own) in the general environment and in our bodies should not be overlooked. Air and water quality are of prime importance in human health and well being and the health department should fullfill its role of protecting the population in all aspects of health..

I am opposed to adding the chemical fluoride to the city water supply and I would like the powers that be whether City Councils or Ministry of Health to stop this practice as some people are sensitive to fluoride and ingesting this substance and its co chemicals adversely affects their health and well being.

I am one of these people and I have found in the past, I can sleep soundly at night, my health and fitness improves and I can sustain physical work whilst spending time in a non fluoride area.

Another reason is that after nearly 35 years of ill health I do not have the financial

means to purchase a water filter to remove fluoride from drinking and cooking water nor do I have the means to remove fluoride from showering and bathing water and that used on the home grown vegetable and fruit garden.

It seems unreasonable to subject people to water fluoridation without being aware of, or ignoring the adverse consequences on their health.

I present below a letter to the ODT Otago Daily Times (the original version, sent friday 8th March 2013) which was published (abridged) in that paper on 15th March 2013 .

The Editor ODT

Dear Sir

I am extremely concerned about the apparent lack of interest from the medical and dental professions in further new research on the harm that fluoride in our water supply can cause to human health.

After all George Waldbott, an American MD, saw and reported on these adverse health effects* back in the 1980s, as noted in Bruce Spittle's book Fluoride Fatigue .

A visit this week from Dr Paul Connett speaking by submission to the city council on March 4, 2013 appeared to elicit derision from the dental fellow Tim Mackay and the public health person Marion Poore appeared completely disinterested, merely quoting her mandate to protect health. I thought science advanced by considering and testing new ideas and evidence... .....

The strong proponent of fluoride to protect children's teeth John Colquhoun , retracted his opinions in a 1997 article on the basis the original studies were flawed and skewed.

He wrote many letters to the Star newspaper to inform the people of Dunedin. So I think it it is long, long over due to reconsider this unsafe and dubious practice.

There are alternatives to raising our children with strong, healthy teeth.

Hip fractures and bone cancer have been linked to using fluoridated water; as have disruptions in thyroid and pineal gland functions .

Fluoride is an enzyme poison and should not be administered willy nilly to the public at large.

I would like to *know* our health people are carrying out their mandate to protect our health in the most fundamental aspects of both water and air quality.

Why should I have to go to the expense of removing a poison from my tap water

when it has been added, albeit in all good faith, but complete ignorance by the local authorities?

--

References and list of adverse health effects

1. Waldbott GL, Burgstahler AW, McKinney HL. 1978
Fluoridation: the great dilemma. Lawrence, Kansas: Coronado Press; 1978.

.* adverse health effects listed on pp.392-3 as
1 chronic fatigue, not relieved by extra sleep or rest
2 headaches
3 dryness of the throat and excessive water consumption
4 frequent need to urinate
5 urinary tract irritation
6 aches and stiffness in the muscles and bones; arthritic-like pains in the lower back, neck,
jaw, arms, shoulders and legs
7 muscular weakness
8 muscle spasms, involuntary twitching
9 tingling sensations in the feet and, especially, in the fingers
10 gastrointestinal disturbances: abdominal pains, diarrhoea, constipation, blood in stools,
bloated feeling or gas, and tenderness in the stomach area
11 feeling of nausea, flu-like symptoms
12 pinkish-red or bluish-red spots, like bruises but round or oval, on the skin, that fade and
clear up in 7–10 days (Chizzola maculae.a They were first recognized by an Italian general
practitioner, Dr M Cristofoloni, in the neighbourhood of an aluminium factory near the village
of Chizzola in northern Italy).
13 skin rash or itching, especially after showers or bathing
14 mouth sores, also with using fluoridated toothpaste
15 loss of mental acuity and the ability to concentrate
16 depression
17 excessive nervousness
18 dizziness
19 tendency to lose balance
20 visual disturbances, temporary blind spots in the field of vision, a diminished ability to

focus
21 brittle nails

2. Dr Bruce Spittle Fluoride Fatigue 2008 , Paua Press Dunedin
Fluoride Poisoning: is fluoride in your drinking water-and from other sources - making you sick?
http://www.pauapress.com/fluoride/files/1418.pdf

3. Drs Paul Connett, James Beck and Spedding Micklem 2010 Chelsea Green Publishing 384pp
The Case against Fluoride: How hazardous waste ended up in our drinking water and the bad science and powerful politics that keep it there

4. Dr John Colquhoun 1997 Why I Changed my Mind About Water Fluoridation. Perspectives in Biology and Medicine. Autumn 1997 v41 n1 p29(16) University of Chicago Press

5. 10 Facts on fluoride hazards. pdf 2013 , a flyer (with references to published literature) that accompanies a video " 10 facts about Fluoride" see www.fluoridealert.org/fan-tv/10facts/

6. Hip fractures

7. Bone cancers

8. Thyroid function

9. Pineal gland functions

Kunz D, et al. (1999). A new concept for melatonin deficit: on pineal calcification and melatonin excretion. Neuropsychopharmacology 21(6):765-72.

Luke J. (2001). Fluoride deposition in the aged human pineal gland. Caries Res. 35(2):125-128.

Luke J. (1997). The Effect of Fluoride on the Physiology of the Pineal Gland. Ph.D. Thesis. University of Surrey, Guildford.

10. Enzyme poison/inhibitor

SUBMISSION FORM

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

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	Hope International (NZ) LTD
Please provide a brief description of the organisation if applicable:	This organisation has been in business for twenty-seven years. We promote vegetarianism, healthy living, and responsible and informed choice.
Address/email:	
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	We are not convinced that the Health Department has provided the public with information regarding the dangers of mass fluoridation of our water.
Question 1 *Do you support the proposed amendment? If not, why not?*	No, because we believe it is the first step toward the Health Department deciding which cities will be fluoridated. This decision is now in the hands of the local bodies.
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	———

Please note that all correspondence may be requested by any member of the public under

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

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

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

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

Fluoride

New Zealanders are not rioting on the streets demanding that their water be fluoridated by Ministry of Health (MOH) officials while they are snoozing at beaches. The MOH has chosen this sleepy time to slip through their dark deceits of forced fluoridation with the known poison hydrofluoric acid. They are tired of New Zealanders pointing out that fluoride is a deadly poison. I believe that most of these blind officials hate pro-choice New Zealanders, while some of them were not even born in our country. This midnight activity usually means there is underhand and dishonesty involved. Why are they doing this in our Christmas holidays? Is it because it is designed to take your opponent by surprise?

History has shown that the MOH has a one-track mind regarding forced water fluoridation. It is as if they have been programmed by some unseen hand. I believe that these submissions will prove to be only a facade for public image and will eventually be filed into the rubbish tin. We believe they will take no notice of any opinions from the public that differ from their blind policy on forced fluoridation.

All agree there is a problem with tooth decay in New Zealand. Around the pacific, children generally have better teeth than children in New Zealand, and yet they have no fluoridated water and few dentists. The main cause of this problem is that there is an unrestrained amount of sugar being poured into our food and drink industry. To date, the MOH has mainly ignored the problem and is hell-bent on treating the effect rather than the cause. This is bad ethics and bad science. They are ignoring the elephant in the sugar bowl. They claim that the poison hydrofluoric acid is the silver bullet that somehow solves most of the tooth decay problems.

The MOH is withholding vital information from the public regarding the dangers of fluoride such as:

- Sodium Fluoride is the active ingredient in 1080 Poison.
- Sodium Fluoride is the active ingredient in some rat poisons
- Sodium Fluoride is the active ingredient in Prozac and many of the same branded psychiatric drugs

Because of their absurd and irrational 'remedy' to the problem, which defies logical explanation, it is reasonable to believe that a section of the MOH has orders from on high to sedate the public of New Zealand.

The MOH quotes experts that say sodium fluoride is both effective and harmless and those who are pro-choice do not know what they are talking about. They are disturbingly withholding the truth from New Zealanders. The MOH cannot explain to the public how the real experts in most western European countries are removing fluoride from their water supplies. The MOH has intentionally discredited world experts on the advertised and dangerous side to forced water fluoridation. They cannot explain this away and keep their credibility.

Experts have been wrong throughout history. The MOH claims "their" experts could not be wrong. Can they not remember how their experts were wrong on thalidomide, DDT, lead in petrol being safe etc.? What a convenient loss of memory when fluoride fraud is fully exposed. Will the "experts" at the MOH resign? Will they pay compensation from their pockets? You can guarantee they will not.

When it is explained to the MOH experts that fluoride is poison, the officials point out that it is harmless in small doses. To answer this cop-out, we quote from the prestigious and world-renowned Hampels Chemical Encyclopedia at page 221: "All inorganic fluorides which have

an appreciable solubility in water are toxic when ingested in quite small amounts. Less than one gram of sodium fluoride constitutes a fatal dose. Somewhat smaller quantities taken over a prolonged period produce fluorosis [of the teeth]. In extreme cases, symptoms include hyper-calcification of bones, and a permanent stiffness of the spinal column, with joints becoming stiff and painful."

When members of the public request information from "their servants" at the MOH they are asked for a large amount of money, which most do not have. In this way the MOH is denying the public the right under the Official Information Act to discover what shady dealings are going on behind the scenes.

The people of New Zealand have the right to hear from scientists such as Mr Paul Connett and many others who are mocked openly and despised by those in the MOH who are pro-force in fluoride issues. Both sides in the Hamilton Fluoridation debate agreed that the benefits, if any, were only topical. If this is the case, how does water fluoridation aid against tooth decay on the outside teeth, which are not contacted when water is drunk? I wonder if the MOH has statistics on these facts. In any event, children drink very little water, because they prefer sugar-laden fizzy drinks made mainly in Auckland using fluoridated water.

This absurd programme to mass medicate the public has not been thought through by the pro-force MOH. If one person has one glass of water per day and another has 12 glasses, then the second is getting twelve times more hydrofluoric acid than the first person. It is a well-established medical fact that no two people react the same way to a medication, and fluoride is a medication, whether the MOH says so or not.

The MOH can play smart games with words, but they are deceiving themselves and the public when they now believe (by their proposed changes) that a poison and medication are now not a poison and a medication. If they are silly enough to believe this lie, then they are silly enough to believe an informed New Zealand public will accept it.

The MOH obviously wants to decide on city and town fluoridation without the help of councils or public referendum, which they have no control over. That is the agenda after the inconvenience and exposure they received in recent debates. We believe that the MOH wants the power alone to force fluoridation on all where they can.

The MOH has ignored another elephant in the room, which is that 99.9% of fluoridated water is wasted because it goes down the toilet, shower, and sink! This is absurd economics at its worst, a waste of tax-payers' and rate-payers' money.

It appears that the MOH has forgotten that we live in a democracy where the little people (who pay their large salaries) should not be despised or held in contempt by "their servants". Some of these "servants" have come to New Zealand with a hidden agenda of Fabian Socialism, whereby individual rights must be sacrificed for the "greater good" of society. In the 1930's and 1940's this was called fascism. Our ancestors spilt their blood to rid the world of this bigoted and intolerant plague.

The MOH is ignoring common sense remedies. For example, why doesn't the MOH promote compulsory fluoride tablets in schools? Why not promote more fluoridated toothpaste, which incidentally has a warning on the label against ingestion?

It appears that the tooth decay problem must only be solved by the MOH forcing mass medication of all citizens. This is a fulfilment of Animal Farm, where the pigs were more equal and "expert" than all the other animals.

The MOH is destroying their credibility by blindingly treating the effect rather than the cause. These submission will not change the hidden agenda of the pro-force MOH, which is to force us all to consume a known poison and then blame and ridicule all those who are pro-choice and whose only "crime" is wanting informed debate and personal responsibility.

Why do not the MOH promote an informed public referendum on this vital issue? As our "servants" you would expect this. They do not want the public to have an informed choice, their actions show this.

We recently elected a government and received all sorts of promises during the election campaign. That was four months ago, and it is now down to the business of forgotten promises and obedience to the U.N., the W.H.O., and the hidden agenda.

The public servants who concocted this clandestine move when everybody is on holiday should be named, shamed, and dismissed from the public service. Forcing a known poison on the public through mass water medication will not solve this problem. The only solution is when the MOH take their head out of the sand and address the cause, which is too much sugar.

Because of the MOH's absurd remedy to the tooth decay problem of forced water fluoridation on all citizens, we can only conclude that they wish to sedate the public of New Zealand with the same poison chemical which is the active ingredient in Prozac.

Vote No

askmedsafe 09/01/2015 02:57 p.m.

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

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

Nam
Ema
Address: , Texas

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

NO. I do not support the proposed amendment because:

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

I am opposed to water fluoridation for the obvious health risks as well as the fact that no municipality, organization, etc. has the right to "medicate" the people without the consent of the people. In the last few years NZ health authorities have gone to some extraordinary lengths to continue their support and promotion of the outdated, unscientific and unethical practice of water fluoridation. But now they have reached a new low in their public relations tactics. They are attempting to change the language itself. Under the NZ Medicines Act they are trying to maintain that fluoride is a medicine in tablet form but not at the concentrations used in water fluoridation programs. But this is absurd. **A medicine is not defined by the dose used, but by the purpose for which it is administered**

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

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

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

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

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

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

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

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

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

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

its compounds is to **treat people**

I do not wish to speak to my submission

Fluoride

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

To whom it may concern:

I wish to make a submission to the consultation concerning the proposed amendment to regulations (Medicines Regulations 1894) under the Medicines Act 1981.

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

Question 1

Do you support the proposed amendment?

I do not support the proposed amendment.

Although I appreciate the need to do something which will reduce the prevalence of dental caries in vulnerable children, I do not believe that this justifies including *'Fluoride-containing substances, including hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the purpose of fluoridating community water* supplies'. Even though fluoride is listed as a nutrient in many, if not the majority, of nutrition texts, research on the physiological effects of fluoride has never found evidence that it is an essential nutrient. On the contrary, it is known to have a number of adverse effects on biochemical pathways, for example inhibiting enzymes which are essential for cellular respiration and thus reducing the formation of ATP which is necessary for normal cellular processes. Fluoride is found in natural waters where it is often bound to other minerals or humic matter. HFA or SSF are not present in natural waters. If a substance which is not been shown to be a nutrient is added to public water supplies to reduce the incidence of a disease, I would consider this to be using the substance as a medicine.

Medicine 1. Any drug or remedy (Dorland's *Medical Dictionary 27th* Ed.*)*

Drug 1. Any chemical compound that may be used on or administered to humans or animals as an aid in diagnosis, treatment, or prevention of disease or other abnormal condition...(*ibid*)

The use of water fluoridation is to reduce the incidence of a disease, namely dental caries. The high prevalence of dental caries in New Zealand children today was not true even as late as the 1930's when the American dentist Weston Price investigated the incidence of dental caries in Maori children who were were still eating a traditional diet.[1] These children were drinking water with no more fluoride in it than children currently living in areas with non-fluoridated water supplies. It is other aspects of diet and lifestyle which have resulted in the present-day high incidence of dental caries.

Fluoride is chemically a very reactive element. If HFA or SSF are added to water, the fluoride ions liberated will react with metallic ions already present in the water; some of these compounds are also physiologically active. For example, fluoride forms many soluble complex ions with aluminium. When alum is used as a flocculating agent to treat water, it has been found that fluoride at 0.8 parts per million (ppm), in particular, can cause markedly elevated levels of residual aluminium in the water [2,3]. Complexes of fluoride with aluminium, especially the AlF_4^- ion are known to have significant physiological effects. Fluoride ions or AlF_4^- ions have been shown to affect a variety of biochemical pathways which are known to be compromised in a number of diseases, for example Alzheimer's disease and Type 1 diabetes. In 2002, a paper by Strunecka[4], entitled "Fluoride plus aluminium: useful tools in laboratory investigation, but messengers of false information", was published in the peer-reviewed journal *Physiological Reviews.* Strunecka wrote, "The long-term synergistic effects of [aluminofluoride] ions in the living environment and their hidden danger for human health are not yet fully recognized."

By forming soluble complexes, such as AlF_4^-, fluoride can increase absorption of aluminium itself. Evidence of fluoride-enhanced absorption of aluminium in animals is provided by the results of a study which found increased levels of aluminium in tissues of animals after sodium fluoride had been added to their drinking water. Levels of aluminium in the brains of rats increased when sodium fluoride (equivalent to 1 ppm fluoride) was added to their drinking water [5]. Aluminium is known to be highly neurotoxic [6] and higher than normal concentrations of aluminium have been found to be present in the brains of people who have had Alzheimer's disease.

Early research on water fluoridation was carried out when sodium fluoride, not HFA or SSF, was used as an additive. Both HFA and SSF can be contaminated with lead, and lead piping and joints made with lead-containing solder are still found in older New Zealand homes. After the publication of research by Masters and Coplan, which showed a statistical correlation between the use of HFA (but not sodium fluoride) to fluoridate water supplies and the blood lead levels of children living in Massachusetts, the study was criticized on theoretical grounds by scientists from the US Environmental Protection Agency. They stated that there would be almost complete hydrolysis of the hexafluorosilicate to release free fluoride ions and there would be essentially no hexafluorosilicate left in the drinking water [7].

Subsequently, Masters *et al* ., in research on blood lead levels in more than 150,000 children living in the state of New York, again found that children living in towns where silicofluoride compounds were used to fluoride the water had consistently higher blood lead levels [8]. The researchers pointed to the need for chemical studies and comprehensive animal testing of water treated with commercial grade silicofluorides. In 2002 the EPA issued a bulletin seeking more information on fluorosilicates [9]. In contrast to earlier statements by EPA scientists, the agency stated "The release of fluoride proceeds through a complex, multi-step equilibrium process that is not well-understood."

There are still many unanswered questions relating to the long-term effects of ingestion of fluoridated water, particularly with regard to the physiological effects of soluble fluoride complexes, or increased absorption of aluminium or other minerals. There is already enough published on the toxicity of fluoride, even at low concentrations, to suggest a precautionary principle be applied to it use in public water supplies. I believe that more research is required before it is possible to say that the addition of HFA and SSF to public water supplies has positive health benefits but no long-term adverse health effects.

I do not support the dentist Dr Martin Lee's opinion that water fluoridation is the "only rabbit we've got to pull out of the hat" [10] in order to reduce dental decay. I believe there are a number of positive actions which could be taken. Some of these are already being followed, but could be extended. Others arise from research which is seldom considered in discussions on dental decay and health. Major factors affecting the progression of dental caries have been summarized by many authors and it is widely recognized that dietary sugar is a major factor in progression of the disease. Many studies have shown that dental caries is more common in children and adults of lower socioeconomic status [11]. There are many interventions have been shown to reduce the risk of dental caries and which could be introduced or extended (e.g. restricting advertising on sugary soda drinks and high-sugar foods, and reducing availability for purchase in schools). These could have not only a positive effect on the incidence of dental caries but also on the incidence of obesity and associated diseases. Even manufacturing sugary soda drinks with fluoride at a concentration of 1 ppm could be considered. This would at least target children who are at highest risk of developing dental caries.

References

1. http://www.westonaprice.org/health-topics/abcs-of-nutrition/principles-of-healthy-diets2/
2. Water Services Assn Australia, Report No. WSAA 85
3. *Environ Technol Letters* 6: 11-20, 1985
4. *Physiol Rev* . 51: 557-6, 2002
5. *Brain Res* . 784: 284-98, 1998
6. *Environ Health Perspect* . 65: 363-441, 1986

7. http://www.fluoridealert.org/ifin-577.htm
8. *Neurotoxicology* 21:1091-100, 2000
9. http://www.epa.gov/ORD/NRMRL/wswrd/rfa-fluoride.pdf
10. *The Press* , Christchurch, 11 May, 2005
11. *Comm. Dentistry Oral Epidemiol.* 1st published online 1 Sep 2004 DOI: 10.1111/j.1600-0528.2004.00173.x

Question 2

There are no other fluoride-containing compounds which I consider used to treat community water supplies that should be specifically named in the regulation.

Email: nz

Putting Fluoride in the water

askmedsafe@moh.govt.nz 09/01/2015 02:18 p.m.

1. I DO NOT support putting fluoride in the water. It is not a water treatment like chlorine.

Fluoride is added to water as a TREATMENT FOR THE DISEASE OF DENTAL CARIES therefore it is a medicine.

The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines reflecting the ethical code of health professionals to "FIRST DO NO HARM".

The proposed amendment would effectively remove this safety protection protecting people from harm and undermining the right of New Zealanders to be safe from the indiscriminate use of medicines.

2. NO. Fluoride and its compounds are not used to "treat" community water supplies. In community water fluoridation (CWF) the purpose of is compounds is to TREAT PEOPLE.

I do not wish to speak to this submission.

SUBMISSION

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

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

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

Name:
Email:
Address.

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

NO. I do not support the proposed amendment because:

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

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

NO.
NO fluoride-containing compounds should be named in the regulation.
Fluoride and its compounds are **not** used to **'treat'** community water supplies.
In Community Water Fluoridation (CWF) the **purpose** of adding fluoride and its compounds is to **treat people.**

I do not wish to speak to my submission.

Post to:
Regulations under the Medicines Act 1981 Consultation
Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
Wellington 6145
Email to: askmedsafe@moh.govt.nz

No to proposed amendment to Medicines Act 1981

askmedsafe 09/01/2015 02:32 p.m.

SUBMISSION FORM

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

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

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

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

Name

Email

Address: 3

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

NO. I do not support the proposed amendment because:

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

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

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

I do not wish to speak to my submission.

Kind Regards,

Proposed Amendment

skmedsafe@moh.govt.nz 09/01/2015 02:34 p.m.

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

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

Sent from my iPad

FYI

): askmedsafe@moh.govt.nz 09/01/2015 02:36 p.m.

-Study by Dr Frank Mueller regarding enamel and fluoride (Germany):

A popular mantra in American dentistry claims that topical fluoride treatments help to protect teeth from cavities by forming a protective shield on the enamel of teeth. However, a new study published in the American Chemical Society (ACS) journal *Langmuir* has found that the "protective layer" created by fluoride is actually 100 times thinner than previously believed, which may render it practically useless as a cavity-preventing intervention.

Frank Mueller, PhD, and his colleagues from Saarland University in Germany discovered that the fluorapatite layer formed by fluoride on teeth is only six nanometers thick. To put this into perspective, the width of an average human hair is roughly 10,000 layers thick. So everyday activities like chewing food, say scientists, are enough to disintegrate this thin fluoride layer in a matter of seconds.

The finding, which researchers say still needs to be validated by follow-up studies, challenges decades of thought concerning the supposed protective benefits of fluoride on teeth. It also adds to the growing body of evidence showing that fluoride is both useless as a teeth protector and a detriment to public health.

Numerous recent studies have challenged the safety of fluoride, including a study published in the journal *Environmental Health Perspectives* which found that toxic fluorides contribute to decreased cognitive function in children. A similar study out of China found that fluoride lowers IQ levels of children.

Ironically, no legitimate study has ever found that fluoridated water actually contributes to overall improved dental health. The idea is nothing more than a modern medical myth backed by pseudoscience. Many unfluoridated areas, including most European nations, for instance, have the same or even lower cavity rates than fluoridated areas.

Sources for this story include:
http://www.eurekalert.org/pub_releases/2011-03/acs-dfr030211.php

Kind regards,

Sent from my iPad

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

askmedsafe@moh.govt.nz 09/01/2015 03:44 p.m.

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

Name:
Email: ‹
Address:

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

NO. I do not support the proposed amendment because:

If fluoride is not added as a medication why is it added? Fluoride is clearly intended to be a medication. If it is not a medication I take that as an admission that it is ineffective. If it is not a medicine then it should not be added.

Fluoride is a poison in miniscule doses. It needs to be regulated and regularly reviewed by the medical profession as more and more studies come to hand condemning it as a medical practise. If it is unregulated by the medical profession there is nothing stopping an enthusiastic Council deciding to add say 4 parts per million or more.

There are already many studies indicating 4 to 5% reduction in IQ at existing rates and substantial increases in cancer etc. inspite of unsubstantiated claims to the contrary.
When the Royal Report on Fluoridation in New Zealand was done it was assumed incorrectly the only source of fluoride was water. We now know it is in everything.
1 cup of tea may contain a daily dose of fluoride. Any more is poison.
5 glasses of fluoridated water contain a daily dose of fluoride any more is poison.
When you cook vegetables in water the fluoride is absorbed adding to your daily dose.
When you shower the chlorine and fluoride are absorbed out of the water. Nobody has studied how much is absorbed but it increases your exposure. The medical profession should take on the responsibility of finding out. Failure to do so is extremely irresponsible.
Most children and adults in New zealand show signs of dental fluorosis which is white or yellow mottling oand even crumbling of the teeth which is caused by an overdose of fluoride otherwise known as fluoride poisoning.
Children as young as one and two are having their teeth extracted because of decay even in fluoridated areas. 1. The fluoride hasn't worked and 2. Sugar such as is in carbonated drinks is responsible.
Babies receiving bottled milk / formula are likely ingesting dangerous doses of fluoride.
Fluoride is not recommended for babies. Non fluoridated water is recommended. Young mothers are not informed of this and probably can't afford to avoid it.
Fluoride is not recommended for pregnant women but it is in their water.
A 50 gram tube of tooth paste contains enough fluoride to kill a child.

People who oppose fluoridation do not oppose chlorine inspite of the fact according to Time magazine that chlorine is 100% responsible for some forms of stomach cancer. We do not oppose it because with out it the water is dangerous. We oppose fluoride because of some of the above scientifically proven and unrefuted facts.

1. Fluoride is not a water treatment like chlorine
2. Fluoride is added to the water as treatment for the disease of dental caries therefore it is a medicine. If it is not a medicine then it clearly should not be added because it is definitely not added as a water treatment.
3. The Medicines Act is designed to protect people from the risk of indiscriminate use of medicines, reflecting the ethical codes of health professionals to "first do no harm". It is imperative that the addition of fluoride remains under the guidance of the Medical profession. It is too dangerous not to be.

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

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

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

I wish to speak to my submission.

Email to: askmedsafe@moh.govt.nz

1344

Fluoride
.
to:
askmedsafe
09/01/2015 03:37 p.m.
Hide Details
From: "
To: askmedsafe@moh.govt.nz,
Please respond to "

1 Attachment

ATTACHMENT A_Fluoridation Legal Opinion June 24-14 (with Thiessen Affidavit).pdf

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

Regulations under the Medicines Act 1981 Consultation which would have the effect of providing legal clarity that the fluoride substances used to treat drinking water are not medicines

Medsafe
Clinical Leadership Protection & Regulation
Ministry of Health
PO Box 5013
WELLINGTON 6145

By email: (putting fluoride in the subject line): askmedsafe@moh.govt.nz

SUBMISSION FORM

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

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	**No**

Please provide a brief description of the organisation if applicable:	**Not applicable**
Address/email:	[redacted]
Your interest in this topic (for example, local body, consumer, manufacturer, health professional etc):	**Long-term student of issue.**
Question 1 *Do you support the proposed amendment? If not, why not?*	**I do not support the amendment which ignores all modern principles of pharmacology and appears to contravene several of Medsafe's own guidelines.** **For detailed reasons please see STATEMENT, ADDENDUM A and ATTACHMENT A**
Question 2 *Are there other fluoride-containing compounds used to treat community water supplies that should be specifically named in the regulation? If so, what are they?*	**No.**

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

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

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

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

I request a summary of submissions

STATEMENT

What I want.

That the Ministry of Health (MoH):

Withdraw this application to make an amendment to the *Medicines Act 1981 (the Act);* and

determine that the MoH recommends to Government that fluoridation of community water supplies should cease forthwith pending the establishment of an extensive, independent and public enquiry to assess submissions (which shall be sworn on oath or by affidavit) regarding the health safety, clinical effectiveness and cost effectiveness of fluoridation and possible alternatives to fluoridation for the purpose of addressing community oral health issues.

Comment

As the New Zealand Medicines and Medical Devices Safety Authority responsible for the regulation of therapeutic products in New Zealand and with the stated mission to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit there is an absolute onus on Medsafe to determine whether or not community water fluoridation is solely a therapeutic dental care treatment or if it also involves negative bodily health effects over a range of reported conditions.

It would be a crass abrogation of its duty of care if Medsafe recommends shedding this responsibility by incautiously promoting an arbitrary and self-serving amendment to the Act.

Introduction

The purpose of this proposed amendment would determine that fluoride-containing substances, including the substances hydrofluorosilicic acid (HFA) and sodium silico fluoride (SSF) are not medicines for the purposes of the Act when they are manufactured and supplied or distributed for the

purpose of fluoridating community water supplies.

[It needs to be stated at this point that both HFA and SSF are not of pharmaceutical grade and are by-products of industrial processes.]

The Medsafe invitation for submissions refers to the recent case *New Health New Zealand v Attorney-General* where the plaintiff sought to prevent or constrain the fluoridation of drinking water, including on the grounds that the fluoride compounds used are medicines under the Act. Yet, with reference to sections 21 and 22 of the Act Collins, J states that:

The purpose of adding fluoride to domestic water supplies leads inevitably to the conclusion that the process of fluoridating domestic water falls within the definition of "therapeutic purpose" in the Act. This is because fluoride is added to domestic water supplies in order to "prevent", "alleviate" and "treat" tooth decay, which is a "disease" or "ailment". Water fluoridation is also designed to "inhibit" the "physiological process" of tooth decay; and

In addition, the placing of fluoride in domestic water supplies achieves its intended action on human beings by a pharmacological process. I am therefore satisfied that introducing fluoride into domestic water supplies is undertaken for therapeutic purposes and satisfies the requirements of s 3(1)(a)(ii) of the definition of "medicine".

Rita Barnett of Chapman Fowler School of Law

In a major September 2014 paper (39 pp) titled *Compulsory Water Fluoridation: Justifiable public health benefit or human experimental research without informed consent?* Rita Barnett of Chapman Fowler School of Law concludes:

> *"The evidence continues to suggest that compulsory water fluoridation is no longer justifiable as a public health benefit.*
>
> *Using a systematic approach, public health officials willing to revisit fluoridation would likely find that the risks of fluoridating significantly outweigh the risks of not fluoridating, that the means chosen are not a good fit to the ends, and that the human rights burden and economic costs are not reasonable or justifiable.*

In addition, in light of NRC and EPA acknowledgement of the significant gaps in research, water fluoridation is in effect an unproven human subjects research experiment, and continued imposition of compulsory water fluoridation schemes violates numerous legal and ethical human subjects research protocols. Public health authorities still hoping to determine the population-wide need for water fluoridation should do so only in compliance with these research protocols, and provide for the informed consent and voluntary participation of all human subjects.

In addition, courts reviewing existing compulsory water fluoridation laws should no longer deny the fundamental rights implicated by compulsory water fluoridation schemes, and should instead conduct the proper heightened scrutiny review under Brainerd, utilizing all scientific evidence available today.

It remains to be seen whether the EPA will in fact lower the maximum contaminant levels of fluoride in the public water supplies, although a refusal to do so despite the NRC's recommendation might reflect an unfortunate political rather than scientific assessment.

Although lowering the MCL and SMCL for fluoride would belatedly recognize the excess amount of fluoride most children and adults are exposed to today, the cessation of all compulsory water fluoridation schemes should be the goal of all public health agencies, ethical lawmakers, and informed citizens."

Warenvertriebs and Orthica

The implications of the European Court of Justice decision (European Court of Justice, 9 June 2005, *HLH Warenvertriebs – Orthica v Deutschland*) on the regulation of 'functional drinks' with regard to the practice of water fluoridation were summarised by Douglas Cross on 12 May, 2009. His abstract reads:

Abstract

In a landmark decision of the European Court (ECJ) in the case of Warenvertriebs and Orthica, on the regulation of foods that appear to be on the borderline between foods and medicines, the Court ruled

• ***Where a product appears to be both a food and a medicinal product, the medicinal legislation must take precedence, and the product is subject to regulation as a medicine*** (my emphasis)

• *National Regulators cannot decline to recognise such products as medicines, and must subject them to pharmaceutical scrutiny with a view to issuing a marketing authorization*

• *Such 'functional drinks' must not be used to prepare foodstuffs, nor may food containing them be exported to other European Community (EC) member states. The ruling must be applied to fluoridated water. It establishes that*

• *Fluoridated water, as a 'near-water drink containing added minerals', is a functional food with recognisable pharmaceutical properties. As such, it must be regulated as a medicinal product.*

In the matter of pharmaceutical law

In the following extracts from the European Court decision distinctions are made between medicinal products and food additives.

In summary, the relevance of this determination to the current exercise is:

• *that the classification of a product as a medicinal product or as a foodstuff must take account of all the characteristics of the product, established both in the initial stage of the product and where it is mixed, in accordance with the method by which it is used, with water or with yoghurt.*

• *that the pharmacological properties of a product are the factor on the basis of which the authorities . . . must ascertain, in the light of the potential capacities of the product, whether it may . . be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings. The risk that the use of a product may entail for health is an autonomous factor that must also be taken into consideration by the competent national authorities in the context of the classification of the product as a medicinal product.*

• *that the concept of 'upper safe levels' . . . is of no importance for the purposes of drawing a distinction between medicinal products and foodstuffs.*

• *that in the context of an evaluation . . . of the risks that foodstuffs or food supplements may constitute for human health, the criterion of the existence of a nutritional need in the population . . . may be taken into consideration. However, the absence of such a need does not in itself suffice to justify. . . a complete ban on marketing foodstuffs or food supplements lawfully manufactured or placed on the market . . .*

SEE: http://www.ippt.eu/files/2005/IPPT20050609_ECJ_HLH_Warenvertriebs_-

Orthica_v_Deutschland.pdf

Further legal arguments against water fluoridation

In a memorandum of June 23, 2014 to Leisa Cianchino , Chair of Concerned Residents of Peel to End Fluoridation, from Nader R. Hasan of Ruby, Shiller, Chan, Hasan, Barristers states in his summary:

> *You have asked me to provide an opinion on the lawfulness of the Region of Peel's fluoridation program. In short, if an Ontario resident can properly present the existing scientific and medical evidence to an Ontario court, then there is a reasonable possibility that an Ontario court would declare the Fluoridation Act and municipal fluoridation programs in Ontario to be unconstitutional and thus invalid. Should that occur, there is also a real possibility that the Region of Peel would be held legally liable to residents in a lawsuit for harm caused by artificial fluoridation.*
>
> *This memorandum proceeds in three parts. Part I discusses the factual background to Ontario and Peel's fluoridation programs and situates these provisions in the global context. Part II discusses the scientific evidence relating to health effects of fluoridation. While fluoridation has significant potential effects on the environment and non-human animal and plant species, I focus on the human health effects because those effects are likely to figure most prominently in a legal challenge to fluoridation. Part III discusses the potential arguments in a legal challenge to fluoridation programs in Ontario as well as other legal issues that may arise in a court challenge to fluoridation in Ontario.*
>
> *I have also appended to this memo an affidavit from Dr. Kathleen Thiessen, a biomedical scientist, who has served on two U.S. National Research Council subcommittees dealing with fluoride exposure and toxicology. Her affidavit was commissioned specifically in connection with the ongoing debate about fluoridation in the Region of Peel.*
>
> **[The Thiessen affidavit dated April 29, 2014 is a statement that is crucially relevant to a Medsafe decision in this current case and is included in the attached Hasan opinion ATTACHMENT A –**
>
> **[ATTACHMENT A IS AN INTEGRAL PART OF THIS SUBMISSION]**

Related Products

(New Zealand Regulatory Guidelines for Medicines Part A: When is an application for approval for a new or changed medicine required?)

In section 1.1 of the guidelines on related products it is clearly noted that:

> ***Note: Fluoride mouthwashes, that are also intended to be swallowed as a supplement, are medicines***

Given that it is now currently accepted that fluoride as a dental therapeutic works primarily via topical mechanisms it is difficult not to conclude that fluoridated water from a community water supply is a mouthwash that is also intended to be swallowed and should be considered as a medicine.

How does Medafe now determine quality assurance, good manufacturing practice, quality control, product quality review and quality risk management under the existing fluoridation practices using HFA and SSF and what assessments of communal harm have been undertaken by the MoH with respect to fluoridation?

Precautions

The "precautionary principle" says that if an action is suspected of causing harm to the environment or human health, then, in the absence of scientific consensus, the onus falls on the individual or organisation promoting a cause to prove safety and effectiveness beyond reasonable doubt.

This principle underlies the conflict between the pro-fluoridation New Zealand dental/health establishment and local citizens in many communities where community water fluoridation exists or is planned. Citizens believe there is ample evidence that suggests that the bodily cumulative toxin fluoride causes health problems and should be banned. With fluoridation, The New Zealand dental/health establishment ignores the precautionary principle and simply repeats the 'safe and effective' mantra.

In my view, the overall weight of evidence from the cumulative body of information contained in the scientific literature demonstrates that there are uncertainties about the kinds of adverse health outcomes that may be associated with fluoridation and the likelihood of the occurrence of adverse health outcomes. (See *A Bibliography of Scientific Literature on Fluoride* - http://www.slweb.org/bibliography.html)

Through this site there is access to abstracts for most of the references, and whole papers or excerpts for many. Virtually all listings are peer-reviewed articles from mainstream medical, dental, and

scientific journals worldwide, and most offer legitimate reason for concern regarding the health effects of fluoride toxicity and consequently fluoridation.

Good questions

On May 26, 2014, in response to a request under the Canadian *Access to Information Act* Amanda Wilson of the Health Canada Access to Information and Privacy Division stated very succinctly (Their file: A-2014-00168 na):

> ***After a thorough search for the requested information, no records were located which respond to your request.***

The original request text is as follows:

> *Documents pertaining specifically to hydrofluosilicic acid in Alberta and Canadian tap water:*
>
> - *Sudies from 1940 showing dental efficacy and human safety.*
> - *Studies from 1950s showing dental efficacy and human safety.*
> - *Any double blind study done by Canada or any province showing dental efficacy and human safety, of any date.*
> - *Any double blind study done by anywhere in the world that was considered.*
> - *Any toxicity study, of any date, done by Canada or the world that was considered.*
> - *Evidence of any kind, (not opinion) that shows statistical viability of water fluoridation in terms efficacy, and margin of error calculations.*
> - *Evidence of any kind, (not opinion) that shows statistical viability of water fluoridation in terms of human safety over a life-time, and margin of error calculations.*
> - *Evidence of any kind, (not opinion) that shows statistical viability of water fluoridation in terms of human safety, and margin of error calculations, for infants, young children, elderly, or any adult with disability, diabetes, bone disease, autism, thyroid ailments, kidney disease, etc.*
> - *Evidence of any kind of consideration of human rights and medical ethics, namely our human right to opt out of the forced water fluoridation program, and if that consideration exists, why the overriding of these well-established medical standards are breached.*

It is my opinion that Medsafe, as the business unit of the New Zealand Ministry of Health, must be able to provide reassuring answers to these pertinent questions in its consideration of this

fraught issue which will not be resolved by way of the proposed amendment to the Act.

Alternative to fluoridation

As a viable alternative to fluoridation the Ministry of Health must seriously consider the Scottish 'Childsmile' programmes of dental health where absence of fluoridation is immaterial and huge dental health gains made.

Over 90,000 nursery school children take part in supervised tooth-brushing programmes and the Scottish government distributes toothpaste and brushes during the first year of life, at nursery and in the first year of primary school.

Latest figures show 68.2% of Scottish children in Primary 1 (4.5-5.5-year-olds) have no obvious dental decay compared with 54.1% in 2005/06.

The comparable 2012 figure for New Zealand as a whole, including all fluoridated communities, was 58.43%.

The Scottish 'Childsmile' programmes are ongoing, recognising the need to maintain efforts to tackle children's dental health issues - particularly for those living in deprived areas.

Conclusion

I append **ADDENDUM A** below for your consideration and repeat my want that:

That the Ministry of Health (MoH):

Withdraw this application to make an amendment to the *Medicines Act 1981 (the Act);* and

2. determine that the MoH recommends to Government that fluoridation of community water supplies should cease forthwith pending the establishment of an extensive, independent and public enquiry to assess submissions (which shall be sworn on oath or by affidavit) regarding the health safety, clinical effectiveness and cost effectiveness of fluoridation and possible alternatives to fluoridation for the purpose of addressing community oral health issues.

9 Januray 2015

ADDENDUM A

Ten Key Papers that Challenge the Pro-Fluoridation Mantra

FLUORIDEALERT.ORG

FAN Bulletins

December 22-23, 2014

Paul Connett, PhD

Introduction.

Promoters of fluoridation repeat ad nauseam the mantra that fluoridation is “safe”, “effective” and “cost effective.” Six of these KEY PAPERS challenge the mantra of fluoridation’s “safety.” Or to be more precise – since there is no question that fluoride is very toxic and damages health – we will demonstrate that there is no adequate margin of safety to protect **all** citizens drinking artificially fluoridated water (and getting fluoride from other sources) from known health effects

Listing of the 10 studies

1. Brunelle and Carlos. 1990. Recent Trends in Dental Caries in U.S. Children and the Effect of Water Fluoridation. *Journal of Dental Research,* 69 (Special Issue):723-727.

2. Featherstone JD. 2000. The Science and Practice of Caries Prevention. *Journal of the American Dental Association (JADA)*, Jul; 131(7):887-99.

3. Warren JJ, et al. 2009. Considerations on optimal fluoride intake using dental fluorosis and dental caries outcomes–a longitudinal study. *Journal of Public Health Dentistry*, 69(2):111-15. Spring.

4. Ko L, Thiessen KM. 2014. A critique of recent economic evaluations of community water fluoridation. *International Journal of Occupational and Environmental Health.*

5. Luke J. 2001. Fluoride deposition in the aged human pineal gland. *Caries Research*35(2):125-128. See also Luke's PhD thesis click here.

6. Xiang Q, et al. 2003a. Effect of fluoride in drinking water on children's intelligence.*Fluoride* 36(2):84-94, and **Xiang Q, et al. 2003b.** Blood lead of children in Wamiao-Xinhuai intelligence study [letter]. *Fluoride* 36(3):198-199.

7. National Resource Council of the National Academies. 2006. Fluoride in Drinking Water: A Scientific Review of EPA's Standards.

8. Bassin EB, et al. 2006. Age-specific fluoride exposure in drinking water and osteosarcoma (United States). *Cancer Causes and Control*, May;17(4):421-8.

9. Choi AL, Grandjean P, et al. 2012. Developmental Fluoride Neurotoxicity: A Systematic Review and Meta-Analysis. *Environmental Health Perspectives*, 120(10):1362–1368.

10. Choi AL, et al. 2015. Association of lifetime exposure to fluoride and cognitive functions in Chinese children: A pilot study. *Neurotoxicology and Teratology*, 47:96–101.

A few words about papers 1-4.

STUDIES ON EFFECTIVENESS OF FLUORIDATION

1. Brunelle and Carlos. 1990. Recent Trends in Dental Caries in U.S. Children and the Effect of Water Fluoridation. *Journal of Dental Research,* 69 (Special Issue):723-727.

This was the largest survey of dental decay in children in the US (the authors studied 39,000 children in 84 communities). The study was organized by the pro-fluoridation National Institute for Dental Research (NIDR). These NIDR authors found an average difference of only 0.6 of one tooth surface between children (aged 5-17) who lived all their lives in a fluoridated community compared to a non-fluoridated community (see Table 6). This result was NOT shown to be statistically significant. The pro-fluoridation bias of the authors becomes apparent in the way they present these unimpressive results in their abstract. They do not report the difference in tooth decay as an absolute value (i.e. 0.6 of one tooth surface) but as a relative % difference. This value of 18% looks more impressive than an absolute saving of 0.6 of about 100 tooth surfaces in a child's mouth (there are 128 when all the teeth have erupted). Nor did the authors admit that they had not shown that this result was statistically significant: it wasn't! Here is an excerpt from their abstract, which says more about the politics of this issue than the science.

"Children who had always been exposed to community water fluoridation had mean DMFS (decayed missing and filled surfaces, PC) about 18% lower than those who had never lived in a fluoridated communities. When some of the "background" effect of topical fluoride was controlled, this difference increased to 25%. ***The results suggest that water fluoridation has played a dominant role in the decline in caries and must continue to be a major prevention methodology.***" (my emphasis, PC)

Really?

2. Featherstone JD. 2000. The Science and Practice of Caries Prevention. *Journal of the American Dental Association (JADA)*, Jul; 131(7):887-99.

In this article, which was a cover story in JADA edition of July 2000, Featherstone reached the same conclusions that many prominent dental researchers had reached over the previous 20 years: Namely, that the predominant mechanism of fluoride's beneficial action is *topical* not *systemic.* The CDC acknowledged the same thing in 1999. In other words you don't have to swallow fluoride to protect your teeth and therefore there is no need to force it on people who don't want it via their drinking water. This is probably one of the reasons why, according to the World Health Organizations data online, that tooth decay rates in 12-year-olds have been declining at about the same rates in non-fluoridated as in fluoridated countries since the 1960s (http://fluoridealert.org/issues/caries/who-data/). Here are Featherstone's conclusions:

CONCLUSIONS:

Fluoride, the key agent in battling caries, **works primarily via topical mechanisms**: inhibition of demineralization, enhancement of remineralization and inhibition of bacterial enzymes.

CLINICAL IMPLICATIONS:

Fluoride in drinking water and in fluoride-containing products reduces caries **via these topical mechanisms.**

3. Warren JJ, Levy SM, Broffitt B. et al. 2009. Considerations on optimal fluoride intake using dental fluorosis and dental caries outcomes–a longitudinal study. *Journal of Public Health Dentistry,*

69(2):111-15. Spring.

If the Brunelle and Carlos (1990) paper was the **largest** US government funded study, the Warren et al (2009) paper was the **most precise.** This investigation was conducted as part of the "Iowa study," which has been examining tooth decay in a cohort of children since birth. Warren et al. examined tooth decay as a function of daily ingestion of fluoride in mg/day (i.e. they examined individual exposure rather than the traditional way of comparing dental decay rates between communities with different concentrations of fluoride in water). The authors could not determine a clear relationship between caries experience and daily dose in mg/day. The authors' state:

These findings suggest that achieving a caries-free status may have relatively little to do with fluoride intake, while fluorosis is clearly more dependent on fluoride intake.

CONCLUSIONS:

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.

Please note that all three of these studies were carried out by pro-fluoridation dental researchers. Many dentists are oblivious of the fact that research carried out by their own pro-fluoridation colleagues has undermined the effectiveness that they claim. In addition it should be noted that in the 70 years since fluoridation was launched in 1945 there has never been a Randomized Control Trial (RCT) to establish in a scientific fashion that swallowing fluoride lowers tooth decay. This is the gold standard used by the FDA to establish the efficacy of any drug. Considering such a flimsy scientific basis for the effectiveness of this practice it is the height of arrogance to force a known toxic substance on people who don't want it.

STUDIES ON THE COST-EFFECTIVENESS OF FLUORIDATION

4. Ko L, Thiessen KM. 2014. A critique of recent economic evaluations of community water fluoridation. *International Journal of Occupational and Environmental Health.*

This paper demolished the claim by Susan Griffin (an economist at the CDC) that for every dollar spent on fluoridation $38 was saved on dental costs. This statement has been used countless times by state dental directors, public health officials and other promoters of fluoridation. We have provided more details on this in a previous bulletin.

STUDIES ON THE TOXICITY OF FLUORIDE AND SAFETY OF FLUORIDATION

5. National Resource Council of the National Academies. 2006. Fluoride in Drinking Water: A Scientific Review of EPA's Standards.

A landmark report on the toxicology of **fluoride** is available to read and search for free online. It is one of the very few reviews of fluoride for which the panel was balanced. It contained both pro and

anti-fluoridation scientists. The report concluded that the current U.S. maximum contaminant level for fluoride (4 ppm) in drinking water is an unsafe level for human health. The panel recommended that the EPA conduct a new risk assessment to establish a *goal* for a safe level of fluoride in drinking water (Maximum Contaminant Level Goal, MCLG) and thence a new Federally enforceable standard (or MCL). After over 8 years the EPA has not completed this determination and so for 8 years the US continued to operate under unsafe standards for fluoride in water.

BONE DAMAGE. Among many health concerns the panel noted that fluoride damages the bone and accumulates there with a significantly long half-live. The first symptoms of bone damage are indistinguishable from arthritis and with further accumulation (fluoride's half-life in bone is at least 20 years) it makes the bones more brittle and prone to fracture.

ENDOCRINE DISRUPTER. The panel also concluded that fluoride is an endocrine disrupter. It lowers thyroid function and accumulates in the pineal gland (see paper 6 below).

NEUROTOXICIY. Many animal studies indicate that fluoride can enter and damage the brain via a number of mechanisms. At the time this review was published only 5 IQ studies were available. Since publication this total has risen dramatically. Including new studies and older Chinese studies that have been translated by FAN, there are now (as of Dec 2014) 49 studies, of which 42 show an association between exposure to fairly modest doses of fluoride and lowered IQ (see papers 7-9 below). For those who want more details of all the animal and human studies on fluoride's toxicity see FAN's health database (www.FluorideAlert.org/issues/health/brain).

OSTEOSARCOMA. At the time of publication the NRC panel had been informed by FAN of a doctoral thesis by Elise Bassin from Harvard, which indicated an association between exposure to fluoridated water at a critical age range in young boys (6-8 years) and succumbing by the age of 20, to osteosarcoma, a frequently fatal bone cancer. The NRC did not take a definitive position on this study preferring to wait for the study to be published. Bassin's publication came in May of 2006 (discussed below, see paper 10). However the same edition of the journal also contained a letter from her pro-fluoridation thesis advisor Chester Douglass claiming that his larger study would show that her thesis did not hold. However, he has never published this promised rebuttal of her thesis.

Subsets of US population exceeding EPA's safe reference dose. While the NRC review did not study fluoridation as such (either its risk or benefits), the authors did provide an exposure analysis (see Chapter 2). The panel showed that several subsets of the population drinking fluoridated water at 1 ppm fluoride (including bottle-fed infants) are exceeding the EPA's safe reference dose of 0.06 mg/kg/day (see the diagram on page 85). **This finding makes nonsense of the claim by both ADA and the CDC that this very important review was not relevant to water fluoridation.**

No margin of safety. Based on this review it is abundantly clear that *fluoride* damages health and that for *several* end-points (including lowered IQ), there is no adequate margin of safety to protect all individuals in a large population drinking fluoridated water. This critical conclusion is often lost on promoters of fluoridation who confuse concentration with dose. They simplistically compare the *concentration* of fluoride in the water of the community examined with the *concentration* of fluoride in artificially fluoridated water. Such a comparison does not provide a margin of safety. For

that one needs two things:

First, one has to **ascertain the range of *doses* in the fluoridated population. This takes into account how much water citizens drink (which can be very large because there is no control on the amount of water consumed) and how much fluoride they get from other sources.**

Second, in order to determine a safe dose (sufficient to protect everyone) one also has to take into account the full range of sensitivity to a toxic substance anticipated in a large population. **It is the failure to do this that has been the biggest and most reckless mistake of the fluoridation program since it began and fluoridation promoters today.**

6. Luke J. 2001. Fluoride Deposition in the Aged Human Pineal Gland. *Caries Research* 35(2):125-128. See also Luke's PhD thesis click here.

Luke showed that fluoride accumulates on the calcified deposits in the human pineal gland and lowers melatonin production in animals. No health agency in any fluoridating country has attempted to repeat Luke's work despite the fact that melatonin levels have been related to many health problems. For example, Autistic children produce no melatonin.

7. Xiang Q, Liang Y, Chen L, et al. 2003a. Effect of fluoride in drinking water on children's intelligence. Fluoride 36(2):84-94, and **Xiang Q, Liang Y, Zhou M, and Zang H. 2003b.** Blood lead of children in Wamiao-Xinhuai intelligence study [letter]. Fluoride 36(3):198-199.

Of the 42 (out of 49) studies (as of Dec 2014) that have found a relationship between fluoride exposure and lowered IQ, the Xiang study is one of the most important.

In the Xiang study, the authors controlled for key confounding values such as lead, and iodine (and arsenic retrospectively), parental income and educational status. In addition to comparing the mean IQ of children *between* the high-fluoride and low-fluoride village (a drop of 5-10 IQ points across the whole age range) they also sub-divided the children in the *high-fluoride* village into 5 groups with mean fluoride concentrations ranging from 0.7 to 4.3 ppm (see Table 8 in their study).

By focusing on one village they eliminated any other environmental differences between the two villages. **They found that as the fluoride concentration in the five sub-groups increased two things happened: 1) the mean IQ systematically decreased and 2) the percentage of children with an IQ less than 80 (borderline mentally handicapped) dramatically increased from 0% to 37.5%.**

Lowest level where IQ lowered. The lowering of IQ is first observed in the sub-group at 1.53 ppm, and bearing in mind the range of fluoride concentration for that sub-group, one has to conservatively assume that some children in this study would have had their IQ lowered at the lower end of the range fluoride concentrations in this group **1.26 ppm.**

Such a result leaves absolutely no margin of safety to protect all children in an artificially fluoridated community (fluoride levels between 0.7 to 1.2 ppm) from this serious outcome. Please note there is **no margin of safety** to protect:

A) Against the full range of exposure, especially when you consider the different amounts of water drunk by children and their exposure to other sources such as toothpaste. It should also be added that in two respects the Chinese children in the Xiang study would have had less exposure to fluoride from two key sources than American children. Children living in rural Chinese villages are less likely to be using fluoridated toothpaste and less likely to be bottle-fed (bottle-fed babies, where the formula is made up with fluoridated water, get about 200 times more fluoride than breast-fed babies).

B) Nor does it protect against the full range of sensitivity expected in a large population (as discussed in 5 above).

The last children that need a further lowering of IQ are children from low-income families, whose IQ has already been compromised by so many other factors (e.g. poorer diet, poorer educational opportunities and more exposure to pollution). Yet it is these children who are the primary target of fluoridation programs.

8. Choi AL, Sun G, Zhang Y, Grandjean P. 2012. Developmental Fluoride Neurotoxicity: A Systematic Review and Meta-Analysis. *Environmental Health Perspectives*, 120(10):1362–1368.

This Meta-analysis of 27 IQ studies was conducted by a team from Harvard including world-famous neuroscientist Philippe Grandjean (an expert on mercury and author of the recent book, "Only One Chance"). This team acknowledged weaknesses in many of the studies but also noted the remarkable consistency of the finding that IQ was lowered in 26 out of the 27 studies reviewed. The average lowering was 7 IQ points, which is substantial, considering that at the population level even an average lowering of one IQ should be avoided.

9. Choi AL, Zhang Y, Sun G, et al. 2015. Association of lifetime exposure to fluoride and cognitive functions in Chinese children: A pilot study. Neurotoxicology and Teratology, 47:96–101.

This Pilot study in China was carried out at fluoride levels, which overlap levels used in US fluoridation programs. They didn't measure IQ specifically in this study but reported the results of a very simple test: the child's ability to repeat a sequence of numbers both forwards and backwards. Even children with very mild dental fluorosis performed less well on this specific mental development test, than children without fluorosis. One of the experts involved in this study was Dr. David Bellenger who is world famous for his studies on lead's neurotoxicity.

Another co-author was Dr. Philippe Grandjean and in an editorial on his website "Chemical Brain Drain" he used this study to counteract the claim from proponents that the IQ findings were not relevant to the fluoride levels used in water fluoridation. For the children in this study, Grandjean writes:

> *"Their lifetime exposures to fluoride from drinking water* ***covered the full range allowed in the US****. Among the findings, children with fluoride-induced mottling of their teeth –* ***even the mildest forms that appears as whitish specks on the enamel – showed lower performance on some neuropsychological tests.*** *This observation runs contrary to popular wisdom that the enamel effects represent a cosmetic problem only and not a sign of toxicity. At least one of five American children has some degree of mottling of their teeth...****Prevention of chemical brain drain should be considered at least as important as protection against caries."*** **(my emphasis, PC).**

10. Bassin EB, Wypij D, Davis RB, Mittleman MA. 2006. Age-specific fluoride exposure in drinking water and osteosarcoma (United States). *Cancer Causes and Control*, May; 17(4):421-8.

This is the only study of osteosarcoma (a frequently fatal bone cancer in children), which studied the age at which exposure to fluoride was experienced. The authors write:

"We observed that for males diagnosed before the age of 20 years, fluoride level in drinking water during growth was associated with an increased risk of osteosarcoma, demonstrating a peak in the odds ratios from 6 to 8 years of age. All of our models were remarkably robust in showing this effect, which coincides with the mid-childhood growth spurt."

The finding that there may a critical window of vulnerability in young men **has never been refuted** – or even investigated – since Bassin's paper was published in 2006. The shocking fact is that with this paper comes the possibility that a few young men each year may be dying from osteosarcoma because they have been exposed to fluoridated water at a critical age. Even though this has not been refuted the practice of fluoridation continues to be pushed by health authorities. Where is the precautionary principle here?

CONCLUSIONS

Between them the TEN KEY PAPERS listed invalidate all three claims of the pro-fluoridation mantra.

Fluoridation is not effective.

The largest US study **(Brunelle and Carlos, 1990)** and the most precise study of children's tooth

decay **(Warren et al., 2010)** provide little evidence that swallowing fluoride reduces tooth decay.**Featherstone, 2000** (and others) have provided the probable reason for these problematic results. The predominant (if any) benefit of fluoride is topical not systemic. There is no need to swallow fluoride to fight tooth decay and there is no justifiable reason to force people to drink fluoridated water against their will.

Fluoridation is not safe.

There is no disputing the fact that fluoride damages health but what about fluoridation? The landmark 500-page review by the **National Research Council (NRC, 2006)** showed that certain subsets of the US public are exceeding the EPA's safe reference dose for fluoride, including bottle-fed infants. The NRC (2006) reviewed many health impacts for which there is no adequate margin of safety to protect all individuals drinking fluoridated water. These include lowered thyroid function, accumulation in the pineal gland **(Luke et al., 2001),** bone damage, and lowered IQ **(Xiang at al, 2003a,b).** Xiang found that some children had their IQ lowered at fluoride levels as low as 1.26 ppm. Xiang' study was one of 42 studies that have found this effect. A Review by a Harvard team **(Choi et al, 2012)** found an average lowering of 7 IQ points in 26 out of 27 studies. **Choi et al, 2015** found learning disabilities in children with very mild fluorosis, which impacts many US children. Thus fluorosis at any level can no longer be considered merely a cosmetic affect. A study by **Bassin et al., 2006** has disturbingly shown that some young boys may be losing their lives each year from being exposed to fluoridated water at 1 ppm in their 6^{th}, 7^{th} and 8th years. This study remains unrefuted.

Fluoridation is not cost-effective.

Lo and Thiessen (2014) have demolished the claim by CDC economist Susan Griffin that for every dollar spent on fluoridation $38 is saved on dental treatment. This claim by Griffin has been used Ad Nauseam by promoters of fluoridation including many state public health officials. Will they continue to do so?

Paul Connett, PhD

Director

Fluoride Action Network

Co-Author of The Case Against Fluoride (Chelsea Green, 2010)

ENDS

attached to 1344

MEMORANDUM

RUBY SHILLER CHAN HASAN
BARRISTERS

TO: [illegible]

FROM: [illegible]

DATE: June 23, 2014

RE: Legal Arguments Against Artificial Water Fluoridation

SUMMARY AND OPINION

You have asked me to provide an opinion on the lawfulness of the Region of Peel's fluoridation program. In short, if an Ontario resident can properly present the existing scientific and medical evidence to an Ontario court, then there is a reasonable possibility that an Ontario court would declare the *Fluoridation Act* and municipal fluoridation programs in Ontario to be unconstitutional and thus invalid. Should that occur, there is also a real possibility that the Region of Peel would be held legally liable to residents in a lawsuit for harm caused by artificial fluoridation.

This memorandum proceeds in three parts. Part I discusses the factual background to Ontario and Peel's fluoridation programs and situates these provisions in the global context. Part II discusses the scientific evidence relating to health effects of fluoridation. While fluoridation has significant potential effects on the environment and non-human animal and plant species, I focus on the human health effects because those effects are likely to figure most prominently in a legal challenge to fluoridation. Part III discusses the potential arguments in a legal challenge to fluoridation programs in Ontario as well as other legal issues that may arise in a court challenge to fluoridation in Ontario. I have also appended to this memo an affidavit from Dr. Kathleen Thiessen, a biomedical scientist, who has served on two U.S. National Research Council subcommittees dealing with fluoride exposure and toxicology. Her affidavit was commissioned specifically in connection with the ongoing debate about fluoridation in the Region of Peel.

PART I – FACTUAL BACKGROUND OF ARTIFICIAL FLUORIDATION

Fluoride is the anionic or reduced form of fluorine and is the thirteenth most abundant element in the Earth's crust. Given that fluorine is so abundant, it is not surprising that fluoride compounds are components of minerals in rocks and soil. Due to these components, and the action of ground water acting upon them, fluoride is released into the groundwater and is the major contributor to the small amounts of fluoride present in most water sources. In general, most ground water contains low concentrations of fluoride, typically less than 0.5 mg/L.

Fluoridation is the controlled addition of fluoride ions to water that has a low fluoride concentration (sometimes called "artificial fluoridation"). In the early 1900s, significant work was done in understanding the root cause of the mottling of teeth and tooth decay. This mottling, and improved dental health, was ultimately attributed to the high fluoride concentrations in the ground water that was ingested by these individuals. Over time, additional studies were undertaken, which were purported to establish a relationship between fluoride and substantially fewer cavities, ultimately leading to four community-wide trials that were established in the mid-1940s. These trials were conducted in Grand Rapids, MI; Newburgh, NY; Brantford, ON and Evanston, Ill. Soon thereafter, the U.S. Public Health Service and many dental associations endorsed community-wide fluoridation as a practical and safe public health measure to prevent tooth decay.

Over the past 65 years, additional investigation has examined everything from the health effects of the various fluoride compounds used in the fluoridation process to the dosage levels that provide adequate dental health protection. Over this time-frame, fluoride dosage levels have on average dropped from 1.0 to 1.2 mg/L to between 0.5 and 0.8 mg/L, while the maximum acceptable concentration (MAC) has been established at 1.5 ppm. The Ontario Ministry of Health and Long Term Care, in partnership with the Ontario Ministry of the Environment, have established a guideline of 0.5-0.8 mg/L for fluoride in drinking water. The Region of Peel claims to "closely monitor" the fluoride levels in the

water supply to make sure the correct concentration is being maintained.[1] Under the *Safe Drinking Water Act Regulations*, the maximum allowable concentration of fluoride in Ontario drinking water is 1.5 mg/L.[2]

In 1961, the Province of Ontario enacted the *Fluoridation Act*,[3] which specifically provided for the establishment and maintenance of fluoridation of drinking water within the Ontario waterworks system. The *Fluoridation Act* does not require fluoridation. Under the *Act*, municipalities were given the discretionary authority, by way of the passing of a by-law "...to establish, maintain and operate, or require that the local board establish, maintain and operate, a fluoridation system in connection with the waterworks system."[4]

Cities that already had a fluoridation program in place were not required to pass a new by-law; the *Fluoridation Act* permitted the continuation of those programs.[5] Accordingly, the *Fluoridation Act* permitted the continuing fluoridation of the water supplies of the City of Mississauga and City of Brampton. In 2007, the Regional Municipality of Peel passed a by-law establishing a fluoridation system in the Town of Caledon.[6]

According to the Canadian Dental Association, approximately 45% of Canadians drink fluoridated public water.[7] However, the figures vary significantly across the country. Quebec has historically opposed artificial fluoridation, and as such, today less than 3%

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[1] Region of Peel, Peel Public Health, "Fluoridation - Frequently Asked Questions", online: http://www.peelregion.ca/health/topics/commdisease/dental/fluoridation.htm#10.

[2] *Safe Drinking Water Act, 2002, Ontario Drinking Water Quality Standards*, O.R. 169/03, Schedule 2.

[3] *Fluoridation Act*, R.S.O. 1990, c. F.22.

[4] *Ibid.*, s. 2(1).

[5] *Ibid.*, s. 2.1(2).

[6] Regional Municipality of Peel, *A by-law to provide for the fluoridation of the Town of Caledon's communal water supply*, online: http://www.peelregion.ca/health/topics/commdisease/dental/by-law.htm.

[7] Danielle Rabby-Waytowich, "Water Fluoridation in Canada: Past and Present" (July/August 2009), 75 JCDA 451, online: http://cda-adc.ca/jcda/vol-75/issue-6/451.pdf.

Quebec's population drinks fluoridated water.[8] Only approximately 3.7% of residents of British Columbia drinks fluoridated water.[9] At 75.9%, Ontario is the most heavily fluoridated province. In recent years, however, some medium-sized municipalities, including Waterloo and Windsor, have ended their fluoridation programs.[10] The debate between pro- and anti-fluoride activists in Ontario municipalities is acrimonious, with both sides accusing the other of "cherry picking" research to boost its argument. Health Canada as well as the Canadian Medical Association and the Canadian Dental Association are staunchly pro-fluoride. The Green Party of Canada, and respected NGOs such as the Council of Canadians, Green Peace Canada and Sierra Club, oppose fluoridation of municipal water supplies.

Canada's rate of fluoridation puts it squarely in the global middle among the Organization of Economic and Cooperative Development ("OECD") countries. According to a 2002 study, approximately 69% of U.S. residents were living in communities with fluoridated water.[11] By contrast, only approximately 3% of the population in Western Europe currently consumes fluoridated water.[12] Despite this fact, the available evidence does not suggest that tooth decay rates are higher in unfluoridated Western European countries than in the United States or other fluoridated countries.

PART II – SCIENTIFIC EVIDENCE CONCERNING FLUORIDATION

The success of any legal challenge to Ontario's fluoridation program will turn on the quality of expert and scientific evidence presented. For the claimants to be successful, they will have to adduce evidence of both (1) fluoride's speculative and/or nominal

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[8] Eric Tchouaket et al, "The economic value of Quebec's water fluoridation program" (June 2013), 21 J Public Health 523 at 524.

[9] *Ibid.* Danielle Rabby-Waytowich, "Water Fluoridation in Canada: Past and Present", *supra* at 452.

[10] See CBC News, Fluoride no longer to be added to Windsor water" (Jan. 29, 2013), CBC.ca online: http://www.cbc.ca/news/canada/windsor/fluoride-no-longer-to-be-added-to-windsor-water-1.1325977.

[11] Centers for Disease Control and Prevention, "Fluoridation Status: Percentage of U.S. Population on Public Water Supply Systems Receiving Fluoridated Water", CDC.gov online: http://apps.nccd.cdc.gov/nohss/FluoridationV.asp.

[12] Fluoride Action Network, "Water Fluoridation Status in Western Europe", online: http://fluoridealert.org/content/water_europe/.

benefit in reducing dental caries; and (2) the risk of harm posed by fluoride in adults and children. To date, the most comprehensive review of the existing scientific evidence on fluoride's toxicity is the study conducted by the National Research Council's Committee on Fluoride in Drinking Water, which was published in 2006.[13] The National Research Council ("NRC") is a non-profit entity in the United States, whose membership includes eminent scientists across the United States. It is funded in part by Congress and the U.S. federal agencies. Its studies are generally considered authoritative.

The review of the evidence below is not meant to be exhaustive. It is meant rather to highlight the types of evidence that could be presented in a legal challenge.

Lack of Evidence of Fluoridation's Benefits

The purpose of fluoridation is to reduce dental caries (tooth decay). Since the 1950s, it has been virtually gospel within the dental community that fluoridation of drinking water is responsible for reducing tooth decay. This belief was once thought to be unassailable. But the evidence available today makes it far from clear. We now know that tooth decay is enhanced or diminished by numerous factors, including dietary, socio-economic, environmental, hygienic and many other factors. Recent studies have shown that tooth decay rates have decreased as fast in unfluoridated areas as in fluoridated areas,[14] leading many to suggest that other factors — i.e., improved diet, modern dental care, more regular trips to the dentist and the availability of fluoridated toothpaste — are the causes of decreases in tooth decay rather than water fluoridation.

In 1999, the U.S. Centers for Disease Control and Prevention conceded what many dental researchers already had concluded: that fluoride's predominant mechanism of action was

[13] Committee on Fluoride in Drinking Water, National Research Council, *Fluoride in Drinking Water: A Scientific Review of EPA's Standards* (National Academies of Sciences Press, 2006) at 4 [hereinafter "NRC Report"].

[14] See, e.g., John Colquhuon, *Child Dental Health Differences in New Zealand*, 9 Comm. Health Stud. 85 (1987); John Yiamouyiannis, *Water Fluoridation and Tooth Decay: Results from the 1987-1987 National Survey of Schoolchildren*, 23 Fluoride 55 (1990).

topical, not *systemic.*[15] In other words, to the extent that fluoride works, it does so via direct exposure to the tooth and not from inside the body. Connett, Beck and Micklem argue persuasively that if the primary benefit of fluoride is through topical treatment on teeth, then it makes no sense to expose every tissue in the body to fluoride through ingestion in drinking water.[16]

Scientific Evidence of Fluoride's Harm

There is significant scientific evidence of harm caused by fluoridation. And even if the harms associated with fluoridation cannot be proven to a degree of scientific certainty, the existing scientific information and literature point to a variety of serious risks inherent in artificial fluoridation.

Dental Fluorosis

There is a scientific consensus that fluoridation can cause "dental fluorosis", which is a dose-related mottling of the enamel of the teeth that can range from mild discoloration of the tooth surface to severe staining and pitting. The condition is permanent after it develops in children during tooth formation. Whether to consider fluorosis to be an adverse health effect or merely a cosmetic effect has been the subject of debate. However, the U.S. National Research Council has concluded that severe fluorosis is more than a cosmetic issue because severe fluorosis can lead to enamel loss, leaving the dentin open to decay and infection and causing structural damage to the tooth.[17]

Muskoskeletal Effects

Skeletal fluorosis is a bone and joint condition associated with prolonged exposure to high concentrations of fluoride. Fluoride increases bone density and appears to exacerbate the growth of osteophytes present in the bone and joints, resulting in joint

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[15] Centers for Disease Control and Prevention, "Achievements in Public Health, 1900-1999: Fluoridation of Drinking Water to Prevent Dental Caries" (Oct. 1999), 48 Mortality and Morbidity Weekly Review 933-40, online: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm.

[16] Paul Connett et al, *The Case Against Fluoride: How Hazardous Waste Ended Up in Our Drinking Water and the Bad Science and Powerful Politics that Keep It There,* at 13.

[17] NRC Report, *supra*, at 4

stiffness and pain.[18] There is no doubt that high concentrations of fluoride cause skeletal fluorosis. The debate within the scientific community is the extent of the risk of skeletal fluorosis at current levels of fluoridation.[19] Defenders of fluoridation argue that a concentration of 1.5mg/L is too low to present a risk of skeletal fluorosis. It should, however, be noted that the first symptoms of skeletal fluorosis are similar to the first symptoms of many forms of arthritis — stiffness and pain in the joints and pain in the bones.

There is also scientific evidence that fluoride can increase the risk of bone fractures. The NRC Report notes that "several strong observational studies indicated an increased risk of bone fracture in populations exposed to fluoride at 4 mg/L."[20] While there are fewer studies dealing with the risk of bone fracture within populations exposed to fluoride at a rate of 2 mg/L or lower, there is a peer-reviewed study from Finland that suggests an increased rate of hip fracture in populations exposed to fluoride at concentrations above 1.5 mg/L,[21] which is the maximum allowable rate of fluoridation in Ontario.

Neurobehavioural Effects

Animal and human studies of fluoride have been published reporting adverse cognitive and behavioural effects. Epidemiological studies conducted in China have reported I.Q. deficits in children exposed to fluoride at 2.5 to 4 mg/L in drinking water. The NRC found these studies to be sufficiently alarming to call for "additional research on the effects of fluoride on intelligence."[22] In 2012, a group of scientists published a systematic review of the literature on developmental fluoride neurotoxicity. The review concluded that the consistency of pre-existing studies showing a link between fluoride

[18] NRC Report, *supra*, at 5.

[19] *Ibid.* at 6.

[20] *Ibid.*

[21] *Ibid.* at 7.

[22] *Ibid.* at 8.

and cognitive deficits shows that potential developmental neurotoxicity of fluoride should be a high research priority.[23]

The NRC also noted that fluorides "increase the production of free radicals in the brain through several different biological pathways. These changes have a bearing on the possibility that fluorides act to increase the risk of developing Alzheimer's disease."[24] The NRC has called for additional studies in this area as well.[25]

Genotoxicity and Carcinogenicity

There have been a number of studies that have suggested a link between fluoride and bone cancer. The NRC Report concludes that fluoride "appears to have the potential to initiate and promote cancers, particularly of the bone, but the evidence to date is tentative and mixed".[26] The NRC cautions readers that at the time of the publication of the NRC Report a major hospital-based study on osteosarcoma (bone cancer) and fluoride exposure was underway at the Harvard School of Dental Medicine.[27] The Harvard study, which was published in 2006, found an association between fluoride exposure in drinking water during childhood and the incidence of osteosarcoma among males (but not females).[28] This is a significant and concerning finding.

PART III – LEGAL ISSUES AND ARGUMENT

Detractors of fluoridation raise a number of policy and moral arguments. These include, *inter alia*, arguments that fluoridation may be harmful to the environment and plant and animal wildlife. They also point out that fluoridated water in much of North America is treated by using hexafluorosicilic acid (H2SiF6) and sodium silicofluoride (Na2SiF6), which are by-products of fertilizer manufacturing and which contain numerous

[23] Anna Choi et al, "Developmental Fluoride Neurotoxicity: A Systematic Review and Meta-Analysis" (2012), 120 Environmental Health Perspectives 1362 at 1367.

[24] *Ibid.* at 222.

[25] *Ibid.*

[26] *Ibid.* at 336.

[27] Ibid. at 10.

[28] Elise B. Bassin et al, "Age-specific fluoride exposure in drinking water and osteosarcoma" (2006), 17 Cancer Causes & Control 421.

contaminants, including heavy metals such as lead and chromium, nonmetals such as arsenic, and even trace amounts of radioactive isotopes.

While these and other arguments may be persuasive policy arguments against fluoridation, a legal challenge to fluoridation based on human health effects is the most likely argument to succeed in Canadian courts. More specifically, if the proper evidence, such as the medical evidence described above, can be presented in court, there is a reasonable possibility that an Ontario court will declare the *Fluoridation Act* and the municipal fluoridation programs in Ontario to be unconstitutional.

The Constitutional Argument

The most viable legal argument against Ontario's fluoridation program is that it is unconstitutional because it violates s. 7 of the *Canadian Charter and Rights and Freedoms*. Section 7 provides that "Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice."[29] Legislation that conflicts with this constitutional right must be struck down.

Section 7 of the *Charter* means that everyone has the right to life, liberty and security of the person. This right, however, is not limitless. The State can limit one's rights to life, liberty and security of the person, but only if it does so in accordance with "the principles of fundamental justice." Thus, to establish a violation of s. 7 of the *Charter*, the claimant must establish: (1) that the law or State action has deprived the claimant of her or his right to life, liberty or security of the person; *and* (2) that the deprivation is inconsistent with principles of fundamental justice. There are strong arguments that a claimant challenging Ontario's *Fluoridation Act* could satisfy both of these legal requirements.

[29] Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11, s. 7 [hereinafter "Charter"]. For an overview of s. 7 and its jurisprudence, see Hamish Stewart, *Fundamental Justice: Section 7 of the Canadian Charter of Rights and Freedoms* (Toronto: Irwin Law, 2012); Nader R. Hasan, "Three Theories of 'Principles of Fundamental Justice'" (2013), 63 S.C.L.R. (2d) 339.

Fluoridation Deprives Residents of the Right to Liberty and Security of the Person

The Supreme Court of Canada has found that the liberty interest protected by s. 7 includes the right to make fundamental personal choices free from state interference.[30] In the context of medical treatment, the Ontario Court of Appeal has held that the right not to be subject to medical treatment without informed consent is an aspect of the security of the person interest under s. 7.[31] Section 7 thus protects "the right to be free from unwanted medical treatment."[32] To deprive individuals of the ability to make decisions with respect to their treatment and to force them to submit to medication against their competent wishes infringes the *Charter* right to security of the person as protected under s. 7 of the *Charter*.[33]

Ontario's fluoridation programs infringe upon the s. 7 right to security of the person. Fluoridation is State-imposed mass medication. This proposition was established by the Supreme Court's 1957 decision in *Toronto (Metro) v. Forest Hill (Village)*.[34] In that case, the residents challenged a municipal by-law that authorized the City "to undertake the treatment of the .... water supply by fluoridation." At that time, the Province's enabling legislation only permitted the municipalities to ensure a "continued and abundant supply of pure and wholesome water." It did not specifically authorize fluoridation or other forms of mass medication. The City argued that the power to make the water supply "pure and wholesome" implicitly authorized fluoridation. A majority of the Supreme Court of Canada disagreed. It held that fluoridation "is not a means to an end of wholesome water for water's function but to an end of a special health purpose for which a water supply is made use of as a means." In other words, the purpose of fluoridation was not to purify the water, but to medicate the population with fluoride.

The Ontario Legislature superseded *Toronto (Metro) v. Forest Hill (Village)* when it passed the *Fluoridation Act* in 1961. But the Supreme Court of Canada's conclusion that

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[30] *Blencoe v. British Columbia (Human Rights Commission)*, [2000] 2 S.C.R. 307 at, para. 54.

[31] *Fleming v. Reid*, [1991] O.J. No. 1083 at para. 31, 39-40 (C.A.).

[32] *Ibid.* at para. 31.

[33] *Ibid.* at para. 40.

[34] *Toronto (Metro) v. Forest Hill (Village)*, [1957] S.C.R. 569.

the purpose of fluoridation is not water purification but rather medication remains the finding of this country's highest court. As such, Ontario's fluoridation programs constitute medication without consent and thus deprives Ontario residents of their s. 7 liberty and security-of-the-person interests.

Fluoridation Violates the Principle of Gross Disproportionality

Given that the *Fluoridation Act* triggers the s. 7 liberty and security-of-the-person rights, the primary challenge for claimants will be in showing that the deprivation is inconsistent with the principles of fundamental justice. If that can be shown, then the claimant will have succeeded in proving that the fluoridation program is unconstitutional. The most relevant principle of fundamental justice here is the principle against *gross disproportionality*.

A law is "grossly disproportionate" if the state action or legislative response to a problem is so extreme as to be disproportionate to any legitimate government interest.[35] In other words, a law will be found to be grossly disproportionate where its benefits are grossly disproportionate to its potential harm.[36]

If a claimant can properly marshal the available scientific evidence, they ought to be able to show that the *risk* of significant harm caused by fluoridation is grossly disproportionate to the speculative benefit of reduced dental carries. As noted above, recent studies suggest that the claimed reduction in tooth decay over the past several decades is more likely attributable to improved dental care rather than fluoridated water. If true, then the benefits of fluoridated water are, at best, marginal, or, at worst, non-existent.

By contrast, the negative effects of fluoridation appear to be real and substantial. As noted above, the authoritative NRC Report concludes that dental fluorosis is more than

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[35] R. v. Malmo-Levine, [2003] 3 S.C.R. 571 at para. 143.

[36] *Canada (Attorney General) v. PHS Community Services Society*, [2011] S.C.J. No. 44, [2011] 3 S.C.R. 134 at para. 153; *Canada (Attorney General) v. Bedford*, 2013 SCC 72 at para. 159.

just a cosmetic effect.[37] Peer-reviewed scientific studies show that water fluoridation can have an adverse impact on children's I.Q..[38] Other studies show that fluoride can affect bone and make fractures more likely.[39] The 2006 Harvard study shows an association between osteosarcoma and fluoridated water.[40] Even if these negative effects are not conclusively proven, the *risk* of potential harm is significant. It would be reckless to expose residents to the risk of cancer, among other things, for the marginal benefit of reduced tooth decay, particularly where, as here, it is no longer clear that fluoridated drinking water is even a significant contributor to reduced tooth decay. Marginal benefit in exchange for significant risk is the *sine qua non* of gross disproportionality.

The likelihood of success of a hypothetical legal challenge to fluoridation will turn largely on the strength of the scientific evidence presented in court because the stronger the scientific evidence of risk of harm, the greater the gross disproportionality.

Previous Legal Challenges Are Not Indicative of Likelihood of Success in Ontario

Skeptics about the viability of a successful legal challenge to Ontario's fluoridation program will point out that since the Supreme Court's 1957 decision *Toronto (Metro) v. Forest Hill (Village)*, which was superseded by legislative action (see *supra* at 10-11), all other legal challenges to fluoridation programs in North America have failed. For the following reasons, I do not regard these cases as barring a legal challenge in Ontario.

The Canadian Cases

In Canada, there have been unsuccessful challenges to fluoridation programs in Alberta and British Columbia: see, e.g., *Millership v. Kamloops (City)*;[41] *Locke v. Calgary (City)*.[42] Those cases, however, are distinguishable on at least three different grounds.

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[37] *Supra* at 6.

[38] *Supra* at 7.

[39] *Supra* at 6-7.

[40] *Supra* at 7-8.

[41] [2003] B.C.J. No. 109 (B.C. Sup. Crt).

[42] [1993] A.J. No. 926 (Q.B.)).

First, those challenges were brought by self-represented litigants. While it appears that these individuals did an admirable job at marshaling the evidence and the arguments, novel constitutional challenges such as this are highly complex and require the assistance of counsel.

Second, the scientific evidence about fluoridation is improving. More information than ever before is known about fluoridation. At the time that *Millership* (2003) and *Locke* (1996) were decided, for example, the NRC Report had not yet been published. Nor had the Harvard study on the association between osteosarcoma and artificial fluoridation been completed.

Third, Canadian constitutional law under s. 7 of the *Charter* has developed significantly over the past five years. The principle of fundamental justice of "gross disproportionality" is a fairly new principle in Canadian constitutional law. Prior to the Supreme Court's recent decisions in *PHS* and *Bedford*, there was some doubt over whether this principle was indeed a principle of fundamental justice and also some doubt over what "gross disproportionality" actually meant. In my view, the best argument against fluoridation relies on the principle of gross disproportionality. This argument was not available to the claimants in *Locke* and *Millership*. Each of these factors suggests that these other cases will not bar a successful constitutional challenge to fluoridation in Ontario.

The U.S. Cases

The U.S. cases are also distinguishable, but for different reasons. There have been a handful of high-profile cases in the United States that involved challenges to municipal fluoridation programs. These challenges have failed on technical grounds, but each time the trial judge made judicial findings of fact that supported the plaintiffs' arguments that fluoridation causes harm to humans. In *Aitkendead v. Borough of West View*, the trial judge granted a preliminary hearing enjoining the municipality from continuing its fluoridation program on the basis that the plaintiffs had shown compelling evidence that fluoride may be a carcinogen.[43] That decision was superseded by legislative action,[44] but

[43] *Aitkendead v. Borough of West View*, No. GD-458578 (Allegheny County Court of Common Pleas, Pa); see also John Remington Graham and Pierre-Jean Morin, "Highlights in North American Litigation During

the factual findings spurred investigations into fluoridation in the United Kingdom and in Quebec, with the latter ultimately imposing a moratorium on fluoridation across the Province.[45]

The next important U.S. case involving a challenge to fluoridation was *Illinois Pure Water Committee v. Director of Public Health*.[46] After a lengthy trial, Judge Niemann concluded that fluoridation legislation, which "exposes the public to the risk, uncertain in its scope, of unhealthy side effects of artificial fluoridation in water supplies, is unreasonable, and [is] a violation of the due process clause of the Illinois Constitution of 1970."[47] He further noted that "[t]his record is barren of any credible and reputable scientific epidemiological studies and/or analysis of statistical data which would support the Illinois Legislature's determination that fluoridation of public water supplies is both a safe and effective means of promoting public health."[48] Accordingly, Judge Niemann entered a permanent injunction enjoining further fluoridation in Illinois. The Illinois Supreme Court granted the State's appeal, but it did not disturb any of Judge Niemann's factual findings.[49] Instead, the Illiniois Supreme Court relied on an expansive doctrine of "police powers", under which the State was granted significant deference on decisions relating to public health. The Illiniois Supreme Court wrote that the "wisdom, necessity and expediency" of the fluoridation program "are no concern of the courts, but are matters primarily for the legislative body of the municipality, and courts are without power to interfere merely because they believe a different regulation might have been wiser or better."[50] Under this heightened evidentiary burden, it was not enough that the

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the Twentieth Century on Artificial Fluoridation of Public Water Supplies," 14:2 J. Land Use & Envtl. L. 195 at 229-232.

[44] *Aitkendead v. Borough of West View*, 397 A.2d 878 (Pa. Commw. Ct. 1979)

[45] See Graham and Morin, "Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water Supplies," *supra* at 232.

[46] *Illinois Pure Water Committee v. Director of Public Health*, No. 68-E-128 (Madison County Circuit Court Ill. 1982).

[47] *Ibid.* at 32.

[48] *Ibid.* at 33.

[49] *Illinois Pure Water Committee v. Director of Public Health*, 470 N.E.2d 988 (Ill. Sup. Ct. 1984).

[50] *Ibid.* at 991-992.

plaintiffs have shown that fluoridation causes "some risk of a higher incidence of cancer."[51]

The court reached a similar result in *Safe Water Foundation of Texas v. City of Houston*, a challenge to the City of Houston's fluoridation program. After a lengthy trial, with ample expert testimony on both sides, the trial judge concluded that artificial fluoridation of public water supplies "may cause or contribute to cancer, genetic damage, intolerant reactions and chronic toxicity, including dental mottling...," and "that the value of said artificial fluoridation is in some doubt as to the reduction of tooth decay in man."[52] Still, the court denied the plaintiffs' motion for an injunction on grounds of police powers. The Texas Court of Appeals denied the appeal on similar grounds, but also acknowledged the significant evidence in the record that fluoridation caused harm. It noted that if the standard had been the normal civil standard of evidence (e.g., a balance of probabilities), the plaintiffs would have won. Indeed, the Texas Court of Appeals expressly found that a fair preponderance of evidence showed that "the injection of fluoride into the City's water system would be harmful," but saved the legislation on police power grounds.[53]

The U.S. cases would likely have reached a different result had Canadian law been applied or if those cases had been litigated in Canadian courts. The U.S. cases applied a very deferential standard to the pro-fluoridation defendants and held the plaintiffs to a nearly impossible burden of proof. A claimant bringing a constitutional challenge under s. 7 of the Charter would not face the same obstacles. In other words, the police powers doctrine would not save the Ontario *Fluoridation Act* if fluoridation was found to cause harm.

The Use Hexafluorosicilic Acid (H2SiF6)

I have been advised that the Region of Peel uses hexafluorosicilic acid to fluoridate its drinking water. Hexafluorosicilic acid is a waste product that is created in the fertilizer

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[51] *Ibid.* at 992.

[52] *Safe Water Foundation of Texas v. City of Houston*, No. 80-52271, Findings of Fact, May 24, 1982, at 1-2.

[53] *Safe Water Foundation of Texas v. City of Houston*, 661 S.W.2d 190 at 192 (Tex. App. 1983).

manufacturing process.[54] When hexafluorosicilic acid is in its gaseous form (hydrogen fluoride (HF) and silicon tetrafluoride (SiF4)), it is a highly toxic substance.

Proponents of using hexafluorosicilic acid as a fluoridating agent argue that by the time it is diluated by about 180,000 to 1 (to reach acceptable fluoride concentrations), the contaminant levels will be below regulatory concern.[55] But this argument overlooks the fact that amounts of other contaminants, such as arsenic, remain in the hexafluorosicilic acid solution. The U.S. Environmental Protection Agency sets the ideal safety goal for arsenic in drinking water at zero because arsenic is a known human carcinogen.[56] While there may be trace amounts of arsenic naturally occurring in water, it is difficult to justify the *addition* of a known carcinogen.[57] Critics of hexafluorosicilic acid also point out that there are no known toxicological studies regarding the safety of using hexafluorosicilic acid to fluoridate water.

Apart from the constitutional argument described above, the use of hexafluorosicilic acid may violate the *Safe Drinking Water Act*. Section 20 of the *Safe Drinking Water Act* provides that "[n]o person shall cause or permit any thing to enter a drinking water system if it could result in ... a drinking water health hazard...." or "is a contravention of a prescribed standard."[58]

The use of hexafluorosicilic acid may also violate the federal *Food and Drugs Act*. Section 4 of the *Food and Drugs Act* prohibits the sale of articles of food or drink that "has in or on it any poisonous or harmful substance." [59] To the extent that hexafluorosicilic acid contains a known carcinogen, then its addition to the water

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[54] Paul Connett et al, *The Case Against Fluoride*, *supra* at 16.

[55] *Ibid.* at 19.

[56] United States Environmental Protection Agency, "Arsenic in Drinking Water", online: http://water.epa.gov/lawsregs/rulesregs/sdwa/arsenic/index.cfm.

[57] *Ibid.*

[58] *Safe Drinking Water Act, 2002*, S.O. 2002, ch. 32, s. 20(1)(a).

[59] *Food and Drugs Act*, R.S.C., 1985, c. F-27, s. 4.

represents the addition of a "poisonous or harmful substance", which is, in turn, sold to the residents of Peel.

Liability of the Region of Peel

A finding that the Region of Peel's fluoridation program is unconstitutional and/or that the use of hexafluorosicilic acid is illegal could have significant pecuniary implications for the Region. If a court should find that the fluoridation program was unconstitutional because of an unacceptable risk of harm, this could pave the way for lawsuits against the municipality.

The *Municipal Act, 2001* imposes a statutory duty of care on those who oversee drinking water systems and makes municipalities liable in tort for acts or omissions.[60] Moreover, as of December 31, 2012, amendments to the *Safe Drinking Water Act* clarified the standard of care for municipalities. Under this standard, municipalities must exercise the level of care, diligence and skill in respect of a municipal drinking water system that a reasonably prudent person would be expected to exercise in a similar situation.[61] The standard of care also extends to the owner of the municipal drinking water system, and to those people who, on behalf of the municipality, oversee the accredited operating authority or who exercise decision-making authority over the system.

The *Safe Drinking Water Act* puts responsibility for ensuring safe drinking water squarely on the municipalities. It also arguably makes those who make decisions about the municipal water supplies — such as Councillors — personally liable for acts or omissions.[62] It follows that if a court should find that fluoridation puts residents of Peel at risk of harm, then the Region of Peel and its Councillors may be liable to its residents for damages on the civil negligence standard.

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[60] *Municipal Act, 2001*, S.O. 2001, ch. 25, ss. 448(2), 448(3).

[61] *Ibid.*, s. 19(1).

[62] *Ibid.*, s. 19(2).

It is also worth noting that the Region faces potential liability not only under a potential civil suit brought by residents but may also be prosecuted by the Province. Under the *Safe Drinking Water Act Regulations*, any person resident in Ontario can ask the Ontario government to investigate the Region for an alleged violation of the *Act*.[63] Furthermore, the *Safe Drinking Water Act* provides that a violation of s. 20 — the prohibition on putting material into water that could cause a health hazard — shall be a criminal offence. Thus, if fluoride is proven to cause harm or a risk of harm, then a municipality that continues to fluoridate could theoretically face *criminal* prosecution.

Thus, a municipality that fails to discharge its duty of care under the *Safe Drinking Water Act* could face (1) civil liability to residents in a civil lawsuit; (2) prosecution by the Ontario government; and (3) potentially, criminal liability. These risks and liabilities ought to be sufficient to encourage municipalities to carefully re-examine their water fluoridation programs.

CONCLUSION AND RECOMMENDATIONS

In sum, if a resident of Peel succeeds in marshaling the available scientific evidence in court, there is a reasonable possibility that the *Fluoridation Act* and the Peel fluoridation programs could be found to be unconstitutional under s. 7 of the *Charter*. And if it is demonstrated in court that fluoridation puts the residents of Peel at risk, the Region is potentially liable in tort to every resident of the Region who drinks fluoridated municipal water.

It is recommended that the Regional Council take the following steps:

1. That the Council pass a resolution to re-examine its fluoridation program;

2. That the Council hear expert testimony from experts in the fields of medicine, epidemiology and dentistry to better understand the risks and benefits associated with water fluoridation;

[63] *Safe Drinking Water Act, 2002, Compliance and Enforcement Regulation*, O. Reg. 242/05, s. 7(1).

3. That the Council hear expert testimony both from experts who support fluoridation and those who oppose fluoridation; and

4. That the Council require that experts presenting their opinions also provide the Council with the underlying data and studies on which they are relying for their opinions. There is enough competing opinion in the scientific community that it will be important for municipalities to understand the bases for scientific opinion as they re-examine this important issue.

I look forward to discussing the foregoing with you further.

Affidavit of Kathleen M. Thiessen, Ph.D.

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April 29, 2014

I, KATHLEEN THIESSEN, of the City of Oak Ridge, in the State of Tennessee, **HEREBY MAKE OATH AND SAY AS FOLLOWS:**

I have been asked to prepare an affidavit concerning the health effects associated with water fluoridation in connection with the Region of Peel's reconsideration of its water fluoridation policies. I make this affidavit for no improper purpose.

Background and experience on the fluoridation issue

I hold a Ph.D. degree in Biomedical Sciences (concentration, genetics) from the University of Tennessee-Oak Ridge Graduate School of Biomedical Sciences and a B.A. degree in Biology and Chemistry from Covenant College. 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 and Related Compounds: Health Issue Assessment* for the Environmental Protection Agency, 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*) and one dealing with guidance levels for air contaminants, including hydrogen fluoride (*Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants: Volume 3*). I am currently a Senior Scientist with Oak Ridge Center for Risk Analysis, Inc., where my projects have involved a variety of assessments of contaminant transport, human exposures, toxicity, and health risks for both radiological and chemical contaminants.

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), academic (Binghamton University, Covenant College), and lay (Metropolitan Water District of Southern California; 2nd Citizens' Conference on Fluoride; the Tennessee legislature; the towns of Yellow Springs, Ohio, and Maryville, Tennessee). I have provided comments on fluoride-related technical reports to Health Canada, the Committee on Health and Social Services of Québec, 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.

Attached hereto as Exhibit "A" to this Affidavit is a true and correct copy of my curriculum vitae.

Introduction

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.

In 1998, I reviewed some materials on fluoridation sent to the county school board on which my father served (Lee 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 tap 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.

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 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) 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 from fluoride exposure. EPA's MCLG is supposed to be set "at a level at which no known or anticipated adverse effect on the health of persons is expected to occur and which allows an adequate margin of safety" (EPA 2012). 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, nor did it specifically evaluate the safety of water fluoridation.

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.

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 documents from the Centers for Disease Control and Prevention, the Department of Health and Human Services, the U.S. Environmental Protection Agency, the National Research Council, Health Canada, the American Dental Association (ADA), the Canadian Dental Association (CDA), 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:

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

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

(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..

The following three sections of this affidavit address these three areas of concern. The fourth section of this affidavit summarizes the typical fluoride intakes that can be expected in fluoridated communities in Ontario and compares them with estimated levels of intake associated with specified adverse health effects.

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

Health Canada "supports water fluoridation as a public health measure to prevent dental decay" (Health Canada 2011a), and the Chief Medical Officer of Health for Ontario has "urge[d] all Ontarians to continue to support the fluoridation of their municipal drinking water systems so that everyone can enjoy the lasting health benefits" (OMHLTC 2011). 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), and the CDC has listed it among the "ten great public health achievements of the 20th century" (CDC 1999; cited by Health Canada 2011a; OMHLTC 2011). Governments and health agencies in several other countries also

consider water fluoridation to be important and beneficial. However, the question of whether water fluoridation actually produces a benefit requires further attention.

The University of York's thorough review of human studies on effects of water fluoridation (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:

> 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)

> 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)

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

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). Health Canada (2010a) cites the York review (McDonagh et al. 2000) and a major U.S. study by Heller et al. (1997), among others, as support for the effectiveness of water fluoridation. Heller et al. (1997), described in more detail below, is used as the basis for Health Canada's determination of an "optimal" concentration of fluoride in drinking water of 0.7 mg/L (Health Canada 2010a).

Neither McDonagh et al. (2000), the ADA (2005), nor Health Canada (2010a) mentions that fluoride exposure appears to delay the eruption of permanent teeth, although this has been known since the 1940s (Short 1944; Feltman 1956; 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.

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, and the general decline in caries rates over the last several decades, independent of water fluoridation status (e.g., Diesendorf 1986; Colquhoun 1993). 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., Barnes et al. 1992; Adair et al. 1999; Hamasha et al. 2006).

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."

A number of sources (reviewed by NRC 2006), including the 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:

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

> 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)

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."

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). This paper, which is not mentioned by Health Canada (2010a), reports 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).

Health Canada (2010a) bases its "optimal" concentration of fluoride in drinking water (0.7 mg/L) on a 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), as reported by Heller et al. (1997). However, these data actually show 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.

Overall, the available data, responsibly interpreted, indicate little or no beneficial effect of water fluoridation on oral health.

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

For most Canadians in fluoridated areas (45% of Canadians, 76% of Ontario residents; Health Canada 2011a), 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 0.7 mg/L (0.7 ppm), considered the "optimal" level by Health Canada (2010a,b; 2011b), estimated average exposures to fluoride from all sources range from about 0.02 mg/kg/day (mg of fluoride per kg of body weight per day) for adults and nursing infants to 0.065 mg/kg/day for non-nursing infants (especially infants fed formula prepared with fluoridated tap water; based on NRC 2006). Note that these are estimated *average* exposures. For individuals with high tap water consumption (discussed by NRC 2006), total fluoride exposures at 0.7 mg/L can exceed 0.1 mg/kg/day for some adults and may approach 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.

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; these groups can reasonably be expected to exist in Canada as well. 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 U.S. 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), and a similar situation can be expected in Canada.

Canada recently reduced its "optimal" concentration of fluoride in drinking water from a range of 0.8-1.0 mg/L to a single value of 0.7 mg/L (Health Canada 2011b). In 2011, The U.S. Department of Health and Human Services (HHS) proposed a similar new recommendation (Federal Register 2011; still not official) of a single value of 0.7 mg/L (0.7 ppm), consistent with the Canadian recommendation. Both the Canadian and U.S. recommendations address 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; Susheela et al. 2005), although this is not addressed by either the Canadian or U.S. recommendations. To the best of my knowledge, no published 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.

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 is expected to occur and which allows an adequate margin of safety" (EPA 2012). 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.

Thus, based on the NRC's review of the EPA standards and EPA's own requirements, neither the Canadian "optimal" fluoride concentration nor the proposed U.S. recommendation for water fluoridation, both at 0.7 mg/L, can be considered adequate to protect against known or anticipated adverse effects, and neither allows 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. The Canadian Maximum Acceptable Concentration (MAC) for fluoride in drinking water, 1.5 mg/L (Health Canada 2010a), is less than a factor of 3 below the value (4 mg/L) that the NRC (2006) concluded is not safe.

According to the Canadian Dental Association (CDA 2009), an "additive" to drinking water "should not add more than 10% of the EPA-established MCL (Maximum Contaminant Level) of any regulated drinking water substance in order to ensure the protection of the public." Fluoride is a regulated drinking water substance, and ten percent of the EPA-established MCL for fluoride (4 mg/L) is 0.4 mg/L. Canada's equivalent to the MCL in the U.S. is its MAC, which for fluoride is 1.5 mg/L (Health Canada 2010a); ten percent of the MAC is 0.15 mg/L. Nevertheless, Health Canada recommends an "optimal" concentration of 0.7 mg/L, thus contradicting the guidelines used for most other regulated substances in drinking water.

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, neurotoxicity, 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.

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.

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.

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.

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 have been documented for fluoride exposure. 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

The main reason for the recent changes in fluoridation levels (instituted in Canada and proposed in the U.S.) 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 Canadian and proposed U.S. recommendations are intended to limit the risk of moderate (Canada) or severe (U.S.) dental fluorosis while maintaining caries protection (Health Canada 2010a; 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). Canada reported a fluorosis prevalence of 16.4% (very mild and mild, with "very low levels of moderate and severe") among children ages 6-12 surveyed in 2007-2009 (Health Canada 2010a;c). Neither the more recent U.S. data nor the Canadian data report dental fluorosis prevalence with respect to local water fluoride concentrations. If the Canadian survey was representative with respect to local water fluoride concentrations, given a fluoridation rate of nearly one-half the population, one could reasonably expect that the fraction of children with fluorosis in fluoridated areas exceeds 20%.

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.

Health Canada (2010a) considers moderate dental fluorosis to be an adverse effect. 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). Neither the Canadian nor U.S. authorities have addressed the costs to

treat the cosmetic appearance of fluorosed teeth, apart from whether dental fluorosis is considered "adverse" in terms of health.

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.

Skeletal fluorosis

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). Chachra et al. (2010) recently reported bone fluoride content for residents of Toronto (fluoridated for 32-36 years at the time of the study) and Montreal (not fluoridated) who were undergoing total hip replacement surgery; most of the individuals had a diagnosis of osteoarthritis. Two of the 53 individuals in Toronto had bone fluoride concentrations in the range reported for skeletal fluorosis (NRC 2006), although both individuals would have been well into adulthood when exposure to fluoridated water began. The study did not include

exposure histories; nevertheless, it does indicate that bone fluoride concentrations in fluoridated Canadian cities can be in the range reported for skeletal fluorosis.

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. or Canada. "Arthritis" (defined as painful inflammation and stiffness of the joints) is a leading cause of disability in Canada and currently affects approximately 16.6% of Canadian adults (4.5 million people); more than half of Canadians with arthritis are less than 65 years old (Arthritis Society 2013). The possibility that a sizeable fraction of "bone and joint pain" or "arthritis" in Canadian (or 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

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).

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.

The Iowa study has 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

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).

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.

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.

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. Kim et al. (2011) actually point out that "if risk is related to exposures at a specific time in life, rather than total accumulated dose, this metric [bone fluoride levels at the time of treatment] would not be optimal." In addition, given that the median age of the controls used by Kim et al. (2011) was

more than twice the median age of the cases, and that the "median cumulative lifetime water fluoride" calculated for each group was similar, the findings of Kim et al. (2011) actually indicate higher average fluoride exposure among cases than controls, by a factor of about 2, supporting an association between fluoride exposure and osteosarcoma.

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.

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

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).

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.

A fluoride concentration of 0.5 mg/L in urine will routinely be exceeded by many people consuming fluoridated water (NRC 2006); for people with substantial fluoride intake, serum fluoride concentrations may also reach or exceed 0.5 mg/L. Acute fluoride exposures (e.g., accidental poisoning, fluoride overfeeds in drinking water systems) have resulted in fluoride concentrations in urine well in excess of 5 mg/L in a number of cases (e.g., Penman et al. 1997; Björnhagen et al. 2003; Vohra et al. 2008). Urine fluoride concentrations can also exceed 5 mg/L if chronic fluoride intake is above about 5-6 mg/day (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

Health Canada (2010a) claims that there is no evidence that fluoride is an endocrine disruptor. However, based on an extensive review, 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).

Thyroid dysfunction and Type II diabetes presently pose substantial health concerns in both the U.S. and Canada (NRC 2006; PHAC 2011). More than 2 million Canadians (7% of the population) are diabetic (PHAC 2011), and some 10% of Canadians have some form of thyroid disease (TFC 2014). Of particular concern is an inverse correlation between subclinical maternal hypothyroidism and the IQ of the offspring (NRC 2006). 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

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). Most fluoridated water systems in Canada and the U.S. use silicofluorides (NRC 2006; CDA 2009). 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).

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 2012).

Neurotoxicity

Grandjean and Landrigan (2006) listed fluoride as an "emerging neurotoxic substance" that needed further in-depth studies. In a follow-up paper (Grandjean and Landrigan 2014), they list fluoride as a documented developmental neurotoxicant. 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). Fluoride is known to cross the placenta in humans (Feltman 1956; Feltman and Kosel 1961; Gedalia et al. 1964; Hanhijärvi et al. 1974; Ron et al. 1986; Malhotra et al. 1993; Gupta et al. 1993; Shimonovitz et al. 1995), and several studies have shown changes in brain chemistry in fetuses due to maternal fluoride exposures (Dong et al. 1997; Du et al. 2008; He et al. 2008; Yu et al. 2000; 2008).

Additional adverse health effects

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.

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).

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 1956; 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).

Summary

The available data, responsibly interpreted, indicate a variety of possible adverse health effects in humans associated with fluoride exposures, at the levels experienced by people with fluoridated drinking water.

(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.

Health Canada (2013) includes as "drug products" several toothpastes and mouthwashes that contain sodium fluoride as an active ingredient. 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 in the U.S. 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; Health Canada 2011b; CDA 2009). 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. The Canadian Dental Association (CDA 2009) claims that "Adding fluoride to water is the best way to provide fluoride protection to a large number of people. . . it benefits all residents in a community." This approach, in both the U.S. and Canada, 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.

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. 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 (Brown et al. 2004; Weng et al. 2000; Casale 2001; Mullenix 2014). The U.S. EPA has set MCLGs of zero for both lead and arsenic (EPA

2012). Health Canada (2006; 2012) states that levels of arsenic in drinking water should be as low as reasonably achievable and exposures to lead should be kept to a minimum. Thus, by adding fluoridation chemicals, a water supplier is also adding contaminants for which the ideal maximum amount in drinking water is zero.

In summary, 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.

(4) Expected fluoride intakes in fluoridated communities in Ontario, compared with "no-effect" levels for adverse health effects.

Table 2 summarizes the estimated intake of water from community (municipal) water sources. These estimates are based on U.S. data (EPA 2004a), but are expected to be reasonably representative of the Canadian population as well. Intakes are summarized in terms of the volume per day (mL per day) and the volume per unit body weight per day (mL per kg body weight per day). Data are summarized by age group (both sexes included) and include both direct and indirect intake for consumers only (people who actually consume municipal water). Data are summarized in terms of an average intake, a typical range of intake among consumers, and a value representative of high consumers (but not necessarily a maximum value).

Table 3 provides a summary of estimated fluoride intakes from community water sources for four concentrations of fluoride in drinking water relevant to the situation in Ontario (targeted range of 0.5-0.8 mg/L, Health Canada's "optimal" level of 0.7 mg/L, maximum allowable concentration of 1.5 mg/L). These estimates are based on the water consumption rates (mL per kg per day) in Table 2. Note that these fluoride intakes represent only fluoride from municipal water sources; they do not include fluoride intakes from other sources (e.g., toothpaste, tea, food). Thus, total fluoride intakes would be expected to be higher than the values provided in Table 3 for a given situation.

Figures 6 and 7 summarize estimated fluoride intakes (from community water alone) from Table 3, together with "no-effect" levels identified for various adverse health effects. Note that for the entire population to be protected against a particular adverse health effect, the upper end of the intake range for all subsets (e.g., age groups) of the population must be at or below the "no-effect" level. Note also that these "no-effect" levels do not include any margin of safety for protection of individuals with greater susceptibility or higher exposure.

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.

Table 2. Estimated intake of water from community sources by age group.[a]

Age group	Average consumption	Typical Range	High consumers
	Intake (mL per day)		
Infants < 1 year	502	28-1147	1517
Children 2-10 years	431	29-1137	1722
Youth 11-19 years	736	58-1973	3689
Adults 20+ years	1176	103-2848	4631
	Intake per unit body weight (mL per kg per day)		
Infants < 1 year	71	3-185	261
Children 2-10 years	21	1-57	92
Youth 11-19 years	13	1-34	60
Adults 20+ years	16	1-39	62

[a] Based on U.S. data (EPA 2004a). Intakes include both direct and indirect intake for consumers only, both sexes combined.

Table 3. Estimated intake of fluoride from fluoridated community water sources (mg F per kg body weight per day), for selected concentrations of fluoride in community water, by age group (both sexes combined) and level of water consumption.[a]

Age group	Average consumption	Typical Range	High consumers
	0.5 mg/L fluoride		
Infants < 1 year	0.036	0.0015-0.093	0.131
Children 2-10 years	0.011	0.0005-0.029	0.046
Youth 11-19 years	0.0065	0.0005-0.017	0.030
Adults 20+ years	0.0080	0.0005-0.020	0.031
	0.7 mg/L fluoride		
Infants < 1 year	0.050	0.0021-0.130	0.183
Children 2-10 years	0.015	0.0007-0.040	0.064
Youth 11-19 years	0.0091	0.0007-0.024	0.042
Adults 20+ years	0.011	0.0007-0.027	0.043
	0.8 mg/L fluoride		
Infants < 1 year	0.057	0.0024-0.148	0.209
Children 2-10 years	0.017	0.0008-0.046	0.074
Youth 11-19 years	0.010	0.0008-0.027	0.048
Adults 20+ years	0.013	0.0008-0.031	0.050
	1.5 mg/L fluoride		
Infants < 1 year	0.107	0.0045-0.278	0.392
Children 2-10 years	0.032	0.0015-0.086	0.138
Youth 11-19 years	0.020	0.0015-0.051	0.090
Adults 20+ years	0.024	0.0015-0.059	0.093

[a] Based on U.S. data (EPA 2004a) for water consumption as summarized in Table 2.

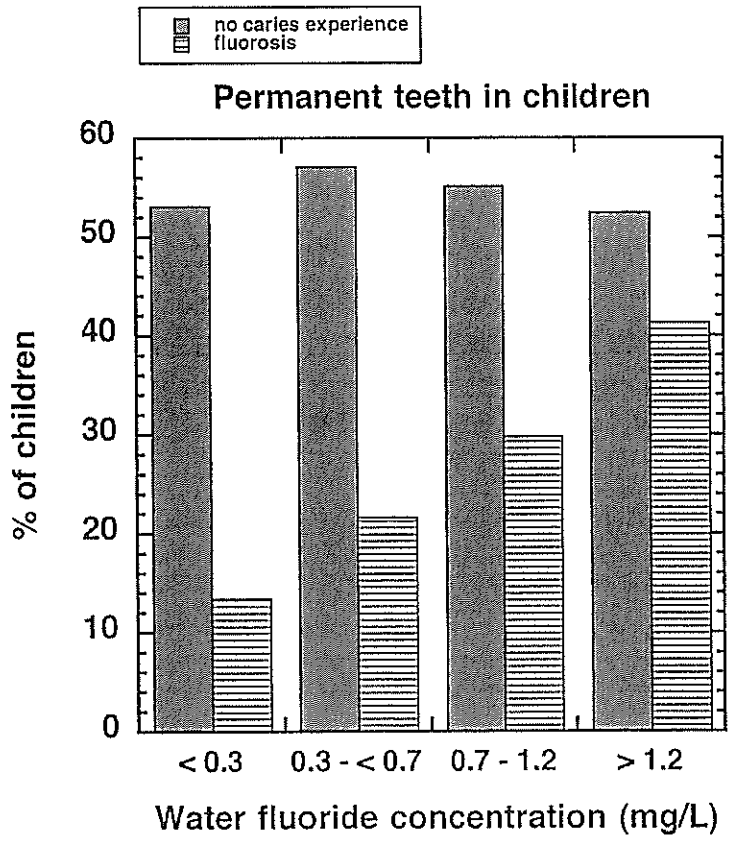

Fig. 1. Percent of children with no caries experience in the permanent teeth (DMFS = 0) and with fluorosis, with respect to water fluoride concentration. Data are shown as % of total children having no caries experience (blue) or having fluorosis (very mild, mild, moderate, or severe, but not questionable;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

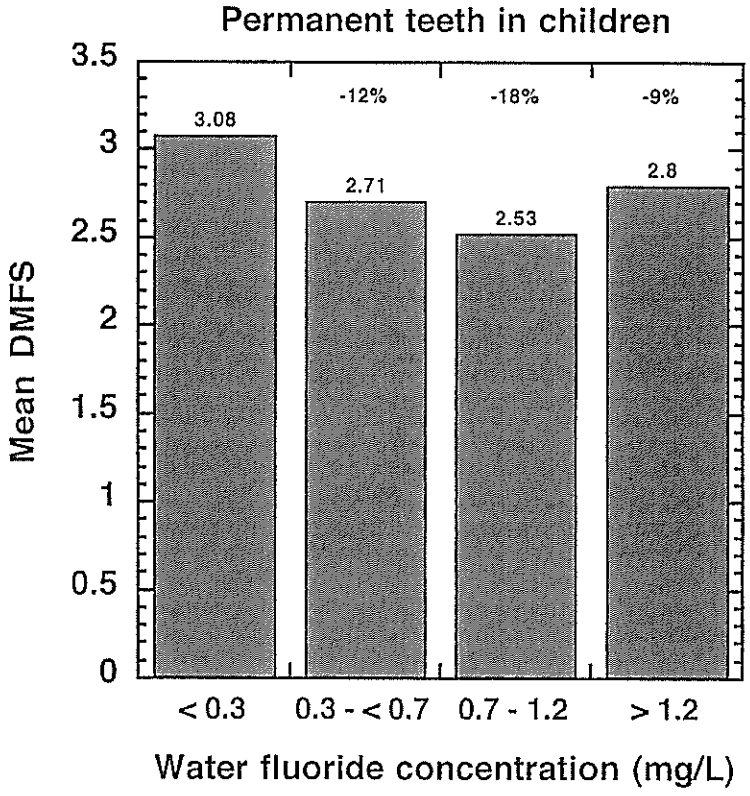

Fig. 2. Mean DMFS score (decayed, missing, or filled permanent tooth surfaces in permanent teeth), with respect to water fluoride concentration. Numerical values are provided in Table 1 of these comments and were obtained from Table 2 of Heller et al. (1997). The percent difference with respect to the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

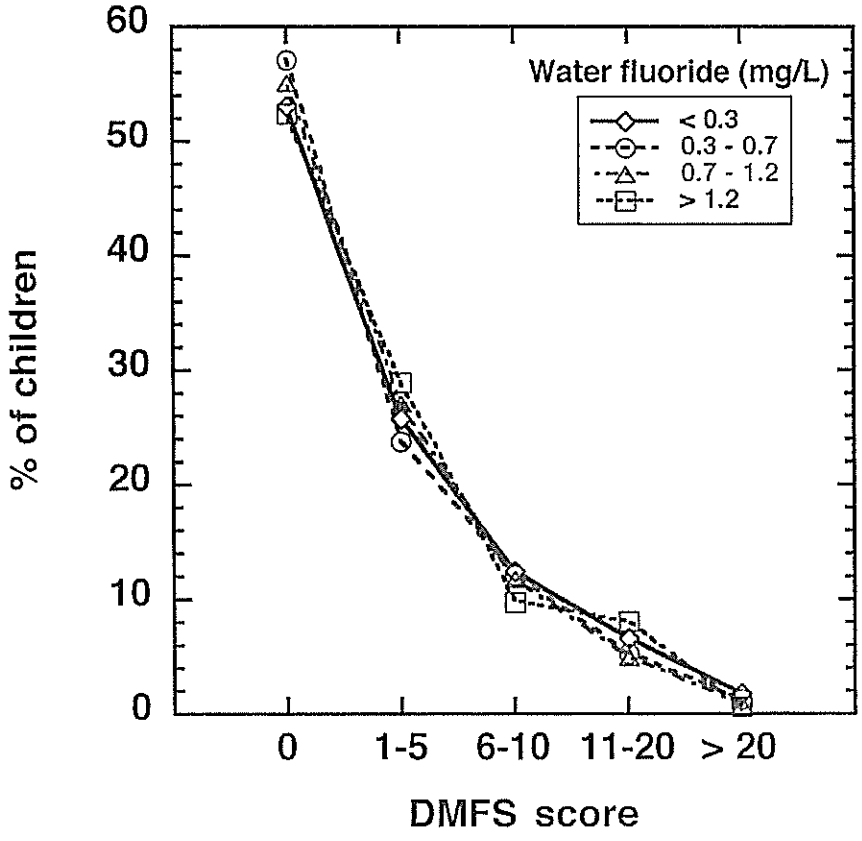

Fig. 3. Percent of children by DMFS score, with respect to water fluoride concentration. Data are shown as % of total children in a given group according to the number of decayed, missing, or filled tooth surfaces in the permanent teeth (DMFS). Data were obtained from Table 2 of Heller et al. (1997).

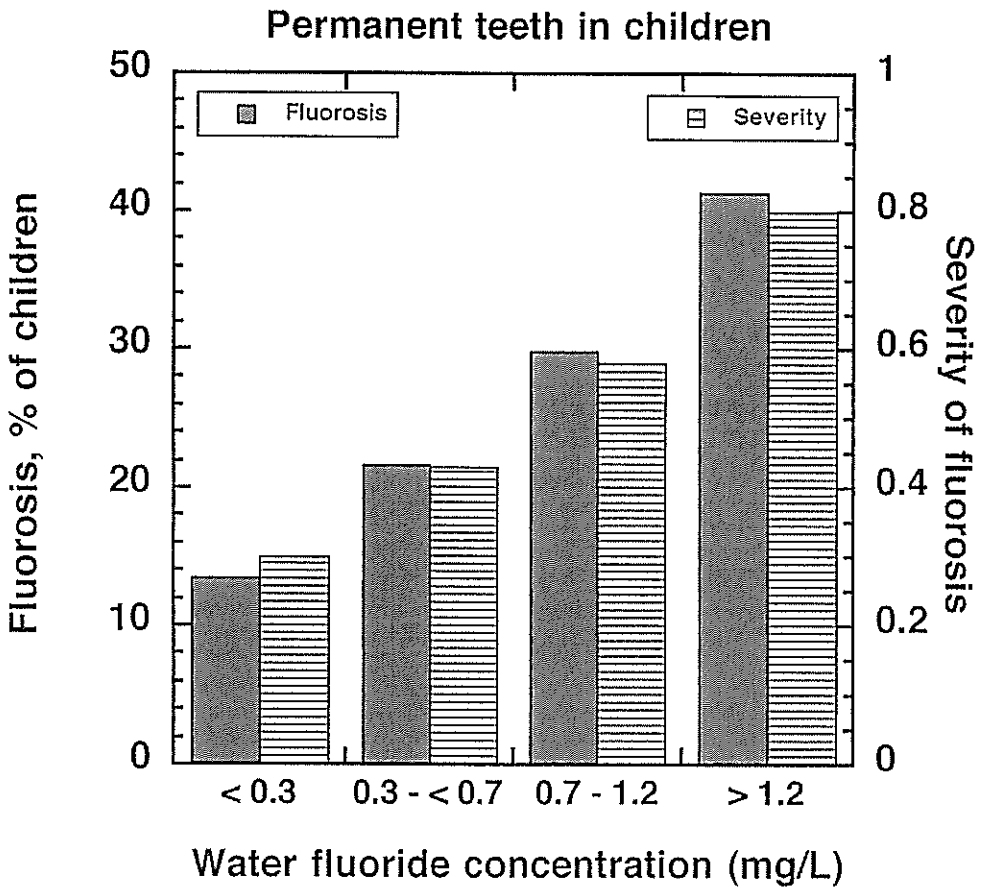

Fig. 4. Fluorosis prevalence and severity with water fluoride concentration for children ages 7-17 with a history of a single continuous residence. Data are shown as (left) % of total children having fluorosis (very mild, mild, moderate, or severe, but not questionable) or (right) severity of fluorosis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

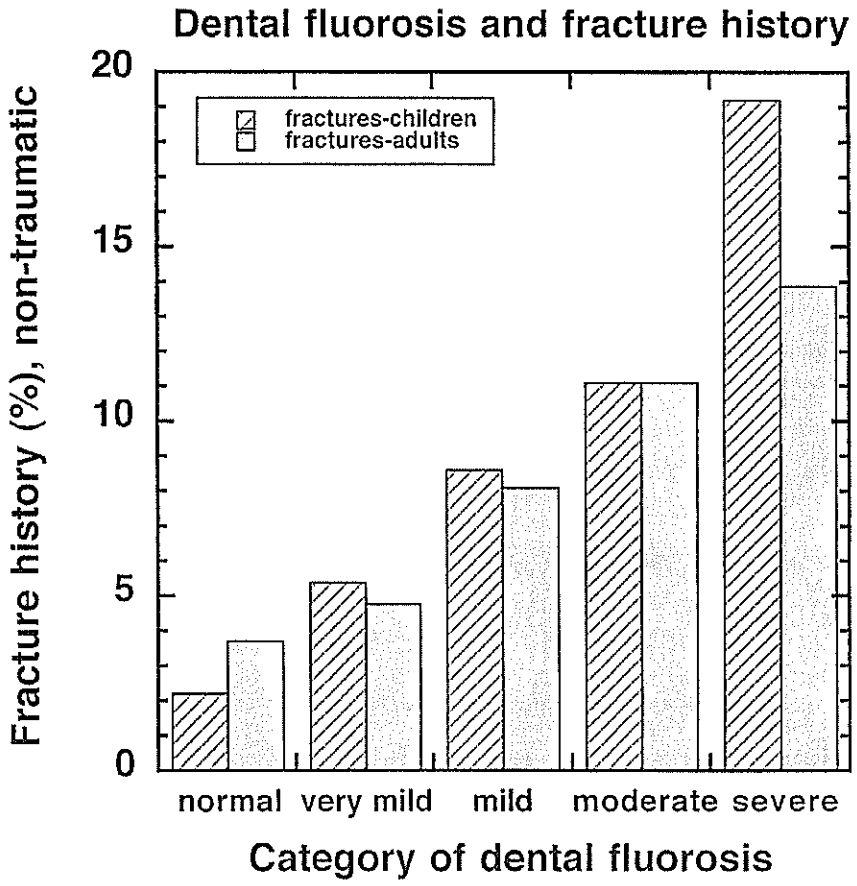

Fig. 5. Fracture history with category of dental fluorosis for children (ages 6-12) and adults (ages 13-60). Numerical values were obtained from information in Tables 5 and 6 of Alarcón-Herrera et al. (2001).

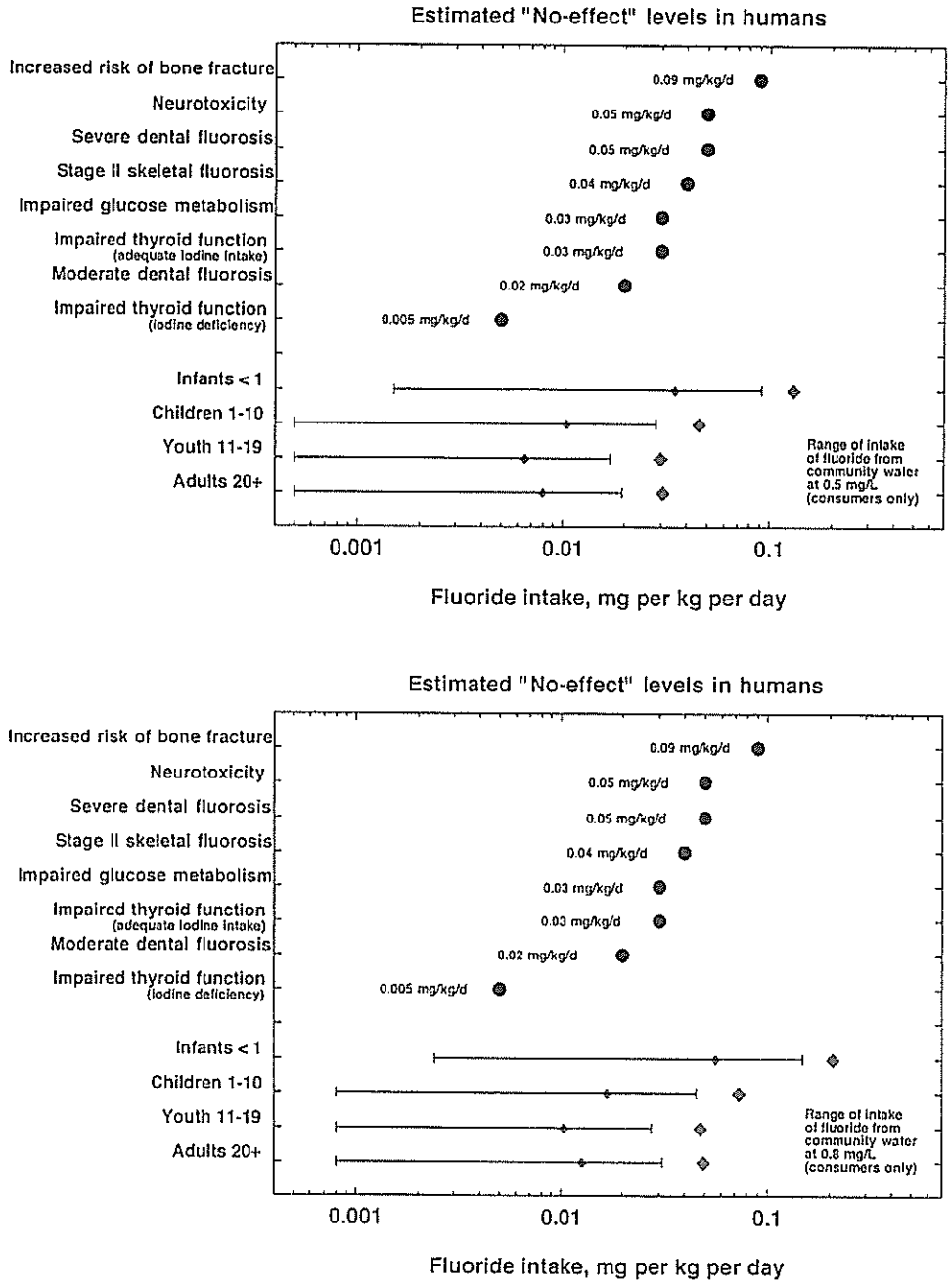

Fig. 6. Comparison of estimated fluoride intakes from community water alone (from Table 3) at the lower and upper limits of the targeted fluoride concentrations for Ontario, 0.5 mg/L (top) and 0.8 mg/L (bottom), with estimated "no-effect" levels of fluoride intake in humans.

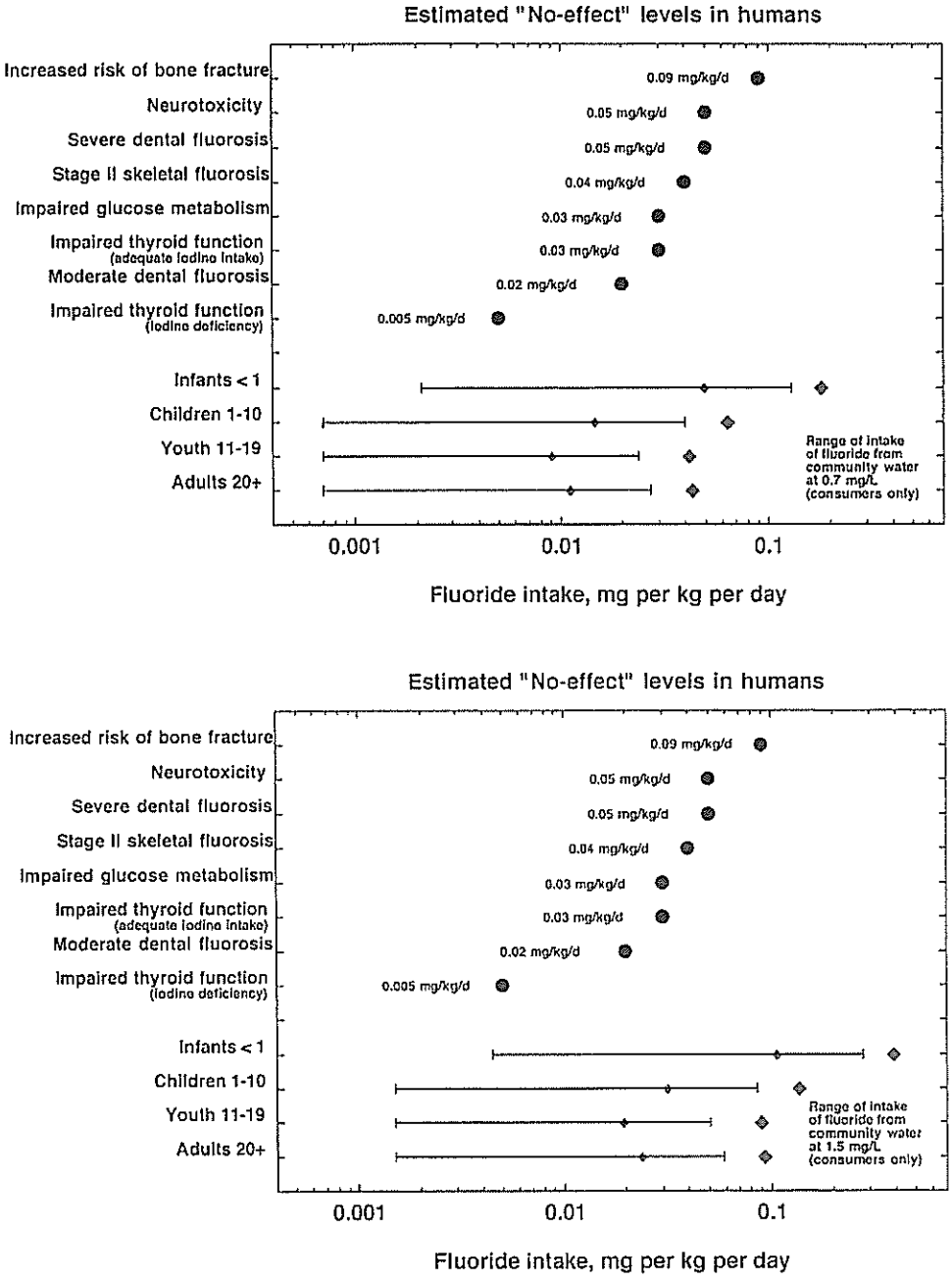

Fig. 7. Comparison of estimated fluoride intakes from community water alone (from Table 3) at Health Canada's "optimal" fluoride concentration, 0.7 mg/L (top), and Maximum Allowable Concentration, 1.5 mg/L (bottom), with estimated "no-effect" levels of fluoride intake in humans.

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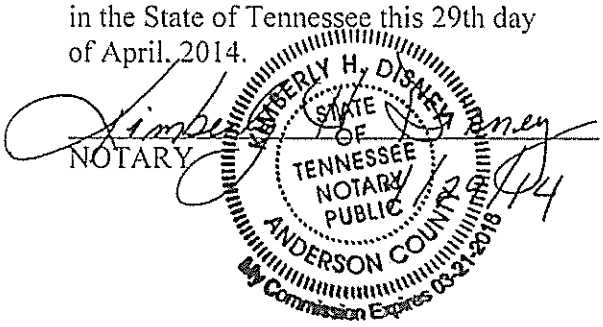
Sworn before me at the City of Oak Ridge)
in the State of Tennessee this 29th day)
of April, 2014.)
)



NOTARY

KATHLEEN THIESSEN

1397
1345

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

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

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

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

Name:

Email

Address:

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

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

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

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

Post to:
Regulations under the Medicines Act 1981 Consultation
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