

I, John Robert McMillan, of Dunedin, Professor of Bioethics, solemnly and sincerely affirm:

1. I am a Professor at the Bioethics Centre, University of Otago. I am the current Director of the Bioethics Centre.
2. I graduated with first class honours in philosophy at Otago in 1994. I completed my PhD in Bioethics in 1998 and then moved to Oxford University for four years as a junior research fellow. In 2002, I was appointed to the University of Cambridge as University Lecturer (2002-4) and later, as Senior Lecturer in medical ethics at the Hull York Medical School (2004-9). From 2009-2012, I was Associate Professor in ethics, law and professionalism at Flinders University. I returned to Dunedin to start as Director of the Bioethics Centre in February of 2013.
3. The Bioethics Centre was established in 1988 and aims to encourage and coordinate teaching and research in bioethics, to stimulate informed public debate, and to provide a consultation and resource service for health professionals and others in the community.
4. I have published on and taught a broad range of issues within bioethics, a number of which are directly relevant to the ethics of fluoridation. These include my publications that examine the ethical principles that are relevant to compelled or coerced treatment, public health research ethics, and the relationship between coercion and consent.^{1,2,3}
5. I was a member of the working party that wrote the Nuffield Council on Bioethics report *Dementia: ethical issues*.⁴ I have direct experience of the level of scholarship, degree of consultation required and aim to provide practical, impartial advice for contentious ethical issues that is a feature of all Nuffield Council reports. I believe that I am well placed to

1 McMillan, J. "Psychiatric ethics" in *International Encyclopaedia of Ethics* Blackwells: February, 2013. <http://dx.doi.org/10.1002/9781444367072.wbiee070>

2 McMillan, J. "Public health research ethics: is non-exploitation the new principle of population based research ethics?" in *Public Health Ethics* Edited by Angus Dawson, Cambridge University Press: 2011.

3 McMillan, J. "The kindest cut? Surgical castration, sex offenders and coercive offers." *The Journal of Medical Ethics* 2013 <http://dx.doi.org/10.1136/medethics-2012-101030>.

4 Nuffield Council on Bioethics. *Dementia: ethical issues* 2009 <http://www.nuffieldbioethics.org/dementia>.

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describe the "Stewardship" model for public health ethics developed by the Nuffield Council on Bioethics.⁵

6. While I have made myself familiar with the current literature about the risks and benefits of fluoridating a water supply, I do not have expertise in evaluating epidemiological data about public health measures such as fluoridation.
7. I confirm that I have read and am familiar with the Code of Conduct for expert witnesses in Schedule 4 to the High Court Rules and agree to comply with it. Other than where I state that I am relying on the advice of another person, this evidence is within my area of expertise.
8. I have read the affidavits of:
 - (a) Associate Professor David Menkes;
 - (b) Professor Martin Ferguson;
 - (c) Professor Paul Connett;
 - (d) Sandra Pryor;
 - (e) Dr Gregory Simmons;
 - (f) Howard Wilkinson; and
 - (g) Dr Robin Wyman,

filed or to be filed in these proceedings.

9. In this affidavit, I discuss whether fluoridation of a public water supply should be considered medical treatment and, if it is, whether adding fluoride to a public water supply violates the right to refuse medical treatment. I also explain an ethical framework for analysing fluoridation in New Zealand, and comment on aspects of Associate Professor Menkes' affidavit.

Is fluoridation medical treatment?

10. I accept that there are some reasonable arguments in favour of the view that fluoridation is medical treatment and these have been presented in

⁵ Nuffield Council on Bioethics. *Public Health; ethical issues* 2007 <http://www.nuffieldbioethics.org/public-health>.

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other affidavits. However, I am of the view that there are some cogent reasons for considering that the addition of fluoride to a water supply by a Council does not constitute medical treatment for reasons that are not discussed in the other affidavits.

11. In my view, a distinction can be drawn between something being a "medical treatment" versus it being "a medicine". Even if it is correct that fluoride should itself be considered a "medicine", and I express no opinion on that matter, it does not follow that a council adding it to a water supply is "medical treatment."
12. The paracetamol in my office drawer is classed as a medicine under the Medicines Act 1981. When I offer some of that paracetamol to one of my colleagues because they have a mild headache, I am not providing medical treatment. Not only am I not a physician, I am not a health care professional of any kind, and cannot be considered to be providing medical treatment.
13. If it is true that fluoride is a "medicine", then when I brush my children's teeth in the evening, I am applying a medicine to their teeth. I might even be described as "medicating" my children. However, I consider that it is also clear that I am not providing "medical treatment" to my children.
14. The Medicines Act states that "bandages and other surgical dressings..."⁶ are not medicines. The General Practitioner who binds my sprained ankle is providing medical treatment even though she does not dispense a "medicine".
15. When considering the legality of withdrawing artificial nutrition and hydration (ANH) from Tony Bland, who was in a persistent vegetative state (PVS), Lord Keith in the House of Lords expressed the opinion that this constituted "medical treatment".⁷ He considered it permissible for a physician to withdraw ANH if, in his or her opinion, ANH would produce no benefit to the patient, and that opinion is consistent with "a large body of responsible and informed medical opinion." On the other hand, if the

⁶ The Medicines Act 1981, section 3(2)(b).

⁷ Airedale Hospital Trustees v Bland [1992] UKHL 5 (04 February 1993)[p.3].

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same action is performed by someone who is not a physician and not providing a regime of medical treatment to the patient, it might constitute manslaughter or murder. My interpretation of Lord Keith's judgment is that a central defining feature of medical treatment is that it is performed by physicians who are providing a regime of clinical care to a patient.

16. Section 11 of the New Zealand Bill of Rights Act 1990 (NZBORA) uses the term "medical treatment" and, for the reasons mentioned in the preceding paragraphs, my opinion is that the fluoridation of the water supply by South Taranaki District Council is not medical treatment.

Can fluoride be refused if it is added to the public water supply?

17. In order to understand whether people can "refuse" fluoride if it is added to the water supply, it is important to distinguish between how a person might be "coerced into", "compelled into" or "inconvenienced by" a public health initiative. To claim someone is "coerced" or "compelled" into undergoing a public health measure implies that they were not free to refuse that measure. However if a person is merely "inconvenienced" by a public health measure, they are still free to refuse that measure.
18. In my view, the Human Rights Commission and the Commission of Inquiry into the Fluoridation of Public Water Supplies were correct in their opinion that adding fluoride to a water supply should be considered an "inconvenience"^{8, 9} for those who wish to drink unfluoridated water. I am also of the opinion that it implausible to describe persons as being coerced or compelled to drink fluoridated water and that South Taranaki District Council is therefore unlikely to be violating the section 11 right, even if the Court considers fluoridation to be a medical treatment.
19. Section 11 of the NZBORA says "Everyone has the right to refuse to *undergo* any medical treatment" [my emphasis]. "Undergo" implies that this right applies to medical treatment that is "done" to a patient. Examples of public health measures that can involve "doing" things to

⁸ Human Rights Commission *Report on Fluoridation* August 1980, p. 3.

⁹ Commission of Inquiry on the Fluoridation of Public Water Supplies *Report of the Commission of Inquiry on the Fluoridation of Public Water Supplies: presented to the House of Representatives by command of His Excellency*. 1957 Wellington: Government Printer p.142 paragraph 518.

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people, or people "undergoing" treatment are immunization and quarantine for tuberculosis.

20. If a competent adult refuses to be immunised against diphtheria/tetanus and is held down and injected with the vaccine, that person has been compelled to accept medical treatment. He or she has not been accorded the freedom to refuse this treatment and this would be contrary to the section 11 right. Likewise, a competent adult with infectious tuberculosis who is treated in a secure clinic so that the person cannot spread infection, when this is contrary to his or her will, has not been accorded the right to refuse treatment.
21. If the same patients were threatened with the consequence that they would be incarcerated if they did not accept treatment, then we should describe their apparent compliance as "coerced". If someone is coerced into accepting medical treatment, then they were not free to refuse it and they "underwent" it.
22. For someone who does not want to drink water that has had fluoride added to it, the addition of fluoride to the water supply by a Council does not compel or coerce that person to drink fluoridated water. They might drink tap water that has been filtered so as to remove the fluoride, collect and drink rainwater, access bore water or purchase bottled water. Even if this meant that they were reluctant to purchase drinks which might have been made using water with fluoride added, they are still not coerced or compelled to consume these drinks. For a person who wants to avoid fluoridated water, this amounts to an inconvenience and while it might be better for that person to not be inconvenienced, they are still able to refuse fluoridated water.

Fluoridation and ethics

23. Fluoridation is a polarising and keenly contested issue partly because it can be viewed from conflicting ethical perspectives. For example, a libertarian might argue that consent is required for every public health measure. While that perspective might be consistent and theoretically appealing to some, it would have the consequence that universal public health measures which have a profound impact upon health and carry

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no risk of harm, would become impermissible without universal consent. At the other end of the spectrum, a utilitarian might argue that it would maximise overall well-being if we vetted potential parents for their suitability as parents, prior to them being able to procreate.¹⁰

24. There is a need for an ethical framework for public health measures that can assist in weighing competing public health aims.
25. Associate Professor Menkes refers to an article by Childress et al.¹¹ that discusses a number of ethical principles and preconditions for ethical public health measures. While this article is co-authored by a number of leading thinkers in bioethics, it is overstating the case to claim that the standards they describe have been "generally accepted".¹² The co-authors say their paper "attempts to provide a rough conceptual map of the terrain of public health ethics" (p.169) and that they have "tried to provide elements of a framework for thinking through and resolving such conflicts [between moral considerations, human rights and public health]" (p176). This is clearly not an article which aims at generating the definitive statement of ethical standards for public health.
26. Associate Professor Menkes refers at paragraph 28 of his affidavit to the "five justificatory conditions" that Childress et al describe for resolving conflicts between promoting public health and other values such as autonomy or justice. He misquotes these conditions and in such a way that makes them appear to lend more support for the conclusion that he wishes to be drawn than is in my view warranted given their actual meaning.
27. For example, when Childress et al. discuss "Effectiveness"(at page 172) they mean that it has to be the case that "infringing" a moral consideration such as autonomy is required to "probably" protect public health. Associate Professor Menkes quotes this as "Be clearly effective" in his paragraph 28a, which is not the same idea at all.

¹⁰ LaFollette, H. "Licensing Parents" *Philosophy and Public Affairs*, Vol 2. No. 2. 1980. 182-197.

¹¹ Childress J, Faden R, Gaare R, Gostin L, et al "Public health ethics: mapping the terrain" *Journal of Law, Medicine and Ethics*, 30 2002: 169-177.

¹² Affidavit of David Menkes, paragraph 28.

28. Also, for example, when Childress et al. discuss "Proportionality" (at page 172) they mean the "probable public health benefits" must outweigh the moral considerations that are compromised. Associate Professor Menkes quotes this at paragraph 28b as "Be proportional" and explains this as meaning that the benefits exceed the harms which is not the same idea.
29. Associate Professor Menkes refers at his paragraph 29 to an article by Niyi Awofeso that applies the "five justificatory conditions" to fluoridation in Australia and concludes that there are good reasons for doubting whether these conditions are met. There are problems with the way that Mr Awofeso has used the sources and evidence he cites. For example, when he considers the "Effectiveness" condition at page 166, he concludes that recent studies have shown that when "compared with fluoride toothpaste, artificially fluoridated water plays only a minimal role of prevention of dental caries in most parts of the world."
30. The two papers Mr Awofeso cites in support of this claim appear to be making a different point. Fejevskov in his paper at page 189 claims that dental caries are a "complicated disease" and that there is "no one single "programme" to be uncritically super-imposed upon all populations."¹³ Moreover, Fejevskov specifically mentions fluoridating the water supply as a way that the incidence of caries is reduced in some populations)(p 189). I was unable to obtain a full version of the second article that Mr Awofeso cites, but the abstract says "fluoridated water and fluoridated salt are still important."¹⁴ And that would appear to be inconsistent with the claim that fluoridated water fails the "Effectiveness" condition.
31. Despite the fact "ethics" is mentioned in the title and that it was published in the journal *Public Health Ethics*, there is no ethical analysis in Mr Awofeso's paper. He claims that he aims to resolve a number of relevant ethical questions such as: "Is mass medication, which is compulsory or expensive to avoid, wrong? Is medication with an uncontrolled dose of a prophylactic drug wrong?" In addition to the

13 Fejevskov, O. (2004) "Changing paradigms in concepts on dental caries: consequences for oral health care" *Caries Research*, 38, 182-191.

14 Zimmer, S Jahn, K Barthel C (2003) "Recommendations for the use of fluoride in caries prevention." *Oral Health and Preventive Dentistry*, 1 45-51.

question begging assumptions built into these questions, there is no attempt in the paper to grapple with these ethical issues.

32. While Childress et al's framework is a useful way to think through some of the relevant considerations, it is in my view only "a map of the terrain." It is also important to mention that the "five justificatory conditions" they describe, do not constitute the considerations that they think are relevant to public health: they have a separate list of these considerations.
33. Since the publication of the Childress et al paper, the Nuffield Council on Bioethics published *Public Health: ethical issues*. This report considers in detail the key ethical considerations that are relevant to public health and develops a "stewardship" model of public health that involves weighing a number of public health aims.
34. The Health Act states that it is "the duty of every local authority to improve, promote, and protect public health within its district..."¹⁵ My opinion is that if there are good reasons why South Taranaki District Council could conclude that adding fluoride to the water supply is necessary to improve, promote or protect the public health of people within its district. Fluoridation is likely to be consistent with its statutory obligations.
35. Section 69O of the Health Act also permits the Minister to issue, adopt, amend or revoke drinking water standards but that "Standards issued or adopted under this section... must not include any requirement that fluoride be added to drinking water."¹⁶ My understanding of this provision in the Act is that a Minister cannot require local authorities to add fluoride to their water supply but that it is appropriate for local authorities to make a judgment about whether fluoridation when it is consistent with their statutory public health obligations.
36. "Stewardship" is the idea that the state, or any publicly funded institution that is involved with implementing public health initiatives, should have a

¹⁵ Section 23 of the Health Act 1956.

¹⁶ Section 69O(3)(c) of the Health Act 1956.

number of aims that include, but go beyond, respecting the autonomy and individuality of persons.

37. The "stewardship" model that the Nuffield Council¹⁷ develops includes six *prima facie* public health aims of the state (or district council) that are highly relevant to fluoridated water (pp.128-131). These are:
1. Reduction of risks of ill-health;
 2. Special care for the health of children;
 3. Reducing health inequalities;
 4. Not intervening without the consent of those affected;
 5. Minimise interventions that affect important areas of personal life;
 6. Not coercing ordinary adults to lead healthy lives.
38. The extent to which water fluoridation is an intervention that reduces ill-health is keenly debated. The Nuffield Council's view of the evidence is that the fluoridation of water does reduce the prevalence of caries, but that the degree to which it is reduced is not clear from the evidence. They concluded that there is evidence of a risk of fluorosis and no evidence of an association with more serious disease, although it is important to note that the evidence required to demonstrate the absence of any such associations was questioned.¹⁸
39. The primary systematic review that the Council relies on is the York review, which was published in 2000.¹⁹ Since then more evidence about the benefits of fluoridation to New Zealand populations has become available, some of which is presented in Dr Robin Whyman's, Sandra Pryor's and Dr Gregory Simmons' affidavits. In my view, this newer and more localised evidence is relevant to how South Taranaki District Council's public health aims should be weighed in the balance.
40. While other methods of delivering fluoride such as salt, or fluoride toothpaste have the advantage that is easier for adults to opt out of being exposed to fluoride, they have the disadvantage that they will reach fewer children, especially children from lower socio-economic

¹⁷ See note 5 above.

¹⁸ Section 690(3)(c) of the Nuffield Council on Bioethics. *Public Health; ethical issues* 2007 p133.

¹⁹ McDonagh M, Whiting P, Bradley M et al. (2000) *A Systematic Review of Public Water Fluoridation*
York: NHS Centre for Reviews and Dissemination

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groups. The public health aim to provide an adequate level of care for all children is a good argument in favour of fluoridation. This obligation is especially relevant to Patea and Waverly and the rest of South Taranaki where, as Dr Simmons indicates at paragraphs 17, 18 and 19 of his affidavit, children have particularly high levels of dental decay.

41. It is clear that there are significant inequalities in oral health within New Zealand.²⁰ The evidence that the Nuffield Council relies upon, from the York review, does not clearly establish that fluoridating the water supply decreases oral health inequalities. However, more recent evidence about New Zealand communities, such as that referred to by Dr Simmons at paragraph 7 of his affidavit²¹, suggests that fluoridation can have a significant impact upon reducing oral health inequalities. This means that it is reasonable in my view for South Taranaki District Council to aim at reducing inequalities in oral health based via fluoridation.
42. When fluoride is added to the water supply, those who would rather their tap water did not have this additive cannot as individuals consent to fluoridated tap water. There is no doubt that for some members of the community the public health aim of not intervening without the consent of those affected will not be honoured if water is fluoridated. Likewise, some would consider fluoridation an intervention that impacts upon an important area of their personal life.
43. My view as discussed above, is that fluoridation does not coerce people into drinking fluoridated water. However, it does have to be conceded that the degree of inconvenience involved in sourcing unfluoridated water could be significant and this frustration to a person's interests should be given appropriate weight, in the way that I describe below.
44. While the absence of individual consent does imply that one public health aim of the council is not met, this can be mitigated by finding other ways in which a state, or local authority, can demonstrate "deliberative democracy." The Nuffield Council's suggestion is that

20 Thomson W. "Social inequality in oral health" *Community Dentistry and Oral Epidemiology* 2012 40 28-32.

21 Lee M, Dennison P. Water fluoridation and dental caries in 5- and 12-year-old children from Canterbury and Wellington. *NZ Dental J* 2004,100, No. 1: 10-15.

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"transparent decision making processes", the involvement of stakeholders in decision making processes, and the opportunity to challenge such interventions can counter balance concerns about absence of consent.

45. The Nuffield Council conclude their chapter on fluoridation with the claim: "The most appropriate way of deciding whether fluoride should be added to water supplies is to rely on democratic decision-making procedures. These should be implemented at the local and regional, rather than national level, because the need for, and perception of, water fluoridation varies in different areas" (p 136).
46. I agree with the recommendation of the Nuffield Council and I believe that the South Taranaki District Council was entitled to consider and weigh in the balance its stewardship and public health aims so as to make an evidence based decision about whether the water supply in Waverly and Patea should be fluoridated.

The New Zealand Bill of Rights - Section 5

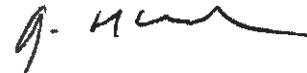
47. As already mentioned, my opinion is that fluoridation is not medical treatment. I also believe that even if others consider it to be a medical treatment, it does not violate a right to refuse medical treatment. My opinion is that South Taranaki District Council's decision to add fluoride to their water supply is reasonable, given their statutory public health role. I also think that it is crucial that they should have the right to make this determination.
48. However, if the Court finds that fluoridation does violate Section 11 of the NZBORA, I consider that fluoridation is a justified limitation on that Section 11 right. Not permitting some the right to refuse fluoridation in Waverly and Patea is justified because of the importance of addressing the oral health needs of children and reducing the oral health inequalities that exist in those areas.
49. Adding fluoride to the water supply without the individual consent of every person in the two areas is rationally connected with the purpose of improving oral health in that area, and in my view the impairment of that

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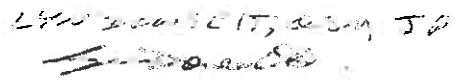
right (on the assumption that it is in fact violated) does not do so any more that is necessary for the purpose improving oral health.

50. Given the poor oral health of many children in Waverly and Patea, that poor oral health is disproportionately high among lower socio economic groups, Maori and Pacifica, and that fluoridation is the most effective way of addressing this issue, not enabling some to refuse fluoridated water is a reasonable given the importance of fluoridation. The Council's proposal to add fluoride to the water supplies is in my view a proportionate means for achieving an important end, improving the oral health of children and oral health inequalities.



John Robert McMillan

AFFIRMED at Dunedin this 1st day of October 2013 before me:



A Solicitor of the
High Court of New Zealand