

My name is Dr Paul Garth Butler. I am from a rural background being raised in Poroporo, a predominantly Maori Community close to Whakatane. I am currently the sole GP for the Tuhoe owned and operated Taneatua and Waimana Medical Centres and also work part time at the Riverslea Medical Centre at Edgecumbe, servicing a population with about a 50% Maori/Pakeha demographic.

Brief CV points.

BSc. MBChB. (1979) Dip. Obst. (Auckland). MSc (2014). (Plymouth)

1978. Trainee Intern. Christchurch. Cook Islands elective.

1973-1979. NZ Army Territorial Medical Core. Final rank Captain.

1979. House Officer. Whakatane Hospital.

Married 1979. Two sons born 1989 and 1991.

1981-1985. GP and Hospital experience UK and Australia.

Principal in Auckland General Practice (1986-2010).

Previous positions held:

Chairman Auckland Faculty RNZCGP.

Member of National Council RNZCGP.

Coordinator of the RNZCGP Environmental Working Party.

Secretary North Shore Branch NZMA.

Member Procure Privacy Committee.

Cofounding Trustee of the Fred Hollow's Foundation New Zealand.

Youthline consulting GP.

Executive member of ASH.

Working party member IPPNW.

Steering party member Mental Health Commission's Depression Management project.

Founding Trustee of Physicians and Scientists for Responsible Genetics.

Founding Trustee of Anew New Zealand Trust. Focusing on integrative indicators for economic progress and national wellbeing.

Widowed 2005.

MSc Plymouth University. Study 2010 to 2013

This submission in respect to the Health (Water Fluoridation) Amendment Bill.

This is an important subject for all New Zealanders, it is self evident that water is critical to life and the purity of water is a major determinant of our health and that of those we love and care for. I am a GP and have been for my whole career. In that role I am, amongst other things an interpreter of relevant health information for my patients, who at times have to make critical health choices.

In this submission I have chosen to focus my submission on attempting to support our non medical decision makers, whose duty it is to protect our public interest, when faced with what can be misleading and confusing statistics, and technical and scientific argument in regards to the health and human rights issues at stake.

The paper 'Adding fluoride to water supplies' [BMJ | 6 OCTOBER 2007 | VOLUME 335](#) which I will attach to my submission is brief, authoritative and relatively recent and indicates that the health authorities in the UK have been less than professional in their presentation of the evidence. Given the strong links between public health in the UK and here it would not be surprising if the advice given by the New Zealand Health authorities may have a similar quality. The paper fifty reasons to oppose fluoridation is also

excellent and has detailed information on possible adverse health effects from fluoridation which give some insight into where health authorities have not looked and should have. <http://fluoridealert.org/articles/50-reasons/>

It seems that the question of whether to add fluoride to public water supplies continues to arise because of the positive therapeutic intention of wishing to preserve the health of the teeth of children from lower socioeconomic groups, coupled with a lack of evidence for or against fluoridation due to poor quality of research in regards to fluoridation outcomes. This poor quality research is evident on perusing the various Systematic Reviews which are available on a Google Scholar search, ‘Systematic reviews of fluoridation’.

Some excerpts are:

‘Conclusion: Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken. As such, this review should provide both researchers and commissioners of research with an overview of the methodological limitations of previous research....’ (BMJ VOLUME 321 7 OCTOBER 2000)

‘Trust in the dissemination of evidence

Public and professional bodies need to balance benefits and risks, individual rights, and social values in an even handed manner. Those opposing fluoridation often claim that it does not reduce caries and they also overstate the evidence on harm.²¹ On the other hand, the Department of Health’s objectivity is questionable—it funded the British Fluoridation Society, and along with many other supporters of fluoridation it used the York review’s findings⁹ selectively to give an overoptimistic assessment of the evidence in favour of fluoridation.²² In response to MRC recommendations,¹³ the department commissioned research on the bioavailability of fluoride from naturally and artificially fluoridated drinking water. The study had only 20 participants and was too small to give reliable results. Despite this and the caveats in the report’s conclusion,²³ this report formed the basis of a series of claims by government for the safety of fluoridation.²⁴

Against this backdrop of one sided handling of the evidence, the public distrust in the information it receives is understandable. We hope this article helps provide professionals and the public with a framework for engaging constructively in public consultations. ‘BMJ | 6 OCTOBER 2007 | VOLUME 335

Conclusions

Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken. As such, this review should provide both researchers and commissioners of research with an overview of the methodological limitations of previous research.

The evidence of a reduction in caries should be considered together with the increased prevalence of dental fluorosis. No clear evidence of other potential negative effects was found. This evidence on positive and negative effects needs to be considered along with the ethical, environmental, ecological, financial, and legal issues that surround any decisions about water fluoridation. Any future research into the safety and efficacy of water fluoridation should be carried out with appropriate methodology to improve the quality of the existing evidence base.

Systematic review of water fluoridation

Marian S McDonagh, Penny F Whiting, Paul M Wilson, Alex J Sutton, Ivor Chestnutt, Jan Cooper, Kate Misso, Matthew Bradley, Elizabeth Treasure, Jos Kleijnen

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The history of poor outcomes research for fluoridation has resulted in a lack of convincing evidence of benefit, harm or safety for the intervention of fluoridating public water supplies. This has created the ongoing controversy over fluoridation and has encouraged public health authorities to pursue a fluoridation agenda based on conventional thinking from the past about the speculative benefits of fluoridating public water supplies, unchallenged but also unsupported by the good quality evidence needed to make an evidence based decision on fluoridation. The public of New Zealand now has a crisis where there is a move to introduce fluoride into our water supplies nationwide. Fluoride is a known toxin with no clear evidence of

significant benefit and with insufficient evidence to show harm or to demonstrate safety. Fluoride's use has been always based on extrapolation from the effect of its naturally occurring presence in some water supplies and speculation that fluoridating water supplies is beneficial enough to justify its use and speculation that it is not harmful enough to stop its use.

Despite the lack of good quality research evidence we do have enough facts about the inherent nature of fluoride and facts about the fact that we do not have sufficient good quality evidence to justify continuing fluoridating public water supplies in New Zealand, much less extending what is a potentially harmful and unethical intervention nationwide. In this situation where there is a lack of sufficiently good quality evidence to make a decision to fluoridate, based on trial evidence, we have to recognise that being guided by the Precautionary Principle, the Health and Disability Commissioner Act of 1994 and its principles of 1996, and the fact that we can achieve control of dental caries with other interventions, such as preventative dentistry, topical fluoride, reducing sugar intake in children's drinks and the diet, dental hygiene and reducing child poverty. It is time to let go of the toxin and use the non toxic approach to keeping children's teeth healthy.

Fluoride has a lot in common with one of the tools of my trade, pharmaceuticals, also known as prescription poisons. Fluoride as a chemical is inherently a toxin or a poison just as many pharmaceuticals are and as many recreational drugs such as alcohol, nicotine and caffeine are. There are undeniable risks when consuming a known toxin and adding a known toxin to a public water supply without good quality evidence of benefit and safety is unjustifiable. A toxin is a bit like a gun, it is inherently dangerous and one always has to treat it with even when using it for a positive purpose.

Is fluoride added to water supplies a medicine?

Fluoride is not in any natural human metabolic pathway. Because it mainly reduces caries by remineralisation of demineralised enamel (box 4), some people regard water fluoridation as a form of mass medication. Other people point out that fluoride occurs naturally at concentrations comparable to those used in fluoridation programmes and is therefore not a medicine. If viewed as a medicine, water fluoridation would require approval from a relevant authority.

The legal definition of a medicinal product in the European Union (Codified Pharmaceutical Directive 2004/27/EC, Article 1.2) is any substance or combination of substances "presented as having properties for treating or preventing disease in human beings" or "which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action." Furthermore, in 1983 a judge ruled that fluoridated water fell within the Medicines Act 1968, "Section 130 defines 'medicinal product' and I am satisfied that fluoride in whatever form it is ultimately purchased by the respondents falls within that definition."¹⁶

If fluoride is a medicine, evidence on its effects should be subject to the standards of proof expected of drugs, including evidence from randomised trials. If used as a mass preventive measure in well people, the evidence of net benefit should be greater than that needed for drugs to treat illness.¹⁷ An important distinction also exists between removing unnatural exposures (such as environmental tobacco smoke) and adding unnatural exposures (such as drugs or preservatives).¹⁸ In the second situation, evidence on benefit and safety must be more stringent. There have been no randomised trials of water fluoridation.

Known benefits of adding fluoride to water

In 1999, the Department of Health in England commissioned the centre for reviews and dissemination at the University of York to systematically review the evidence on the effects of water fluoridation on dental health and to look for evidence of harm.⁹ The review was developed with input from an advisory committee, which included members who supported and opposed fluoridation, or who had no strong views on the matter. Exceptional steps were taken to avoid bias and ensure transparency throughout.

Given the certainty with which water fluoridation has been promoted and opposed, and the large number (around 3200) of research papers identified,⁹ the reviewers were surprised by the poor quality of the evidence and the uncertainty surrounding the beneficial and adverse effects of fluoridation.

Studies that met the minimal quality threshold indicated that water fluoridation reduced the prevalence of caries but that the size of the effect was uncertain. Estimates of the increase in the proportion of children without caries

in fluoridated areas versus non-fluoridated areas varied (median 15%, interquartile range 5% to 22%). These estimates could be biased, however, because potential confounders were poorly adjusted for.⁹

Water fluoridation aims to reduce social inequalities in dental health,¹⁰ but few relevant studies exist. The quality of research was even lower than that assessing overall effects of fluoridation. The results were inconsistent—fluoridation seemed to reduce social inequalities in children aged 5 and 12 when measured by the number of decayed, missing, or filled teeth, but not when the proportion of 5 year olds with no caries was used.

Potential harms of fluoridation

The review estimated the prevalence of fluorosis (mottled teeth) and fluorosis of aesthetic concern at around 48% and 12.5% when the fluoride concentration was 1.0 part per million,⁹ although the quality of the studies was low.

The evidence was of insufficient quality to allow confident statements about other potential harms (such as cancer and bone fracture). The amount and quality of the available data on side effects were insufficient to rule out all but the biggest effects.

Small relative increases in risk are difficult to estimate reliably by epidemiological studies, even though lifetime exposure of the whole population may have large population effects. For example, an ecological study from Taiwan found a high incidence of bladder cancer in women in areas where natural fluoride content in water is high. The authors attributed the finding to chance because multiple comparisons were made.¹¹ Testing the hypothesis that drinking fluoridated water increases the risk of bladder cancer would need to take account of errors in estimating total fluoride exposures; potential lack of variation in exposure; the probable long latency between exposure and outcome; the illustrated by a case-control study on hip fracture in England.¹² It reported “no increase” in risk associated with average lifetime exposure of ≥ 0.9 part per million fluoride in drinking water. Although exemplary in many other aspects, the study had less than 70% power to identify an odds ratio of 1.5 associated with exposure. If the odds ratio was only 1.2—which would mean more than 10 000 excess hip fractures a year in England if the population was so exposed—the study would have a less than one in five chance of detecting it.

Thus, evidence on the potential benefits and harms of adding fluoride to water is relatively poor. This is reflected in the recommendations of the Medical Research Council (MRC)¹³ and the Scottish Intercollegiate Guideline¹⁴ on preventing and managing dental decay in preschool children (box 3). We know of no subsequent evidence that reduces the uncertainty.

There is no such thing as absolute certainty on safety. While the quality of evidence on potential long term harms of fluoridated water may be no worse than that for some common clinical interventions, patients can weigh potential benefits and risks before agreeing to treatments. In the case of fluoridation, **people should be aware of the limitations of evidence about its potential harms and that it would be almost impossible to detect small but important risks (especially for chronic conditions) after introducing fluoridation.**

‘Toxicology, while formally considered a new science, has ancient roots and is closely linked to medicine. Toxicology's counterpart in medicine is pharmacology, the study of the beneficial and adverse effects of medicinal drugs. The adverse effects of drugs, often termed side effects, are really the toxicological or undesired aspects of the drug that one must endure along with the benefits. The basic principles of pharmacology and toxicology are very similar, with just a different emphasis on the outcome’. (Gilbert, S.G. *A Small Dose of Toxicology. The health effects of common chemicals.* 2nd edition, January 2012)

The idea that in New Zealand we maybe poisoned by our public water supplies is still somewhat foreign to our way of thinking, perhaps with the exception of microbes more recently. However as a population our understanding of the effects of toxins is gradually increasing, with the recognition of the counterbalancing risks and benefits posed by many chemicals and even foods. This includes pharmaceuticals, alcohol, pesticides, solvents, alcohol, nicotine, salt and sugar.

Chemicals such as pesticides, fertilizers, vehicle discharges and pharmaceuticals pollute many rivers and also the public water supplies drawn from them. Even chemicals deliberately added to water supplies, such as chlorine, a close relative of fluoride, have known serious toxic effects. Domestic hot water contains elevated

copper levels leached from hot water cylinders and should not be used for drinking. Some historians claim that the major influence bringing about the fall of the Roman Empire was lead contamination of public water supplies, leached from water pipes.

Public water supplies in New Zealand can be contaminated with chemical toxins/poisons, which arise from completely natural-sources, such as arsenic. Just because fluoride, or any other chemical in water can be naturally occurring does not make it safe.

In some distant past water sources naturally contaminated with fluoride were noted to offer some protection against dental caries. Fluoride was thus investigated and approved for use in public water supplies. This occurred in an era when the quality of scientific studies was often poor and the fluoride studies have been reported in several systematic reviews to be of poor quality both in regards to demonstrating benefit and harm. Furthermore at this time consciousness around possible toxicity of chemicals in general was low, as there were relatively very few artificial chemicals in circulation then. It was also before the mechanism of action of fluoride on the teeth was found to be topical and not systemic. It is only in more recent times that many of the practices of preventative dentistry, that along with societal changes have dropped the rates of dental caries in both fluoridated and non fluoridated areas to similarly low levels, were developed.

When considering the evidence in regards to the risks of using fluoride in public water supplies, it is critical to understand that a lack of evidence of harm, does not constitute evidence for a lack of harm. This statement is even more meaningful when one considers that all pharmaceuticals, approved before the time of thalidomide, lacked research into their risk profile and therefore were likely to lack evidence of harm purely on the basis that it had not been adequately looked for. This lack of research into harm also applies to fluoride, both naturally occurring and added to water supplies.

It is worthwhile contrasting the current approach to prescription poisons/toxins/pharmaceuticals with the provision of the toxin/poison fluoride to the public via water fluoridation. Doctors are taught to follow the ethic 'First do no Harm' when considering potentially damaging interventions. Even in today's world of the heightened regulation post-thalidomide and the huge research effort now required to achieve the approval of a new pharmaceutical, it is accepted that any approval of a new drug will only come with a partial elucidation of the risk profile. With medications the risk profile is revealed with the experience of use of the pharmaceutical in more and more people over time. However it is understood that a part of the risk will remain a mystery, as there are no research tools available to fully quantify and qualify all risks related to toxins. Even after extensive experience with a new drug its use continues to be limited to prescription to consenting patients for specific indications by a qualified doctor. In practice doctors should demonstrate caution with a new drug because of the risk of unexpected side effects and they should understand that many risks of using the new pharmaceutical will only become clear after the drug/pharmaceutical has been used by many patients for a long time. Furthermore over recent years there has been a notable example where one of the most common groups of drugs, that had been very widely used for a long period of time for arthritis, was retested in a different way to look at long term use rather than

short term use, to investigate a new possible therapeutic use, cancer prevention. Surprisingly with that retesting a greatly increased risk of a life threatening side effect, increased heart attacks was discovered for the first time, even though those drugs must have caused many deaths from that cause in the past. This example informs us that with a prescription poison, or any toxin or poison consumed for therapeutic purposes, as is the case with fluoride, that serious hidden adverse effects may not be detected even after long term extensive use.

It must be noted that with pharmaceutical medicines, which are all prescription poisons have to pass extensive testing costing vast sums of money before they achieve approval to even be prescribed by a doctor for specific health problems and then the patient has to be informed and has the choice to decline. Fluoride on the other hand has been very poorly tested for toxicity in those it is targeted for, when placed into public water supplies. In the public water supply it is effectively given to all human beings of all ages from the unborn to the very old and in all stages of health. Patients also are often on a large range of medication and are also subject to other chemical exposures or deficiencies which may interact with fluoride such chlorine and iodine or exposure to many other environmental sources of fluoride from tea bags to medication.

There are lies, damn lies and statistics. (Attributed to Benjamin Disraeli.) To avoid being deceived by statistics, as a non statistician decision maker, requires some basic understanding of statistical terms and methods and how they can deceive. There are two main ways to present the change (effect) caused by an action (intervention). These are 'relative' and 'absolute' measures of change. Presenting only relative or absolute measures in isolation, or without adequate context is misleading and it is often done with a disrespect for honest communication. A hypothetical example is; if a particular intervention, reduced the risk of dental caries of tooth surfaces from an average of two surfaces with caries in a year amongst 4.5 million people to an average of one surface with caries in a year amongst 4.5 million people the change could be represented as a 50% reduction in dental decay i.e. from 0.000044% to half of that which is 0.000022%. This is presenting the change as a relative measure. However looking at absolute measures the change can be seen as going from 2/4,500,000 to 1/4,500,000. This is a change from 0.000022% to 0.000044%, an absolute change of 1 surface in 4,500,000 people or a 0.000022%. It can be seen here that what maybe trumpeted as a 50% improvement in dental caries rates in the full context is not only an impressive 50% relative improvement but also only a very unimpressive 0.00002% absolute improvement or a 1 in 4,500,000 difference.

Tooth decay has been a significant health concern since the introduction of high sugar diets in populations with inadequate dental hygiene and inadequate access to preventative dentistry. Many of my current patients fit into this category. My own experience is that the promotion of dental health cannot be separated from the promotion of general health. Improving socio economic and educational status and public health action towards reducing the consumption of simple sugars, particularly sugar in drinks and foods will all support dental health in a manner that does not expose the whole population to a known toxin.

In regards to the ethics of putting fluoride into the public water supply it is worth reflecting on the standards for the administration of health interventions that the HDC

Act envisions. We are considering the mandatory continuity and initiation of adding a known toxin or poison; fluoride to water supplies. To make matters even worse fluoride is introduced into water supplies, in an impure form where it is mixed with other water born toxin contaminants, and introduced into the only source of water that each of us, including our children and women carrying unborn children, pay for, use for our drinking and cooking water in our private homes.

The law may inexplicably argue about definitions of whether fluoride meets the definition of a medicine under the terms of a particular act. This legal abstraction does not alter the chemical and biological reality that fluoride is a biologically active poison/toxin which has inherent health risks and potential health benefits and in the case of fluoridating water supplies it is being used with the intent of being a therapeutic substance or medicine. The essential question, with poisons used for health benefit, is whether their benefits outweigh their risks. This question needs to be addressed to the individual who has the right to the availability of an appropriately qualified advisor.

The ethics and law of our democratic society appear to dictate that the person being administered the toxin/poison as a medication has the right to informed choice, as to whether they agree, that in their particular case the benefit being offered them outweighs the risk of harm from taking the toxin/poison/medication. They need to choose whether it is in their or their dependents best interest to take it or not, given that children and unborn children are much more vulnerable to toxins.

In 1996, New Zealand's first Health and Disability Commissioner, Robyn Stent, took on the task of creating The HDC Code of Health And Disability Services Consumers' Rights Regulation 1996, the code of rights recommended by Judge Cartwright in her Report. Enshrined in the Code are the following rights:

- The right to be treated with respect;
- The right to freedom from discrimination, coercion, harassment, and exploitation;
- The right to dignity and independence;
- The right to services of an appropriate standard;
- The right to effective communication;
- The right to be fully informed;
- The right to make an informed choice and give informed consent;
- The right to support;
- Rights in respect of teaching or research; and
- The right to complain.

Making fluoridation of water supplies mandatory against the wishes of many individual New Zealanders, with the potential consequence of causing harm does not appear to fit with these HDC act rights. The HDC act rights flowed on from what became known by many as the 'Unfortunate experiment', an approach that failed to respect the rights of the individual to appropriate standards of health care. I think law makers need to reflect on whether they are being led towards becoming the joint authors of another 'unfortunate experiment' where people in authority over their fellow New Zealanders dictate the continuation and expansion of a significant and potentially harmful health intervention, water fluoridation. It appears to me that the intervention of fluoridation of public water supplies breaks each and every one of the HDC act rights. This group of decision makers could make history by leading New

In contrast to water fluoridation, topical fluoride applications allow for a much lower dose of fluoride to be recommended by a dental healthcare professional to individuals in a context where they can be provided instruction on appropriate use and provided with the information they may need to be informed in regards to the indications for treatment and the risk of treatment, as required by the HDC Act 1994.

With our current absence of evidence we need to be guided by the HDC act 1994 above and by the precautionary principle below:

"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically." from the January 1998 Wingspread Statement on the Precautionary Principle.

For further information on the fluoridation issue I would recommend this link.
<http://fluoridealert.org/articles/50-reasons/>

I would like to speak in support of my submission.

Conclusion:

Given the level of interest surrounding the issue of public water fluoridation, it is surprising to find that little high quality research has been undertaken. As such, this review should provide both researchers and commissioners of research with an overview of the methodological limitations of previous research.

The evidence of a reduction in caries should be considered together with the increased prevalence of dental fluorosis. No clear evidence of other potential negative effects was found. This evidence on positive and negative effects needs to be considered along with the ethical, environmental, ecological, financial, and legal issues that surround any decisions about water fluoridation. Any future research into the safety and efficacy of water fluoridation should be carried out with appropriate methodology to improve the quality of the existing evidence base.

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The ability to quantify the safety concerns of your population through a review, albeit from studies of moderate to low quality, allows your health authority, the politicians and the public to consider the balance between beneficial and harmful effects of water fluoridation. Those who see the prevention of caries as of primary importance will favour fluoridation. Others, worried about the disfigurement of mottled teeth, may prefer other means of fluoride administration or even occasional treatment for dental caries. Whatever the opinions on this matter, you are able to reassure all parties that there is no evidence that fluoridation of drinking water increases the risk of cancer.

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Five steps to conducting a systematic review
Khalid S Khan MB MSc Regina Kunz MD MSc¹ Jos Kleijnen MD PhD² Gerd
Antes PhD³ J R Soc Med 2003;96:118–121

Gilbert, S.G. A Small Dose of Toxicology. The health effects of
common chemicals. 2nd edition, January 2012.

Points: Statistics and how they mislead

The precautionary principle
Ethics and law.

difficulty in specifying risks of toxins leave us with. such a toxin added to the public
water supply could be playing on human health.