IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

CIV-2014-485-004138
[2014] NZHC 2487

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

Hearing: 2 October 2014

Counsel: L M Hansen for Plaintiff
J Foster and M F Clark for Defendant

Judgment: 9 October 2014

JUDGMENT OF COLLINS J

Introduction

[1] I have concluded that Hydrofluorosilicic Acid (HFA) and Sodium Silico Fluoride (SSF) are not medicines under the Medicines Act 1981 (the Act) as currently used to fluoridate domestic water supplies in New Zealand.

[2] I am therefore dismissing an application by New Health New Zealand Inc (New Health) in which it seeks two declarations that:

> 1. When manufactured, sold to and supplied or distributed by local authorities for the purpose of community water fluoridation, HFA and SSF are medicines under the [Act].

> 2. The Ministry of Health is required to take all necessary steps to ensure the manufacture, distribution, sale and supply of HFA and SSF complies with the [Act] and Regulations.

[3] I shall:

(1) explain the background to this proceeding, including its genesis in a related case;

(2) examine the relevant legislation;

(3) set out my analysis of the law and the reasons for my decision; and

(4) summarise my conclusions.

Background

Water fluoridation

[4] Trace elements of fluoride are naturally present in some water supplies. In some communities, particularly in the United States, the natural concentration levels of fluoride in water are so high that steps have to be taken to reduce fluoride in those communities' water supplies. This is called de-fluoridation.

[5] In contrast, the process known as water fluoridation increases the concentration of fluoride in water. This process was first commenced in New Zealand in 1954 when water fluoridation was introduced in Hastings. Water fluoridation is primarily achieved through the introduction of HFA and SSF into water supplies by local authorities.

[6] Water fluoridation is usually undertaken after domestic water supplies have been treated and cleaned by adding a number of chemicals, including chloride. Fluoridation is achieved by adding measured quantities of HFA and SSF which, when dissolved in water, release fluoride ions, thereby increasing the concentration of fluoride ions in water.[1]

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[1] First Affidavit of D B Menkes, 23 June 2014 at [10].

[7] HFA is a by-product of the manufacture of phosphate fertiliser. Phosphate rock, which contains fluoride and silicon is treated with sulphuric acid. This produces two gases which are then exposed to water to form HFA. SSF is produced by adding either sodium carbonate or sodium chloride to HFA. For convenience, I will, when possible, refer in the balance of this judgment to HFA and SSF as fluoride even though they are really compounds which contain fluoride.

[8] The Drinking Water Standards for New Zealand (the Drinking Water Standards) are set by the Ministry of Health (the Ministry) under s 69O of the Health Act 1956. In setting the Drinking Water Standards the Ministry relies on advice from an expert committee which in turn has based its recommendations on World Health Organisation (WHO) guidelines. The Drinking Water Standards set the maximum allowable concentration level of fluoride in domestic water supplies in New Zealand.

[9] The maximum allowable level of fluoride in domestic water supplies in New Zealand is 1.5 milligrams per litre (1.5 mg/l). This maximum allowable concentration level for fluoride was set in 1984 and was based upon a WHO guideline issued in 1984. The WHO guideline has not changed since it was promulgated and was calculated on the basis of a person consuming two litres of water a day over a lifetime. In New Zealand the maximum allowable levels of fluoride in domestic water is consistent with those in domestic water supplies in Australia and England, and much lower than the maximum allowable level of fluoride in the United States which is set at 4 mg/l.[2]

Purpose of fluoridation

[10] The sole purpose in placing fluoride into water is to prevent and reduce tooth decay. The Ministry of Health believes that introducing fluoride into water is "… a safe, effective and affordable way to prevent and reduce tooth decay".[3] The Ministry of Health says that:[4]

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2 Affidavit of P F Prendergast, 7 July 2014 at [46]-[47].
3 Affidavit of S S Jessamine, 7 July 2014 at [13].
4 Above n 3.

> … Other public health authorities and medical science bodies and international organisations, including the New Zealand Medical Association, the New Zealand Dental Association, the World Health Organisation and the World Dental Federation share the view that fluoridation of drinking water supplies is [an] effective way of preventing and reducing tooth decay.

[11] When fluoride is dissolved in water the increased concentration of fluoride ions affects mineralisation of tooth enamel, thereby preventing tooth decay.[5] Thus, the addition of fluoride to domestic water supplies aims to prevent or reduce dental decay by a pharmacological process.

[12] There are others who do not share the Ministry of Health's views about the positive effects of fluoride being added to community water supplies. New Health is an interest group which was established in 2005 to promote "the best interests and health freedoms of consumers".[6] New Health opposes the adding of fluoride to community water supplies. Mr Sloan, the Chairman of New Health, has produced three affidavits in which he refers to a number of reports including:

(1) a report prepared at the University of York in 2000 (the York report);

(2) a report prepared by the New Zealand National Research Council in 2006 (NRC report);

(3) an affidavit from Dr Kathleen Thiessen in October 2013; and

(4) a report prepared in 2011 by a European based organisation, the Scientific Committee on Health and Environmental Risks (SCHER report).

[13] In his first affidavit Mr Sloan explains that New Health is opposed to fluoridation of water supplies by New Zealand local authorities for reasons which include:[7]

(1) fluoridation removes consumers' freedom of choice;

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5 First Affidavit of D B Menkes, 23 June 2014 at [21].
6 First Affidavit of P D Sloan, 1 April 2014 at [4].
7 First Affidavit of P D Sloan, 1 April 2014 at [10].

(2) fluoride is potentially harmful to health;

(3) fluoridating water supplies is not an effective way of providing fluoride for the purposes of preventing dental decay;

(4) fluoridation conflicts with core principles of contemporary pharmacology; and

(5) the fluoride added to water supplies in New Zealand is obtained from the phosphate fertiliser industry and contains heavy metal contaminants including arsenic and lead.

[14] The efficacy and safety of fluoridation of water is a topic that engenders strong debate and disagreement. There has been a raft of litigation over the introduction of fluoride to domestic water supplies in New Zealand[8] and many other western countries.[9] However, I do not have to address those issues in this proceeding. My task is to interpret the Act and decide if fluoride falls within the definition of "medicine" in the Act when used for the purpose of fluoridating community water supplies.

Genesis to this proceeding

[15] In *New Health New Zealand Inc v South Taranaki Council*,[10] New Health challenged the lawfulness of community water fluoridation. In that case New Health said that adding fluoride to domestic water supplies:

(1) constituted treatment for the purposes of s 11 of the New Zealand Bill of Rights Act 1990 (NZBORA) and that consumers of fluoridated

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8 *Attorney-General of New Zealand v Lower Hutt City Corp* [1964] AC 1469 (PC); *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834; *Safe Water Alternative New Zealand Inc v Hamilton City Council* [2014] NZHC 1463.

9 See David Shaw "Weeping and Wailing and Gnashing of Teeth: The legal fiction of water fluoridation" (2012) Medical Law International 12; Dean Farrer "Fluoridation: Compulsory Medication of Municipal Water Supplies?" (1973) 5 Urb Law 504; Jeff Wurzburg and Corrine Propas Parver "Community Fluoridation around the Nation: Significant Case Law and Legislation" (2013) 7 Health Law and Policy Brief 1, 2.

10 *New Health New Zealand Inc v South Taranaki District Council*, above n 8.

water had a right to refuse treatment associated with drinking fluoridated water;[11]

(2) was not authorised by the Local Government Act 2012;

(3) required ministerial approval under s 94(1) of the Act because it was a "therapeutic food"; and

(4) was not authorised by the Health Act 1956.

[16] All of these arguments were rejected by Rodney Hansen J. In addressing the claim based on s 11 of the NZBORA Rodney Hansen J said:[12]

> … although the addition of fluoride [to water] does no more than to elevate it to levels which often occur naturally, it is nevertheless a process undertaken for the purpose of preventing or arresting a disease … the process of fluoridation is undertaken for a therapeutic purpose.

[17] This aspect of Rodney Hansen J's judgment has been focused upon by New Health to support its claim for declarations that fluoride is a medicine within the meaning of the Act when added to community water supplies for the purposes of treating or preventing tooth decay.

[18] Rodney Hansen J's observation that fluoride additives are added to water for therapeutic purposes was consistent with the view of Lord Jauncey in *McColl v Strathclyde Regional Council*[13] in which he said that fluoride, when added to water, is a "medicinal product" within the meaning of s 130 of the Medicines Act 1968 (UK).

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11 **11 Right to refuse to undergo medical treatment**
Everyone has the right to refuse to undergo any medical treatment.

12 *New Health New Zealand Inc v South Taranaki District Council*, above n 8, at [79].

13 *McColl v Strathclyde Regional Council* [1983] SC 225 (CS).

Relevant legislation

Overview

[19] The importation, manufacture, distribution and use of chemicals including those used as medicines or to make medicines are governed by a range of statutes and regulations. Acts such as the Hazardous Substances and New Organisms Act 1996, the Health Act 1956 and the Misuse of Drugs Act 1975 regulate a wide-range of drugs and dangerous substances. HFA and SSF are hazardous substances under the Hazardous Substances and New Organisms Act 1996. That Act regulates the importation of those chemicals and how they can be modified, transported and stored.[14]

[20] Other statutes and regulations control the way in which products can be manufactured, supplied to and administered to humans. In addition to the Act, statutes and regulations which fall into this category include the Food Act 1981, the Dietary Supplements Regulations 1985 and the Medicines Regulations 1984 (the Regulations).

Medicines Act 1981

[21] The Act regulates medicines, related products and medical devices in New Zealand.

[22] Medicine is defined in s 3 of the Act. The relevant part of the definition provides:

> (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…

[14] Affidavit of P F Prendergast, 7 July 2014 at [44].

[23] Certain items are specifically excluded from the definition of "medicine" in the Act. Items that are excluded include any food as defined in s 2 of the Food Act 1981, or "… 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".[15]

[24] "Administer" is defined in s 2 of the Act to mean:

> … administer to a human being, either–
>
> (a) Orally … by introduction into the body in any other way;
>
> …
>
> and every reference in this Act to administering a substance or article is a reference to administering it 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.

[25] "Therapeutic purpose" is defined in s 4 of the Act. The relevant portion of that definition provides:

> In this Act, unless the context otherwise requires, therapeutic purpose means …
>
> (a) Preventing, … alleviating, treating, curing … a disease, ailment, defect …; or
>
> (b) Influencing, inhibiting, or modifying a physiological process …

[26] The Act regulates and places restrictions on the sale, supply and administration of five categories of medicines:

(1) new medicines;

(2) prescription medicines;

(3) restricted medicines;

(4) pharmacy-only medicines; and

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[15] Medicines Act 1981, s 3(1)(c)(vi).

(5) general sale medicines.

[27] The regulation of new medicines under the Act is not relevant to the issue I have to consider. For present purposes it is only necessary to explain that:

(1) prescription medicines; and

(2) restrictive medicines; and

(3) pharmacy-only medicines

are identified by regulations or notices issued under s 106 of the Act. General sale medicines are medicines that may be lawfully sold, other than as pharmacy-only, prescription and restricted medicines.[16] General sale medicines are identified in a list of such medicines published by the Director-General of Health.[17]

Medicines Regulations 1984

[28] Fluorides are identified in Parts 1, 2 and 3 of Schedule 1 to the Regulations as prescription medicines, restricted medicines and pharmacy-only medicines.

Concentrations of fluorides

[29] The term concentration can be applied to any kind of chemical mixture. For present purposes concentration refers to the volume of a medicine in one litre of water. Schedule 1 of the Regulations states that "unless reference is made otherwise, every reference to a medicine in this Schedule applies … only if the concentration of the medicine is greater than 10 milligrams per litre …".

Dosages of fluorides

[30] The Regulations then categorise fluorides, generally by reference to doses and dosages. A dose is a quantity of a medicine.[18] The term "dosage" refers to the

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16 Medicines Act 1981, s 99(2).
17 Section 99(1).
18 Derived from the definition of "dose"; Lesley Brown (ed) *The New Shorter Oxford English Dictionary* (4th ed, Oxford University Press, New York, 1993).

rate of application of a dose of medicine.[19] Footnotes 20, 21 and 22 set out in full the classification of fluorides as pharmacy-only, restricted and prescription medicines. It is sufficient to say at this juncture that, subject to certain exceptions, fluorides are classified as:

(1) Prescription medicines:[20] when used in medicines used for internal use containing more than 0.5 milligrams per dose unit except in medicines containing 15 milligrams or less per litre or per kilogram.

(2) Restricted medicines:[21] when used in liquid medicines for external use containing 5.5 grams or less and more than 1 gram per litre or per kilogram and when sold in packets approved by the Minister or the Director of Health for distribution as restricted medicines.

(3) Pharmacy-only medicines:[22] when used in medicine used for internal use containing more than "0.5 milligrams or less per dose unit … except in medicines containing 15 milligrams or less per litre or per kilogram".

[31] The Director-General has categorised fluorides as a general sale medicine.[23] With certain qualifications that are explained in footnote 23 a fluoride is a general

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19 Derived from the definition of "dosage"; Lesley Brown (ed) *The New Shorter Oxford English Dictionary*, above n 18.

20 Fluorides; for internal use in medicines containing more than 0.5 milligrams per dose unit except in medicines containing 15 milligrams or less per litre or per kilogram; except in parenteral nutrition replacement preparations; for external use in medicines containing more than 5.5 grams per litre or per kilogram except when supplied to a dental professional registered with the Dental Council.

21 Fluorides; for external use in liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as restricted medicines; for external use in non-liquid form in medicines containing 5.5 grams or less and more than 1 gram per litre or per kilogram, except in medicines containing 1.5 grams or less and more than 1 gram per litre or per kilogram; except when supplied to a dental professional registered with the Dental Council.

22 Fluorides; for internal use in medicines containing 0.5 milligrams or less per dose unit; except in parenteral nutrition replacement preparations; for external use in liquid form in medicines containing 1 gram or less per litre or per kilogram and when sold in packs approved by the Minister or the Director-General for distribution as pharmacy-only medicines except in medicines containing 220 milligrams or less per litre or per kilogram and in packs containing not more than 120 milligrams of total fluoride; except when supplied to any dental professional registered with the Dental Council; except in medicines containing 15 milligrams or less per litre or per kilogram.

23 For external use in liquid form in medicines containing 220 milligrams or less per litre or per

sale medicine when it is used for external use in liquid form in medicines containing 220 milligrams or less per litre or per kilogram.

[32] For completeness I note that reg 58A states that dentrifice products,[24] which are primarily toothpastes and mouth washes, are not medicines provided that:

> (i) the dentrifice product does not contain a medicine specified in Schedule 1; and
>
> (ii) the dentrifice product is not claimed to be for use in relation to any therapeutic purpose other than one or both of the following:
>
> (A) preventing dental decay:
>
> (B) improving oral hygiene.

Analysis

[33] In approaching my task I have focused upon three questions:

> (1) is fluoride added to domestic water supplies for a therapeutic purpose?
>
> (2) is fluoride "administered" to a human being when it is added to domestic water supplies?
>
> (3) does the "context otherwise require" me to conclude that fluoride, when added to domestic water supplies, is not a medicine within the meaning of the Act?

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kilogram and in packs containing not more than 120 milligrams of total fluoride, which have been approved by the Minister or the Director-General for distribution as general sale medicines; for external use in non-liquid form in medicines containing 1.5 grams or less per litre or per kilogram and, when containing more than 1 gram per litre or per kilogram, sold in packs approved by the Minister or the Director-General for distribution as general sale medicines; in medicines containing 15 milligrams or less per litre or per kilogram; in parenteral nutrition replacement preparations; Medsafe "Database of Medicine Classifications" (14 July 2014) Medicine Classification <www.medsafe.govt.nz/profs/class/classification.asp>

[24] "Means any substance or mixture or substances used or represented for use for the purpose of cleaning the mouths or teeth (natural or artificial) of human beings, and includes any denture fixative"; Medicines Act 1981, s 2.

Therapeutic purpose

[34] 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.

[35] 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" which I have set out in paragraph [22].

To administer

[36] Ms Foster, senior counsel for the Attorney-General said that the lynchpin of her client's case was that fluoride is not administered to any person within the meaning of the Act when it is added to domestic water supplies. She submitted that although HFA and SSF are chemicals that are used to increase the fluoride levels in water they cannot be said to be manufactured or supplied to be administered to a human being. This argument was based on the contention that HFA and SSF in their undiluted form cannot be administered to a human being for therapeutic purposes because if they were so administered the consequences would be fatal. It is fluoridated water, rather than HFA and SSF that is administered to humans.

[37] The deficiency with this aspect of Ms Foster's argument is that it does not take account of the full definition of "administer" in the Act. The definition of "administer" includes administering a substance "either in its existing state or after it has been dissolved in, or diluted or mixed with some substance in which it is to be administered".

[38] HFA and SSF are dissolved and diluted in water to enable fluoride to be consumed at very low concentrations by human beings.

[39] Accordingly, I am satisfied fluoride is administered to human beings, albeit at very low concentrations, when it is added to community water supplies for therapeutic purposes.

Context

[40] Parliament prefixed the definition of "medicine" in the Act with the words "unless the context otherwise requires". The same qualification precedes other definitions in the Act, including the definitions of "administer" and "therapeutic purpose".

[41] Although Parliament elected not to refer to "context" when it passed s 5(1) of the Interpretation Act 1999,[25] it is widely accepted that legislation today should be interpreted in light of its context.[26] This approach parallels what Lord Steyn described as the "pendulum" swing "towards purposive methods for construction"[27] which is now firmly entrenched in this country in s 5(1) of the Interpretation Act 1999. A contextual approach requires Judges to ascertain the meaning of legislation by referring, where necessary, to the broader legislative and policy contexts.[28] A leading example of this approach can be seen in *L D Nathan & Co Ltd v Hotel Association of New Zealand*[29] in which low-strength beer was held not to be "liquor" as defined in s 2 of the Sale of Liquor Act 1962 when viewed in the broader legislative and policy context of the definition of "liquor". A contextual approach is essential "in order to make an Act work as Parliament must have intended".[30]

[42] Ms Hansen, counsel for New Health advanced a contextual argument which requires careful analysis. Ms Hansen explained that fluoride tablets, which, when sold as a pharmacy-only medicine, contain 1.1 milligram of sodium fluoride. She submitted that ingesting two 1.1 milligram sodium fluoride tablets supplies a person

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25 Interpretation Act 1999, s 5(1):

> The meaning of an enactment must be ascertained from its text in the light of its purpose.

26 *Agnew v Pardington* [2006] 2 NZLR 520 (CA) at [32]; JF Burrows & RI Carter *Statute Law in New Zealand* (4th ed, LexisNexis, Wellington, 2009) at 232.

27 *R (Quintavella) v Secretary of State for Health* [2003] 2 AC 687 at 700.

28 *9 Cornwall Crescent London Ltd v The Mayor and Burgesses of the Royal Borough of Kensington and Chelsea* [2005] EWCA Civ 324 at [52].

29 *L D Nathan & Co Ltd v Hotel Association of New Zealand* [1986] 1 NZLR 385 (CA).

30 See for example, *Northland Milk Vendors Association Inc v Northern Milk* [1988] 1 NZLR 530 (CA) at 538.

with the approximate amount of fluoride he or she ingests when he or she drinks one litre of water fluoridated to the maximum allowable level.[31]

[43] Ms Hansen pointed out that there are no controls over how much water a person can drink and that when viewed in this context, fluoridated water should not be treated any differently from pharmacy-only fluoride tablets which plainly are a medicine.

[44] It will be apparent Ms Hansen's argument relies upon the dosages of fluoride prescribed in Schedule 1 of the Regulations.

[45] The defect in Ms Hansen's approach is that it ignores the threshold concentration required for substances to be medicines in Schedule 1 of the Regulations. As I have explained in paragraph [29], Schedule 1 of the Regulations specifies that every reference to a medicine in the Schedule only applies if the concentration of that medicine is greater than 10 mg/l.

[46] The concentrations of fluoride in domestic water supplies must not exceed 1.5 mg/l. When fluoride is added to domestic water supplies within the maximum allowable concentration of 1.5 mg/l the concentration of fluoride in domestic water supplies will be well below the concentration threshold required for fluoride to be a medicine in Schedule 1 of the Regulations.

[47] When viewed in the context of the maximum allowable concentrations of fluoride in domestic water, and the concentrations of fluorides that are classified as medicines in Schedule 1 of the Regulations, I am drawn to the conclusion that the definition of "medicine" in the Act cannot include fluoride when it is added to domestic water supplies to produce a concentration of no more than 1.5 mg/l.

[48] I appreciate the approach I have taken focuses upon concentrations of fluoride and not dosages and that there is no legal limit placed on how much fluoridated water a person can consume. However, because fluoridated water is not

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[31] Affidavit of D B Menkes, 23 June 2014 at [26].

administered in dosages the only practical way fluoride can be measured and regulated in domestic water supplies is by referring to concentrations.

[49] I am required to interpret the meaning of "medicine" in the Act in context which includes the Regulations and the Health Act 1956. This approach leads to the conclusion that the concentration threshold for fluoride in Schedule 1 of the Regulations is so vastly higher than the maximum allowable concentration of fluoride in domestic water supplies that, when fluoride is added to domestic water at the authorised levels, it falls outside of the definition of "medicine" in the Act.

[50] It follows from my reasoning that fluoride would be a medicine under the Act *if* it was added to domestic water supplies in concentrations of 10 mg/l or more.

[51] While I am confident my conclusion is correct, the Ministry may wish to consider recommending a Regulation that exempts HFA and SSF from the definition of "medicine" when those compounds are used to fluoridate water.

Conclusions

[52] When HFA and SSF are added to domestic water supplies in New Zealand to produce fluoride concentrations within the current allowable level of 1.5 mg/l they are not medicines within the meaning of the Act.

[53] The application for declarations is dismissed.

[54] Under normal circumstances the Attorney-General would be entitled to costs on a scale 2B basis. However, I take the view that because New Health has advanced legitimate arguments in the public interest, this is one of those rare situations where an award of costs is not appropriate.[32]

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[32] *Gibbs v New Plymouth District Council (No 2)* HC New Plymouth CIV-2004-443-115, 5 October 2006.

D B Collins J

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