

There is Really No Such Thing as Alternative Medicine

The Natural Health and Supplementary Products Bill

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*“There is really no such thing as alternative
medicine, just medicine that works, and
medicine that doesn’t.”*

– John Diamond, “Quacks on the Rack”^{1,2}

¹ John Diamond “Quacks on the Rack” *The Observer* (online ed, London, 3 December 2000).

² John Diamond was an English journalist, perhaps best known for being married to Nigella Lawson. However, he was an accomplished writer and wrote a series of books and articles recounting his experiences after being diagnosed with throat cancer. He was highly critical of alternative medicines, writing “Snake Oil and Other Preoccupations” as an “uncomplimentary look at the world of complementary medicine”.

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Introduction

Conventional medicine has improved our quality of life dramatically. Substances like antibiotics and vaccines have reduced our vulnerability to infectious diseases. But some still view conventional medicine with scepticism. These detractors say that we should put our faith in alternative therapies because they are “natural”.

In all fairness, conventional medicine has had its share of mishaps. But are natural remedies actually superior? Oliver Wendell Holmes decried this view as “the nature trusting heresy”.³ Others have pointed out that proponents of alternative medicine often conveniently forget about the less positive effects of nature.^{4,5}

Some alternative therapies have undergone regulation. For example, chiropractors are subject to standards set out in the Health Practitioners Competence Assurance Act 2003 (HPCAA). Right 4 of the Code of Health and Disability Services Consumers’ Rights grants consumers the right to services of an appropriate standard. This applies even to health practitioners that are not included under the HPCAA.⁶

However, natural health products (NHPs) still largely fall outside the scope of regulation. This category of products is wide and varied, ranging products as innocuous as fish oil to those as dubious as saw palmetto.⁷ They are all derived from “natural” sources and taken for some kind of health benefit, whether to treat a condition or general improvement of health. In many cases the NHP is efficacious, but in other cases, the evidential basis for the product amounts to pseudoscience. Recent incidents involving

³ JH Warner “‘The Nature-Trusting Heresy’: American Physicians and the concept of the healing powers of nature in the 1850’s and 1860’s.” (1978) 11 *Perspect Am Hist* 291.

⁴ Ted J Kaptchuk and David M Eisenberg “The Persuasive Appeal of Alternative Medicine” (1998) 129(12) *Ann Intern Med* 1061.

⁵ It should be remembered that anthrax, mercury and snakebite are all “natural” too.

⁶ Health and Disability Commissioner “The Code of Rights” (2009) <<http://www.hdc.org.nz/the-act--code/the-code-of-rights>>.

⁷ Saw palmetto is a plant native to the United States. At one point, extracts from its fruit were thought to prevent prostate cancer. Despite some promising pilot studies, it has subsequently been proven to be of little efficacy. See for example: J Tacklind and others “*Serenoa repens* for benign prostatic hyperplasia” (2009) 2 *Cochrane Database Syst Rev* CD001423.

quality have also tarnished the clean, wholesome image of NHPs as well.⁸ Such issues suggest that NHPs need to be regulated on some level.

Whereas New Zealand has lagged behind, jurisdictions such as Canada and Australia already have legislation in place to regulate NHPs. For example, Canadian NHP regulation has been in place for approximately 12 years already.

Some steps have been taken to rectify this. The Natural Health and Supplementary Products Bill (“NHSP Bill”) was introduced to Parliament in 2011, and purports to set out a new regulatory regime for NHPs. This is encouraging news, but the question remains if the Bill is suitable for purpose.

Chapter 1 examines the status quo of health products regulation in New Zealand. This chapter will consider the individual pieces of legislation, and I argue that there are deficiencies with the status quo. Also, examination of existing legislation creates an internal “yardstick” by which we can measure the adequacy of the NHSP Bill.

Chapter 2 focuses on regimes instituted by foreign jurisdictions. These are not absolute standards for New Zealand to adhere to, but it is wise to consider how other jurisdictions have attempted to tackle the issue of regulating NHPs. It provides an external yardstick for evaluation. The jurisdictions under consideration are Canada and Australia. They have been chosen for the similarities they share with New Zealand. These include their political traditions, demographic profiles and in Australia’s case, close economic ties.

Chapter 3 discusses the NHSP Bill itself. It will evaluate the regulatory principles that underpin the Bill, the definition of “natural health product” and the regulatory scheme against the “internal” and “external” yardsticks. This chapter seeks to show that the Bill is an improvement over the status quo, but that there are some serious concerns. It does not adequately give effect to safety concerns. There are features in the scheme that may leave loopholes for manufacturers and suppliers to exploit. These concerns are further reinforced when considered against more rigorous foreign regimes.

⁸ Laura Gartry “Heavy metals, pharmaceuticals and endangered species DNA found in traditional Chinese medicines, research finds” *Australian Broadcasting Corporation* (online ed, 11 December 2015).

Chapter 1: The Status Quo

Natural health products have never been the specific target of regulation in New Zealand. But a number of systems are already in place to deal with products used for health purposes. Most importantly, these include the Medicines Act 1981 and the Dietary Supplements Regulations 1985 (made pursuant to the Food Act 1981). Other legislation that forms part of the regulatory context include the Misuse of Drugs Act 1975, the Psychoactive Substances Act 2013 and the Fair Trading Act 1986.

I The Medicines Act 1981

The long title of the Medicines Act says that it is to “consolidate and amend the law relating to the manufacture, sale and supply of medicines, medical devices and related products”. It does not have a purpose section or otherwise allude to any underlying policy goals, but it is clear that safety is one of its major purposes.

In *Ministry of Health v Pacific Pharmaceuticals Ltd*, the High Court held that the self-evident purpose of the Medicines Act is safety: “New Zealand’s monitoring and enforcement mechanism which...ensures that the New Zealand public is protected from any risks inherent in untested or experimental drugs”.⁹ Subsequent cases have acknowledged these observations.¹⁰ In fact, the Court of Appeal in *R v Standard 304 Ltd* commented that the Medicines Act not only protects New Zealanders, but also those who may be the target of export sales.¹¹

The Ministry of Health also explicitly states that safety and protection from risk is the aim of the Medicines Act.¹² Medsafe alludes to safety in their mission statement: “to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit”.¹³

⁹ *Ministry of Health v Pacific Pharmaceuticals Ltd* (2001) 9 TCLR 681 at [26].

¹⁰ *Ministry of Health v Ink Electronic Media Ltd* HC Hamilton CRI2004-419-000084, 18 August at [72].

¹¹ *R v Standard 304 Ltd* [2008] NZCA 564 at [11].

¹² Ministry of Health “Medicines Act 1981” (26 May 2014) <<http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-act-1981>>.

¹³ Medsafe “About Medsafe” (29 September 2015) <<http://www.medsafe.govt.nz/other/about.asp>>.

For the Act to apply, a product must fall within the definition of “medicine”, “related product” or “medical device”. A “medicine” is:¹⁴

- (1) In this Act, unless the context otherwise requires, medicine –
 - (a) Means any substance or article that –
 - (i) Is manufactured, 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)...

A “related product” is “any cosmetic, dentifrice or food which has been claimed to have a therapeutic purpose”.¹⁵ Medsafe lists throat lozenges and fluoride toothpaste as examples of this.¹⁶ “Medical device” is defined as a “device, instrument, apparatus, appliance or other article that is supposed to be used for a therapeutic purpose in humans, and its mechanism of action is not through pharmacological, immunological or metabolic means, although it may be assisted in its function by such means”.¹⁷ In layman terms, its effect is to be achieved physically rather physiologically. Examples include synthetic heart valves and wound dressings.¹⁸

The three definitions are mutually exclusive, but all hinge on the term “therapeutic purpose”, which covers a wide range of aims. “Therapeutic purpose” is defined as:¹⁹

- In this Act...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

¹⁴ Medicines Act 1981, s 3.

¹⁵ Medicines Act 1981, s 94(1).

¹⁶ Medsafe “About Medsafe” (29 September 2015) <<http://www.medsafe.govt.nz/other/about.asp>>.

¹⁷ Medicines Act 1981, s 3A.

¹⁸ Medsafe “About Medsafe” (29 September 2015) <<http://www.medsafe.govt.nz/other/about.asp>>.

¹⁹ Medicines Act 1981, s 4.

- (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.

The only case applying these definitions is *New Health New Zealand v Attorney General* [2014] NZHC 2487. In that case, New Health New Zealand (NHNZ) argued that hydrofluorosilicic acid (HFA) and Sodium Silico Fluoride (SSF) are medicines under the Medicines Act for the purpose of community water fluoridation.

Justice Collins accepted that HFA and SSF were being added for a therapeutic purpose because these substances prevent, alleviate and treat tooth decay, which is considered a disease or ailment. Additionally, water fluoridation inhibits tooth decay through a physiological and pharmacological process.²⁰ The Attorney General sought to argue that HFA and SSF could not be “administered” to humans as they were lethal if undiluted, but Collins J said that “administer” includes a mode of administration where the substance had been dissolved or diluted. Diluting HFA and SSF in water clearly met this criterion.²¹

But NHNZ’s application was ultimately dismissed because fluorides were only considered medicines where the concentration was greater than 10 milligrams per litre. As the maximum level of fluoridation authorised was only 1.5 milligrams per litre, HFA and SSF were excluded from the scope of the Act in this case.²²

It is arguable that many NHPs should fit within the definition of “medicine”. Some, like fish oil and vitamins, are merely taken for maintenance of health, and thus fall outside the statutory definition. Yet there are many others that are taken for a “therapeutic purpose” and clearly have an effect through physiological or metabolic means. An example of this would be St John’s wort. While normally marketed for “mood support”,

²⁰ *New Health New Zealand v Attorney General* [2014] NZHC 2487 at [34-35].

²¹ *Ibid* at [37-38].

²² *Ibid* at [49].

it is commonly used in treating depression.²³ It contains hyperforin,²⁴ a substance that inhibits re-uptake of monoamines.^{25,26} This clearly qualifies as a physiological mechanism of action.

If so, St John's wort should be regulated as a medicine, but manufacturers have never been challenged for marketing it as a dietary supplement. Careful wording in labelling and advertisement may help to explain why it is considered to be a dietary supplement, but this state of affairs is questionable.

The Act also provides for a special category of medicines called "herbal remedies". This is defined as a medicine that does not contain a prescription, restricted or pharmacy-only medicine but consists of a substance derived from plant material in some way, and may be mixed with other inert substances.²⁷ Herbal remedies do not require Ministerial consent for distribution as long as certain statutory requirements are met, such as not being supplied with a recommendation for use for a therapeutic purpose.²⁸

Once again, a product like St John's wort should fall within the definition, but it is not marketed as an herbal remedy. Given that Ministerial approval is not needed, it is not entirely clear why this provision is not utilised more by manufacturers. Perhaps the regime set up by the Dietary Supplements Regulations 1985 has a more favourable regulatory tilt, as there are almost no restrictions on dietary supplements except for misleading labelling.

²³ K Linde and others "St John's wort for depression" (2005) 186(2) BJP 99.

²⁴ Joanne Barnes, Linda A Anderson and J David Phillipson "St John's wort (*Hypericum Perforatum*): a review of its chemistry, pharmacology and clinical properties" (2001) 53(5) JPP 583.

²⁵ A Singer, M Wonnemann and WE Müller "Hyperforin, a Major Antidepressant Constituent of St John's Wort, Inhibits Serotonin Uptake by Elevating Free Intracellular Na⁺" (1999) 290(3) JPET 1363.

²⁶ Monoamines are neurotransmitters which are commonly involved in the regulation of emotion and mood. If released by the neurons, they produce a physiological response which translates into a lift in mood. However, if reuptake of the monoamines by the neurons is too quick, the response could be muted or even absent altogether. Monoamine reuptake inhibitors slow uptake, thus amplifying the physiological response.

²⁷ Medicines Act 1981, s 2(1).

²⁸ Medicines Act 1981, s 28.

The Medicines Act establishes a number of controls over medicines. First of all, it institutes a general ban on the sale, distribution and advertising of new medicines without Ministerial approval.²⁹ The definition “new medicine” applies to a range of situations beyond where a new medicine has been developed. It also includes situations where the medicine in question has been unavailable for five years or more, even if it was previously approved.³⁰ But obtaining approval is a long and expensive procedure, with detailed information to be submitted for evaluation. Such information includes comprehensive clinical studies on their safety and efficacy.³¹ Other important features of the licensing regime include a scheme to authorise manufacture and sale of medicines,³² restrictions on advertising,³³ as well as post-market controls.³⁴

These legislative controls on medicines in themselves indicate that a strong emphasis on public health and safety. The restrictions on advertising suggest that there are other consumer protection goals as well, such as prevention of misleading claims. However, given the nature of medicines and their uses, clearly misleading claims could cause dangerous outcomes. This re-emphasizes safety as the fundamental purpose of the Act.

II The Food Act and Dietary Supplements Regulations 1985

Currently most NHPs are thought to be regulated under the Dietary Supplements Regulations 1985. These regulations were made pursuant to s 42 of the Food Act 1991, which has since been replaced by the Food Act 2014. However, the Dietary Supplements Regulations are to remain in force till 28 February 2019, and thus they remain a relevant part of the regulatory framework.³⁵

The Food Act 1981 clearly is consumer protection legislation.³⁶ Safety is one of its most important aspects, as is evident from its general scheme. For example, Part 2 of the 1981

²⁹ Medicines Act 1981, s 20.

³⁰ Medicines Act 1981, s 3(3).

³¹ Medicines Act 1981, s 21.

³² Medicines Act 1981, s 52.

³³ Medicines Act 1981, s 56-58.

³⁴ Medicines Act 1981, s 35-36.

³⁵ Food Act 2014, ss 413(3), 420(3).

³⁶ *Honey New Zealand (International) Ltd v Director-General of the Ministry of Primary Industries* [2015] NZHC 2764 at [24] and [27].

Act regulates the sale and advertisement of good. In particular, it prohibits the sale of food that is “unsound or unfit for human consumption or contaminated” or contains “any extraneous thing that is injurious to health or harmful”.³⁷ Part 2A grants the Minister of Primary Industries power to issue standards with regards to food. While the purpose of this section is to “provide greater flexibility in regulatory matters”, the Minister must still have due regard to certain matters.³⁸ One of these matters is “the need to protect public health”.³⁹ There is judicial authority (albeit limited) to allude to safety concerns underpinning the 1981 Act.⁴⁰

The Food Act 1981 has a stronger emphasis on economic concerns than the Medicines Act. For example, the Minister should consider the “desirability of avoiding unnecessary restrictions on trade” when setting food standards.⁴¹ This is understandable, given New Zealand’s economic dependence on agricultural industries.⁴²

The purpose of the Food Act 2014 is to:⁴³

- (a) Restate and reform the law relating to how persons trade in food; and
- (b) Achieve the safety and suitability of food for sale; and
- (c) Maintain confidence in New Zealand’s food safety regime; and
- (d) Provide for risk based measures that –
 - (i) Minimise and manage risks to public health; and
 - (ii) Protect and promote public health; and
- (e) Provide certainty for food businesses in relation to how the requirements of this Act will affect their activities; and
- (f) Require persons who trade in food to take responsibility for the safety and suitability of that food.

³⁷ Food Act 1981, s 9(4).

³⁸ Food Act 1981, s 11C.

³⁹ Food Act 1981, s 11B(a)(i).

⁴⁰ *Ministry of Primary Industries v Fonterra Ltd* [2014] DCR 279 at [15-16].

⁴¹ Food Act 1981, s 11B(a)(ii).

⁴² For example, New Zealand’s dairy export revenue for 2013-2014 reached \$NZS 18.1 billion: Ministry of Primary Industries *Situation and Outlook for Primary Industries 2015* (June 2015) at 6.

⁴³ Food Act 2014, s 4.

The purpose section speaks of providing certainty for businesses, but four out of six aims are related to safety in some way. This might suggest that despite the importance of food to New Zealand's economy, safety is the Act's predominant concern.

“Dietary supplement” is defined in the Regulations as:⁴⁴

- (1) In these regulations, dietary supplements means something to which subclauses (2) to (6) apply.
- (2) It is an amino acid, edible substance, herb, mineral, synthetic nutrient or vitamin.
- (3) It is sold by itself or in a mixture.
- (4) It is sold in a controlled dosage form as a liquid, powder or tablet (which might be described on the label as a cachet, capsule, lozenge or pastille...).
- (5) It is intended to be ingested orally.
- (6) It is intended to be supplemented the amount of amino acid, edible substance, herb, mineral, synthetic nutrient or vitamin normally derived from food.

Clearly, this definition would cover products such as vitamins and protein powders, but there is little judicial authority on how far the definition actually ends. Guidance is provided instead by guidelines and decisions of various regulatory authorities.

Medsafe has a flowchart on its website explaining how it categorises products.⁴⁵ If the product has a therapeutic purpose, it is no longer within the ambit of the Dietary Supplements Regulations and is instead regulated by the Medicines Act. If it has a psychoactive effect, it is characterised as a psychoactive substance regulated by the Psychoactive Substances Act 2013. If it has neither a therapeutic purpose or psychoactive effect, but is designed for oral administration in a “therapeutic type dose form”, then Medsafe considers it to be a dietary supplement. According to Medsafe, a “therapeutic type dose form” refers to a form such as tablets or controlled amounts of oral liquids as opposed to presentation as good, but with added substances.⁴⁶

There is a decision by the Psychoactive Substances Authority that provides some guidance on what is a dietary supplement. The case involved a pre-workout stimulant

⁴⁴ Dietary Supplements Regulations 1985, cl 2A.

⁴⁵ See Appendix I.

⁴⁶ Medsafe “Information for Industry: Categorisation of Products” (22 June 2015) <<http://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp>>.

called “Frenzy”, which contained 4-methyl-2-pentanamine citrate, otherwise known as DMBA. This substance is similar in structure to 1,3-dimethylamylamine (DMAA), which can cause increased energy, elevated mood and mental clarity.⁴⁷ It is a known active ingredient used in party pills, with reported cases of adverse reactions from consumption.⁴⁸ Based on the structural similarities to DMAA and preliminary animal studies, there was evidence to suggest that DMBA could have similar effects.⁴⁹

The manufacturer claimed that DMBA could be found in Pouchong tea, thus arguably the product was intended to supplement the amount of “edible substance” normally derived from food.⁵⁰ However, one study showed that Pouchong tea only contains DMBA in trace amounts (0.012 ppm),⁵¹ whereas another studied questioned if DMBA is present at all.⁵² In contrast, the powder contained 120 mg per serving, a quantity impossible to be derived normally from simply drinking the tea. The product could not be said to supplement the amount of DMBA normally ingested in food.⁵³

This decision suggests that substances that are normally found in negligible quantities in food cannot be regarded as dietary supplements. However, it remains unclear as to the level required before it can be considered to be “normally derived from food”.

There is likely to be some leeway in how “therapeutic purpose” is interpreted in regards to dietary supplements. In the Medicines Act, this includes “influencing, inhibiting or

⁴⁷ NZ Drug Foundation “DMAA: Health Effects” (9 October 2012) <<http://www.drugfoundation.org.nz/dmaa/health-effects>>.

⁴⁸ Paul Gee, Suzanne Jackson and Josie Eaton “Another bitter pill: a case of toxicity from DMAA party pills” (2010) 123 N Z Med J 124.

⁴⁹ EE Swanson and KK Chen “Comparison of pressor action of aliphatic amines” (1946) 88 J Pharmacol Exp Ther 10.

⁵⁰ Predator Nutrition “Driven Sports: Frenzy” <<http://www.predatornutrition.com/pre-workout/driven-sports/frenzy.html>>.

⁵¹ YS Chen and ASM Ou “Changes in volatile components of Pouchong teas during storage” (1998) 36 J Chin Agric Chem Soc 630 [in Chinese].

⁵² Pieter A Cohen, John C Travis and Bastiaan J Venhuis “A synthetic stimulant never tested in humans, 1,3-dimethylbutylamine (DMBA), is identified in multiple dietary supplements” (92015) 7 Drug Test Analysis 83.

⁵³ Psychoactive Substance Regulatory Authority “Products containing 1,3-dimethylbutylamine (DMBA)” (13 May 2015) Psychoactive Substances Regulatory Authority <<http://psychoactives.health.govt.nz/compliance>>.

modifying a physiological process”. Most products that are regarded as dietary supplements clearly affect physiological functions. For example, vitamin C, amongst other things, acts as an antioxidant and prevents build-up of free radicals.⁵⁴ Free radicals are a natural by-product of metabolic processes.⁵⁵ This means that it influences a physiological process, but it is clearly a dietary supplement.

No pre-approval process is needed for dietary supplements, unlike medicines. However, Medsafe says that there is an onus on the sponsor to ensure quality control of the product, its safety and compliance with the law.⁵⁶

There are some requirements imposed on dietary supplements, but these are relatively limited and generally relate to product labelling. For example, labels must contain recommended daily dosages and warnings of the dangers of overdose.⁵⁷ Misleading statements and therapeutic claims are both prohibited, although the Medicines Act allows therapeutic claims in limited circumstances.^{58,59} In addition to this, specific categories of dietary supplements may have specific restrictions. For example, minerals and vitamins may not contain more than a maximum dosage as stipulated in the Regulations.⁶⁰

Dietary supplements have even less regulation than herbal remedies. Herbal remedies may not require a license under the Medicines Act, but are still “subject to the other provisions of this Act and to any regulations made under this Act”.⁶¹ There are legal requirements for dietary supplements too, but the onus to comply rests on the supplier. This means that the attitude towards dietary supplements is considerably more

⁵⁴ Sebastian J Padayatty and others “Vitamin C as an Antioxidant: Evaluation of Its Role in Disease Prevention” (2003) 22(1) J Am Coll Nutr 18.

⁵⁵ Norman I Krinsky “Mechanism of Action of Biological Antioxidants” (1992) 200 Experimental Biology and Medicine 248.

⁵⁶ Medsafe “Regulation of Dietary Supplements” (5 April 2013) <<http://www.medsafe.govt.nz/regulatory/DietarySupplements/Regulation.asp>>

⁵⁷ Dietary Supplements Regulations 1985, cl 5.

⁵⁸ Dietary Supplements Regulations 1985, cl 10.

⁵⁹ Dietary Supplements Regulations 1985, cl 11.

⁶⁰ Dietary Supplements Regulations 1985, cl 3.

⁶¹ Medicines Act 1981, s 28.

permissive. It likely explains why most NHP suppliers prefer to market the products as “dietary supplements” rather than “herbal remedies”.

A product like St John’s wort is generally accepted as a dietary supplement. It is marketed as such, and carefully worded product descriptions ensure that no therapeutic claims are made. Medsafe seems to have accepted such wording and not challenged this. But as mentioned before, it is questionable whether this should be allowed.

Based on the decision concerning DMBA, it does not seem that St John’s wort fits within the definition of “dietary supplement”. It is arguably an edible substance, but it does not satisfy the requirement that it supplement the amount normally derived from food. St John’s wort has an extensive history of human consumption, but as a herb for treating various disorders.⁶²

A carefully worded product description seems to avoid any direct breach of the rules. But this seems to be a case of adhering to only the letter of the law. Given its history of use, it is clear that many consumers use St John’s wort for therapeutic purposes. For all intents and purposes, the general public treats it as a “medicine”, even if they do not think of it as one. Given that both the Medicines Act and Food Act aim to protect public safety, it is contrary to legislative policy to interpret these provisions so narrowly.

III Miscellaneous Provisions

There are some other regulatory schemes that are not directly related to regulation of NHPs, but remain relevant to the extent that their scope may overlap with either the Medicines Act or Dietary Supplements Regulations. Among them are the Misuse of Drugs Act 1975, the Psychoactive Substances Act 2013 and the Fair Trading Act 1986.

The Misuse of Drugs Act has a strong penal emphasis. It seeks to regulate substances that are classified as “controlled drugs”. This is defined as “any substance, preparation, mixture or article specified or described in Schedule 1, Schedule 2 nor Schedule 3; and

⁶² University of Maryland Medical Center “St John’s Wort” (26 June 2014) University of Maryland <<http://umm.edu/health/medical/altmed/herb/st-johns-wort>>.

includes any controlled drug analogue”. A “controlled drug analogue” is a substance with a structure that is “substantially similar to that of any controlled drug”.⁶³

Generally, the Misuse of Drugs Act does not regulate NHPs. However, it is conceivable that products which are marketed as NHPs could fall under its scheme if safety concerns prompt its addition to the controlled drugs list, or if it contains substances with structural similarities to existing controlled drugs. But give the perceived low risk that NHPs pose, this is unlikely to happen.

The Psychoactive Substances Act is another Act that could have relevance to the regulatory framework of health products. A “psychoactive substance” is one that is a “substance, mixture, preparation, article, device or thing that is capable of inducing a psychoactive effect (by any means) in an individual who [uses them]”.⁶⁴ “Psychoactive effect” is defined as the “effect of the substance on the individual’s mind”.⁶⁵ This would mean that a product like St John’s wort is prima facie a psychoactive substance because of its use in treating mild to moderate depression. However, the Act specifically excludes controlled drugs, medicines and dietary supplements from its ambit. Thus, St John’s wort is unlikely to actually be regulated by this Act. Nonetheless, the lack of judicial guidance on what actually constitutes a dietary supplement makes the boundaries between the legislation unclear.

The last Act to take note of is the Fair Trading Act (FTA). This statute does not specifically regulate NHPs, but as products on the market, they are subject to other forms of consumer protection legislation. For example, the FTA states that “no person shall, in trade, engage in conduct that is misleading or deceptive or is likely to mislead or deceive”.⁶⁶ More specifically, they are not to engage in conduct that is “liable to mislead the public as to the nature, manufacturing process, characteristics, suitability for a purpose, or quantity of goods”.⁶⁷ Thus, NHP suppliers may be liable under the FTA if they engage in misleading advertising or labelling of their products.

⁶³ Misuse of Drugs Act 1975, s 2(1).

⁶⁴ Psychoactive Substances Act 2013, s 9.

⁶⁵ Psychoactive Substances Act 2013, s 2.

⁶⁶ Fair Trading Act 1986, s 9.

⁶⁷ Fair Trading Act 1986, s 10.

The product descriptions that allow many NHPs to be classified as dietary supplements presumably prevent them from falling afoul of the FTA. While St John's wort has evidence to show that it is effective in treating mild to moderate depression, not all NHPs have been proven to be as efficacious. For example, milk thistle has been used to treat liver disease, but the data at present is inconclusive as to its efficacy. The inconclusive evidence might prevent a prevent a successful claim of misrepresentation (as it would be difficult to show that there is in fact no efficacy at all), but the product descriptions add another layer of protection.⁶⁸ The vague nature of the term "support" makes it likely that a claim will succeed.

IV Is the Status Quo Good Enough?

The status quo has significant issues. This dissertation has already raised the issue of manufacturers and suppliers taking advantage of legal loopholes (i.e. deliberately vague product descriptions) to avoid stricter regulation. As will be discussed in more detail later, NHPs may not be deserving of the perception that they are low risk. But if they are not as low risk as the public perceives, then it is a serious concern that manufacturers are able to utilise such loopholes.

The Ministry of Health raised a related point in its Regulatory Impact Statement (RIS) on the development of the NHSP Bill. They said that the Dietary Supplements Regulations were only meant to cover a relatively small range of products that were on the market at the time. These mainly consisted of vitamins and minerals, alongside a limited range of herbal substances. Ostensibly, the nature of the products and the small range of products meant that the risk was low enough to justify a relaxed regulatory scheme. That was more than 30 years ago, and the range of products has grown exponentially since then.⁶⁹

To rely on the term "edible substance" as a catch-all for products that are not amino acids, minerals, synthetic nutrients and vitamins is artificial at best. While it is true in a

⁶⁸ For example, Healtheries claims that their Liver Aid capsules, which contain milk thistle, "soothe[s] and supports your liver and digestion": "Healtheries Liver Aid capsules" (2016) Healtheries <<http://www.healtheries.co.nz/products/product-details/healtheries-liver-aid-capsules>>.

⁶⁹ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 4.

technical sense that most NHPs can be consumed orally, shoehorning them all into this category seems to stretch the natural meaning of “edible” too far. It is unlikely that a substance like St John’s wort can be considered to be edible in the same way as food.

The same RIS also raised a number of other issues with the status quo. Despite the legal loopholes, the RIS notes that many manufacturers have chosen to directly breach the regulations by promoting their treatments for disease rather than as mere supplements. The Ministry attributes this to increasing pressure to maintain a competitive edge as the number of manufacturers increase. The need to obtain approval under the Medicines Act is seen as too costly for what is ostensibly a low risk product, and the difficulty in patenting natural substances further exacerbates the problem. A long and expensive approval process is seen as out of proportion to potential rewards and suggested to have a chilling effect on the industry.

The Ministry of Health is aware of the compliance issues surrounding NHP legislation. In particular, the regulatory impact statement pointed out that inadequate or misleading information was a major problem. In their own study done in March 2007, it was found that 78 percent of companies reviewed made therapeutic claims in relation to their NHPs, a clear breach of both the Medicines Act and the Dietary Supplements Regulations.⁷⁰

It was also conceded in the RIS that enforcement has been limited. This was attributed to two main complicating factors. Firstly, as adverted to above, the interface between the Medicines Act and the Dietary Supplements Regulations is not clear. This means that even those responsible for enforcement are unsure about how to enforce the system except in the more serious circumstances, such as promoting a cure for cancer that is not an approved medicine.⁷¹

The other problem for enforcement is the resistance of suppliers and consumers of NHPs to attempts to increase awareness and enforcement. The suppliers resist because they would lose sales, while the consumers fear losing products that they consider

⁷⁰ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 6.

⁷¹ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 6.

(whether correctly or not) as important to maintenance of their health. In any case, as there is no register of dietary supplements or their suppliers, practical enforcement can be difficult.⁷²

Even if manufacturers were fully compliant with the Regulations, concerns still remain over legislative controls for quality and safety. What makes this even more concerning is the fact that dietary supplements are seen by the Ministry of Health as occupying a status between that of food and medicines.⁷³ However, in some respects dietary supplements are regulated at a lower level than foods. For example, the RIS noted that safety assessments are required for novel ingredients to be used in food, yet no assessment is required of ingredients used in dietary supplements. Also, in recent times there have been increasing reports of natural health products being adulterated with prescription medicines or other toxic substances (such as heavy metals). There is nothing to prevent this other than general safety standards under the Food Act.⁷⁴

One final concern is that consumers are unable to detect any safety or quality defects; nor do they have the knowledge and skills to properly evaluate claims made in respect of NHPs. In such a case, the Ministry of Health acknowledged that consumer protection legislation has little use as problems are seldom detected, let alone reported.⁷⁵

⁷² Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 4.

⁷³ *Ibid* at n 69.

⁷⁴ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 5.

⁷⁵ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 6.

Chapter 2: Foreign Jurisdictions

Other jurisdictions have already put legislation in place to regulate NHPs, and the Ministry of Health has acknowledged that New Zealand is out of step with them.⁷⁶ Some of these jurisdictions include Canada and Australia. Consideration of their legislative framework and case law may give valuable insight into the strengths and weaknesses of the New Zealand Bill. More importantly, it provides an external yardstick by which we can evaluate regulatory tilt.

I Canada

The Food and Drugs Act 1985 (FDA) has quite a wide ambit, as it regulates food, drugs, cosmetics and medical devices. Unlike New Zealand which has separate regulatory systems for medicines, food and natural health products, Canada regulates food and health products under a single piece of legislation. It even used to regulate controlled drugs, but these are now regulated under the Controlled Drugs and Substances Act 1996.

The FDA reads more like a single regime that recognises the different needs of different products. This is evident from common restrictions that apply to all categories of products regulated in the Act.⁷⁷ Also, while there are separate regimes for each category of product, each regime has certain identically worded provisions. For example, food cannot be advertised for sold in a misleading way,⁷⁸ and there is an identically worded provision in respect of drugs.⁷⁹ There are some advantages to such an approach, like a more coherent regulatory framework.

A Regulatory Purpose of the Canadian Legislation

The purpose of the FDA is not stated in the legislation itself, but the case law makes it clear that it is for consumer protection. Earlier versions of the Act were said to “protect the public from injury to its health due to the improper manufacture, advertisement or sale of foods, drugs, cosmetics and devices”.⁸⁰

⁷⁶ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 5.

⁷⁷ Food and Drugs Act RSC 1985 c F-27, s 3.

⁷⁸ Food and Drugs Act RSC 1985 c F-27, s 5(1).

⁷⁹ Food and Drugs Act RSC 1985 c F-27, s 6.

⁸⁰ *Re Levkoe v The Queen* 1977 18 OR (2d) 265.

This purpose remains the same in the current Act. For example, in *Canadian Pharmaceutical Technologies International Inc. v Canada (Attorney General)*, Kelen J states that the purpose of the Act is to “protect the health and safety of the Canadian public”.⁸¹ This position has been supported by other Canadian courts.⁸² The FDA also has “important trade and commerce aspects”, although these are “incidental” and public health and safety remains the “main thrust”.⁸³

In itself, the FDA does not regulate NHPs. It empowers the Governor-General in Council to make regulations for any product under its scope.⁸⁴ As such, the Natural Health Products Regulations 2004 (NHP Regulations) sets out the relevant rules for NHPs. Regulations must be interpreted consistently with primary legislation; thus the purpose of the NHP Regulations must also be regarded as public health and safety.

There is some judicial comment to demonstrate that safety is the primary concern of the Regulations, such as in *Swarath v AG of Canada*. In that case, the plaintiffs brought an action against Health Canada, claiming that it owed a duty of care to protect private economic interests of manufacturers and distributors of NHPs.⁸⁵ Pursuant to this, the plaintiffs claimed the Minister was obliged to issue a license upon application. If the plaintiffs’ argument was successful, it would be a strong indicator that economic concerns are the primary purpose of these Regulations. However, Moseley J rejected the plaintiffs’ argument, saying that to recognise a duty of care would conflict with the purpose of the Regulations, which was to “protect the health of Canadians”.⁸⁶

These comments lend support to the notion that legislation concerning health products should primarily be judged on its ability to protect public health and safety. There is some scope for assessing such legislation on its commercial effects (as these are

⁸¹ *Canadian Pharmaceutical Technologies International (C.P.T.) Inc. v Canada (Attorney General)* 2006 FC 708 at [15].

⁸² *R v Wookey* 2006 ONCA 611 at [45].

⁸³ *Saputo Inc. v Canada (Attorney General)* 2011 FCA 69 at [72].

⁸⁴ Food and Drugs Act RSC 1985 c F-27, s 6.

⁸⁵ Health Canada is a federal government agency under the Canadian Minister of Health, and is broadly analogous to the Ministry of Health in New Zealand.

⁸⁶ *Swarath v AG of Canada* 2014 FC 75 at [28].

undoubtedly important too), but as the case law suggests, economic interests should be secondary to safety concerns.

B The Canadian Regulatory Scheme

The NHP Regulations apply to the sale, manufacture and distribution (amongst other things) of NHPs. A “natural health product” is defined as:⁸⁷

- A substance set out in Schedule 1 or a combination of substances in which all the medical ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in
- (a) The diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
 - (b) Restoring or correcting organic function in humans; or
 - (c) Modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health...

This definition is very similar to the definition of drug in the FDA:⁸⁸

- ...a substance or mixture of substances manufactured, sold or represented for use in
- (a) The diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
 - (b) Restoring, correcting or modifying organic functions in human beings or animals, or...

In fact, this definition has much in common with the New Zealand definition of medicine. The wording is not the same, but the uses listed broadly correspond to those described as a “therapeutic purpose” in the Medicines Act. For example, the provision speaks of preventing, treating and diagnosing diseases. It also refers to modification of organic functions in humans, which should have a similar scope to “influencing, inhibiting or modifying a physiological process”.⁸⁹

The definition of NHPs in the Regulations recognises the way the average consumer is likely to use NHPs. It suggests that the Canadian Parliament has effectively classified NHPs as therapeutic substances, albeit of a kind warranting less rigorous evaluation. Even if manufacturers do not claim a therapeutic function, it would be naïve to think

⁸⁷ Natural Health Products Regulations SOR/2003-196, s 1(1).

⁸⁸ Food and Drugs Act RSC 1985 c F-27, s 2.

⁸⁹ Medicines Act 1981, s 4.

that consumers would not use it therapeutically. This definition also recognises the fact that some NHPs are likely to have a pharmacological impact.

Under the NHP Regulations, a person is generally prohibited from dealing in NHPs. They must obtain a license to do so, and even then they may only deal with the particular NHP for which the license grants permission.⁹⁰ This means that NHPs in Canada are subject to a pre-approval scheme, which indicates that the regulatory tilt tends towards prohibition. As already demonstrated in *Swarath*, the process can be relatively stringent, but a pre-approval scheme is more consistent with a stricter attitude.

Applications for approval are made to the Minister of Health.⁹¹ They are assisted in this process by Health Canada through the Natural and Non-Prescription Health Products Directorate (the “Directorate”).^{92,93} The Directorate whose role is to assess NHPs, ensure proper manufacturing standards and engage in post-market monitoring.⁹⁴

Section 5 of the Regulations stipulates the information that must be submitted as part of a license application. Most relevantly, it stipulates that an applicant must submit information that “supports the safety and efficacy of the natural health product”.⁹⁵ Section 7, on the other hand, says that a license must be issued if all of the listed criteria are fulfilled. Among them is included the need to submit an application in accordance with s 5 of the Regulations,⁹⁶ and issuance of the license must not be likely to result in injury to the health of a consumer.⁹⁷ Beyond this, the Regulations do not explicitly provide any further guidance on how safety and efficacy is assessed.

⁹⁰ Natural Health Products Regulations SOR/2003-196, s 4.

⁹¹ Natural Health Products Regulations SOR/2003-196, s 5.

⁹² Health Canada “Drugs and Health Products: Natural and Non-prescription Health Products” (27 September 2016) <<http://www.hc-sc.gc/cadhp-mps/prodnatur/new-neuf-eng.php>>.

⁹³ The Directorate was initially named the Natural Health Products Directorate, but the name has since been changed to Natural Health and Non-prescription Health Products Directorate to accommodate its expanded regulatory mandate to oversee non-prescription and disinfectant drugs. This is further proof that Canada sees NHPs as a subset of drugs with a risk level equal to that of non-prescription drugs, rather than a separate product category.

⁹⁴ Health Canada “Drugs and Health Products: Natural and Non-prescription Health Products” (27 September 2016) <<http://www.hc-sc.gc/cadhp-mps/prodnatur/new-neuf-eng.php>>.

⁹⁵ Natural Health Products Regulations SOR/2003-196, s 5(g).

⁹⁶ Natural Health Products Regulations SOR/2003-196, s 7(a).

⁹⁷ Natural Health Products Regulations SOR/2003-196, s 7(d).

In *Winning Combination Inc. v Canada (Minister of Health)*, the Federal Court of Canada acknowledged that the Regulations do not set a standard for efficacy and there was no legal jurisprudence on point either.⁹⁸ However, Russell J accepted the appellant’s argument that s 7(d) of the Regulations sets out a substantive test for safety, although he did not engage in further discussion on this point.⁹⁹ With regards to efficacy, he also seemed to accept the appellant’s argument that s 5(g) does not set out a substantive test because s 7 already does.¹⁰⁰ Nonetheless, even from an administrative point of view, the information provided as part of the application must “support” efficacy.

Justice Russell stated that “information” meant “meaningful and acceptable documentation”, which suggests some degree of validity is required.¹⁰¹ In this case, phase I and II clinical trials were submitted, although it was argued by the appellants that this went beyond what was required for such a test. However, this information only had to “support” some degree of efficacy, which is significantly lower than what is required for therapeutic drugs, where the evidence must “satisfy” the Minister of the drug’s efficacy.¹⁰²

Other than saying the evidence submitted satisfied the threshold for “support”, Russell J did not make any further comments on what constitutes “support”. He did concede that even allowing for s 5(g) to be read as a merely administrative provision, it still left open the question of what discretion the Directorate had to assess whether the information is adequate to support efficacy.¹⁰³ But the comments are obiter, as the case was ultimately decided on the basis of procedural fairness.

⁹⁸ *Winning Combination Inc. v Canada (Minister of Health)* 2016 FC 381 at [137].

⁹⁹ Natural Health Products Regulations SOR/2003-196, s 7(d) states that the Minister shall issue a product license if: “the issuance or amendment of the license...is not likely to result in injury to the health of a purchaser or consumer”.

¹⁰⁰ Natural Health Products Regulations SOR/2003-196, s 5(g) states that an application must contain: “information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use”.

¹⁰¹ *Winning Combination Inc. v Canada (Minister of Health)* 2016 GC 381 at [140].

¹⁰² *Nu-Pharm Inc. v Canada (Attorney General)* [1997] FCJ 624.

¹⁰³ *Winning Combination Inc. v Canada (Minister of Health)* 2016 GC 381 at [139].

Other earlier case law seems to demonstrate that the judgment of the Directorate is given a significant amount of deference by the courts, subject to the principles of judicial review. In *North American Nutraceutical Inc. v AG of Canada*, O’Keefe J said that the appropriate standard for review of decisions on questions of fact and the exercise of discretion by Health Canada under the Food and Drugs Regulations was reasonableness.¹⁰⁴ Like the NHP Regulations, they were also enacted pursuant to s 30 of the FDA. Both sets of Regulations set out a mandate for regulators to assess safety and efficacy of proposed new products. O’Keefe J said the same standard should apply to the NHP Regulations, commenting: “decisions on questions of fact and the exercise of discretion are thus entitled to similar levels of deference”.¹⁰⁵ The Court would not intervene unless the Directorate’s (on behalf of Health Canada) decision was “not transparent, justifiable and intelligible and within the range of acceptable outcomes based on the evidence”.¹⁰⁶

The Directorate rejected the application in this case because the evidence did not assuage concerns over product safety. In particular, there was evidence to suggest that the product (a type of avian sternal cartilage) could exacerbate disease activity in rheumatoid patients.¹⁰⁷ The applicant did supply studies to prove otherwise, but the Directorate was reluctant to rely on them as it was not clear if the types of collagen studied were comparable to the applicant’s product. Some of the studies used different dosages and their collagen was manufactured differently. In other cases, the collagen used was of a completely different kind.¹⁰⁸ Other studies had insufficient detail, as they were only provided as abstracts.¹⁰⁹ Justice O’Keefe conclude that based on the evidence before the Directorate, the finding that safety concerns remained as a reasonable one.¹¹⁰

Although the standard for safety is lower than that of therapeutic drugs (and in the case of efficacy, ostensibly even lower than that), the cases demonstrate that the process is a technical one, involving detailed scientific analysis. While the law is not necessarily to

¹⁰⁴ *North American Nutraceutical Inc. v AG of Canada* 2012 FC 1044 at [78].

¹⁰⁵ *North American Nutraceutical Inc. v AG of Canada* 2012 FC 1044 at [78].

¹⁰⁶ *Ibid* at [79].

¹⁰⁷ *Ibid* at [18].

¹⁰⁸ *Ibid* at [28].

¹⁰⁹ *Ibid* at [29].

¹¹⁰ *Ibid* at [104].

pander to the scientific process, where health products are involved it is prudent to give greater technical knowledge its due.

Health Canada guidelines provide greater detail of this process. In general, a NHP is classified according to its risk profile. Depending on the level of risk that a product poses (high, medium or low), it may be subject to different evidential requirements.

For example, a high risk product would be one where usage presents a “serious health risk” to the consumer. This may be because of their narrow safety margins or their use in treating debilitating and potentially life threatening diseases.¹¹¹ Such diseases include conditions like cancer, asthma, or even “acute anxiety states”. If a product is considered high risk, a high level of evidence is required to support safety and efficacy of the specific product. Acceptable forms of evidence include Directorate-published monographs, meta-analyses and results from phase II/IV clinical trials of the product.

On the other hand, a low risk product has a wide safety margin, as it is used to treat minor conditions which naturally resolve or to maintain health.¹¹² Examples of such a product include vitamins and minerals. In such a case, pilot studies and reputable textbooks may be adequate as evidence. Demonstration of use of the product as food is also deemed acceptable evidence for safety.¹¹³ That said, it is uncontroversial that many low risk products are safe.

Traditional use claims are allowed in respect of any product.¹¹⁴ These are claims to prevent or treat conditions based on the knowledge, skill and practices derived from theories, beliefs and experiences “indigenous” to a specific culture. If all of the medicinal ingredients that constitute a product come from a single recognised traditional

¹¹¹ Health Canada *Pathway for Licensing Natural Health Products Making Modern Health Claims* (December 2012) at 9.

¹¹² Health Canada *Pathway for Licensing Natural Health Products Making Modern Health Claims* (December 2012) at 9.

¹¹³ *Ibid* at 8.

¹¹⁴ *Ibid* at 19.

system (e.g. traditional Chinese medicine or Ayurvedic medicine), it may be classified as a traditional medicine.¹¹⁵

The use of traditional evidence is relatively circumscribed. For example, traditional use claims are not permitted in respect of serious diseases and condition. Also, such claims are not allowed if the condition is not one that can be diagnosed within a particular traditional system. Perhaps most importantly, the Canadian guidelines do not give traditional evidence precedence over scientific evidence. If the scientific evidence suggests that there is a risk, then traditional evidence cannot be used to answer those concerns.¹¹⁶ This precedence only applies to safety and not efficacy, which is consistent with *Winning Combination Inc.* Disappointingly, homeopathic remedies are allowed to use homeopathic references as evidence to support safety and efficacy.¹¹⁷ As will be discussed later, the underlying philosophy of homeopathy is dubious, and using such references to support claims undermines a regime's credibility.

St John's wort fits within the ambit of the NHP Regulations. It is a plant, as listed in Schedule 1 of the Regulations. St John's wort is used to treat depression (which is recognised as disease). Alternatively, it has an effect on organic function. A monograph in the Natural Health Products Ingredients Database confirms this.¹¹⁸

It is not as clear as to which risk level St John's wort belongs to. Ostensibly, this will depend on the claim that is made for St John's wort. If it is claimed to treat depression, then at the very least it will be a medium risk product. A medium risk product is one that is for treating conditions that are "not resolved in a timely manner".¹¹⁹ Arguably, depression falls into this category. In any case, the numerous clinical studies referenced in the monograph provide ample support for St John's wort's safety and efficacy.

¹¹⁵ Health Canada *Pathway for Licensing Natural Health Products Used as Traditional Medicines* (December 2012) at 3.

¹¹⁶ *Ibid* at 7.

¹¹⁷ Natural and Non-prescription Health Products Directorate *Evidence for Homeopathic Medicines* (Health Canada, July 2015).

¹¹⁸ Health Canada *Monograph: St John's Wort – Oral* (12 November 2009) Natural Health Products Ingredients Database < <http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/monoReq.do?id=163&lang=eng> >.

¹¹⁹ Health Canada *Pathway for Licensing Natural Health Products Making Modern Health Claims* (December 2012) at 9.

The Canadian regulatory system has many features that serve to improve outcomes for consumers. First of all, they have instituted a pre-approval scheme, which provides a degree of reassurance that products will be fit for use. Secondly, the evaluation process involves scientific analysis, more akin to the process required for medicines.

The Canadian system is not perfect. Relegating s 5(g) of the NHP Regulations to a mere administrative provision detracts from the regime's credibility, as does allowing homeopathic references as evidence. Nonetheless, it provides a good example to which we can compare the NHSP Bill.

II Australia

Australia has separate legislation for food and medicines, unlike Canada. Each state has its own food legislation, but “therapeutic goods” are regulated at the federal level by the Therapeutic Goods Act 1989 (Cth) (TGA). Therapeutic goods cover a wide range of products, including drugs, medical devices and NHPs. There is considerable scope under the TGA for various state legislatures to institute complementary legislation.¹²⁰ Because of the close ties the two countries share, Australia is particularly important for comparison purposes.

A The Regulatory Purpose of Australian Legislation

According to the TGA, its object is to “provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods”, whether for use in or export from Australia.¹²¹ It also provides a framework for the various States and Territories to facilitate controls of poisons.¹²² From the wording, it is implicit that the TGA is consumer protection legislation.

The Australian Courts have done little analysis on the purpose of the TGA, with most cases simply citing s 4.¹²³ Perhaps this indicates that the TGA is so obviously consumer

¹²⁰ See for example the Medicines, Poisons and Therapeutic Goods Act 2008 (ACT) and the Medicines and Poisons Act 2014 (WA).

¹²¹ Therapeutic Goods Act 1989 (Cth), s 4(1)(a).

¹²² Therapeutic Goods Act 1989 (Cth), s 4(1)(b).

¹²³ See for example *Roche Products Pty Ltd v National Drugs and Poisons Schedule Committee* [2007] FCA 1352 at [7], *McGrath; in the matter of Pan Pharmaceuticals Ltd (in liq) v Australian Naturalcare*

protection legislation that there is little need for significant discussion. For example, Stone J in *Secretary, Department of Health and Ageing v Prime Nature Prize Pty Ltd (in liq)* said the TGA's objects made it "evident" that it was an "important public health and safety measure."¹²⁴

Hui v Lane is one of the few cases to discuss the TGA's underlying policy. In that case, Gray J took note of a speech made during the TGA's second reading. The speech recognised that many therapeutic goods were entering the marketplace without scrutiny. This posed an unacceptable risk to the public, especially in light of the potentially serious consequences that could be caused by a defective product. This risk was exacerbated by globalisation, large scale production and distribution of therapeutic goods.¹²⁵

In addition to public health and safety, Gray J noted that the TGA was intended to assist the Australian therapeutic goods industry and both a domestic and international level.¹²⁶ Unfortunately, the judge did not engage in further discussion on this point, but the comment hints at the fact that economic interests remain a significant aspect of health product legislation.

In an article by Michael Weir, he points out that s 4 of the TGA indicates there are three main policy objectives: (1) ensuring appropriate market access of therapeutic goods, (2) consumer protection from potential risk, and (3) providing adequate information as to the nature and efficacy of such goods. He claims that the TGA regime is to balance these policy objectives, which would suggest that no one policy has primacy over the others.¹²⁷

Products Pty Ltd [2008] FCAFC 2 at [8]; and *Secretary, Department of Health and Ageing v Pagasa Australia Pty Ltd* [2008] FCA 1545 at [5].

¹²⁴ *Secretary, Department of Health and Ageing v Prime Nature Prize Pty Ltd (in liq)* [2010] FCA 597 at [22].

¹²⁵ *Hui v Lane* No. SCCIV-02-1437 [2003] SASC 401 at [34].

¹²⁶ *Ibid* at [33].

¹²⁷ Michael Weir "Therapeutic Goods Act and the Regulation of Complementary Medicine" in *Alternative Medicine: A Regulatory Model* (Australian Scholarly Publishing, Melbourne, 2005) 231-259 at 233.

Weir points out that the standard of regulation for “complementary medicines” (the Australian legislative term that covers NHPs) continues to attract debate. On the one hand, he notes that some suggest that pharmaceutical levels of evidence are required. But others argue that the risk complementary medicines pose to consumers are lower than that of food. Statistics on adverse events for complementary medicines would support such an assessment.¹²⁸ However, for reasons that will be discussed in Chapter 3, such a view should be regarded as overly optimistic.

Weir also says that regulation of complementary medicines raises cultural issues, which is little discussed in case law. He observes that using complementary medicines is an aspect of cultural identity, and so a regulatory system should be slow to restrict access just because a substance has failed to meet scientific standards of evidence. Different health traditions are based on different philosophies, which means that denying a product’s validity based on scientific evidence is to “deny a person’s ability to choose how they are healed”.¹²⁹

Both of these factors (perceived low risk and cultural sensitivity) have some validity, and they militate against enacting a stricter regulatory regime. Nonetheless, similar to Canada, the TGA regime seems to consider that public health and safety is its dominant concern, and that while access to products should not be unnecessarily limited, restrictions should be proportionate to the risk. For example, in *Hui v Lane*, Gray J described quality, safety, efficacy and timely availability” as the “core purpose” of the TGA.¹³⁰ This suggests that despite the other policy aims of preserving the economic interest in NHPs, it should not come at the expense of the public interest.

B The Australian Regulatory Scheme

“Therapeutic goods” are defined in the TGA as goods:¹³¹

- (a) That are represented in anyway to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - (i) For therapeutic purposes; or

¹²⁸ Ibid at 235.

¹²⁹ Ibid at 242.

¹³⁰ *Hui v Lane* No. SCCIV-02-1437 [2003] SASC 401 at [35].

¹³¹ Therapeutic Goods Act 1989 (Cth), s 2.

- (ii) For use as an ingredient or component in the manufacture of therapeutic goods; or
- (iii) For use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- (b) Included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(i) or (ii)...

However, certain foods may be excluded from the scope of the definition pursuant to an order made under s 7 of the TGA.¹³²

The definition of “therapeutic goods” hinges upon the term “therapeutic use”, similar to how “therapeutic purpose” is the key term for defining medicines in the New Zealand Medicines Act. “Therapeutic purpose” means:¹³³

Use in or connection with:

- (a) Preventing, diagnosing, curing or alleviating a disease, ailment, defects or injury in persons; or
- (b) Influencing, inhibiting, or modifying a physiological process in persons; or
- (c) Testing the susceptibility of persons to a disease or ailment; or
- (d) Influencing, controlling or preventing conception in persons; or
- (e) Testing for pregnancy in persons; or
- (f) The replacement or modification of parts of the anatomy in persons.

As one judge puts it: “the Act regulates the use of substances which are claimed to have some effect on the human body”.¹³⁴

The definition of “therapeutic use” is very similar to the definition of “therapeutic purpose”. Both refer to the prevention, diagnosis and curing of diseases and injuries. They are both identical in referring to “influencing, inhibiting or modifying a physiological process”, and the Medicines Act also includes testing for pregnancy or replacement and modification of human anatomy as “therapeutic use”.

“Complementary medicines” are defined in the Therapeutic Goods Regulations as a therapeutic good which consists entirely or principally of one or more designated active

¹³² Therapeutic Goods Act 1989 (Cth), s 2.

¹³³ Ibid at n 130.

¹³⁴ *Secretary, Department of Health and Ageing v Export Corporation (Australia) Pty Ltd* [2012] FCA 42 at [5].

ingredients, each of which has a clearly established identity and a traditional use.¹³⁵ Conceptually, this has some similarity to the “herbal remedies” provision in the Medicines Act, although it has wider scope. Designated active ingredients are those listed in Schedule 14 of the Regulations, and includes substances such as vitamins, amino acids, plant/herbal materials and non-human materials.¹³⁶

The term “complementary medicine” itself indicates that NHPs are regarded in Australia as a form of medicine. This suggests that the Australian system grants more certainty, a desirable characteristic for legislation. Currently, the New Zealand status quo does not grant this certainty, as multiple regulatory systems could legitimately apply to NHPs. By contrast, it seems very clear that the majority of NHPs will be considered complementary medicines under the TGA. This can also be easily confirmed by doing a search on the Australian Register of Therapeutic Goods (ARTG). For example, St John’s wort is listed on the ARTG.¹³⁷

Australia uses a two-tiered system in regulating therapeutic goods, which also applies to complementary medicines.¹³⁸ Depending on their risk level, therapeutic goods will either need to be registered or listed on the ARTG. Generally, higher risk complementary medicines will need to be registered. An example of this is high dosage calcium supplements. It is a mineral (a substance under Schedule 14 of the Regulations) and they have been linked to serious adverse events.¹³⁹

A product will need to be registered if it does not satisfy the criteria for being a “listable good”.¹⁴⁰ If it needs to be registered, as part of the application process the product will need to be evaluated as to its quality, safety and efficacy.¹⁴¹ The Minister must also be

¹³⁵ Therapeutic Goods Regulations 1990, reg 2.

¹³⁶ Therapeutic Goods Regulations 1990, Schedule 14.

¹³⁷ See for example, the entry on Extra Strength St John’s wort, ARTG ID 95359.

¹³⁸ Therapeutic Goods Administration *Australian regulatory guidelines for complementary medicines (ARGCM)* (July 2015) at 14.

¹³⁹ Mark Bolland and others “Calcium supplements with or without vitamin D and risk of cardiovascular events: reanalysis of the Women’s Health Initiative limited access dataset and meta-analysis” (2011) *BMJ* 342.

¹⁴⁰ *Secretary, Department of Health and Ageing v Export Corporation (Australia) Pty Ltd* [2012] FCA 42 at [8].

¹⁴¹ Therapeutic Goods Act 1989 (Cth), s 25(1)(d).

satisfied that it complies with any other relevant product standards and the presentation of the good is acceptable.¹⁴²

The evaluation of a registered medicine was discussed in *Sylvan Health Pty Ltd v Minister for Health and Ageing*. In that case, Sylvan Health's product, Cholesen (which was accepted to be a complementary medicine) was denied registration for failure to establish safety. Cholesen capsules contained extracts of Red Yeast Rice (RYR), which is rice fermented with red yeast (*Monascus purpureus*).¹⁴³ However, RYR also contains Monacolin K, which is chemically identical to Lovastatin, a prescription drug.¹⁴⁴

The Minister raised a number of safety concerns. Firstly, Monacolin K had been recorded to cause adverse reactions in people. Secondly, the Minister also noted a lack of data as to its long term safety, particularly in terms of pharmacological reactions with other drugs. While RYR has been used traditionally for a long time, Cholesen used RYR in a way that increased the risk to safety. The Minister also pointed out the lack of studies on possible synergistic effects between the components (Monacolin K was not the only active component).¹⁴⁵ This shows the use of scientific analysis to evaluate the evidence. On appeal the Administrative Appeals Tribunal reiterated these concerns, even after hearing expert evidence and reviewing the scientific studies.¹⁴⁶

The FCA pointed out that the evaluation process was subject to the standard grounds of judicial review, such as procedural fairness and mistake of fact.¹⁴⁷ However, similar to *North American Nutraceutical*, the FCA found that the Tribunal was entitled to make such a finding based on the medical evidence before it.¹⁴⁸ This suggests that like Canada, there is a robust process for evaluating the safety and efficacy of NHPs, albeit subject to judicial review.

¹⁴² Therapeutic Goods Act 1989 (Cth), s 25(1).

¹⁴³ *Sylvan Health Pty Ltd v Minister of Health and Ageing* [2010] FCAFC 121 at [10].

¹⁴⁴ Lovastatin belongs to a family of drugs known as statins, which are prescription drugs used in lowering cholesterol levels. They are generally safe for use, but have been linked to certain adverse side effects, such as myopathy (muscle wastage), which has led to their inclusion on the Poisons Standard.

¹⁴⁵ *Sylvan Health Pty Ltd v Minister of Health and Ageing* [2010] FCAFC 121 at [17].

¹⁴⁶ *Ibid* at [23].

¹⁴⁷ *Ibid* at [25].

¹⁴⁸ *Ibid* at [45-46].

On the other hand, lower risk complementary medicines tend to be classified as “listable goods”. This is defined in the TGA as therapeutic goods that are required to be listed under regulations, or pursuant to a notice made under s 9A(5).¹⁴⁹ Most relevantly, Schedule 4 of the Therapeutic Goods Regulations 1990 says that a listed food must only contain low risk ingredients permitted for use in listed medicines, and only carry indications permitted for use for listed medicines. Schedule 4 also says that the product must not be required to be sterile.

The TGA does not require pre-market evaluation of listed medicines, although the sponsor still has to certify that the medicine satisfies the relevant legislative requirements.¹⁵⁰ This includes certifying the product’s safety and quality, although not efficacy. The Therapeutic Goods Administration could require that the sponsor provides extra information, but Weir notes that this is seldom done. Despite not undergoing pre-market evaluation, some listed goods may be selected to undergo post-market review.

For listed foods, Perram J in *Secretary, Department of Health and Ageing v Export Corporation* said that the Secretary is only concerned to ensure that these matters have been certified and has no interest in whether the certification is correct.¹⁵¹ This is consistent with a simplified process that does not require evaluation. However, that does not mean that there are no safeguards in place.

The TGA imposes significant sanctions (both criminal and civil) for any contraventions. For example, a person in relation to whom goods are registered or listed must give information that indicates quality, safety or efficacy of the goods is unacceptable as soon as they become aware of it.¹⁵² If not, that person could be liable to twelve month’s imprisonment or 1000 penalty units, or both.¹⁵³ One penalty unit is AUD\$110, thus the maximum penalty is AUD\$110,000, a significant sum.¹⁵⁴ A civil penalty for the same contravention can range up to 3000 penalty units for an individual and 30,000 units for

¹⁴⁹ Therapeutic Goods Act 1989 (Cth), s 2.

¹⁵⁰ Therapeutic Goods Act 1989 (Cth), s 26A.

¹⁵¹ *Secretary, Department of Health and Ageing v Export Corporation* [2012] FCA 42 at [7].

¹⁵² Therapeutic Goods Act 1989 (Cth), s 29A(2).

¹⁵³ Therapeutic Goods Act 1989 (Cth), s 9A(1).

¹⁵⁴ Crimes Act 1914 (Cth), s 4AA.

a body corporate. Generally, a proactive strategy is preferable to a reactive one, but heavy penalties could create sufficient deterrent to make this less of a concern.

The fact that listed foods can make claims generally only relating to self-limiting conditions (such as colds and sore throats) justifies a simple process for listed foods. Furthermore, listed goods can only be made from ingredients on the permitted list. This list contains ingredients that have been evaluated for their suitability for use in listed medicines. According to the Australian Regulatory Guidelines for Complementary Medicines (ARGCM), the primary reason for the evaluation is to ensure the ingredient is of an acceptable quality and safety.¹⁵⁵ Efficacy is not a main consideration, but the Therapeutic Goods Administration says in the ARGCM that often this will be considered indirectly. A product's safety will need to be considered in relation to therapeutic effect. For example, is the product safe at a particular dose or duration of exposure in order to achieve an alleged therapeutic effect?¹⁵⁶

Overall, the Australian regulatory scheme for NHPs is quite stringent. In part, this is likely to be due to the classification of NHPs as “complementary medicines”, rather than a separate category of product. Natural health products in Australia may be subject to the same evaluative process as prescriptive medicines, and as demonstrated by *Sylvan Health*, this can be very rigorous. Even for listed goods, there are safeguards in place despite the simplified process.

There are several features about the Australian system that warrant consideration when enacting a New Zealand model. Firstly, the TGA's two-tiered system grants a fair bit of flexibility. Natural health products vary in nature and use, and it may be that simply lumping them together as a single category is an oversimplification of the issue. For example, fish oil is usually taken for the maintenance of health. Furthermore, their consumption poses fairly low risk to the consumer. In contrast, high dosage calcium tablets are used in treatment of osteoporosis and have been known to cause

¹⁵⁵ Therapeutic Goods Administration *Australian regulatory guidelines for complementary medicines (ARGCM)* (July 2015) at 55.

¹⁵⁶ Therapeutic Goods Administration *Australian regulatory guidelines for complementary medicines (ARGCM)* (July 2015) at 59.

cardiovascular events.¹⁵⁷ Their pharmacological properties (if such a thing can be said for fish oil) are different. Applying the two-tiered system would recognise that even within the category of NHPs, there are varying levels of risk.

This flexibility should save time and cost in getting low risk products onto the market, which would prevent any chilling effect regulation might have on the NHP industry. However, this flexibility does not come at the expense of safety, as the safeguards even within the listed goods regime gives considerable reassurance that the public interest is protected.

In terms of statutory definitions, New Zealand and Australia have close similarities. Perhaps it could be argued that the Canadian regime is sufficiently different that comparisons with the proposed New Zealand scheme are not appropriate. But in terms of an external “statutory” yardstick, the fact that Australia has chosen to effectively classify NHPs as medicines is a significant reason for New Zealand to regard NHPs similarly.

It may be in New Zealand’s interest to have a system similar to Australia. On one hand, it is clear that there are strong ties between both countries, especially economically. Food standards have already been standardised, and in fact there were discussion of setting up a joint standard for therapeutic goods, although the idea ultimately was not carried out.

¹⁵⁷ See above at n 136. Cardiovascular events are incidents that may cause cardiac muscle damage, such as a myocardial infarct, colloquially known as a heart attack.

Chapter 3: The Natural Health and Supplementary Products Bill

The NHSP Bill was introduced in the House of Representatives on 7th September 2011, and passed its second reading on 20th March 2013. One might wonder why the Bill has not been passed by this point, but a Supplementary Order Paper (SOP) released on 15th March 2016 indicates it remains in plans to be enacted.

The SOP makes some significant changes to the wording and layout of the Bill, but retains the overall scheme. As the SOP version is the version most likely to be enacted, it will be the focus of this dissertation. The NHSP Bill is different to the Canadian and Australian legislation in several ways. It puts less emphasis on protection of public health and safety. The definition of natural health product is markedly different, and the Bill sets up a notification scheme, which is less strict than the pre-approval scheme of Australia and Canada.

I The Regulatory Principles

The NHSP Bill changes a number of things about the current status quo. In particular, it indicates a change in attitude towards NHPs. Clause 3 says the Bill's purpose is to set up a new regime for NHPs and supplements, but cl 4 is more illuminating:

This Act is based on the following principles:

- (a) That natural health products should be fit for human consumption or use;
- (b) That the regulation of natural health products should be proportionate to the risks associated with their use;
- (c) That natural health products should be accompanied by information that –
 - (i) Is accurate; and
 - (ii) Tells consumers about any risks, side-effects or benefits of using the product;
- (d) That health benefit claims made for natural health products should be supported by scientific or traditional evidence.

These principles demonstrate an effort to remedy the issues raised in the RIS. Clearly, the emphasis has shifted to safety and risk. For example, cl 4 uses language such as “fit for human consumption or use”, which highlights safety as a major concern. On the other hand, the RIS stressed the need to create a regulatory system that is in proportion

to the level of risk NHPs pose. In light of New Zealand's political tradition, this is a desirable attitude to take, but it does raise the question: how risky are NHPs?

When first introduced to Parliament, cl 4(a) said that NHPs "must" be fit for human consumption or use. But after review by the Health Committee, this was amended to "should" be fit for human consumption or use, indicating a more relaxed stance. Taken to its logical conclusion, the wording also suggests that in certain circumstances, NHPs do not need to be fit for human consumption and use. This has also been the case for clauses 4(b) and (c).

Unfortunately, the Health Committee Report for the NHSP Bill did not provide any reasons for this change. Some degree of flexibility is required regardless of regulatory system to account for changes over time and unforeseen circumstances. But it is likely that this particular change was driven by economic concerns. The RIS pointed out that an overly stringent process (like that of the Medicines Act) is a barrier to suppliers.

In a broadly similar situation, a Health Committee Report in 2011 made several recommendations regarding clinical trials.¹⁵⁸ These recommendations were meant to streamline the process and make New Zealand more attractive for conducting such trials. The report noted criticism that the New Zealand system discouraged private funding for clinical trials. It justified its recommendations on the basis of "spill-over" benefits for patient care and professional development. However, a more cynical view would note that economic benefits were also a major justification.¹⁵⁹ While it is not possible to conclusively say that similar thinking led to a change of wording in the NHSP Bill, it seems more than likely.

Understandably, New Zealand may lose out if an overly strict approach to regulation of NHPs is adopted. As a country, we have much to offer by way of NHPs. For example,

¹⁵⁸ Health Committee *Inquiry into improving New Zealand's environment to support innovation through clinical trials* (June 2011).

¹⁵⁹ *Ibid* at 11.

Manuka honey has long been known to have antibacterial properties.¹⁶⁰ There has been recent evidence to show that in a medical preparation, it is an effective wound dressing.¹⁶¹ It would be undesirable for New Zealand to lose out on economic opportunities simply because of excessive red tape.

It might be possible that the more relaxed wording was a concession to proponents of NHPs. Some of these lobby groups have made strong criticisms of the Bill. For example, Health Freedom NZ said that if the Bill is passed, consumers stand to lose access to “life-saving” NHPs.^{162,163} The New Zealand Health Trust also strongly opposed to the Bill, saying that it is “draconian and heavy-handed ‘Nanny state’ regulation” with no evidence to back it up.¹⁶⁴

But the relaxed standard sits uncomfortably with the emphasis on safety and risk. The Food Act 2014 says its purpose is to “achieve the safety and suitability of food for sale” and to “require persons who trade in food to take responsibility for the safety and suitability of that food”.¹⁶⁵ The language is directive, and taking its natural meaning would suggest that maintenance of food standards is not optional.

As noted earlier in Chapter 1, the Ministry of Health RIS regarded “dietary supplements” as occupying a risk level between food and medical products. It even acknowledged that the current regulation did not fit the level of perceived risk. Although the NHSP Bill clearly attempts to improve safety, being more permissive than the Food

¹⁶⁰ E Mavric and others “Identification and quantification of methylglyoxal as the dominant antibacterial constituent of Manuka (*Leptospermum scoparium*) honeys from New Zealand” (2008) 52(4) *Mol Nutr Food Res* 483.

¹⁶¹ Bhavin G Visavadia, Jan Honeysett and Martin H Danford “Manuka honey dressing: an effective treatment for chronic wound infections” 46(1) *Br J Oral Maxillofac Surg* 55.

¹⁶² Health Freedom New Zealand Trust “Effects and Implications for Consumers of the Natural Health & Supplementary Products Bill” (4 February 2016) <http://www.healthfreedom.co.nz/component/acymailing/archive/view/listid-1-mailing_list/mailid-21-effects-and-implications-for-consumers-of-the-natural-health-a-supplementary-products-bill.html>.

¹⁶³ If these NHPs are really life-saving, then surely they should come under the scope of the Medicines Act because they have a therapeutic purpose. Also, if these products are as efficacious as their proponents say, what is the harm in holding them to the same standard as conventional pharmaceuticals?

¹⁶⁴ New Zealand Health Trust “Submission from the New Zealand Health Trust on the Regulation of Natural Health Products” at 1.

¹⁶⁵ Food Act 2014, ss 4(b) and 4(f).

Act seems to be inconsistent with the view expressed in the RIS. Judged against the Medicine and Food Acts, the NHSP Bill falls short of what is required.

The NHSP Bill's regulatory principles do not measure up to the external yardstick of foreign legislation either. Both Canada and Australia have made public health and safety of paramount importance. This is evident from comments in the case law, but also from the way NHPs are regulated in these jurisdictions. The legislative definitions clearly show that both jurisdictions regard NHPs as a category of medicine. That alone indicates that Canada and Australia view NHPs as being of a higher risk level than food. NHPs are also subject to more onerous statutory requirements than food. The fact that other jurisdictions have chosen to adopt a relatively stringent attitude towards NHPs should encourage reconsideration of the NHSP Bill in its current form.

It is controversial whether NHPs are actually low risk enough to justify light touch regulation. Admittedly, it is difficult to assess the true risk that NHPs pose because of a general lack of evidence. However, there is sufficient reason to be concerned. One systematic review conceded that most research was of poor quality, but still concluded that it was likely that contamination of NHPs occurred with "some regularity". Contaminants included prescription drugs such as diazepam and prednisolone,¹⁶⁶ but also heavy metals such as arsenic and mercury.^{167,168}

Herbal remedies are often pharmacologically active substances and can interact with other drugs. This is an area that has been better studied, although the varying nature of different NHPs makes it difficult to make general statements. But as an example, St John's wort has been shown to increase the activity of cytochrome P450. Cytochrome

¹⁶⁶ Diazepam is better known by its trade name "Valium". It belongs to the family of drugs known as benzodiazepines, and is used to treat conditions like anxiety disorders. Side effects include blurred vision and problems with muscle control. Prednisolone is an anti-inflammatory steroid used in treating conditions such as arthritis and asthma. Side effects include nausea, vomiting and bone fractures.

¹⁶⁷ Paul Posadzki, Leala Watson, Edzard Ernst "Contamination and adulteration of herbal medicinal products (HMPs): an overview of systematic reviews" (2013) 69 *Eur J Clin Pharmacol* 295 at 307.

¹⁶⁸ Arsenic has been known to cause cancer and skin lesions, and in serious cases acute arsenic poisoning will lead to death. On the other hand, mercury can have harmful effects on the nervous, digestive and immune systems. See World Health Organisation "Arsenic" (June 201) < <http://www.who.int/mediacentre/factsheets/fs372/en/>>; World Health Organisation "Mercury and Health" (January 2016) < <http://www.who.int/mediacentre/factsheets/fs361/en/>>.

P450 is a liver enzyme responsible for drug metabolism, and it acts on at least 50% of all marketed medications. This means decreased clinical effectiveness for many commonly used medicines, including anticoagulants and oral contraceptives.¹⁶⁹

Many herbal remedies contain pharmacological compounds. This makes it hard to understand why their “natural” form should allow them to be regulated differently from “conventional” pharmaceuticals. They may be even more deserving of regulation because NHPs lack the controlled dosages of drugs. Perhaps a distinction could be drawn where the NHP is merely for the maintenance of health, such as with fish oil. But it must be recognised that many of them are touted (at least unofficially) as providing an alternative cure, which warrants greater caution. These concerns were raised in submissions by the Royal New Zealand College of General Practitioners (RNZCGP).¹⁷⁰

These issues are exacerbated by poor medical understanding amongst lay persons. The findings between studies differ, but the common consensus is that the average patient rarely, if ever reports NHP use to their physician. One study also found that 56.2% of respondents believe that NHPs do not cause side effects merely because they are natural, and noted that such a view was “potentially dangerous”.¹⁷¹

The stance of foreign legislations also suggest that NHPs may not be low risk. Neither Canada nor Australia has chosen to enact a completely separate regime for NHPs but have chosen to classify them as a special category of medicine. Presumably this is because they have concluded that the risk is not as low as it is for food.

Conceptually, it seems strange to create a double standard between medicines and NHPs. Many pharmaceuticals were initially derived from “natural” sources. An

¹⁶⁹ John Markowitz and others “Effect of St John’s wort on Drug Metabolism by Induction of Cytochrome P450 3A4 Enzyme” (2003) 290(11) JAMA 1500.

¹⁷⁰ Royal New Zealand College of General Practitioners “Submission to MOH on the regulation of Natural Health Products” at 2 and 3.

¹⁷¹ Shmuel Giveon and others “Are people who use ‘natural drugs’ aware of their potentially harmful side effects and reporting to family physicians?” (2004) 53 PEC (Patient Education and Counselling) 5.

example of this is aspirin (acetylsalicylic acid), a synthetic form of salicylic acid.¹⁷² It is as effective as its natural version and in fact causes less irritation of the human digestive system.¹⁷³ Even now an estimated 11% of the 252 drugs that the World Health Organisation (WHO) considers basic and essential were derived from flowering plants.¹⁷⁴

It is difficult to say with any certainty whether NHPs justify light touch regulation in light of their perceived low risk. However, there are enough signs to suggest that at least some kinds of NHPs are not as low risk as one might think. It would be prudent for more research to be undertaken so that legislation can be drafted more appropriately.

II The Definition of “Natural Health Product”

The definition of “natural health product” is the important to the NHSP Bill, as it acts as the gateway provision.¹⁷⁵

- (1) Natural Health Product means, any product that –
 - (a) Is, or is represented as having been, manufactured –
 - (i) For human use; and
 - (ii) For the primary purpose of bringing about a health benefit to the person who uses the product; and
 - (b) Contains, or is represented as containing, only natural substances, and –
 - (c) Is not a food, or is not presented as, a food; and
 - (d) Is not, or does not contain –
 - (i) A medicine listed in Schedule 1 of the Medicines Regulations 1984; or
 - (ii) A psychoactive substance with the meaning of s 9 of the Psychoactive Substances Act 2013.
- (2) ...
- (3) In subsection (1), food means anything that is ordinarily used or represented for use as food or drink for human beings.

¹⁷² Salicylic acid is found naturally in willow bark, and has been used across many cultures as pain relief. For example, the Greek physician Hippocrates recommended it for easing pain in child-bearing and reducing fever.

¹⁷³ I Raskin “Role of Salicylic Acid in Plants” (2002) 43 Annu Rev Plan Physiol Plant Mol Biol 439 at 440.

¹⁷⁴ Ciddi Veeresham “Natural products derived from plants as a source of drugs” (2012) 3(4) J Adv Pharm Technol Res 200.

¹⁷⁵ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 6.

“Natural substances” is defined as “any substance or class of substance listed in Schedule 1”.¹⁷⁶ Schedule 1 has a wide ambit, containing a general description of “a plant or plant material, an alga, a fungus, a mineral, or a non-human animal material”. It also lists vitamins, amino acids and synthetic versions of the other substances listed in Schedule 1.¹⁷⁷

The definition of “health benefit” includes any one of the following:¹⁷⁸

- (a) The maintenance or promotion of health or wellness:
- (b) Nutritional support:
- (c) Vitamin or mineral supplementation:
- (d) Affecting or maintaining the structure or function of the body:
- (e) The relief of symptoms.

The wording is different to the Canadian and Australian definitions, but the definition should still cover a wide range of products, including dietary supplements, herbal remedies and as the Health Committee indicated, homeopathic remedies.¹⁷⁹ These substances are also covered by Canadian and Australian legislation. The real concern is that the definition of “natural health product” and “health benefit” indicates an overly relaxed attitude towards NHPs, and does not fully recognise the way they are actually used by consumers. For example, “health benefit” does not refer to treating or curing disease, but only “relief of symptoms”.

The other problem with the definition is more evident when the previous definition of “natural health product” is considered. In the official report of the Bill, it is defined as:¹⁸⁰

- (1) Natural health and supplementary product means...any product that –
 - (a) Is or appears to be manufactured –
 - (i) For human use; and
 - (ii) For the primary purpose of bringing about a health benefit to the person who uses the product; and
 - (b) Contains only permitted ingredients unless –

¹⁷⁶ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 5.

¹⁷⁷ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), Schedule 1.

¹⁷⁸ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 5.

¹⁷⁹ Health Committee *Natural Health Products Bill* (31 October 2012) at 8.

¹⁸⁰ Natural Health Products Bill 2011 (324-2), cl 6.

- (i) Section 22(2)(b)(i) applies; or
- (ii) The product is a dietary supplement; and
- (c) Is not, or is not presented as, a food.

The definition is similar, except for the wording of cl 6(1)(b). It is supposed to fulfil the same function as the term “natural substances”, but the wording indicates a shift in thinking. The original wording suggests that NHPs were regarded to be conceptually different from dietary supplements. The RNZCGP suggests that a distinction should be drawn between those that treat conditions (like St John’s wort) and those that promote health (like fish oil).¹⁸¹ This distinction recognises that even among NHPs there are varying levels of risk. If the Health Committee was concerned to create a regime to save time and expense, then recognising this distinction would have been desirable.

The Health Committee acknowledged the difficulty of differentiating between NHPs, food and medicines, but they were wary of making the Bill too prescriptive. For example, products such as herbal teas are commonly consumed and only make lower claims of “clarity” or as a “pick-me-up”. The Committee thought that to classify such a product as a NHP would be to subject the product to over-regulation. It suggested that such products be referred to the Food Act, which explains the explicit exclusion of food and medicines from the scope of the Bill.¹⁸²

Herbal teas should be fairly excused from the scope of the NHSP Bill because of their low risk. But the definition may not remove the existing legal loopholes. The Health Committee said that honey may be classified as a NHP, food or medicine “depending upon the claims that were made for the particular product”.¹⁸³ This suggests that manufacturers may still be able to choose their preferred regulatory system if they word their claims carefully. For example, the meaning “maintenance and promotion of health and wellness” is vague. A manufacturer could avoid the more rigorous process under the Medicines Act if they framed any therapeutic claims as merely promoting health.

¹⁸¹ Royal New Zealand College of General Practitioners “Submission to MOH on the regulation of Natural Health Products” at 3.

¹⁸² Health Committee *Natural Health Products Bill* (31 October 2012) at 4.

¹⁸³ *Ibid* at n 179.

III The Regulatory Regime

Natural health products are subject to two main regulatory mechanisms under the proposed scheme. The first is a system of product notification, while the other sets out a licensing regime for manufacturers. These will be administered by the Natural Health Products Regulatory Authority (the “Authority”), as established by the Bill. The Authority is the Director-General of Health, and its office is administered by the Ministry of Health.¹⁸⁴ The Authority is granted a number of powers to ensure the smooth running of the regime, including the discretion to issue licenses, audit products and order product recalls. It is also to be aided by the Natural Health Products Advisory Committee, which is to “provide expert advice to the Authority on matters referred to it by the Authority”.¹⁸⁵

The NHSP Bill has improved on the status quo by setting out new offences and penalties. The Dietary Supplements Regulations only imposed a fine of \$500 for breaches, with an extra \$50 per day for a continuing breach.¹⁸⁶ The RIS noted that this provided little deterrence, especially if the seller was a multinational corporation.¹⁸⁷

The Bill proposes much more stringent penalties for breaches, which should improve standards overall. For example, if a person is found to be selling a NHP without a product notification, then they may be subject to a fine of up to \$50,000 for an individual or \$250,000 for a body corporate.¹⁸⁸ These are significant sums of money, even for a large company. In the case of endangerment of human health, the monetary penalties are even higher, and an individual convicted of this could even be imprisoned.¹⁸⁹

¹⁸⁴ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 50.

¹⁸⁵ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 52.

¹⁸⁶ Dietary Supplements Regulations 1985, cl 21.

¹⁸⁷ Ministry of Health *Regulatory Impact Statement: The Development of Natural Health Products Bill* (June 2011) at 6.

¹⁸⁸ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 42.

¹⁸⁹ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 45.

A Product Notification

Perhaps the most important feature of the Bill is product notification, described as the “fundamental regulatory rule” of the scheme.¹⁹⁰ The prospective seller or exporter cannot sell or export NHPs unless they have a valid notification.¹⁹¹

To be eligible for notification, a NHP can only contain “permitted substances”.¹⁹² At this point, it is not clear what will be included as a permitted substance. The Authority is granted the discretion to declare any natural substance to be permitted. In deciding whether to declare a substance to be permitted, the Authority must consider a number of factors: (1) whether a recognised authority permits the use of the substance in a similar product and if it imposes any restrictions on the use of the substance,¹⁹³ (2) whether the substance is recognised in traditional medicine or pharmacopoeias, and (3) any other matter the Authority considers relevant in the circumstances.¹⁹⁴

The Authority may choose to conduct a safety assessment of the proposed permitted substance, but it is not mandatory.¹⁹⁵ If the Authority does not raise any concerns or commence a safety assessment within 90 days of an application, the substance is considered to be permitted.¹⁹⁶

A valid notification requires that a product notifier provide details of the product “in the manner specified by the Authority”.^{197,198} This information includes details such as product name, identity of the product notifier and any health benefit claims made. Any

¹⁹⁰ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2) (explanatory note) at 4.

¹⁹¹ Supplementary Order Paper (158) Natural Health and Supplementary Products Bill (324-2), cl 21(1)(b).

¹⁹² Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 24.

¹⁹³ A recognised authority is one that the Natural Health Products Authority recognises as doing similar work such as evaluating natural health products and ensuring compliance with standards: Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2). The Natural and Non-prescription Health Products Directorate and the Therapeutic Goods Administration are like to be considered “recognised authorities”.

¹⁹⁴ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 36(3)(b).

¹⁹⁵ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 37(4).

¹⁹⁶ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 37(5).

¹⁹⁷ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 25(3)(b).

¹⁹⁸ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 55. Obviously, the Authority has not prescribed the manner in which a notification is to be made yet.

health benefit claims made must be substantiated by making a summary of the evidence on an Internet site.¹⁹⁹ The Authority can evaluate the evidence and request that more evidence be provided, but this is a matter of the Authority's discretion.²⁰⁰

1 The Problem with a Notification Scheme

During the second reading of the Bill; the Honourable Simon Bridges was at pains to point out that the Bill did not institute a pre-approval process. He noted that other jurisdictions chose to institute pre-approval schemes, but in New Zealand this was rejected because of the time and expense that this would incur.²⁰¹

A notification scheme is better than no scheme at all, but notification is still a less strict approach to regulation. It is less like a process of product evaluation, and more like an administrative formality. This would be appropriate if the objects of regulation were low risk. But saving time and expense are not acceptable justifications where there is a real chance that health and safety may be affected. It remains unclear if NHPs as a whole are low risk, but as discussed earlier, there is sufficient evidence to raise concerns.

The nature of a pre-approval scheme indicates a stricter attitude towards regulations. Both Canada and Australia chose to use pre-approval schemes. Immediately, this raises questions about New Zealand's choice to employ a notification scheme. These foreign jurisdictions evidently think that NHPs are enough of a safety concern that it warrants a more stringent regulatory regime.

It might be argued that Canada and Australia are different countries with differing cultural and social contexts. In particular, the attitude of the Canadian public is likely to be influenced to some degree by the United States. They are also more involved on the global stage than New Zealand, which could increase the risk level.²⁰²

But these arguments do not completely obviate the relevance of Canada and Australia as external yardsticks. Our political traditions are similar. Significantly more research

¹⁹⁹ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 25(3)(b)(i).

²⁰⁰ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 25(5).

²⁰¹ (20 March 2013) 688 NZPD 8810.

²⁰² For example, Gray J in *Hui v Lane* noted that globalisation likely exacerbates the risk posed by therapeutic goods.

and discussion on NHP use has been conducted overseas.²⁰³ On the other hand, the New Zealand Ministry of Health RIS acknowledged that information on the NHP market in New Zealand was scant.²⁰⁴ Also, the Ministry of Health simply accepted that NHPs were low risk without any consideration of empirical data, seemingly basing their view on the attitude of consumers.²⁰⁵ Without proper research to distinguish the New Zealand context from foreign jurisdictions, these concerns cannot be dismissed so easily.

A notification scheme allows manufacturers and suppliers a considerable amount of leeway. NHPs are effectively presumed fit for consumption as long as there is a valid notification. Actual evaluation of the evidence is not required to complete product notification and the onus is put on the Authority to raise any issues. This was a source of concern for the Pharmaceutical Society of New Zealand. They considered that if the Authority does not raise an issue (for example, because of an oversight) then products could be released onto the market without adequate proof for their claims.²⁰⁶

There are some exceptions to the requirement of notification. Products that are made by a practitioner for the personal use of a patient do not need to be notified.²⁰⁷ The Medicines Act has a similar provision in which medicines may be made by a natural therapist for the personal use of a patient if it does not contain prescription, restricted or pharmacy-only medicines.²⁰⁸ Presumably, this concession was made because a practitioner is likely to be subject to professional standards anyway.²⁰⁹ The Authority

²⁰³ See for example: Timothy Caulfield and Colin Feasby “Potions, Promises and Paradoxes: Complementary Medicine and Alternative Medicine and Malpractice Law in Canada” (2001) 9 Health LJ 183; T Bubela and others “Media Portrayal of Herbal Remedies Versus Pharmaceutical Clinical Trials: Impacts on Decision-Making” (2007) 26 Med Law 363; Elizabeth Robertson “In the Public Interest” (2008) 33 LawNow 21.

²⁰⁴ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 2.

²⁰⁵ Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011) at 23.

²⁰⁶ Pharmaceutical Society of New Zealand Incorporated “RE: The Regulation of Natural Health Products Consultation Document” at 2-3.

²⁰⁷ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 22(a)(i).

²⁰⁸ Medicines Act 1981, s 32.

²⁰⁹ For example, a natural health practitioner is subject to the professional standards of Natural Health Practitioners New Zealand: Natural Health Practitioners New Zealand “Membership Requirements” (2016) < <http://nhpnz.org/membership-requirements/> >.

may also exempt substances from notification, although it must be satisfied that the product presents no public risk to health.²¹⁰ Both of these exceptions are consistent with the policy goal of safety.

The decision to exempt products where the active ingredient is of a concentration less than 20 parts per million is more controversial.²¹¹ This will include homeopathic remedies.²¹² The Health Committee had serious concerns about this, but said that homeopathic remedies were so dilute that it would be impractical to audit the product itself, and they would be subject to manufacturing requirements anyway.²¹³ Unapproved health benefit claims are still prohibited even if no notification is required, and the Health Committee suggested that no health benefit claims should be made in respect to homeopathic remedies because of the lack of scientific evidence as to their efficacy.²¹⁴

In this respect, the NHSP Bill is consistent with the Canadian and Australian positions. They see homeopathic remedies as being sufficiently low risk due to the extremely low concentrations of active ingredient. Most homeopathic remedies are exempt from their pre-approval processes, although homeopathic remedies that are required to be listed under the TGA (for example, if it is part of a preparation that is required to be sterile) must satisfy the requirements for listed medicines.

Some commentators have raised concerns. In her article, Kate Tokeley says that the Health Committee's reasons for exempting homeopathic remedies are an "unconvincing argument" and that it "makes no sense". She says that it may be difficult for homeopathic suppliers to comply with the requirements (because of the lack of

²¹⁰ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 22(b).

²¹¹ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 22(c).

²¹² Homeopathy is a health philosophy based on the theory that "like cures like". So to cure a headache, one must take a headache-inducing substance. But to prevent the harmful side-effects of the substance, it is repeatedly diluted and shaken to concentrations where the original substance is practically undetectable. Homeopaths claim that the higher the dilution, the stronger the effect of the solution. This has led many to regard homeopathy as nothing more than pseudoscience. See Kate Tokeley "Homeopathy, the Truth and the Placebo Effect" (2014) 26 NZULR 422 at 423-425 for a more detailed explanation of homeopathy.

²¹³ Health Committee Natural Health Products Bill (31 October 2012) at 8.

²¹⁴ *Ibid* at n 199.

evidence of efficacy), but it is not impractical for these requirements to be made in the first place.²¹⁵

2 Traditional Evidence

A significant change to the status quo is that claims made in respect of NHPs must be substantiated by evidence. This evidence could be either scientific or traditional. Whereas scientific evidence is derived from empirical studies and repeatable experiments, traditional evidence is evidence of use of a substance based on knowledge, beliefs or practices passed down from generation to generation.²¹⁶ In itself, requiring manufacturers and suppliers to substantiate health claims is an improvement on the status quo. But is it desirable to allow the use of traditional evidence to support claims?

Traditional evidence may be used in two ways. Firstly, health benefit claims can only be made in respect of named conditions if it is an “allowable claim”.²¹⁷ A named condition is effectively any health condition recognised by the WHO, which includes conditions like heart disease and asthma.²¹⁸ The Authority may determine if health benefit claims are allowable in respect of an NHP.²¹⁹ In doing so, the Authority must consider regulatory principles and be satisfied that the risk level posed by the product is low. They must also consider the nature and quality of evidence in support of such a health benefit claim, which can include traditional evidence.²²⁰ In fact, cl 27(3) anticipates that traditional evidence will be used by explicitly stating that references to information in approved pharmacopoeia is to be regarded as evidence, and that no consideration of quality is needed.

Health benefit claims in respect of unnamed conditions must also be substantiated.²²¹ Unnamed conditions, as Tokeley suggest, are conditions in the nature of sweaty feet, grief and fatigue, which are unpleasant, but generally not considered to be a disease as

²¹⁵ Kate Tokeley “Homeopathy, the Truth and the Placebo Effect” (2014) 26 NZULR 422 at 434.

²¹⁶ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 5.

²¹⁷ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 26.

²¹⁸ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 6A.

²¹⁹ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 27(1).

²²⁰ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 27(2).

²²¹ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 25(3).

such.²²² Similarly to “allowable claims”, scientific or traditional evidence may be provided in support of claims to alleviate these conditions.²²³

Some have expressed concern over allowing traditional evidence to be used to support health benefit claims. Even Dr Paul Hutchison, who chaired the Health Committee that reviewed the NHSP Bill, remarked during the second reading that using traditional evidence to support claims was “quite a leap for [him] personally”.²²⁴

As the RNZCGP puts it, the worry is that traditional evidence will become a legal loophole for ineffective products to make therapeutic claims.²²⁵ It conceded that therapy involves more than clinical effectiveness as health also involved intangible aspects such as spiritual and cultural dimensions.²²⁶ In more recent times, there has been recognition that psychosocial factors could hinder recovery.²²⁷ Traditional evidence could have use in explaining the intangible aspects of health.

But the RNZCGP points out that evidence of use is not evidence of efficacy.²²⁸ Tokeley shares similar sentiments when she says that traditional evidence is merely evidence of use, and not of efficacy.²²⁹ The most obvious example of this is homeopathy. Homeopathy has been used since the 18th century for a variety of conditions, but conclusive scientific evidence shows that homeopathy does not work.²³⁰

²²² Kate Tokeley ““Homeopathy, the Truth and the Placebo Effect” (2014) 26 NZULR 422 at 435.

²²³ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 25(2).

²²⁴ (20 March 2013) 688 NZPD 8811.

²²⁵ Royal New Zealand College of General Practitioners “Submission to MOH on the regulation of Natural Health Products” at 2 and 5.

²²⁶ Royal New Zealand College of General Practitioners “Submission to MOH on the regulation of Natural Health Products” at 5.

²²⁷ Accident Compensation Corporation *New Zealand Acute Low Back Pain Guide: Incorporating the Guide to Assessing Psychosocial Yellow Flags in Acute Low Back Pain* (October 2004).

²²⁸ Royal New Zealand College of General Practitioners “Submission to MOH on the regulation of Natural Health Products” at 5.

²²⁹ Kate Tokeley “Homeopathy, the Truth and the Placebo Effect” (2014) 26 NZULR 422 at 433.

²³⁰ Aijing Shang and others “Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy” (2005) 366(9487) *Lancet* 726; E Ernst “A systematic review of systematic reviews of homeopathy” (2002) 54(6) *BJCP* 577.

The Health Committee itself was concerned that ineffective claims could delay treatment, thus presenting safety risks. The concern was sufficiently strong that it led them to amend the definition of “health benefit” to “relief of symptoms”, rather than “relief of symptoms of any condition that is not a serious condition”. This ensured that all claims, no matter how minor, would need to be substantiated. But this safety precaution is meaningless if traditional evidence continues to be allowed.

In fact, evidence of use may not even demonstrate safety of the product itself. For example, the ARGCM gives the example of black cohosh herbal extracts.²³¹ No reports of adverse reactions have been reported for traditional formulations before which may suggest they are safe.²³² But there is scientific evidence to show that modern, highly concentrated black cohosh extracts have been linked to serious adverse reactions. The link between use and safety and efficacy is at best, tenuous.

Worryingly, the New Zealand draft guidelines say that scientific evidence does not take precedence over traditional evidence. If traditional and scientific evidence conflict, they should both be stated on product labelling and the summary of evidence.²³³ This was unacceptable to the RNZCGP, particularly where safety is involved. To allow a health benefit claim to be made when scientific evidence has clearly established the harmfulness of a NHP would severely undermine the policy goal of improving safety.

The Bill requires the Authority to be satisfied that the risk will be low when determining an allowable claim. However, given the permissiveness of the regulatory principles and the allowance of traditional evidence, it is not clear how effective this requirement will be.

Australia and Canada do not impose any requirements that evidence on efficacy be scientific. Perhaps this decision was made because preventing consumers from taking ineffective substances would be a disproportionate infringement on individual autonomy and personal beliefs.

²³¹ Black cohosh (*Actaea racemosa*) is a North American plant traditionally used by Native Americans as an analgesic and anti-inflammatory.

²³² As discussed earlier, patients seldom report adverse reactions caused by NHPs to their doctor. Thus, the true incidence of serious adverse reactions could in fact be much higher.

²³³ Ministry of Health *Draft Guidelines for Natural Health Products Evidence Requirements* (Nov 2015).

However, as countries that share similar liberal traditions as New Zealand, it is important to note that their more stringent stance on safety. Canada does not allow traditional evidence to be used in disproving safety concerns raised by scientific studies. The Australian guidelines say that “data must be of sufficient standard to enable full scientific assessment”. While history of use is accepted evidence, presumably this means that it can be overridden by scientific evidence. Clearly, the safety concerns were sufficient to justify limiting traditional evidence in this way.

B Manufacture

The manufacturer licensing scheme is outside the main scope of this dissertation, but a quick overview is relevant to the discussion of the scheme.

Under the Bill, a NHP can only be manufactured by a person who holds a license for that NHP.²³⁴ A license may only be granted if the manufacturing facilities meet the requirements of a code of practice,²³⁵ and the applicant is a “fit and proper person”.²³⁶ In deciding whether the person is fit and proper, the Authority must consider: (1) any conviction of the person for offences related to manufacture of products for human consumption, (2) whether there has been a serious or repeated failure to comply with the Act, (3) whether there are grounds for considering that the person will be non-compliant with the Act, and (4) any other relevant matters.²³⁷ If licensed, a manufacturer must continue to comply with the code.

The Authority will have powers of enforcement to allow them to police the scheme. It has the discretion to audit manufacturers.²³⁸ Pursuant to this, the Authority may authorise a person to enter manufacturing facilities to assess their compliance. The authorised person may inspect relevant documents and take samples for further evaluation.²³⁹ Based on the results of the audit, the Authority may issue a notice for the

²³⁴ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 13.

²³⁵ Clause 53 stipulates the Authority must establish a code of practice for the manufacture of NHPs. At this point, it is not known what the code will be like. However, the Authority is required to consider the regulatory principles, and comply with any prescribed requirements as to content.

²³⁶ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 14(2).

²³⁷ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 14(3).

²³⁸ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 16.

²³⁹ Supplementary Order Paper 2016 (158) Natural Health and Supplementary Products Bill (324-2), cl 17.

manufacturer to refrain or do something that may affect compliance with the code. Alternatively, the Authority can suspend or revoke a license for failure to comply.

The application process is unusual in relation to foreign jurisdictions, as neither Australia nor Canada requires a manufacturer to be “fit and proper”.²⁴⁰ However, the Medicines Act also uses the terminology of “fit and proper” in deciding whether to grant a manufacturing license.²⁴¹ By elevating licensing requirements to a level similar to that of medicines, it suggests that Parliament is taking safety concerns over manufacturing practices seriously. It is also consistent with the government’s view that NHPs occupy a risk level higher than that of food. In this respect, the NHSP Bill seems to be achieving an adequate level of regulation for NHPs.

²⁴⁰ Therapeutic Goods Act 1989 (Cth), s 38; Natural Health Products Regulations SOR/2003-196, s 28.

²⁴¹ Medicines Act 1981, s 51.

Conclusion

The NHSP Bill represents a step in the right direction for New Zealand. Despite the benefits NHPs can provide to consumers, they should not remain (relatively) unregulated. Regulation may be a limitation on individual autonomy, but even the libertarians recognise the validity of the harm principle. There is enough evidence to show that regardless of how low risk NHPs are perceived, they can still pose significant safety risks if used or manufactured improperly.

New Zealand's current regulatory framework is not equipped to deal with NHPs adequately. The expansion of the NHP industry has led to regulatory disconnect. Standards for NHPs are not proportionate to their perceived risk level. Manufacturers and suppliers can choose their regulatory regime by using legal loopholes. This problem is exacerbated by limited enforcement, which in turn is compounded by the resistance of suppliers and consumer to regulation.

The statutory definition of NHP in Canada and Australia bears substantial similarities to their definitions of medicine. Australia in particular regulates NHPs under the same regime as medicines. The regulatory mechanism of choice is a pre-approval scheme, with scientific analysis playing a key role. All these factors indicate that these jurisdictions view NHPs as a product category with a significant level of risk and deserving of a more stringent regulatory regime.

The fact that a Bill has been put before the New Zealand Parliament shows that the risks to safety and health are now taken seriously. The new definition of natural health product also provides some certainty. On the other hand, there are issues with the Bill. The regulatory principles are overly permissive compared to other legislation. Foreign legislation makes clear that safety is the main aim, and even the Food Act's purposes are worded in stronger language, and food is supposed to be of a lower risk than NHPs.

Canada and Australia have pre-approval schemes, which suggests that NHPs are of a significant risk level. This raises questions as to why New Zealand has deliberately chosen to institute a notification scheme. Such a scheme grants manufacturers and suppliers considerable leeway, as assessment of the product is not a mandatory part of

the notification process. This means that some NHPs could be released onto the market without adequate proof for their claims.

The notification scheme also presents loopholes for manufacturers and suppliers to exploit. The status of a substance depends on the claims made for it. But the definition of health benefit is vague enough that with careful wording, products that should be regulated as medicines may be able to avail themselves of a less strict regime.

Traditional evidence presents the biggest loophole for manufacturers and suppliers to exploit. Adducing traditional evidence could allow these people to make claims about a product, despite any contrary scientific evidence. This not only raises safety concerns, but also runs the risk of misleading consumers.

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Appendix 1

Figure 1: [Medsafe Dietary Supplements Flowchart] (2015, June 22). Retrieved October 6, 2016, from <http://www.medsafe.govt.nz/regulatory/categorisation-or-products.asp>.

