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The Regulation of Natural Health Products: An Unhealthy Absence

LLM RESEARCH PAPER

LAWS 535: CONSUMER LAW

FACULTY OF LAW

TE WHARE WĀNANGA O TE ŪPOKO O TE IKA A MĀUI
VICTORIA
UNIVERSITY OF WELLINGTON

2020

CONTENTS II

Abstract

This paper will briefly examine the shortcomings of the current regulatory framework for products coming out of the health and wellness industry, by contrasting it to the advancements which might have been realised by the enactment of the Natural Health and Supplementary Products Bill. It will also examine the possible benefits which New Zealand stands to gain by spearheading the efforts to introduce such a regulatory framework.

Word length

The text of this paper (excluding table of contents and bibliography) comprises 7,485 words.

Subjects and Topics

Natural Health and Supplementary Products Bill
Fair Trading Act
Regulation of the Natural Health Products

I Introduction

The global health and wellness industries have seen a remarkable boom in recent years, with markets across the world being flooded with new products. Role-players often position themselves as viable alternatives to established medical avenues, with the claims of their products ranging from the harmless to the absurd – and everything in between. Evidence for the claims of these products is not always forthcoming, however, leading to calls for increased regulation the world over. Regrettably, the regulatory environment of New Zealand has failed to keep abreast of developments in the industry despite concerted efforts having being made in that regard. This paper will briefly examine what the regulatory environment might have looked like by means of a case study, and what consumers are left with in its stead. It will include a discussion on the avenues available to consumers to pursue claims they might have. Given the possible harms likely to result from a maintenance of the status quo, and in light of the possible benefits of reform, this paper will argue that a renewed and urgent legislative intervention is required to urgently bring New Zealand up to speed.

II Te Kiri Gold: A Product of the Wellness Boom

The 20th and 21st centuries have seen a remarkable upswing in the populations of developed countries, in particular, partaking in social trends with the aim of improving their health and lifestyles.[1] New Zealand is no exception.[2] A distinguishing feature among many of these trends is their confrontational attitude towards medically-based solutions to poor health – as well as the frequent positioning of themselves as viable alternatives.[3] According to the Global Wellness Institute, the industry's total value grew to US$4.2trillion in 2017, which amounted to 5.3% of total global economic output in that year.[4] Furthermore, this amounted to just over half of the world's total health expenditure.[5] Three of the sectors of this burgeoning market involve products intended for human use, and together amount to US$1.6trillion.[6] Yet, despite the growth of the industry, one does not have to look far at all to find "…misinformation and pseudoscience aplenty."[7] As a result, the wellness industry as a whole has faced a commensurate backlash from more established voices in the scientific and medical communities, as well as the general public.[8]

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1 Lawrence G, Lyons K and Wallington T *Food Security, Nutrition and Sustainability* (Routledge, Abingdon-on-Thames, 2009) at 175.

2 Author Unknown "The rising scoby: How wellness culture gained a foothold across the world and in New Zealand" (7 May 2019) IdeaLog <www.idealog.co.nz>

3 Lawrence, Lyons and Wallington above, no 1, at 175.

4 Yeung O and Johnston K "Global Wellness Economy Monitor" (October 2018) Global Wellness Institute < www.globalwellnessinstitute.org> at iii.

5 Yeung and Johnston above, no 3, at iv.

6 Yeung and Johnston above, no 3, at 5.

7 Turner P *The Wellness Rebel* (Head of Zeus, London, 2018) at 22.

8 Turner above, no 7, at 21.

Despite the growing size of the industry it is frequently left largely to its own devices, where its regulation in New Zealand is concerned. Te Kiri Gold, referred to by some as a "snake oil cancer cure", is still produced and sold in New Zealand for $100 for a 4-litre container.[9] This is despite the product's inventor, Dr Feller, being struck off as a medical practitioner, fined $5000 and ordered to pay no less than $56,100 in costs after a two day tribunal before the Health Practitioners Disciplinary Tribunal last year.[10] The product in question, being unique largely for its high content of chlorine and salt, does not even meet minimum standards for drinking water – yet is still being sold despite a lack of advertising.[11] Much of the industry is far more benign and requires little, if any, scrutinous regulation. However, one does not have to be an advocate of hard-paternalism to see the growing need for a regulatory net to catch those products that do need more careful examination. Products such as Te Kiri Gold, with their notable lack of scientific backing and possibly harmful effects, should be subjected to careful inspection and possible regulation, as will be demonstrated below. What one needs when considering regulation of the industry is something of an industrial sieve that will let the harmless grains of sand pass through unhindered, while catching larger pebbles and stones that need closer inspection.

III The Natural Health and Supplementary Products Bill

Just such a sieve arrived in 2011 in the form of the Natural Health and Supplementary Products Bill (hereafter "the Bill").[12] The Bill was formulated according to four founding principles contained in Section 4 thereof.[13] The first of these require the product to be 'fit for human use' – with the exact meaning of this concept clarified later in the document.[14] The second principle maintains that the regulation a product is submitted to should be proportionate to the 'risks associated with its use'.[15] The third principle pertains to the information accompanying the products the Bill applies to – requiring it to be accurate, and including any 'risks, benefits and side-effects' relating to the product.[16] The fourth principle underpinning the Bill is that any health benefit claims made by a product to which the Bill applies must be substantiated by either 'scientific or traditional evidence'.[17] A brief explanation of some of the Bill's aims and workings will be given below, with a practical examination of its efficacy as a metaphorical sieve - Te Kiri Gold constituting the pebble that needs to be caught.

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9 Author Unknown "Te Kiri Gold Shop" (September 2020) Te Kiri Gold < www.tekirigold.com/shop/>

10 Keith L and Macandrew R "Untested Te Kiri Gold 'cancer cure' still for sale despite Taranaki doctor involved being struck off" (24 July 2019) Stuff < www.stuff.co.nz>

11 Keith and Macandrew above, no 10.

12 Natural Health and Supplementary Products Bill 2011 (324—2) (hereafter "the Bill").

13 The Bill, above no 12, at s 4.

14 The Bill, above no 12, at s 4(a).

15 The Bill, above no 12, at s 4(b).

16 The Bill, above no 12, at s 4(c).

17 The Bill, above no 12, at s 4(d).

A Is it a Medicine or a Food?

Section 6 of the Bill is the logical jumping off point for determining the range of products it seeks to regulate. It defines a natural health and supplementary product as one that is, or appears to have been, manufactured for human use with the primary benefit of bringing about a health benefit to that person.[18] Additionally, the product must contain only permitted ingredients unless it is a dietary supplement, or if the Authority[19] established by the Bill has not raised any concerns within 90 days of being informed of the use of a new ingredient.[20] Excluded from the definition are products which constitute food, or the presentation thereof.[21] Usefully the Bill elaborates and defines food as anything that is *ordinarily* used or presented as food for human beings.[22] Furthermore, the Bill expressly excludes medicines and medical devices from its sphere of application.[23] Interestingly, the initial draft of the Bill contained a closed list of 'applications' to which it applied – despite the detail it went into, notably excluded from the list were a great deal of products currently dominant in the wellness industry, such as essential oils. Fortunately, the 14 subsections detailing the applications of products to which the Bill applies were reduced to just one: those products intended for human use.[24] In light of the definition provided in Section 6 of the Bill, any product intended for human use with the claim of bringing about a health benefit, which is not a food, a medicine or a dietary supplement, would be subject to the Bill. Now turning back to the metaphorical pebble. Upon entering the Te Kiri Gold website one is greeted with very clear writing that "Te Kiri Gold is not a drug or a medicine."[25] It is not enough for a producer to put such a disclaimer on their website or product labelling, however, in an attempt to escape the much stricter regulatory environment surrounding medicines.

1 Medicines Act 1981

Section 6 of the Bill expressly refers to the Medicines Act 1981 (hereafter "the Medicines Act") and excludes any medicines regulated by that legislation from the Bill's sphere of application.[26] Whether or not a product is a medicine should then be determined in light of the provisions of the Medicines Act, which defines a medicine as any substance or article wholly or principally intended for administration to a human for a "therapeutic purpose" - what exactly constitutes a therapeutic purpose will be briefly examined later.[27] Additionally, the product should achieve its intended action through "…pharmacological, immunological, or metabolic means."[28]

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18 The Bill, above no 12, at s 6(1)(a).
19 The Authority is established in terms of Section 8 of the Bill, above no 12.
20 The Bill, above no 12, at s 6(1)(b)(i).
21 The Bill, above no 12, at s (6)(1)(c).
22 The Bill, above no 12, at s 6(2)(3).
23 The Bill, above no 12, at s 6(2)(2).
24 The Bill, above no 12, at s 6(1)(a).
25 Author Unknown "Te Kiri Gold Shop" (September 2020) Te Kiri Gold < www.tekirigold.com/shop/>
26 The Bill, above no 12, at s 6(2)(a) and (b).
27 Medicines Act 1981, s 3(1)(a)(i).
28 Medicines Act 1981, s 3(1)(a)(ii).

Important to take note of is the list of exclusions contained in Section 3 of the Medicines Act, among them the exclusion of products deemed to be food by Section 2 of the Food Act 1981 (hereafter "the Food Act").[29] The Medicines Act helpfully defines what exactly will constitute a "therapeutic purpose".[30] The definition is broad enough to capture a range of claims and purposes, not limited to the outright curing of diseases or ailments. Of note for the present circumstances, is the fact that any product with an intended purpose of "…*alleviating*, treating, curing, or compensating for, a disease, *ailment*, *defect*…" will constitute a product to which the Medicines Act applies.[31]

Medsafe have provided a Guideline on the Regulation of Therapeutic Products in New Zealand (hereafter "the Guidelines") for determining the applicability of the Medicines Act to products.[32] In the Guidelines, a widened explanation is given for purposes possibly deemed therapeutic.[33] The Guidelines make it clear that a product will be intended for a therapeutic purpose where that purpose is claimed or, alternatively, implied on either the label or in promotional material associated with the product.[34] Additionally, the guidelines point out that typical indicators pointing to the presence of a therapeutic purpose are instances where the product labelling or promotional material contain words such as "remedy, medicated or therapeutic.[35] Additionally, consumers and sellers alike should be alert to indications that such a product might give relief to sufferers of a disease or condition.[36] Consumers are furthermore advised to be on the lookout for directions provided by the producer, such as dosage instructions for the product's optimal efficacy.[37] The Medicines Act regulates not only medicines, but "related products" as well, with the distinction between the two found in whether the therapeutic purpose is the primary or secondary purpose of the product in question.[38]

Should a product meet the requirements of constituting a medicine to which the Medicines Act applies, that product is subject to pre-market approval before its sale or distribution will be permitted.[39] Were a producer to sell, distribute or advertise a product deemed to be a medicine prior to the granting of approval, they would have committed an offence and are liable on conviction to imprisonment or a fine.[40] Producers of medicines are reminded by the Guidelines that their products, being "articles of commerce", are still subject to relevant consumer legislation such as the Fair Trading Act 1986.

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29 Medicines Act 1981, s 3(1)(c)(ii).
30 Medicines Act 1981, s 4.
31 Medicines Act 1981, s 4(a) (emphasis added).
32 Medsafe "Guideline on the Regulation of Therapeutic Products in New Zealand" (October 2014) Ministry of Health <www.medsafe.govt.nz>
33 Medsafe above, no 32, at 4.
34 Medsafe above, no 32, at 4.
35 Medsafe above, no 32, at 4.
36 Medsafe above, no 32, at 5.
37 Medsafe above, no 32, at 5.
38 Medsafe above, no 32, at 19.
39 Medicines Act 1981, s 20.
40 Medicines Act 1981, s 20(4).

While it has already be pointed out that Te Kiri Gold deny their product is either a drug or a medicine, a mere denial is not enough to escape regulation as a medicine. It should be clear at this point that it can be difficult to discern accurately between products with a health benefit claim, and those intended for a therapeutic purpose. The producers of Te Kiri Gold have avoided the naming of any disease or ailment, other than that it "…addresses some of the issues in unchecked abnormal cell growth via glycolysis."[41] That unchecked cell growth is a 'defect' is indisputable - it is a necessary precursor to a diagnosis of cancer.[42] This arguably fulfils one of the requirements laid out in the Medicines Act, namely that a product is intended to "compensate for" a defect or disease.[43] Additionally, it could also be argued as fulfilling the requirement of inhibiting a physiological process.[44] When read with the Guidelines, it is clear that the Medicines Act not only extends to products explicitly intended for a therapeutic purpose, but also those products whose therapeutic purpose is implied.[45] In the present circumstances it is clear that there is an argument that Te Kiri Gold should be regulated as a medicine given their implicit claims of addressing symptoms of a disease. Nevertheless, upon contacting Medsafe this author was informed that as they were "advised by the company" producing Te Kiri Gold that they were not making therapeutic claims, regulation rested with the Ministry of Primary Industries as a result of its being advertised as a water.[46]

2 Food Act 2014

One might be hard pressed to conclude that a liquid with the admitted odour of chlorine constitutes "food" in the *ordinary use* of the word, a requirement laid down by the Bill for a product to be excluded from its application.[47] Yet that is exactly what Te Kiri Gold is currently regarded as from a regulatory perspective. A food is defined as any substance intended for human consumption.[48] Additionally, it is worthwhile pointing out that while there are strict regulations, including a registry, for drinking water suppliers in New Zealand, bottled water would appear to be excluded from such stringent regulatory measures – being subject only to the Food Act 2014.[49] Te Kiri Gold is currently classified as a bottled water. Being a food, it is therefore subject to the Food Act 2014, while its regulation at a governmental level is

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41 Author Unknown "About Te Kiri Gold" (May 2018) Te Kiri Gold < www.tekirigold.com/about/>

42 O'Connor CM and Adams JU *Essentials of Cell Biology* (NPG Education, Cambridge, 2010) at 99.

43 Medicines Act 1981, s 4(a).

44 Medicines Act 1981, s 4(b).

45 Medsafe above, no 32, at 4.

46 Email from K Marsh (Advisor, Product Safety) at Compliance Management (Medsafe, Ministry of Health) regarding the regulation of Te Kiri Gold (21 October 2020).

47 Author Unknown "About Te Kiri Gold" (September 2020) Te Kiri Gold < www.tekirigold.com/about/> and s 6(3) of the Bill.

48 Food Act 2014, s 9.

49 Author Unknown "Drinking-water Standards for New Zealand 2005 – Revised 2018" (19 December 2018) Ministry of Health <www.health.govt.nz> at 2.

determined according to Food Standards Australia New Zealand.[50] There are strict composition requirements for the maximum levels of certain chemicals permitted in bottled water.[51]

At present, there is no mention on the list of chemicals referred to by the Australia New Zealand Food Standards Code 2002 of hypochlorous acid, the supposed active ingredient in Te Kiri Gold. There are, however, upper limits set for the content of salt and chlorine – two chemicals researchers have found present in Te Kiri Gold.[52] An independent study commissioned by the New Zealand Herald found that the unusually high quantities of salt and chlorine would render the product effective as a surface disinfectant, but possibly harmful if ingested – given its likelihood of killing off helpful microbes in the gastrointestinal tract.[53] As was mentioned above, in contrast to the case for drinking water suppliers, there is no need for producers of bottled water to register their product before advertising and selling it to consumers. As such, it appears to be a task left largely to the consumer to allege and establish a breach of the minimum chemical composition standards for packaged water sold in New Zealand. This would explain the fact that Te Kiri Gold is still sold and produced in New Zealand, despite numerous authors highlighting the fact that the product itself does not meet minimum requirements for drinking water as laid down by the Ministry of Primary Industries.[54] In the interest of examining the possible efficacy of the Bill, however, the assumption will be made that Te Kiri Gold would qualify neither as a food nor as a medicine, but a natural health product to which the Bill would have applied.

B Is there a health benefit claim?

The Bill largely forbids health benefit claims being made in relation to "named conditions"[55] – a closed list of conditions contained in the International Statistical Classification of Diseases and Related Health Problems (commonly known as the "ICD") which is published by the World Health Organisation.[56] Any such claims relating to a named condition would need to firstly be "allowed" in terms of the Bill,[57] otherwise rendering the product susceptible to possible regulation as a medicine – with the necessarily far stricter regulatory environment established by the Medicines Act.[58] The Bill does not outright exclude health benefit claims made in relation to named conditions – it does, however, require careful inspection by the Authority of the evidence in support of such a claim[59], with the Authority being guided by the

50 Author Unknown "Water" New Zealand Beverage Council <www.nzbeveragecouncil.org.nz>
51 Australia New Zealand Food Standards Code 2002, cl 2.6.2.
52 Australia New Zealand Food Standards Code 2002, cl 2.6.2.
53 Meng-Yee C "Water-based product Te Kiri Gold used by rugby great Sir Colin Meads does not meet the Government's safe drinking water guidelines" (7 April 2017) NZ Herald <www.nzherald.co.nz>
54 Keith L and Macandrew R "Untested Te Kiri Gold 'cancer cure' still for sale despite Taranaki doctor involved being struck off" (24 July 2019) Stuff < www.stuff.co.nz>
55 The Bill, above no 12, at s 12A.
56 The Bill, above no 12, at s 12C.
57 The Bill, above no 12, at s 12B.
58 Medicines Act 1981
59 The Bill, above no 12, at s 12B(2)(b).

founding principles mentioned above.[60] Additionally, the Authority must have made a finding that the risk associated in allowing the claim is low.[61] The Bill furthermore compels the Authority to publish on an internet website a list of allowable claims for those natural health products which the Authority has permitted to make health benefit claims relating to named conditions.[62]

Te Kiri Gold became notorious in light of its use amongst those diagnosed with cancer, with some very notable figures attesting to its efficacy – among them Sir Colin Meads who had been diagnosed with pancreatic cancer, and who swore that Te Kiri Gold had extended his life.[63] The Bill, however, does not aim to regulate rumoured or speculative health claims propagated by users of the product – it requires there to be a specific health benefit claim made by the manufacturer of the product concerned.[64] Not once is the word "cancer" mentioned on Te Kiri Gold's website. They do, however, claim that the active ingredient in their product, hypochlorous acid, "…addresses some of the issues of unchecked abnormal cell growth via glycolysis."[65] Another term for 'unchecked abnormal cell-growth' is neoplasia, essentially constituting a tumour with its diagnosis as cancerous or not dependent on the presence of malignancy.[66] As has been pointed out above, it can be challenging to distinguish between a product with a mere health benefit claim, and one intended for a therapeutic purpose - whether explicit or implied.

When determining the allowability of a health benefit claim related to a named condition, the Authority must be guided by the principles of the Bill.[67] Being thus guided, the Authority must carefully examine the evidence provided by the producer in support of their health benefit claim.[68] In addition, the Ministry of Health has published a Consultation Document elucidating some of the factors considered in deciding which conditions can be addressed by health benefit claims.[69] Among the factors utilised in determining the inclusion of a condition are whether or not it is self-limiting (would likely resolve itself over time without any treatment), non-serious, and suitability for self-diagnosis and management.[70] In light of the underlying principles of the Bill, the evidence presented by the producer in support of their claim should, at a minimum, satisfactorily fulfil the following requirements:

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60 The Bill, above no 12, at s 12B(2)(a).
61 The Bill, above no 12, at s 12B(2)(c).
62 The Bill, above no 12, at s 12B(5).
63 Keith and Macandrew above, no 10.
64 The Bill, above no 12, at s 6(1)(a)(ii).
65 Author Unknown "About Te Kiri Gold" (May 2018) Te Kiri Gold < www.tekirigold.com/about/>
66 Author Unknown "After a Biopsy: Making the Diagnosis" (January 2020) Cencer.Net <www.cancer.net>
67 The Bill, above no 12, at s 12B(2)(a).
68 The Bill, above no 12, at s 12B(2)(b)(i).
69 Author Unknown "The Regulation of Natural Health Products – Consultation Document" (November 2015) Ministry of Health <www.health.govt.nz>
70 Author Unknown "The Regulation of Natural Health Products – Consultation Document" (November 2015) Ministry of Health <www.health.govt.nz> at 7.

(1) The evidence presented should render the product fit for human use.
(2) The either scientific or traditional evidence used to support the claim should be accurate.
(3) The evidence should identify any risks, side-effects and benefits of using the product.

Were the Authority to establish that Te Kiri Gold advances health benefit claims related to a named condition - as it possibly could - the evidence provided by the producers of Te Kiri Gold would have to at the very least satisfy all three requirements above. The first requirement, being 'fit for human use', means the product would be safe and suitable for human consumption. Te Kiri Gold meeting that requirement would depend, in this case, on the dosage recommended to the consumer. The dosage recommended by the manufacturer of Te Kiri Gold extends from a minimum of 50ml a day, to a maximum of 600ml a day.[71] Experts have already cautioned against the possible harmful effects of ingesting large amounts of the chemical ingredient in Te Kiri Gold, even at a concentration of less than 1% as claimed on the bottle's labelling.[72] This finding was supported by testimonials of some patients experiencing "severe bleeding and clots" in their urine after consuming the maximum dosage.[73] In the same article highlighting these complaints by consumers, experts have highlighted the possible negative effect of consumption on the gastrointestinal tract at high dosages.[74] Nowhere on Te Kiri Gold's website is the consumer made aware of these risks and possible side-effects, which have already manifested in users of the product. Thus, it is clear that the evidence currently provided by Te Kiri Gold on their website would likely fail the third requirement listed above.

While Te Kiri Gold might have attempted to support their evidence and claims with the favourable findings of a clinical trial conducted by the inventor of the product, the accuracy and reliability of that trial would be vulnerable. One expert, Dr Shaun Holt, maintained that the clinical trial was very far indeed from coming close to the international standards required of such clinical trials, given its lack of ethical approval before commencement.[75] Indeed, it was the dubious circumstances surrounding the conducting of that clinical trial that resulted in the founder and inventor of the product, Feller, being stripped of his registration as a health practitioner.[76] In summation, it is highly unlikely that the evidence thus far provided by the producers of Te Kiri Gold would meet the requirements laid out in the Bill for claims relating to a named condition.

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71 Manch T "Cancer sufferers put faith in Te Kiri Gold bleach water" (8 April 2017) Stuff <www.stuff.co.nz>
72 Manch, above no 69.
73 Manch, above no 69.
74 Manch, above no 69.
75 Manch, above no 69.
76 Keith L and Macandrew R "Untested Te Kiri Gold 'cancer cure' still for sale despite Taranaki doctor involved being struck off" (24 July 2019) Stuff < www.stuff.co.nz>

C Does it contain only permitted ingredients?

As pointed out above, the Bill requires the use of only permitted ingredients in order to qualify as a product to which it applies.[77] The Bill demonstrates its flexibility by nonetheless permitting the use of new ingredients, upon the failure of the Authority to raise concerns or launch a safety assessment for the product after the required 90-day notice period given by the producer of their intention to use a new ingredient.[78] The Health Committee responsible for the drafting of the Bill acknowledged in the Commentary that such a list would be beneficial in the future, while in its absence reference is to be made to those lists found in comparable overseas jurisdictions.[79]

The Authority is given discretion with regards to the conducting of a safety assessment to determine the permissibility of the new ingredient.[80] The Authority is compelled to consider whether another recognised authority permits the use of the ingredient or substance in a *similar* product, and whether any restrictions are imposed on its use by that authority.[81] Additionally, the Authority must consider whether the ingredient in question is recognised in traditional medicine or "pharmacopoeias"[82] – a publication containing a list of medicinal drugs as well as their directions for use. Additionally, the Authority is given the discretion to consider any other matter they might consider relevant to their determination.[83] The Bill furthermore gives the Authority the power to declare certain ingredients prohibited, upon examination of any harms incurred in the history of its use.[84]

One peculiarity to be found in the Bill is that regarding product notification for producers intending on using new ingredients. The Bill expressly forbids the selling of a product classified as a natural health product in New Zealand prior to approval by the Authority, given after compliance with the prescribed notification procedures.[85] The Bill, however, clearly defines a natural health product as containing only permitted ingredients.[86] The Bill therefore provides no compulsion for distributors of products which would otherwise be readily classified as natural health products - but for the fact that they contain a new ingredient – from having to follow those prescribed notification procedures. The Bill does require notification by a distributer or seller if they intend to use a new ingredient in a natural health product[87] – which, as has been established, excludes those products which contain *none* of the ingredients found on the permitted ingredients list. The same section of the Bill compelling notification for

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77 The Bill, above no 12, at s 6(1)(b).
78 The Bill, above no 12, at s 22(2)(b)(i).
79 The Bill, above no 12, at Commentary.
80 The Bill, above no 12, at s 20(3)(a).
81 The Bill, above no 12, at s 20(3)(b)(i).
82 The Bill, above no 12, at s 20(3)(b)(ii).
83 The Bill, above no 12, at s 20(3)(b)(iii).
84 The Bill, above no 12, at s 21(2).
85 The Bill, above no 12, at s 13(1).
86 The Bill, above no 12, at s 6(1)(b).
87 The Bill, above no 12, at s 22(2).

products using new ingredients defines those new ingredients as any substance, or class thereof, falling within the definition of Schedule 1.[88] Schedule 1 captures a broad range of substances and was ostensibly borrowed from the Canadian regulations of similar classes of products in that country.[89] The Canadian regulations, however, avoid this problematic anomaly altogether by simply defining a natural health product as any substance, or combination thereof, as set out in Schedule 1.[90] Similarly to the Bill in New Zealand, the Canadian definition of a natural health product excludes products deemed to be food.[91] The inclusion in the Bill's definition of a natural health product as one that contains only permitted ingredients sits awkwardly with the rest of the definition contained in Section 6, and might serve to preclude its application from a wide variety of products it was specifically intended to regulate.[92]

Turning once again to the product, Te Kiri Gold, the active ingredient on which the health benefit claims for the product hinges is Hypochlorous Acid, with its compound formula being HOCl.[93] It is a weak acid that forms upon the dissolution of chlorine in water[94] – explaining the self-admitted chlorinous smell associated with the product in question.[95] One example of a list from a comparable jurisdiction, is the inventory of notices for ingredients 'Generally Recognized As Safe' (hereafter and commonly referred to as "GRAS"), which is updated regularly by the USA's Food and Drug Administration.[96] A search on the GRAS inventory of both the compound formula and advertised name of the active ingredient in Te Kiri Gold, hypochlorous acid, yields no results. Therefore, and for the purposes of further examination, the assumption will be made that the active ingredient in Te Kiri Gold is not a permitted ingredient. This is but one list in one comparable jurisdiction, however, with the possibility arising of producers of products containing new ingredients merely finding a jurisdiction that can be argued is comparable, and which has included said ingredient. Certainty in this regard is crucial – such certainty could readily be achieved with the wholesale recognition of a comparable jurisdiction's relevant list. As has been pointed out, the fact that Te Kiri Gold contains a new ingredient could lead to its exclusion from application by the Bill on one reading of Section 6, barring the possibility it also contains another ingredient which is permitted. At present, where a product such as Te Kiri Gold uses a new ingredient which fails to be captured for regulation by relevant food standards, the Medicines Act or Dietary

88 The Bill, above no 12, at s 22(1).
89 Natural Health Products Regulations 2004 (Canada), Schedule 1.
90 Natural Health Products Regulations 2004 (Canada), at s 1, Interpretation.
91 Natural Health Products Regulations 2004 (Canada), at s 2(2).
92 The Bill, above no 12, at s 6(1)(b).
93 Author Unknown "About Te Kiri Gold" (May 2018) Te Kiri Gold < www.tekirigold.com/about/>
94 Marshall RJ *Food Safety: A Practical and Case-Study Approach* (Springer Science & Business Media, Berlin, 2006) at 262.
95 Author Unknown "About Te Kiri Gold" (May 2018) Te Kiri Gold < www.tekirigold.com/about/>
96 Author Unknown "GRAS Notices" (24 September 2020) U.S. Food and Drug Administration < www.cfsanappsexternal.fda.gov

Supplements Regulations – that product has no restrictions on its use, as the Bill did not pass into law.[97]

D A closer examination required?

Te Kiri Gold is undeniably a product to which the Bill would ideally have applied. Whether it would have fallen under its application with the current definition of a natural health product, is not entirely certain. While the product is accompanied by a health benefit claim, whether this claim is for a "named condition" or not, is debatable. The product in question does, however, contain a new ingredient – something which the Bill immediately flags as worthy of further inspection. It is in this element where the product in question is yet again unlikely to withstand closer scrutiny.

The Health Committee responsible for the drafting of the Bill included in the Commentary and their discussion of the powers granted to the Authority, their expectation that it should exercise its functions in such a way that the principles underpinning the Bill are adhered to. An explicit duty to do so is imposed upon the Authority when deliberating on whether to allow health benefit claims relating to "named conditions".[98] What, then, of those portions of the Bill also dealing with determinations by the Authority, where no such duty is named – as is the case when determining whether a new ingredient should be deemed permitted or not.[99] This is a shortcoming of the Bill, in this author's view. The last two principles maintain requirements that products to which the Bill applies should be attached with information that is accurate and informs the consumer of risks, side-effects etc. related to the product, and that any health benefit claims should be supported by scientific or traditional evidence.[100] These are incredibly useful compulsory guiding factors to aid the Authority in their examination of the permissibility of a new ingredient.

Nevertheless, it is likely that given the specific health benefit claim of the current product, and that it contains a new ingredient, the claim and its evidence would in any event come under closer scrutiny by the Authority. There are a substantial amount of 'claims' on the Te Kiri Gold website.[101] Under many of these claims are references to sources of seemingly scientific evidence – upon closer inspection, none of those sources are consistently or appropriately cited. Indeed, many of them are dead links that lead nowhere.[102] Even departing on the assumption that the sources listed in support of the efficacy of hypochlorous acid hold some weight, expert evidence to the contrary has already been presented on record. The Health

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97 Email from Ooi K (Senior Analyst) at Health System Improvement & Innovation (Medsafe, Ministry of Health) regarding the use of "unpermitted ingredients" in natural health products (19 October 2020).

98 The Bill, above no 12, at s 12B(2)(a).

99 The Bill, above no 12, at s 20(3).

100 The Bill, above no 12, at s 4(c) and (d).

101 Author Unknown "About Te Kiri Gold" (May 2018) Te Kiri Gold < www.tekirigold.com/about/>

102 Author Unknown "About Te Kiri Gold" (May 2018) Te Kiri Gold < www.tekirigold.com/about/>

Practitioners' Disciplinary Tribunal, responsible for stripping the founder of Te Kiri Gold of his registration, heard testimony from industry expert Mark Hampton that upon ingestion of hypochlorous acid, the chemical would immediately break down - never reaching any of the tumours in the consumer's body, rendering claims of its efficacy in slowing the growth of such tumours dubious at best.[103] A lack of scientific evidence would not preclude the makers of Te Kiri Gold attempting to prove their claims with traditional evidence.[104] The Bill usefully defines traditional evidence as "…traditional use of a substance based on knowledge, beliefs, or practices passed down from generation to generation."[105] This provision was inserted to allow more benign products to enter the market, as well as demonstrating respect for the Treaty of Waitangi in approaching regulation of Maori *taonga* with sensitivity and flexibility.[106] Despite this flexibility, it is unlikely that Te Kiri Gold will meet the requirements of traditional evidence – rendering it, potentially, without either scientific or traditional evidence to support its claims.

E Te Kiri Gold: Weighed in the Balance and Found Wanting

In summation, a very preliminary application of a few of the provisions of the Bill above has determined their possible efficacy in filtering out potentially problematic products from entering the market – not for them to be issued with outright bans, but instead giving an opportunity for their claims and ingredients to be examined more closely. Were the Bill to have come into force, it is unlikely that Te Kiri Gold would have passed muster. The Bill was, however, scrapped in 2017 with little in the way of progress towards further regulation of the industry since that time.[107] At present, even those with expert knowledge of the industry are unsure of where the responsibility of regulation of Te Kiri Gold should rest. In correspondence from Natural Health Products New Zealand, a representative intimated their belief that the product does not appear to be a food and is thus subject to regulation by Medsafe as it likely constitutes a medicine.[108] Correspondence with Medsafe has in turn led to a belief on their part that the product constitutes a food, and as such the responsibility for regulation sits with the Ministry of Primary Industries.[109] A response from the Ministry of Primary Industries to queries regarding the matter was not forthcoming. However, to say that New Zealand's consumers are left without any form of legal protection would be wrong. A very brief examination of how exactly protection is currently provided to consumers, as well as the usefulness thereof, will follow.

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103 Keith L and Macandrew R "Untested Te Kiri Gold 'cancer cure' still for sale despite Taranaki doctor involved being struck off" (24 July 2019) Stuff < www.stuff.co.nz>

104 The Bill, above no 12, at s 20(3)(b)(ii).

105 The Bill, above no 12, at s 5.

106 The Bill, above no 12, at Commentary.

107 Kenny K "Misinformation runs rampant in the unregulated market of alternative medicine" (22 January 2020) Stuff < www.stuff.co.nz>

108 Email from S Gray (Managing Board Director) at Natural Health Products NZ regarding the regulation of Te Kiri Gold (16 October 2020).

109 Email from Daly K (Principal Technical Specialist) at Compliance Management (Medsafe, Ministry of Health) regarding the regulation of Te Kiri Gold (20 October 2020).

IV Fair Trading Act 1986

Currently, some of the only protection consumers are afforded is that provided by the Fair Trading Act 1986 (hereafter "the Act"). The Act prohibits misleading conduct in relation to a product.[110] Additionally, the Act prohibits the making of false and/or unsubstantiated representations relating to a product.[111] Theoretically, this fulfils the same protective role as that provided by the Bill with regards to substantiation of health benefit claims, discussed above. It is up to consumers, however, to bring a civil claim against the seller of products found in contravention of the Act.[112] Already highlighted in the case of Te Kiri Gold is the legal evasiveness demonstrated by many role-players in the industry. Many are familiar with the law, and know how to structure their health benefit claims in such a way that breach of the Act is not readily apparent – least of all to a lay consumer. In any event, the onus rests on the consumer to prove that such a breach has occurred – a heavy burden in most cases, which will be examined below.

A Disputes Tribunal

The first port of call for most consumers looking to prove such a breach of the Act would be the Disputes Tribunal. It is an admittedly speedier and cheaper solution than court proceedings, and the referees appointed by the Ministry of Justice can deliberate on matters the value of which do not exceed $30,000.[113] The fees involved in making a claim range from $45 to $180, dependent on the total value of the dispute.[114] The referee hears the matter after notification of the other claimant, whereupon both parties can submit their arguments.[115] Legal representation is not permitted at the Tribunal itself, although there would be nothing stopping either party from seeking legal advice prior to the hearing of the matter. Given the ambiguously drafted claims some products in the industry rest on, it more often than not might require the input of a legal practitioner to distil the essence of the claimant's argument. Given the power imbalance frequently present between sellers and consumers in any industry, it is not unlikely the seller will avail themselves of legal advice prior to the matter being heard. Additionally, parties must attend the hearings in person – a burdensome requirement that is likely to dissuade many from pursuing claims they might have.[116] With the onset of the COVID-19 pandemic, provision has been made for hearings to be conducted via teleconference – a state of affairs

110 Fair Trading Act, s 9.
111 Fair Trading Act, s 12A.
112 Micklitz HW and Saumier G *Enforcement and Effectiveness of Consumer Law* (Springer, Cham, 2018) at 429.
113 Author Unknown "Disputes" (31 August 2020) Disputes Tribunal of New Zealand <www.disputestribunal.govt.nz>
114 Author Unknown "Forms & Fees" (21 July 2020) Disputes Tribunal of New Zealand <www.disputestribunal.govt.nz>
115 Micklitz and Saumier, above no 62, at 420.
116 Micklitz and Saumier, above no 62, at 420.

which will remain in place until modified or revoked by the Tribunal.[117] It is hoped that this state of affairs will persist, given the increased access to justice it provides. Additionally, there is nothing stopping a consumer from pursuing a claim in the District Courts – small claims in that venue are rare, given the increased fees required to institute proceedings in that forum, as well as the possibility of a costs order being granted against the claimant.[118]

The goal of the Act was never to prevent any possible detriment at all from befalling a consumer. The goal of existing legislation was always to prevent only the worst cases of detriment from occurring in the first place, to ensure that consumers are better informed in their dealings with sellers, and that where harm has befallen either party, they have an adequate remedy available to them.[119] As has been pointed out, the Act makes it illegal for a business to make unsubstantiated representations to consumers about their goods.[120] This prohibition does not, however, extend to the common use of 'puffery' by businesses – consumers will still have to prove that the representation was not made on reasonable grounds. The review of consumer law conducted by the Ministry of Business, Innovation and Employment found that the reforms of the Act regarding unsubstantiated representations have been largely successful – with the majority of consumers polled reporting satisfaction with the current state of affairs.[121] Yet out of the 595 complaints relating to unsubstantiated representations received by the Commerce Commission (discussed below), between 2014 and 2018, only four were taken to court.[122] Many products, such as Te Kiri Gold, might not actually cause readily discernible detriment to a consumer. This leads consumers with little understanding of the intricacies of legislation in place to protect them, with a high evidentiary hurdle to overcome. In one news article discussing Te Kiri Gold, an industry expert Dr Shaun Holt maintained that even if Te Kiri Gold itself is actually 'harmless', people with terminal cancer are wasting both time and money on a product based on unsubstantiated representations.[123] Quantifying this sort of detriment is a far more nuanced task than the average consumer is equipped to do in deciding whether to take their matter to the Disputes Tribunal or not.

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117 Author Unknown "Disputes" (31 August 2020) Disputes Tribunal of New Zealand <www.disputestribunal.govt.nz>

118 Micklitz and Saumier, above no 62, at 421.

119 Author Unknown "Review of consumer law – Fair Trading Act evaluation report" (October 2019) Ministry of Business, Innovation and Employment <www.mbie.govt.nz> at 7.

120 Author Unknown "Review of consumer law – Fair Trading Act evaluation report" (October 2019) Ministry of Business, Innovation and Employment <www.mbie.govt.nz> at 31.

121 Author Unknown "Review of consumer law – Fair Trading Act evaluation report" (October 2019) Ministry of Business, Innovation and Employment <www.mbie.govt.nz> at 32.

122 Author Unknown "Review of consumer law – Fair Trading Act evaluation report" (October 2019) Ministry of Business, Innovation and Employment <www.mbie.govt.nz> at 32.

123 Manch T "Cancer sufferers put faith in Te Kiri Gold bleach water" (8 April 2017) Stuff <www.stuff.co.nz>

B Commerce Commission

The Commerce Act 1986 established the Commerce Commission, which is tasked by that legislation to perform, independently, any tasks assigned to it by the Commerce Act or any other legislation expressly providing for its authority thereunder.[124] It is therefore the regulatory body responsible for the enforcement of relevant provisions in the Act. Widespread reforms of consumer law have since expanded the powers of the Commerce Commission, which is presently vested with the authority to issue infringement notices to those distributors found in breach of the Act, similar to 'parking fines.'[125] As has been pointed out, the Act prohibits the making of false and/or misleading representations to a consumer about a product.[126] The Act makes a breach in that regard an offence – with the Commerce Commission given the authority to prosecute a distributor on behalf of a consumer.[127] A person found in breach of the Act is liable on conviction to a fine not exceeding $200,000, with the amount rising to $600,000 for body corporates found to have committed such a breach.[128]

The Commerce Commission has helpfully issued its own guidelines to help both distributors and consumers determine under which circumstances the Commerce Commission is likely to prosecute.[129] Whether or not the Commerce Commission will prosecute a matter or not will depend on the meeting of the 'Evidential Test' – namely, whether the available evidence is sufficient to lead to a "reasonable prospect of prosecution."[130] Additionally, the Commerce Commission must be satisfied that the pursuing of prosecution will be in the public interest, fulfilling the requirements of the 'Public Interest Test.'[131] The factors which the Commerce Commission is obliged to take into account are thoroughly laid out in the abovementioned guidelines, giving both consumers and sellers the opportunity to discern likelihood of prosecution.[132] As pointed out by Micklitz and Saumier, however, the helpfulness of the Commerce Commission in assisting consumers is hampered by its limited jurisdiction and lack of adequate financial resources to pursue every possibly worthy claim.[133] Turning once again to Te Kiri Gold, it is possible that given the widely acknowledged impact Te Kiri Gold has had on those affected by cancer, prosecution might be found to be in the public interest. In its own guidelines, however, the Commerce Commission make it clear that in determining whether the public interest requires criminal prosecution, they will factor in the cost of such prosecution –

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124 Commerce Act 1986, s 8.
125 Micklitz and Saumier, above no 62, at 417.
126 Fair Trading Act, s 12A.
127 Fair Trading Act, s 40.
128 Fair Trading Act, s 40(a) and (b).
129 Author Unknown "Criminal Prosecution Guidelines" (October 2013) Commerce Commission New Zealand <www.comcom.govt.nz>
130 Author Unknown "Criminal Prosecution Guidelines" (October 2013) Commerce Commission New Zealand <www.comcom.govt.nz> at 4.
131 Author Unknown "Criminal Prosecution Guidelines" (October 2013) Commerce Commission New Zealand <www.comcom.govt.nz> at 4.
132 Author Unknown "Criminal Prosecution Guidelines" (October 2013) Commerce Commission New Zealand <www.comcom.govt.nz> at 5-6.
133 Micklitz and Saumier, above no 62, at 423.

with their funds, as has been pointed out, being constrained.[134] Given the widespread news coverage surrounding Te Kiri Gold, coupled with its continued production and sale in New Zealand, it would seem that prosecution of its producers has been found to be have a low likelihood of prosecution, or not to be in the public interest.

C Customer Testimonials

A notable phenomenon present with the marketing of Te Kiri Gold is the use by the producer of customer testimonials to buttress their health benefit claims. Instead of directly making claims which would likely be categorised as "therapeutic", or providing evidence which might expose them to more careful regulatory scrutiny, they encourage new customers to make contact with existing customers. Those existing customers predictably make claims about the product which the producer is trying to avoid explicitly making themselves. The efficacy of the product is also usually extolled by those existing customers, thereby serving as the 'evidence' of the product's value, in the eyes of new consumers.[135] This is not a unique occurrence, with Tokeley highlighting the use of the same tactics in the homeopathy industry, where distributors "cherry pick" trials which have results favourable to their claims – despite possible faults in those trials' design.[136] Tokeley goes on to highlight the instances where producers of homeopathic remedies refrain from making any possibly therapeutic claims at all, instead encouraging consumers to "ask shop staff" or research the matter themselves, inevitably encountering literature on the product which makes the claims and provides the desired 'evidence' for the product.[137] This cherry-picking is the same technique used by the producers of Te Kiri Gold but instead of reputable clinical trials or peer-reviewed literature in support of the product – of which there are none – new customers are urged to 'draw their own conclusions' based on carefully directed communications with existing customers.

That this is both ethically and legally dubious is beyond doubt. As a result of the actions of the producer, the consumer is misled – this constitutes a breach of Section 9 of the Act. The Fair Trading Act does not require the producer themselves to have misled a consumer for a breach to have occurred. It is enough if they have "engaged in conduct" which is "likely to mislead or deceive" the consumer.[138] Yet the law in this regard is poorly enforced, if at all. This is a situation unlikely to occur in the environment the Bill sought to establish. It would not be enough for a producer to make vague claims with elusive methods of providing evidence for

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134 Author Unknown "Criminal Prosecution Guidelines" (October 2013) Commerce Commission New Zealand <www.comcom.govt.nz> at 6.

135 Manch T "Cancer sufferers put faith in Te Kiri Gold bleach water" (8 April 2017) Stuff <www.stuff.co.nz>

136 Tokeley K "The Natural Health and Supplementary Products Bill: Homeopathy, the truth and the placebo effect" (2014) 26 New Zealand Universities Law Review 421 at 422.

137 Tokeley K "The Natural Health and Supplementary Products Bill: Homeopathy, the truth and the placebo effect" (2014) 26 New Zealand Universities Law Review 421 at 430.

138 Fair Trading Act, s 9.

those claims. Any health benefit claims made by a producer would have to be supported by evidence.[139]

D Regulation: prevention is better than treatment

It is conceivable that most claims originating in the industry the Bill sought to regulate would not involve amounts large enough to warrant institution in the District Court. While the Disputes Tribunal is an admittedly more accessible venue for resolution, it is nonetheless daunting for the average consumer to embark on such a venture. In the 12 months preceding March of 2014, the average costs involved in all claims heard by the Disputes Tribunal amounted to $600-$650 per claim.[140] Turning back to Te Kiri Gold for a moment, it is worthwhile noting that a one month supply of the product costs $100, although some consumers have spent in excess of $7,000 on that product.[141] One could forgive a consumer for not seeing the worth in pursuing a breach of the Act in the Disputes Tribunal.

Had the Bill come into effect, a product such as Te Kiri Gold would likely not have made an inroad into the market in New Zealand in the first place. Given the seriousness of the conditions Te Kiri Gold has been used to treat – and *in lieu* of established medical routes - many would argue that lives have been lost due to the lack of an adequate regulatory environment. The drafters of the Bill sought to protect consumers from possible harm in the first instance, whereas the current state of affairs provides them with an outdated remedy for harm they have likely already incurred. That there is a need for further regulation is undeniable. While the Bill was not perfect, much can be said in its favour. Additionally, much has transpired since its scrapping in 2017, leaving drafters of any future regulatory legislation the opportunity to examine novel innovations in foreign and comparable jurisdictions, incorporating those desirable and appropriate elements into an instrument tailor-made for New Zealand.

V Incentives to Regulate

The introduction of a more structured regulatory environment for natural health products should not only be motivated by its harm-reduction capabilities, but also its potential to foster further growth for New Zealand producers of natural health products. As was pointed out above, the global industry is growing at a rapid rate and New Zealand is no exception. Calls for regulation are coming not only from consumers, but the producers and manufacturers in the industry itself. Natural Health Products New Zealand (hereafter "NHPNZ") counts among its members over 80% of the industry in New Zealand.[142] It is an organisation which was established in 2002 with

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139 The Bill, above no 12, at s 4(d).

140 Micklitz and Saumier, above no 62, at 424.

141 Strongman S "Cancer patients, a deregistered doctor and a bleach 'cure' that's still for sale" (23 July 2020) RNZ <www.rnz.co.nz>

142 Author Unknown "Members" (2019) Natural Health Products NZ <www.naturalhealthproducts.nz>

one of its goals being the maximisation of the industry's competitive advantage and potential.[143] Additionally, the organisation seeks to ensure that natural health products in New Zealand maintain high standards of "quality, safety and efficacy."[144] The organisation points out the fact that the value of New Zealand's natural health product market is currently valued at upwards of $2.3billion with an already well-established market presence in North America and Asia. In correspondence with this author, a representative of the organisation confirmed their active commitment and promotion, in cooperation with successive governments, of an updated and "fit-for-purpose" regulatory environment for New Zealand's natural health product industry.[145]

According to NHPNZ, slightly more than half of industry role-players consist of small to medium enterprises.[146] Altogether, the industry in New Zealand exported $642million worth of natural health products in 2019, which constituted a 125% increase in value compared to figures 5 years prior.[147] In fact, Koe points out that 70% of the producers of products in New Zealand export their products – predominantly to the country's biggest trading partners in the industry - China, Australia, the United States and Canada.[148] In research conducted by NHPNZ, out of the four hurdles identified by respondents to increased growth of the industry, restrictions arising from the country's current regulatory environment were the primary one.[149] This one major stumbling block was followed by increased costs and competition.

The lack of regulatory certainty might be hindering New Zealand's ability to supply natural health products internationally, but it has done nothing to slow down the global demand. The important point is that those international buyers of natural health products are taking their business elsewhere. Executive Director of NHPNZ, Alison Quesnel, said in 2016 that their Asian customers confirmed the perceived advantage which competing markets, such as Australia, had over New Zealand due to their more established and internationally-recognised regulatory systems.[150] She went on to highlight the potential benefits of aligning New Zealand's regulatory schemes with those of its international partners, as it would undoubtedly facilitate greater volumes of trade.[151] In a post-COVID world, no country can afford to neglect such ready opportunities for economic growth.

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143 Author Unknown "The Voice of New Zealand Industry" (2019) Natural Health Products NZ <www.naturalhealthproducts.nz>

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145 Email from S Gray (Managing Board Director) at Natural Health Products NZ regarding the regulation of Te Kiri Gold (16 October 2020).

146 Koe T "Growth challenge: NZ supplements sector's huge potential hampered by regulations and low capital" (22 June 2020) Nutra Ingredients Asia <www.nutraingredients-asia.com>

147 Koe above, no 143.

148 Koe above, no 143.

149 Koe above, no 143.

150 Author Unknown "NZ natural health industry seen as second best to the Aussies, industry group says" (31 July 2016) Stuff <www.stuff.co.nz>

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VI Conclusion

The global health and wellness industries are a rapidly growing and constantly evolving phenomenon. Despite well-intentioned efforts to bring the industry under a more expansive and appropriate regulatory umbrella, New Zealand still boasts legislation which provides consumers with a wholly inadequate level of protection. Possibly harmful products are currently produced and sold in New Zealand without any regulatory scrutiny or intervention. The growth of the industry shows no signs of slowing down, with the absence of up-to-date legislation becoming more and more apparent with time. Much harm may already have needlessly befallen consumers – much more is to come, without renewed and concerted efforts to address the regulatory shortcomings provided by the status quo. Regulatory reform is not driven solely by its harm-reduction possibilities, however, with the possible benefits having been briefly extolled above. There is a rapidly growing list of valid reasons for New Zealand to urgently introduce a regulatory framework for natural health products. The list of reasons not to is dwindling and growing increasingly indefensible.

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