Legal Challenge to the Proposed Natural Health Products Bill

Legal Brief
Dr. Guy Hatchard 11th April 2016

Executive Summary

Preamble: Discusses problems concerning *suppression of matters of fact, information about health benefits of foods, treatment of serious conditions* and *assessment of risk* which pose insurmountable obstacles to a fair and rational implementation of the bill in its current form.

1) The definitions of a **food**, a **health benefit**, and a **natural health product** so overlap as to render the clauses of the bill contradictory to one another. As a result the bill is liable to lead to arbitrary enforcement of regulations and consequent litigation. This confusion has been the subject of decisions by the EU courts which clarify the difficulty of making such distinctions even in principle. They have ruled that botanicals should not be regulated in the manner that the NZ bill mandates.

2) Clause 46 in sum total restricts the natural right of an individual to communicate information that benefits health; as such it violates the human rights to free speech, food choice, and healthcare. It also mitigates against scientific investigation of the benefits of natural healthcare.

3) The bill is discriminatory against ethnic and cultural practises in as much as it claims to allow the practice of traditional medicine but will actually restrict it, since the bill fails to understand or take account of the nature of the practice of traditional medicine.

4) One of the stated key regulatory principles of the bill is that *the regulation of natural health products should be proportionate to the risks associated with their use* however the bill specifies that this principle *cannot be enforced in a court of law*. This last clause frustrates natural justice and the rule of law.

5) The bill is out dated and regressive. There are serious scientific reasons behind this statement. The bill fails to promote health and serve the demonstrable needs of preventive healthcare in the light of recent developments in our understanding of the aetiology of disease.

6) The bill does not mandate a rational decision-making process. Ministry of Health processes adopted to date do not reflect the regulatory principles of the bill. An alternative **rational decision tree** is suggested which will protect the practise of traditional medicine.

7) The regulations concerning allowable health claims need clarification and elaboration. As matters stand, the Ministry of Health and its proposed Authority are being encouraged by past statements of government ministers in select committee or to parliament to impose restrictions that will fall outside the written text and fundamental regulatory principles of the bill.

8) The Ministry of Health and Medsafe lack the necessary expertise to implement the Natural Health Products Bill fairly.

9) The bill's definition of a Natural Health Product permits huge classes of substances which fall outside the accepted understanding of 'natural'. This will deny the public right to choice by allowing the use of the term *natural* to cover a wide range of synthetic substances and additives.

10) The Australian and Canadian lists used by the Ministry of Health as the basis for its *draft list of permitted ingredients* were compiled using methodologies in conflict with the regulatory principles of the NZ bill. As a result, a significant number of herbs are restricted without just cause.

Preamble

Recently I received a communication from an official at Medsafe warning me that if I persisted in claiming that Ayurvedic remedies were foods, I should be aware that the Food Bill regulates health claims even more stringently than the Natural Health Products Bill proposes to. In essence, this attempted 'coup de grace' was made: about the *Natural Health Products Bill*, by an official administering the *Medicines (1981) Act* with reference to the *Food Bill*. A cursory examination of all three, reveals that these statutes are over lapping and contradictory in their intent, definitions, and provisions. **There has been no credible attempt to rationalise these three statutes. Therefore the introduction of the Natural Health Products Bill will result in the rule of confusion rather than the rule of law.** There are crucial legal issues at stake:

(i) Serious Conditions: MoH (through Medsafe) has published a list of mild health conditions (Addendum K) for which Natural Health Products suppliers may apply for approval to make an allowed health benefit claim. To be successful, suppliers must submit scientific or traditional evidence (to a standard which will be determined by the Authority). There remains a very long list of conditions (referred to as *serious conditions*) for which no health benefit claim may be made. Note that EU law has not attempted to make such a distinction for good reasons.

It is very clear that many natural products (which are often also foods) do provide health benefits for serious conditions. This is self-evident: foods support life and health. Without food you die. Lets take a specific example: epidemiological studies indicate that daily intake of turmeric reduces your chance of developing bowel cancer. Yet bowel cancer is a *serious condition*. Therefore you cannot make a health benefit claim if you are selling turmeric capsules (unless of course turmeric is registered as a medicine which turmeric is clearly not). (N.B. EU courts ruled on a similar case involving garlic capsules and extended the ruling to cover virtually all plant ingredients: see point (1) below).

The rule of law is intended to sort truth from untruth. The question of whether turmeric can benefit health is a scientific question, not a question of law. To restrict the capacity of individuals to communicate scientific fact, amounts to a restriction on science, truth, and free speech. Clause 46 is even stricter than that, as you may not even *'by implication'* state or communicate in any way that a natural health product sold in NZ may benefit a serious condition.

The select committee on health has admitted that the definition of a *serious condition* is not something they have managed to construct in words. There is good reason for this. A minor illness can be fatal, yet you can recover from a serious condition that is usually fatal. Your physiological, biological, and psychological health including the efficiency of your immune response are the underlying factors which contribute to your recovery. Food benefits all of these. It would be a scientific fallacy to suggest otherwise.

Now imagine that a new law is passed. As a result the local authority states that anyone owning a house in a city must apply for government permission to claim that their grass is green. All well and good. A stupid law, but the law is allowed to be stupid. Now imagine that the authority sets aside certain areas of the city where you are not allowed to claim that your grass is green, (but you may do so if you pretend your grass is plastic even though it is not). This is now a law that turns fact into fiction. The provisions of the Natural Health Products Bill will achieve precisely this. No one will be able to claim that a food/natural health product will benefit a *serious condition* even if there is incontrovertible evidence that this is the case. **Thus the provisions of the bill will suppress matters of fact and cede the sovereignty of truth. This will impede scientific enquiry, everyday communication, and the rule of law. It will obstruct everyone's personal endeavour to maintain their health** (See points 2 and 5 below).

(ii) Risk: I have a similar problem with the concept of *risk* as presented in the bill. I am a scientist. Risk should be, in the context of food and medical safety, a scientifically definable quantity. I have worked in the food industry sector that deals with testing and risk. My assessments of risk had to be quantifiable. The bill states: *that the regulation of natural health and supplementary products should be proportionate to the risks associated with their use* .The term *'proportionate'* has a quantitative meaning. There is a reason why Clause 4 (2) seeks to exclude this principle from being *enforceable in a court of law*. Any scientific assessment of the risk of truly (See point (9) below) natural products would conclude that there is little or no risk; certainly the risk that pharmaceuticals, tobacco products, alcohol, etc carry is not only far greater but more importantly of a completely different character.

Natural products made from whole plants with a history of safe use are not inherently risky in any way that is similar to or comparable with the risk of pharmaceuticals, etc. There is no scientific way to quantify the risks of plant-based natural products that would justify a medicine-type risk regime. And let us be clear that many of the provisions of the bill bear a close resemblance to those of the Medicines Act. Yes, traditional natural health products should contain what their label says they contain; Yes, they should be made in a clean environment; but there is no quantifiable risk of danger to the public beyond the risk of contamination which is not a risk of the product itself, but a risk in its manufacture which is already well covered by other laws such as the trade description act, the food bill, etc. Pharmaceuticals are known to be dangerous in a way plant-based natural products are not. Pharmaceuticals cause deaths, plant-based traditional natural products do not. No coroner has ever recorded a death from a natural product in New Zealand. There is no scientific way to *proportionately* compare the risks of a product that can cause fatal illness with a product that cannot.

I suppose that the Authority will take its lead from discussions by the select committee and suggest that the risk the bill aims to regulate is *the risk that an individual with a serious condition may defer going to a GP since they have been misled by a description of a natural health product*. There is no evidence that this is happening, but even so the discussion in (i) above clearly shows that the distinction between a mild and a serious condition has not been rationally defined. It is an arbitrary distinction. The process of drawing up the list of mild conditions has not been definable in law. Moreover and importantly, this imagined danger is already well covered by the Medicines Act and the Food Bill.

I have drawn up a rational decision tree (See point 6 below). This is a rational approach to managing risk, but this decision tree does not justify the regulation of plant, animal, and mineral material that carries no demonstrable risk. The process of drawing up a list of permitted substances which the bill envisions, and which is already happening, is exactly the same process currently used to control food additives, but food additives pose a completely different class of risk since they are often synthetic substances known to be capable of causing illness (see point (9) below). There is no rational, proportionate justification for using this approach of *permitted substances* for truly natural products containing plant, animal, and mineral substances. It is in fact disproportionate to the risk as well as practically unworkable (See points 2 and 4 below).

Therefore the regulations proposed by the bill are not *proportionate* to the risks, in this regard the intents and provisions of the bill appear to be based on hearsay or imagined risks rather than science. This means the bill is not internally consistent because its provisions do not conform to its own regulatory principles, nor can the proposed Authority be constrained to conform to the regulatory principles. The bill obviates the rule of law by preventing its principles from being enforced in law. **Any discussion of risk should be a rational process and its exclusion from discussion in a court of law represents a denial of the fair and rational nature of the law.**

Legal Challenge: Detailed Discussion

1) Food, Natural Products, and Health Benefits

It is the case that all five definitions of a **Health Benefit** (Addendum (C) below) apply to foods. Therefore the definition of a **Natural Health Product** (Addendum (B) below) inescapably implies that all foods are Natural Health Products and therefore fall under the scope of the bill. Alternatively the definition of a **Food** (Addendum (A) below) can be taken to mean that all plant and animal products should be removed from the scope of the bill as they are potentially foods.. ***In reality the distinction between a plant or animal product as medicine and a plant or animal product as food is not definable in law.*** A food is always medicinal because it maintains life and health, provides nutrition, supports metabolism and immunity, prevents the emergence of disease, and aids in the cure of illness. The overlapping definitions (A), (B), and (C) below mean that enforcement of the bill will involve arbitrary decisions which will inevitably be the subject of legal challenges. The select committee examining the second reading of the bill acknowledged that this was the case in their preamble discussion of honey and teas. This is not a semantic objection to the bill as EU case law shows. (See also discussion in point 5 below concerning Ayurvedic remedies as foods). The EU courts have recognised that the distinction between a food and a medicine is a problem area and they have ruled to rectify this situation.

AMBIGUITIES IN EU REGULATIONS HAVE BEEN RECTIFIED BY THE COURTS
In the EU similar efforts by member states to regulate plants and botanicals in a similar way to medicine have run into trouble in the courts. According to EU law, a product can be considered medicinal either if it is *"presented as having properties for treating or preventing disease in human beings"* (medicinal product "*by its presentation*") or if it *"may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis"* (medicinal product *"by its function")*. These definitions (which are similar to some discussed in various iterations of the NZ Bill), whilst sounding detailed, are in fact so vague that EU member states have applied these same legal definitions differently to such an extent that it has hampered inter state trade. The courts have reprimanded states who have sought to restrict the sale of medicinal herbs by classifying them as medicines.

EU case law on the subject revolves around the fact that many plants, herbs, and foods are medicinal but this does not mean they should be regulated as medicines. For example in the Garlic Judgment (ECJ Judgment of 15 November 2007, Commission v Germany, Case C-319/05, ECR 2007 Page I-09811), the German authorities classified a garlic extract powder capsule as a medicinal product *by function* without taking into consideration the extent of the therapeutic effects of the product. However, the Court confirmed that products containing medicinal plants are not medicinal products *per se*. As it is the case with vitamin and mineral preparations, the ECJ stated that *products which, irrespective of their composition, do not significantly affect the metabolism and do not strictly modify the way in which it functions should not be classified as medicinal products by function*. In the *Garlic Judgment*, the ECJ extended this case-law to botanical foods. The Court held that a garlic extract powder capsule could not be classified as a medicinal product *by function* precisely because its physiological effects were "*no more than the effects of a foodstuff consumed in a reasonable quantity*"; the physiological effects alleged by the German authorities, essentially with respect to the prevention of arteriosclerosis, could also be obtained by ingesting 7.4 g of garlic as foodstuff. Whilst this reasoning might have been motivated because garlic is commonly used as a

foodstuff in its natural state, thereby limiting the legal implications of the ruling, the ECJ later confirmed that this understanding should be extended to virtually all medicinal plants.

EU COURTS RESTRICT THE BANNING OF INGREDIENTS

Some national states in the EU have sought to justify their stricter interpretation of EU directives concerning food supplements and medicines by referring to the so called *'rule of doubt'* provided under Article 2(2) of the Medicinal Products Directive. In this case, they argued that they were justified in classifying a food as a medicine because they were in doubt as to its exact physiological effect. (A similar approach is being used in Australia to compile its 'white' list which MoH NZ has adopted) This approach was also thrown out by the courts who stated that if there is doubt, the authorities themselves must conduct and fund detailed research to justify their position before imposing restrictions on a food. The court ruled that the Medicinal Products Directive *"does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, even if that possibility cannot be ruled out"* (ECJ Judgment of 15 January 2009, Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg, Case C-140/07). In other words, botanical food supplements are presumed to fall out of the scope of the Medicinal Products Directive unless the national authorities, having regard to the entirety of the products' characteristics, prove to the contrary. This principle closed the door to those Member States who rely on the application of the precautionary principle in order to justify the aprioristic or ad hoc classification of "suspicious" (i.e. borderline) products as medicinal products.

2) Violation of Free Speech, Food Choice, and Right To Healthcare

Clause 46 (See (F) below) will prevent the free discussion of the benefits of Natural Products:

It prevents any individual from communicating in any way, even in an email or other personal communication, and even by implication, that any health product that is sold anywhere in New Zealand can assist in the treatment of any health condition unless it is an allowed claim.

This is draconian, absurd, dictatorial, and gross assault on free speech and the communication of matters of fact. We note again that the definition of a **Health Benefit** (Addendum (C) below) can be applied to foods. Therefore the bill will restrict individuals from talking about and sharing the health benefits of foods (see points 9 and 10 below). Alternatively the definition of a **Food** (Addendum (A) below) implies that only 'ordinary' foods can be excluded from regulation and therefore many foods will be restricted. There are approximately 100,000 known edible plants but only 2,500 on the current list of approved ingredients. It is envisioned that this list may grow but it will still exclude a great many exotic plants that are regarded as foods within cultural groups. In any case, the inclusion of an ingredient on the list of approved ingredients still does not allow any individual to claim it benefits health unless a separate costly application has been made and the approval of the Authority granted. **The huge number of edible plants mean that the bill is arbitrarily restrictive and practically unworkable.**

Every time our scientific understanding of the health benefits of everyday foods and plants increases, we will have to pay a fee and go cap in hand to the government to ask permission to speak to one another about it. If they benefit a *serious condition* this permission will be withheld. Therefore Clause 46 restricts the availability of information about potential options for healthcare and products that may benefit health. This is especially important since there are a great many diseases for which modern medicine has no cure (See 5 below). **This will have the effect of restricting the right of individuals to seek a cure for an illness for which modern medicine has no proven curative interventions.**

3) The Bill Discriminates Against Traditional Medicine

New Zealand has become a multicultural society with existing relationships to information and knowledge from a wide range of sources and traditions. To arbitrarily cut off large segments of the population from their traditional medicines (See point 10 below) is a form of cultural and ethnic discrimination that will have implications for the health of large groupings of our population. I will develop this point with reference to Ayurvedic medicine of India as I have expertise in this area, but it equally well applies to Chinese medicine and other cultural medicinal traditions.

Ayurveda is a 3000 year old continuous tradition of medicine. Even today the majority of medical consultations in India are Ayurvedic. There is in India an established system of training for Ayurvedic practitioners. There are universities, colleges, hospitals, professional associations, and manufacturers of Ayurvedic herbal products. There are extensive books of Ayurvedic pharmacopeia, materia medica, training, and practise that include both ancient and modern texts. There are hundreds of modern research papers on the effectiveness of Ayurveda which complement the millennia of successful practice which guarantees its safety and usefulness.

In particular the bill naively assumes that the practice of traditional medicine is carried on by and limited to individual practitioners consulting with individual patients to whom they prescribe a traditional remedy which the practitioner himself prepares for the individual patient (See Addendum (H) below). **This is NOT the case. Yet Medsafe officials are continuing to erroneously brief ministers that the provisions of the bill will not discriminate against traditional medicine** (See point 10 below for specific examples of discrimination and ref: private communication from the Rt. Hon. Peter Dunne MP). In practise, Ayurveda uses multi-ingredient preparations which include common and exotic plant material, minerals, and animal products. In many cases the preparation processes involved are complex, varied, and time consuming and they require fresh, pure ingredients. In India there are family businesses and manufacturing concerns who have sufficient resources to maintain traditional practices as far as the preparation of remedies is concerned. For this reason, Ayurvedic practitioners rely on manufacturing companies and suppliers in India since they have access to locally grown ingredients and can undertake the complex traditional preparation procedures. A similar situation holds for Chinese traditional medicine. There are also medical doctors who use complementary medicine who rely on the availability of these over-the-counter products. The bill as it stands will inhibit this traditional process.

The potential effect of the Natural Health Products Bill on Ayurveda in New Zealand is devastating. A comparison between the common Ayurvedic preparations and the approved list of 5500 ingredients proposed by the Ministry of Health shows that 75% of the multi-ingredient Ayurvedic formulations could be banned or restricted. This will undermine the practice of Ayurveda in NZ as has happened in Australia. The Minister of Health has admitted that there are good grounds to suppose that this will be the case (Ref: private communication from Peter Dunne MP quoting the Minister of Health)

The effect of the bill will be to limit cultural experiences of traditional medicine to consultations with individual practitioners cut off from the wider values of traditional practise. This amounts to a cultural affront and an assault on traditional practises. To put the matter in context, you have to understand that historically Ayurveda has been subject to attempts by the British to eradicate its practise. The British in India destroyed Ayurvedic libraries, educational institutions, and banned its use. Their purpose being to undermine and deter Indian culture and society. The restrictions imposed by this Bill will be viewed in this colonial light.

More recently, there have been attempts by western pharmaceutical businesses to patent Indian plants and their compositions. The reporting conditions mandated by the Bill will be viewed as a channel to hand over propriety traditional information about plants, their medicinal effects, and their preparation and combination to individuals hostile to the interests of Ayurveda. Contrary to assurances given to the House by Dr Jonathan Coleman, the current preparations to implement the bill are being carried out by Medsafe whose officials may have close ties to the pharmaceutical industry. This connection is deeply offensive and damaging to Ayurvedic traditions, practitioners, doctors, and suppliers who wish to protect their cultural heritage. In this regard, the protection of Ayurvedic traditions is also a priority of the Indian government.

4) Risk Assessment

Clause (4) (1) (b) states that: *"the regulation of natural health and supplementary products should be proportionate to the risks associated with their use"*, but Clause (4) (2) says that this *"does not confer any right that is enforceable in a court of law"*. The government has not presented any evidence of historical risk and any test of risk will show that the bill is disproportionate in its regulatory stance. Since no evidence of risk has been presented to parliament, this principle, which has been repeated often to reassure the public that the legislation will be light-handed, amounts to a misleading preamble to the bill. In contrast, the risks associated with approved pharmaceutical products are many orders of magnitude greater. Examination of the MoH draft list of permitted substances and banned substances shows that natural products will be regulated using some methodologies more strict than those applied to pharmaceuticals. For example, some ingredients are proposed to be banned on the basis of a vague reference to a minor adverse effect that is poorly documented and occurred in a single case more than twenty years ago overseas. In some cases these hearsay instances have been imported from overseas literature without investigation of fact. This shows that the implementation of the bill already diverges widely from its core regulatory principles.

There are frequent references to the regulatory principles in the text of the bill which appear to require fairness in the implementation and interpretation of the bill, but since the regulatory principles cannot be enforced in a court of law, these safeguards are meaningless. There are other clauses in the bill which allow the authority too much leeway in making decisions such as Clause 36 (3) (b) (iii) *any other matter that the Authority considers relevant in the circumstances*. This type of codicil tacked on the end of carefully worded provisions effectively create a Henry VIII bill — a highly undesirable circumstance. This is especially concerning since the MoH lacks a demonstrable expertise in Natural Medicine (see Point (8) below). **Clause (4) (2) and other open ended codicils should be removed, since they frustrate natural justice and the rule of law. There is a presumption in the bill that MoH needs to demonstrate a rational relationship between their chosen regulatory stance and assessed risk. Not only has this has not been done, but it has already been ignored.**

In fact, modern allopathic medicines assessed by clinical trials have accepted a far, far greater degree of risk than traditional medicine. **The FDA reported that in 2014 123,000 people in the USA died from the side effects of 'properly' prescribed allopathic medicines, while 800,000 had serious adverse outcomes.** The FDA report also records that adverse reactions to prescription drugs have tripled during the last ten years. Adverse drug reactions are now the third leading cause of death after heart disease and cancer for all age groups. In the UK, one third of hospital admissions for the over 75s are due to adverse drug reactions and one quarter of those patients die as a result. There is no documented case of a death occurring in NZ through the consumption of a natural product. **Therefore according to the core regulatory principles of the bill there is little or no justification for any regulation**

The epidemic of side effects from modern medicine has arisen under a safety process dominated by random controlled trials (RCTs). In most cases serious side effects are not anticipated by the results of clinical trials. It important to note that widespread use over time is considered a better indicator of safety and efficacy than the results of clinical trials even when considering allopathic medicine. RCTs are a poor indicator of safety because they tend to focus only on one or two outcomes, when in fact safety requires an examination of a great number of variables or potential outcomes. This level of safety is only available when long term safe use is verified. This is the case with traditional systems of medicine. In fact, it is far, far safer to take an Ayurvedic medicinal product than it is to consume a bowl of salad. A significant history traditional of safe use is a very good criteria to use when evaluating any products. **There is a need to more fully recognise this in the regulatory processes by removing proposed restrictions on the application of traditional medicine in the treatment of named and serious conditions since it offers complementary value in the treatment of disease** (see Addendum (E) for definition of a *named condition* and Point 7 below)**.**

There is also a danger that the Authority will insist on the completion of RCTs before allowing a health benefit claim for named and serious conditions as has happened in Australia.

5) The Bill is Outdated and Regressive–It fails to support government health policy

One of the key regulatory principles of the bill (Clause (4) (1) (c) (ii)) aims to ensure that the public is accurately informed about the benefits of natural health products. As such, it is evident that the bill aims to improve health outcomes. This is certainly a need of our times, but the bill does almost nothing to ensure this is the case. Instead it burdens and restricts self-help, preventive, healthcare rather than encouraging it and researching it, or funding its proven solutions. It is a missed opportunity out of step with demonstrated public healthcare needs.

BACKGROUND: MODERN MEDICAL PRACTISE IN CRISIS
Modern medical practise took centre stage in the twentieth century, when antibiotic classes of drugs were discovered that miraculously eliminated bacterial infections at the same time as vaccination promised to eradicate viral illness. As a result the concept of ***'gold standard'*** treatments became established in medical thinking. The principle idea being that certain pharmaceutical drugs are the only suitable interventions for certain specific conditions. Medical doctors were enjoined to use only *'gold standard'* treatments, while the use of any other approach to a particular condition came to be regarded as *mal practise*.

In the late twentieth century, this rosy view of pharmaceutical-based medical practice began to erode. Antibiotic resistant bacteria became widely prevalent. It was also realised that many viral illnesses have mutated forms that frustrate efforts to create a single effective vaccine. New virulent illnesses such as HIV emerged that defied our best efforts at cure. At the same time, modern life began to be submerged in rapidly growing epidemics of cancer, heart disease, diabetes, stress, and many other chronic illnesses. In the USA, around 50% of the population now suffer from chronic conditions. As a result, quality of life is being eroded. Increasingly it has been realised that life-style choices, foods, behaviours, and environmental factors play significant roles in the emergence of disease. In fact 80% of health care spending in America is attributable to unhealthy lifestyle choices. These factors also interact with genetic makeup which predisposes individuals to specific illnesses.

Simultaneously the costs of modern medical care have ballooned. Health care costs are rising so rapidly that they threaten to overwhelm both the national budget and individual resources. As a

result, governments and insurance companies have had to ration medical interventions. Pharmaceutical companies and researchers have struggled to keep up with mutating disease-causing micro-organisms and with conditions, like cancer, whose causes are unclear. Vast sums spent on research and development have failed to locate new antibiotics or miracle cures.

Faced with an epidemic of chronic diseases that resist eradication or successful treatment, pharmaceutical approaches to health have tended to become palliative in approach. Relief of symptoms is a more superficial type of medical intervention which has inherent limitations and significant dangers. Many prescription drugs are addictive. Over two million people in the UK are addicted to painkillers. Moreover drugs lose their effectiveness over time and must be taken in greater doses. They also have side effects which require suppressing by other drugs. These drugs may in turn cause other problems and interact adversely with the initial prescription. This is particularly evident among the elderly. It is interesting to note that the pharmaceutical regimes have become so complex that research studies such as those conducted by D. Mangin at Otago Medical School and others show that almost all elderly become more healthy if they cease all medication.

In contrast, research into diet and health is a rapidly evolving field. The pivotal role of food combinations and specific foods in protecting against cancer and other diseases is increasingly being recognised; and the role of diet and alternative health products in DNA repair and immune system protection is an expanding research field that the Ministry of Health Authority cannot hope to keep abreast of (see point (9) below). Plant foods play a role in creating and maintaining our individual epigenetic environment which is also a key factor in promoting health. Molecular shape has been discovered to be a factor in disease creation and prevention. The aetiology of disease is recognised as having multiple determinants within complex physiological and biochemical pathways. Many of these factors, which are in some cases early precursors of disease, are recognised in traditional systems of medicine such as Ayurvedic and Chinese medicine which specialise in maintaining optimum health and preventing of disease.

Modern research is beginning to reveal the complex responses of individual body types to everyday foods. For one person sugar will disrupt the digestive process, for another it will fulfil a useful purpose. It is increasingly understood that custom diets and medicines can target specific problems for particular individuals. This is not news, individuals have been managing their diet for millennia. We all know that one man's meat is another man's poison. Our taste and responses to food assist us in making choices along with publicly available information. In many cases traditional practitioners are leading the field by implementing simple treatments for modern ills that are effective, inexpensive, preventive, and free from side-effects and specifically suited to their individual patients.

These same practitioners will effectively be outlawed from practicing in New Zealand because many of the products that they know to be effective will not be allowed to be sold. Information about health choices will be severely restricted as has happened in Australia. In fact it will become an offence to send any communication in NZ suggesting that a specific natural product can benefit health (see point (2) above) unless it is an allowable health claim. Given that the incidence of chronic illness is ballooning, this is not good news for public health.

In this climate, it has become increasingly untenable to claim that there are 'gold standard' or 'magic bullet' pharmaceutical interventions for chronic or serious conditions which should always be used while other approaches are restricted, an understanding the government appears to promote in close conjunction with the bill (see point (7) below)**.** Many illnesses can be prevented or treated by changes in lifestyle, diet, exercise, etc which are

commonly advocated successfully by traditional practitioners. Alternative and complementary approaches to health have become popular in the public arena. In some countries, main stream medicine is beginning to recognise the value of complementary interventions. Over 75% of US medical colleges now offer courses in complementary approaches. **There is sufficient evidence of their worth to incorporate them in medical practise.** As British economist John Maynard Keynes famously said when he was asked why he switched his position on monetary policy, he uttered the immortal, and possibly apocryphal words "***When the facts change, I change my mind. What do you do, sir?"***

Ayurveda is primarily a preventive system of healthcare. It recognises that imbalance in the body begins through imbalances in thinking, behaviour, food, and the environment. It has forty strategies to restore balance in these four areas. It places great emphasis on food, food preparation, and daily routine. It understands that different foods have different effects on the physiology and it's functioning. Ayurveda classifies these foods and their effects in great detail. Its materia medica mentions over 5000 plants. One of its central principles, written down over 3000 years ago, is as follows: *if diet is incorrect medicines won't work, if correct diet is followed medicine is not necessary.* Recognising that some plants may not be available as foods in the market place, Ayurvedic pharmacopoeia and traditional knowledge categorise and combine foods and preparation processes into traditional multi-ingredient formulae for supplements used in health maintenance and medical interventions. These have a long history of traditional safe use. This is no more strange than the concept of a balanced meal. **This demonstrates that Ayurvedic remedies are in fact foods and should not be heavily regulated. To do so violates our fundamental right to choice of food and food security.** Moreover the planned excessively restrictive regulations contradict statements of ministers that they wish to improve uptake of preventive approaches and self-regulation of health.

In this context, it is important to realise that the bill will impose a financial burden on natural health product suppliers and consumers while the government continues to subsidise allopathic medicines and consultations. This will set in concrete a huge negative imbalance between the known effectiveness of preventive measures and the ineffectiveness and dangers of many pharmaceutical interventions. A pharmaceutical medicine may only cost us $6 at the pharmacy, but it may cost the government thousands, tens of thousands, or even hundreds of thousands of dollars every year in subsidies for each individual taking them. A company producing such a medicine can afford to comply with complex regulations which may run into millions of dollars for even one product. It can use the profits they make through government subsidies to pay for marketing, research, and lobbying on a grand scale (see point (9) below). For example our government recently spent $32 million to stockpile Tamiflu, an ineffective medicine whose manufacturer had suppressed the evidence that it was ineffective. A natural health practitioner offering plant-based alternatives that have been tried and tested for thousands of years has insufficient means to comply with the proposed regulations. There are no huge profit margins in the plant based natural products food chain and therefore the regulatory model proposed under the bill, whereby the user pays, discriminates against the known benefits of traditional medicine.

These points demonstrate a stark contradiction between the stated aims of government policy to improve public health and the content and scope of the bill. This is a huge missed opportunity with significant negative downstream consequences for public health.

6) Rational Decision Tree For The Regulation of Natural Products

This section contains further points on risk assessment and decision processes within the Bill.

Firstly Clause 4 (2) (see Addendum (D) below) is a great concern: the regulatory principles may not be enforced in a court of law and yet they are referred to in subsequent clauses such as Clause 27 (2) (a) (See Addendum (I) below) where they should form a guarantee of a consistent and fair approach to implementation of the regulations. If this cannot be enforced by a court, the bill will not work as law.

If we take the four Regulatory Principles seriously (See Addendum (D) below), products need to be: (a) safe, (b) assessed for risk, (c) accompanied by accurate health information that is (d) backed by scientific or traditional evidence.

I have constructed a decision tree which contains a consistent view on how these principles should work if they are applied rationally and systematically. The information we have received so far from the Ministry of Health does not indicate that they will approach this matter in this way, rather they appear to be prepared to adopt the rulings of the Australian and Canadian authorities which have been made by applying very different legislation from that being offered in the March 16 SOP (see point 10 below).

The important point to note here is that there has been no significant risk associated with the consumption of traditionally used natural products containing plant, mineral, and animal matter.

I present my decision tree below with explanatory notes and references to how it satisfies the regulatory principles. Any decision tree must take into account risk assessment as this does.

RATIONAL DECISION TREE FOR REGULATION OF NATURAL PRODUCTS

1) Does it contain a known dangerous toxin? (important see note 1 below, definition of a toxin)

No - Go to 2

Yes - MoH to submit evidence to prove that this is the case

2) Is it composed exclusively of natural unprocessed edible plant material? (see Note 2 risk assessment and definition of unprocessed below)

No - Go to 3

Yes - exclude from regulation

3) Is it a traditional medicine including plant material and other non-plant ingredients used safely for over thirty years or based on a traditional formulation?

No - Go to 4

Yes - exclude from regulation (see Note 3)

4) Does it contain natural plant extracts obtained through destructive processes?

No - Go to 5

Yes - obtain information and go to 5

5) Is there a history of safe use over the last thirty years?

No - Go to 6

Yes - exclude from regulation

6) Does it contain manufactured or synthetic bio identicals of plant materials or so called active extracted ingredient(s) (see note 6 below)

No - Go to 7

Yes- regulate

7) Does it contain novel synthetic chemicals?

No - Go to 8 Yes - regulate

8) Does it contain permitted minerals in dosages exceeding current statutory limits?

No - Go to 9 Yes - regulate

9) Does it contain vitamins exceeding allowable doses?

No - Go to 10 Yes - regulate

10) Does it contain synthetic biologically active ingredients

No - Go to 11 Yes - regulate

11) Is it produced through genetic engineering or by using some GMO ingredients?

No - Go to 12 Yes - regulate, refer to HSNO

12) Does it contain novel products not included in Q1-11 above?

No - investigate Yes - regulate

NOTES TO THE DECISION TREE

Note 1: DEFINITION OF DANGEROUS TOXIC OR SEVERE ADVERSE EFFECTS
Point one of the decision tree is designed to address Clause (4) 1 (a), i.e. is it safe? When classifying plant materials it is important to be aware of the limitations of designating a plant as toxic. In particular minor alkaloid ingredients of plants are not always toxic in a whole plant even if they may be toxic on their own. It should be the case that if a constituent of a plant or product is flagged as toxic the Authority will need to test the whole plant or product as it is presented for the suspected toxicity before imposing restrictions as the EU courts have ruled (see point 1 above). It also appears that the therapeutic products authorities in Australia, and by proxy MoH here, have in the past been prepared to be very uncritical when assessing reports concerning traditional medicine. Single instances have been felt sufficient to ban products. They have also confused the effect of inadvertent contamination with the effect of the product itself. Anecdotal reports of one or more minor adverse effects are not sufficient reason to impose blanket bans on products without thorough investigation. Food allergies are common. Some nuts are dangerous for some people and beneficial for others. Historically this has not been a reason to ban nuts from sale. Where it is an issue, it has been sufficient to require the manufacturer/supplier to label the presence of possible allergens clearly. The permitted maximum dose of a product should also be stated. Occasionally in traditional medicine, an ingredient that could produce adverse effects on its own in large quantities is entirely safe when used in low concentrations in combination with other ingredients or when prepared in a specific way. Regarding this, traditional use and supporting evidence of safety should be relied upon.

Note 2: RISK ASSESSMENT OF PLANT MATERIAL To date the government has presented no evidence of risk from natural products to justify the bill. In particular having passed step (1) of the decision tree, there is no reason to suppose that plant material poses any risk to health whatsoever. It should be sufficient for the manufacturer to provide evidence that their products are prepared in an environment that protects against contamination. Any attempt

to regulate edible plant material will fall foul of the lack of any definable distinction between a food and a medicine. The only rational way to proceed is to allow edible plant materials to be sold unregulated.

DEFINITION OF UNPROCESSED Preparation of traditional medicines can involve a number of techniques which do not constitute processing. These can include mixing, compressing, dissolving in water or alcohol, extraction of oils through pressing, boiling, decoction, tinctures, etc. They may also include minute quantities of proven safe agents to facilitate the preparation of tablets and the preservation of plant materials. Processing should only be defined as including destructive processes likely to cause chemical changes of composition such as high heat treatment, extraction of active ingredients using catalysts, biological, chemical, or hot fractionating techniques. Mass replication of plant material using bacteria should be regulated.

Note 3: In EU legislation traditional use is consider evidence of both safety and efficacy, recital 5 of the Traditional Herbal Medicines Products Directive (THMPD) (2004/24/EC) states that: *'The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience'*. This logic is also valid for long traditional of use of products for health maintenance.

Note 6: ACTION OF PLANT IDENTICALS
Much has been made over recent years of the creation of chemical or biochemical substitutes for natural ingredients. These are claimed to be identical to the naturally occurring plant components they are designed to imitate. In fact, many bio identicals are significantly different from their naturally occurring relatives in their molecular composition and structure and may have unintended side effects. This area requires regulation. It is also the case that some commercial natural products purport to contain the so called 'active ingredient' of naturally occurring products. An extract of a natural product or a synthetic copy does not necessarily have the same effect as the whole plant. A health benefit claim supported by traditional or scientific evidence based on the consumption of an unprocessed whole plant or specific part of a plant cannot be ported to a highly processed extract without proper investigation and evidence.

7) The Regulations Concerning Allowable Health Claims Need Clarification.

Clause 27 (see Addendum (I) below) empowers the Authority to allow a health claim for a product based on scientific or traditional evidence. Clause 55 (see Addendum (J) below) empowers the Authority to specify the manner in which such a claim can be made. This is open to misinterpretation. In particular, the Authority may, under this clause, decide to adopt the Australian model for assessing claims regarding new ingredients or health benefits. Since 1990, the therapeutic products authority in Australia has allowed only 30 new products to be registered—approximately one each year. The cost of making these applications is significant, approaching $100,000 or more for each ingredient. The requirements to present scientific evidence are significant; RCTs (see point (4) above for a discussion of RCTs and safety) being the standard of scientific evidence required by the Australian authority (TGA). The TGA has consistently stone-walled applications based on traditional use citing the *rule of doubt* (see point (1) above). **Clause 55 is insufficient to ensure that the *regulatory principles* are followed unless procedures such as the decision tree are adopted in law.**

Statements made to the house by MPs speaking on behalf of the government and by the health select committee in its report concerning the second reading (see below) **indicate**

that their intention is that claims of health benefits based on traditional evidence will only be allowed for mild conditions. This point is not discussed specifically in the March 16th SOP. This is such a critical element of the bill that it needs to be addressed specifically in the clauses of the bill (See Preamble (i) above). This is again an indication that the bill as presented is a Henry VIII bill. Regulators may take their cue from discussions in the House and impose conditions outside the text of the bill relying on the many discretionary clauses in the bill.

The Rt. Hon. Simon Bridges statement to the house introducing the second reading of the bill includes the following:

"As initially drafted, the bill prevented any health claim being made that related to a serious condition. Everyone on the select committee agreed that it was important to make sure people were not discouraged from seeking clinical advice when necessary. This is still the intention of the bill.
What was found during the select committee's consideration of the bill was that there is no definition of "serious condition" that worked. Either they were too loose and left the way open for excessive claims to be made, or they were too tight and would prevent claims being made about things like the relief of the symptoms of hay fever. The solution we have found is to allow the regulator to publish a list of conditions that sellers will be able to make claims about. This does not restrict any other claim, just ones about specific conditions. We expect the list to be long. We look forward to working with the Greens and the industry to make sure it is comprehensive."

Note that **no** evidence has been presented that people avoid seeking allopathic help because of advice they receive from natural health practitioners or suppliers. The Rt. Hon Simon Bridges here specifically admits another difficulty with the bill. The select committee found that it was too hard to construct a definition of a *serious condition* and postponed its discussion to inter-party talks which have not taken place since (See Preamble (i) above). This leaves the regulators free to exclude any traditional evidence of health benefits except in cases of mild conditions. It appears that the result will be to misinterpret clause (4) (d) as "scientific and traditional" evidence rather than "scientific or traditional" evidence. The select committee commentary to the second reading of the bill admits this as follows:

"The authority will assess the evidence available, and make a judgement on whether a health benefit claim is reasonable on the basis of the quality of the evidence. However, in the case of some claims for low-risk conditions, the authority is expected to be satisfied with the evidence of traditional use. For example, it is likely that a claim for milk thistle, which has traditionally been used for the treatment of mild digestive disorders, would be accepted."

There is no scientific justification for suggesting that natural health products cannot benefit *serious conditions*. In fact there is overwhelming evidence that they can. For example turmeric and cumin are known to have a strong preventive effect against bowel cancer. There is no natural food that does not benefit a serious condition in some way. Food is life, without food you die (see also point (1) and Preamble (i) above).

For these reasons, it is apparent that some of the major intended effects of the bill are not even discussed in the text of the bill. These intended effects are in conflict with the fundamental regulatory principles stated in the bill and it is admitted that the concepts involved are difficult to define. **The bill should be amended to include clauses that cover and define all the substantive intentions of the legislation.**

8) The Ministry of Health appears to have little interest in natural medicine or competency to pass judgements on natural health methods and products.

There is a suspicion that that permanent members of the Authority will be recruited from within MoH ranks and from Medsafe (see point (3) last paragraph above). Yet the Ministry of Health currently fails the most basic competency assessment tests. The following points have been made to me by one of my colleagues a retired government official:

1. Does the Ministry has a dedicated section for natural health care? No. The Ministry's website lists all its sections. There is no section dedicated to natural health care.

2. Does the Ministry have any staff with natural health qualifications? No evidence of this. (I have requested confirmation from the Ministry but they have not responded.)

3. Does the Ministry subscribe to any natural health journals? No. The list of journals which the Ministry subscribes to, as provided by the Ministry's librarian, does not contain any natural health journals.

4. Does the Ministry invite natural health practitioners to speak to their staff? No evidence of this. (I have requested confirmation from the Ministry but they have not responded.)

5. Does the Ministry send staff to attend natural health conferences and seminars? No evidence of this. (I have requested confirmation from the Ministry but they have not responded.) The natural health care industry often invite Ministry staff to their conferences but my sources (such as the NZ Association of Medical Herbalists) indicate that Ministry staff do not usually attend unless the Ministry personnel are also invited as speakers.

Clearly the Ministry lacks even a basic level of natural health competency. Does the Ministry acknowledge this lack and have a strategy in place to address it? No. The Ministry does not appear interested in natural health. Recently an overseas expert on natural health visited NZ and his local hosts invited the Ministry's senior officials to meet him. The expert has authored 100 published studies in his field, is on the editorial board of several journals, and has been a member of US government natural health advisory boards. No one in the Ministry of Health agreed to meet him.

A group without competency in an industry has the responsibility of regulating that industry!! This situation would be totally unacceptable in any other industry. For example: imagine that the Ministry of Primary Industries as overseer of the fishing industry did not have a dedicated section for fisheries, had no one with qualifications in fishery studies, did not subscribe to any fishery journals, had no interest in fishing, and held the fishing industry in suspicion. Would that be acceptable?

The Ministry's lack of natural health care competency certainly disqualifies it from assessing and regulating the natural health industry. Moreover, the bill as it stands fails to acknowledge the fundamental role that natural products, including foods, remedies, and supplements, already play in maintaining health, nor has the MoH significant understanding of or interest in natural healthcare. There are two paradigms which clash here and fail to understand one another:

(i) The allopathic 'magic bullet' pharmaceutical paradigm healthcare aimed at destroying the pathogen which is still regarded as a 'gold standard' by mainstream medical professionals (see point (5) above), and

(ii) The natural health industry paradigm of primarily preventive measures aimed at strengthening the body's own immunity based on diet, nutrition, detoxification, and lifestyle changes.

These paradigms are, and should be regarded as, complementary, as has happened overseas (see point (5) above). It fact, Sue Kedgeley MP (Green Party) addressed the House as co-sponsor of the original bill to the effect that the Green Party hopes that natural and traditional medicine will be integrated into mainstream medicine for the betterment of our healthcare system as has happened overseas.

"We want to see natural health practitioners working alongside nurses and doctors, using whatever treatment is judged to be most effective, and to see natural remedies and treatments being offered in public health organisations and hospitals."

The current version of the bill ignores this aspiration completely. This may be largely due to conventional medical education whereby doctors spend little time learning about nutrition and prevention, while complementary medicine and natural healthcare are omitted as a topic of study. Proponents of paradigm (i) are proposing to regulate and restrict the application of paradigm (ii) in which they lack interest or expertise without presenting any supporting evidence of just cause. **The bill will restrict the application scientific advancements in preventive healthcare which are based on plants. This will have the effect of propping up the current allopathic monopoly of aspects of government healthcare thereby imposing major limitations on potentially significant gains in public health, quality of life, longevity , and very significantly the costs of our healthcare system.** (See point 9 below).

9) Inappropriate definition of a natural health product

In recent years, there has been an explosion and significant evolution of published research on foods and their health benefits. To gauge the huge extent of this research, google "turmeric and pubmed" or "ginger and pubmed", or in fact any other common food recognised as healthy. Consequently the public and health professionals are in possession of great deal more information concerning specific health benefits of foods. There are articles in the main stream media appearing pretty much daily, sharing information about these studies. An article may say that ginger is beneficial for migraines or that daily consumption of turmeric is a preventive for bowel cancer and a boost to the immune system. **This does not mean, as our government apparently has come to believe, that classes of foods have suddenly become medicines that need close regulation as a separate class of natural health products** (See point 10 below). Foods have always been healthy. It is simply the reflection of a growth of information and an ongoing process of scientific discovery. Moreover research is expanding so rapidly that no government regulator could hope to keep abreast of it. As we have already said in the Preamble above, it is simply a matter of fact and scientific enquiry which has its own standards.

However, some industrial producers of medicines, vitamin and mineral health supplements, and processed foods have looked carefully at the growth of scientific information about the health benefits of foods. They have decided that there is a rapidly growing market and resulting commercial opportunity for nutraceuticals (see the following). They wish to capture this market. These producers are already highly regulated and they realise that a high degree of regulation will leave them ideally placed to monopolise the production and sale of synthetic copies of foods and/or extracted so-called 'active' ingredients of common foods that can be marketed as conferring a health benefit (commonly known as nutraceuticals). Their experience in Australia has been that small scale producers of truly natural products and healthy foods have been

unable to meet the costs of regulation nor surmount the other barriers that regulation imposes. We note again that proven health benefits of foods, should not be allowed to be ported to synthetic copies and so-called active ingredients without separate investigation.

A major error in drafting the new legislation has been to lump together two very different kinds of products: (i) Truly natural products made of plants, animal products, and minerals, and (ii) products described as *'natural'* which contain synthetic substances and additives. These two types of product carry completely different risks. The definition used by the bill (See Addendum (B) Schedule 1 below) includes both types. This is a fundamental error, the first type of product is really natural, the second can contain an unlimited range of substances which are not natural and are more rightly described as nutraceuticals. **Thus the bill starts off on the wrong foot. It assumes products described as 'natural' are all members of a single class of product. This is not the case.** Natural medicine that really is 'traditional' falls in the first category. If the principle of 'proportionate' risk is followed, remedies that have been prepared traditionally do not need excessive regulation. If synthetic substances and additives are used, it is not traditional. My decision tree takes full account of this. If it is adopted, truly natural products with a history of safe use will not be disadvantaged. If it is not adopted, truly natural products will be subject to unnecessary regulation and many small natural products companies will be forced to cease operation. **Moreover the bill's current definition of a natural health product will confuse the public by allowing a broad range of synthetic substances to be described as natural.**

The MoH list of 5500 approved natural health product ingredients includes 3000 chemicals or synthetics. In effect the draft permitted ingredient list will change the way the public understands the word 'natural'. These chemicals and synthetics would formerly have been found predominantly in supplements and vitamin pills. Now under the proposed bill, they will be liable to be claimed as 'natural' thereby debasing the common meaning of the term. This is in conflict with **Clause (4) 1c ii** *that natural health and supplementary products should be accompanied by information that is accurate* and informs consumers. **This is a matter of the public's right to choose.** Whatever is argued about the scientific difference or similarity between plants and their synthetic copies, it remains true that there are a great many people who hold that there is a significant difference and wish to choose accordingly. They are entitled to do so for their own reasons and the information should not be obfuscated as this bill will do.

10) The Australian and Canadian lists used by the Ministry of Health as the basis for its list of permitted ingredients were compiled using methodologies in conflict with the regulatory principles.

The basic assessment process used in Australia by the TGA has ignored safe history of use in favour of the scientific identification of the constituent molecular substances found in a plant. If any constituent substances such as alkaloids, etc are known to have effects on their own, which are considered to be undesirable, restrictions have been applied including outright bans, restrictions on dose, maximum permitted alkaloid content, restrictions on which parts of a plant may be used, and restrictions on use. Essentially, the flaw in this methodology is that a whole plant does not act in the same way as all of its dozens of molecular parts might act separately.

I have examined a list of 340 commonly used ayurvedic herbs and compared them with the list of 5500 permitted ingredients so far approved by the MoH in preparation to implement the Natural Health Products Bill. Of these 340 herbs, 25% have already had restrictions imposed on their use. Restrictions have been imposed using a faulty methodology. For example under the

Natural Health Products bill the following common kitchen foods and well known folk remedies will soon be restricted in various ways:

- Aloe Vera
- Cardamon
- Betel Nut
- Neem
- Mustard
- Tea
- Coconut
- Almond
- Castor
- Tamarind
- Valerian
- Grape

The fact that Australian and/or Canadian investigators have restricted commonly used foods, spices and remedies available in local supermarkets, shows that a methodology has been used that is very different from that mandated in the NZ bill. In particular, **Clause (4) 1d** states that *health benefit claims made for natural health and supplementary products should be supported by scientific or traditional evidence*. If a requirement to accept traditional evidence had been applied, the above common ingredients and others would not have been restricted.

The decision to adopt the Canadian and Australian lists is highly prejudicial to the regulatory principles and clear intentions of the Natural Health Products Bill.

(a) The fact that 25% of commonly used ayurvedic ingredients are already restricted means that traditional medicine is being restricted from the outset. **This means that some companies will be forced to close as soon as the bill comes into force.** This conflicts with the intent of the bill to apply only 'light-handed' regulation that will enable the practice of traditional medicine to continue.

(b) Since the above data is compiled by examining only 6% of the total number of ingredients that the MoH has listed, it is clear that there will almost certainly be many other unintended impacts of the draft list of approved ingredients **including detrimental impacts on traditional Chinese medicine.**

(c) MoH may argue that the effect of the methodology adopted by the TGA in Australia will fulfil the purpose of Clause (4) 1a *that natural health and supplementary products should be fit for human use*. This is not the case, since as we have argued elsewhere in this legal brief (see point 5 above), a history of safe use is a better indicator of safety that RCTs and other approaches to safety. Moreover the bill recognises this is the case by mandating that scientific **or** traditional evidence be accepted.

(d) MoH may argue that any conflict between the intent of the bill and the draft list of permitted ingredients may be ironed out using the appeals and review process, but the timeframe of two months allowed for free applications and the timeframe proposed to bring the bill into operation are very much too short to achieve this. The shear number of ingredients on the list mitigates against the common sense and practicality of persisting with this approach. Moreover the approach currently adopted by the MoH to place ingredients on a pending list if there is any appeal, may force companies to close in the interim. **Rather the MoH should recognise that the draft list of permitted ingredients is in conflict with the bill and should be disqualified.**

Conclusion

Although the stated intention of the bill is a light-handed approach to the regulation of natural health products, it is a poorly drafted bill. From a constitutional perspective it is a prime example of worrying over-reach in recent NZ legislation:

- ***It empowers unfettered regulation.***
- ***It distorts matters of fact.***
- ***It restricts communication of information.***
- ***It protects and promotes powerful commercial interests.***
- ***It expands the nanny state without just cause.***
- ***It stifles truly natural alternatives***

Of these, the distortion of fact and suppression of information have the hallmark of the autocratic state. It sends a now familiar message that we, the government, know better than the public and we are prepared to ignore the facts, restrict information, and turn a deaf ear to dissenting voices however many they may be and however cogent their concerns. It underscores the passing of an old-fashioned conception of democracy that the government has a duty of care to <u>all</u> the people rather than just its perceived constituency. It speaks of a slavish devotion to limited conventionalities, staid habits, and commercial interests despite the fact that we live in a rapidly changing world. As British economist John Maynard Keynes famously said when he was asked why he switched his position on monetary policy, ***"When the facts change, I change my mind. What do you do, sir?"***. We urge the government to change its mind about this demonstrably poor and unfair bill which ignores some very obvious facts, fetters choice, and restricts a rapidly evolving body of scientific knowledge concerning specific foods and their substantial contribution to the prevention of disease and the promotion of health.

In summary, the bill in its present form:

- Is unnecessary, other legislation already covers the areas it seeks to regulate
- Confuses foods, natural products, and medicines, and their effects
- Classes synthetic chemicals under the term *natural* which will confuse the public
- Poses obstacles to matters of fact, scientific enquiry, and everyday communication
- Has a provision that prevents redress in a court of law for inconsistencies
- Fails to define rational procedures to fulfil its aims including proportionate risk
- Imposes out-dated restrictions on health care, self-care, and preventive health care
- Makes an arbitrary and undefined distinction between mild and serious conditions
- Inhibits the practice of traditional medicine and the availability of cultural foods
- Is a Henry VIII bill which fails to protect the public from arbitrary restrictions
- Confers a commercial advantage on large-scale manufacturers of nutraceuticals
- Has allowed the MoH to adopt a permitted ingredient list inconsistent with the bill

This legal brief was prepared by Dr Guy Hatchard, formerly director for the Natural Product Industry sector at Genetic ID. Genetic ID is a global food testing company.

Please contact <u>ghatchard@gmail.com</u> for more information

Addendum

Extracts From the Natural Health Products Bill, SOP No. 158 dated 15th March 2016 to be considered by the Health Select Committee

(A) Food means anything that is ordinarily used or represented for use as food or drink for human beings.

(B) A natural health product means any product that—
• is, or is represented as having been, manufactured for human use and for the primary purpose of bringing about a health benefit to users; and
• contains, or is represented as containing, only natural substances; and
• is not a food, or is not presented as a food; and
• is not or does not contain a medicine listed in Schedule 1 of the Medicines Regulations 1984 or a psychoactive substance.

natural substance means any substance or class of substance listed in *Schedule 1*

Schedule 1
Suitable Natural substances

1 A plant or a plant material, an alga, a fungus, a mineral, or a non-human animal material
2 A substance or mixture of substances—
(a) obtained by expressions, extraction, distillation, purification, or a traditional preparation of a material described in **item 1**; and
(b) not subject to any other process involving chemical transformation other than hydrolysis or electrolysis
3 A vitamin or provitamin, including salts and other compounds, of the following types:
vitamin A
vitamin B1
vitamin B2
vitamin B3
vitamin B5
vitamin B6
vitamin B12
vitamin C
vitamin D
vitamin E
vitamin K
biotin
choline
folate
4 A synthetic equivalent of any substance specified in item 2, 3, or 8
5 A mineral compound
6 A micro-organism, whole or extracted, except a vaccine
9 An additive
10 A formulation aid.

(C) Health benefit means any 1 of the following benefits:
(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

(D) Clause 4. Regulatory principles
(1) This Act is based on the following principles:
(a) that natural health and supplementary products should be fit for human use:
(b) that the regulation of natural health and supplementary products should be proportionate to the risks associated with their use:
(c) that natural health and supplementary 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 and supplementary products should be supported by scientific or traditional evidence.
(2) Subsection (1) does not confer any right that is enforceable in a court of law.

(E) Named conditions
(1) In this Act, named condition means any disease, disorder, condition, ailment, or defect that is listed or described in the *International Statistical Classification* of Diseases and Related Health Problems (the ICD) published by the World Health Organization, as amended from time to time by that organisation.

(F) Clause 46 Offence to publish certain advertisements relating to natural health products
(1) A person must not publish or cause to be published (either on that person's own account or as the agent or employee of the person seeking to promote the sale) any advertisement that:
(c) includes any health benefit claim that directly or by implication states or suggests that a natural health product for sale in New Zealand is able to treat or can assist in the treatment of a named condition.
(2) Subsection (1)(c) does not apply if—
(c) the advertisement is distributed solely to persons claiming to be available for consultation by other persons for therapeutic purposes (within the meaning of section 4 of the Medicines Act 1981) and to persons privately consulting them.
(4) In subsection (1), **publish** means—
(a) insert in any newspaper or other periodical publication printed or published in New Zealand; or
(b) send to any person by post or otherwise; or
(c) deliver to any person or leave upon premises occupied by any person; or
(d) bring to the notice of the public in New Zealand by broadcasting within the meaning of the Broadcasting Act 1989; or
(e) bring to the notice of the public in New Zealand in any other manner.

(G) advertisement—
(a) means any words, whether written, printed, or spoken, and any pictorial representation or design used or appearing to be used to promote the sale of any natural health product; and
(b) includes any trade circular, any label, and any advertisement in a trade journal

(H) Clause 22 Natural health products that do not require product notification
The following natural health products do not require product notification:
(a) any natural health product that—
(i) is made by a person (person A) who claims to be available for consultation for

therapeutic purposes (within the meaning of section 4 of the Medicines Act 1981); and

(ii) is made to be administered to an individual after being requested by or on behalf of the individual that person A use his or her own judgment as to the treatment required

(I) Clause 27 Authority may determine allowable claims

(1) The Authority may, on its own initiative or on application by any person,—

(a) determine, in accordance with subsections (2) and (3), that a health benefit claim for a natural health product or class of natural health product be an allowable claim; or

(b) determine, in accordance with subsection (4), that 1 or more health benefit claims be an allowable claim.

(2) In determining whether a health benefit claim for a natural health product or class of natural health product should be an allowable claim, the Authority must—

(a) be guided by the regulatory principles; and

(b) consider, subject to subsection (3),—

(i) the nature and quality of the evidence provided in support of the claim; or

(ii) if the Authority is determining the matter on its own initiative, the nature and quality of the evidence before the Authority; and

(c) be satisfied that the level of risk associated with use of the natural health product or class of natural health product is low.

(3) If any traditional evidence provided to or before the Authority in support of a health benefit claim is a reference to information contained in an approved pharmacopeia,—

(a) the Authority must accept the reference as evidence if satisfied that the information to which it refers is relevant to the health benefit claim; and

(b) subsection (2)(b) does not apply to the evidence.

(4) In determining whether 1 or more health benefit claims should be an allowable claim, the Authority must—

(a) be guided by the regulatory principles; and

(b) be satisfied that the level of risk associated with allowing the health benefit claim or claims to be made is low.

(5) The Authority must publish on an Internet site maintained by or on behalf of the Ministry—

(a) a list of allowable claims determined under subsection (1)(a) and the natural health product or class of natural health product for which each claim is made; and

(b) a list of allowable claims determined under subsection (1)(b) and the named condition or class of named condition to which the claim or claims may relate.

(6) An application under this section must be made in the manner specified by the Authority (*see* section 55).

(J) Clause 55 Manner in which product notification and certain applications must be made

(1) The Authority must, by written notice, specify—

(a) the manner in which a product notification must be completed, including the manner in which information referred to in section 25(3)(b)(i) must be provided:

(b) the manner in which an application under section 14, 27, 37, or 60 must be made.

(K) A draft list of mild health conditions for which an application may be made to register an allowable health claim is available from the MoH natural health products bill website.

ENDS