Preliminary Notes

1. We've coded the clause headings in the following way so you can determine if you will answer all, or some of the clauses.

2. The most alarming of the clauses have a double astrix by them in purple. The alarming or unacceptable clauses are in purple and the unacceptable clauses (but not so alarming) are in black.

3. Then we have listed the exact working from the Bill, made it it bold big text, and put the offending words in red. Underneath each clause are our comments that you can use to formulate your own.

4. You will note that after many of our clauses we have added something like:

   Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's (non government organizations) have unanimously agreed on. Please do what you said you would do and implement these recommendations found on page 18 & 19 of the Joint Industry NTHP's Bill Feb 2009. (pages change depending on the clause).

5. We would like you to add that paragraph but in your own words, after every comment we have to point the Government back to the statements they agreed to implement.

6. **THESE COMMENTS ARE IN NOTE FORM, IN NO WAY SHOULD THEY BE COPIED**. YOUR ORIGINAL COMMENTS ARE REQUIRED. Use our notes only as a guideline to formulate your comments.

Thanks.

List of Objectionable Clauses

1. General Policy Statement Page 1 –
2. Part 1 Preliminary Matters Clause 4 Page 12 – Principles
3. Part 1 Preliminary Matters Clause 5 (e) Page 13 – Interpretation
4. Part 1 Preliminary Matters Clause 5(a) & (b) Page 14 – Interpretation
5. **Part 1 Preliminary Matters Clause 6(1)(a)(i)-(iii) & (2)(iv)(b)(c) Page 14 & 15 – Interpretation
6. **Part 1 Preliminary Matters Clause 8 (2) Page 15 – Natural health product regulatory authority
7. **Part 1 Preliminary Matters Clause 9 (1) (3)(a) & (b) Page 16 – Authority may declare recognised authorities
8. Part 1 Preliminary Matters Clause 10 (1), (3), (4) & (6) Pages 16 & 17
9. Part 2 Regulation of Natural Health Products Clause 13 (8)(a) Page 18
10. Part 2 Regulation of Natural Health Products Clause 16 (1) & (2)(b) Page 19
11. Part 2 Regulation of Natural Health Products Clause 20 (1), (2), (3)(b)(i) & (iii) & (4)Page 21
12. Part 2 Regulation of Natural Health Products Clause 21(1) & (3) Pages 21 & 22
13. Part 2 Regulation of Natural Health Products Clause 22(1)(a) & (b) Pages 22- New Ingredients
14. Part 2 Regulation of Natural Health Products Clause 24 Page 24 – Labelling
15. Part 2 Regulation of Natural Health Products Clause 27(1), (2)(a) Page 25 - Code of practice for manufacture
16. Part 2 Regulation of Natural Health Products Clause 28(1), (2)(a), Page 25 – Licence to manufacture
17. Part 2 Regulation of Natural Health Products Clause 29 (2)(a), (3)(a)(i) & (ii), (d) & (4)(a)Page 26 – Application for licence to manufacture
18. Part 2 Regulation of Natural Health Products Clause 30 (2) Page 26 – Conditions of licence
19. Part 2 Regulation of Natural Health Products Clause 35 (2) Page 27 - Authority may prescribe fees
20. **Part 2 Regulation of Natural Health Products Clause 36, 37 & 38 Page 28-30 - Sanctions and penalties
21. **Part 2 Regulation of Natural Health Products Clause 40(1)(a) & (b) Page 30 - Sanctions and penalties
22. **Part 2 Regulation of Natural Health Products Clause 44(a) & (b) – Recall natural health products

23. Part 2 Regulation of Natural Health Products Clause 45 (1), (2)(a)-(d) & (3)(a) & (b) Page 32 & 33 – Delegation

24. **Part 2 Regulation of Natural Health Products Clause 47(1)(a)-(l) Page 34 – Regulations

25. **Natural Health Products Bill Schedule / Schedule 5, 20(1), 22(1), 47(1) / Suitable classes of substances

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Notes to help draft Submissions.

General Policy Statement Page 1 –

"The Natural Health Products Bill establishes a system for the regulation of low-risk natural health products in New Zealand."

Suggesting here that there is high risk natural health products? Given that there have been zero deaths around the world, what natural health products are high risk? None. This bill should cover all natural health products "which we recognize have low risk".

(**Note to HFNZ Members Only**: Publicity has been given to the so called dangers of Vitamin A, E and certain herbs. By default a doorway is open here in this definition to exclude therapeutic grade products that the MOH could deem at any time High Risk, which fall under the Medicines Act - thereby making them illegal drugs unless some pharmaceutical company makes them, synthesizes them, so they can patent them, to justify the high cost of registering a new drug – clear as mud?)

This should be amended to say "regulation of natural health products in New Zealand".

Part 1 Preliminary Matters Clause 4 Page 12 - Principles

"This Act is based on the following principles: "

Principles too narrow.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's (non government organizations) have unanimously agreed on. Please do what you said you would do and implement these recommendations found on page 22 on principles, of the Joint Industry NTHP's Bill Feb 2009.

Part 1 Preliminary Matters Clause 5 (e) Page 13 – Interpretation

"Health benefit means any 1 of the following benefits:

(e) relief of symptoms of any condition that is not a serious condition "

Unacceptable. Is not the relief of symptoms of a serious condition a health benefit? Why the discrimination of serious illnesses? That restricts my right as a consumer to choose what medicine I want or not, consistent with my rights protected under the Bill of Rights of which New Zealand is a signatory.

Since there is a history of safe use, no deaths, of any natural health product therapeutic or other, why can't consumers choose to relieve their symptoms of ANY condition as a matter of right protected by the Bill of Rights?

This exclusion (e) breaches the Bill of Rights of which New Zealand is a signatory. **New Zealand should not be creating regulations that breach the Bill of Rights.**

Part 1 Preliminary Matters Clause 5(a) & (b) Page 14 – Interpretation

"Natural health product ingredient means any substance that—

(a) belongs to a class of substance that is listed in the Schedule; and

(b) is declared by the Authority to be a natural health product ingredient under section 20"

(a) & (b) Implies a white list which has been rejected by thousands of consumers who marched the streets against ANZTPA. Whether an ingredient is natural or not is self evident. Don't need a list that declares whether a product is natural or not. Our current black list approach is what I want. I marched against the white list approach and will march again if I have to.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's (non government organizations) have unanimously agreed on. Please do what you said you would do and implement these recommendations found on page 18 & 19 of the Joint Industry NTHP's Bill Feb 2009.

Part 1 Preliminary Matters Clause 6(1)(a)(i)-(iii) & (2)(iv)(b)(c) Page 14 & 15 – Interpretation

"Definition of natural health product

(1) In this Act, unless the context otherwise requires, a natural health product means a product—

(a) that is intended by the sponsor of the product—

(i) to be administered to a human being; and

(ii) to bring about a health benefit to the person to whom the product is administered; and

(iii) to be administered by any of the methods specified in subsection (2); and

(iv) not to be administered by any of the methods specified in subsection (3);

(b) application to the eye:

(c) application in the ear."

With the exception of Intravenous products that do need to be manufactured under GMP, the form of administering to a human being should not determine whether or not the product is natural. The biological state of the product should be the determining factor.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's (non government organizations) have unanimously agreed on. Please do what you said you would do and implement these recommendations found on page 18 & 19 of the Joint Industry NTHP's Bill Feb 2009.

(b) and (c) exclusions means saline eye solutions, homeopathic remedies and essential oil products, with NO history of ever causing harm, will be unnecessarily regulated as drugs under the Medicines Act which is not acceptable. Predjudice, discrimination, high entry and compliance cost, the fact that a natural product can't be patented act as barriers for these products to be regulated at all using a Pharmaceutical model. This will restrict access to perfectly safe natural health products, that at not time, have every caused harm or death – unlike approved drugs.

Part 1 Preliminary Matters Clause 8 (2) Page 15 – Natural health product regulatory authority

"(1) This section establishes the Natural Health Products Regulatory Authority.

(2) The Authority is the Director-General of Health."

UNACCEPTABLE: As the entire Bill on the Authority is written, The Director-General of Health (DGH), an unelected bureaucrat, holds complete power as the 'Authority'; Is this the Governments intention to set up an unaccountable autocratic system?

the office of the Authority is a maximum (no minimum) of 8 members (see clause 10(2) which are appointed under any terms and conditions that DGH thinks fit.

The DGH has the power to delegate to any corporate (aka person) any powers, functions or duties (see clause 45)

and they can then delegate to anyone they see fit (see clause 45 (3).

This includes the power to demand that any natural health product be recalled and disposed of in any time and manner for a mistake on the label (see clause 44(a), (b).

The Joint Industry Proposal, which has been agreed upon unanimously by consumers groups, NGO's and Industry, is the acceptable structure. Please refer to this document and insert the necessary changes.

Part 1 Preliminary Matters Clause 9 (1) (3)(a) & (b) Page 16 – Authority may declare recognised authorities

"Before declaring a person or body to be a recognised authority for a specified purpose under this Act or provision of this Act, the Authority must be satisfied that the person or body (whether in New Zealand or any other country)—

(a) makes decisions in respect of natural health products that require the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act; or

(b) is engaged in an area of work that requires the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act."

(This is a doorway to bring in the TGA regulators as in NZ we don't have that type of experience.) Vague and unclear as to whether the authority you are referring to is other regulators as say 'person or body'. If all those who act in authority in any capacity as advisors, technical staff have to have experience as a regulator that is not acceptable. Regulators are not always qualified to be an authority on natural products.

If this yard stick is used to measure other 'specified purposes' that relate to the advisory board, technical advisors and committees, then that excludes people in the Natural Health Industry in New Zealand since we have no such staff with any such experience, because this is new legislation. Not acceptable.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's (non government organizations) have unanimously agreed on. Please implement the recommendations found on pages 18 through 24 of the Joint Industry NTHP's Bill Feb 2009.

Part 1 Preliminary Matters Clause 10 (1), (3), (4) & (6) Pages 16 & 17

"Natural health products advisory committee

(1) The Authority must establish an advisory committee to provide expert advice to the Authority on matters referred to it by 25 the Authority.

(3) The members of the committee must be appointed by the Authority on any terms and conditions that the Authority thinks fit.

(4) In appointing members of the committee, the Authority must ensure that each member has expertise in at least 1 area of knowledge that relates to or is relevant to natural health products.

(6) The committee may, subject to any provision in this Act, the regulations, and the terms of reference, determine its own procedure.

(The Authority in this case is the Director General of Health who is usually a Big Pharma lacky – one man or woman) Too vague. "any terms and conditions that the Authority thinks fit", is not acceptable and too open to corruption. Anyone on the authority must be qualified and not a self professed 'expert'.

FYI: Dr Kevin Woods is currently the Director-General for Health having been the chief executive of the National Health Service (NHS) in Scotland. Dr Woods had held senior health management roles in England and Scotland since 1990. He has played a leading role in the development of health policy in Scotland. **Has a PhD and Bachelor of**

Science (Honours) in geography from the University of London. Not the most qualified person to autocratically write regulations for natural health products.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations found on pages 18 through 24 of the Joint Industry NTHP's Bill Feb 2009. It would save them a lot more money.

Part 2 Regulation of Natural Health Products Clause 13 (8)(a) Page 18

"In this section, evidence means either of the following types of evidence, each of which must be consistent with any prescribed standard:

(a) scientific evidence:"

Scientific evidence is subjective. The current structure of what is considered 'scientific evidence' is not scientific when applied to natural health products, and discriminates against NHP's because it is formulated specifically for testing dangerous and toxic pharmaceutical drugs.

In 2007 The British Medical Journal's Clinical Evidence report published findings that of the 2,500 common medical treatments evaluated, **only 13 percent of them had sufficient reliable evidence to be beneficial.** Yet ALL medical treatments from drugs to procedures are considered to have proper 'scientific evidence' backing their inclusion into the medical system. The system is fraught with corruption. Apply this inappropriate yard stick to natural health products and you are creating an authority that is open to corruption.

In 2005 "Nature" (one of the most prestigious science journals in the world) titled 'Scientists Behaving Badly', found as much as 20% of scientists admitted to changing the methodology, design or results of their study because of pressure from the funding body. Yet these scientific studies are accepted as scientific evidence.

Precisely what scientific evidence will be the yard stick here? The 87% of studied medical treatements found to have no benefit or no sufficient reliable evidence? Or the 20% of studies that are fraudulent?

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations found on pages 18 through 29 of the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 16 (1) & (2)(b) Page 19

"Authority may suspend or cancel product notifications

(1) The Authority must, as soon as practicable, suspend the product notification of any natural health product that the Authority has reasonable grounds to believe has caused, is causing, or is likely to cause harm to any person.

(2) The Authority may suspend a product notification if—

(b) The Authority has reasonable grounds for concern because of new information about the safety, quality, health benefit claims, or manufacturing standards of the natural health product."

Hearsay, concern, belief, reason and 'new information' are unscientific and not grounds for suspension. It's too vague and leaves the foundation of the Authority open wide to corruption.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations found on pages 23 through 29 of the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 20 (1), (2), (3)(b)(i) & (iii) & (4)Page 21

"Ingredients of natural health products

Authority may declare substances to be natural health product ingredients

(1) The Authority may, for the purpose of this Act, declare any substance that belongs to any class of substance listed in the Schedule to be a natural health product ingredient."

(1) the proposed schedule reads more like the TGA white list. Essentially a bureaucracy should not declare whether or not something is natural. Nature should. Door open here for them to declare GM and GMO ingredients to be natural health product ingredients based on 'recognized authorities like Codex.

(FOR YOUR INFO HEALTH FREEDOM MEMBERS from the JIP

3. Definitions

(a) 'Natural and Traditional Health Product' means:

i. A product intended to provide a health or nutritional benefit and intended for oral, nasal, or topical use or use via enema, but not intravenous, intramuscular, or subcutaneous use, and

ii. Containing one or more 'Natural or Traditional Health Product Ingredients' and necessary acceptable excipients.

"(2) The Authority may impose restrictions on the use of any substance it has declared to be a natural health product ingredient."

(2) on what grounds are restrictions of use being made? Too vague, not enough details. This is the power the TGA has. We don't' want that here, it was rejected by a large number of New Zealanders who took to the streets against ANZTPA, Since no one has ever died of a natural product in decades of use, no restriction of use is needed to the products currently on the market.

"(3) In considering whether a substance should be declared a natural health product ingredient, the Authority—

(b) must have regard and give weight to, as it considers appropriate, the following:

(i) whether a recognised authority permits the use of the substance in a natural health product and, if so, whether it imposes any restrictions on the use of the substance:

(ii) whether the substance is recognised in traditional medicine or pharmacopoeias:

(iii) any other matter that the Authority considers relevant in the circumstances."

Not Acceptable. Too open to corruption of other regulators around the world contaminating New Zealand regulations.

"(4) Every substance declared to be a natural health product ingredient must be listed on the natural health product database along with any restrictions on the use of the substance. "

White list has been rejected. Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations found on pages 18 & 19 of the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 21(1) & (3) Pages 21 & 22

"Prohibited ingredients

(1) The Authority may, for the purpose of this Act, declare a substance to be a prohibited natural health product ingredient.

(3) Every substance declared to be a prohibited natural health product ingredient must be listed on the natural health product database.

Unnecessary bureaucracy. We already have a list of poisons. Having a prohibited natural health product ingredient list is tantamount to a white list approach which has been rejected. If it's a natural 'health' ingredient that is not on the poisons list, why does it need to be prohibited?

What purpose are you trying to serve here? Makes no sense. If it's a toxic substance that is natural it belongs on the current poisons list. No extra list is needed. Save money, red tape and unnecessary bureaucratic process.

White list has been rejected. Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 22(1)(a) & (b) Pages 22- New Ingredients

"If new ingredient intended for use in natural health product

(1) In this section and section 23, new ingredient means any substance that belongs to a class of substance listed in the Schedule and that is not—

(a) a natural health product ingredient; or

(b) a prohibited ingredient."

This could pave way for GE, GMO and non bio-identical ingredients to be added to a natural product that fit into the class of substance listed in the Schedule. Not acceptable. A new ingredient should be either natural or bio-identical.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 24 Page 24 – Labelling

"A natural health product that is distributed in New Zealand must comply with the labelling requirements prescribed in regulations. "

Where are those regulations? Too vague. Signing a blank check is unacceptable. Writing the regulations after the law is passed in unacceptable since the righting of that law is going to be one man – the Director General of Health and anyone he passes his power on to and anyone they pass there power's on to. ANY ONE?! See clause 45.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on page 31 through 34 in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 27(1), (2)(a) Page 25 - Code of practice for manufacture

"(1) The Authority must establish a code of practice for the manufacture of natural health products.

(2) In developing the code and any amendments to the code, the Authority must—

(a) comply with any requirements relating to the content of the code that is prescribed in regulations: "

What is that code? Where are the regulations? Too vague. Agreeing to something before we know what we are agreeing to not acceptable. Since codes of manufacturing already exist there is no need for costly reinvention of the wheel.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on page 29 & 30 in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 28(1), (2)(a), Page 25 – Licence to manufacture

"Licence to manufacture natural health products (1) A person must not manufacture a natural health product without a licence to manufacture granted under section 29."

Regulations are not included in this Bill. Too vague. Signing a blank check is not acceptable. Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on page 29 & 30 in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 29 (2)(a), (3)(a)(i) & (ii), (d) & (4)(a)Page 26 – Application for licence to manufacture

"(2) The Authority may grant a person a licence to manufacture natural health products if—

(a) the Authority has conducted an audit of the manufacturing facilities and is satisfied that the facilities meet the requirements of the code; and (b) the Authority is satisfied that the person is a fit and proper person to hold the licence.

(3) In determining whether a person is a fit and proper person to manufacture natural health products, the Authority must take into account the following:

(a) (ii) any offence specified in the regulations:

(d) any other matters that the Authority considers relevant."

What code? Where's the code? Regulations are not included in this Bill. Too vague. Signing a blank check is not acceptable. Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement

these recommendations on page 29 & 30 in the Joint Industry NTHP's Bill Feb 2009.

"(4) A licence to manufacture remains in force for 3 years after the date that it is granted, unless—

(a) the Authority specifies a shorter period for the licence; "

Why only 3 years? This feels like TGA open door to corruption to me? Based on what grounds do they shorten it? Unnecessary red tap and compliance costs leads to expensive products. Auditing process should take care of issues.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on page 29 & 30 in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 30 (2) Page 26 – Conditions of licence

"(2) The Authority may, when granting a licence to manufacture, impose conditions on the licence as the Authority thinks fit."

Shouldn't there be guidelines for this? Too open to corruption. Blank check. This is TGA in drag.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on page 29 & 30 in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 35 (2) Page 27 - Authority may prescribe fees

" (1) The Authority may, by notice in the Gazette, prescribe fees payable in respect of any notification, application, notice, certification, audit under this Act.

(2) For the purpose of ensuring that any fee prescribed under subsection (1)"

Guidelines for those fees should be in the Bill. Too vague. Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations in the Joint Industry NTHP's Bill Feb 2009 on fees being proportionate to turnover so as not to disadvantage smaller businesses with a substantial list of products.

Part 2 Regulation of Natural Health Products Clause 36, 37 & 38 Page 28-30 - Sanctions and penalties

"36 Deception

(3) A person who commits an offence against subsection (1) is liable,—

(a) in the case of a body corporate, to a fine not exceeding $500,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $100,000."

"37 Sale of natural health products that have not been notified or do not meet standards

(4) A sponsor who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual."

" 38 Manufacturing without licence

(1) A person commits an offence who knowingly manufactures a natural health product in contravention of section 28(1).

(2) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.

(3) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual. "

This fee structure is completely unacceptable for a victimless breach of regulations and far exceeds fines set out in the Medicines Act and updated 22nd September 2011, with much lower scale of penalties for products that have a history of being dangerous, toxic and in some cases cause death.

The max for a body corporate for breaching the Medicines Act is $100,000 and in the case of an individual, to imprisonment for a term not exceeding 6 months or a fine not exceeding $20,000 (eg S61 Misleading branding and S39 Adulteration of medicines.

The penalty for false statement (S76) is imprisonment for a term not exceeding 6 months or a fine not exceeding $1,000!

There is a general penalty (S78) for offences where no penalty is provided elsewhere of imprisonment for a term not exceeding 3 months or a fine not exceeding $500, and, if the offence is a continuing one, to a further fine not exceeding $50 for every day or part of a day during which the offence has continued.

Is it the Governments intention to impose stiffer penalties for breaches regulations of products that have never killed anyone but have low penalties for breaching regulations of dangerous products that do kill people?

In order for me to accept this Bill the fee structure should follow the recommendations in the (Joint Industry Proposal) on page 37.

Part 2 Regulation of Natural Health Products Clause 40(1)(a) & (b) Page 30 - Sanctions and penalties

"Endangerment of human health

(1) A person commits an offence who, being the manufacturer or sponsor of a natural health product, contravenes or fails to 15 comply with any provision of this Act or of regulations made or any notice given under this Act, knowing that the contravention or failure would or is likely to endanger the health of the public or the health of any individual.

(a) may create, directly or indirectly, a risk to human health; or

(b) may, directly or indirectly, increase the likelihood of an existing risk to human health."

Reference to may and indirectly is subjective and should be taken out. Considering you can beat the crap out of someone and get a term of two years, this is excessive and unjustified unless death is the concluding result.

In order for me to accept this Bill the term "is likely" needs to be specifically clarified and the penalty structure should follow the recommendations in the (Joint Industry Proposal) on page 37.

(5) A person who commits an offence against subsection (2) is liable,—

(a) in the case of a body corporate, to a fine not exceeding $300,000:

(b) in the case of an individual, to imprisonment for a term 5 not exceeding 2 years and a fine not exceeding $75,000.

See above comments.

Part 2 Regulation of Natural Health Products Clause 44(a) & (b) – Recall natural health products

(1) If the Authority has good reason to believe that a natural health product is not fit for its intended purpose, or is mislabelled or incorrectly identified, the Authority may, by written notice, require the sponsor of the product to—

(a) arrange for the recall of the product (for example, by issuing recall notices to retailers and consumers); and

(b) dispose of the product.

(2) The notice may specify the time and manner by which the sponsor must arrange for the recall of the product or dispose of the product.

Unacceptable. The only reason a product should be recalled and 'disposed of' is if there is satisfactory reason, and not doctored evidence, that the product is contaminated and is causing harm. Not fit for intended purpose or mislabelling is no cause for destruction of product or recall. Too vague.

Is it the Parliamentary Committee's intention and the Governments intention to destroy companies by having them dispose of perfectly safe products just because the label is not right?

This recall process is a direct page out of the TGA type regulations and scaremongering tactics, that has been overwhelmingly rejected by New Zealanders.

In order for me to accept this Bill the term "not fit for its intended purpose, or is mislabelled or incorrectly identified" needs to be taken out, "recall" and 'dispose of product' only relates to contamination and products that caused harm, and the Bill adds recommendations in the (Joint Industry Proposal) on page 29 and in other clauses that addresses this issue.

Part 2 Regulation of Natural Health Products Clause 45 (1), (2)(a)-(d) & (3)(a) & (b) Page 32 & 33 – Delegation

"(1) The Authority may, as he or she thinks fit, delegate to any person any of his or her powers, functions, or duties under this Act. "

Completely unacceptable! To vague and no guidelines. The Authority must at all times be answerable to the public who pay their salaries, and not be able to empower an individual or a corporation or non-government organization to perform their duties. This leaves a door wide open for massive corruption and delegation to individuals or associations with corporate interests that conflict with consumer rights and interests.

"(2) A delegation under subsection (1)—

(a) may be made subject to any conditions or restrictions that the Authority thinks appropriate:

(b) may be made generally or in any particular case:

(c) does not prevent the Authority from exercising any power, or carrying out any function or duty:

(d) does not affect the responsibility of the Authority for the actions of any person acting under delegation."

Completely unacceptable. So who ever is delegated tasks by the authority, if they act in an acceptable manner, the Authority who appointed them is not responsible? Unaccountability, lack of transparency leads to corruption.

IT'S ALL BEEN SAID BEFORE and is equally relevant here in New Zealand -

"Unless we put medical freedom into the Constitution, the time will come when medicine will organize into an undercover dictatorship...To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic..., and have no place in a republic...The Constitution of this Republic should make special provisions for medical freedom as well as religious freedom."

~ Dr. Benjamin Rush, signer of Declaration of Independence; member, Continental Congress; B.S. Princeton U.

"(3) A person who is delegated any powers, functions, or duties under subsection (1)—

(a) may, with the prior written approval of the Authority, delegate those powers, functions, or duties to any other person:

(b) may, subject to any conditions or restrictions, exercise those powers, functions, or duties in the same manner and with the same effect as if they had been conferred on that person directly by this Act and not by delegation."

WHAT! Any One! The CEO of Merck who can pass it on to the CEO of Phizer or some kid fresh out of Med School?

So now the person or corporation or NGO who has been delegated power and duties by the Authority (Regulating Agency), can now delegate their power and duties to ANY Person! Completely unacceptable. This structure is one of the makings for a corrupt foundation.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on pages 23-27 in the Joint Industry NTHP's Bill Feb 2009.

Part 2 Regulation of Natural Health Products Clause 47(1)(a)-(l) Page 34 – Regulations

" (1) The Governor-General may, by Order in Council made on the recommendation of the Minister of Health, make regulations—

(a) amending the Schedule: (based on what guidelines? – handing a blank check over to the GG without guidelines - unacceptable).

(b) prescribing the manner in which a product notification for a natural health product must be completed: (based on what guidelines? – handing a blank check over to the GG without guidelines - unacceptable).

(c) prescribing the standards of evidence required to support a health benefit claim: (based on what guidelines? shouldn't the regulations stipulate that to avoid any necessary reinventing of the wheel GR – handing a blank check over to the GG without guidelines - unacceptable).

(d) prescribing the information that must be provided by the sponsor or applicant for the purposes of any application or matter under this Act: (shouldn't the regulations

stipulate that to avoid any necessary reinventing of the wheel ? – handing a blank check over to the GG without guidelines - unacceptable).

(e) prescribing the criteria by which new ingredients will be assessed: (shouldn't the regulations stipulate that to avoid any necessary reinventing of the wheel ? – handing a blank check over to the GG without guidelines - unacceptable).

(f) prescribing requirements for the labelling of natural health products: (shouldn't the regulations stipulate that to avoid any necessary reinventing of the wheel ? – handing a blank check over to the GG without guidelines - unacceptable).

(g) specifying any offences that the Authority must take into account for the purposes of section 29(3)(a)(ii): (shouldn't the regulations stipulate that to avoid any necessary reinventing of the wheel ? – handing a blank check over to the GG without guidelines - unacceptable).

(h) prescribing the manner in which applications for a licence to manufacture natural health products must be made: (shouldn't the regulations stipulate that to avoid any necessary reinventing of the wheel ? – handing a blank check over to the GG without guidelines - unacceptable).

(i) prescribing requirements relating to the manufacture of natural health products:

(j) prescribing the procedure, conduct, and time required for appeals:

(k) prescribing requirements relating to access to the natural health product database, and any other requirements relating to the use of the database: (shouldn't the regulations stipulate that to avoid any necessary reinventing of the wheel ? – handing a blank check over to the GG without guidelines - unacceptable).

(l) providing for any other matters contemplated by this Act necessary for its administration, or for giving effect to any provision of this Act. (shouldn't the regulations stipulate that to avoid any necessary reinventing of the wheel ? – handing a blank check over to the GG without guidelines - unacceptable).

Essentially this means the Governor General, by recommendation of the Minister of Health, can re write the regulations without any public consultation or guide lines, any time he sees fit. Unacceptable. Asking the public to give a blank check to the Minister of Health and the Governor General, that they can use any time is crazy and not acceptable.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. If those recommendations are followed, they are governed by principles so the need for GG intervention should be unnecessary.

Natural Health Products Bill Schedule

Schedule ss 5, 20(1), 22(1), 47(1)

Suitable classes of substances

Item Class of substance

1 A plant or a plant material, an alga, a fungus, a mineral**, or a non-human animal material** (vitamins and antioxidants should be included here rather than specificly listed as a restricted list in number 3 below – by omission it default classifies vitamins not in this schedule as drugs regulated under the Medicines Act)

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 for preparation of the substance or mixture of substances in an active medicinal form

3 A vitamin or provitamin, including salts and other compounds, of the following types: (why are we resitricting vitamins?)

vitamin A

vitamin B1

vitamin B2

vitamin B3

vitamin B5

vitamin B6

vitamin B12

vitamin C

vitamin D

vitamin E

vitamin K

biotin

choline

folic acid

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

7 Prebiotics (what about probiotics).

8 Any of the following amino acids:

Alanine

Arginine

Asparagine

Aspartic acid

Cysteine

Glutamic acid

Glutamine

Glycine

Histidine

Isoleucine

Leucine

Lysine

Methionine

Phenylalanine

Proline

Serine

Threonine

Tryptophan

Tyrosine

Valine

All 24 amino acids in their natural form should be included here. Classifying some amino acids as natural health products and others as drugs, by default, is unacceptable.

Too narrower description on natural products. This is tantamount to a white list. I marched on the streets because a white list is unacceptable. Please refer to the Joint Industry Proposal on definition that I support. A natural product should be defined by it's biological structure or bio-identical to nature, and not listed in some arbitrary restricted list.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on page 18 in the Joint Industry NTHP's Bill Feb 2009.

Missing Clause on Claims

There is no section relating to health claims. Claims were outlined in the recommendations for the drafting of this Bill, but completely omitted from this Bill. Since the Dietary Supplements Act will be replaced by this Bill, then claims fall under the Medicines Act. This is not acceptable.

Government agreed to implement recommendations outlined in the Joint Industry Proposal that consumers, industry and NGO's have unanimously agreed on. Please do what you said you would do and implement these recommendations on page 35 & 36 in the Joint Industry NTHP's Bill Feb 2009.