SUBMISSION ON PROPSAL P235

"REVIEW OF FOOD-TYPE DIETARY SUPPLEMENTS"

by

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Who we are

Citizens for Health Choices is one of New Zealand's leading and most visible advocates for consumer choice in health care.

Citizens for Health Choices was founded in 1992 by a group of consumers, health practitioners and people from the dietary supplements industry. Since then it has been working to make sure New Zealanders have continued access to the natural health products they know and trust.

Today Citizens for Health Choices comprises more than 1000 consumer members, an Advisory Board of industry representatives, and support from New Zealand companies and individuals from across the dietary supplement sector – manufacturers, distributors, importers and practitioners.

INTRODUCTION

Citizens for Health Choices has not had the time to carefully consider the whole of P235 in the time allowed. In most cases, therefore, we make the following submission on general principles rather than specifics.

The comments in this submission apply to the future regulation of dietary supplements (including vitamins, minerals, herbs, homoeopathics, amino acids and other nutritional supplements), whether they are regulated under a Joint Agency with Australia or under a New Zealand-only regime. For the purposes of this submission when we refer to dietary supplements **we are including both TTDS and FTDS**.

We disagree that TTDS and FTDS should be regulated under separate regulations. Therefore, the comments in this submission cover not only FTDS but TTDS. **As we do not separate FTDS from TTDS, please accept as part of this submission Parts I and II from our submission on "A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS".**

OBJECTIVES and PARAMETERS

We agree with the objectives as stated on page 7:

(a) the protection of public health and safety; and

(b) the provision of adequate information relating to food to enable consumers to make informed choices; and
(c) the prevention of misleading or deceptive conduct.

We agree with the parameters for regulation set out on Page 7:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food.

2- CATEGORY or 3-CATEGORY SYSTEM?

INTERNATIONAL SYSTEMS

The basic problem in the international regulation of dietary supplements is identified on Page 16 of Review P235:

> ”In some countries regulation is effectively based on a 3 category system - dietary supplements (or another term), foods and medicines. The regulations pertaining to dietary supplements (or other) generally sit under a broader (2 category) legislative umbrella for either foods or medicines. For example the NZ Dietary Supplement Regulations places them under the Food Act while in Australia they are under therapeutic products (medicines) and the TGA. Countries with a 3 category approach include New Zealand, the United States, Canada (proposed system), Europe and Japan.
>
> *Countries using a 2-tier system include Australia and the United Kingdom (although their system is mixed).”*

It is obvious from this that New Zealand is similar to the majority of our trading partners and Australia is out of line and that this creates severe legislative problems.

There is a very strong case to be made for the retention of the New Zealand 3 category system which would create a more seamless regulation of products than the Australian 2 category system.

Many of these countries with a 3 category system allow some form of statement of purpose or claims, even though they classify dietary supplements under food.

To the Productivity Commission the CHC states ‘ *Since the introduction of the full cost recovery on therapeutic goods, there has been an explosion of innovative healthcare food products (**food type dietary supplements**) in the Australian market using the same ingredients as in complementary healthcare products. These products are not subject to the costs that apply under the therapeutic goods regime - both regulatory and cost recovery.’*

This is further evidence that the Australian two-tier system is not working and the proposed system has the same faults.

NEW ZEALAND SYSTEM, CURRENT AND FUTURE

The establishment of separate regulations for dietary supplements is clearly needed. The current regulation in New Zealand of these products already does that. It may be found that the administration of these regulations falls more naturally under the NZ Food Safety Authority (as is done currently in New Zealand) than under any other regime, including any joint regulation with Australia.

We do not agree that "food-type dietary supplements" that clearly fall within the classification of Dietary Supplements under current regulations should be regulated separately from other dietary supplements. This is especially the case for products that are called dietary supplements in one dose form, and become (as if by magic) a Food-type Dietary Supplement if they are in powder form. This type of anomaly must not be allowed to happen in New Zealand. Examples of this problem in Australia include colostrum – which is allowed in powder form as a food, but not in capsule or tablet form. (We understand that registration of colostrum in capsule form is underway with the TGA at great expense, while colostrum powder is merrily on the market unhindered.) Other examples of this dilemma are ingredients such as spirulina, barley grass and wheat grass – all of which have been on the New Zealand market for many years.

WHEN IS A FTDS NOT A FTDS?

We would like to see stopped the addition of dietary supplement-type ingredients to food when clearly the motive is a marketing ploy rather than enhancing the health of the consumer. Examples of this currently are the adding of *Ginkgo biloba* and/or Echinacea to yoghurt – with naming the herb on the front panel.

The inclusion as a dietary supplement of Formulated Caffeinated Beverages (FCB) and fruits drinks, etc, that have added vitamins and/or minerals is clearly either a marketing ploy or an attempt to get around other food regulations. This practice needs to be stopped, but not at the expense of liquids which are clearly dietary supplements such as liquid herbal extracts, vitamin formulas, etc.

It is our understanding that the current rules ban the enrichment of a grain. An example of this is Enriched Rice Dream drink. We also understand the current thinking is to allow this product to be put in the category of Novel Food. In New Zealand this product is not "novel". It is on the open market and has been used safely by New Zealander's for many years. The regulation just needs to be changed to allow the enrichment of a grain.

WHAT IS A DIETARY SUPPLEMENT?

The statement on Page 12 that "The key element of these products appears to be a supplementary role (to the normal diet) and an intended function over and above that provided by the usual diet." could be a starting point for a good definition of what constitutes a dietary supplement. Any **addition** of a dietary supplement type ingredient to a food product must be in an amount which could be expected to be of value to the consumer before it could be labelled as a dietary supplement. These levels would need to be carefully considered by people who are familiar with these levels. They must not be "picked out of the air", so to speak, but must have a rational basis.

The following definitions could also be considered as starting points:

CURRENT NEW ZEALAND DEFINITION OF DIETARY SUPPLEMENT FROM "THE DIETARY SUPPLEMENT REGULATIONS 1985"

"Dietary supplement" means any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders or tablets, which are intended to supplement the intake of these substances normally derived from food.

CURRENT UNITED STATES OF AMERICA DEFINITION OF DIETARY SUPPLEMENT FROM "DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994"

The term 'dietary supplement' means-
(1) a product intended to supplement the diet by increasing the total dietary intake that bears or contains one or more of the following dietary ingredients: (A) a vitamin, (B) a mineral, (C) an herb or other botanical, (D) an amino acid, (E) another dietary substance for use by man to supplement the diet by increasing the total dietary intake; (F) or a concentrate, metabolite, constituent, extract, or combination of any ingredient described (A), (B), (C), (D), (E), or (F);
(2) a product that-
(A)(i) is intended for ingestion in a form described (tablet, capsule, powder, softgel, gelcap or liquid form).
(ii) complies with
(B) is not represented for use as a conventional food or as a sole item of a meal or the diet and
(C) is labelled as a dietary supplement.

The term 'drug' does not include a dietary supplement

WHAT CLAIMS SHOULD BE ALLOWED?

Any truthful health claims should be able to be made for dietary supplements without the need of classifying them as medicines. This is especially true of low-level claims such as the "structure and function" claims allowed in the USA. Backup for the claims would need to be held by the company manufacturing the product. Resources could be recognised, such as the EU & USA pharmacopoeias and monographs; and claims already allowed in Australia and Canada, for example, should be able to be made. There are many recognized herb manuals and pharmacopoeias that could be used as allowed sources. The New Zealand Fair Trading Act 1986 (p 5) covers the regulations of claims, so additional regulations are unnecessary.

There are problems with the regulation of claims allowed for Dietary Supplements internationally. Attached are two documents from the USA which demonstrate some of these problems:

1. CLAIMS CONTINUUM – JIM LASSITER
2. UNDERSTANDING FDA'S 'MAGIC WORDS' – JIM LASSITER

LABELLING

Any requirement for country-specific labelling for dietary supplements, for the small New Zealand market, would be in effect a trade barrier. No overseas company will do special labels for the small New Zealand market for most imported dietary supplements sold currently.

INGREDIENT LISTS

Any listing of ingredients which can be included in Dietary Supplments must be on the basis of a negative listing of what cannot be used, rather than a positive listing of what can be used.

NEW ZEALAND DIETARY SUPPLEMENTS REGULATIONS 1985 – CANCEL OR CHANGE

As authorities in both FSANZ and Medsafe are having difficulty with the dietary supplement category, we suggest that the date for the cancelling of the current New Zealand Dietary Supplements Regulations 1985 be extended until a good solution can be found. The current date of December 2002 for their being repealed is clearly not a feasible goal for this category.

There is much support in the New Zealand industry for not cancelling the regulations, but to just change and expand them. Portions of the current Medicines Act and possibly other acts or regulations would need to be incorporated in order for them to be complete of and by themselves.

Any regulation must be risk based. Most dietary supplements are safer than foods. The fact that many fortified foods make claims that are not allowed for similar ingredients in dietary supplements is clearly not risk-based regulation. These ingredients are obviously safe and claims should be allowed no matter what category they are regulated under. Current practice does not follow either Australia's or New Zealand's Code of Good Regulatory Practice.

In order for a system to be risk-based there must be empirical risk analysis undertaken. As far as we are aware, no such analysis has been done in New Zealand for Dietary Supplements.

HARMONISATION WITH AUSTRALIA

On Page 13 it states: “The States and Territories have undertaken to amend their respective Food/Health Acts in line with the Model Food legislation and this will include adoption of the definition of food within that Act in due course.” Until the states of Australia are harmonized, it seems that New Zealand should not be expected to harmonize. It is most probably the best solution that New Zealand “opt out” of any joint agency with Australia for the regulation of dietary supplements.

There is nearly unanimous agreement within the New Zealand Dietary Supplement industry that harmonization with Australia is not an option for Dietary Supplements.

OTHER POINTS

On Page 14 it states: “Traditional health food stores, previously found in malls and shopping centres, have largely been replaced by suburban health food stores. These new-age stores are more like health food supermarkets and mimic mainstream supermarkets in layout and product choice.” We find this statement curious, as in New Zealand this is far from the case. We are aware of only four outlets in New

Zealand that could possibly fit into a “supermarket” category. The other 200 + stores are in malls and shopping centres.

Page 15 – As far as we are aware, the type of market information requested is not available in New Zealand.

[redacted]
SECRETARY
CITIZENS FOR HEALTH CHOICES

SUBMISSION ON DISCUSSION PAPER

"A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS"

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Outline of this submission

This submission is in three parts:

- Part I: Introduction
- Part II: CFHC's views on the Discussion Paper
- Part III: Detailed analysis.

Part I: Introduction

The comments in this submission apply to the future regulation of dietary supplements (including vitamins, minerals, homoeopathics, amino acids and other nutritional supplements), whether they are regulated under a Joint Agency with Australia or under a New Zealand-only regime. Citizens for Health Choices (CFHC) expresses no opinion on how the proposal would affect other categories of products.

CFHC wants a sensible regime for dietary supplements that promotes the interests of New Zealand consumers and the industry that meets their needs.

Our goals for the outcome of this process are:

- We want consumers to have access to a wide range of safe dietary supplements.
- We don't want costs to rise unnecessarily.
- We want consumers to have good information on what the products are used for.
- We want to make sure that the products are labelled accurately and are manufactured to the appropriate standard.

So this submission is made in a constructive vein, with a view to facilitating a sensible Dietary Supplements regime for New Zealand, whether or not that is achieved through harmonisation with Australia.

Because the systems for regulating dietary supplements are so different in New Zealand and Australia, it may be necessary for New Zealand to insist on excluding dietary supplements from co-regulation. The two systems have major philosophical differences and have been entrenched for many years, making it difficult to harmonise without creating major difficulties, especially in New Zealand.

The Discussion Paper emphasises common outcomes between Australia and New Zealand, as if commonality is a goal in itself. There is too little focus on *good* outcomes, and whether the proposal is good for New Zealand.

It is a real fear that the costly and, in our view, draconian rules that are in effect in Australia would dominate this Agency. This would limit consumer choice and damage many New Zealand businesses for no good reason.

Given that the states in Australia are not harmonised under the Therapeutic Goods Act, it is reasonable that New Zealand should reserve the same right for itself.

Nothing in this proposal should be taken as acceptance of the proposed Joint Agency. Although our comments are made constructively, in our view the current proposal is fundamentally flawed in three respects:

- Dietary supplements should logically be treated as a distinct category – i.e. separate both from medicines and food – as in most other countries.
- The proposed Agency has too much power to make rules, determine for itself the level of enforcement, and pass on costs without limit.
- The proposed governance arrangements damage New Zealand sovereignty and its citizens' rights to self-determination.

Summary of key points

Insofar as it would affect dietary supplements, the Discussion Paper:

- provides insufficient evidence of a problem to justify the proposed regime
- is fundamentally flawed in classifying dietary supplements as medicines, rather than in a separate category distinct both from medicines and food
- proposes a regime that does not meet the Code of Good Regulatory Practice, nor the New Zealand Government's aim of reducing business compliance costs and red tape
- proposes governance and accountability mechanisms that are dangerously flawed
- while purporting to regulate products according to their risk, would regulate dietary supplements much more tightly than food – even though food is demonstrably more risky
- gives the bureaucracy virtually unfettered power to make rules for which no need has been established – and then to set fees to pay for a level of enforcement that it alone decides
- makes claims for the benefits of regulation that in fact can be achieved through simpler and less expensive means
- proposes extending Australia's protectionist barriers to New Zealand – in direct contradiction to the supposed goal of freeing-up trade
- is likely to eliminate hundreds or thousands of safe products from the New Zealand market without justification, thus limiting consumer choice.

Cost-benefit analysis

It is of extreme concern that the public has been required to comment on the Discussion Paper in the absence of an independent cost-benefit analysis.

The New Zealand Institute for Economic Research has been commissioned to prepare such an analysis. Citizens for Health Choices is aware that many New Zealand firms and individuals contributed to the NZIER study more than six months ago.

Nonetheless, the study is yet to be released, and our request for access to the relevant material has been denied in terms of the Official Information Act.

The Government and its officials have thus put us, and all submission-writers, in the position of assessing the proposal in the absence of a key piece of information.

PART II: CFHC'S VIEW ON THE DISCUSSION PAPER

In this Part of our submission, we respond to the Discussion Paper under the following headings:

- What is the "problem" to be fixed?
- The need for a separate category for dietary supplements
- Risk management of dietary supplements
- Funding and fees of the Agency
- Objectives of the proposal
- Accountability of the proposed new Agency
- Recognition of international standards
- The proposed "positive list"
- Claims and advertising
- Appeals and enforcement
- Code of good regulatory practice.

What is the "problem" to be fixed?

The Discussion Paper does not demonstrate that there is a problem with dietary supplements currently on the market in New Zealand.

Indeed, it states that *around 95% of complementary healthcare products would fall into the low-risk category* (p. 101). What is the justification for extensively regulating products that are known at the outset to cause almost no problems?

Medsafe has from time to time provided anecdotes of supposed harm from dietary supplements to support tighter regulation. These anecdotes:

- are frequently based on unscientific assertions as to cause and effect
- typically relate to products that are illegal now – and therefore make a case for enforcement of the existing rules, not for new rules
- where valid, demonstrate issues that can be resolved more simply and efficiently than through the proposals in the Discussion Paper.

There should be evidence that Australian consumers of dietary supplements are any safer than their New Zealand counterparts. No such evidence is presented.

Conversely, if regulation of the type proposed is worthwhile, after 10 years of similar regulation there should be evidence that Australian consumers of dietary supplements are any safer than their New Zealand counterparts. No such evidence is presented.

The need for a separate category for dietary supplements

The proposal takes for granted – without acknowledging nor analysing its assumptions – that dietary supplements should be treated as medicines. No consideration is given to treating them as a sub-category of foods (as in New Zealand) or in a separate category of their own.

To the best of our knowledge, Australia is the only industrialised country that insists on a strict medicines-food dichotomy in this way. Other countries acknowledge that dietary supplements are different both from medicines and foods – in purpose, usage, ingredients and risk profile – and thus regulate them in a separate category.

Risk management of dietary supplements

The proposed regulations are supposedly based on a *risk management approach* (p. 98), yet the proposal fails to take proper account of relative risk.

It is obvious that a risk-based approach requires that a risk assessment be undertaken to determine actual risk. The Discussion Paper offers no such analysis, and thus does not attempt to justify putting dietary supplements under the same regime as medicines.

New Zealand's current regulations, which regulate dietary supplements as a category under the Food Act, are closer to the mark in terms of risk management.

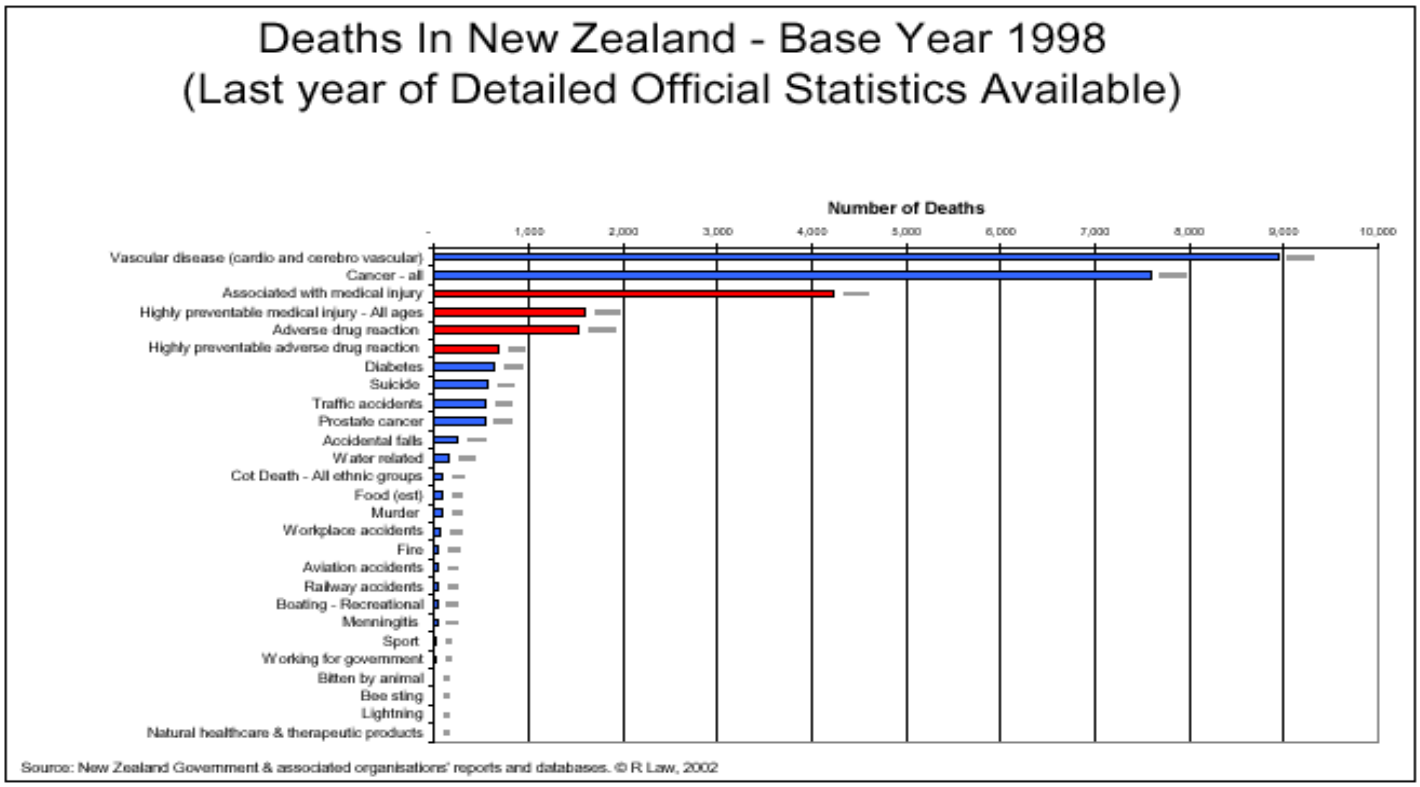
Dietary supplements simply do not belong in the same regulatory regime as high-risk pharmaceuticals.

It is a key point that *most supplements are safer than many foods*, and should be regulated accordingly.

It is not justifiable to place dietary supplements at the "low risk" end of a continuum that includes the highest-risk pharmaceutical drugs. Those products do not belong in the same diagram, let alone in the same regulatory regime – except, presumably, that this is how it is done in Australia.

Illustration 1:

Which products should be most heavily regulated?



Source: Ron Law, Lecturer, School of Business, Auckland University of Technology; former Executive Director of National Nutritional Foods Association, Member of Ministry of Health's "sentinel event" working group that advised on the reporting and management of medical injury.

Funding and fees of the Agency

Among the Discussion Paper's fatal flaws is that the proposed Agency has no maximum budget, has no limits on its fee-setting ability, decides the extent of its own work programme, and *the operating costs would be fully funded by fees and charges recovered from industry* (p.20).

This gives the Agency unfettered power to levy taxes in order to meet a work programme that it alone decides, enforcing rules it alone sets. There is no other trans-Tasman police force with such powers.

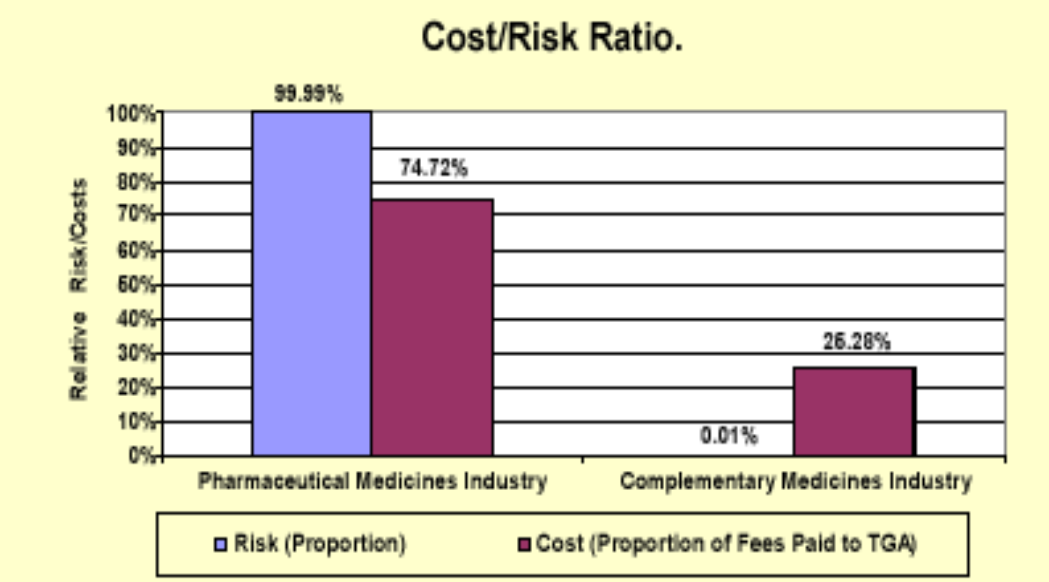
The Agency would have unfettered power to levy taxes in order to meet a work programme that it alone decides, enforcing rules it alone sets.

No other trans-Tasman police force has such powers.

There must be prior restraint on fee levels, and on the Agency's powers to set fees and enforce compliance. Since fee levels will be driven directly by the level of enforcement, **the onus of proof must be on the Agency and its Directors to show that enforcement is proportionate to risk. Further, cost minimisation should be an explicit goal of the Agency, in order to restrain its otherwise unlimited powers to decide enforcement levels paid for by others.**

It is completely unacceptable, for example, to adopt the Australian situation, where complementary healthcare products incur 25% of the therapeutic product fee income of the Australian Therapeutic Goods Agency, despite causing less than 1% of the risk.

Illustration 2:
Who pays for the Australian TGA?
(Source: Ron Law)



In Australia, new ingredients – whatever their history of safe use – cost an average of $12,000 to register. Products cost several hundred dollars to register in the first year, and hundreds of dollars a year more to keep on the market. It is of real concern that the Discussion Paper provides no indication of the proposed fee levels – thus making

it impossible for consumers and industry to estimate the effects of the proposals in the real world.

Given the very low levels of risk posed by dietary supplements, any significant fees – higher than a few dollars per registration – are unjustified. Certainly the current proposal leaves the door open to significant abuse of bureaucratic power that cannot be justified by risk.

The method of paying for food regulation is instructive. The costs of the new food regulations coming into force in New Zealand in 2002 are to be paid out of general taxation. **Given that the food industry causes more risk and more actual harm, there can be no justification for paying the cost of any regulation of dietary supplements through industry fees while food regulation is paid from general taxation.**

Using general taxation to pay for any increased regulation of dietary supplements has another advantage, in that it provides an external and democratic check on the powers of the Agency. It must seek an Appropriation through the Parliaments of the two countries, thus ensuring *ex ante* scrutiny of its enforcement plans.

Finally, it is of concern that the current "low-volume" concessions available in Australia are not mentioned in the Discussion Paper. Significant fees would have the effect of driving low-volume products – and their manufacturers and distributors – off the market. As the Minister of Health noted very recently:

> "It is certainly possible that distributors will choose to remove from the market some products with very low sales volumes." (Hon Annette King, letter to correspondent, 28 June 2002)

There are hundreds of these "low-volume" products, and they play a valuable role. They are often:

- required by people with rare or unusual conditions, in order to meet their particular needs
- are at the leading edge in terms of innovation, and thus promote competition and genuine choice.

Any fee settings that push low-volume products off the market would have the effect of "McDonalds-ising" the dietary supplements market to the detriment of consumers and their health. Innovation has been severely limited in Australia since the introduction of the TGA regime.

Objectives of the proposal

It can be seen from the above that the proposed regulations clearly do not meet the objectives set out in the Discussion Paper. The proposal states:

> *The regulatory framework should be designed to manage the risks in a way that is efficient and cost-effective, does not impose inappropriate compliance costs on the*

industry, and does not unnecessarily restrict the range of dietary supplements consumers are able to access (p. 90).

But the proposal contains regulations that are not justified by risk factors, and that will effectively restrict the range of dietary supplements by imposing inappropriate compliance costs -- such as licensing fees (p. 21), special labelling (p. 52), lengthy forms (pp. xii & 27), and appeals processes (pp. 132 & 138-142).

The notion that government should compulsorily tax the whole industry in order to enhance its reputation is obnoxious. It raises the spectre of a supposed "regulator" that is actually captured by industry interests.

It is curious that another supposed objective of the proposal has been omitted from the Discussion Paper. In many discussions with the relevant Medsafe team, it has been stated that one of the purposes of the proposal is to lend "credibility" to the dietary supplements industry. Indeed, at an industry meeting hosted in Wellington by Medsafe in early May, Australian industry representatives said that this – and specifically not safety or risk management – was the chief benefit of the proposal.

Yet credibility is surely up to any industry to earn, and most sectors have Industry Associations specifically for that purpose. The notion that government should compulsorily tax a whole industry in order to enhance its reputation is an obnoxious hoax from the point of view of consumers – and raises the spectre of a supposed "regulator" that is actually captured by industry interests.

There is no evidence that as a result of the Australian regime that Australian dietary supplements enjoy any more credibility than do New Zealand dietary supplements.

Accountability of the proposed Agency

The proposal creates an extremely powerful Managing Director and Board appointed by the Health Ministers of both countries to run the new Joint Agency (pp. 3 & 166).

The appointed executive would make decisions that are presently made by the Minister of Health, an elected official who is publicly accountable (p. 4).

The Agency will have unfettered power to make rules and orders (p.9), then enforce the rules and orders, (pp. 132-137) and determine the level of enforcement (p. 132) and set fee levels (p. 21).

Stakeholder input is very limited. There would be only two meetings a year to discuss issues of concern to the industry and consumers – and those would be merely advisory.
The people who make, import, sell and use dietary supplements will be effectively excluded from the decision-making process.

New Zealand sovereignty is not protected. Australians will dominate the Board. Three out of five members are to be Australian citizens, and *all instruments of appointment to be signed by the Australian Minister on behalf of the MC* [Ministerial Council] (p. 162). In cases of dispute over Board appointments, the Australian Health Minister will appoint two members, while New Zealand only appoints one (p. 3). It is unacceptable that, in any disagreement, the Australian minister would make most of the final decisions.

New Zealand sovereignty is not protected.

A number of constitutional dilemmas also lead us to question whether there will be sufficient accountability on the Managing Director and Board:

- Will Australia really accept New Zealand's Official Information Act, which is considerably more liberal in terms of access to, for example, Cabinet papers? Or will New Zealanders have to accept poorer access to information on regulation of health products than they enjoy on other topics?
- Will Australia really accept the jurisdiction of the New Zealand Ombudsman?
- Will the Regulations Review Committee of the New Zealand Parliament have any real oversight? And with what authority or influence in Australia?
- Should New Zealanders have to accept binding rulings on their access to products being made by Australian courts? And will Australians really be bound by decisions made by the New Zealand courts, including the Privy Council (which otherwise has no jurisdiction in Australia) or by the proposed Supreme Court of New Zealand?

Recognition of international standards

It is a significant oversight that the Discussion Paper provides only superficial information on the regimes in countries other than Australia. There is no meaningful analysis of these, nor reasonable justification of why, out of all the other models available in the world, the Australian system is considered the appropriate starting point for regulation of dietary supplements.

Country-specific rules will have the effect of taking off the market some of the highest-quality products from around the world.

These are non-tariff trade barriers that effectively extend Australia's protectionism to New Zealand, thus inhibiting international trade.

If supplements are approved for safe use overseas in countries with high standards, they should be accepted for use in New Zealand. If supplements are acceptable in the USA, Canada, Britain and Europe, why would they harm New Zealanders? Many of these supplements have been used safely in New Zealand for 20 to 30 years.

A number of aspects of the Australian regime should not be imported into New Zealand. Each of these proposed country-specific rules will have the effect of taking off the market some of the highest-quality dietary supplements from around the world for no good reason:

- Any unique labelling requirements will impose unnecessary additional costs on dietary supplements imported from countries other than Australia. In Australia,

all complementary medicines must include a TGA-approved claim on the label – this rule alone would force many safe dietary supplements off the New Zealand market, as it is too small to bear the extra costs (pp. 101-103).

- Any other special rules for dietary supplements in New Zealand and Australia would also create additional costs and would effectively ban some products – for example, requiring the product licence number on all labels.

  (It is instructive that the new labelling requirements for the New Zealand food industry, controlled under the Australia New Zealand Food Authority (ANZFA), have already cost food manufacturers millions of dollars and may force some imported and small-volume products off the market (See *NZ Herald*, 3 June 2002 – clipping attached). This may be justified for food, and seems to have been accepted by food manufacturers, but the effects on international trade and thus competition are acknowledged. The equivalent costs are not justified for the dietary supplements sector when the benefits proposed are available through other means.)

The proposed "positive list"

We do not accept that the "positive list" is an appropriate method for regulating the ingredients in dietary supplements.

"Positive list" systems are cumbersome and expensive, requiring both a safety review by the regulator and additional fees (currently in Australia a minimum of AU$10,000) before a new ingredient can be added to the list (p. 99). **This lengthy and expensive process is not appropriate for dietary supplements.**

New Zealand's "negative list" bans certain substances from sale. This is efficient and cost-effective, and has not been shown to compromise the safety of consumers in New Zealand or the many other countries where negative lists operate.

The positive list system is sometimes seen as a way of eliminating supposed loopholes that enable suppliers to market as "dietary supplements" dangerous and unknown products (e.g. "party drugs") that would not be allowed under any other category. We point out that such products are illegal now, since they are not covered by the current definition of dietary supplements in New Zealand (see Part III). There is no reason to believe that a supplier willing to flout the current negative list system would be any more constrained by self-certification under a positive list. Such issues are best dealt with through positive enforcement.

It is acknowledged that the Discussion Paper includes a proposal to expand the current Australian "positive list" to include ingredients safely available in New Zealand (pp. 105 & 150). This does not address the new-ingredients issue discussed above. Further, the proposal to expand the positive list is acceptable only if this exercise "is funded as part of the Government-funded set-up costs of the Agency" as proposed on page 105.

Claims and advertising

It is positive that the proposal would enable the use of approved claims (indications) for dietary supplements (pp. 101-103). Clearly the legislation in New Zealand needs to be changed – but this can be done without imposing a system of fees, licences and advertising controls.

It should be noted that given the number of dietary supplements on the New Zealand market (estimated at 20,000 to 25,000 products), the "problem" of false claims is minute. There appears to be a lack of will to enforce current laws in New Zealand – presumably reflecting a rational judgement by the regulator that these products are safe compared to other enforcement priorities.

In product information or advertising, any truthful statement should be lawful. If someone tells an untruth, then the Fair Trading Act, Commerce Act and Advertising Standards Authority can and should be brought into force. **Advertising controls must not be included in the jurisdiction of any proposed Joint Agency. Advertising controls do not belong under a Joint Agency scheme, nor should they be under the jurisdiction of the Ministry of Health in New Zealand.**

Putting a claim on the label must be voluntary. If there are no claims being made, then at most, a simple notification to the Ministry of Health that the product is on the market, along with name of product, name of manufacturer, name of distributor, and basic ingredient information, would be sufficient. This simple notification system should include dietary supplements making low-level claims such as the structure and function claims allowed in the USA.

Appeals and enforcement

As discussed above under fees, the Agency would have the power to conduct random audits, but no principles for, or limits on, such powers are specified (p. 106). The Executive would have the power to decide when, how, what and who is audited and whether fees or sanctions are imposed.

It is proposed that only "certain regulatory decisions would be subject to review…" or "appeal" (p 34). **All regulatory decisions must be open to review.**

Where appeals are allowed, no indication is given about length or cost of this process (p. 104). Suppliers will be opposed in court by a regulator that they fund, and who can pass its legal costs back to the industry. Effectively, suppliers will be dragged through the courts with their own money.

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The "…power to take prosecutions through the New Zealand and Australian courts to impose criminal sanctions" (p. 132) gives the Agency far too much power. This power should remain in the country of origin,

and in New Zealand the Fair Trading Act and the Commerce Act cover this area adequately.

Code of Good Regulatory Practice

It is apparent from the discussion above that the proposal does not meet New Zealand's Code of Good Regulatory Practice. The Code requires regulations that:

- *are the minimum required, and least distorting, in achieving the desired outcomes*. The desired benefits can be achieved through much simpler means, and without distortions such as eliminating safe products through compliance costs and fees.
- *have benefits that outweigh costs.* This analysis cannot be done on the basis of the Discussion Paper, as benefits are not quantified and costs are unknown (but potentially limitless).
- *have reasonable and fair compliance costs*. See above.
- *have a minimal negative impact on competition*. This proposal is likely to eliminate hundreds of products, thereby reducing competition and innovation.
- *are compatible with relevant international or internationally accepted standards or practices, in order to maximise the benefits of trade*. This proposal uses very limited comparisons with other countries. No meaningful comparison with the USA system is included. Further, it would have the effect of restricting trade. New Zealand has few trade barriers in dietary supplements now; any compromise with Australia's rules would create international trade barriers where few now exist.

Legal Update

Understanding FDA's "Magic Words"

by Jim Lassiter
http://www.naturalproductsinsider.com/articles/231legup1.html

There really isn't any magic in the *Federal Food, Drug and Cosmetic Act* (FFDCA). It only appears that way. FFDCA essentially assigns products to classes based on the claims made about them. Primary definition comes from the use of five common words in the English language. If a product claims to **cure, treat, diagnose, prevent** or **mitigate** any disease or disease state, it is classified as a drug. It's just that simple. Use any of these five "magic words" in a claim and *presto*--the product is a drug regardless of form or presentation.

Then there is the interpretation of the meaning of the words **disease** or disease state and the additional, non-statutory magic words that will equally render your product a drug. The Food and Drug Administration (FDA) has taken great pains to review the English language and identify additional words that ultimately place your product in the category of drugs. The synonyms for the original five magic words are equally applicable and this interpretation is understandable. However, FDA's linguistic review reaches beyond this. The focus of wording resides primarily in making claims for dietary supplements. FDA has in place a Final Rule (Section 101.93 of the *United States Code of Federal Regulations, Title 21*) mandating that companies submit their so-called "structure/function claims" within 30 days of first use in the marketplace. This rule insists that virtually all claims on dietary supplement products must be submitted for FDA review. How is this involved in the magic word listing? The answer is simple. FDA is, through its actions in commenting negatively on the submitted claims, adding to the list of magic words.

First, let's take the word **cholesterol**. FDA has long objected to claims for products other than drugs concerning a substance's effect on cholesterol. Every human being has a certain level of cholesterol. If a substance in a dietary supplement is capable of lowering cholesterol levels, even if the company has complete substantiation of this fact, making a claim concerning this effect renders your product a drug. Why? Because FDA says so. In their view, cholesterol is the *de facto* sixth magic word. FDA contends that the average consumer relates cholesterol levels to coronary artery and heart disease.

"FDA ... [reviewed the comments submitted concerning cholesterol claims and] does not believe that any of them have provided a principle that distinguishes between claims that consumers will understand as disease claims and those that will not be understood as disease claims." (*65 Federal Register*, Jan. 6, 2000, p. 1015)

As for what would happen next, FDA allowed that:

"... [it] will review all cholesterol claims to determine whether the labeling as a whole implies that the product is intended to lower elevated cholesterol levels. In such cases, FDA would consider the labeling to create an implied disease claim." (*Ibid*, p. 1019)

Thus far, the results speak for themselves. FDA has probed the mind of the consumer and determined any claim submitted that uses the word cholesterol is an implied disease claim and thus renders the product a drug. This disallows the claim and supports the magic contained in the single word. Thus, if you state your product has an impact on cholesterol levels, you have (in FDA's consumer mind-reading) made a claim concerning these serious diseases. This is an interesting interpretation of the law as written since cholesterol is clearly a "structure" in the human body. This position is one of long standing and there are no allowable "structure/function" claims for dietary supplements and cholesterol in spite of FDA's contention that one could be made. (*Ibid*, p. 1017-1019.) The issuance of negative responses to companies attempting to comply with FDA's suggestion is sufficient evidence of this. Therefore, cholesterol claims remain available exclusively to drug products, even if the statement is truthful and not misleading. The truth simply does not matter when consideration and interpretation of FDA's mind-reading takes place.

As time progresses, evidence mounts (witness FDA's issued courtesy letters to the makers of dietary supplements) that there are other words gaining magical status. **Blood sugar** and **blood fat** are approaching this level of magic. Claims that a product may help maintain healthy blood sugar levels will receive objection from FDA. Why? FDA believes that, in the consumer's mind, reference to blood sugar levels means only one thing: diabetes. A serious disease to be certain, but the stretch from the words blood sugar solely to diabetes is a link made exclusively in FDA's interpretation. Similarly, blood fat (or lipids) is gaining magical properties. Review of the claims submitted and subsequently rejected by FDA demonstrates that they have read the minds of consumers again and found correlation between this structure and a disease in the consumer's consciousness. Again, this is in spite of FDA's published position in the preamble to the final rule (21CFR 101.93).

"... if the statement were ... 'use as part of your diet to help maintain a healthy blood sugar level,' the claim would be considered acceptable." (*Ibid*, p. 1028)

However, the reality is that companies have been issued courtesy letters after submitting claims that are virtually identical to the quotation presented here. The apparent mind-probe FDA applies to consumers continues and its interpretation of the results evolves.

What happened? A brief historical review sheds some light on the matter. Some years ago, before the final rule on "structure/function" claims came into being, FDA discussed its then proposed rule with industry. FDA's perspective was that there exists a "continuum of understanding" in the consumer's mind that apparently FDA alone has tapped into. This in part serves to explain FDA's position on cholesterol claims. As a further example, at that time, FDA allowed mention of a dietary supplement's effect in lowering homocysteine levels in a "structure/function" claim. The agency noted that it did not believe the consumer makes a direct connection between homocysteine levels and heart disease. At least not then. As of today, it is possible that you can, with appropriate substantiation, make a claim that your product lowers homocysteine levels. If, however, we project this model and FDA's mind-reading abilities into the future, you have the following scenario:

Company A sells a product that is demonstrated to lower homocysteine levels in humans. Company A makes a label claim concerning this fact, submits it and receives no negative feedback. Company A is interested in providing further information and education to the consumer regarding the relevance of homocysteine levels. It proceeds to offer additional truthful, non-misleading information in its labeling and advertising. This information discusses the significance of homocysteine levels and what their control might mean. Company A continues this practice for some time and attains a solid reputation for being concerned about educating the public. However, if it does too good a job--that is if it promotes consumer awareness that elevated homocysteine levels are potentially indicative of heart disease at too high a level--trouble results. FDA continues to perform its mind-reading act. Once FDA divines that the consumer, ironically through Company A's efforts, understands the link between elevated homocysteine levels and heart disease, Company A (and everyone else) is suddenly precluded from making any claims concerning homocysteine and **homocysteine** becomes another of the magic words. This disallowance theoretically continues until the existing consumer population dies off and a fresh batch of naïve consumers enters the market without such awareness. Then Company A could again tout the benefits of its product.

The absurdity of this flies in the face of the wording of the Dietary Supplement Health and Education Act (DSHEA). When passed in 1994, the intent (as spelled out by Congress) included:

"... there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health; consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements ..." [emphasis added] (Public Law 103-417, *Dietary Supplement Health and Education Act of 1994*, Section 2, (7), (8))

Congress was also specific in directing FDA to avoid hindering the consumer from gaining information concerning the benefits of dietary supplements:

"... although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of ... accurate information to consumers ..." [emphasis added] (*Ibid*, Section 2, (13))

FDA's take on this is presented in the preamble to the Final Rule:

"Although Congress, in enacting DSHEA, did expand the scope of information in dietary supplement labeling by providing for claims to affect the structure or function of the body and the other types of claims ... Congress also explicitly limited statements to those that do not claim to 'diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.' This rule does not create new restrictions but merely implements the provisions ... of the act." (*65 Federal Register*, Jan. 6, 2000, p. 1036-1037)

Clearly, Congress did not anticipate the mind-reading capabilities of FDA and its subsequent ability to apply regulations based on this bit of telepathic capacity. The

real challenge, therefore, is how does the dietary supplement industry provide the E in DSHEA (remember, it stands for Education) without cutting itself off from continuing the education? Perhaps FDA's ability could be overwhelmed by an industry capable of performing as the old radio show hero *The Shadow* did. They could gain the ability to "cloud men's minds." This would prevent the information offered from remaining in the consumer's thoughts or perhaps block FDA's imaging abilities as it delves into the consumer's consciousness.

How can this be solved? There appears to be no easy method, but there are options. The efforts of the plaintiffs and attorneys in the *Pearson v. Shalala* decision addressed a similar matter concerning health claims from a free speech perspective. The situation with this other class of claims is little different. We can assume that the ability to speak freely about the "structure/function" effects of dietary supplements is protected by the First Amendment to the Constitution and further affirmed in DSHEA. This would dismiss the mind reading results applied today. Taking on FDA in this matter through litigation is an expensive proposition but is becoming the only available option.

An opportunity to fight this matter inexpensively is not as obvious, yet the opportunity still exists. Another glimpse into recent history concerning these claims is useful. When the current Section 101.93 was a proposed rule, comments flew to FDA concerning the intent of the rule and how badly written it was. Universal agreement from the trade associations representing the dietary supplement industry and from other consumer groups (whose minds apparently were not read well by FDA) requested that the rule be withdrawn and redrafted. FDA's response to these requests was to publish the Final Rule. Subsequent petitions from some (only after severe prompting from industry members) modestly addressed the errors made in FDA's Final Rule action, but the industry as a whole did little else to object. Rather than fight for the original proposition that the rule be withdrawn and redrafted, the industry accepted the Final Rule and allowed FDA's Kreskin-like approach to continue to interpret what the consumer is thinking and, in the end, permitted the list of magic words to grow.

To date, the petitions have not received response from FDA. There remains opportunity to re-address the issue directly with FDA owing to this lack of response. This can only be accomplished, however, if the industry recognizes the reality of an increasingly limited claims territory--which is continually narrowed by FDA's clairvoyance--and determines to take action. Direct address of the issue through a petitioning processes will at least gain FDA's attention and force the issue into the open. The dietary supplement industry must, however, demonstrate resolve and take strong action on the matter without the cost of litigation. Through its magic act, FDA creates an ever-smaller range of acceptable claims.

Clearly, without action from the industry, the acceptable claims territory will continue to shrink as the list of magic words grows. The real loss, though, comes to the consumer who still craves accurate information regarding the potential benefits of his dietary supplements and who will find less and less information available to him.*

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