Toward a New Regulatory Model:

Harmonizing Complementary Healthcare Products

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New Zealand's Current Position

- **New Zealand Does Regulate Complementary Healthcare Products through the Dietary Supplement Regulations under the Food Act**
  - **Such regulation is appropriate for healthcare products with extremely low levels of risk**
  - **The major weakness of the dietary supplement regulations is that they do not allow truthful statements of purpose to be made resulting in customers being unable to make properly informed choices**
  - **Regulators have prevented maintenance of the system thereby creating the perception that the system is inappropriate**

Benefits of New Zealand System

- **New Zealand has one of the largest ranges of safe and effective complementary healthcare product ranges in the world.**
- **New Zealand has one of the lowest cost and least restrictive regulatory systems in the world.**
  - **There is no scientific or anecdotal evidence that New Zealand's current hands-off system is less safe than Australia's restrictive and expensive hands-on system.**

Benefits of New Zealand System Cont'd

- **There is no scientific evidence that New Zealand products are of less quality than those available in Australia**
  - **New Zealand industry has voluntarily embraced GMP**
  - **It is expected that over 95% of product sold will be manufactured and distributed via GMP audited businesses within 3-years VOLUNTARILY**
  - **GMP is simply good business practice**

New Zealand Products Are The Equal of Australia's

- **Despite TGA's claim to the Productivity Commission that its regulatory system gave Australian industry a competitive advantage**
  - **New Zealand companies are unaware of any evidence in the world markets that Australian sourced product is more sought after or fetches a premium**
    - **(Australia's excessive regulatory costs do, however, operate as a very effective trade barrier)**

Post Market Monitoring In New Zealand Is Effective

- **In the past 14 years since the dietary supplement regulations were enacted, there have been less than a handful of cases where product has been withdrawn from the market for safety reasons**
  - **There have been no confirmed deaths associated with dietary supplement consumption in New Zealand**
- **As far as industry knows, in all cases these products were imported, their distributors were easily identified, as required by law, and product was quickly recalled**
- **Every day, products are recalled from the world market place – even in Australia with its pharmaceutical GMP**

Assumptions Regarding Trans-Tasman Harmonisation

- **TGA**
  - **Refuses to accept New Zealand's existing safe, effective and low cost system**
  - **Therefore, Mutual Recognition is unacceptable**
- **New Zealand Industry**
  - **Insists on a regulatory model commensurate with the scientifically validated very low risks associated with complementary healthcare product use**
  - **Therefore, Australia's existing inappropriate drugs and poisons system is unacceptable**

Non-Negotiables

- **Safety**
  - **Risk Management Based Regulation**
- **Quality**
  - **GMP – Appropriate for Complementary Healthcare Products**
- **Honesty**
  - **Fair Trading Law**
  - **Informed Choice**

Essentials of Any Agreed Model

- **Code of Good Regulatory Practice**
  1. **Efficient**
  2. **Effective**
  3. **Transparent**
  4. **Clear**
  5. **Equitable**

1. Efficiency

- **Good Regulation should**
  - **Adopt and maintain only regulations for which the costs on industry are justified by the benefits to society, and**
  - **Adopt and maintain only regulations that achieve objectives at the lowest cost, taking into account alternative approaches to regulation**

Efficiency Case Study

Royal Jelly

- **An efficient regulatory system would not have required huge ongoing effort and cost from both industry and regulators to sort out the resulting mess**
- **A good regulatory system would not have resulted in industry losing more than 30 million dollars in existing market and lost opportunity due to regulatory systems failure**

2. Effectiveness

- **Good Regulation**
  - **Should be designed to achieve the desired policy outcome**
  - **Should be flexible**
    - regulatory measures should be capable of revision to enable them to be adjusted and updated as circumstances change
  - **should be performance-based**
    - specified outcomes rather than inputs should be used, unless prescriptive requirements are unavoidable

Effectiveness Case Studies

I. Folic Acid in New Zealand

- **Good Regulatory Practice would have updated the New Zealand dietary supplement regulations years ago**
- **The scientific evidence has, for ten years, overwhelmingly proven the efficacy and safety of folic acid dietary supplements at levels greater than 300 ug**
- **Good Regulatory Practice would allow legitimate health benefit claims in New Zealand and would have lead to public health officials formally endorsing the use of folic acid in dietary supplement form**

Effectiveness Case Studies Cont'd

II: Comfrey in Australia

- **Potential problem is the Alkaloids**
- **Good Regulatory Practice would focus on outputs and establish standard for acceptable alkaloid levels administered through GMP**
- **Good Regulatory Practice would not ban Comfrey, thus making GMP pointless**

3. Transparency

- **Good regulation making process should be transparent to both the decision-makers and those affected by regulation**
  - **Transparency Includes:**
    - **Adequately defining the problem**
    - **Clearly identifying the objective of regulation:**
    - **Full cost benefit analysis**
    - **Evidence based risk assessment**
    - **Appropriate risk management options being implemented**

Transparency Case Study:

- **Selenium, Iron, Boron**
  - **A regulatory system adhering to the code of good regulatory practice would have:**
    - **Enabled industry to see objective reasoning behind TGA's severe restrictions on selenium and iron supplements, and the banning of boron**
    - **Provided evidence based risk analyses for all to see**
    - **Provided full cost benefit analyses involving input from industry**
    - **Identified appropriate risk management options and implemented the most effective for least cost**

4. Clarity

- **Good regulatory processes and requirements should be as understandable and as accessible as practicable**

Clarity Case Study:

- **Consultants**
  - **Good regulatory practice would not have resulted in the proliferation of complementary healthcare consultants to explain Australia's restrictive regulatory system at further cost to industry**

5. Equitable

- **Regulation should be fair and treat those affected equitably**
  - **A good regulatory system is regarded as fair or equitable when individuals agree on the rules of that system, and any outcome of the system is considered just**
  - **A good regulatory system would not be causing so much distress and contention among stakeholders**
  - **A good regulatory system would not impose 25% of the cost recovery on the complementary medicines industry when 99.99% of the risk is associated with pharmaceuticals**

Case Study:
Regulatory Costs Relative to Risks

- **Perceived Risks**

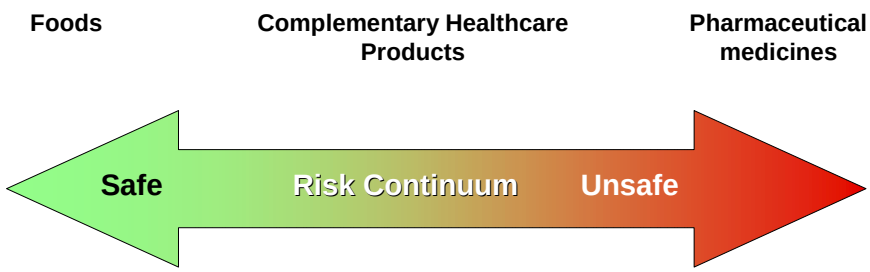
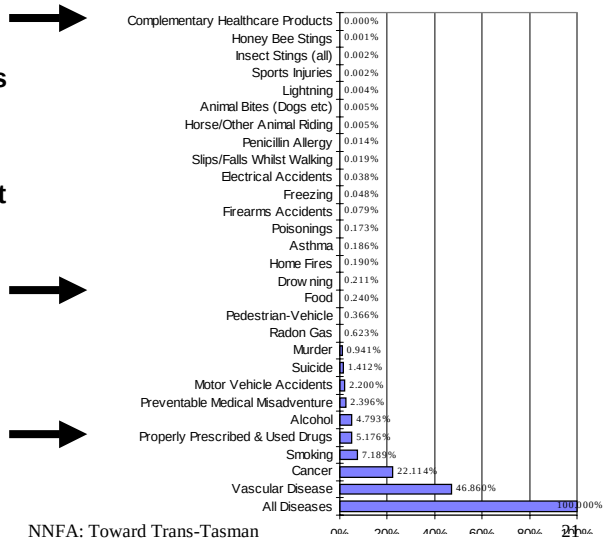


Figure 1. **Perception of comparison of safety** of foods, complementary healthcare products and pharmaceutical medicines.

Evidence Based Relative Risks

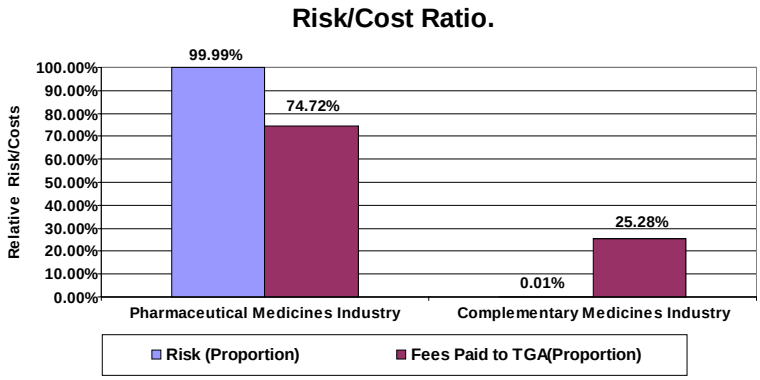
- **Real Risks**
  - **Causality of fatalities in the USA**
  - **When we look at the evidence we see that perceptions can be misleading**



Evidence Based Relative Risks

Figure 3. **Evidence based comparison of safety** of foods, complementary healthcare products and pharmaceutical medicines.

TGA's Cost Recovery Fees Relative to Risk



Costs Paid Relative to Risk

- **Pharmaceutical products 0.75**
- **Complementary Healthcare Products 2,500.00**

- **Relative to risk, the complementary healthcare industry is paying more than 3,000 times its fair share**
- **A Good Regulatory System would not be so inequitable**

Where Did We Get Our Good Regulatory Practice Principles From?

- **New Zealand Government's Code of Good Regulatory Practice**
  - http://www.med.govt.nz/buslt/reg_man/regprac.html

&

- **Australian Government's Code of Good Regulatory Practice**
  - http://www.dewrsb.gov.au/smallBusiness/publications/timeForBusiness/Time%20For%20Business.pdf
- **New Zealand Industry believes that it's time that these codes were utilized**

Summary

- **What New Zealand Industry Wants**
  - **A non-drugs & poisons regulatory system commensurate with complementary healthcare products scientifically proven extremely low-risk profile**
    - Such a system must be based on :
      - **Safety**
      - **Quality**
      - **Honesty**
    - Such a system would be staffed by personnel with qualifications, skills, and understanding of the important role that complementary healthcare products have to play in maintaining and restoring wellness in modern society

Such a System Must Be Driven By:

- **The Existing Codes of Good Regulatory Practice which provide for regulation that is:**
  - **Efficient**
  - **Effective**
  - **Transparent**
  - **Clear**
  - **Equitable**

Neither Australia's or New Zealand's regulators presently operate such a system

Given the Above, the Question Is,

- **"What is the best vehicle to deliver the goods"**

  - **The NNFA has developed a regulatory model that we believe meets all of the objectives expressed by regulators**
  - **The framework of the model was placed on the Trans-Tasman Harmonisation Table in Wellington in August 1998**
  - **Regulators have ignored it ever since**

Good Faith Negotiating

- **We believe that for meaningful progress to be made, the modern era of negotiating mandates that regulators come to the negotiating table in Good Faith to discuss the proposed model**
- **We have been waiting at the table since August 1998 for such negotiations to begin**

Why The Injustice?

- **In Australia and New Zealand the population of a city the size of Christchurch (~250,000) has been killed as a direct result of preventable medical error (170,000) and properly researched, properly regulated, properly prescribed and properly used pharmaceutical drugs (80,000) during the past decade.**
- **During this same period there has been one death with any likelihood of causality established involving complementary healthcare products – even that death is disputed.**
  - **<u>This begs the question…</u>**
  - **"Why should Complementary Healthcare Products be regulated in a similar fashion to dangerous drugs and poisons when they simply do not have the same risk profile?"**

What Industry Does Not Want

- **We can say quite categorically, that the following is not a part of New Zealand's future.**

Australian Industry's Regulatory Burden: What New Zealand does not want