To: Clerk of the Committee
Government Administration Committee
Select Committee Office
Parliament Buildings
WELLINGTON

5 February 2007

Submission on the Therapeutic Products and Medicines Bill to establish a trans-Tasman joint regulator for therapeutic products to replace the Australian Therapeutic Goods Administration (TGA) and The New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

I wish to appear before the committee to speak to my submission.

Dear Government and Administration Select Committee Members,

The Parole act of 2002 Is a law that is now recognised as having been 'ill conceived and poorly drafted'. It required the parole board to release a convicted killer, who went on to kill Karl Kuchenbecker and attempted to kill 3 others soon after being released.

The Hon Lianne Dalziel had this to say in a speech to Buller Grey power in July, 2002:

The Sentencing & Parole Act now requires the Parole Board to give paramount consideration to the safety of the community in considering whether to parole an offender – until the Parole Board is satisfied about the risk, the offender does not get parole, and may never get parole. Offenders can now stay in prison until the end of the sentence imposed, if that risk is there, something that did not exist before, because before 1 July this year offenders were automatically released at two-thirds of the sentence served.

It serves as a reminder that parliament does not always get it right, and the cost of not getting it right can be the lives of innocent citizens.
This law is to be amended as parliament learns from its mistakes.

There will be no such option with this bill. International Trade obligations will make the decision to hand over control of all therapeutic substances and devices to an Australian corporation virtually irrevocable, and this time many more lives are to be placed at risk.

I greet the members of the Government administration committee, Shane Arden, Charles Chauvel, Brian Connell, Darien Fenton, Sandra Gouldie, and Dover Samuels.

I thank the National Party MP's for opposing the bill at the first reading.

I offer my sympathy to the Labour MP's, for I know you will be expected to support this bill. By the time you have completed your investigation, you will surely realise (as have both previous all party select committees) that regulating medical devices and Natural Health Products (NHP's) in this way opposes every principal of common sense and natural justice.

Natural products are to be regulated as Pharmaceutical products, by means of a white list. NHP's have not caused one death in the last 20 years. They are safer than food. Properly prescribed Pharmaceutical products kill people at three times the rate of the road toll **(1)**.

This bill will achieve the seemingly impossible – it will make safe natural products harmful and even lethal - by their absence. It is Orwellian in nature, achieving the opposite of its purported intent.

Dr. Matthias Rath, a medical specialist in nutritional medicine demonstrated that nutritional supplements reversed many conditions including heart disease. He states. "If the Codex Commission (or other regulators – submitters insert) is (are) allowed to obstruct the eradication of heart disease by restricting access to nutritional supplements, more than 12 million people world-wide will continue to die every year from premature heart attacks and strokes. **Within the next generation alone, this would result in over 300 million premature deaths, more than in all the wars of mankind together."**

In a nutshell, based on what has happened in other countries that have enacted legislation of this type approximately 2/3rds **(2 & 3)** of the currently legally available NHP's will become illegal. This has been achieved by overturning a cornerstone of English Common Law – namely the principal of being considered innocent until proven guilty.

Natural medicines are currently regulated by means of a *black* list. Any natural substance that is known to be toxic (e.g. hemlock) has access to it restricted by being put on the black list. Anything that is not on the black list is permitted. This is the 'Considered innocent until proven guilty' approach.

One arbiter of which products will stay legal and which won't is money. If a supplier can't afford to register an unlisted product and/or the associated compliance costs it becomes an illegal substance.
The costs of compliance are not as yet known, and will not be known until the bill has been passed. If we look at the costs in Australia and Canada, where this type of system is already in place, we see they are unsustainable for all but the largest companies.

The draconian and uncertain nature of the regulations regarding offences and penalties will also result in many suppliers simply deciding to leave the industry, as they refuse to risk losing everything they have built up in their lives, including their homes, under penalties such as $5.5 million dollars for a company, and $550,000 for a director for breaking rules which have not been made yet, which can be prosecuted up to 6 years after the alleged offence. Please refer to page 5 & 6 of footnote **(4)** for a summary of the key points relating to this.

Clause 193 states that the actions of the 5 member board (one of whom is the managing director) will stand even if they have not followed the required procedures. This means they can do whatever they like without fear of any consequences.
The managing director can issue orders which will have the effect of law. Important details such as orders relating to what products may be sold, what fees will apply, and what advertisements will be allowed are to be made after the bill has been passed, when it will be too late to take back control.

The compliance requirements have been made far more stringent than the inherent safety of the products justify. In their current loosely regulated form they are already safer than food **(1)**; therefore Good Manufacturing Practice (GMP) standards similar to those for food production are all that should be required to ensure a safe product. Requiring pharmaceutical GMP standards only serves to regulate many products out of existence.

It will furthermore hand the control of NHP's and medical devices over to an Australian corporation managed and staffed by people with a Pharmaceutical mindset. They operate within the dominant paradigm of mainstream medicine, and sociologists have a term to describe their reaction to any innovation that originates from outside their ranks: they call it the Semmelweiss Syndrome.

Semmelweiss is the doctor who discovered in 1847 that the washing of hands before assisting in childbirth resulted in lowering the incidence of puerperal fever. He instructed all the surgeons in his hospital to wash their hands between patients, which reduced the incidence of the fever from 13% to less than 2%.

Puerperal fever was fatal, killing mothers within days of contracting it, thus an infection rate of 13% meant that for every 100 women who entered the hospital to give birth, 13 would die.
Despite the dramatically lowered death rate, his methods were not welcomed by his superiors. The concept of bacterial infection was not yet known, there was professional jealousy, and doctors were reluctant to admit responsibility for being the cause so many deaths.
Semmelweiss was eventually dismissed for his unorthodox views, after which the mortality rate climbed as high as 30% in the same hospital, as doctors made a point of not washing their hands to distance themselves from the radical doctor who had just been fired for doing just that.
He replicated his results at another hospital and set about to scientifically prove his theory, publishing the results of his clinical trials in 1861 – fourteen years after he had proved empirically that washing your hands meant your patients wouldn't die.

He circulated his findings to medical societies and leading obstetricians in Germany, France, and England. The response was the same. His work was rejected by the medical mainstream, and women in childbirth continued to die in their thousands.

At this point he became very angry, and wrote,

'It is owing to the doctors that there is so high a mortality in childbed. Murder must cease and I shall do my utmost to ensure the cessation of murder, for everyone who dares to disseminate dangerous fallacies concerning puerperal fever will find in me an extremely fierce opponent."

I am firmly convinced that there is no other way of putting a stop to these murders than the ruthless exposure of my adversaries, and no one whose heart is in the right place will blame me for the means I use'.

Was Semmelweis justified in accusing doctors of murder? It is an interesting question.
They justified their refusal to adopt a procedure that did no harm (washing their hands) that showed empirical evidence of saving many lives by their insistence on scientific evidence that would explain the link between washing hands and contracting the fever. The evidence of bacteria was not available; therefore the washing of hands was classed as a superstition.
I note that the bill before you still forbids activities that are viewed as superstitious with no provision to allow for recognition of empirical evidence supporting the so called superstitious behaviour.
While his evidence was only empirical his colleagues demanded scientific evidence. When he provided the scientific evidence, they still didn't want to know. (That pattern of behaviour has been repeated so many times it has now become predictable – refer to enclosed book: Politics in Healing. It leads us to ask, "What is the real reason for opposing innovation?")
That is when he accused them of murder. Murder or not – we now know that thousands of mothers died needlessly at the hands of doctors because they refused to wash their hands.
We have an opportunity today to challenge this form of irrational behaviour that has cost so many lives, and demand a more humane and sensible approach.

Herbal treatments enjoy a wealth of empirical evidence regarding their efficacy. How do they work? The answer still eludes science. One of the reasons for this is the scientific principal of observing only one 'active ingredient' at a time. Any given herb contains many bioactive compounds, all of which have a part to play in creating the sum of its properties. Garlic alone contains over 100 bioactive compounds.
Pharmaceutical companies like to pick one of them as the 'active ingredient', to artificially replicate, patent, and make a lot of money out of.
Herbalists consider every compound in a herb has its part to play. If science is not yet capable of discovering what goes on amongst 100+ compounds to explain why it works, that is no reason to deprive people of its empirically noted benefits. To that extent we find ourselves in the same situation as Semmelweis who was unable to prove the existence of bacteria, particularly when we start to combine herbs, making the analysis even more complex.

Supporters of this bill will be enhancing and perpetuating the mind set of ignoring life saving empirical evidence in the name of science.

Death or injury that occurs at the hands of a doctor is known as *iatrogenic* death or injury. Semmelweiss could never come to terms with the complacency of his colleagues towards people dying in their care. One of their objections to washing their hands was that they did not have time.
Today's regulators appear to be similarly relaxed about the current iatrogenic death toll relating to properly prescribed pharmaceutical medicines, which according to the officially released statistics is about three times the road toll.**(1)** The actual rate is likely to be far higher, due to under reporting. There is no legal requirement for doctors to report adverse reactions to the drugs they prescribe, it is done voluntarily.
The sacred cow status currently enjoyed by Pharma means that this issue is kept well out of the public arena; in much the same way as sexual abuse in the state and religious institutions was in the past. Our road toll is far too high, and a high profile awareness campaign has been in place for many years, yet the much higher iatrogenic toll is swept under the carpet.
For his troubles Semmelweiss was eventually classed by his peers as 'Obsessed' and committed to a lunatic asylum, where he received a severe beating from the hospital orderlies. He died two weeks later, at the age of 47.

Semmelweiss Syndrome behaviour includes the following:
Refusal to consider ideas that threaten the status and the established belief system of the dominant group.
Refusal to adopt a procedure that can do no harm but has the possibility of doing substantial good.
Refusal to acknowledge the obvious.
Refusal to take into account unnecessary suffering which is a consequence of all of the above.

Is the Semmelweiss syndrome still valid today?

Absolutely. It is a recognised and predictable pattern of dominant group behaviour.

A more recent example of the Semmelweiss syndrome in our very own country involves Arthur Lydiard. His unorthodox training methods led to medals for 3 New Zealand runners (Peter Snell, Murray Halberg and Barry Magee) at the 1960 Olympics in Rome.
Instead of being applauded, he was treated as an embarrassment by Athletics NZ, who could not come to terms that a milkman had developed an unorthodox method of training athletes that was better than the established way.
They wouldn't give him an official role at the Olympic Games in 1964 and it took a national appeal to raise his fare so he was able to attend and watch Peter Snell take the 800 m and 1500 m double.
Despite these successes Athletics NZ refused to acknowledge him and ultimately succeeded in making it impossible for him to further his work in NZ, so he left. They only recognised him in November 2003, shortly before his death.
How many Olympic medals did Athletics NZ bad grace cost NZ? We will never know, and at the end of the day they are only medals. Lives however are a much more serious issue.

This is very important for you as a committee to consider, for once you realise that highly respected professionals in a group are capable of behaving in this way, and are in fact likely to do so, it follows that this should be taken into account when allocating control of one group over another.

Mainstream medicine's hostility towards NHP's goes back over 80 years, and is very well documented.

This is why I have included as part of my submission copies of the book 'Politics in Healing' by Daniel Haley, which details how health regulators have successfully withheld 10 different low cost cancer cures from the public they were paid to protect over the past 80 years. These cures were non pharmaceutical and non surgical in nature, and in almost every case not patentable and therefore not profitable. These characteristics excluded them from the mindset of the regulations and regulators.

If you do not accept that mainstream medical health regulators are responsible for withholding effective cancer treatments from the public you have a duty to read this book before rejecting this statement.

It is not acceptable to turn a blind eye.

You will place yourself in the same category as those doctors who didn't have time to wash their hands if you do, for you as parliamentarians have a duty to be fully informed before supporting legislation that has potentially lethal consequences .

As you read Politics in Healing keep in mind that there is a 33% chance that you will one day be diagnosed with Cancer. If there are two more people that are close to you there is a 100% likelihood that one of you will be diagnosed with Cancer. How many choices will there be for you on that day? The answer will be influenced by you when you make your recommendations on the bill AND when you cast your vote in parliament.

The Semmelweisses of this world continue to be snubbed, ridiculed, and persecuted. Nothing has changed!

What are the Puerperal Fevers of today? They are Cancer, Heart disease, Diabetes, and many more. Are there Semmelweiss solutions out there? There have been many, but as you are about to find out, the regulators have kept them from us.

If NHP's and medical devices are excluded from this bill there will be no loss of access to mainstream medicine, but there will be wider choice. If it is passed in its present form you will have succeeded in updating the regulators powers to suppress non-toxic therapies.

This leads us to the question: What is the difference between Pharmaceutical medicines and Natural Health Products? Why shouldn't they be treated the same?
Natural medicines, not surprisingly, are defined as having come from Nature. They are not man made, and are therefore not patentable. Their risk profile is lower than food. **(1)**

Pharmaceutical medicines are man made, and therefore patentable, which also makes them highly profitable. When they enter the bloodstream our bodies treat them as toxic substances, and that is why they are only available on prescription. Access to them is tightly controlled, because if we take too high a dose, they can kill or injure us. Sometimes they kill or injure us at the standard dose. Their risk profile is extremely high. **(1)**

Natural medicines are currently regulated by means of a *black* list. Any natural substance that is known to be toxic (e.g. hemlock) has access to it restricted by being put on the black list. Anything that is not on the black list is permitted. This is the 'Considered innocent until proven guilty' approach.

Pharmaceutical medicines are regulated by means of a *white* list. Because they are all known to be toxic, they have to be thoroughly tested to prove they deserve to be put on the white list. Anything that is not on the white list is forbidden. This is the 'Considered guilty until proven innocent' approach.

The regulators want to treat both the non toxic and the toxic substances as toxic. This will of course create an enormous amount of extra work, which is to be paid for on a 'Full cost recovery basis'* i.e. the user pays.
In reality the "full cost recovery" policy actually only applies to naturally occurring substances, by virtue of the fact that the pharmaceutical drugs are subsidized by the taxpayer.
This allows the pharmaceutical industry to pass their regulatory costs on to the taxpayer, whereas the natural product industry can only pass their costs on to the customer. This results in a selectively applied tariff barrier.
* Full Cost recovery – the minister has offered a 5 year 50% subsidy to assist NHP's to transition into the system. This does not address any of the fundamental flaws in the regulations. It may just delay the demise of the industry a little.

Let's step back and examine this.

The regulators show no inclination or ability to reduce or even acknowledge a death toll which is at best 3 x the road toll, caused by the properly prescribed toxic medicines they are currently responsible for. **(1)**
They now also want to regulate natural therapies which haven't caused one death in the past 20 years in the same way. They want to treat them as toxins by means of a white list.
The costs associated with doing so will likely result in 2/3rds of them disappearing is of no concern. Also of no concern is the harm caused by the non –availability to those who depend on them – currently or in the future.
This is classic Semmelweiss syndrome behaviour. These rules will achieve the seemingly impossible, turning harmless therapies into lethal ones – lethal by their absence.
Just as the dominant group in Semmelweises first hospital banned a procedure they didn't understand which resulted in a 15 fold increase in the mortality rate (from 2% to 30%), today's regulators are set to do the same with this sweeping change.
They have created a bill that has all the ingredients required to maintain the ability to suppress safe and effective treatments in the face of an explosion of innovation and consumer preference for them.

What are the immediate consequences of this bill proceeding? Well, if someone who currently relies on an NHP to keep them alive, its withdrawal will result in them dying. Someone who is currently free from a serious illness such as emphysema or chronic angina thanks to a NHP will again become seriously ill - gasping for air or crippled with chest pain 5 or 6 times per day. By overturning the way we regulate NHP's we will also be overturning their safety record.

The Bill does not require such consequences to be taken into account, and it has already been established in courts overseas that regulating NHP's in this way has resulted in deaths **(5)**. The administrators and bureaucrats who were involved in causing the deaths by applying the regulations have not faced any disciplinary action. One Health Canada Official (Miles Brosseau) confirmed in court, under oath, that Health Canada policy overrides consideration of human life. The court transcript reads as follows:
So, if you were sent a document showing that people were dying because of what Health Canada was doing…..you would just ignore that because it was not a policy or directive? Miles Brosseau's answer: "Yes".

This is the type of legislation that you are considering, and that some of you have already voted for.

Yours is the third select committee to examine harmonization with the Australian way of regulating medicines and medical devices. The previous two had more time, more members to devote to the task and more experience in the subject, given that they were both Health Select committees.
Both of them were all party committees, and both were unanimous in their rejection of the regulatory principles embedded in this bill.

They took their responsibilities seriously, as I hope you will too. In years to come, it is my hope that when a government chooses to ignore the recommendations of a select committee, there will be a threshold higher than 50/50 required for the bill to pass into law.

When considering new types of legislation, it makes sense to see what impact it has had in countries where it already exists. We can look to Australia and Canada for such examples.

Let's first go to Canada, where we will examine the background to the court case referred to in footnote **(5)**.

Imagine that you have a son, daughter or spouse who starts to suffer from a mental illness such as depression or bipolar disorder.
The doctor puts them on drugs, which work for a while but then the symptoms return. Stronger and stronger drugs are provided, many of them causing severe side effects such as rapid weight gain, with diabetes, liver and kidney failure likely to appear over time.
Your loved one grows worse, eventually attempting suicide. The illness is destroying the family, and you have nowhere to turn.
Then someone tells you about a natural formula containing nutrients that is showing very promising results. You follow it up and your mentally ill loved one joins the program. Their symptoms gradually disappear, and they come off all of the other drugs. They are well again.
A year goes by and the mental illness seems like a bad dream. You hear that a University has started doing clinical trials on the nutritional formula which are going really well, showing an 80% success rate – an unheard of result. Many of the other drugs are released to market with a success rate of as little as 26%.
Then one day you go to re-order and find that the formula has been banned by Health Canada. You ring the supplier, they tell you that Health Canada has intervened and instructed the University to immediately halt the clinical trial. They also tell you that Health Canada has banned the formula because it had developed a reputation for benefiting a serious illness, and it did not have a Drug identification Number (DIN). No DIN would be issued because the trial had not been completed.
Your loved ones supply runs out and they can't get any more.
You call a crisis line that has been set up by Health Canada. There is a recorded message which states: "You are mentally ill, the formula you were taking has been withdrawn for your own safety, go back to your doctor or psychiatrist and go back on the drugs that they prescribe. You may leave a message but it will not necessarily be responded to."
Your loved one starts to regress, all of the old symptoms return. They vow they are not going to endure all of the side effects of the drugs they were on before, which didn't work anyway. They say they would rather die.
You decide to drive 10 hours across the border to the US where the product is not banned, but it gets confiscated on the way back by Canadian Customs, who are under strict instructions to seize the formula. You break down in tears, you beg them to let you have it, but it's no use. You go home empty handed.
You call the head of the Canadian Mental Health Association. You describe your situation, and he asks what's in the formula. You read out all of the ingredients – they are nothing but vitamins and minerals, and he says he will try and help. He calls Health Canada and tries to intervene on your behalf. He tells them that your loved ones life is at risk without this product, can they make an exception and allow the confiscated product at the border to be released. The answer is no.
Your loved one does commit suicide out of despair, and there was nothing you could do to stop it.
Later the suppliers are taken to court by Health Canada for ignoring their directive to stop selling the product. The verdict makes headlines.
The Judge rules in favour of the suppliers, granting them the defence of necessity. He said that if the directors had not ignored Health Canada's directives they would have been liable for criminal charges of withholding the necessities of life support. He labeled Health Canada's actions as 'vexatious'. During the trial it was also established that Health Canada considered all of the ingredients to pose minimal risk.

You also read that some of the people who called the crisis line were put through to a call centre, and that records were kept of the calls.

Health Canada refused to release these records, saying they were 'undiscoverable' (Again, turning a blind eye), until ordered to do so by the court.

This is some of what call centre operators wrote. In 730 pages of notes not a single caller notified the call centre of an adverse event with the supplement:

- "I'd like to know what you're going to do about my possible suicide in a few weeks when I run out of the supplement".
- "I require the supplement to live"….Also feels as if a death sentence has been handed to her.
- Was severely suicidal before taking the supplement, and is now afraid for his life if the product is banned.
- Does not feel that she will be able to function without it.
- Caller is desperate and is pleading with me to tell the Minister to change her mind.
- She has 3 kids she has to take care of…if government stops this, it will be the end of her life. "It is a question of life or death and it is extremely serious".
- "Government can not stop this product because I will die".
- She is crying a lot and says it is the only product that will keep her alive.
- She states that this will destroy her life, she is pleading with the Minister (from a mother to a mother) crying and pleading, to please allow her to have access to the product.
- "Feel betrayed…turned my life around…Didn't know that it was some peoples mission to hurt people. Haven't slept for two days"…Client crying…"we don't need a crisis line, we need the supplement".
- "Please tell the Minister that she has to find a way because my daughter is going to kill herself".
- Child has rare disease, he is hugely improved. Desperate because by end of June his supply will run out. She does not want him to return to his previous level of functioning.
- She added that the title "Honorable" should not be associated with the Ministers name. She says she is no longer proud of her country, that this situation is inhumane and moronic….she wanted to know how I could sleep at night knowing about this.
- No other approach, including drugs and shock therapy has worked.
- I spent 2 full years in bed, and with this supplement I can now work and have an active life.
- Suicidal since age 8…. (now) pays taxes…..works for 1st time.

Next, you find out that the Health Canada officials responsible for banning the product will not be prosecuted. They were just doing their job. Due to a change of government the New Minister of Health has provided a special dispensation for the product to be allowed to be imported for personal use. The clinical trials have started again, but the product remains banned by Health Canada.

A transcript of the entire court case is available by email upon request.
A video of press gallery interviews of consumers who came to parliament to plead for help is also enclosed. Parliament was powerless to intervene on their behalf, just as you will be if this bill goes ahead.
Footnote **(6)** is a copy of an email to local industry from one of the directors of Truehope Nutritional Support Ltd, the company that makes the nutritional formula outlined above. In it he outlines his views on this form of regulation.
Truehope have recently obtained approval on the product in question under a different name, with only minor health claims attributed to it. It cost them $100,000 Canadian to register this blend of Vitamins, minerals, and herbs. The identical formula with a reputation for benefiting mental illness remains banned by Health Canada to this day.

So we see the Semmelweiss syndrome is alive and well in Canada.

A note on the intervention of the new Minister of Health. This would not be possible in NZ or Australia. Neither minister will have the authority to intervene on matters such as this. To that extent both countries are relinquishing their authority to the Managing Director of the corporation that runs everything. The bill states: The Managing Director will be responsible to the board for financial and administrative matters. (pg 88 of the bill) There is no mention in the bill of any accountability for regulatory matters.

Next we look at Australia, the country we are about to hand our sovereign health rights over to:

There are few people in NZ who will not recall the mass recall of PAN products in 2003. 1369 PAN dietary supplements were the subject of a class one recall along with Travacalm, a pharmaceutical product that had been poorly blended and had caused adverse reactions.
Equally few realise that no evidence was ever provided of any justification for recalling even one of the 1369 dietary supplements. The immediate incineration of the recalled product means that such evidence will never be provided.
The Pan Debacle clearly illustrates that the Australian health regulator is out of control, biased, and seemingly immune from being reigned in. The following article did not reach our mainstream media, but is certainly required reading for anyone involved in surrendering this country's health freedom to Australia.

Eve Hillary's article, filed May 12, 2003

PART 1

Part 1 April 29th, 2003 was a cool autumn day in Australia. To the average Aussie it seemed a day like any other. Most tuned into the 6 o'clock news, aware that history was being made in other countries with SARS and the U.S. invasion of Iraq. But few were aware that something of historical importance was unfolding in the "Lucky Country". To seasoned observers who saw it coming it was nothing short of breathtaking when the near mortal blow to health freedom was finally struck, and for a while, dissenting voices were stunned into silence. Many pundits expected other countries to be the more likely targets but like any interesting social experiment, there was an elegant logic behind the choice. Australians were historically spared the great upheavals of the twentieth century. They seemed more trusting, less suspicious of political and corporate agendas than their counterparts in the northern hemisphere or in Europe where entire populations still recall the spin-doctoring of totalitarian governments under the guise of this or that benefit for the public good.

The largest, quickest and most comprehensive recall of health care products in world history occurred in Australia following an announcement on Monday April 29th by the TGA that they had served Pan Pharmaceuticals with an order to suspend its operations for a six month period. The company supplied 75% of Australia's complementary healthcare products such as nutritional supplements in the form of vitamins, minerals, omega oils, and herbal products. Pan also supplied a range of over-the-counter and other drugs, which were sold under various brand names by other companies. Jim Selim, the founder and CEO of Pan is an Egyptian born pharmacist who by all accounts has a passionate belief in natural products and expert knowledge of herbs and supplements. Selim had single handedly built up his company and within 20 years was the largest supplier of complementary health products in Australia. His astonishing success catapulted him onto the world stage as the fourth largest manufacturer of natural health products. Along with this distinction came some unwanted attention from the multi-national pharmaceutical industry, which had been lobbying against natural health supplements and products because of the significant erosion they made into drug company profits.

Studies show that 60% of consumers have spent some of their health dollars on supplements and natural remedies. Many use natural products to maintain good health or facilitate recovery from various conditions after orthodox medicine has failed, as it often does in the case of chronic illness. Doctors trained in nutritional medicine as well as qualified naturopaths; use supplements therapeutically as an adjunct to orthodox treatments or as wholistic treatments. The science behind natural medicine has been widely denied by orthodox medicine and is largely kept out of medical student's curricula. However nutrients have been used and studied for thousands of years and there is a large body of valid scientific evidence that shows therapeutic nutrients are highly effective in treating a wide range of conditions. Most health consumers take supplements because they perceive a health benefit and are not even aware that there is solid science behind nutritional therapies.

This research is little mentioned in the media, which nearly always portrays nutritional therapies as being solely practiced by unqualified quacks. Media disinformation is issued directly from pharmaceutical company public relations departments

on a daily basis through journalists and industry-sponsored doctors embedded in the media and other key positions. (8) This has been occurring for over 40 years and is well documented in the chemical industry archives, documents released through litigation. (7)

Much of the public confusion on the issue results from drug industry misinformation, which frequently refers to nutrient supplements as medicines or even drugs. Nutrients are not drugs. Humans require dozens of essential nutrients such as vitamins and minerals and antioxidants to stay alive and healthy. The body knows how to use these and eliminates the excess as it has done for millions of years. The need for supplements has increased recently, after it has been shown that plant-based foods are now grown on barren and demineralised soils, which do not supply plants with optimum nutrients. Humans then eat nutritionally deficient plants. Orthodox doctors claim the standard western diet contains all we need and additional supplements are 'flushed down the toilet'. This view appears to be myopic or at least poorly informed, given that 75% of all Australian deaths are a result of lifestyle factors. This includes poor diet and the resulting nutritional deficiencies.

On the other hand, drugs are mostly synthetic chemicals. There are many drugs that are life saving and beneficial when prescribed responsibly. But the massive proliferation of drugs has given rise to a statistic, which the multi-national pharmaceutical industry attempts to hide. Dangerous or inappropriate pharmaceutical drug treatments and medical interventions have now become the third leading cause of death.

The "problem" for the pharmaceutical industry is twofold. Healthy people avoid consuming pharmaceuticals. Illness generates profits to drug companies, mainly through their exclusive sale of patented drugs. Wellness and preventative medicine has been less profitable for the multinational drug industry because smaller companies like Pan and many other vitamin companies formulate and sell most of the world's nutritional and vitamin products. Nutrients and herbs are naturally occurring substances and therefore cannot be patented unless their structure is changed through genetic engineering or chemical processes. Pharmaceutical industry PR departments and industry-funded scientists have been behind unnecessary herb and vitamin scares, citing lack of uniformity or actual danger to persons who take supplements. Subsequently some natural products have been withdrawn from sale while massive drug and biotech multi-nationals work behind the scenes to chemically alter and patent natural substances as pharmaceuticals. In Australia alone the increasing popularity of natural products has deprived the global pharmaceutical market of 2 billion dollars annually.

This has brought in its wake an accelerating clampdown on complementary medicine (using natural products). The drug industry is worth trillions of dollars worldwide and it has some powerful friends.

In January 2003, the TGA moved to recall Travacalm, Pan's over-the-counter travel sickness tablet when it was tested and found to be defective. After the January recall, Pan discovered a problem with one of its analysts whom the company claimed was responsible for the lapse in quality control over the defective product. The company dismissed the analyst, and set out to correct the problem with its recalled product, while continuing to manufacture its other unaffected product lines. So far the protocol followed normal procedure for a recall, a commonplace occurrence even in the multi-national pharmaceutical industry.

However, neither Jim Selim nor Pan's board members anticipated the special attention they were about to receive from the TGA. The company had become used to the regular TGA inspections in the previous few years and neither Pan nor the TGA found any serious cause for concern. In fact, Pan's vitamin and herb factory had been inspected more often and more rigorously than the Australian-based operations of multi-national pharmaceutical drug companies. However, after January the TGA conducted a number of audit raids on Pan which foreshadowed trouble. In April, the TGA shut down Pan's entire operation and slapped a class 1 recall over 1369 Pan products which were unrelated to Travacalm. This involved mostly vitamins, minerals and herbal products, which the company supplied to over 75% of the complementary health care market. The regulator cited serious concerns as to the quality, safety or effectiveness of these natural remedies. Class 1 recalls are only issued when it has been shown that the product is likely to cause serious, irreversible health damage or death. By its extreme action of issuing a class 1 recall, the TGA indicated to the general public that the calcium tablet or vitamin C or Echinacea or chamomile or any other of the 1369 natural products they had been taking without any problems, are now expected to cause death or irreversible health damage. Many consumers questioned this logic when they had experienced no adverse health effects from the supplements they had already taken. Those whose suspicions were aroused were even more surprised that the TGA had not given specific information about the nature of the problem with the products. Then Mayne Health, a large health care company whom Pan supplied with health care products, stated that their company had regularly conducted their own rigorous testing of Pan's product and had not found a cause for concern. The TGA offered no explanation as to why an independent distributor of Pan's products could find no problem on testing when the regulator claimed there was a life-threatening problem.

During the week of the shock announcement, the TGA left its responsibilities as a provider of accurate and useful public information, to the daily tabloids who rushed to fill the information vacuum with headlines such as; Honeymoon Ruined, Babies in Danger, It's a Sick Business, Bad Medicine. By the end of the week the TGA had still not explained the specific problem and which of the vitamin company's products were affected and in what way.

Instead they stood by as the press had a field day whipping up the story while the more vulnerable consumers of health care products, elderly people and young mothers, panicked and imagined all types of horrific scenarios. The interim week saw a run on 5000 health food stores which reported an influx of panicked customers demanding refunds for all manner of products, even those they'd fully consumed, and those that were out of date. Some demanded money for taxi fares.

The TGA remained tight lipped about the offending substance that had allegedly rendered these supplements life threatening overnight. Instead, the regulator issued numerous public announcements stating that; "drugs and pharmaceuticals are perfectly safe and persons should keep on taking them". The NSW State Premier chimed in with his own message to that effect.

By the end of the week the dailies continued running weekend feature stories about the grave dangers of taking vitamins. The conundrum sent freelance and independent researchers scurrying to their computers to research product recalls. A short search of the FDA drug recall list and medico-legal websites, list thousands of recalls, adverse events and warnings pertaining to drug and chemical products manufactured by multi-national drug and chemical companies. Many of the listed products are known to be either dangerous or toxic to humans and even carcinogenic. Multi-national drug company recalls are rarely given much press, and have never been given as much negative media attention as Pan had received. Even more incredibly, no large multi-national company has ever been shut down by a government regulator after one of its products has been recalled, even if deaths have occurred as a result of using the drug or chemical. This discovery was guaranteed to make any independent journalist even more curious about the TGA and the vitamin company.

In the second week, Pan stocks plummeted and other companies scrambled to fill the manufacturing gap while their share prices surfed a rising wave. The mainstream media had settled into the role of investigators and de-facto TGA spokespersons, breathlessly informing the public of the "facts" behind the "vitamin scandal". "Snake Oil Jim Quits..." screamed the tabloids, while the "prestigious" Sydney Morning Herald ran the story; "Tangled Tale of Lucky Jim", a vicious little expose` of Selim's daughter and her 1997 battle with drugs. Any parent would consider it a tragedy to watch their child suffer from the disease of addiction, let alone have it published in the newspaper. The journalists Mercer and Stevenson used a psychologist's report to speculate on Jim Selim's shortcomings as a parent. Hardly a need-to-know issue for the Australian public who had still not been informed as to the results of the regulator's testing of the 1369 urgently recalled products. Not surprisingly, Jim Selim voluntarily resigned as CEO from his own company, amidst one of the most vicious tabloid vilification campaigns in the history of the Australian press.

While grannies thought they had been poisoned, Australia's investigative journalists wrote about interviews with disgruntled employees who thought they should have had longer breaks and the production should have been slower at the vitamin factory. The dailies stated opinion as gospel while offering no real facts from the TGA. While the thinking public waited for the facts, young mothers still thought they had poisoned their babies. The tabloids made fun of Jim Selim and columnists wrote ditties about vitamins and herbs being "eye of newt". Embedded industry-sponsored TV journalists worked feverishly behind the scenes to spin horror exposés about herbs and vitamins that were screened within a week of the breaking news. And still no one had suffered any adverse effects from having taken vitamins. Embedded "experts" emerged from the closet with their editorials, published under the guise of objective articles. Still the TGA remained silent about the exact reason why the natural products were classed as being capable of causing death.

Pundits assumed TGA was checking all recalled products just as they had checked Travacalm and made public the exact nature of the problem.

By the end of the week Jim Selim, once a man with a zest for life, had been forced to leave his home after journalists crawled all over his garden by day and night. They interviewed his neighbours, one of whom complained that the Selim family had visitors who banged the gate when they left. The other complaint was about the noise when the family swam in their pool. The facts gleaned by the reader from this in-depth investigative journalism were that the Selims had friends and they indulged in occasional exercise. By week's end the Selim family retreated to parts unknown, amidst Jim's friend's concerns that "he is in a very bad way."

While the media was beating itself to death with the vitamin factory story, a little known posting appeared in an obscure place on the TGA website. The regulator is also in charge of being a public watchdog with respect to food, chemicals and consumer items. On the same day as the TGA recalled Pan products, they also issued another recall. A small goods company packaged a large quantity of ham, which was found to be contaminated with bacteria known to cause serious food poisoning, which sometimes results in death. The media never mentioned this, and there were no public press releases issued by the TGA.

At the end of the second week following the world's largest recall, the TGA had still released no results of their product testing to Australian consumers or the thousands of businesses that relied on accurate information. But many of the 5000 or so Australian health food store proprietors were about to start the cascade into insolvency. To hasten the process, they were forced by the consumer watchdog ACCC to issue consumer refunds when they had no guarantee of reimbursement by the now ailing manufacturer. Health food shops were left saddled with the difference between the wholesale and retail price, which they had to find out of their own pockets. With their backs to the wall they still had precious little by way of an

explanation. However, TGA did issue clear instructions to clear shelves of recalled product. Now, virtually overnight natural products disappeared leaving many shops bare.

The largest mountain of vitamins, minerals, oils and herbs in the world was hurriedly designated for destruction by the Australian Government in a special location and using a special process usually reserved for toxic waste. The evidence is destined for destruction. The TGA has still not informed the public as to why their natural products were classified as being deadly, when no one had previously suffered adverse effects. The regulator has released no test results. It is not known if tests were ever conducted. When the mountain of vitamins finally rests in its mass grave, incinerated and entombed as the remains of what the Australian government regards as toxic waste, we will never know. And the epitaph on the headstone could well read; "Here Lies Health Freedom".

Among the mystery and intrigue surrounding this historical event, one thing appears to be certain. Had any test shown a lethal toxicity supporting a class 1 recall, the TGA would have told us by now.

Unlike some issues that rest in peace, the ghost of this recall will haunt the government for years to come. The story of the recall started years ago in a bustling European city. But first, a little more about the regulator.

PART 2 - TGA "Protecting the Health and Safety of All Australians"

Like its US FDA counterpart, the Australian TGA states that it "is obligated to take action where there is concern in relation to the quality, safety and effectiveness of medicines." The regulator also oversees the safety of food and chemical products as well as consumer items and medicines. The TGA states its role is to "…protect the health and safety of all Australians." However, an audit of the regulator's performance reveals an astonishing picture.

TGA Regulating Chemicals

In 1999 a woman lodged a complaint with the TGA about a chemical product that she had used, as directed on the label. Using this product had caused her to be violently ill and she required hospital treatment. She was pregnant at the time of the toxic exposure. Serious health effects became apparent as a result of the poisoning, affecting both the woman and her child for many years. Both were subsequently diagnosed with chemical poisoning by two Australian doctors and one U.S. specialist physician. She reported this to the then director of the Chemicals and Non-prescription Medicines Branch of the TGA, Mr. Graham Peachey. The director replied to her complaint, claiming that all chemicals are rigorously tested and regulated by Australian government departments. He maintained that her claim that this chemical product had caused serious illness was a result of "a strong interaction with personal belief factors". By this, he dismissed her complaint, alleging that she was imagining the (medically diagnosed) serious effects the chemical exposure had on herself and her child.

The woman wrote back enquiring as to what kind of testing is done by the regulators on toxic chemicals that are manufactured by large multi-national companies and that stream directly onto the Australian market. She received no reply. She later found out that no independent testing of any kind is done on these products before they reach the consumer. Meanwhile she encountered others who'd had similar experiences with the same chemical and other toxic consumer products. She discovered that they too had written letters of complaint to the TGA, and they had received the same response. She joined a support group for chemically injured persons, and became the group's newsletter editor. Soon she was inundated with letters from persons who related the identical or similar responses from the TGA after they had lodged complaints to the regulator about harmful effects from toxic chemicals in consumer products. Intrigued, she investigated these allegations and found that the TGA had dismissed all of them. None of these dozens (and possibly thousands) of complaints alleging serious and sometimes life threatening effects on consumers by various chemical products were ever investigated by the TGA. The multi-national chemical manufacturers were never held accountable and the TGA never co-operated with calls to start an adverse events register for chemical products despite years of lobbying by individuals, advocates and support groups.

TGA Regulating Drugs

Like its U.S. FDA counterpart, the TGA regulates and approves drugs. Ten years ago in 1994 there were 157.5 million prescriptions issued annually. That figure has now increased exponentially as hundreds of new drugs have come on line. It would be reasonable to assume that a large part of the huge modern TGA building in Canberra would be devoted to ensuring public safety through monitoring of potent pharmaceutical drugs. However more oversight committees and manpower is devoted to herbs and vitamins. Why? A quick overview of just one drug regulating example will yield some disturbing answers and raise even more questions.

In the mid 1980's GlaxoSmithKline marketed buproprion as an antidepressant, released under the brand name of Wellbutrin and later Zyban. In 1986 bupropion was briefly withdrawn due to the high rate of convulsions associated with its use, and later inexplicably returned to the marketplace. By 2002 bupropion was recognised as the third most common

cause of drug related seizures with cocaine found to be the number one cause (2).Buproprion is often placed in the same category as Prozac type drugs, but its exact mode of action remains unclear after many years of study. Since 1998, statistics indicated some serious adverse effects were occurring among patients taking the drug. Complaints were flowing in to Health Canada, to the UK regulator and to the manufacturer, GlaxoSmithKline. The company had received 1127 adverse reports about the drug from Canada alone between May 1998 and May 28, 2001. This included 19 deaths. Meanwhile the Medicines Control Agency, UK's version of the FDA/TGA, reported 3,457 adverse reaction reports to the drug including 18 deaths. Since then there have been 7,500 adverse reactions and 58 deaths in the UK up to April 2002.

In 2000, GlaxoSmithKline lodged an application to the TGA to approve bupropion, to be marketed in its new guise, not as an antidepressant, but as an anti smoking drug called Zyban. By then the drug had collected a number of skeletons in its closet. The drug had enjoyed another life as a weight loss pill, and was written up in an Obesity Journal as being a fat buster, since loss of appetite had been determined in 3% of the side effects reported while in use as an antidepressant. However, the "research" was far from ethical, as it was commissioned and paid for by the drug's manufacturer. (3,4)Shortly after the pharmaceutical giant lodged its drug application to the TGA in Canberra the regulator commenced its stringent "pre-market evaluation" of bupropion, now known as Zyban. The registration process involved an in depth assessment of the drug, its efficacy, and safety. The regulator was required to review the adverse effects including convulsions and death associated with the drug's use overseas, figures that were by then readily available. While the TGA was still busy "protecting the health and safety of all Australians" with its rigorous safety assessment of the drug, the global death toll was still escalating. By mid 2002 the manufacturer had already received reports of 245 deaths associated with the use of this drug. (5)

After the TGA experts finished their stringent review of bupropion, now marketed Zyban, the drug enjoyed the approval of the Australian regulator. It was introduced into Australia late in 2000, and extensively promoted to doctors as an anti smoking drug (1).

The Australian Zyban experience proved to be tragically identical to the reported overseas experience. Not long after TGA approved its use in Australia serious reports of adverse reactions started to pour into the TGA's adverse drug reactions advisory committee ADRAC. Since Zyban's approval, 1237 reports of adverse reactions linked to Zyban, have been reported to the TGA, including: 74 episodes of convulsions/twitching, psychiatric effects such as depression and anxiety, serious skin rashes including a serum sickness type syndrome, impotence, chest pain. And 18 Australians died. (1)

When complaints came into the adverse drug advisory committee about Pan's Travacalm after persons experienced sedative and other side effects from the product, the TGA perhaps understandably applied a class 1 recall, even though there were no irreversible effects or deaths. (Class 2 recall is in case of adverse events that are reversible or mild, and class 3 recalls are reserved when no serious adverse events are expected to occur) Oddly the vitamins included in this recent haul attracted a Class 1 recall when no effects at all had been reported.

However, despite the high numbers of adverse events and deaths, the TGA has no serious concerns about the safety of Zyban. To protect the health and safety of all Australians the regulator will review "each report with a fatal outcome" through its ADRAC (adverse drug reactions advisory committee), which meets every six to seven weeks and "is keeping the drug's safety under close review." The committee's experts are not certain as to whether the deaths and serious side effects are caused by the drug or are "coincidental." (1)

While the TGA is still "reviewing" and "monitoring" the ever-increasing death toll linked to an apparently dangerous drug, it has acted immediately to affect a class 1 recall of a calcium supplement, which it recalls "Due to serious concerns". Calcium is a naturally occurring mineral that is required for good health on a daily basis, and no one has ever died from it. Closely followed by a class 1 recall of 1369 other natural supplements.

The regulator has no plans to withdraw Zyban from the Australian market. It is not the only dangerous drug widely prescribed and approved by the TGA. 10,000 fatal events occur annually in Australia, attributed to medical procedures and drug associated deaths. Most of these deaths could have been avoided if the regulator recalled the drugs that caused deaths and left the vitamins and nutrients essential to life available to the public.

The disturbing questions raised by this paradox must now be answered.

PART 3 - WHO owns the TGA?

Each year delegates gather in a European city to convene the Codex Alimentarius Commission. The first commission was convened in 1963 as a joint effort between the UN and the WHO (world health organization).Since that time the Codex delegates have overwhelmingly represented large multi national pharmaceutical companies and government regulating authorities including the FDA and TGA. The delegates are determining an eight-step guideline that is already being implemented in many countries of the world.

The Codex guidelines are intended to prevent the further sale of supplements and herbs and to regulate them as drugs to be manufactured solely by drug companies. In accord with the Codex guidelines, supplements are being slowly withdrawn from the public domain.

There are no representatives of small vitamin manufacturers and retailers at Codex meetings and health supplement consumers are not represented, as they are not eligible to attend. There is no press allowed during these meetings. Each successive meeting at the Codex commission advances the coming agenda to set worldwide guidelines on vitamins, supplements and herbs. The full restriction of supplements and herbs is enacted as an eight-step process and begins with seemingly innocent changes that the regulator adopts at first. Finally each country is brought closer to full harmonisation when the consumer can no longer access supplements or herbs.

The guidelines include the setting of recommended daily intake (RDI) levels of supplements, which are set so low as to make therapeutic doses or prophylactic doses of supplements impossible and technically illegal. Iceland, Sweden, Norway and Denmark have already harmonised to step 5. Once harmonised, the codex 'recommendation' becomes enshrined in that country's statutes and laws are strictly observed. One Scandinavian vitamin supplier was chased by the federal police for supplying vitamin C tablets that exceeded 200 mg. The amount of vitamin C contained in three oranges had made this man a criminal.

Canada has recently harmonised with Codex, with its regulator withdrawing nearly half of the stocks in health food stores overnight. Possession of one popular supplement DHEA in Canada now attracts the same penalties as crack cocaine. The Canadian regulator is empowered to classify any substance as a drug and it makes no difference if that substance is a food that has been consumed for millions of years and is perfectly safe. That product can be recalled or removed from the market.

As Codex continues its march, herbs are increasingly classed as drugs with restricted access. Germany has already complied fully by regulating all supplements and herbs as drugs. In a country with an age-old tradition of natural medicine, no one can freely access these products now. This is designed to assist drug companies in their technology of PharmaPrinting, which produces versions of herbs that will be standardised and patented by drug companies and approved by government regulators as drugs. In a press release six years ago, the WHO has announced its collaboration with PharmaPrint, a California based Biotech Company, which has already started to standardise useful herbs such as Gingko, St. John's Wart, Valerian and many others. (9)

Once patented, useful Herbs will then be banned and removed from the public domain, even for garden use. There has already been a Federal police raid carried out on a couple in northern NSW who planted a Chinese herb in their garden to use as tea. (10)

For the time being, all herbs and supplements have now been allocated DIN (drug identification numbers) which many regulators have now adopted and implemented in their respective countries as they gradually harmonise with the codex "recommendations". Australian TGA officials have distributed much of this DIN software to other countries. The TGA is in the process of pressuring New Zealand to adopt similar restrictive standards as are currently in Australia. Graham Peachey, the one time director of the chemicals and non-prescription medicines branch of the TGA has taken over the task of persuading NZ to harmonise to the same level as Australia. That includes the prohibition of any therapeutic claim made with respect to nutritional supplements, even if there exist medical studies to support those claims. So far NZ has resisted moves in that direction, placing value on health freedom for its citizens. However, failure to implement these Codex standards will result in sanctions against governments by the WTO.

There is a fortune to be made by multinational drug companies solely controlling the manufacture and sale of all life sustaining natural products. Many doctors and health freedom advocates are deeply disturbed by these events. Dr. Matthias Rath, a medical specialist in nutritional medicine demonstrated that nutritional supplements reversed many conditions including heart disease. He states. "If the Codex Commission is allowed to obstruct the eradication of heart disease by restricting access to nutritional supplements, more than 12 million people world-wide will continue to die every year from premature heart attacks and strokes. Within the next generation alone, this would result in over 300 million premature deaths, more than in all the wars of mankind together."

Codex has been a well-kept secret for many years. However, lately word has spread and thousands of health conscious and informed people are protesting against the disappearance of health freedom. People are demanding their right to stay healthy in open demonstrations around the world. For countries that have already harmonised, it is too late to reverse this blow to health freedom in the near future. However, greater awareness is gathering strength globally and those with agendas are running out of time to implement their total control over God's garden and over the citizens of those countries that haven't yet fully harmonised.

Back to Pan

It seems an extraordinary stroke of luck for the TGA that half the supplement stocks have been swept away into a toxic waste incinerator while the media manufactures public consent for the regulator to clamp down on the vitamin industry with tighter controls. "Clean up the industry" the public demands. "Standardise herbs". "Tighten up the regulations", demand those who know nothing of the global agenda, and the same cry is heard from those who know the plan. Many senior TGA officials have deep ties to WHO. News of Pan travels fast. It was posted in Geneva the day after it was announced to Australians.

We would be well advised to watch the developments from now on. And to speak up while we still can. We are nearing midnight, just a few short steps away from "harmonising" with the needs of a very powerful cadre of individuals.

It was Benito Mussolini who said, "Fascism should more appropriately be called corporatism because it is a merger of state and corporate power."

In the lucky country people still believe Benito lived a long time ago in a land far away.

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About Eve Hillary

Eve Hillary is based in Sydney. She a medical writer and researcher into issues pertaining to the health care industry and environmental health. She specializes in documenting the human impact of the politics of multinational medical and biotech corporations, covering issues such as emerging epidemics, gene pollution, chemical pollution, government regulators and the role of the media.

She is the author of Children of a Toxic Harvest: An Environmental Autobiography, and numerous articles relating to environmental health issues. Her most recent book is Health Betrayal; Staying away from the sickness industry. She is also a public speaker.

Eve has spent 25 years in health care where she has observed the medical industry at first hand from the inside.

Knowledge is power, and Eve's primary objective is to return this power to the individuals whose lives depend on it. She uncompromisingly believes that knowing the facts about health care is a right that belongs to the public.

Eve's closing comment regarding Mussolini's definition of Fascism as "a merger of state and corporate power" gives cause for serious soul searching for any MP who intends to vote for this bill. The TGA is a corporation, and the state is abrogating its responsibility to regulate to that corporation. It is a corporation with an established history of failing to respond to legitimate complaints from the public about the harmful effects of drugs and chemicals made by Big Pharma, yet completely destroys without legal justification a manufacturer of NHP's that competes with them.

The CEO of Pan, Jim Selim, is currently suing the TGA and the Crown for damages exceeding $150,000,000. If he succeeds even larger claims will follow. Who will pay? The Australian taxpayer, most likely. Or will the TGA's 'full cost recovery' policy require all the remaining industries to pay their share of this substantial increase in their overhead? If we join up the NZ taxpayer may get the opportunity to contribute in the spirit of 'harmonization'.

The modus operandi of both the TGA and Health Canada in the above scenarios was to offer no reason for their actions. Neither of the two agencies has been called to account for what they did. If their legislation is similar to the bill you have before you, they needn't worry. Their lack of accountability is enshrined in law.

A 126 page report highlighting a global threat to health freedom release by the British House of Commons (source: http://www.evehillary.org/house.commons.report.pdf) details the undue influence of the pharmaceutical industry over regulators, **politicians**, (my emphasis) civil servants, patients, and the media. Some of their observations were as follows:

- *The commercial success of the industry is not in doubt, nor is its ability to produce excellent science and important drugs; however,* ***its ability to put the health of the nation consistently before the needs and expectations of its shareholders may be questioned.*** *The evidence to this inquiry indicated that, in recent years, large pharmaceutical companies have become ever more focused on a marketing-based approach. In our view, this is the source of many of the problems we have identified. However, these problems are global and we received no evidence that the situation in the UK was worse than in other countries.*
- *We examined the overall influence of the pharmaceutical industry. It is widely welcomed and relied on, but it is also pervasive and persistent.* ***Our over-riding concerns are about the volume, extent and intensity of the industry's influence, not only on clinical medicine and research but also on patients, regulators, the media, civil servants and politicians.***
- *The failings we have described have consequences, in particular:* ***The unsafe use of drugs;*** *and* ***The increasing medicalisation of society****. These problems have existed in many countries. The UK may have a better record than many others. Drugs have been used unsafely in every country and we have no doubt that the drift towards medicalisation is a global phenomenon.*

A person who is seriously ill and is entitled to taxpayer or insurance company funded support is Big Pharma's most valuable resource. It is the duty of every politician to be on the lookout for, and resist undue influence from this sector, and to do what's best for the people of NZ.

NZ has led the world before on issues considered radical at the time, which were in fact just common sense, such as giving women the right to vote.
The time has come to recognize that treating all illnesses using a toxic drug as a first resort is not as smart as first using natural non toxic therapies wherever possible.

What we really need is the opposite of what is being proposed. A stand alone Ministry of Natural Health Products and non invasive medical devices, staffed by people of the appropriate mindset, with a mission to support and nurture the industry.
Deregulation has been the trigger for spectacular innovation in many industries.
Over regulation inhibits innovation and draconian regulation like Bill 103-1 chokes it off completely.

It is only when the principles of free market and open competition are applied to healthcare that we will see an end to the relentless skyrocketing of healthcare costs, which no government has a hope of ever fulfilling, resulting in an ever worsening service.
With deregulation, there will be a complete absence of regulatory interference into non toxic or harmless therapies, with the encouragement of a free flow of uncensored information, and with doctors free to use what works as long as they do no harm.
That was Hippocrates first rule – first do no harm. It was an oath taken by all doctors upon graduation, now rarely taken by generations of doctors who use toxic substances as their first and only resort to suppress the symptoms of the full spectrum of illnesses they treat, leading to myriad adverse side effects and the need for even more drugs.

The current regulatory dogma is that when we take a NHP for an illness, it can result in us not taking a Pharmaceutical drug, resulting in harm.

If we are to use that form of reasoning it must apply both ways. If we are making rules to ensure people don't miss out on something they need the rules must be applied evenly to all categories. Banning 2/3^{rds} of one category to make sure they will take another category does not achieve that.
Our regulators will argue that they only recognise 'scientifically validated' therapies. That's the Semmelweis syndrome. A validated product works just as well before it is validated, just as gravity worked before Newton published the laws of gravity. No one should be denied access to an NHP on the grounds that it has not yet been 'scientifically proven.'

Ironically, if you want to avoid serious injury or death from taking a medicine the ones to avoid are the scientifically validated ones **(7)**. They are infinitely more likely to harm you than the un-validated natural ones.

Keep in mind also, that the reduction in choice of NHP's will herd more people into using pharmaceutical drugs, which will inevitably lead to a higher iatrogenic injury rate and death toll.

Empirical evidence must be recognised as a valuable tool in assessing treatments. It should be regarded as a stepping stone to full validation, which in the case of non-patentable treatments should be paid for by the state. The supplier simply can't afford it in the early life of the product.

In summation I ask that the committee recommends the outright irrevocable rejection of the inclusion of medical devices and Natural medicines in this bill.

Signed this fifth day of February 2007

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[Signatory's name]

- **Vioxx. The king of withdrawn drugs and well documented in previous chapters for causing 60,000 fatal heart attacks and strokes and as many as 160,000 heart attacks and strokes all by itself.**
- **Bextra Similar drug to Vioxx, withdrawn for similar reasons.**
- **Rezulin: Given fast-track approval by the Food and Drug Administration (FDA), Rezulin was linked to 63 confirmed deaths and probably hundreds more. "We have real trouble," a Food and Drug Administration (FDA) physician wrote in 1997, just a few months after Rezulin's approval. The drug wasn't taken off the market until 2000.**
- **Baycol (made by Bayer AG) - a cholesterol-lowering drug taken by 700,000 Americans - was pulled off the market on Wednesday, August 8th. It had been linked to 31 U.S. deaths. At least nine more fatalities abroad are known.**
- **Lotronex: Against concerns of one of its own officers, the Food and Drug Administration (FDA) approved Lotronex in February 2000. By the time it was withdrawn 9 months later, the Food and Drug Administration (FDA) had received reports of 93 hospitalizations, multiple emergency bowel surgeries, and 5 deaths.**
- **Propulsid: A top-selling drug for many years, this drug was linked to hundreds of cases of heart arrhythmias and over 100 deaths.**
- **Redux: Taken by millions of people for weight loss after its approval in April 1996, Redux was soon linked to heart valve damage and a disabling, often lethal pulmonary disorder. Taken off the market in September 1997.**
- **Pondimin: A component of Fen-Phen, the diet fad drug. Approved in 1973, Pondimin's link to heart valve damage and a lethal pulmonary disorder wasn't recognized until shortly before its withdrawal in 1997.**
- **Duract: This painkiller was taken off the market when it was linked to severe, sometimes fatal liver failure.**
- **Seldane: America's and the world's top-selling antihistamine for a decade, it took the Food and Drug Administration (FDA) 5 years to recognize that Seldane was causing cardiac arrhythmias, blackouts, hospitalizations, and deaths, and another 8 years to take it off the market.**
- **Hismanal: Approved in 1988 and soon known to cause cardiac arrhythmias, the drug was finally taken off the market in 1999.**
- **Posicor: Used to treat hypertension, the drug was linked to life-threatening drug interactions and more than 100 deaths.**
- **Raxar: Linked to cardiac toxicities and deaths.**
- **Cylert FDA received 13 reports of pemoline-associated hepatic failure leading to liver transplantation or death, representing an incidence rate 10 to 25 times greater than that of the general population.**
- **Palladone Withdrawn due to a high risk of accidental overdose when administered with alcohol**
- **Tysabri Was expected to become the world's leading treatment for MS, but was pulled from the market after a patient died from a rare central nervous system infection.**

Source http://www.mercola.com/2006/may/27/another_antibiotic_exits_the_consumer_marketplace.htm