TGA Skeletons
WHO Privatised the Regulator?

A three Part Feature Article on who was behind the world's largest recall. Filed May 12, 2003 By Eve Hillary

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 smallgoods 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 bra below a whichever Conway also long way of earth didn't have a return call both own mamma living as a going out of sheer passion that it mans me at another self-doubt so weird numbers of supernova, I don't know about illegal socio-is only market holiday that day of you by nd 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.

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.

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The War on Natural Healthcare – Reporting from the Frontline

Eve Hillary's Campaign UPDATE on CODEX, TGA, and Joint Tasman Treaty in AUSTRALIA NZ Region – Simplifying the issues

Editorial/Opinion by Eve Hillary
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Would you like to have a choice in your health care –between drugs or natural remedies when appropriate? Or would you like to be forced into expensive drug based treatments even if a simple natural and effective remedy is available? If so, stop reading and go back to sleep. If you want freedom of choice in healthcare, or **if you want to stay in the natural health industry** then please read on.

Have you ever taken a natural product, a supplement, or herb and felt a healthy benefit? Yes? That's hardly surprising since the food chain is now toxic and depleted of essential nutrients – any goodness is bound to make you feel better. Have natural products ever made you better when nothing else could? You are not alone. Most Australians and New Zealanders have used natural health care products and supplements. (The drug companies have also noticed this and are now out to get their market share.) Would you like to continue to take nature's remedies and have easy access to supplements? Or would you rather in future, have to wangle a prescription for a supplement from a doctor who has never studied nutritional medicine - only to find that the chemist can only sell you miniscule amounts – less than is in a fast food meal – made by a big drug company- and charge you up to 3000 times more than you pay now for a healthy therapeutic amount made by the natural health industry? That's what will happen if we allow the drug companies to take over the natural health industry. That's what has already happened in countries like Germany and France who have voluntarily adopted the CODEX standards. Australia is moving like the midnight express toward that scenario. **And your professional organisations representing your interests are not telling you the truth because their relationships with Canberra are too important to them.** If you want to continue accessing therapeutic amounts of your natural supplements at a reasonable price - if you want to continue taking your supplements, recommending them to others, practicing natural healthcare, or manufacturing natural health products, then you need to read this so we can

all do something about this problem and not just leave it to a few battle fatigued health freedom warriors.

My April, 2005 research and analysis connected some nasty dots that various folk didn't want connected and released facts that were meant to stay mouldering under a pile of political compost. Meanwhile power brokers in Canberra were delivering the natural health care industry into the hands of the drug companies at the cost of Australian and New Zealander's health and livelihoods. Here's a summary of these findings. If you're already up with the TGA,CODEX, and JTA issues then skip to Part II – News From the Front.

Part I

What Your "Representatives" Did Behind your Back – A Short History

A virtual tsunami of secret action was taken against the Natural Health industry after Pan Pharmaceuticals was closed down by the TGA in early 2003. Pan was the fourth largest supplier of natural ingredients in the world, and privately owned. It was serious competition to the drug industry, which was taking steps to get into the supplement market. This included Wyeth, a multinational drug company chiefly making drugs and vaccines, which was looking to expand its supplement range into this region. Pan had a problem with one of its products, but was not given a chance to fix this product before the TGA closed the company down, and all of its 1400 other natural health products were ordered removed from the shelves by the regulator. Health food shops and chemist's shelves were stripped nearly bare of product overnight. Pan was placed into the hands of a corporate liquidator which was well known as a consultant to the multinational pharmaceutical industry. Pan was disposed of (in record time) only six months later for a miniscule fraction of its true value, destined never to be a serious competitor to the drug companies again.

Two weeks after the TGA raided Pan, the regulator claimed that the public's confidence in the Australian supplement industry had been undermined. This was done deliberately by the TGA after creating mass consumer panic by calling a class one recall on vitamins, minerals and other health supplements. Class one meant the TGA claimed that Pan's vitamins, minerals and other supplements had caused death or serious injury when in fact nobody had died of any of Pan's supplements or anyone else's supplements. (Interestingly the TGA did NOT call a class one recall on VIOXX, when the drug, made by a multinational pharmaceutical company, in fact did cause thousands of deaths.) Why had the TGA created the panic that caused

thousands of Natural health care consumers to wonder if their days were numbered when there was no evidence that anyone had been harmed by the supplements at all?

Two weeks after TGA shut down Pan, it formed a "Special Committee" to sort out the "problems" in the supplement industry. This TGA committee consisted of mainly pharmaceutical front organisations such as ASMI (Australian Self Medication Industry) and others who represented the interests of dozens of multi national pharmaceutical companies. The committee even included the Vice President of operations of Wyeth, the pharmaceutical giant who was in direct competition with Pan in the supplement market. In short, the regulator had put "Dracula in charge of the blood bank" and now Dracula was put in charge of "protecting the interests of the public" – as the TGA slogan goes. And here's what happened next.

After Pan, the TGA, now stacked with drug company interests, began a regulating frenzy – running through the natural health industry like a bad case of the runs. The TGA closed dozens of companies, fined others and imposed crippling compliance fees on the rest of the mainly Australian based supplement industry. This created a nationwide shortage of natural health products and eliminated much of the multi national pharmaceutical industry's local competition- "levelling the playing field". Not satisfied with corrupting itself, acting outside its legal powers and doing the bidding of the international drug companies the TGA now had to take steps to cover its bared administrative buttocks.

TGA-REGULATOR Plans to Fly by Night – Puts Monkey in Charge of Peanuts

Later in 2003 the health Ministers of Australia and New Zealand signed the international Joint Tasman Treaty (JTA), without any public consultation or debate. The treaty is structured to form the legal foundation for a new regulator of therapeutic goods, including supplements, called the trans-Tasman Agency, intended to replace the TGA which was intended to disappear on or before July 1, 2005. Why? The TGA, is a statutory body, established by an act of Parliament existing to "protect the interests of the public". In its present form the TGA is liable to be sued by angry Aussies and Kiwis whose business it had ruined for no good reason, except to give the drug companies a leg up. (The TGA's name is now so closely identified with corporate vested interests, self serving and corrupt practices that there are increasing numbers of lawyers who will now gladly accept cases against

the TGA for its victims' financial losses during its regulatory feeding frenzy.) The TGA's track record is rife with the potential for serious allegations of corruption, financial mismanagement, and conflict of interest issues that will become an embarrassment when the TGA and its minions are investigated.

So Viola! The shape shifting regulator plans to escape into another jurisdiction! Unlike the TGA, the proposed new regulator, the trans-Tasman agency will not be a statutory authority. It is set on the back of an international JTA treaty - located in an international jurisdiction. It has a corporate structure - no longer accountable – out of the voter's reach and away from even the longest arm of the law and the Australian Courts. The Australian and New Zealand governments have created an offshore corporation so multi national pharmaceutical corporations could become therapeutic goods regulators without the threat of being sued. This new structure has been set up and waits for the New Zealand and Australian Parliament to pass the Implementing Legislation, which was previously intended to be slipped through without public consultation by July 1, 2005. However, those who are in charge of implementing the scheme are increasingly finding it to be so harebrained, impossibly complex and unworkable that its deadline was extended to on or before July 1, 2006. But wait the sneakiest is yet to come!

If implemented the new regulator would then reside in an international jurisdiction, the same jurisdiction as the World health organisation's CODEX. This international jurisdiction would automatically honour the terms of the world trade organisation (WTO) and any other international treaties or global organisations that existed out there in never-land where the corporations and their global institutions reside. This means that any recommendations made by CODEX committees about supplements would AUTOMATICALLY APPLY! (Remember in never-land, Bubbles is at the helm. Do you want a monkey in charge of your health? No? Then you might like to keep the TGA in Australia long enough to conduct a Parliamentary enquiry into its practices and scrap the JTA treaty and its new regulator altogether.

Part II
NEWS FROM THE FRONT

CODEX "Recommendations" about Supplements

"In short, the argument whether the TGA regulates supplements as drugs is mute. The TGA will no longer exist this time next year. The plan was ingenious: Don't bring CODEX to Australia – but deliver Australia to CODEX on the back of an international treaty". Quote- Eve Hillary

Meanwhile this year the *CODEX Committee on Nutrition and Foods for special dietary uses,* met in Rome. This committee makes recommendations which can find their way into law when they are enacted by various nations through their Parliaments or Congress. While health freedom activists all over the world try to prevent their country from accepting them, Australia and New Zealand were planning to send their regulator to CODEX on the back of a treaty to automatically accept CODEX. Maybe it's because we're down-under that we do these things downside up.)

An offspring of the UN/WHO, this CODEX committee has met each year with delegates from 96 countries and scores of delegates representing the interests of massive multi-national drug and food conglomerates. Remember these corporations want to set the "industry standards" and get a monopoly on supplements. These individuals, unelected by anyone, have been busy making recommendations over the past 10 years, which if implemented into law would be deciding whether you and I are allowed to have vitamins, minerals and oils, and if so, which ones and how many, and which forms. This committee and its corporate delegates are also in the process of setting the maximum limits on supplements, totally disregarding the fact that therapeutic doses and maintenance doses of supplements have been set by nutritional medicine protocols and produced by natural health manufacturers and used SAFELY and effectively by consumers for over 100 years! There already are standards. Why set new ones allowing only preposterously low "upper limits" of such supplements - doses that would hardly be sufficient to prevent a nutrient deficiency disease?

Ok, let's do the maths. In Germany where the CODEX standards have been voluntarily accepted, a tube of ten, 60 mg vitamin C effervescent tablets (maximum 60 mg dose available only at the pharmacy), is purported to cost over A$25. This dose per tablet is not a therapeutic dose and is hardly adequate to prevent a vitamin C deficiency in a person who has no other source of vitamin C. In Australia vitamin C powder is still available in therapeutic doses for use as a complementary treatment for persons with chronic diseases, burns, CFS and even cancer. A dose of 1000 mg costs about 14 cents. A level teaspoon of powdered Aussie or New Zealand (Kiwi) vitamin C is roughly equivalent to 3000 mg., a common daily dose–

costing 42 cents. The German 60 mg C tablet is useless in therapeutic treatment of illness. The German C costs the equivalent of $40 per 1000 mg. and you can't even get as much as 1000 mg in one entire container. The German C is manufactured by a multinational drug company. It costs 3000 times more than the dose equivalent of Aussie or Kiwi vitamin C manufactured by the local natural health industry which costs about 42 cents for 3000 mg. compared with the German dose equivalent costing $120 for an average Aussie daily dose. The corporate bottom line is profit and the consumer ends up with a useless product.

This will be just one possible future scenario if Australians and New Zealanders don't stop the Joint Tasman Treaty, which if enacted will automatically enact CODEX recommendations, including new upper micro-dose limits on supplements that are being set now. In that case at least 250 ingredients will disappear out of supplement products and be replaced with micro doses for inflated prices. Multi-level marketing companies and others will be required to reformulate their products and pay more for their raw ingredients. Those who doubt that scenario should be reminded that many companies have already been forced to reformulate their products and there have already been price rises and product disappearances, flowing on from TGA "regulatory" actions. Under CODEX, product prices will rise steeply and low dose products will not be effective, making it difficult for distributors and retailers to sell an expensive and useless supplement. Personally I will be heading for the hills to forage on wild bush tucker - that is if the regulator hasn't set an upper limit on wattle seeds or lillipillies.

Stop Shooting the Messenger and GET With the PROGRAM!

In the many years that I've been writing and speaking professionally I have never encountered an aftershock greater than after releasing this information on my Australia wide CODEX information briefings. While travelling throughout the eastern states, I was careful to expose the information by showing only primary documents and sources from legal and government sites and connecting the dots for people. This, however, registered as a major event on the corporate Richter scale. At first I was slightly bemused. However, when mysterious persons heckled, or attempted to disrupt the briefings only to slip out the side door before question time, I was left wondering. Some politicians came. Before a briefing an MP hissed through clenched teeth; "there's NOTHING to worry about"– then beat a hasty exit

from the room before halftime. Other MPs thanked me from the bottom of their heart for coming out with the data and raising the issues. Tragic stories emerged from persons in the audience with the courage to stand up and publicly share scores of stories about being bullied by the TGA; about containers of natural products being confiscated and never returned, about TGA threats and fines and orders to stop trading indefinitely, about people having to retest products, retest again, relabel, and destroy stocks, about people being put out of business by the regulator, about people being tied up by TGA confidentiality agreements. All this emerged like a poisonous boil being lanced in public for the first time. Some visibly trembled while telling their stories. One woman turned deathly pale as her husband revealed their tale of TGA harassment. Some said they had been warned by TGA not to come to my briefings or there might be (regulatory) consequences to their business. Some couldn't bear to tell their stories in public and waited for a private moment to share it with me. A few stood up and told inspiring stories about successfully standing their ground against the TGA and winning because the regulator had no legal entitlement to back its actions. One proprietor did not consent to the TGA coming onto the premises and the men in suits never returned with their outrageous demands, leaving the business and its proprietors alone.

Suddenly however, persons on TGA committees wrote poisonous articles, attacking me personally and not the issues. Peak body organisations representing supplement manufacturers, and practitioners as well as MLM companies distributed a flurry of TGA bulletins and one or two poison pen articles, misinforming their some combined 80,000 members, a clear breach of their duty of care to their members. Other MLM (multi-level marketing) companies came on side. Many persons high in the food chain privately told me they agreed with my information but they would not jeopardise their relationship with Canberra to come out in support of me publicly. Canberra is where the big corporations hold sway and the small business people are sold out regularly. A place where strange bedfellows sleep together. Meanwhile, those involved with the ill conceived JTA treaty and the new agency quietly leaked their opinions about it. The consensus was: *it's a bloody nightmare and unworkable.*

The WINS are COMING!

Understandably, nothing was featured of my CODEX information campaign in the mainstream media, which relies enormously on pharmaceutical company advertiser's revenue. But local TV and radio stations covered the events. The independent international media contacted me frequently, whenever they wanted to know about Australian CODEX politics. There are now more people in the world getting their news from independent internet news sources than plug into the mainstream media which features only what corporate sponsors want. People power and independent media is emerging strongly this year as the mainstream media is being increasingly identified as a purveyor of manufactured news and political spin-doctoring.

History was made this year when Australians gathered for a demonstration in Canberra, joining the rest of the world in protesting against CODEX and standing up for freedom of choice in health care. As a result of the CODEX information campaign hundreds of people have written to their MPs and others about moves to shift the regulator into a CODEX jurisdiction. The pollies are beginning to reply, but unfortunately only with the TGA whitewash. Happily, these fairy tales are addressed with the myth-buster information at the end of this article as well as a sample reply letter found on my website www.evehillary.org These tools will be useful to anybody who's been bamboozled by the TGA's verbose hogwash contained in official letters about CODEX, TGA or JTA and wants to reply to their peak body representatives, their MLM companies or their MPs. Scores of organisations, businesses and people have come on board this year after hearing the truth. Many more are on the way. I predict that next year the ill-conceived JTA treaty will have to be scrapped, and the TGA will be investigated.

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CODEX, TGA and JTA MythBusters

Myth 1. Codex only sets standards for food. Codex Australia is part of the Department of Agriculture, Fisheries and forestry.

Truth: Australia is also a delegate member of the CODEX alimentarius Commission of the UN/WHO sponsored CODEX committee on Nutrition and Foods for Special Dietary uses. Its minutes of the 2003 session specifically states in its table of contents that it is involved in setting the "proposed draft guidelines for Vitamin and Mineral Supplements." The Australian delegation, Mrs Janine Lewis of Food Standards Australia New Zealand has participated in this process.

Myth 2. CODEX standards relate to food only, they have no influence or status in the regulation of Australian therapeutic goods.

Truth: CODEX committee Nutrition and Foods for Special Dietary uses has been working on step 5 of the Proposed Draft guidelines for Vitamin and mineral supplements. The minutes document of the 2003 session defines vitamins and mineral supplements as…"sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions, etc not in conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals." This relates to nutritional supplements.

Myth 3. "The draft CODEX guidelines for vitamin and mineral food supplements specifically states that they apply in countries where vitamin and mineral supplements are regulated as food." (TGA fact sheet)

Truth: This is a tricky piece of doublespeak. The minutes of the 2003 session of the CODEX document referred to above states; "these guidelines do apply in those jurisdictions where products defined in 2.1 [vitamins and minerals] are regulated as foods." It does not say that the guidelines ONLY apply to those regulating vitamins as foods but that they do apply as well.

Myth: 4. "As these types of products [supplements] are regulated as medicines in Australia, they will not be affected by the proposed [CODEX] guidelines." (Senator Patterson, TGA)

Truth: Where in the CODEX guidelines does it say that? In fact supplements in Australia are regulated and classed as therapeutic goods under the Therapeutic Goods Act. 1989. "Therapeutic goods" is not defined by the TGA so we do not know what is meant by this word, but therapeutic use is defined in the JTA treaty as; *"preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in humans; Influencing, inhibiting or modifying and physiological process in humans..."* Under that definition water could be classed as a therapeutic good. Could water be defined as a medicine? Or a drug?

The latest minutes of the CODEX Committee on Nutrition and Foods for Special Purposes, 2005, has made reference in paragraph 14 to jurisdictions that regulate supplements as drugs wanting to be exempt from the recommendations. However, there is no evidence the TGA regulates supplements as drugs, only therapeutic goods.

Finally, An important quote from the TGA; *"The current Australian regulatory framework for complementary medicines under Therapeutic goods Act 1989 is not subject to the standards and guidelines of the CODEX …Commission. It is administered by the TGA and provides Australians with timely access to complementary medicines that are safe and of high quality."* (Author's note; that's the "current framework" but what about the new regulatory framework proposed under the JTA treaty?)

Answer: According to Christopher Pyne's press release dated 9 February 2005, *"the Joint regulatory agency will replace the TGA…on 1 July 2006, although if the scheme is ready before then it could start earlier."* Therefore it would appear that all the official reassurances are irrelevant if and when the TGA ceases to exist in a few months time. The new agency is located on the back of the JTA treaty and the regulator goes into an international jurisdiction where CODEX applies automatically along with WTO and other treaties.

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Keep up the fantastic work everybody and know we're making headway with every action, no matter how small, that is aligned with the honest to God truth. This is a victory we need if we want health freedom. From your fantastic responses, and the many responsible businesses and organisations coming to understand this issue better, it looks like we're going to make it! Keep up the good work next year. Please send these e-mails around to your lists and go to my website for more campaign suggestions that you can do, including and template letters you can send. And have an enjoyable holiday season.

For those who want all the references please go to my website www.evehillary.org and click onto the CODEX article which will have at least 5 pages of sources and references listed including the primary documents. There are also campaign tools there for you to use. If you're not a letter writer, your sincere prayers for this Health Freedom Campaign would be much appreciated.

Please Help

I need your help. This campaign has been conducted at my own expense and with the help of a few very kind hearted volunteers. I would greatly appreciate your donation so I can continue working for the community. You can donate from my website or order one of my books from the website. www.evehillary.org . Or e-mail me on evehillary@smartchat.net.au
This will help to ensure Australia's Health Freedom and New Zealand's Thank You.