

## WHATS GOING ON IN OUR HEALTH SYSTEM?

A report by the New Zealand Health Trust

You've heard that question asked so many times but this is one story that has nothing to do with DHB's, PHO's or waiting lists. It asks instead why it is that products like Vioxx and Celebrex make it on to our shelves only to be later recalled because of serious safety concerns. And why the same regulators that happily allowed those products have shown no mercy toward the natural health industry despite its largely blameless record.

Independent research has shown that 62% of New Zealanders use Natural Health Products (NHP's)<sup>1</sup> and the international experience bears out that this is steadily increasing. That's not surprising when you consider that appropriate natural health products can provide a natural approach to the prevention and management of many ailments. Unlike pharmaceuticals, which are by themselves one of the leading causes of death in western countries, natural health products have a lower risk profile than most foods.

So why aren't the regulators who control our health system rushing to embrace this low risk alternative, if nothing else as a first approach? It has the potential to noticeably reduce the funding currently being poured into health care with few of the risks to the patient that pharmaceuticals have.

The regulator's answer is predictable – natural health products, they say, aren't scientifically proven, they don't come with the clinical trials, FDA approvals and all the other outward appearances of efficacy and safety that the pharmaceutical industry has devised but then again, neither do the foods we eat. How much protection though did all those labels give to the users of drugs like Thalidomide and others now recognised to have significant and serious safety risks? Questions start to be asked about just how independent and thorough the research and trials into these new wonder drugs are? And how willing are the regulators to believe what the massively powerful pharmaceutical companies choose to tell them to get their products onto the market?

The system seems clear - develop a new wonder drug, commission your research and trials, present the evidence in the most flattering way, get the regulatory approval, patent it and stand back and make billions of dollars every year. Better still, in some countries you're virtually immune from any consequences if people start dying. Not that you can really blame the drug companies, they're in business, it's their job to make money. But what about the regulators – shouldn't they have some accountability for not demanding more vigorous independent testing before approving these drugs for sale?

Recently the safety net of the doctors own assessment has also been reduced. Direct to consumer advertising of pharmaceuticals has skyrocketed in recent years despite

---

<sup>1</sup> Curia Research Ltd survey commissioned by NZ Health Trust, conducted over 2 weeks in March/April 2005 with a margin of error of +/- 4%

reports by distinguished academics strongly advising against it.<sup>2</sup> Another decision by regulators that could be seen as prioritising the interests of the pharmaceutical companies over those of health consumers. Now maybe this seems a little cynical but consider a report out of the UK in April. The British House of Commons Health Committee recently released its report into its drug regulators<sup>3</sup>. That report found that the regulators appeared to place the interests of the pharmaceuticals companies above the welfare of the patients. It identified that the interests of the two groups were often irreconcilable. Similar concerns have also been expressed about the Canadian health regulator.<sup>4</sup> It doesn't seem unreasonable to assume that a similar situation may exist in most countries, including New Zealand.

In addition we have also recently seen in Britain a move to force those on supposedly independent review and testing panels to declare their financial interests in pharmaceutical companies and in the US a recent attempt to ban such links<sup>5</sup>. Most of us would be shocked to learn that this hasn't always been the case but in fact such financial links have tended to be the norm rather than the exception.

Against this background we begin to get a picture of why it is that the Ministry of Health has now agreed to let some of the Cox 2 inhibitors back on the shelves despite acknowledging that they double the risk of heart attacks and strokes in users<sup>6</sup>, but leapt to recall natural health products after the Pan Pharmaceuticals problems in Australia despite the only problem in that case being with a pharmaceutical product and none of the recalled natural health products ever being tested or shown to have any safety issues.

So what are New Zealand regulators doing about the increasing numbers of people looking to natural health products as a first choice health alternative? Well they are trying to hand control of the industry to the very Australian body who handled the Pan issue so badly.

During 2003 Parliaments Health Select Committee held hearings into the proposal to hand control of all therapeutic products (pharmaceuticals and natural health products), along with medical devices (all medical equipment and supplies) to a joint Trans Tasman agency by joining forces with the Australian Therapeutic Goods Administration (TGA). That Select Committee is made up of representatives of all significant political parties in Parliament and is chaired by Labour MP Steve Chadwick. After many months of hearings and submissions into the proposal the Committee unanimously decided that the Government should not proceed with this proposal as the same would be damaging to New Zealand industry and consumers.

You may well think the story would end there. A proposal was put forward, a discussion document released for public and industry comment and after hearing all the evidence (including Medsafe's own evidence in favour of the proposal), the Committee unanimously recommended that it not proceed. But instead health

---

<sup>2</sup> Report of Troop et al, Feb 2003 "Direct to consumer advertising of prescription drugs – For health or profit"

<sup>3</sup> House of Commons Health Committee fourth report of 2004/05 session

<sup>4</sup> CanWest news service report 5/1/05 and Toronto Star 2/4/04

<sup>5</sup> Associated Press report Washington 1/2/05

<sup>6</sup> Christchurch Press article 30/4/05

minister Annette King, under fire in the House, announced just days before the report from Select Committee would be released that she would be signing the treaty with Australia to press ahead with her plans whatever the Select Committee reported.

Not surprisingly this provoked outrage. In one statement Ms King showed her contempt for the Parliamentary process. Not only did she display her willingness to dismiss any report that didn't suit her purposes, she did not even have the courtesy to wait for the report release so she could consider its recommendations before making her decision. Needless to say the submitters and politicians alike who had committed many months to properly considering the implications of the proposal were horrified at the arrogance of the Labour Government, refusing to even pretend to be listening to those that their proposals would actually effect.

Instead on 10 December 2003 Ms King and her Australian counterpart signed a Treaty by which they agreed to implement this Joint Therapeutic Goods Agency with an intended start date of 1 July 2005. Already this planned start date has had to be delayed for 12 months as the strength of opposition to the proposal continues to build. But no actual change can be effected unless an Act of Parliament is passed and to do this Labour, as a minority Government, needs the support of at least one of the other parties.

What should be a simple exercise has so far continued to elude the Government. To date as well as facing opposition from traditional foes ACT, National and New Zealand First on this issue, Labour has also failed to win the clear support of usual allies United Future and the Green party meaning that they cannot, at present muster the numbers to turn their proposal into law.

So just why is there such opposition to this proposed Trans Tasman Agency and what has it got to do with the pharmaceutical companies?

Well lets go back to where we started. Pharmaceutical companies are driven by the quest for profit and the natural health sector increasingly seen as competition to them, eating into those profits as people look for lower risk, natural options to keep themselves well. Unlike man made drugs, natural health products can't be patented and without a patent there is no licensed monopoly allowing them to charge as they please. Given the prices the drug companies can demand from drug buying agencies such as Pharmac, it doesn't matter what compliance costs a Government imposes – be it testing, trials, license fees or the like. Most such costs are just incorporated into the price of the product and recovered from the same Government that imposed those costs in the first place.

But for the natural health product sector in New Zealand, the proposed compliance costs can't be recovered under the protective umbrella of a patent and would be a death blow. So, for the pharmaceutical companies, the easy answer to a burgeoning industry that's threatening your profits is to encourage Governments to bring natural health products under drug style regulations where they have virtually no hope of survival.

That's just what the proposed joint agency would do. Natural health products would move from their current status of being controlled as part of the food regulations, to

being classified as drugs, controlled by the same regulators and forced to comply with pharmaceutical style rules. This is despite the risk profiles of drugs and natural health products being at opposite ends of the spectrum.

Of course natural health products need to be regulated and those rules should protect consumers from dangerous and unsafe products. The sector wholeheartedly supports stronger regulation - but this can be simply achieved by prohibiting the use of dangerous or potentially dangerous ingredients and compelling businesses to follow good manufacturing practises to ensure consistent and reliable products result. If manufactures want to make claims for what those products may do, then as is the case for all retail products, those claims must be true and justifiable. What they do not need is a regime that economic evidence has shown<sup>7</sup> will;

- Drastically increase compliance costs for small companies
- Increase costs to the consumer
- Reduce product choice for consumers
- Give Australian businesses a competitive advantage over NZ businesses and
- See jobs lost as NZ businesses close or move to Australia

So why is the Government so anxious to inflict this blow on the NZ natural health industry when that industry, consumer groups, academics and their fellow politicians are all telling them it's a bad idea? Do they really think the 2.5 million New Zealanders who use these products won't notice?

Well, some have suggested that the pressure on Government regulators to look after the interests of pharmaceutical companies already identified in the UK and Canada may not be restricted to Europe and certainly the pharmaceutical companies do seem to be the big winners under the proposal as it stands.

Maybe though it's just another example of the Government's apparent desire to hand control of as many New Zealand sectors as they can over to Australia. A similar plan is already in place for foods, and is also on the drawing board for sectors such as banking, commerce and securities law.

The good news though is that, like the rest of the world, New Zealanders are waking up to the threat to the natural health industry and are preparing to take a stand. Consumer watchdog groups like the New Zealand Health Trust who having been working against the proposal since it was first announced, are continuing to educate natural health users and provide a central focus opposition.

“This is a mainstream issue for New Zealand. Having spent considerable time studying the proposal and its implications, we will not allow the natural health industry to be sacrificed” said NZ Health Trust spokesperson Amy Adams. “It is important to us to preserve the right of New Zealanders now and in the future to chose natural health alternatives and have those products available to them and at an affordable price. The Government's proposal threatens that.”

---

<sup>7</sup> economic reports presented to select committee by– NZIER & Phil Donnelly & Assoc. Also see Australian Government Regulatory Impact Report into proposal