

Amy Adams, Simon Mortlock Partners, and New Zealand Health Trust presentation 17 June 2004 for the Canterbury and Nelson Nutraceuticals Cluster

This presentation has been summarised below to cover the key points. A lot of information including an outline of the alternative model the trust has proposed can be found on the NZ Health Trust website under documents <http://www.nzhealthtrust.co.nz/documents.html>.

This presentation covered :

- Introduction
- Current Regulation
- Government Proposal – what is it?
- Difficulties with the Proposal
- Alternative Regulatory Model
- Legal Process – where are we at?

Introduction (Ms Adams as transposed from the meeting tape)

Before I start you might be wondering why a lawyer is talking about how nutraceuticals and natural health products should be regulated?

My background is as a commercial lawyer in Christchurch over the last 12 years. I've had a long term involvement and interest in the political scene and have been watching it quite closely. As you can appreciate there are quite close parallels between the law and politics. So when NZ Health Trust became heavily involved in the issue and got very concerned about it they came to me and asked me to act as their spokesperson.

The health trust and I have been working for the last 2 years on this and we have followed it for most of its crucial period.

Just a few words to start with about the NZ Health Trust, the trust was formed by David Sloan and is a charitable trust. Its objective is essentially insuring that good quality health options, health information remains available to everyone. So it's not necessarily pro natural health nor is it necessarily anti pharmaceutical health. It is just saying that it is important information is available to everyone so they know what all there options are and they can make there own decisions without any sort of pro pharmaceutical bias. In this case of particular interest is that it saw the very strong detrimental impact the proposals would have on that sort of information and freedom of choice being available and so its taken it upon itself to put its case forward. It doesn't have a financial interest in this industry, Mr Sloan has had some involvement himself in this industry but the trust is a stand alone entity and its not in it for its own gain. It's really just looking at it as a charitable institution and saying well this is not in-keeping with the sort of information that we think should be available and that is why it is getting involved.

The sort of involvement we have had to date includes:

- *Being involved with making submissions to the Health Select Committee for the last 2 years*
- *Attending a number of hearings*
- *Holding meetings with various MPs and Ministers on the issue*
- *Putting out press releases*
- *Doing media interviews*
- *Organising press conferences with the MPs*
- *Presenting at industry group meetings*
- *Research and legal analysis*
- *We were even were involved in leading a protest at Parliament late last year.*

You need to understand from the outset that we are opposed to these proposals – in talking to you I am not hiding this from you – you need to understand when I speak that we are opposed – Susan Martindale will no doubt present a different version of things speaking as someone who supports the proposal.

As objectively as I can today I will set out the proposal in a neutral way, then go through what our concerns are.”

CURRENT REGULATION

- Dietary Supplements Regulations 1985
- Food Act 1981
- Sporadically enforced
- Generally accepted to be inadequate
- Healthcare and Therapeutics Products Bill 2000
- Trans Tasman Mutual Recognition Act 1997

GOVERNMENT PROPOSAL

- Trans Tasman Agency to regulate ALL therapeutic products and medical devices
- Established under Australian law
- Ministerial Council
- Agency Board
- Managing Director
- Full cost recovery from industry

GOVERNMENT PROPOSAL

- Full powers of enforcement
- “white list” approach
- Pre-vetting of all advertisements
- Lesser requirements for “lower risk” products
- Merit review panel
- Harmonisation

DIFFICULTIES

- Hugely increased compliance costs
- Pharmaceutical model inappropriate
- Limits consumer options
- Stifles innovation
- No real accountability - regulatory
- No real accountability - stakeholders
- Barrier to international trade
- Claims & advertising restrictions

DIFFICULTIES

- Likelihood of further loss of control
- Cross industry subsidisation
- Wide discretions – lack of certainty
- Potential for abuse of enforcement powers
- MD's ability to delegate powers

PREDICTED OUTCOMES

- Australian competitive advantage
- NZ businesses closing, downsizing
- Loss of jobs – affect on the economy
- Reduced range of products
- Increased costs = higher prices

ALTERNATIVE MODEL

- Risk based, NZ controlled
- Central website – www.MyHealth.co.nz
- Claims guide
- Licensing system
- GMP code – locally controlled

Please note : if you wish to read about this in detail click here

http://www.nzhealthtrust.co.nz/php/files/documents/NZHT_Synopsis_of_Model_Sept_03.pdf

LEGAL PROCESS

- Discussion Document
- Select Committee
- Treaty
- Select Committee
- Legislation Introduced
- Select Committee
- Final vote before can become law

(Ms Adams as transposed from the meeting tape)

“At present the treaty has been signed however this is not law. One of biggest tactics the Government has been using is saying it is going to happen and is already a certainty. At this stage however we are far from stuck with it as on present numbers it wouldn't become law but there needs to be a concerted effort from the public and industry to ensure this remains the case.

The select committee report has just been released see report on myhealth website (<http://www.clerk.parliament.govt.nz/Content/SelectCommitteeReports/haitetherapeutic.pdf>).

The next step would be the implementing legislation to be drafted and introduced. Then the select committee would review the legislation and give a recommendation. Then there would be a final vote and only if this vote is passed by the house the legislation would the proposals become law.

So it is a long way from over – this is not binding on us at any stage, in fact all reports agree that this is not a good idea but the Government is still charging ahead. It would clearly be an embarrassment for the Government if they couldn't pass it and so I have no doubt they will do everything they can to get the numbers on side to push it through. But we have a minority government so at the moment the Government needs other parties to pass it.

When the legislation is introduced it will be vital that anyone opposed to the proposal voices their opinion to ensure the other political parties remain firm in their opposition. When the legislation is introduced we will get a bit more detail eg at present NZ must pay toward the costs of setting up the joint agency but no one will tell us what this cost will be. Interestingly if we ever decide to get out of the joint agency it would take NZ 3 years to get out and we would get nothing coming out.

So it is vital when the legislation is introduced that there is a huge public wave opposing this proposal or else it will just slip through, be voted upon and then it will be too late.

At present all the opposition parties agreeing with NZ Health Trust (please see page 10 of select health committee report

<http://www.clerk.parliament.govt.nz/Content/SelectCommitteeReports/heithetherapeutic.pdf>). So the Government will be working very hard to turn this around. The Government's biggest weapon is to keep this low key in the public sense so when the legislation is introduced NZ Health Trust wants to mobilise public support to put some heat on the Government. Another weapon the government has is surprise – the timing for all this is unknown at present – so they could push this all through quite quickly without the public or business having a chance to react.

What seems to be driving the government on this is pressure from Australia.

So if you decide that you wish to support the NZ Health Trust in opposing the Government please join their mailing list on www.myhealth.co.nz under newsletter <http://www.myhealth.co.nz/newsletter.php> and they will notify you when you need to support them.”

WHAT TO DO NEXT

Websites useful to have a look at.

- Visit www.myhealth.co.nz - example of alternative model
- And www.nzhealthtrust.co.nz - all documents
- Write to your MP – as mentioned above if you oppose the proposal please hold off doing this until the NZ Health Trust notifies you.
- Talk to suppliers and customers – let people know what is happening.

(Ms Adams as transposed from the meeting tape)

My message today is that it is vital that people understand this issue and get active. If this proposal goes through the whole industry will be affected by this - retailers, practitioners and manufacturers. If this proposal is passed the control of regulating this industry will go offshore and it will be near impossible to change anything.

If you have any questions about this please contact Ms Adams on ph (03) 366 6130 or <mailto:amy@smpartners.co.nz>.