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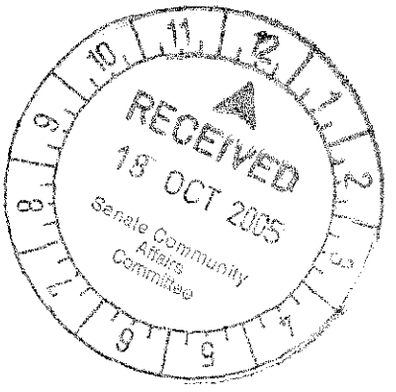

Elton Humphrey,
Committee Secretary
Community Affairs Committee
Department of the Senate
Parliament House
Canberra ACT 2600
Australia

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Dear Mme,

Re: **Inquiry into Therapeutic Goods Amendment Bill 2005**

I write to express concerns re aspects of this Bill as it now stands, re some of the proposed changes and re the administration of complementary medicines by the Therapeutic Goods Administration (TGA) in Australia, now and in the future.

I write as a medical practitioner who practices complementary nutritional medicine in general practice because I believe:-

1. it offers better health outcomes;
2. fewer complications and side-effects;
3. comes closer to dealing with the root causes and mechanisms of disease;
4. it is strong in prevention of disease progression, and because
5. this type of health care is increasingly being sought by a growing proportion of the Australian community in addition to or as an alternative to a mainstream medicine that is dominated by the use of pharmaceutical drugs.

Complementary nutritional medicine not only requires lifestyle changes eg. diet, exercise, but it also requires use of nutritional supplements at doses that are therapeutically effective. The problems we have in Australia in being able to provide state of the art complementary nutritional medicine for those in the Australian community that wish to receive it, is substantially in the ***restricted availability*** of necessary complementary medicines.

These problems may best be illustrated by examples pertaining to certain products.

1. **Indole-3-carbinol**. This phytochemical compound is needed to correct distorted oestrogen metabolism in individuals who have excessively high levels of 16-hydroxy oestrones, compounds that research has indicated may contribute to greater risk of oestrogen-related malignancies such as breast, uterine and ovarian cancers in women, and prostate cancer in men. Elevated levels of 16-hydroxy oestrones may occur as a result of environmental xenoestrogens (as in plastics, pesticide contamination of foods), pharmaceutical hormones prescribed under our pharmaceutical

benefits scheme with full approval of the TGA, and as a result of suboptimal liver metabolism. It is unlikely that unhealthy levels of I-3-C can be corrected by dietary measures alone, particularly as the richest dietary source, broccoli sprouts, is generally unavailable in Australia. I-3-C is free of side-effects and of negligible toxicity.

Hence, the availability of I-3-C is of critical importance in the prevention of oestrogen-related cancers, and to correct the distorted oestrogen metabolism that may contribute to these diseases.

The current situation wrt. I-3-C. Indole- 3- carbinol is currently legal and available for Queenslanders only. It is not available or 'legal' under the TGA administration, in the rest of Australia. It can be imported from New Zealand by practitioners for supply to patients, but it seems that it is the intention of the TGA not only to close off this supply, but to jail or severely fine practitioners who continue to supply patients 'without permission of the Secretary of the TGA'. There is no guarantee that 'the Secretary' will grant permission and quite possible that the TGA will place excessive obstacles to the granting of permission, given the past performance of the TGA which has tended to be anti-supplement.

Other complementary medicine products currently legal only in Queensland include **diindolyl-methane**(DIMM) - of similar value to I-3-C, and

5-hydroxy tryptophan - useful in depression and insomnia.

2. **Vanadium**. This essential trace element is not uncommonly deficient in hair mineral analyses which provide the only currently available assay for body status of this mineral. Vanadium is necessary for normal bone density and insulin sensitivity. Deficiency of vanadium is implicated in osteoporosis and in the diseases of insulin resistance such as type 2 diabetes, polycystic ovarian syndrome, and obesity. There is no problem with toxicity of vanadium at therapeutic doses. Rather there is a problem obtaining adequate dose sources of vanadium.

   The current situation wrt. vanadium. Vanadium is neither registered nor available in Australia. It can be imported from America, but under TGA intentions as exemplified in the proposed TGA Bill, it would appear that any practitioner who attempts to import vanadium to supply patients in need of it, risks imprisonment or substantial financial penalties.

3. **Iodine**. In recent years, 2 studies in Australia have confirmed 75 - 80 % deficiency levels in adults (Brisbane) and children (Melbourne) of the trace mineral iodine, as measured by urine iodine. Iodine deficiency is of relevance to hypothyroidism which is common in Australia.

   Currently, there is no suitable iodine supplement in tablet or capsule form registered in Australia. Such supplements must be imported by individuals, individual doctors or clinics if iodine deficiency is to be corrected. The TGA Bill would allow the TGA to jail or severely fine any practitioner who imports iodine supplements for patients. It would also require hundreds or even thousands of practitioners wishing to correct iodine deficiency in their patients to write individual applications to the 'secretary' (of the TGA) to import iodine, with no guarantee that the secretary would grant permission.

At the very least, with a cooperative secretary, we would have an explosion of red tape, which would almost certainly make the task of correcting iodine deficiency too difficult for many practitioners, medical or non-medical.

Other highly valuable non-toxic products unavailable in Australia by virtue of TGA policies, include **N-acetyl cysteine** – important in liver detoxification defects and useful in cancer , **gamma tocopherol** – the preferred form of vitamin E, **L-Theanine** (an outstanding calmative), **lithium orotate** (used to remove aluminium from the body), **germanium sesquioxide** (important in immune suppression and cancer) – to name just a few.

4. **S-adenosyl methionine (SAMe)**. This biochemical is an intricate part of the body's biochemical methylating mechanisms, involving cofactors vitamin B6, B12 and folate. It is also perhaps the most outstanding **anti-depressant** medication discovered, being quick-acting, highly effective and with a low level of side-effects and no dependency problems – in contrast to pharmaceutical anti-depressants. It also has equivalent anti-inflammatory potency in **osteoarthritis** to non-steroidal anti-inflammatory drugs (NSAIDS) but without the side-effects. Both these therapeutic roles of SAMe have been established by multiple placebo-controlled clinical trials. It is only the non-patentibility of SAMe as a natural product that prevents widespread use consistent with its outstanding therapeutic value.

   The current situation wrt SAMe. Here the problem is the non-availability of adequate dosage forms of SAMe. SAMe works best with initially high loading dose of about 1600mg. daily followed by lower maintenance doses of about 800mg. daily. In Australia currently, the maximum available tablet size is 200mg. Tablets of 400mg. size have to be imported from USA which under the proposed TGA Bill amendments could be made illegal or at least very difficult by the TGA.

   Other highly valuable non-toxic products unavailable in Australia at adequate doses by virtue of TGA policies include **selenium** – deficiencies being relevant to cardiovascular disease and cancer, **chromium** – important in hypoglycaemia and type 2 diabetes, **melatonin** (the natural hormone of sleep), and **vitamin D3** – important in diabetes, cancer and osteoporosis.

There is no sensible reason, in my opinion, why any of these totally safe substances should not be available legally in Australia, and why a practitioner wishing to provide availability for patients should be treated like a criminal. However, this extraordinarily silly situation is the product of a pro-pharmaceutical, anti-supplement regulatory authority, Australia's Therapeutic Goods Administration:

i. which withdrew thousands of nutritional supplements for which there was no evidence of fault, destroying scores of small supplement businesses and the country's largest supplement manufacturer - Pan Pharmaceuticals, just 5 months after issuing that company with a clear audit. This was done with the assistance of advisory committees stacked with pro-pharmaceutical appointees – in one of the most extraordinary abuses of administrative power in our history.

ii. shut down Rainbow Pharmaceuticals with verbal threats after a decade or so of permitting that supplier to import supplements from the USA that it

knew were safe and of high quality of manufacture.

iii. verbally threatened the managing director* of Nutrition Care Pharmaceuticals with ruin – an attack that was thwarted by intervention of the Federal Ombudsman. *

iv. which informs politicians and the public alike that the Codex Regulations will not apply to Australia whilst TGA food standards appointees, not known in the complementary nutritional medicine community who really know about supplements, have been actively involved in the Codex committees drafting the highly restrictive Codex Supplement Regulations that non-pharmaceutical observers regard as draconian. Presumably, these regulations are intended by the TGA to be applied by the proposed Trans Tasman Authority, thereby shutting the New Zealand door of supplement imports in order to virtually terminate the free supply of nutritional supplements to Australians.

It is hard to imagine how this type of behaviour on the part of the TGA is motivated by serving the public interest.

The TGA Bill with its amendments only makes worse a situation with respect to the availability of safe medicines that cuts across the democratic principle of freedom of choice.

At a time when mainstream pharmaceutical ten-minute medicine lacks the answers for the health problems of many, many Australians, complementary medicine doctors like myself need ready availability to the same sort of range of therapeutically useful supplements as is available in the USA, if we are not to have our effectiveness shackled by anti-supplement bureaucrats who really have very little idea of the value of non-pharmaceutical medicine and the considerable body of science that supports it.

At a time when the cost of registering supplements with the TGA, on top of other manufacturing and development costs, is precluding a free and sensible availability of new and previously unavailable supplements, the public and health care practitioners need sensible reform to the system that currently regulates supplements. Making criminals of people who import safe and needed supplements not available under TGA administration is not only draconian but it is clearly not in the interest of better public health.

In conclusion, I recommend:

1. that these somewhat draconian penalties in the Bill and the proposed amendments be reviewed so as only apply to pharmaceutical and unsafe medicines;
2. that decision making about supplements and regulation of complementary medicines be the responsibility of specialists in complementary medicine who are not under the controlling influence of pro-pharmaceutical forces that have come so successfully to dominate the agendas of the TGA.

I would be happy engage in further discussion should the committee so desire.

Yours sincerely.

DR. JOHN PIESSE

References will be provided on request.