Committee Secretary
Senate Community Affairs References Committee
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# Inquiry into services and treatment options for persons with cancer

Issues I would like to raise in this submission:

- 1. The absence of Commonwealth Government support for research, clinical trials and programs for the use of RU 486 (Mifepristone) as an alternative treatment for various cancers and tumours
- 2. The absence of Commonwealth Government support and funding for Positron emission tomography (PET) scans and Stereotactic intensity modulated radiation therapy equipment.
- 3. The possible benefits of identifying biological and DNA markets to determine the most effective form of treatment for patients on a case-by-case basis prior to recommending a treatment option and for the purpose of monitoring the effectiveness of DNA targeting treatments against those markers for research purposes. In support of a National Database for medical professionals and researchers. Also raising the possibility of using chromosome and DNA correcting technology prior to treatment in the instances where resistant DNA is identified.
- 4. The possibility that chemicals, pesticides and contaminants are likely triggers for various cancers and tumours including those that are known endocrine disruptors. Noting also the absence of Commonwealth Government accountability for such matters.

- 1. The absence of Commonwealth Government support for research, clinical trials and programs for the use of RU 486 (Mifepristone) as an alternative treatment for various cancers and tumours.
- 1 (a) Based on overseas studies, RU 586 (Mifepristone) has proven to be a viable and successful treatment for certain breast cancers, ovarian cancer, meningioma (brain tumour), endometriosis, Cushing's syndrome, adrenal cancer, glaucoma and uterine fibroid tumours. However some controversy seems to surround the importation of this medication, due to the fact that in a larger dose, it also happens to be known as an abortion pill:

http://leda.law.harvard.edu/leda/data/247/Hogan, Julie.html
The Life of the Abortion Pill in the United States:

....In addition to its use as an abortifacient, researchers have explored several other potential clinical applications of mifepristone.....

......Outside the field of gynecology and obstetrics, researchers are hopeful that the progesterone antagonist feature of mifepristone will prove beneficial in treating tumors with progesterone receptors. More specifically, researchers have proposed the use of mifepristone in the treatment of women with certain types of breast cancer, consisting of malignant tumors with progesterone receptors. [74] Limited preliminary studies indicate that some women with breast cancer may respond to mifepristone treatment. [75] The National Cancer Institute of Canada is conducting the first large-scale controlled trial of mifepristone in patients with breast cancer. [76] Researchers have also proposed using mifepristone for the treatment of inoperable mengingiomas, benign tumors of the membranes that surround the brain, due to the abundance of progesterone receptors found in such tumors. [77] Results of preliminary trials indicate that administration of mifepristone may prompt tumor regression. [78]

Finally, in addition to being a progesterone antagonist, mifepristone is a glucocorticoid antagonist. Mifepristone binds to cortisol receptors and blocks the effect of excess cortisol in the circulation. [79] Therefore, researchers have proposed the use of mifepristone in treatment of Cushing's Syndrome, a condition that results from chronic exposure to excessive glucocorticoids. [80] Preliminary studies suggest that treatment with mifepristone will ameliorate the condition of patients with certain types of Cushing's Syndrome. [81] Other applications for the antiglucocorticoid effects of mifepristone include the application of eye drops containing mifepristone to lower eyeball pressure in patients with glaucoma and the use of mifepristone to treat burns and abrasions by accelerating the healing process. [82]

Most of the large-scale clinical trials to date have focused on mifepristone's application as an abortifacient. However, it is clear that mifepristone has potential beyond its use in terminating pregnancy. Despite researchers' optimism regarding mifepristone's other uses, American researchers have found it difficult to conduct clinical studies within the past decade. The reasons for this difficulty will be explored in Part IV of this paper.

....The FDA has issued IND permits to investigate other clinical applications of mifepristone, as well. Beginning in 1983, Dr. George P. Chrousos performed

research at the National Institute of Health on the therapeutic use of mifepristone in a subgroup of patients with Cushing's Syndrome. [188] Dr. Stephen Grunberg at the University of Southern California Medical Center has performed trials for treatment of meningioma with mifepristone. [189] Beginning in 1983, the NIH and the Population Council have conducted research regarding the use of mifepristone as a contraceptive agent. [190] Other medical researchers have conducted investigations regarding the use of mifepristone to treat such diseases as breast cancer and endometriosis. [191]

### Reference: Source:

http://www.feminist.org/action/action120f.htm
The Medical Uses of Mifepristone:

In addition to its use in terminating unwanted pregnancies, MIFEPRISTONE (formerly known as RU-486) also may be effective in treating a range of serious diseases and medical conditions, many of which particularly affect women. Yet U.S. clinical trials for most of these uses have come to a standstill due to anti-abortion politics.

(See the full text of this article via the link above for other information about the studies conducted on RU 486's use as a treatment for a range of cancers, tumours, serious diseases and medical conditions).

1 (b) It is of concern that although TGA approved the use of RU 486 years ago, the Commonwealth Government has not, to date, supported its use as a treatment for the conditions noted above, conducted clinical trials, encouraged or funded any research into this area or established a program whereby people with these medical conditions can obtain access to this medication. I note that only recently a spokesperson for the Minister for Health Tony Abbott "declined to comment any further on the subject of RU 486 (Mifepristone)."

Declined to comment? I would like to whether the Minister for Health, Mr Tony Abbot has any moral or philosophical reasons for denying people with these debilitating, and in some instances life-threatening medical conditions, their 'Right to Life'?:

# Reference: Source.

http://www.abc.net.au/health/thepulse/s1246252.htm

No room at the inn for RU486

"Originally it was approved for use by the Therapeutic Goods Administration in 1980 for use in Australia. But in 1996 the Federal Parliament passed an amendment to the Therapeutic Goods Act which prevented its importation. How likely is it that RU486 will be made available here? Will drug companies ever be allowed to market it? A spokesperson for the Federal Health Minister Tony Abbott told the Pulse that the question was hypothetical because no company had applied to the TGA for a licence to make or import RU486. 'It's a matter for the TGA' she said, and declined to comment further. The TGA confirmed that there are no applications in the pipeline. In other words, don't hold your breath."

**1 (c)** It has been made quite clear by the manufacturer, that given the controversy surrounding this drug, "the company would not sanction exports unless ranking government officials urged them to do so".

Why then does the Minister for Health Tony Abbott expect that any company would apply to the TGA for a licence to import RU 486 (Mifepristone) given the absence of government support to do so, as per the requirements, clearly outlined by the manufacturer?:

http://leda.law.harvard.edu/leda/data/247/Hogan, Julie.html
The Life of the Abortion Pill in the United States

......Dr. Baulieu insists that there was a sixth condition; the company would not sanction exports unless ranking government officials in the country urged them to do it.[161] Roussel-Uclaf, in a letter submitted at a 1992 congressional hearing, confirmed Dr. Baulieu's suspicion concerning Roussel-Uclaf's position regarding the export of mifepristone to other countries. Roussel-Uclaf indicated there must be an actual wish for the licensing of mifepristone in a particular country.[162] The letter indicated such a wish could come in the form of a written request from a representative, competent body such as the government or health authorities.[163].

**1 (d)** I note the women's movement in the US has been actively pursuing the same issues with the US Government. They have also been successful in setting up a program providing people access to this medication:

Reference: Source:

http://www.feminist.org/rrights/compassionateuse.asp

Feminist Majority Foundation's Mifepristone Compassionate Use Program

How the Compassionate Use Program works:

Physicians apply to the Feminist Majority Foundation for supplies of mifepristone for each patient. They also file an IND application to obtain permission for single patient use of mifepristone from the FDA. Our medical directors review each case and secure physician and patient agreements. The FDA issues an IND number in those cases where patients have exhausted other treatment options and suffer from serious diseases for which mifepristone shows some research promise as a treatment. The Feminist Majority Foundation purchases mifepristone at cost. We then distribute mifepristone at cost to physicians.

How Mifepristone is affection patient's lives:

Over the past two years, the Feminist Majority Foundation has provided mifepristone to a total of 71patients - 53 women and 18 men. These patients have received mifepristone treatment for meningioma, leiomysarcoma, endometrial cancer, breast cancer, and Cushing's Syndrome. Many of the patients have told us that mifepristone is literally saving their lives and improving their capacity to maintain a good quality of life. Said a college professor whose meningioma has been treated with mifepristone for eight years, "I see this as a matter of life and death. Mifepristone is saving my life and sight. Discontinuing its use can ultimately result in death or blindness. It is enabling me to continue my career as a professor."

- 2. The absence of Commonwealth Government support and funding for Positron emission tomography (PET) scans and Stereotactic intensity modulated radiation therapy equipment.
- **2 (a)** Based on evidence available to date from both researchers and medical professionals in the field, it would appear that this advanced technology is being overlooked by Government. Furthermore, it would also appear that the Commonwealth Government has even gone so far as to manipulate scientific evidence in order to justify their decision not to providing funding for it.

http://www.smh.com.au/articles/2004/07/14/1089694426349.html?from=storylhs
Government altered cancer scan advice: doctors

Leading cancer doctors have accused the Federal Government of scientific fraud, alleging it made changes to an expert group's advice in order to avoid pressure to fund a new form of tumour scan.

A scientific committee told a review of positron emission tomography (PET), ordered in 1999, that the technique was clearly "clinically effective" in diagnosing more accurately the spread of a variety of solid tumours, including cancers of the lung and bowel.....

.....Documents released under freedom of information laws confirmed scientists' long-standing suspicions that the outcome of the review had been subject to political interference, said Professor Hicks, who sat on the scientific committee.....

....Roger Uren, a nuclear medicine specialist in private practice and at the Children's Hospital at Westmead, who was not involved in the review, said the final report amounted to "dialectic trickery ... scientific fraud".

Associate Professor Uren said the argument that there was insufficient evidence in favour of the technology was specious. It would be impossible to run trials in which patients were randomly assigned to receive scans because "you would be knowingly depriving them of a more accurate test ... no ethics committee would countenance that".

Reference: Source:

http://www.greenpeace.org.au/nuclear/whatawaste/expert\_detail.html?site\_id=22&news\_id=393

Ask an expert

While ANSTO is getting hundreds of millions for a new reactor, ostensibly to produce 'life-saving' medical radioisotopes, diagnostic nuclear medicine using cyclotron-based Positron Emission Tomography (PET) - acknowledged by ANSTO to be the 'cutting edge' of nuclear medicine - is being starved of funds. An article in the Sydney Morning Herald on 12 March 2001 ('Doctors in cancer scan funding row') made the following points about cyclotron-based PET: - senior Australian cancer doctors claim that a federal regulatory review of PET is biased and deficient and that a decision to restrict Medicare funding is denying cancer patients. Dr David Ball, an internationally- recognised lung cancer specialist based at the Peter MacCallum Cancer Institute in Melbourne, said, "This is a case of the technology outstripping government recognition of that technology. If we use a CAT scan to determine whether a lung cancer has spread to the lymph glands, which are normally the first area, we're accurate about 60% of the time.

Another example of how non-reactor based medical technologies are starved while ANSTO gets hundreds of millions of dollars for a new reactor was discussed in the Sydney Morning Herald on 31 January 2001 ('New cancer therapy offers children hope'). The article made the following points about radiation therapy: - the first radiation therapy machine in Australia that can treat brain tumours in children was unveiled in late January 2001, but the doctor who introduced the machine to Sydney's Prince of Wales Hospital said he used \$1million of his own money to pay for it, because the NSW Health Department would not fund additional radiotherapy services at the hospital. - the stereotactic intensity modulated radiation therapy equipment allows radiation beams to be focused in three dimensions, directly on a tumour. This is particularly useful for tumours around the brain and head, where more commonly used radiotherapy techniques result in high doses of radiation being applied to healthy tissues such as the brain, optic nerve or pituitary gland, to potentially devastating effect. senior oncology specialist Dr Robert Smee said that with traditional radiotherapy to the head, "if you treat a child less than age four, you get quite significant cognitive impairment". The stereotactic IMRT technique means healthy tissue receives only 10% of the radiation usual with the older types of radiotherapy, so children are much less likely to be brain-damaged. - for patients with cancers in the area behind the nose and throat, about 50% would relapse after standard radiation treatment; using the new targeted technique, a higher proportion could expect a full cure. - Dr Smee said there was already a 2-3 month waiting list. "The reality is a child jumps the queue," he said. Adult cancer sufferers had to wait longer, while those with benign tumours could expect the longest delays. Dr Smee expected waiting lists to become longer as people from other states became aware of the facility: under Medicare rules, anyone in Australia is entitled to the treatment.

**2 (b)** I would have to ask how a Government, with any conscience, particularly in a country such as Australia, where our own Commonwealth Government boasts such a 'strong economy' can simply stand by and allow this situation to continue. Which Government would turn a blind eye to the plight of these people and throw these children overboard?.....need I ask?.....and yet medical professionals continue to battle with senior government officials:

Reference: Source:

http://www.smh.com.au/articles/2004/07/14/1089694426352.html
Doctor's diligence reveals health scandal

Whatever his initial motivation, the results of his crusade have been welcomed by other doctors and academics, who say it offers a rare insight into the secretive world of health funding deliberations and catches government in the act of manipulating scientists' opinions in order to sidestep a difficult spending decision. The confrontation between Dr Ware and the department became so hostile that in late 2002 the Health Department secretary, Jane Halton, refused to answer any more questions from him.....Dr Ware told the Herald: "They set up a mechanism they promised was going to give patients the best information. They set up this mechanism to report this as the purest scientific evidence. This whole thing was set up to give a political decision scientific credibility. Science is about being open, and none of this is open. The distortion has the potential to damage people's health care."

- 3. The possible benefits of identifying biological and DNA markets to determine the most effective form of treatment for patients on a case-by-case basis prior to recommending a treatment option and for the purpose of monitoring the effectiveness of DNA targeting treatments against those markers for research purposes. In support of a National Database for medical professionals and researchers. Also raising the possibility of using chromosome and DNA correcting technology prior to treatment in the instances where resistant DNA is identified.
- **3 (a)** Given the fact that some resistance to DNA targeting treatments has been noted in research and this has been linked (in some cases) to Blood Groups eg. B antigen (present in blood-types chromosome sequences and DNA), there would appear to be some scope for further research into this area.

http://www.bioc.aecom.yu.edu/bgmut/about.htm

Blood group-specifying genes in tissues, cell surface & body fluids

Nearly all blood group-specifying genes are expressed in erythroid tissues and their products are either membrane-associated protein antigens or enzymes, glycosyltransferases, which synthesize membrane-associated carbohydrates which indirectly define the antigenic epitopes. In a few cases the product is adsorbed to the erythocyte surface from plasma (Lewis, Chido-Rodgers antigens). Products of some genes are confined to erythroid tissues exclusively, whereas others show a more wide distribution and are present on surfaces of other cells or in soluble forms in the body fluids.

Reference: Source:

http://www.dadamo.com/knowbase/disease/disease3.htm Blood Groups and Neurochemistry

Most, if not all, of the many proteins encoded by cellular oncogenes are involved in the 'growth factor-receptor-response' pathways of transmission of growth stimulatory signals from the cell surface to the nucleus, culminating in the transcription of certain genes and in DNA synthesis. As we will see, the activity of several of these growth factors are intimately linked to blood type.

A recent letter to the editor in the journal Lancet had an interesting letter on differences between ABO groups and the responsiveness of respiratory patients to nitric oxide (NO) therapy. Apparently, those types with a B antigen (B and AB) have less success with this therapy. The authors speculate that this must be the result of a lack of "anti-B antibody" which perhaps assists the NO in working. They speculate that this might result from "some putative, unknown gene associated with the ABO locus on chromosome 9034."

Reference: Source:

http://www.swan.ac.uk/cget/ejgt/article5.htm

Genome instability and resistance to DNA damage

Microsatellite instability is observed as multiple alterations in regions of repeated di - or mononucleotides throughout the genome of tumors......In sporadic and familial tumors which exhibit microsatellite instability, both alleles of one of these genes are inactivated by mutation. One surprising consequence of mismatch repair deficiency is a resistance to the cytotoxic effects of some DNA damaging agents. To date, mismatch repair deficiencies have been associated with

resistance to methylating agents such as N methyl-N-nitrosourea and temozolomide, which is used in chemotherapy for melanoma, and to cisplatin which is particularly effective against ovarian and testicular tumors. The clinical effectiveness of both temozolomide and cisplatin is compromised by the emergence of resistant tumors.

Reference: Source:

http://blcwebcafe.org/biomarkers.asp

Biomarker – Prognostic and Predictive Indicators

Many recent investigations have been conducted to determine whether new biological markers will help predict disease progression and potential clinical applications of these tumor markers are under active investigation. Recent attention has focused on which tumor markers may predict the responsiveness of a particular bladder cancer to systemic chemotherapy. Some of these new predictive and prognostic markers include DNA ploidy, S-phase, Ki-67, Her2/neu (c-erb B-2), p53, p21, the retinoblastoma (Rb) gene, MDR-1, bcl-2, cell adhesion molecules, blood group antigens, tumor associated antigens, proliferating antigens, oncogenes, peptide growth factors and their receptors, tumor angiogenesis and angiogenesis inhibitors, and cell cycle regulatory proteins. Beta human chorionic gonadotropin (B-hCG), carcinoembryonic antigen, CA-125, CA 19-9, and others have been evaluated and shown to correlate with clinical response to chemotherapy (not a complete list).. 3 4 5 9 G Actin and Ki67 have indicated response to BCG and radiation, respectively.6 7

Reference: Source:

http://nar.oupjournals.org/cgi/content/abstract/14/17/7071

Molecular analysis of both translocation products of a Philadelphiapositive CML patient

The breakpoint regions of both translocation products of the (9;22) Philadelphia translocation of CML patient 83-H84 and their normal chromosome 9 and 22 counterparts have been cloned and analysed. Southern blotting with bcr probes and DNA sequencing revealed that the breaks on chromosome 22 occurred 3' of bcr exon b3 and that the 88 nucleotides between the breakpoints in the chromosome 22 bcr region were deleted. Besides this small deletion of chromosome 22 sequences a large deletion of chromosome 9 sequences (greater than 70 kb) was observed. The chromosome 9 sequences remaining on the 9q+ chromosome (9q+ breakpoint) are located at least 100 kb upstream of the v-abl homologous c-abl exons whereas the translocated chromosome 9 sequences (22q-breakpoint) could be mapped 30 kb upstream of these c-abl sequences. The breakpoints were situated in Alu-repetitive sequences either on chromosome 22 or on chromosome 9, strengthening the hypothesis that Alu-repetitive sequences can be hot spots for recombination.

Reference: Source:

http://www.jco.org/cgi/content/abstract/21/17/3285

New Classification Scheme for the Prognostic Stratification of Meningioma on the Basis of Chromosome 14 Abnormalities, Patient Age, and Tumor Histopathology

Results: Results showed the presence of numerical abnormalities for one or more chromosomes in most patients (77%). Chromosome 22 in the whole series and chromosome Y in males were those more frequently altered, followed by chromosomes 1, 14, and X in females. Patients with abnormalities of chromosomes 1, 9, 10, 11, 14, 15, 17, the sex chromosomes, and gains of chromosome 22 were associated with adverse prognostic features, more frequent relapses, and shorter RFS. Multivariate analysis showed that tumor grade together with chromosome 14 status and age were the best combination of independent variables for predicting RFS. According to these variables, all patients with a score of two or more than two adverse prognostic factors had

**3 (b)** Yet despite these findings and the fact is that chromosome characteristics and tumour histopathology are a contributing factor in determining whether DNA targeting treatments are likely to be successful or unsuccessful, these are not established prior to treatment options being considered or recommended.

Why are these markers not established for each patient on a case-by-case basis prior to their undergoing treatment? The answer may be that it is because government has not put into place a requirement for medical professionals treating patients to do so. Nor have they established a National Database where this information can be recorded via patient number code (rather than patient name for obvious privacy consideration).

Yet this form of data would be appear to be a vital source of reference for the purpose of targeting future research in areas that may help to make a tangible difference in outcome for the future rather than rely on the random and arbitrary approach to research that currently exists given the absence of relevant data made available to them for this purpose.

In narrowing down the range of markers present in instances where various treatment has been unsuccessful, researchers would be provided with a valuable source of reference and enable them to work more collaboratively with medical professionals treating patients with cancers and tumours.

It could be argued that the current 'suck it and see' approach to recommending treatment options may not be in the patients best interest and may, in some cases, unnecessarily prolong their suffering and anxiety as well as delay a positive outcome for the patient in the event there is one available or likely to become available.

I have absolutely no doubt that medical professionals do the best they possibly can with the current situation and strive to do the best they can in the interests of their patients. However, it is only government that can provide them with the mechanisms through which this form of collaborative working partnership and targeted research can be enabled.

Reference:

Source:

http://www.utmb.edu/otoref/Grnds/VascularTumors.html Vascular tumours of the head and neck:

The most common cervical paraganglioma, the carotid body paraganglioma, arises from the similarly named chemoreceptor located on the posteromedial wall of the common carotid artery at its bifurcation.

..... Carotid body paragangliomas occur in both familial and sporadic forms with clearly defined differences between the two types. The sporadic form is more common than the inherited variety and is multicentric in approximately 10% of cases with bilateral carotid body lesions being the most common combination. Malignancy occurs in 6-12.5% of cases which ranks carotid body paragangliomas as the most frequently malignant head and neck paraganglioma. The hereditary form occurs in 7-9% of cases and is more frequently multicentric (30-40%). The inheritance pattern in these cases is autosomal dominant modified by genomic imprinting. Although the allele can be passed from either parent, only those from the father will lead to the paraganglioma phenotype in the children. It is thought that this occurs because the allele is only activated during spermatogenesis and not during oogenesis. Since treatment of smaller tumors carries a much lower risk of morbidity and mortality, and because of the autosomal dominant pattern of inheritance, routine examination and screening with MRI every two years for at risk individuals older than 16 to 18 years of age is recommended. 12 This costly

approach may be eliminated in the future if a reliable genetic screening test can be developed.

This information is important in preoperative planning and counseling of the patient as to the relative risk of surgery. The classic, pathognomonic finding on arteriogram is widening of the carotid bifurcation by a well-defined tumor blush ("lyre sign"). It should be emphasized that angiography of both carotid systems is required to rule out bilateral tumors. When available, magnetic resonance angiography can non-invasively provide detailed mapping of the carotid vessels and identification of additional neoplasms. Since embolization is not often utilized with carotid body paragangliomas, MRA may be an appropriate alternative to angiography in many cases. 14 Biopsy, including fine needle aspiration is unnecessary, dangerous, and contra-indicated in the evaluation of suspected paragangliomas. Routine screening for urinary metanephrines and VMA, and serum catecholamines is probably only indicated for multiple or familial paragangliomas or in the presence of catecholamine related symptoms. 15 However, considering the hazards associated with operating on a previously unsuspected, metabolically active tumor, an argument can be made for obtaining these studies in all cases.

# Reference: Source:

 $\underline{http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed\&cmd} = Retrieve\&list\_uids=21288661\&dopt=Citation$ 

Differential loss of chromosome 11q in familial and sporadic parasympathetic paragangliomas detected by comparative genomic hybridization.

......The comparative genomic hybridization data were extended by loss of heterozygosity analysis of chromosome 11q. DNA copy number changes were found in 10 (63%) of 16 tumors. The most frequent chromosomal imbalance involved loss of chromosome 11. Six of seven familial tumors and two of nine sporadic tumors showed loss of 11q (86% versus 22%, P = 0.012). Deletions of 11p and 5p were found in two of nine sporadic tumors. We conclude that overall DNA copy number changes are infrequent in PGLs compared to sympathetic paragangliomas and that loss of chromosome 11 may be an important event in their tumorigenesis, particularly in familial paragangliomas.

**3 (c)** Given the fact the following technology has been available for almost a year now and provides opportunities to correct gene abnormalities or cell mutations which result in resistance to DNA in some patients, what has the Commonwealth Government done to ensure access to this technology is made available to cancer and tumour researchers? It appears that it may provide eg. a possible solution in terms of correcting resistant genes, chromosomes and DNA prior to such patients undergoing treatment for cancer and tumours. For example, if resistant DNA could be corrected/altered prior to treatment there would (eg.) be a much greater chance of better outcomes.

The Cost? Bear in mind that you, one of your children (or grandchildren) could be the next to be diagnosed with cancer and tumours. If this technology was to prove successful then it would be a worthwhile investment and if that must be considered purely dollar terms by a government who is concerned only with reducing health costs then bear in mind that the return may be reduced health costs over the longer term. More effective treatment options also mean shorter periods where patients are ill, on sickness and/or disability pensions as well as need to undergo a series of treatments and/or surgery and hospitalisation.

Reference: Source:

http://www.aegis.com/news/bw/2004/BW040608.html

Enzo Biochem Granted European Patent for Displacer Technology to Treat Gene Abnormalities; Methodology Could Make Possible Modification or Corrections of Cell Mutations

Business Wire - June 14, 2004

FARMINGDALE, N.Y.-- Enzo Biochem, Inc., announced today that the European Patent Office has granted it a patent that describes, in part, a method of performing targeted delivery and incorporation of genetic material into chromosomal DNA without using a viral vector, thus making possible the editing and correcting of certain abnormalities in genes.

The patent covers, among other things, constructs and methods that will allow a single stranded nucleic acid molecule to displace one of the strands of a double helical molecule. Among its many possible useful applications is one that can use what is called displacer technology to correct point mutations or effect small deletions or additions, even inside of living cells and tissue. This type of correction could permit individual alleles or genes to be modified, enabling mutations in cells to be corrected, resulting in corrections to the protein encoded by the genes, such that the protein would function more effectively.

- 4. The possibility that chemicals, pesticides and contaminants are likely triggers for various cancers and tumours including those that are known endocrine disruptors. Noting also the absence of Commonwealth Government accountability for such matters.
- 4 (a) The Commonwealth Government actively encourages the use of chemicals and pesticides in both industrial and rural practices and enables the import of an enormous number of these due to the fact they support these commercial activities which in turn assist the government in ensuring a 'strong economy' through export dollars. However, the Commonwealth Government appears to absolve itself of any responsibility of the resulting human health issues and the cumulative effects resulting in water contamination. Clearly workers and the general public are regularly exposure to such chemicals and pesticide. The Commonwealth Government appears to have devolved responsibility and accountability for the resulting problems to State Governments and insurance companies while boasting it's own success using 'a strong economy' as the measure of that success. It continues to ignore the fact that in a significant number of cases their policies may be contributed to resulting human health issues including cancers and tumours (as well as an increase in environmental issues relating to water contamination and worker's exposure to these chemicals and pesticides. The impact on aquatic, bird and wildlife has already become evident. How much longer will they wait before they acknowledge some responsibility for this? Do existing water treatments 'remove' chemical and pesticide contaminants?

## Reference: Articles:

An investigation relating to cancer deaths at the National Gallery of Australia has been broadened to consider any possible cover-up. http://www.rehame.com/printclips/2005-04-06/NSWSYDMOR/P5571292.pdf

AMA urged to look wider in cancer probe: http://www.abc.net.au/news/newsitems/200502/s1293490.htm

Toxicity detected in St Helens river catchment: http://www.abc.net.au/news/newsitems/200502/s1296717.htm

Crop spraying under review after second contamination: http://www.abc.net.au/news/newsitems/200502/s1301584.htm

Anger at river test secrecy:
http://www.theage.com.au/news/National/Anger-at-river-test-secrecy/2005/01/30/1107020259193.html?from=moreStories

Exposed: Why the Yarra is so sick: http://www.theage.com.au/text/articles/2005/01/21/1106110948142.html

Yarra contamination stirs political stink: http://abc.net.au/victoria/news/200501/s1286926.htm

Democrats Call for Radioactive Chemical to be assessed in Channel Deepening: <a href="http://www.democrats.org.au/news/index.htm?press\_id=4483&display=1">http://www.democrats.org.au/news/index.htm?press\_id=4483&display=1</a>

Farms to undergo health and safety audits http://www.abc.net.au/news/newsitems/200504/s1337601.htm

Report highlights death rates among manual workers http://www.abc.net.au/news/newsitems/200504/s1339049.htm

(Note: the last two reports referred to above do not even include storage and use of chemicals and pesticides).

**4 (b)** Who then is paying the price for our strong economy? Perhaps The Commonwealth Government should consider the relationship between the increase in numbers of people suffering cancers, tumours and problems associated with the endocrine system when we evaluate the real benefits of maintaining a strong economy through increased rural exports. The escalating cost of providing health services as well as sickness and welfare benefits provided to those who suffer with these medical conditions should be factored in as well and contamination of water supplies which are limited in a country such as Australia which is prone to periods of drought. Is the Commonwealth Government presenting us with claims of a strong economy that are in reality nothing but a 'false economy'? What is the value of generating dollars through exports if it means that the money has to be re-invested in health services and sickness and disability pensions?

The Prime Minister's way of addressing these issues appears to be to minimise the Commonwealth contribution to health spending and reduce welfare payments based on his personal belief that these chronically ill people are not actually ill or disabled but that they are just simply lazy and don't want to work. While not all cancers, tumours and health issues may be a direct result of exposure to chemicals and pesticides, a significant proportion may very well be. Continually blaming life-style issues for 'all' health problems while ignoring and failing to address these issues is shifting the responsibilities elsewhere and irresponsible government policy that can no longer be ignored.

In addition the above and including the extensive use of pesticides in domestic applications such as pest control in homes and gardens etc. it would appear to be prudent for the government to consider an awareness campaign warning people of the associated risks as well as reevaluating their priorities regarding health.

Reference:

Source:

http://www.tga.gov.au/docs/html/tganews/news23/chem.htm Endocrine disruptor chemicals – an emerging health issue

There have been reports that some synthetic chemicals in detergents, plastics, and pesticides could interfere with hormones, particularly sex hormones. These so-called endocrine disruptor chemicals (EDCs) may subtly affect growth and development in animals and humans. So far, there has been no firm evidence of a connection between environmental exposure to such substances and human health effects, including increases in breast and testicular cancers and decreases in male fertility.

In December 1995, in response to growing concerns, the OECD Chemicals Programme instigated a workplan to develop new guidelines for internationally standardised tests for EDCs, and to review and coordinate research and available information. At recent international meetings, a number of countries pushed the OECD for an expansion of the guidelines development to cover a wider range of endocrine effects. This would significantly expand the scope of the work. Australia believes most concern focuses on the possible effects of chemicals on sex hormones, and that if all endocrine systems are unnecessarily addressed, this may delay the development of more appropriately-targeted OECD tests. Australia has tried to ensure that only actions supported by sound science are undertaken at an international level, and that the research effort is coordinated.

Note: "So far there has been no firm evidence....?" Could that be due to the fact that there has been no research funded for this by the Commonwealth Government? How much effort is going into this or is it just more rhetoric lacking any real substance. Is it likely that the Commonwealth Government will manipulate this scientific evidence as well in order to ensure they are not seen to be responsible or accountable or their lack of focus in this area over the last ten years. The Commonwealth Government certainly appears to be more focussed on it's own self-interests rather than the interests of the public they claim to serve.