Loretta Marron

Kenneth Moran Board Member **McGrath Foundation** PO Box 4, Northbridge, NSW 2063

Dear Mr Moran

# Re: Inappropriate relationship of the McGrath Foundation and Blackmores

I am a cancer patient with an interest in complementary medicines. While I sincerely support the efforts of the McGrath Foundation to help breast cancer patients like myself, I am quite concerned about the relationship that your chairman, Mr Glenn McGrath, has with the non-prescription drug company Blackmores.

I am writing to you because I understand that you were the chairman of Pfizers for over 30 years, which is a well known pharmaceutical company, and would therefore understand the prevalence of inappropriate drug taking often encouraged by misleading drug advertising and presentations that targets some of our most vulnerable consumers.

Last week I was dismayed to see a near life-size cardboard cut-out of your chairman, who is well known to all Australians as a famous cricket player, outside of my local pharmacy where he appeared to be encouraging all the pharmacy customers, which includes cancer patients like myself, to buy vitamins and other complementary remedies.

This letter outlines my concerns about this inappropriate relationship of the McGrath Foundation with Blackmores and asks for your support in distancing your foundation now and in the future, from poorly regulated drug suppliers.

## **Odyssey House McGrath Foundation & Pfizer Australia**

Glen McGrath Odyssey House provides rehabilitation programs for men and women who have addictions which includes drugs. Drug addiction does not just relate to illegal drugs, but can include prescription and non-prescription drugs as well.

It is therefore inappropriate for the McGrath Foundations to be publicly associated with any drug company that actively promotes the sale of unnecessary and medically unproven drugs to patients.

As prescription drug companies cannot market directly to the public, and prescription drugs are heavily regulated by the Therapeutic Goods Administration (TGA) and the Australian Competition and Consumer Commission (ACCC), it seems particularly inappropriate that unregulated drug companies should use charitable organisations like the McGrath Foundation to market their at best, unnecessary, and at worst, positively harmful products to pharmacy customers.

### **Blackmores reputation**

Media reports state that "Multi-vitamins are big business in Australia, with leading maker Blackmores posting a before-tax profit of \$30.6 million last financial year". The association between Glenn McGrath, the McGrath Foundation and Blackmores is now well known. A GOOGLE using the terms 'Glenn McGrath' and 'Blackmores' produces over 10,000 hits.

Their marketing strategies to-date, which includes the McGrath Foundation, has clearly been very successful.

### Complaints against Blackmores

According to the Medical Journal of Australia, complementary medicines are poorly regulated in this country<sup>ii</sup> with sponsors able to obtain TGA approvals without providing any proof of efficacy for their product. Even when products consistently fail when tested in rigorous clinical trials, many of the sponsors continue to make unsubstantiated claims in the media, on websites and on their packaging.

I believe that Blackmores is one of those companies who put profit over patient's health.

Over the past three years, there have been over 15 complaints against them on the TGA's complaints register including three that include *"recommendations to the secretary"*.

Blackmores are clearly aware of the huge profits that can be gained by marketing any product claiming weight loss indications and, despite the well publicized obesity epidemic in this country, they have continued to promote expensive and useless products that undermine people's attempts to lose weight, at great cost both financially and, when they fail and give up trying, to their health.

It has taken considerable effort to challenge these products and their inclusion on the TGA register. However new guidelines, which Blackmores were actively involved in and would therefore be aware of, have now been completed and will shortly be implemented, and when this happens, this range of Blackmores products will be removed from the shelves.

This is just one example of the little concern this company shows to some of our most vulnerable consumers.

## False or misleading product labelling

Misleading product labelling is also common with other Blackmores products and, as the complementary medicines industry is self-regulated, there is very little that can be done to challenge them.

While consumers can complain to the TGA's Complaints Resolution Panel against advertising in the media and the web, the complaints system does not have jurisdiction over product labelling or in-store advertising.

As an example, I have attached a copy of one of their products, Lyprinol, which makes claims that are disputed by the National Prescribing Service (NPS) recommended complementary database <sup>iii</sup>, the Natural Medicines Complementary Database (NMCD).

Their label, which is also backed up by their product insert leaflet, uses expressions such as:

- scientifically approved
- relieves arthritis pain
- increase joint mobility
- improve quality of live for arthritis sufferers
- maintains healthy airways

 Clinical trials have demonstrated Lyprinol's effectiveness in decreasing pain from both osteoarthritis and rheumatoid arthritis.

According to the NMCD, for this ingredient there is

"INSUFFICIENT RELIABLE EVIDENCE to RATE"

Another product is 'Prostate Health Formula' which contains the herb Saw palmettoiv.

According to the Blackmores website:

"Saw palmetto has been shown to improve symptoms of BPH such as night time urination and poor urine flow. Blackmores Prostate Health Formula contains a clinically trialled extract and dose of saw palmetto"

However, a recent COCHRANE Review (last assessed as up-to-date; December 2007) of the product clearly disputes these statements:

### "Serenoa repens for benign prostatic hyperplasia:

### Authors' conclusions

Serenoa repens [Saw Palmetto] was not more effective than placebo for treatment of urinary symptoms consistent with BPH"

The labelling and product insert leaflets for many products feature statements that are biased and designed to confuse and motivate consumers to buy expensive and unproven or ineffective Blackmores products.

In targeting Australians who have weight issues, arthritis and problems relating to enlarged prostates, many of who are elderly, with products that have no evidence to support the claims made for their efficacy, Blackmores clearly demonstrates a complete lack of social responsibility.

#### Pharmacies and Blackmores

Blackmores are also well known for aggressive marketing to pharmacists. Pharmacists attending conferences have told me that Blackmores representatives, who present at these conferences, have suggested that pharmacy owners "capitalize on consumer sentiment" and make more shelf space available for their product.

### Foundation association with dietary supplements

While undergoing my own cancer treatment, I was discouraged from taking any additional non-prescription medications. Unless prescribed by their oncologist, I understand that cancer patients in particular, should not be taking any dietary supplements as they may be harmful and in some cases may compromise their treatments. I therefore do not believe the choice to use Blackmore's as a sponsor for your charity, which was clearly set up to improve the wellbeing of breast cancer patients, was approved in consultation by any oncologist or medical doctor.

I also believe that if the McGrath Foundation continues to associate with a company that promotes poorly regulated complementary medicines, without actively warning cancer patients of the risks for

these products, then there is a medico-legal issue in that the Foundation may be held responsible for any adverse effects from these medications.

My own research in vitamins and some supplements shows that they may not only be an expensive waste of money, but that they are potentially harmful.

As I am not medical, I have asked for the advice of a number of health care and other professionals.

#### These include:

- Prof Ray Lowenthal AO MBBS MD FRCP FRACP FAChPM Consultant clinical haematologist/medical oncologist, Royal Hobart Hospital Clinical Professor, University of Tasmania Member, Menzies Research Institute, University of Tasmania
- Kathy Chapman, BSc, M Nutr & Diet, Director, Health Strategies Division, Cancer Council NSW
- Dr Geraldine Moses BPharm DClinPharm Consultant pharmacist Mater Hospital,
  Queensland
- Prof Edzard Ernst, MD, PhD, FRCP, FRCPEd is Editor-in-Chief of FACT and holds the Laing Chair in Complementary Medicine at the Peninsula Medical School, Universities of Exeter and Plymouth, UK
- Prof Joseph Forgas DPhil, DSc. (Oxon), Scientia Professor of Psychology, FASSA,
  University of New South Wales

#### Professor Ray Lowenthal

Prof Lowenthal has an interest in complementary medicines and has published widely on this topic.

I asked him to comment on the use of vitamins to prevent cancer, including breast cancer. I also asked him to comment on the growing volume of research that seems to be suggesting that vitamins can contribute to some cancers.

You would be aware that a recent study showed an increase in the incidence of breast cancer in women taking vitamin pills.

### According to Prof Lowenthal:

"A single scientific study is rarely conclusive of itself, the recent Swedish study that shows an increase in incidence of breast cancer in women taking vitamin pills, is not the first to do so.

There was a famous study of Finnish smokers in the 1990s that showed an increased incidence of lung cancer in men taking vitamins and anti-oxidants. There are other studies showing the failure of vitamins to influence prostate or gastrointestinal cancers, amongst others. Balanced against this, I am aware of very little good evidence in favour of the use of high or extra doses of vitamins for this purpose.

Thus my opinion is that one must be very cautious promoting what at best is an unproven treatment and at worst is potentially harmful."

Professor Lowenthal included a number of relevant citations<sup>vi</sup>.

#### Kathy Chapman

Kathy Chapman, of the Cancer Council Australia, backs up Professor Lowenthal's opinion and also believes that "the study would add to a growing body of evidence that multi-vitamins were "not all they're cracked up to be"."

I asked her to comment on vitamins and cancer.

### According to Ms Chapman

"The World Cancer Research Fund (WCRF) found that the evidence does not support the use of high dose supplements as a means of improving outcomes in people with a diagnosis of cancer. High dose supplements <u>may</u> be harmful. See Chapter 9 of the World Cancer Research Fund and American Institute for Cancer Research. Food, nutrition, physical activity and the prevention of cancer: a global perspective.

Washington DC, AICR. 2007 - <a href="http://www.wcrf.org/research/expert\_report/index.php">http://www.wcrf.org/research/expert\_report/index.php</a>). This World Cancer Research Fund Report is one of the most comprehensive analyses of the literature on diet, physical activity and cancer."

"It is much more advisable to have a healthy diet with a variety of fresh fruit and vegetables than rely on getting our nutrients from multivitamin pills.

The recent study on vitamins and breast cancer (ref Larsson SC, Akesson A, Bergkvist L, Wolk A. Multivitamin use and breast cancer incidence in a prospective cohort of Swedish women. Am J Clin Nutr. 2010) adds to the growing body of evidence that multivitamins are not all they're cracked up to be in their marketing hype.

Cancer patients can be very vulnerable to suggestions, including marketing promotions, that taking supplements can do them more good than what can be backed up by clear evidence.

Heavy marketing of vitamin supplements undermines the message that people should be eating more fresh fruit and vegetables."

#### **Dr Geraldine Moses**

Dr Geraldine Moses is one of the clinical pharmacologists responsible for the Mater Hospitals Adverse Events Medicine (AME) line. Part of her responsibilities is to try to discourage the families of cancer patients from supplying these very ill patients with complementary medicines, particularly while they are undergoing chemotherapy.

I asked Dr Moses to comment on the risks and benefits of vitamins and other herbal remedies for breast cancer patients.

### According to Dr Moses:

"As you know, there is a galaxy of vitamin products available on the market, but many of them contain **non**-vitamin ingredient, such a bioflavanoids, herbs and minerals, that carry their own potential for drug interactions and adverse effects.

eg. Furanocoumarin bioflavanoids such as rutin and quercetin may be in the product, yet can block Cytochrom P450 enzymes which can lead to adverse reactions and drug interactions.

Herbs such as ginseng, ginkgo or garlic may be in the product for no other reason than to look good, but they can cause adverse effects and drug interactions.

Bitter orange extract (an adrenergic stimulant) and caffeine-containing compounds like guarana or green tea, may be in the product and the energising effect be falsely be attributed to the vitamins. Minerals such as boring old calcium are often in these products and can inactivate a myriad of medicines, but most frequently osteoporosis medicines, and sometimes I've seen Lithium in multivitamin and mineral preparations.

No one should take lithium if they don't need it.

As you know, this problem often arises because people don't think of vitamins as pharmaceutical drugs (even though they are) and, therefore, they don't criticise them as they would a prescription drug.

Finally, an under-recognised problem is overdosing of vitamins.

Many consumers take multiple vitamin products, for multiple reasons, but few pay attention to overlapping ingredients. A common problem is pyridoxine (Vitamin B6). Only 25-50mg may be in each individual product, but if the patient takes >100mg /day, they are at risk of peripheral neuropathy from B6 toxicity. (NB: Vitamin B6 in doses >100mg is only available on prescription in the UK)

So, the bottom line is vitamins are still drugs, with potential benefits and risks like any other drug. The products they are sold in however, often contain ingredients not banked on, which can present unexpected benefits and risks.

Perhaps it all boils down to the medico-legal issue that consumers should at least be warned of the potential risks of vitamin products, otherwise the people promoting them could be held responsible for adverse effects."

### **Prof Edzard Ernst**

Prof Edzard Ernst is the world expert in complementary and alternative medicines and is so highly regarded that he was recently invited to Australia by the Complementary Healthcare Council to present a paper at their conference 'Tackling the 'Burden of Disease' where he discussed herbal medicines within the context of scientific evidence and looked at issues to do with balancing the benefits and risks.

I asked Prof Ernst what complementary and alternative therapies worked and he directed me to his Focus on Complementary and Alternative Therapies articles.

### According to Prof Ernst:

"The most fundamental [precondition for integrating complementary and alternative therapies] are that therapies ought to be safe, effective and cost-effective. These preconditions are intimately interconnected and ensure that a treatment does more good than harm. What is the evidence then for complementary medicine regarding these criteria? Overall, it is inconclusive" viii

"it is, therefore, largely unknown whether a given complementary treatment does more good than harm and whether the same effect (if any) can be achieved at lower costs. If safety, effectiveness and cost-effectiveness are not established beyond reasonable doubt the integration of any therapy, whether complementary or mainstream may be premature"

More research has recently been completed which supports his concerns about the risks and benefits of complementary medicines. For example, he refers to Hawthorn as having "solidly evidence-based CAM".

Since his article was published, evidence has now emerged that Hawthorn, which is used for chronic heart failure, has shown an increase in incidence of death and hospitalization.

This NPS recommended Natural Medicines Comprehensive Database now considers Hawthorn as "possibly ineffective" and that new research suggests that it is possibly harmful:

"But new research suggests hawthorn might increase the risk of death and hospitalizations due to heart failure. A retrospective safety analysis found that patients taking these hawthorn extracts for up to 6 months had a 1.7% increase risk of death and an 18% increased risk of hospitalizations. This research is preliminary, but concerning. Until more is known about the effects of hawthorn on these ultimate outcomes, advise patients not to use hawthorn for heart failure."

A number of Blackmores products which contain Hawthorn, including Ginkgo Plus, continue to be marketed to consumers.

### Prof Joseph Forgas

I know first-hand the close association cancer patients have with their community pharmacists. While I appreciate that your Foundation is not actively promoting vitamins and supplements for cancer patients, it cannot deny the power and influence of advertising by high profile Australians which include sporting hero's, especially when they see the cardboard near life-size cut-out of Mr McGrath outside their pharmacy when they go to get their prescriptions filled.

I believe this image is a powerful motivator which would undoubtedly encourage us to believe that these products are safe and work.

I asked Prof Forgas to comment on the association you have with Blackmores.

### According to Prof Forgas:

"I have become aware of your [McGrath Foundation] association with Blackmores, and in support of Loretta Marron, I would also like to register my concern about this association.

People are not usually able to critically evaluate the substance of conflicting and often unsubstantiated claims about alternative therapies. There is a great deal of confusion about these matters, and the mere association of an organisation like yours with companies that have a commercial interest in selling medically useless products is liable to create even more confusion in peoples' minds.

In essence it seems that you are trading your good name and credibility for financial support.

This doesn't seem like a sensible long-term strategy for an organisation like yours."

#### Conclusion

In this letter I have outlined my concerns relating to an inappropriate relationship that the McGrath Foundation has with the drug company Blackmores. To support my concerns, I have enlisted the advice of a number of medical and other experts to comment on this relationship and they have not

only detailed the considerable risks of unnecessary drug taking by cancer patient's like myself, but have identified the undue influence put on us by high profile Australians when we make our decisions of health medications particularly when placed in pharmacies where we purchase our medications.

This overt association of the much publicised McGrath Foundation, that was set up to improve the wellbeing of breast cancer patients like myself, with any company that has a commercial interest in selling medically useless product, only adds to patient confusion while at the same time undermining the important message that people should be eating more fruit and vegetables.

Cancer patients, in particular, are extremely vulnerable to heavy marketing promotions, such as the Blackmores/Glenn McGrath vitamin advertising campaign, which targets them both in the media and when they have their prescriptions filled.

Blackmores are well known for their aggressive marketing to pharmacists and to consumers. They also have a reputation for false and misleading advertising which is backed by many complaints to the TGA's Complaints Resolution Panel and inappropriate and biased labelling on and in their packaging.

With regard to weight loss products, despite their involvement in new standards in evidence for these products, they continue to promote them even though these products will be taken off the shelves for their failure to meet the level of evidence required for effective weight-loss.

Despite claims by Blackmores, that many of their products have scientific evidence, this is not substantiated by up-to-date reviews from COCHRANE nor the conclusions of the NPS recommended database.

Surviving cancer is already an extremely difficult and challenging journey. Cancer patients will not thank the McGrath Foundation for being badly informed, when at the end of the day we desperately need to be supported and not exploited. For our benefit, you should give clarity to the mission of your Foundation and distance yourself from Blackmores.

I would like to ask you for your support in this matter.

Yours sincerely

Loretta Marron Breast Cancer Survivor

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Prof Ray Lowenthal, Royal Hobart Hospital Prof J Forgas, University of NSW Dr Geraldine Moses AME

Prof Ian Olver, Chief Executive Officer, The Cancer Council Australia. Kathy Chapman, Nutrition Program Manager, Cancer Council, NSW

Dr Helen Zorbas, CEO and Executive Director of National Breast and Ovarian Cancer Centre

Glenn McGrath AM, Co-Founder and Chairman

Tracy Bevan, Executive Director Terry Brown, Board Member

Peter Tracey, Board Member

Kylea Tink, Managing Director

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