Personal Submission

To

Senate Standing Committee on Community Affairs

Inquiry Into

The National Health Amendment (Pharmaceutical and Other Benefits-Cost Recovery) Bill 2008

By

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1.0 Statement of Responsibility for This Submission

This submission is the sole responsibility of the author, developed in his own time, supported by his own resources and made on his own behalf.

The University of Notre Dame Australia is not responsible for the content of this submission, and has not endorsed or supported this submission in any way.

Mercy Health and Aged Care is not responsible for the content of this submission, and has not endorsed or supported this submission in any way.

2.0 Summary Details of the Background and Relevant Experience of the Author of This Submission

Allan McLean is a medical graduate and Consultant Physician in General Medicine and Geriatric Medicine and a Consultant Physician in Clinical Pharmacology and Therapeutics.

He initially trained in Australia as a medical graduate and then as a Consultant Physician in Internal Medicine with special training in Cardiovascular Medicine and Hypertension.

He then trained in the scientific disciplines of Pharmacology and Toxicology (BMed Sci and PhD). He was trained in the USA and Canada in the disciplines of Clinical Pharmacology, Clinical Toxicology and Therapeutics supported by an NHMRC Clinical Sciences Fellowship.
He concurrently extended his clinical training as a Consultant Physician in General Internal Medicine, Clinical Therapeutics, and Geriatric Medicine, and is registered to practice in New York State, USA.

He returned to Australia and was a pioneer in the areas of rational scientific assessments of effectiveness and safety in the clinical applications of medications. He served as a Consultant physician and Consultant Clinical Pharmacologist to leading hospitals in Victoria (Alfred Hospital, Prince Henry's Hospital, Queen Victoria Hospital and Monash Medical Centre). He also served on all Ministerial Working parties on hospital drug use in the State of Victoria in the 1980's, and was a member of the Therapeutic Advisory Committee of the Royal Australasian College of Physicians 1988-1993.
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He was at the forefront of the development of the discipline of pharmaco-economics nationally and internationally, and was the lead author in the landmark papers on cost benefit analyses in the use of surgical antibiotics and the cost-benefit of antihypertensive medications.

He maintained a parallel career in academic clinical medicine. He was the Foundation Professor in Clinical Pharmacology and Therapeutics at Monash University, the Foundation Professor in Geriatric Medicine at the Canberra Clinical School of the University of Sydney, Professorial Fellow at the Australian National University, Professor of Ageing at the University of Canberra, Professorial Fellow in Medicine and Professor of Geriatric Medicine at the University of Melbourne, and is currently the Foundation Mercy-Notre Dame Chair of Medicine at the University of Notre Dame Sydney School of Medicine.

He undertook formal business training in the decade 1995-2004 in areas of technology management and general management. He graduated from Mt Eliza Business School with an Executive MBA degree in 2004.

A copy of his Curriculum Vitae is an attachment to this submission.

3.0 Relevance of This Submission to Terms of Reference to the Senate Standing Committee on Community Affairs

This submission addresses in detail the following formal terms of reference to the Committee:

1(a) (i)-"patient's timely and affordable access to medicines"
and
1(c) -"how cost recovery will improve timelines and effectiveness of the current PBS processes for listing of new medicines"

4.0 Executive Summary

1. This inquiry allows the Senate to review the operations of the PBS system so as to guarantee the continuing affordability of the access of Australian citizens to medicines.
2. The affordability of the PBS is under rapidly increasing threat as illustrated in the projected escalation of costs of the PBS detailed in the Intergenerational Reports of 2002 and 2007 *(www.treasury.gov.au/igr)*.
3. There is no effective mechanism to modify the listing of medicines on the PBS, either to remove agents from the listing if evidence emerges as to lack of the safety, or evidence of inferior effectiveness, or evidence emerges of relative lack of cost effectiveness from comparative studies made between listed medicines in any one category after the original listing.
4. Important examples of this situation are provided in this submission related to medicines to lower blood pressure (anti-hypertensive drugs) and the therapeutic prevention of cardiovascular disease. **It has been shown that the thiazide drug class produces equal blood pressure lowering and life-saving benefit at some 1.1% of the cost of the ACE Inhibitor class. Similarly the use of a standard diet achieves the equivalent effect of the statin class of cholesterol lowering drugs at some 3% of the cost.**
5. The data presented illustrate the need for ongoing review of PBS listing against the relative cost and effectiveness of at least major classes of drugs and preferably all categories of drugs.
6. This situation represents an unsustainable management and commercial absurdity and mandates a major change in the requirements for listing on the PBS.
7. Candidate medications for listing should be required to undergo comparative assessments of effectiveness and safety against existing medications available on the PBS prior to unrestricted listing
8. Listed drugs should be regularly reviewed for effectiveness and cost-benefits in the light of new knowledge
9. A system termed the Special Access Scheme (SAS) was maintained by the past equivalent of the Department of Health and Ageing and historically provided extremely early availability of new drugs to patients under the care of hospital based specialists, with required reports of effectiveness and any side-effects to the TGA. The renewal of this service and system would guarantee early availability of new drugs under expert supervision from specialist practitioners and the PBS if appropriate staff with clinical and Clinical Pharmacology expertise was recruited.
10. The availability of the Department of Veteran's Affairs clinical databases allied to CSIRO Preventive Health Flagship statistical technologies would allow precise and early comparisons of effectiveness between any candidate agent for listing and existing medicines under clinical conditions representative of usual clinical conditions of use.
11. These proposed changes to listing processes would avoid repetition of decades of unnecessary expenditure in the PBS in a variety of categories, and reduce the risk of loss of affordability of the PBS. All of this can be achieved without compromising early access to new drugs.
12. These issues of affordability and sustainability of the PBS transcend the relatively trivial (but politically sensitive) issue of funding of the listing of agents on the PBS through cost-recovery from industry sources.

5.0 The urgent need to maintain the affordability of the PBS detailed in the Intergenerational Reports of 2002 and 2007

Forward projections by Treasury in the Intergenerational Report of 2007 ***(www.treasury.gov.au/igr)*** from financial year 2006/7 to the end of financial year 2046/7of the overall budgetary position of the Commonwealth Government contained in IGR 2 (Chart 7 of the IG Report of 2007) are included her as Figure I of this text.

The Treasury projections foreshadow a gradual decline in budgetary balances from the surplus outcomes of the last decade to a negative budgetary balance after 2023, escalating to an annual deficit of more than 3% at the end of the financial year 2046/7.

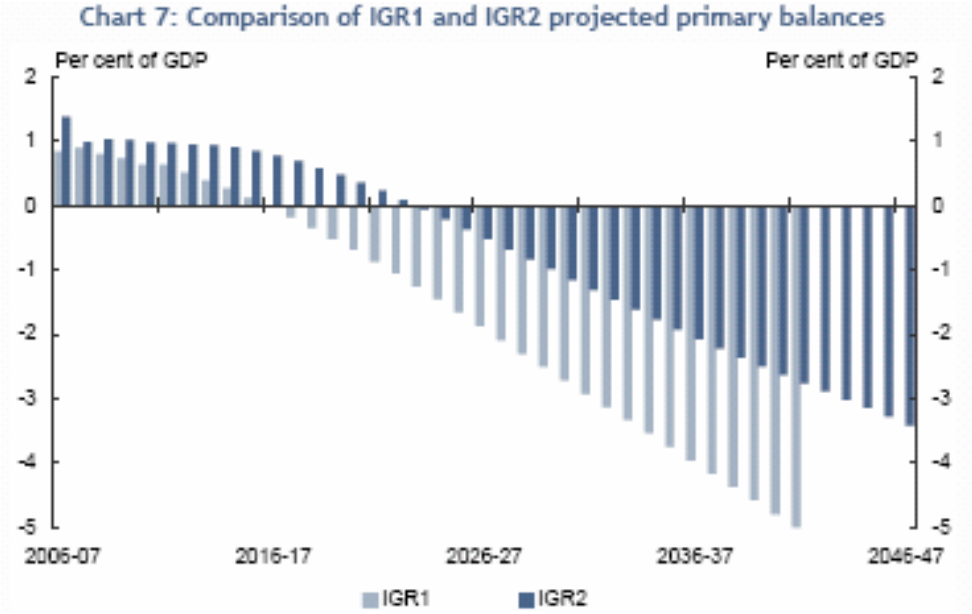

Figure I Commonwealth public sector primary budget balances. The data shown are June 2006/7 actual together with modelled projections to the end of the financial year 2046/7. The data in Figure I is Chart 7 of the IGR2 Report of 2007.

The largest increase in projected expenditure is in health, and not in aged care or aged pensions as common belief might predict (see Figure II below). The lack of any significant increase in projected expenditure on defense is surprising, and the lack of any projected increase in education budgets is surprising in the light of emerging workforce issues.

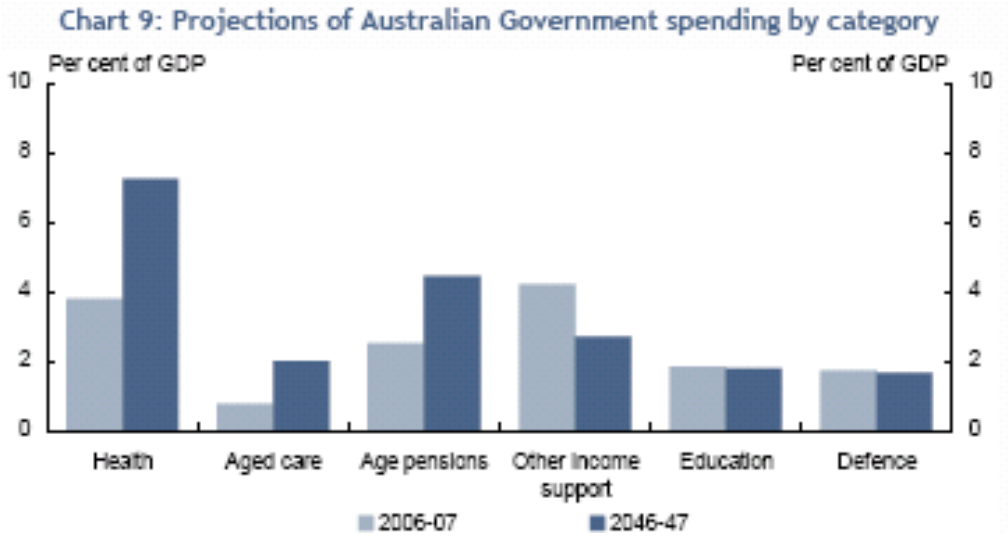

Figure II Projections of Categories of Australian Governmental Expenditure Against the Base of Actual expenditure in the 2006/7 Financial Year (Chart 9 of IGR2)

Projected change in expenditure in the health sector has been analysed into the component parts illustrated in Figure III below. The major increases projected were in "hospitals and health services" and the supply of pharmaceuticals.

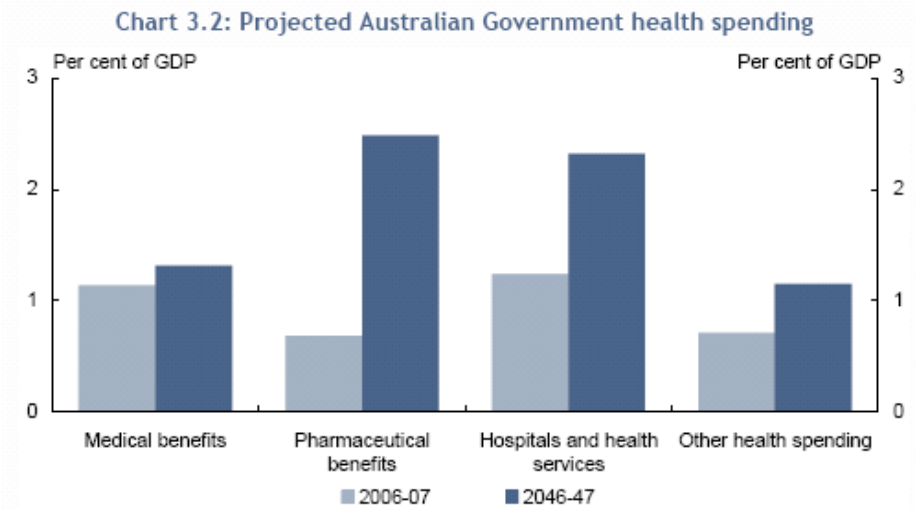

Figure III Projected change in components of health service expenditure against 2006/7 actual

6.0 Evidence of a Lack of Effective Mechanism to Modify the Existing listings of Medicines on the PBS so as to Reflect New Knowledge Relevant to Clinical Effectiveness and Cost-benefit Analyses-Example related to medicines to lower blood pressure (anti-hypertensive drugs) and cardiovascular disease.

The Treasury data in IGR2 establishes that the costs of purchase and distribution of pharmaceuticals is central to the cost of operating the health service.

Long established data show that the present method of assessing cost-benefits are unable to establish equivalent cost-benefit judgements that the average customer for the purchase of a motor car achieves on their own behalf.

Differences between the costs of equivalent therapies are clearly shown in Figure IV below. This Figure/Table contains data the relative costs of saving a single life for one (1) year from heart disease using some established and recognised common forms of treatment. **The cost of a the use of a thiazide diuretic to save a life for one year is some 1.1% of the cost of using an ACE Inhibitor drug. Similarly the use of a standard diet achieves the equivalent effect of the statin class of cholesterol lowering drugs at 3% of the cost.**

Treatment Type	Cost in £ Sterling of each year of life gained from the use of each treatment studied
Aspirin	50
Thiazide (anti-hypertensive drug)	66
Mediterranean diet	290
ACE Inhibitor (antihypertensive drug)	5634
Simvastatin (cholesterol lowering drug)	8240

Figure IV The Relative Costs of Saving a Year of Life from Heart Disease as the Cause of Death (Data from Ebrahim and coworkers (1999) published in Health Technol Assess;3: 19)

Data published in the ALLHAT Trials* clearly establish that the effectiveness of the ACE Inhibitor drug category is significantly below that of the thiazide class. **Accordingly these estimates of relative cost at approximately 1represent significant underestimates of relative costs.**

Despite these cost-benefit data being available since 1999, and the ALLHAT data since 2002*, there has been no response from the Pharmaceutical Advisory Committee (PBAC) to the PBS in Australia.

*(ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial.
Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT).
JAMA. 2002 Dec 18; 288(23):2981-97)

The American Heart Association has recently (June 2008) published a definitive position statement on practical therapy for the treatment of hypertension, endorsing the principal and "first-line" role for thiazide diuretic in the most difficult categories of antihypertensive therapy.**

** Calhoun DA, Jones D, Textor S, Goff DC, Murphy TP, Toto RD, White A, Cushman WC, White W, Sica D, Ferdinand K, Giles TD, Falkner B, Carey RM; American Heart Association Professional Education Committee.
"Resistant hypertension: diagnosis, evaluation, and treatment: a scientific statement from the American Heart Association Professional Education Committee of the Council for High Blood Pressure Research".
Circulation. 2008 Jun 24;117(25):510-26.

The situation with the broader of issue of management of cardiovascular risk generally is similarly dysfunctional if reference is made to the Table in Figure IV. The data related to the Mediterranean Diet establishes that an equivalent effect to the use of statins for cholesterol lowering is 97% more costly than the use of the Mediterranean Diet.

Despite this, there is no effective mechanism for requiring the competent management of dietary therapy as a condition for use of the statin class of anti-cholesterol drugs.

This situation with anti-hypertensives and prevention of myocardial infarction illustrates the extraordinary structural deficiencies of the current system of PBAC advice and the resulting deficiencies in management of PBS listings.

6.0 Pathway to a Solution-The availability of Department of Veteran's Affairs Clinical Databases allied to CSIRO Preventive Health Flagship analytical technologies would allow precise and early comparisons of effectiveness between any candidate agent for listing and existing medicines under clinical conditions representative of usual clinical conditions of use.

In Department of Health and Ageing and Australian Research Council funded pilot studies on health databases, the CSIRO Division of Mathematics and Information Sciences and the CSIRO Preventive Health Flagship have developed techniques designed to detect adverse drug reactions and identify beneficial outcomes of drugs, particularly in combination.

It has been proposed to apply these techniques retrospectively to existing drugs, and then prospectively to newly introduced drugs as a novel addition to existing post-marketing surveillance techniques. The results will have immediate application in informing medication policy and in the practice of safe and effective therapeutic prescribing for the Veteran and War-Widow population, and will potentially have wider impact on national medicines policy in Australia generally.

The technologies also have the potential to detect previously unsuspected positive effects of individual drugs on disease outcomes. Similarly the technologies have the capacity to detect positive outcomes of combinations of pharmaceuticals not systematically studied in clinical trials as combinations.

The technologies have the potential to assess primary and secondary preventive interventions in a variety of important conditions such as stroke, where disease processes generate disability and consequent dependence with reduction in quality of life.

Adverse drug reactions are a major determinant (approx 20%) of hospital admissions in the elderly, reflecting altered systemic bioavailablity and altered drug clearance, and operating through various mechanisms including confusional states and falls.

It is entirely feasible to establish a list of drugs whereby prescription change in older people (avoidance of use or dosage reduction) would be part of future clinical best practice in Geriatric Medicine and the medical profession generally, adding to current World Health Organisation recommendations.