Newsletters, News and Events

Submissions

April 1998

SUBMISSION TO THE HEALTH AND MEDICAL RESEARCH STRATEGIC REVIEW

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1 Background

The Australian Society for Medical Research

The Australian Society for Medical Research (ASMR) is a registered Australian Company (ACN 000 599 235, Head Office: 145 Macquarie Street, Sydney 2000). The ASMR was formed in 1961 with the goals to foster excellence in Australian health and medical research, and to promote community understanding and support for health and medical research in Australia.

Structure of the ASMR

The ASMR is run by a Board of eleven Directors who, apart from the President and President-

Elect, have a two year term of office. The Directors of the Society are:

President: Dr. Steven Wesselingh
President-Elect: Dr. Matthew Gillespie
Hon. Secretary: Dr. Judy Halliday
Hon. Treasurer: Dr. Peter O'Loughlin
Directors:

Dr. Carol Armour
Dr. Moira Clay
Dr. Bruce Lyons
Dr. John Mamo
Dr. Robert Ramsay
Dr. Peter Schofield
Dr. Jason Smythe

This structure ensures that the Board is always aware of, and responsive to, current issues within the health and medical research community. An Executive of the Board comprises the President, President-Elect, Secretary and Treasurer. The Board of Directors meets three times each year. The ASMR is incorporated as a limited liability company. Our Executive Officer, Ms Cath West, can be contacted at our Sydney Office.

Who does the ASMR currently represent?

At the present time there are 1070 financial members of the Society of whom 89% are ordinary members and 11% student members. The ASMR is affiliated with 37 specialist societies representing a further 14,800 members. The Society also receives strong support from pharmaceutical and biomedical companies who contribute financially to the Society often in the form of sponsorships for the National Scientific Conference or with travel grants for younger members.

Affiliate Member Organizations:

Arthritis Foundation of Australia
Association of Australian Medical Research Institutes
Australasian Association of Clinical Biochemists
Australasian Menopause Society
Australasian Society for Free Radical Research
Australasian Society for HIV Medicine Inc
Australasian Society for Immunology
Australasian Society for Infectious Diseases
Australasian Society for the Study of Hypertension in Pregnancy
Australasian Society of Blood Transfusion
Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
Australasian Society of Clinical Immunology and Allergy
Australian and New Zealand Bone and Mineral Society
Australian and New Zealand Society for Cell & Developmental Biology
Australian and New Zealand Society of Nephrology
Australian Association of Neurologists
Australian Atheroscelerosis Society
Australian Cystic Fibrosis Association
Australian Diabetes Society
Australian Kidney Foundation
Australian Neuroscience Society

Australian Physiological and Pharmacological Society
Australian Rheumatology Association
Australian Society for Biochemistry and Molecular Biology
Australian Society for Psychiatric Research
Australian Society for Reproductive Biology
Australian Society for the Study of Obesity
Cardiac Society of Australia and New Zealand
Clinical Oncology Society of Australia
Community Health and Anti-tuberculosis Association
Endocrine Society of Australia
Fertility Society of Australia
Gastroenterological Society of Australia
Haematology Society of Australia
Haemophilia Foundation of Australia
High Blood Pressure Research Council of Australia
Human Genetics Society of Australasia
Juvenile Diabetes Foundation of Australia
Muscular Dystrophy Association of South Australia Inc.
National Association of Research Fellows
National Heart Foundation of Australia
National Multiple Scelerosis Society
Paediatric Research Society of Australia
Perinatal Society of ANZ
Thoracic Society of Australia and New Zealand
Transplantation Society of Australia and New Zealand

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2 Introduction

ASMR through its regular members and affliate members represents almost 15,000 medical researchers.

Currently health care is going through dramatic and rapid changes, due to rapid advances in our understanding of human physiology, particularly at the molecular level. Thus, in the current boom in biomedical understanding, research and development efforts are driving the health care system to advance at a rate which is arguably much faster than at any other time in history. The burgeoning information technology industry, while facilitating the dissemination of information does not facilitate the ability to interpret new findings in the field of medicine. The ability to interpret and implement the major advances in biomedical understanding can only be achieved through direct experience in the research that leads to those advances. Research experience for Australia's health care workers enables them to put into practice new diagnostic, therapeutic and management techniques many years before they are available as off-the-shelf technology. Australians deserve to have access to the best of health care as it evolves."

We believe that there has been lack of imagination and vision in the funding of R&D in Australia and consequently there has been a significant dismantling of Australia's R&D capacity. The future means understanding technology, inventing it and translating it in a meaningful way to our industrial sector and into our hospitals and clinics.

ASMR believes that a healthy level of medical research investment would be 5% of total health expenditure. The figure of 5% is an international benchmark and is in accordance with the amount invested by other technology driven industries. As part of the 5% investment target, ASMR believes that the NHMRC peer-reviewed grant budget should be doubled over the next

5 years. This is necessary to adequately meet the challenges that advances in knowledge-based technologies will bring to the Australian health system and to adequately capture the economic benefit of national and international developments in health R&D.

This submission highlights some the significant achievements of Australian Medical Researchers and documents the economic, social and medical benefits that have have derived from those achievements. There is absolutely no doubt the return on investment in medical research has been substantial in terms of job creation, export substitution and improvements in the health and welfare of Australians. We have given examples of the benefits of both fundamental research and applied research.

ASMR, has developed a list of recommendation which are critical to the continuing welfare of medical research in Australia.

Steven Wesselingh
President, ASMR
April, 1998

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3 Recommendations

- ASMR supports a merit driven, peer-reviewed broad based biomedical research effort.
- Expenditure on biomedical research should be at a minimum of 5% of national health outlays and the NHMRC budget should be doubled in the next five years.
- There must be mechanisms for assured stability and continuity of medical research funding.
- ASMR supports better Government initiated mechanisms for Industry support of biomedical research.
- The levels of, and mechanisms for, infrastructure support of Medical Research in Universities and Hospitals requires urgent attention.
- The retention of the highly skilled workforce is required to maintain excellence in Australia's health and medical research effort.
- In order to ensure that young Australian researchers have input into the political process ASMR should be represented on PMSEIC.

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4 Attitudes to Health and Medical Research

The survey commissioned by ASMR and conducted by Newspoll Market Research found that -

- Australian adults almost universally believe that medical research in Australia is important for improving health and preventing and treating disease in Australia.
- Almost as many also believe medical research is important for helping to keep health care costs down.
- The amount of medical research conducted in Australia matters to the majority of Australians with half of the adult community believing the amount conducted is insufficient.
- More than three-quarters of adult Australians believe that any additional medical research should be paid for by the government.
- A similar number also believe that at least 5 per cent of the total health care bill in Australia should be directed toward medical research.
- Australian taxpayers are prepared to pay, on average, an additional 4.7 cents a day in taxes if the money is guaranteed to fund medical research.
- Most people would be concerned if their preferred political party did not include in its health policy improvements in suppport for medical research.

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5 Health and Medical Research activities

A strategic review of Health and Medical Research in Australia must take into account evolving trends of conversion of our industrial based society into an information based one. Research is an activity which is conducted because of a lack of current knowledge or information about a specific problem. Until such information is available, it is not possible to develop new solutions to the problem, thus Research is the key to obtaining solutions to our societal needs for better Health and improved Medicine.

Case Studies of the Outputs of Health and Medical Research

In each of the following case studies of the outputs and economic and medical value of health and medical research, we have sought to define the value generated by that discovery. The list of such examples is far from exhaustive and other relevant examples of the investment in biomedical research have been documented in the successful case for increased science funding in the USA or at the Prime Minister's Science and Engineering Council (1). Our overriding goal has been to demonstrate that the outputs of a merit driven, broad based, peer reviewed biomedical research effort are indeed delivering solutions to the health and medical problems that face Australian society. Not only do these research outputs lead to significant savings in the number of Australians who do not die from disease or have their disease effectively treated or cured, they also contribute to the economic well being of the Australian and global economies.

(1)Stanley F et al 1994 Research for a Healthy Society. Department of the Prime Minister and Cabinet.

Use of immunosuppressive therapies to enhance organ transplantation

Australia has been at the forefront of clinical research on the immunosuppressive drug cyclosporine. This is evidenced by some of the earliest publications which represented participation in the international clinical trials of this medicine and early reports of its successful use (1). This has led to our rapid adoption of this drug, with consequenct imporvement in the survival rate of transplanted organs and reduction in the costs associated with end-stage organ failure. An example of the savings benefit of successful transplantation, provided by the Transplantation Society of Australia and New Zealand Inc is that a dialysis patient cost $15,000 - $45,000 per year to maintain while the same patient with a successful kidney transplant costs approximately $25,000 in the first year and $5,000 per year thereafter. As there are currently about 4570 transplant patients (475 in 1996) in Australia. This results in treatment cost savings of around $100 million per annum. With the ability to successfully conduct kidney transplants, even small improvements in the transplantation success rate leads to large savings to the national health budget as well as significantly enhanced quality of life for those affected individuals.

(1)Hall BM, et al. (1988) Comparison of three immunosuppressive regimens in cadaver renal transplantation: long-term cyclosporine, short-term cyclosporine followed by azathioprine and prednisolone, and azathioprine and prednisolone without cyclosporine. New England Journal of Medicine 318: 1499-1507.

Sudden infant death syndrome (SIDS)

Australia has had one of the highest incidences of sudden infant death syndrome (SIDS or cot death). Epidemiological research undertaken at the Menzies Centre for Population Health Research in Hobart has examined the causes of SIDS through the use of a prospective cohort study. Of the 3110 members of the cohort born between 1988 and 1990, 23 infants later died of

SIDS. Sleep position information was available for 15 of these. Analysis of sleep position and other data showed that prone sleeping position was associated with a 4 1/2 fold increased risk of SIDS. The findings were strengthened by the results of a concurrent retrospective case-control study of 42 SIDS cases in which the prone position was also associated with a 3 1/2 increased risk of SIDS. This research was described in the paper by Dwyer et al (1) and resulted in multiple public health activities to reduce the prevalence of the prone infant sleeping position. In a comparison of the whole population incidence of SIDS before and after this intervention the researchers obtained significant statistical proof that the sleep position intervention more than halved the SIDS death rate from almost 4 deaths per 1,000 live births from the period 1975 to 1990 to only 1.5 deaths per 1,000 live births in 1991 to 1992 (2).

In this instance, the use of the information (scientific publication) of medical research was able to be rapidly and directly applied towards public health education campaigns. This information now results in the saving of a significant number of Australian babies each year.

(1)Dwyer T, Ponsonby AL, Newman NM, Gibbons LE. (1991) Prospective cohort study of prone sleeping position and sudden infant death syndrome. Lancet 337: 1244-1247.

(2)Dwyer T, Ponsonby AL, Blizzard L, Newman NM, Cochrane JA. (1995) The contribution of changes in the prevalence of prone sleeping position to the decline in sudden infant death syndrome in Tasmania. Journal of the American Medical Association 273: 783-789.

Helicobacter pylori: a paradigm shift in the management of gastroduodenal disease

Helicobacter pylori infection is strongly associated with predominant forms of peptic ulcer disease and plays an important contributory role in their pathogenesis. Annually, world-wide, 4 million people are affected by ulcers. The link between H. pylori infection and ulcers was made in 1982 (1,2) by Drs Robin Warren and Barry Marshall in Perth with support from the Royal Perth Hospital Research Foundation and the Fremantle Hospital Research Foundation. The world of gastroenterology first rejected the the concept that peptic ulcers were an infectious disease. However, in the short space of 16 years Warren and Marshall have been completely vindicated such that the NIH now recommends that peptic ulcers in infected persons should be treated for H. pylori infection and has concluded that the bacterium is an early risk factor for gastric cancer which remains the world's second most common malignancy.

Warren and Marshall's ground breaking discovery has led to the development of combination treatments by several multinational companies including Glaxo-Wellcome, Astra, Abbott and Pharmacia/Upjohn. Furthermore, national based research groups in NSW, Victoria and WA are now entirely devoted to understanding the epidemiology, drug reactivity and antibiotic resistance of *H. pylori*.

Treatment of H. pylori with antibiotics and acid-suppressing drugs has now reduced healing time in most peptic ulcer patients to a few weeks and is associated with only minor side-effects. Moreover, eradication of H. pylori may enhance healing of ulcers refractory to conventional therapy. It is now well accepted that treatment of H. pylori results in a substantial reduction in the risk of ulcer recurrence (to <10 percent in 1 year) and also appears to prevent future problems in peptic ulcer patients with a history of bleeding or other complications. There has been a decrease in time off work and in pain, suffering and inconvenience to ulcer patients. This reduction in disease morbidity is also of significant financial and quality of life benefit to the individual, their employer and to the nation.

The dollar value of the discovery of *H. pylori* can be estimated from the following statistics: combination treatment of *H. pylori* infection has resulted in the need for less upper gastro-intestinal surgical procedures. Thus, endoscopy of the stomach has decreased by 50% resulting

in a direct dollar saving to our health budget. Chronic treatment for ulcers is no longer needed at an estimated saving of $5000 per patient. With an affected patient population in excess of 40,000 this saving results in a reduced expenditure on pharmaceuticals of over $200 million per annum.

(1)Warren JR, Marshall B. (1983) Unidentified curved bacilli on gastric epithelium in active chronic gastritis. Lancet 1983,i: 1273-1275.

(2)Marshall BJ, Warren JR. (1984) Unidentified curved bacilli in the stomach of patients with gastritis and peptic ulceration. Lancet 1984, I: 1211-1315.

Biota Holdings and the flu drug RelenzaTM

The company Biota was founded in 1985 to exploit some significant research discoveries about the influenza virus that were made by Australian scientists working in Australia. The important milestones were the production of crystals of the influenza virus sialidase by Graeme Laver and the solving of the 3D structure by Peter Coleman and colleagues. This seminal work eventually led to the identification of a specific site in the viral enzyme that was the same in all strains of influenza. This presented an ideal opportunity for the rational design of a specific drug that could occupy this site and consequently interfere with the virus' ability to multiply. The rational drug design program was carried out under the direction of Mark Von Itzstein and Wen-Yang Wu at the Victorian College of Pharmacy. This phase of the project was funded through Biota. The key scientists involved in the progression of this project from the research lab to a drug candidate were awarded the Australia Prize in 1996 (Laver, Coleman, Von Itzstein).

The most promising drug candidate from the VCP labs was liscensed by Biota to Glaxo-Wellcome for development. The prophylactic drug known as Relenza (Zanamivir, GG167) has passed through the clinical trials phase and Biota filed an application for commercial release in Australia to the TGA (Therapeutic Goods Administration) on 30 March 1998. Application for FDA approval will follow later in 1998 (1,.2).

Biota will receive royalties from the sale of this drug internationally (10% from sales in Australia, NZ, Indonesia & South Africa; 7% from the rest of the world). It is estimated that the stable market for this type of drug is US $ 1 billion per year and that the Biota drug will have 50% market share. Biota is predicited to be earning $14.3 million in royalties in 2000 and $116.4 million in 2007 from this drug (1,2). Biota has invested AUD$ 17.8 million in research projects between 1992 and 1998. By 2001 the company will have invested an estimated total of AUD$ 48.9 million in Australian biomedical research.

Other positive outcomes from this medical research include the development of specific and sensitive diagnostic tests by Biota that will generate income in the near future. The other economic and social benefits that flow from this drug will include reduced length and severity of the disease.

(1) Merrill Lynch in-depth report on Biota Holdings &endash; 17 Feb 1998

(2)http://www.biota.com.au

Cervical Cancer Vaccine

In 1991 Dr Jian Zhou and Prof Ian Frazer of the Centre for Immunology and Cancer Research, Univeristy of Queensland, discovered that the expression of the papillomavirus coat protein gene in cells caused the formation of virus-like particles. This was a major breakthough as human papillomavirus was not able to be grown in the laboratory before. This finding was

funded by NHMRC and patented. Uniquest, the commercial arm of the Univeristy of Queensland, laised with CSL Ltd (Melbourne) to develop this finding into a vaccine to prevent genital warts and cervival cancer. Commerical rights were sold to Merck Sharp and Dome (USA) who are developing the vaccine and permission has been obtiained from the FDA for phase 1/II trials. It is envisaged that such a vaccine if successful would have universal use and is expected to generate revenue of in excess of $100m per year and save up to $500 million per year in direct health care costs. The agreement with CSL lead to substainal funds for the Centre which allowed for the expansion from a lab of 10 to a Centre of 60 people, most supporting new research programs via competitive external funding mechanisims. The Centre has 10 PhD students. Furthermore, a number a new commercial projects are now underway and a SPIRT grant has commenced between CSL (as commercial partner) and CICR (as University partner).

Haemolytic Uraemic Syndrome Outbreak from fermented mettwurst

Medical research provides essential training for Australia's health care workers, enabling them to respond to health-emergency situations. A prime example is the outbreak of haemolytic uraemic syndrome (HUS) in Adelaide in 1995. This was the the result of fermented mettwurst contaminated with Shiga toxin-producing Eschericia coli (STEC). In this case a research group at the Molecular Microbiology Unit of the Women's and Children's Hospital with an interest in STEC were able to identify the source of infection more rapidly than the alternative epidemiological investigations. The researchers who had an established track record in this area, as evidenced by their publications in the area, were able to test cultures of faeces and suspected foods for the presence of organisms carrying the Shiga toxin genes using a specific assay that had been developed in their laboratory.

The outbreak resulted in 1 death, more than 20 cases of HUS and more than 120 reported cases of diarrhoea. Many of the HUS cases have sustained permanent renal damage necessitating renal dialysis and may require kidney transplants. The majority of affected individuals were young children. Any delay in the identification of the source of infection would undoubtedly have led to higher levels of mortality and morbidity. Not only would this have had a devastating emotional effect on the community, it would have led to increased health care costs for the treatment of diarrhoea in milder cases and ongoing costs for renal dialysis and renal transplantation in the more severe cases.

This case illustrates just one example of the benefits of medical research in hospital laboratories. A close relationship between research laboratories and diagnostic laboratories facilitates the essential medical research training of health care workers.

HIV/AIDS Research in Australia 1989-97

The first Australian national HIV/AIDS Strategy (1987/8) was the outcome of widespread public and political debate. It was (and still is) based on Ottowa Charter principles and it enshrined a partnership approach to all aspects of policy development and implementation. The outcome of the sequential National HIV/AIDS strategies has been extensively evaluated. In summary, the incidence of HIV dropped 8-fold between 1987/8 and 1992, the burden of illness for the individual and community has diminished from a peak in the early 1990's and the implementation of the HIV/AIDS Strategy has been associated with a reduction of STD's and a harm-minimisation approach to injecting drug use.

The HIV/AIDS policy was clearly a public health initiative that relied heavily upon research. When HIV began to have an impact in Australia in 1985/6 there was no national communicable diseases surveillance system, it was not possible to grow the virus, antibody testing was unreliable, education strategies directed at reducing sexual and drug-taking risk were poorly developed and the systems of clinical care were not adapted to coping with lethal infections

amongst young people who were often disenfranchised and discriminated.

Based on the success of the HIV/AIDS programme, the following elements are cited as key features: clear definitions of aims for the overall programme; scoping of the aims in terms of the types (disciplines) of research required; fostering the development of those disciplines by way of training awards and basic research in the discipline; funding specific research programmes on the basis of scientific merit, feasibility and relevance, monitoring outcomes closely; requiring the research community to participate in policy developments, implementation and/or service as appropriate; and setting Australian research within the international context.

Regulating bacterial expression for production of recombinant pharmaceuticals

In fundamental studies concerning the mechanism of translational initiation of mRNA molecules in E. coli, two Australian scientists identified a key regulary sequence, the ribosome binding site (1). This study was of only academic interest until combined with other discoveries concerning recombinant DNA technology and cDNA cloning. In combination, these technologies enabled the efficient expression of human hormones such as growth hormone and insulin in simple bacterial cells as well as the production of entirely new biopharmaceuticals such as filgrastim (granulocyte colony stimulating factor). The sale of recombinant pharmaceutical products synthesised in E. coli now results in five (Neupogen, Humulin, Intron A, Betaseron & Humatrope) of the top ten selling biopharmaceutical products. The 1996 global sales of these products was worth $US 3,046 million ($A 4,686 million) (2) of which approximately 1- 2% represents the Australian market. This example further highlights how fundamental or basic medical research can be rapidly translated into commercial opportunity.

(1) Shine J and Dalgarno L (1975) Determinant of cistron specificity in bacterial ribosomes. Nature 254: 34-38.

(2) Morrison SW and Giovannetti GT. (1998) New Directions 98. 12th Biotechnology Industry Annual Report. Ernst & Young LLP

Health and Medical Research Enhances Tourism in Australia

There are also many indirect financial benefits of Australian medical research. For example, international tourism as a result of attending International Conferences. An example provided by the Transplantation Society of Australia and New Zealand has been the hosting of the International Congress of the Transplantation Society in Sydney in 1988 and its current bid to host the 2004 meeting. The Congress is attended by over 4,000 international delegates, each of whom spends over $3,000 in Australia on conference fees, accomodation and sightseeing. Australia can only be successful in attracting such international congresses and the tens of millions of dollars they generate within our economy by having a local organising committee of international calibre. This is very much dependent on the quality of the Australian research which in turn is dependent on the level of research support. ASMR represents a total over 35 affiliate medical and scientific societies, who on average host one such international congress per decade. This results in an estimated national income of $40 million per annum.

Further activities in the tourism sector based on our high profile in the international transplant community include the hosting of the International Transplant Games in Sydney this year.

Years of potential life lost

Morbidity and mortality are two key costs of disease at the personal level. Analysis of the causes of death in Australia shows that premature death, that is death before age 76 (the

average life expectancy) results in more than 900,000 years of potential life being lost in 1993 (1). The costs of such lost contributions to society are enormous, yet they can be regained by investment in health and medical research. For example, a reduction of only 10% in years of potential life lost can be shown to have a net value in the billion of dollars. As can be seen from the examples given above, investment in health and medical research is delivering these benefits. However, the investment has not yet been maximised and so neither have the returns to the individual, society and the nation.

(1) Causes of Death in Australia (1993), Australian Bureau of Statistics

Summary

These case studies highlight just a few of the significant achievements of Australian Medical Researchers and documents the economic, social and medical benefits that have derived from those achievements. It is crucial that it is clearly understood that the return on investment in Australian medical research is substantial in terms of job creation, export substitution and improvements in the health and welfare of Australians. This link has been recognised by our international competitors, the most vivid example being the recent increases in NIH funding announced by President Clinton. We must make our politicians understand that the current inadequate levels of medical research funding are leading to lost opportunities in terms of job creation and health improvement.

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6 Future Directions

ASMR supports a merit driven, peer reviewed broad based biomedical research effort.

Defining the direction of our national health and medical research effort, and assigning appropriate funding priorities to research programs, are issues of fundamental significance as Australia prepares for the next millennium. Moreover, the ability to maintain a broad based-research capacity capable of rapidly evolving to meet the changing needs of the Australian health system is essential. To achieve this objective will require a measured balance of funding for both basic and applied health and biomedical research, a balance that can only be driven by the process of investigator-initiated, peer reviewed grant funding. This system of expert analysis and peer-review of research grant applications is currently the preferred mechanism for assigning funding priorities by national and international government-based funding agencies, such as the Australian NHMRC, the British MRC, or the U.S. NIH which currently distributes some $13.65 billion for health and biomedical research on the basis of peer-reviewed ratings. The process in it's current form not only allows objective analysis of the quality, merit and feasibility of research projects and programs, but also ensures that health and biomedical research remains focussed on relevant disease processes. To subvert the current system, for example, by defining health and medical research priority areas on the basis of opinion from disease advocacy groups, or by a policy driven agenda, may lead to inequitable levels of funding to groups with political leverage. Consequently, the ASMR strongly recommends maintaining the current NHMRC system of investigator-initiated, peer-review based funding for health and medical research projects, and endorses the NHMRC as the appropriate body to define priority research areas.

Expenditure on biomedical research should be at a minimum of 5% of national health outlays and the NHMRC budget should be doubled in the next 5 years.

Medical research funding is in crisis. Australia's current level of investment in the Research and Development arm of our Health Care System is extremely low and under threat with proposed future funding cuts. Compared to other developed nations we produce high quality research

and yet the level of funding is under siege. Australian research initiatives have already contributed to the health and well being of our nation. Australian research discoveries are admired and sought after by other nations, particularly in our local economic region. In order for future developments to take place in health care, we must have a strong R&D base. The potential for export of these discoveries needs to be realised.

The Australian Society for Medical Research believes that expenditure on health R&D should be at a minimum of 5% of total expenditure on health. In stark contrast to Australia's low levels of health and medical research investment, President Clinton recently announced that the NIH budget will be increased by 8.4% this year and doubled in the next five years.

As part of an increased investment in Health for the future, the Federal Government should support the 5% core R&D funding by doubling the NHMRC budget to $320 million within the next 5 years so that the NHMRC can become the peak national body for funding and applying research discoveries to the health environment.

In order for the application of research discoveries to take place the NHMRC must remain in the Department of Health. Only then can basic, clinical and public health research be combined and involved in "cross-talk" so that there is a realistic network for transfer of basic and fundamental discoveries to the clinical level and to preventative health strategies for the future of our nation.

There must be mechanisms for assured stability and continuity of medical research funding.

The Australian Society for Medical Research believes that the NHMRC is the appropriate body for managing and determining the distribution of federal government funded health and medical research (see Recommendation 2).

Continual uncertainty associated with the level of funding has made it difficult for the secretariat to implement long term strategies for health and medical research. Recent problems which have occurred because of the current funding arrangements have included a reduction in the number of Douglas Wright Fellows, insufficient funds to meet industrial award agreements and an inability to fund large equipment requests.

Moreover, the process by which funding is determined and the amount allocated each year is not readily transparent to the secretariat or the research community. Table 1 list NHMRC funding provided to us by the Minister for Health Dr. Michael Wooldridge for the period 1992-1997. There appears to have been a base allocation of $100 million per year increasing by $2 million in each subsequent year and projected by that amount to the year 2001. In 1993, the federal government gave a further commitment for an additional $35 million per annum for a four year block (1993-1996). In 1994, the federal government gave yet another four year commitment of $25 million per annum.

Table 1

	92/93	93/94	94/95	95/96	96/97	97/98	98/99	99/2000	2000/01
Endowment base funding	$100	$102	$104	$106	$108	$110	$112	$114	$116
($AUD million)									
additional funding #1		$35	$35	$35	$35				

additional funding #2			$25	$25	$25	$25			
Funding projected funding	$100	$137	$164	$166	$168	$135	$112	$114	$116

The total level of funding in 1990 was $100 million, $137 million in 1993, approximately $165 million for the period 1994-1997. Based on these figures, the federal government in 1998 needs to recommit $35 million just to maintain status quo.

Clearly planning by the secretariat as to how projected funds might be allocated, has contributed to career instability, uncertainty for research programmes and generally diminishing morale. Collectively, Australia's international research competitiveness will erode, particularly given recent evidence that other developed nations are increasing government funded medical R&D.

It is not clear how the present model of funding has evolved, but it poses major difficulties for the NHMRC and no doubt the federal government.

The Australian Society for Medical Research has considered several options to improve the mechanism of funding so that more accurate, longer term forward projections can be made. A defined funding model will assist the research community in meeting Australia's longer term health objectives.

The NHMRC budget operates through an 'endowment' fund which is allocated funds annually from the federal government. The Australian Society for Medical Research strongly recommends that the endowment fund be increased on a 'once off' basis to a level which will provide a sufficient return on investments to the NHMRC. The fund could be established such that a proportion of the returns are returned to the endowment fund in order to keep pace with inflationary pressures. The federal government should provide the larger proportion of the endowment fund but in addition actively encourage input from private enterprise. Similar 'health heritage schemes' have been succesfully introduced abroad.

Table 2 provides a simple model as to how an endowment fund might operate for the period 2000-2005.

Table 2

	2000	2001	2002	2003	2004	2005
Endowment fund	3,000,000,000	3,148,500,000	3,304,350,750	3,467,916,112	3,639,577,960	3,819,737,069
15% return	450,000,000	472,275,000	495,652,613	520,187,417	545,936,694	572,960,560
5% return to endowment fund	148,500,000	155,850,750	163,565,362	171,661,848	180,159,109	189,076,985
Funds available	301,500,000	316,424,250	332,087,250	348,525,569	365,777,585	383,883,575

ASMR supports better government initiated mechanisms for Industry support of biomedical research

The R&D taxation concession reduction from 150% to 125% has weakened the capacity of Australian medical researchers to find partners to join in the commercial development of research discoveries. The current 125% concession is an inadequate incentive to industry and

commercial interests to invest in medical R&D compared to the previous 150% taxation concession that resulted in extensive investment. The original Syndicated R & D scheme was even more attractive to investors and served to take empirical discoveries through to commercialisation. Furthermore, the dropping of the percentage level and major changes in the legislation relating to the tax concession created uncertainty and loss of confidence in the investment sector which requires long term strategies to stabilise the long process of discovery through to commercialisation. A commonly held view is that a patented discovery may take 10 years before it is translated into commercial reality. Such ten-year cycles are accepted as standard in Japan and Germany.

There is general agreement that part of the guidelines governing the Syndicated R&D scheme were too flexible and allowed investments by parties without a genuine interest in medical research discoveries. However, the ASMR is of the view that the replacement scheme punished those syndicates that were satisfying the aims of the original legislation and soured the relationship between research stake-holders, venture capital and commercial investors. Nonetheless a number of R&D Syndicates in the medical research field are now in the process of commercialising discoveries.

It is abundantly clear that venture capitalists are rare and relatively cautious in Australia, and are now less inclined to invest due to the unpredictable nature of government policy. The ASMR strongly urges reconsideration of the concession level with an aim to reinstate the original 150% incentive with appropriate legislative safe guards to exclude parties without a genuine interest in developing Australian research discoveries. These proposed safe guards could be best formulated by parties currently involved in R&D and would include those who are receiving the 125% concession and the commercial organisations that operate within the Co-operative Research Centres. The CRCs represent the research operatives with links forged between commercial and academic interests and have developed a business ethos with strong goal oriented product discovery and commercialisation intent. We see the CRCs as bodies best equipped to bring medical research discoveries closer to commercial realisation. Parties to these CRCs may then progress to the next phase of commercialisation and would be the most appropriate and logical beneficiaries of the 150% taxation concession. Finally, the adopting of bipartisan support and the commitment to long term R&D policy is essential to reverse the negative atmosphere created by the 20th August 1996 tax changes. It may also be legislatively possible to relax some of the guidelines governing the START scheme that is seen to favour projects at the end phase of the R&D cycle.

Therefore the recent debate over the value of the CRC system warrants comment. The ASMR strongly supports the concept and current structure of the CRCs. We endorse the AAS President's (Sir Gustav Nossel) comments on this topic who points out that the CRCs are just in their infancy and should be seen as enormously successful in terms of changing the research culture and building trust and alliances between business, academia and government in Australia. Furthermore, any premature changes in their funding would send another destabilising message to Australian business that Government policy is unreliable and that there is no *long term commitment by Government to actually develop Australian medical research discoveries.

*Long term meaning 7-10 years commitment with periodic, inbuilt, realistic goal achievement targets

The levels of, and mechanisms for, infrastructure support of Medical Research in Universities and Hospitals requires urgent attention.

In order to be internationally competitive biomedical researchers require access to sophisticated, expensive and modern infrastructure

There is not a widely accepted definition of infrastructure for research [PFS Liehne, page 8]. However it does include things like:-

libraries,

computing facilities and networks,

equipment purchase and maintenance,

departmental and institutional overheads directly related to the support of research activities.

What is however clearly apparent is that the current mechanisms of competitive project grant funding do not have sufficient resources for the funding of equipment. This is highlighted by the inability of the NHMRC to fund equipment grants in 1998 and 1999. In 1996 of a total of $125.9 million allocated by MRC and PHRDC only $1.5 million was allocated to equipment.

Although there are several funding mechanisms available for the purchase and technical support of large pieces of equipment (>$100,000) [Mechanism C, Research Infrastructure Funding, Wellcome trust]. It is very difficult to fund equipment purchases valued in the $10,000 to $100,000 range. This encompasses the majority of standard laboratory equipment.

In order to promote links between basic research and the clinical applications of this research, it is essential to adequately fund the necessary infrastructure within the hospital system.

ASMR recommends that a widely applicable definition of infrastructure for biomedical research is identified. The appropriate formula for determining the required levels of funding for this infrastructure must be found. The sources [responsibility for] of funding must be identified.

Reference:- PFS Liehne " Research infrastructure and capital works for Health and Medical Research" Report to 122nd session of NHMRC council, November 1996

The retention of a highly skilled workforce is required to maintain excellence in Australia's health and medical research effort.

The ASMR recommends the establishment of a career path structure for medical research scientists that reflects remuneration commensurate with training and experience and clear mechanisms for advancement. This will ensure the retention of the highly skilled workforce that is required to maintain excellence in Australia's health and medical research effort.

In order to maintain a network of well-trained investigators, a research training and career development program is required for each of the training and developmental stages leading to an independent research career. Currently in the US, the NIH offers an extensive program of peer-reviewed fellowships to assist graduate students and postdoctoral scientists along the path to becoming an independent researcher. Such programs have a success rate of 40-50%. For example, in the 1997 fiscal year, the F32 award (individual postdoctoral NRSA fellowship) and the K08 award (mentored clinical scientist development award) had a success rate of 41% and 48% respectively (NIH Office of Extramural Research). In 1998, the NHMRC peer-reviewed fellowships for new appointments, had a success rate of 13% and the RD Wright Awards, had a success rate of 6%. These figures show that there are limited opportunities in Australia for our best new investigators to reach independence. In 1998 NHMRC Fellows had a 41% success rate in applying for promotions suggesting that the major problem is a lack of funds to support new investigators entering the current career path structure.

The benefits of having a well structured career path program cannot be underestimated. The 1996 survey of performance indicators of NARF fellows showed that scientists who have entered the present fellowship scheme have high levels of peer-reviewed research output and make extensive contributions to the national and international scientific communities (National Association of Research Fellows). However, many of the best Australian young scientists are now working abroad in a clear illustration of the perceived brain drain. In 1995 - 1996, the ASMR conducted a "Brain Drain" survey to determine why researchers leave Australia and then fail to return in the short to medium term. Many of the researchers (73%) that had gone overseas completed the most expensive part of their training in Australia, yet Australia does not benefit from the investment in their training. It was apparent that the main reasons that biomedical researchers leave Australia were to gain international experience and learn new techniques. However, once they had a position overseas many found that the research environment and conditions were much better than those in Australia. A clear example of this is that 73.4% of the survey respondents felt that their current salaries were better than or equivalent to Australian positions. Unfortunately 66% said that they will remain overseas for some time yet as they feel that they are unlikely to get equivalent job security and career prospects in Australia.

In order to ensure that young Australian medical researchers have input into the political process ASMR should be represented on PMSEIC.

We urge the Prime Minister to include a nominee of the Board of Directors of the Australian Society for Medical Research as a permanent member of Prime Minister's Science, Engineering and Innovation Council. In conjunction with its 37 affiliated professional societies and 9 associate foundation members, the ASMR represents more than 15,000 medical researchers throughout Australia, covering the broadest range of clinical, public health and basic biomedical research disciplines. As the peak medical research body in Australia the Society is in a prime position to provide informed advice on all aspects of biomedical research to the Council. The close relationship between the effectiveness of the health care system and the results of R&D raises specific issues which ASMR is uniquely placed to represent. ASMR is concerned that these issues may not be adequately represented on PMSEIC by a single broad-based organisation such as FASTS. We have a long track record in advocacy of health and medical research issues and a strong communication network with the medical research community. ASMR has made significant contributions in the area of policy-related fora and providing input through responses to Government.

The stated objectives of the Society are closely matched to the terms of reference of PMSEIC, ie:

·To support the advancement of medical research in Australia.

·To provide constructive comment to Government on research funding.

·To promote an understanding in the community of the benefits of medical research.

·To represent the medical research community.

·To promote and foster suitable career structures for medical researchers.

We believe that an ASMR nominee would bring to PMSEIC an effective voice representing the health and medical research community.

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