Dear Senators,

The attached Submission was originally written in July 2014 for the Senate Standing Committee on Economics inquiry into Australia's Innovation System. Much of the submission focuses on the need for a commercialization component for the proposed Medical Research Future Fund, otherwise any Australian inventions will immediately be taken off-shore and the benefits and potential profits and taxes will be lost to Australia.

The Biotech and Related Industries Leadership Group signed off on the document and for convenience I am sending the full submission.

Yours sincerely,

David Langsam
Convenor
Biotech and Related Industries Leadership Group

Senate Standing Committee on Economics

Australia's Innovation System

Dear Senators,

The Biotechnology and Related Industries Leadership Group was formed in 2009 to respond to the inquiry to establish a Commonwealth Commercialization Institute.

Today, we propose the core recommendations from our submission to that previous inquiry to create a self-funding and growing facility to commercialize the excellent research and development already coming from our universities and research institutions and set to increase rapidly with the establishment of the $20 billion Medical Research Future Fund.

Commercialisation Australia had about $80 million a year to fund innovation and as we set out in our earlier submission, to achieve results similar to world innovation competitors, about $1 billion a year would be required.

The Biotechnology and Related Industries Group welcomes the Federal Government's $20 billion Medical Research Future Fund (MRFF) which will be a strong encouragement to basic medical research.

But the gap remains that, with the axing of the Innovation Investment Fund program in the 2014 Budget and the previous Government's axing of the Commercial Ready Program, which in their own right were insufficient, there is no Australian mechanism for translating the medical discoveries to commercial success.

Despite low levels of support for commercialization, pharmaceutical and medicinal products have become Australia's largest manufactured export industry, surpassing the car industry in 2009. It is a growing sunrise industry creating jobs and income, that is not being eroded by low-cost and low salaried economies, unlike traditional manufacturing.

Importantly, biotechnology products are protected by patents and a strict regulatory environment, so low-cost countries can't manufacture products without infringing the patent, and if they do, they are unable to sell the product due to strict regulatory guidelines governing such sales in all major economies.

The MRFF provides the opportunity to capture the innovation benefit, providing health, job and economic outcomes, and stem the loss of Australian intellectual property to overseas corporations.

The Group believes that without a substantial commercialization mechanism any ground-breaking discoveries will continue to be picked up by off-shore pharmaceutical companies and Australia will lose the high-end value of marketing the drug, device and diagnostic discoveries.

Given that the fund is proposed to be of the significant order of $20 billion when fully funded in 2020, we propose that 25 percent of the fund be set aside for commercialization of the discoveries. Should Budget issues, including the potential absence of the Medicare co-payment, reduce the total size of the fund, we believe that the set-aside for commercialization should remain at 25 percent.

There has been some discussion about the level of funding required for commercialization, but when fully funded at $20 billion and providing 5% a year ($1 billion), the 25% provision equates to $250 million. With matching private sector investment the Commercialization arm would reach the levels proposed by the 2013 Simon McKeon-chaired Review of Health and Medical Research in Australia.

Through the Innovation Investment Fund (IIF), the Australian Government has successfully seeded new venture managers and obtained strong whole-of-fund returns such as GBS Biosciences Trust. Most recently the Medical Research Commercialization Fund and Uniseed-backed Fibrotech, supported with $3 million in Federal funds and returning $24 million to the Federal Treasury, was sold to Shire Plc for an upfront fee alone of $80.9 million in a total deal worth about $600 million.

Both the IIF program and the R&D Tax Incentive have shown themselves valuable ways to leverage private sector investment for Australian innovation. So too, should the MRFF.

This is why such commercialization funds are needed to support the excellent work of Australian universities and research institutes, rather than simply giving away all the benefit to foreign corporates.

There are many policy changes that would provide impetus to commercialization of Australia's biomedical research, including full funding of indirect costs of research, valuing commercialization and the application of peer-reviewed research, and the encouragement and removal of barriers to transfer researchers between the private and public sectors.

Although these factors are crucially important to an innovative and entrepreneurial medical research sector, we limit our comments to programs that directly relate to research commercialization, noting that funding is also required to bridge the gap between medical research and commercializable inventions, including but not limited to, intellectual property protections and proof-of-concept studies.

In the US, academic institutions receive between 60c and $1.10 for indirect costs - everything except researchers' salaries and money spent on experiments - for every $1 they receive from NIH for research, freeing the philanthropic funding for the institutions to be entrepreneurial and stimulating commercialization of basic research in the US compared with Australia. Australian medical research institutes receive between 15c and 25c in the dollar and hospitals receive little, so the gap between the real and funded indirect costs of research severely impacts our competitiveness.

To address the specific points set out by the Senate Economics References Committee we propose:

1. Medical Research Future Fund Commercialization

A single authority able to support the commercialization of both institutional and individual research supporting inventions from the proof-of-concept stage in the field, workshop or laboratory, to preparation for regulatory approval and the global market.

The BRIL Group is unanimous in supporting:
* a lean bureaucracy with a small secretariat and administration costs to be kept to a minimum;
* at arms length from Government;
* led by a successful start-up leader or a respected scientist, with appropriate managerial and commercial experience;
* supported by three advisory groups (drugs, devices and diagnostics);
* the pace of commercialization needs to be swift, so the decision-making process needs to be rapid and dexterous.

2. Market-Testing and Clinical Trials Funds

A key to successful innovation is the timely funding of cutting edge programs. Israel's Office of Chief Scientist provides its grants in some cases with just three or four months from application to payment.

The pace of commercialization is critical and the speed of granting is as important an issue as the size and availability of grants.

In 2009, the Group unanimously agreed that there would be no 'palliative care' for failing technologies and proposals for any grants would be closely scrutinized and objectively vetted. Only those proposals that are both innovative and have commercial potential will be considered for market testing and/or clinical trials.

The BRIL Group believes that well-vetted and timely grants of $2 million, $5 million or $10 million can make significant differences to innovation outcomes. Venture capital organizations use an approximate six-to-one leveraging scale for investments.

The Group would expect that small MRFF Commercialization grants would be the fulcrum to leverage sufficient funds for market-testing and early (phase I and phase II) clinical trials.

Larger amounts would be considered on merit for 'verge of success' pivotal and phase III trials, but these are rare as anything significant is generally licenced before this point.

The direct grants available from MRFF Commercialization are expected to be required for early stage testing and trials, post proof-of-concept and able to take the product or technology to pre-market development, and in some cases to final registration.

Any grant made available would carry a trailing fee from successful commercial development back to MRFF Commercialization sufficient to provide further funding for MRFF Commercialization. As commercialized innovation demonstrates success, MRFF Commercialization will become self-funding and able to encourage further success.

The BRIL Group comprises:

Chancellor of Monash University Dr Alan Finkel;
WEHI director Prof Doug Hilton;
AusBiotech CEO Dr Anna Lavelle;
Bio-Melbourne Network CEO Dr Krystal Evans;
Brandon Capital managing Partner Dr Chris Nave;
GBS Venture Partners' Dr Joshua Funder;

and has taken advice from across the constituent groups of the sector including a range of biotechnology chief executive officers and other interested parties.

The BRIL Group has been convened and chaired by Biotech Daily editor David Langsam

July 30, 2014