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June 6th, 2016

Medical Research Future Fund Secretariat
MRFF@health.gov.au

Dear Sir / Madam,

Medical Research Future Fund: Consultation on Strategy and Priorities

Thank you for the opportunity to provide input to the development of the strategy and priorities of the Medical Research Future Fund (MRFF).

As an Australian-based, global biopharmaceutical company R&D is central to CSL's business. We have a long-term and abiding commitment to support world-class medical research and development in Australia and we are one of the nation's largest private-sector investors in research and development.

CSL made a supportive and substantive submission to the MRFF Inquiry in June 2015. Our recommendations remain unchanged, and they are summarised here as specific suggestions for both the overall strategy and shorter term priorities.

As an over-arching comment, it is CSL's belief that the MRFF should be cognisant of not simply replacing or increasing existing research funding streams (such as the NHMRC, ARC, commercial investment) but should instead be looking to fund existing gaps and big initiatives that in a longer term timeframe address significant emerging material issues for the Australian and global population.

STRATEGY RECOMMENDATION:
'Maximise the Social and Economic Benefits of Australian Medical Research'

Australia has world class early research and biotechnology hubs which are emerging as globally significant.

CSL believes Australia's medical research community is a rich source of potential new discoveries to address the world's unmet medical needs. However, we do not believe that Australia reaps the maximum social and economic value from its research base because too often Australian intellectual property is either not translated from an idea into a product or, it goes offshore for development at a very early stage.

Intellectual property at the *pre-translational* stage is far less valuable (economically and socially) than that same intellectual property at the *post-translational* stage. Thus when Australia underwrites early research but does not reap the post-translational rewards it could be argued that Australia is under-writing research for the rest of the world to reap the development and commercialisation benefits.

CSL

An overarching strategy of maximising the social and economic benefits of medical research could lead into several different priority areas but CSL recommends that at least one of these should have as its objective, keeping Australian intellectual property onshore for as long as possible by improving the environment for translational research in Australia. Targetting translational research will increase the likelihood that the large investment government makes in tertiary education and basic research would actually translate into projects that can be taken through to patients/market (or at least closer to patients) by Australian firms.

PRIORITY RECOMMENDATION:
'Improving the Environment for Translational Research in Australia'

1. Direct Financial Support to Help Cross the 'Valley of Death'

Translational research is the development of a concept from early research (fundamental science) to its practical application. It involves identifying development candidates and funding their transition from the necessary animal experiement to proof-of-principle in human clinical trials. Basically, it sits at the cusp between academic and commercial medical research and represents the key step to recruiting commercial investment. It is typically more complex and costly than the basic research upon which it relies, it is characterised by large knowledge spillovers (where non-funders benefit from others R&D activities/spend) and there is still significant scientific risk.

This combination makes translational research a high-risk / high reward investment and it is demonstrably under-resourced in Australia. The impact of this is that the overall productivity of the medical research sector is impeded with many potentially valuable projects failing to attract the level of resource required to progress further (either at all, or within Australia). For example, at CSL we look at over 100 new product opportunities each year, of these, we choose 5-10% for full evaluation and then fewer still for licensing. The MRFF could offer vital support by providing targetted funds for translational research. This would likely help recruit substantial, complementary research funding from the commercial sector, increase the value of intellectual property before it goes offshore, and increase the pool of sound research projects that firms like CSL can take forward to the later stages of development (thus increasing revenue and royalty flows to Australia).

CSL recommends that once the Medical Research Future Fund is fully funded and established, at least 20% of its annual $1 billion disbursements should be allocated to translational research. This should be in addition to the funding mechanism offered by the new Biomedical Translation Fund and could be directed to academic researchers on their own or, partnered with a credible industry partner like CSL or other start-up and small biotech companies.

We recommend the MRFF should support a wide range of possible disbursement avenues, through innovative mechanisms including to corporations. In supporting commercial organisations, it would be important to ensure that MRFF funds do not simply replace the

R&D that they should be undertaking anyway or funding research which would be classified as late-stage commercialsiation.

2. Improve Capability for Conducting Phase 2 Clinical Trials in Australia

With additional funding flowing from the MRFF into medical research generally and specifically targetting support for translational research it would be a significant value-add to enable this money to be spent and this translational science to be done in Australia.

In particular, the conduct of Phase 2a and Phase 2b trials, where a likely therapy (drug) is tested on patients for efficacy and safety.

Clinical trials provide significant resource injections into the health system, generate significant knowledge spillovers and provide patients with access to the newest medications.

Regrettably Australia is slipping in its relative attractiveness as a destination for Phase 2 trials as a result of slow start-ups times (multi-site bureaucratic complexity) plus, the dearth of highly trained specialist clinicians able and/or willing to help design and conduct sophisticated trials for novel and complex medicines.

Support from the MRFF could help to address both of these issues. This would help keep intellectual property onshore as well as maximise resource injections into the health system from the clinical trials.

To help illustrate the above strategy and priority recommendations I have attached a graphic illustration of the biopharmaceutical value chain. This shows where existing government policies and programs sit as well as proposed new programs and CSL's recommended scope for the MRFF.

CSL would be happy to provide further information or participate in public and/or private consultation as appropriate. To arrange please contact Ms Anna Schulze, CSL Public Policy Director, O3 9389 3428 / 0438 084 045 anna.schulze@csl.com.au.

Sincerely,

Dr Andrew Cuthbertson
Chief Scientific Officer and R&D Director

Attachment: Figure 1

FIGURE 1: The value chain for intellectual property emanating from medical research begins with early research and ends with commercialisation. The further along the value chain IP progresses the greater the social and economic value. If the MRFF provided targetted support for translational research it would help retain IP onshore in Australia and therefore maximise the returns to Australia from its significant and growing investments in early research.