# CSL Submission to the Senate Community Affairs Legislation Committee Inquiry into the Medical Research Future Fund

10 July 2015

## Summary of comments and recommendations

In May 2015, the Commonwealth Government proposed to establish the Medical Research Future Fund, designed to provide a significant and stable supply of funding for medical research in Australia. The proposed legislation was subsequently referred to the Senate Community Affairs Legislative Committee which is due to report on the 10th August 2015.

CSL develops, manufactures, and markets biopharmaceutical products to treat and prevent serious human medical conditions. CSL is Australia's largest biotechnology company and a global leader in plasma-derived therapies and protein-based medicines. The CSL Group, headquartered in Melbourne Australia, operates globally while maintaining a substantial research and development presence in Melbourne. CSL has a successful track record in the development of innovative medicines for global markets.

CSL is an important component of Australia's health research and development sector. We are one of the few Australian-based companies that has the skills and resources to develop Australian medical research into products for sale into global markets. As such, we have a strong interest in the size and quality of the Australian medical research base. CSL welcomes the opportunity to participate in the Senate's review.

In summary, CSL is a wholehearted supporter of the MRFF initiative which represents a visionary measure that could substantially enhance the medical research sector in Australia. It will increase the value of the Australian medical and pharmaceutical sectors to the Australian economy, and enhance the health and wellbeing of the community.

This submission provides some observations on how the fund might best meet this bold objective, and seeks to place the fund within the overall context of the medical research space.

## The MRFF is a welcome boost to medical research funding in Australia

The contributions of the broader health and medicines sectors to Australia have been and are substantial. Their contribution is intimately linked to health and medical research in Australia. Enhanced investment in medical research will help ensure a continuing flow of internationally competitive research discoveries capable of being turned into products, and a critical mass of highly trained and skilled medical scientists that can undertake the research and turn these discoveries into therapies. This will deliver health and wellbeing benefits as well as economic benefits to the community.

The MRFF has the potential to significantly enhance the sector by close to doubling government funding over the next decade. If the MRFF progresses as the Commonwealth Government has suggested, it will increase the overall level of government support for medical research from 0.06% of GDP to closer to 0.1%, representing a welcome increase in funding for a sector of the economy that, despite its relatively small size, is very

successful. The MRFF will raise Australia's overall expenditure on medical research to around the average level of our OECD peers, close to the level of expenditure in the UK in terms of percentage of GDP.

## The MRFF should focus on translational research

CSL believes that medical research is disproportionately productive in economic, health and wellbeing terms. Australia should therefore aspire to being well above the OECD average. There are, however, many calls on the public purse. This aspiration can best be fulfilled if a significant portion of the MRFF is directed at translational research, which would in turn recruit substantial additional and complementary research funding from the commercial sector.

Translational research involves identifying development candidates developed during the discovery phase and funding their transition from the necessary animal experiment to proof-of-principle in human clinical trials. It sits at the cusp between academic and commercial medical research and represents the key step to recruiting commercial investment. CSL believes that it is under-resourced in Australia and that this impedes the overall productivity of the medical research sector.

Accordingly, CSL recommends that the MRFF should, in its steady state, allocate at least 20% of its available disbursements to translational research.

## The proposed MRFF legislation

In terms of the specifics of the MRFF, CSL is broadly supportive of the amended proposed legislation but has some observations that should be considered. Specifically:

- the MRFF should place considerable importance on funding projects that foster additional private sector investment in medical research;

- the MRFF supports a wide range of possible disbursement avenues, including to corporations. In supporting corporations, it is important to ensure that MRFF funds do not simply replace the R&D that they should anyway undertake;

- the MRFF should be cautious in funding late-stage commercialisation of medical research in Australia, which is predominantly a private-sector activity. Otherwise, there is a high risk that the funding will see no more success than previous commercialisation measures, and will in any case substitute for investment that businesses themselves should undertake. MRFF funds should be directed more at resolving scientific uncertainty than commercial risk;

- the MRFF must not evolve into a supplementary source of funds that, in practice, makes up for shortfalls in government support for medical research that should be

non-discretionary even when budgets are tight. The benefits that CSL perceives from the MRFF are dependent upon governments' continued commitment to funding existing avenues of support for medical research;

- it is important that the MRFF and NHMRC have separate but complementary roles in medical research, and that they do not as a practical matter coalesce into a single fund. The governance arrangements in respect of the relationship between the MRFF and NHMRC provide some safeguard that this will be not be the case; and

- there is nevertheless a risk that disbursement of MRFF funds through existing funding bodies such as the NHMRC and COAG will effectively subjugate MRFF priorities to their own; and

- to mitigate these risks, the Advisory Board should be required to prepare a report, attached to the Health Minister's report to Parliament, on compliance of disbursements with the MRFF's strategy and priorities.

## The MRFF should be seen in the context of a broader policy

CSL believes that the MRFF should be seen as one component of a broader policy towards medical research and innovation, each of which is necessary to maximise the value of medical research to the community. In CSL's view, this broader policy should have five key strands:

- continued high levels of state and Commonwealth government support for education, basic science and early stage research, in which the private sector will not typically invest, which generates

    - substantial knowledge spillovers;

    - the necessary ongoing supply of skilled scientists; and

    - sufficient basic research to underpin later and more targeted research efforts.

- continuation of the role of the NHMRC in funding discovery, translation research and clinical research that is unlikely to prove attractive to the private sector;

- addressing the dearth of translational research in Australia by means of continued funding from the NHMRC but, particularly, a targeted funding priority by the MRFF in order to:

    - increase the pool of sound research projects that Australian firms like CSL can take forward, addressing what is otherwise a very thin market; and

- encouraging greater expenditure on medical research by businesses in the clinical research phases, raising the overall level of expenditure on medical research in the community;

- continued support for business R&D through tax offsets at current rather than proposed levels, because economically valuable knowledge spillovers arise from clinical development (and business R&D outside of the medical research sector); and

- urgent action to address Australia's lack of competiveness as a location for the manufacture of innovative products that derive from its research base, so that Australia can reap the full benefits of its medical research. CSL believes that this is best addressed by introducing an advanced manufacturing tax which offers competitive rates of corporate tax on advanced manufacturing that takes place in Australia and which derives a large proportion of its value from Australian intellectual property. CSL has set out this recommendation in detail in its submission to the Government's Better Tax Review.

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# 1. Introduction

CSL develops, manufactures, and markets biopharmaceutical products to treat and prevent serious human medical conditions. CSL is Australia's largest biotechnology company and a global leader in plasma-derived and protein-based therapies. The CSL Group, headquartered in Melbourne Australia, operates globally while maintaining a substantial research and development ('R&D') presence in Melbourne.

CSL has a successful track record in the development of innovative medicines for global markets. Our Australian operations have and continue to play a pivotal role in that development process. Fulfilling this role involves substantial expenditure on R&D to develop new medicines, with the large risks that this entails. It also requires substantial R&D to maintain, develop and improve the existing portfolio of therapeutic products for global markets.

CSL is an important component of and significant player in Australia's health research and development sector. We are one of the few Australian-based companies that has the skills and resources to develop Australian pharmaceutical and health research into products for sale into global markets. As such, we have a strong interest in the size and quality of the Australian health research base. CSL welcomes the Medical Research Future Fund ('MRFF') initiative as a means of enhancing that base.

## 1.1. The Medical Research Future Fund

On 27 May 2015, the Commonwealth Government introduced the *Medical Research Future Fund Bill 2015* into the House of Representatives. This proposed to establish the MRFF, designed to provide a significant and stable supply of funding for medical research in Australia.

Initially, the fund was to be established through a $1bn transfer from the uncommitted balance of the Health and Hospitals Fund. This would allow a planned $10m distribution in 2015/16 and estimated disbursements of $400m over the next four years. The government has indicated that the MRFF could reach its target capital level of $20bn by the middle of 2020[1] which, if achieved, could deliver disbursements of $1 billion per year in 2022-23.[2]

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[1] Commonwealth, *Parliamentary Debates*, House of Representatives, 27 May 2015, (Joe Hockey – Treasurer) at http://parlinfo.aph.gov.au/parlInfo/genpdf/chamber/hansardr/2f554bb1-776c-4c6f-b693-214bf49ecaa3/0005/hansard_frag.pdf;fileType=application%2Fpdf

[2] Research Australia (2014) M*edical Research Future Fund*, accessed 3 July 2015 at http://www.researchaustralia.org/mrff/mrff

Although the fund was originally planned to commence 1 August 2015, the Bill was subsequently referred to the Senate Community Affairs Legislative Committee which is due to report on 10 August 2015.[3]

CSL is a wholehearted supporter of the MRFF initiative, which represents a visionary measure that could substantially enhance the medical research sector in Australia. It will increase the value of the Australian medical and pharmaceutical sectors to the Australian economy, and enhance the health and wellbeing of the community. We welcome the opportunity to participate in the Senate's review.

## 1.2. Overview of support for medical research

CSL believe that, if the MRFF is properly targeted at those aspects of medical research that would benefit most from additional government funding, then it will significantly improve the health and wellbeing of Australians.[4]

The research pathway, from early basic science to commercial products and services used in day to day health care, comprises a number of linked but otherwise discreet stages, each of which has its own unique characteristics. At the earliest stage, broad based funding of education and basic science is most important. At the later stages, as innovative products enter the market, ensuring Australia is a competitive location from which to manufacture is most important.

The MRFF is a critical initiative that will underpin valuable medical and health research, but it is important to recognise that no single program is capable of driving Australian innovation in this area. The MRFF should therefore be seen as one part of a broader strategy, made up of a number of different government policy measures which collectively maximise the value of Australia's medical research and development base, for the benefit of all Australians.

## 1.3. Structure of the submission

In order to assist the Committee, CSL has reviewed the proposed legislation for the MRFF set against this policy objective, as follows:

- section 2 provides an overview of CSL and the importance of R&D to the organisation, before reviewing the policy considerations that derive from CSL's experience of undertaking R&D and commercial manufacture in Australia;

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[3] Parliament of Australia (2015) *Medical Research Future Fund Bill 2015,* accessed 3 July 2015 at http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r5397

[4] Supplementary Explanatory Memorandum, Medical Research Future Fund Bill 2015 (Cth)

- section 3 describes the overall medical research pathway, from discovery to treatment, which is costly and uniquely risky, in order to assess the role that governments should play in medical research;

- in that context, section 4 sets out what we consider should be the priorities for the MRFF and outlines a number of issues raised by the draft legislation;

- section 5 sets out the MRFF in the broader context of government policy towards the medical research and development sector; and

- section 6 presents some concluding remarks.

The Committee should also be aware that CSL has previously made a number of submissions that address government support for medical research, development and commercialisation in Australia upon which this submission draws.[5]

[5] See: CSL (December 2006) *Submission to the Productivity Commission Research Study into Public Support for Science and Innovation in Australia;* CSL (April 2008) *Submission to the Review of the National Innovation System;* CSL (March 2012) *Submission to the McKeon Strategic Review of Health and Medical Research;* CSL (July 2014) *CSL Submission to the Senate Reference Committee Inquiry into Australia's Innovation System;* CSL (December 2014) *Boosting the commercial returns from research, a CSL submission to the Department of Education and the Department of Industry;* and CSL (July 2015) *CSL submission to the Treasury in response to the "Re:think" tax discussion paper*.

# 2. Innovation at CSL

CSL Limited is Australia's largest biotechnology company, with a market capitalisation of around A$42bn, and over 13,000 employees globally. CSL develops, manufactures, and markets biopharmaceutical products to treat and prevent serious human medical conditions. The CSL Group, headquartered in Melbourne Australia, operates globally while maintaining a substantial R&D presence in Parkville, Melbourne.

CSL was established in 1916 to provide the Australian community with human vaccines and sera that could not be guaranteed in the event of war. CSL continues with that proud tradition, supplying products of national interest such as seasonal and pandemic influenza vaccines, plasma products made from Australian plasma, antivenins and other vaccines.

CSL was incorporated in 1991 and sold by the Commonwealth Government in 1994. CSL's evolution into a global speciality biopharmaceutical company involved the acquisition of the Swiss Red Cross fractionator ZLB (2000), US blood collection centres from NABI (2001) and Aventis Behring (2004). Since then, CSL has consolidated its position as a leader in the global market for plasma-derived medicines and as an innovator in these products, vaccines, and recombinant proteins. CSL is also a global leader in influenza vaccines, a position that it has consolidated with its impending acquisition of Novartis' global influenza vaccine business (which will also extend CSL's manufacturing base into the UK).

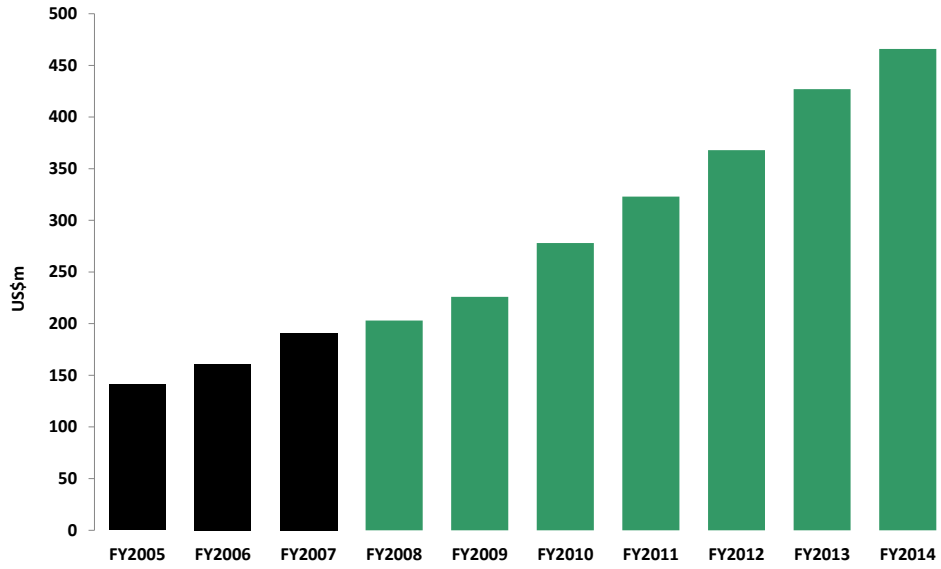
In 2013/14, CSL's Australian operations comprised total sales of A$935 million, including A$185 million in export sales; A$252 million paid in wages and salaries to Australian workers; A$758 million in goods and services bought from other Australian and overseas businesses; and 1,816 full-time equivalent employees. Globally, CSL had total sales revenue if US$5,335m and a total R&D expenditure of US$466m. CSL's largest centre for R&D is Australia. Of the 1,852 Australian staff, approximately 400 are involved in R&D functions across the Melbourne sites, of which in excess of 80% are graduate scientists. This does not include graduate scientists and engineers working in other Australian CSL divisions.

## 2.1. CSL's R&D activities and expenditure

CSL has continued to increase its R&D expenditure (see Figure 1), which remains a cornerstone of CSL's growth plans. CSL has a successful R&D track record. For example, CSL successfully advanced[6] research relating to a potential HPV vaccine to the stage where it was ready for development into the global product Gardasil® by Merck, as a result of which CSL earned royalties flowing back into Australia of US$117m in 2013/14 alone.

[6] This was done through its collaboration with Professor Ian Fraser at the University of Queensland.

**Figure 1. CSL's global R&D expenditure**




FY2005-FY2007 in AU$m. FY2008-FY2013 in US$m.

CSL now has sufficient resources, skills and global reach to take innovative products from the discovery phase through to the market. That process is best exemplified by CSL's portfolio of recombinant blood clotting factors (referred to by their R&D project codes - CSL627, CSL654, CSL689), three of CSL's innovative products that are in the later stages of their clinical development (see Figure 2).

CSL expects to invest as much as $15bn into R&D and new manufacturing facilities across its global network over the next decade.

CSL has consistently ranked in the top two or three Australian companies in terms of its global R&D expenditure. According to PwC's 2013 Global Innovation 1000 Study,[7] CSL ranked second to Telstra in its global R&D expenditure, and was one of only six firms ranked within the global top 1000. In the 2013 EU Industrial R&D Investment Scorecard[8] CSL ranked second to Telstra amongst the Australian non-financial firms;[9] on these measures, CSL ranked 329th in the global list.

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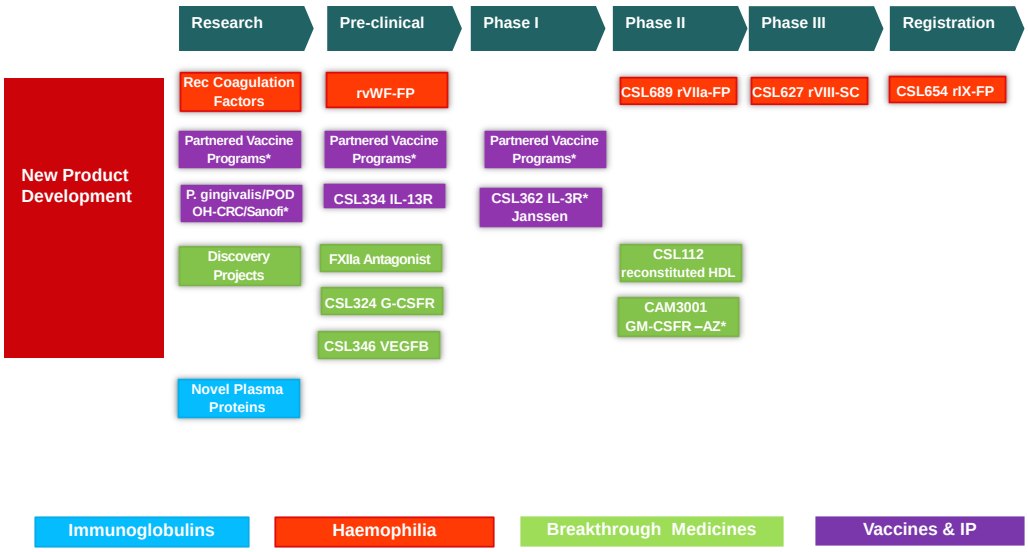
[7] PWC (2013) *The Global Innovation 1000: Navigating the Digital Future* http://www.strategyand.pwc.com/global/home/what-we-think/global-innovation-1000 (last viewed 16 July 2014).

[8] European Union (2013) *2013 EU Industrial R&D Investment Scoreboard* http://iri.jrc.ec.europa.eu/scoreboard13.html (last viewed 16 July 2014).

[9] The *2013 EU Industrial R&D Investment Scoreboard* (*ibid*) characterisation of Telstra and CSL expenditure on R&D is consistent with reports by other commentators. However, it places three of Australia's largest banks above CSL, indicating that it has adopted broader definition of R&D expenditure.

**Figure 2. CSL global new product pipeline (April 2015)**




## 2.2. Government support for R&D received by CSL

CSL currently benefits from the Australian government R&D tax incentive scheme. The benefit is a 40% tax offset for all eligible Australian R&D expenditure. Of the US$466m of R&D expenditure in 2013/14, approximately A$96.9m million was eligible for the tax concession.[10] This generated an additional A$9.69m tax benefit. At first glance, the Australian Government's support for CSL's R&D contributed about 2.0% of CSL's total R&D expenditure in 2013/14.

CSL also benefits from direct government funding in the form of co-investment grants. In the 2013 and 2014 financial years, CSL received valuable State and Commonwealth grants (totalling A$17m) for the construction of facilities at Broadmeadows, including the Biotechnology Manufacturing Facility which can be used for the later stage clinical development and early stage commercialisation of recombinant-protein based medicines. CSL also benefits indirectly from government activity. For example, 80% of CSL's R&D staff are skilled scientists that emerge from Australia's education and research institutions, which are predominantly funded by State and Commonwealth governments.

CSL maintains its centre of excellence in early stage R&D in Australia in large part because of the high quality of IP that Australian institutions generate. A number of patented antibodies, the P gingivalis candidate vaccine, and several discovery projects in CSL's R&D portfolio all emerged from Australia. CSL does not just benefit by acquiring patentable targets and molecules, but also from technologies independent of these such as new experimental processes and paradigms.

[10] Not all Australian R&D expenditure qualifies for the tax concession.

CSL believes (for the reasons set out in section 4 below) that government support across the breadth of the medical research and development delivers substantial benefits to the Australian economy considerably in excess of the amount of funding. In so doing it enhances the health and wellbeing of the Australian community. The MRFF, we believe, can further enhance these benefits.

## 2.3. Commercialisation of Australian research

Although the rationale for the MRFF is to increase funding for medical research, the full benefits of additional research that the fund engenders will not be achieved unless that research results in new medicines and treatments. While Australian research that is commercialised offshore delivers economic returns to Australia, in CSL's view, maximising the value of Australia's research base for the benefit of all Australians requires that Australia becomes an attractive location from which to commercialise.

CSL now has sufficient resources, skills and global reach to take innovative products from the discovery phase through to the market. Development to proof of concept and subsequent preclinical development of these products took place in various locations around the world. The clinical trials for these products are being conducted at a number of global sites. CSL's specially constructed Biotechnology Manufacturing Facility ('BMF') at Broadmeadows[11] will support early commercialisation of at least one of these products. However, full commercialisation requires a large scale dedicated facility.

CSL recently committed to such a facility, undertaking an extensive analysis of alternative sites to find a jurisdiction likely to maximise the value of the new products to CSL's shareholder. The candidate countries included *inter alia* Australia, Ireland, Singapore and Switzerland. The selection criteria were broad encompassing factors such as availability of suitably skilled staff, labour costs and flexibility, geographical proximity to important target markets, corporate tax rates, and extent of government assistance.[12] The result of the review was that Switzerland was chosen as the site for development.

Australia was not a competitive location from which to commercialise these products for a number of reasons. However, since the IP for the new recombinant coagulation products during its early development was held in and funded by CSL from Australia, the new manufacturing facility has purchased the necessary IP from Australia on an arms-length basis through a once-off payment to be followed by a series of technical and commercial milestone payments and an appropriate royalty rate on commercial sales.

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[11] For which CSL received both Victorian State and Commonwealth support.

[12] Not simply financial assistance, although this was a consideration, but non-financial factors such as permitting etc.

Although these payments constitute taxable revenue in Australia, in the same way as some third party arrangements are structured such as the royalties paid by Merck to CSL on its Gardasil® sales, Australia nevertheless misses out on the multiplier, follow-on, tax and skilled employment benefits that commercial manufacture from Australia would deliver.[13]

## 2.4. Implications of CSL's experience

CSL believes that there are important policy implications from CSL's own experience of researching and developing new medicines from Australia. These policy imperatives involve government funding or related measures to overcome impediments to successful creation of new medicines from Australia. The MRFF is a critical and welcome policy measure.

CSL believes that government intervention is important in the medical research sector. There is compelling evidence that without it Australia will not reap the full benefits. Specifically:

1. Government support for education, basic science and early stage research remains fundamental. It provides the foundations for Australia's medical research, not least in ensuring an ongoing supply of skilled scientists, and sufficient basic research to underpin later and more targeted research efforts.

2. Australia does not undertake enough translational research, to convert basic research into candidate medicines suitable for clinical research and further development. This holds back the potential for Australia's health and medical research investment to be fully maximised. Because of the complexity and expense of translational activities through to proof-of-concept, many potentially valuable projects fail to attract the level of resource required to progress further, which limits the supply of sound research projects that Australian firms like CSL can take forward. The MRFF could be particularly valuable in this area.

3. The development phase of R&D, which in the pharmaceutical sector primarily involves clinical trials in man, best lies in the commercial province. Nevertheless, it generates knowledge spillovers that the firms undertaking the development cannot capture. As a result of these spillovers, private companies alone tend to invest less than is economically desirable. Government support can offset this effect, encouraging Australian businesses not to underinvest in R&D.

4. To reap the full benefits, Australia must urgently address its lack of competiveness as a location for the manufacture of innovative products that derive from its research base.

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[13] For a more detailed analysis of this issue see CSL (July 2015) *CSL submission to the Treasury in response to the "Re:think" tax discussion paper*.

> If Australia is to knit itself into global supply chains, it needs to offer tax rates that make it an attractive location for footloose investment in advanced manufacturing.

These are discussed in more detail in section 4. In CSL's view, the MRFF will be of most value (in terms of the economic, health and wellbeing benefits it can generate) if it is used to address the second of these, translational research.

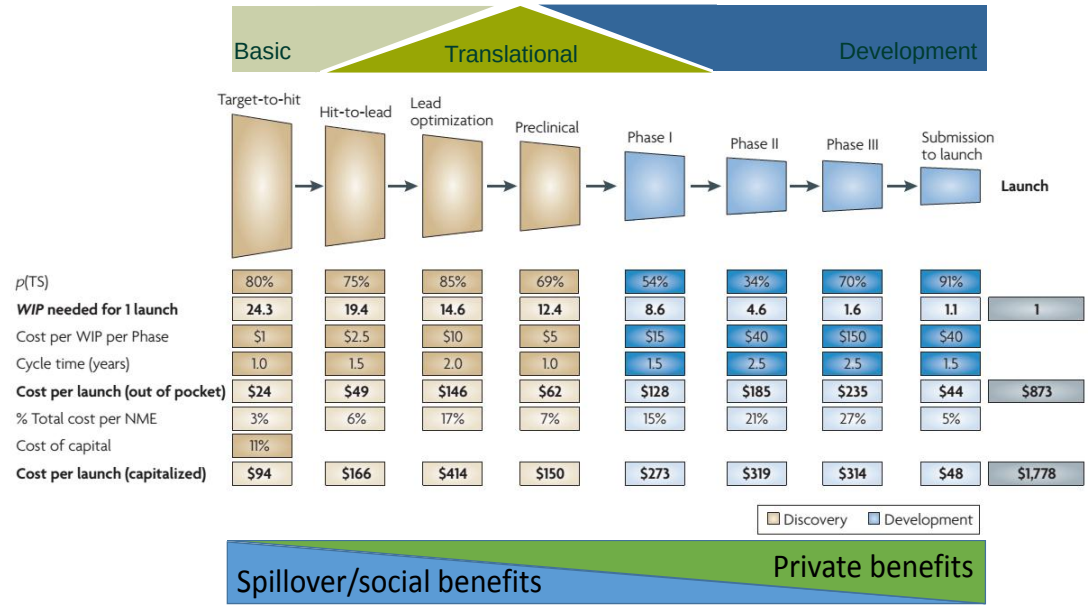
# 3. The costs and risks of medical research

To fully understand role that the MRFF should perform, and why all four of the foregoing policy measures are important, it is helpful to set out the research and development pathway in medical research from CSL's perspective as a global pharmaceutical firm with an Australian base.

## 3.1. The development process for new products

Developing new pharmaceutical products targeted at unmet medical need is expensive and risky. Whilst it differs significantly depending on the type of therapy being developed, Paul *et al* estimate a development cost for a new drug of approximately US$1.8bn[14] (see Figure 3) and cite previous estimates by other authors ranging between US$800m and US$1.7bn.

**Figure 3. Pharmaceutical development pathway and costs**




*Source:* Paul SM et al (March 2010) *amended by CSL*. In the stylised typical pathway, 'target to hit' represents the first stage of discovery after the identification and validation of a target for drug action, both of which are the province of basic research. It involves the identification of compounds that are active against the target. These are then refined to a lead compound ('hit to lead') which is then optimised in anticipation of preclinical development. WIP refers to 'works in progress.

Typical failure rates for a project might be 46% in phase 1, 66% in phase 2, 30% in phase 3 and 9% at the stage of submission to launch; the overall clinical development success rate is around 12%. Total development costs per compound typically increase by between 2 and 3 fold across each of the clinical development stages. In capitalised terms, phase 3 costs are

[14] Paul SM, Mytelka DS, Dunwiddie CT, Persinger CC, Munos BH, Lindborg SR, Schacht AL, 'How to improve R&D productivity: the pharmaceutical industry's grand challenge', *Nature Reviews Drug Discovery* 9, 203-14 (March 2010).

on average around US$200m per compound while phase 1 costs are around US$32m. The costs of resolving technical risk[15] are therefore substantial and occur later in the development.

## 3.2. The private and social rewards from innovation

The development of new medicines from Australian research is likely to deliver health, welfare and economic benefits to the community. The economic benefits can include knowledge generated by the research that is valuable in other research areas; more, and more valuable, research; high skill, high wage jobs that are secure; and more value adding industries located in Australia. The commercial benefits can include royalties on IP or the proceeds of sale of IP, if Australian IP is developed and commercialised elsewhere, or they can extend further into the value chain if Australian IP can be developed and commercialised (including manufacture) in Australia for global markets.

Some of these economic benefits, such as royalties, can be captured by investors. Some, such as knowledge spillovers, cannot. As a result, the social gains from medical research are greater than the gains that investors make. This is particularly so in earlier phases where knowledge spillovers are large, even if the projects fail.[16] This is illustrated stylistically in Figure 3).

The practical consequence of this, from a policy perspective, is that private firms tend to under-invest (relatively to the socially desirable level) in R&D, particularly so in discovery and translational phases. As a result, government support for R&D is justified when it gives rise to these knowledge spillovers, even if that R&D is conducted by businesses.

[15] Technical risk is the risk that the product will fail to work as intended. This may be for a variety of reasons including low efficacy or unacceptable adverse events. This is distinct from commercial risk whereby a product works as intended but fails to make an acceptable return. This could arise, for example, if development costs are too great, if market prices are forced down through regulation or monopsony purchasers, or through competition that diminishes price and/or market share.

[16] Oxera Consulting. (2005). Innovation market failures and state aid: developing criteria. Report prepared for Directorate-General for Enterprise and Industry, European Commission. http://www.pedz.uni-mannheim.de/daten/edz-h/gdb/06/innovation_market_failures_and_state_aid.pdf (last accessed 14 July 2014).

# 4. The proposed MRFF

The contributions of the health and medicines sectors to Australia have been and are substantial. They are intimately linked to our health and medical research. Enhanced investment in medical research will, in CSL's view, further the health and medicines sectors in Australia. For example, it will help ensure a continuing flow of internationally competitive research discoveries capable of being turned into new medicines, and will sustain a critical mass of highly trained and skilled medical scientists that can undertake the research and turn these discoveries into therapies. These both deliver health, wellbeing and economics benefits to the community.

Accordingly, CSL is an enthusiastic supporter of the MRFF initiative, a visionary measure that could substantially enhance the medical research sector in Australia. CSL has some observations on how the fund might best meet its bold objective.

## 4.1. The size of the fund

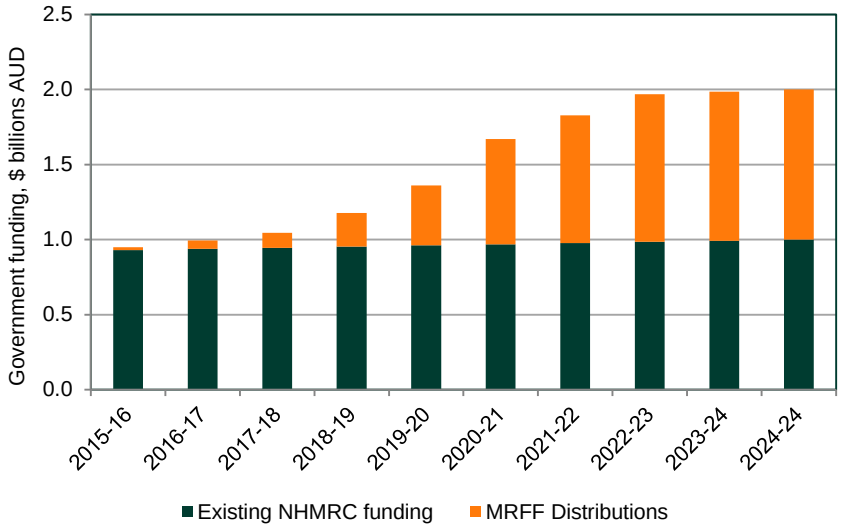
The government has indicated that the MRFF could reach its target capital level of $20bn by the middle of 2020.[17] Under the original proposal, distributions from the fund would grow from $10m to $1b by 2024. Commonwealth medical research funding through the NHMRC was projected to grow from approximately $930m per year in 2015 to $1 billion per year in 2024 (i.e. constant in real terms). The MRFF would therefore effectively double planned government funding of medical research by 2022 (see Figure 4).[18]

To place this in context, NHMRC funding represents around 0.06% of GDP. The OECD reports that Australia spends approximately 0.075% of GDP on medical research indicating that the NHMRC represents a substantial share of that total. An increase in total disbursements from both the NHMRC and the MRFF to $2bn (in nominal terms) by 2025 will raise government expenditure on medical research to 0.1% of GDP.

[17] Commonwealth, *Parliamentary Debates*, House of Representatives, 27 May 2015, (Joe Hockey – Treasurer) at http://parlinfo.aph.gov.au/parlInfo/genpdf/chamber/hansardr/2f554bb1-776c-4c6f-b693-214bf49ecaa3/0005/hansard_frag.pdf;fileType=application%2Fpdf

[18] Commonwealth, Department of Treasury (2014) *Budget Overview: Medical Research Future Fund*, accessed 3 July 2014 at http://www.budget.gov.au/2014-15/content/overview/html/overview_12.htm

**Figure 4. Projected growth in medical research funding under the MRFF**




**Note:** NHRMC funding grown at 2.5% per annum from 2018-19 onwards for indicative purposes. Spending subject to change.
**Source:** Budget 2014-15, http://www.budget.gov.au/2014-15/content/overview/html/overview_12.htm

The MRFF will raise Australia's overall expenditure on medical research to around the average level of our OECD peers, close to the level of expenditure in the UK. In contrast, our current level of expenditure is 36% below the OECD average[19] (see Figure 5), which is too low in CSL's view given the performance of Australia's medical research sector. In comparison, Australia already sits somewhere close to the average in respect of the proportion of its GDP spent on all R&D, at 2.21%.[20]

CSL believes that medical research is disproportionately productive in economic, health and wellbeing terms. Australia should therefore aspire to being well above the OECD average in terms of expenditure on medical research. The Commonwealth Government's proposed MRFF scheme demonstrates a recognition of the benefits of greater government support, and an ambition to move Australia up the OECD rankings.

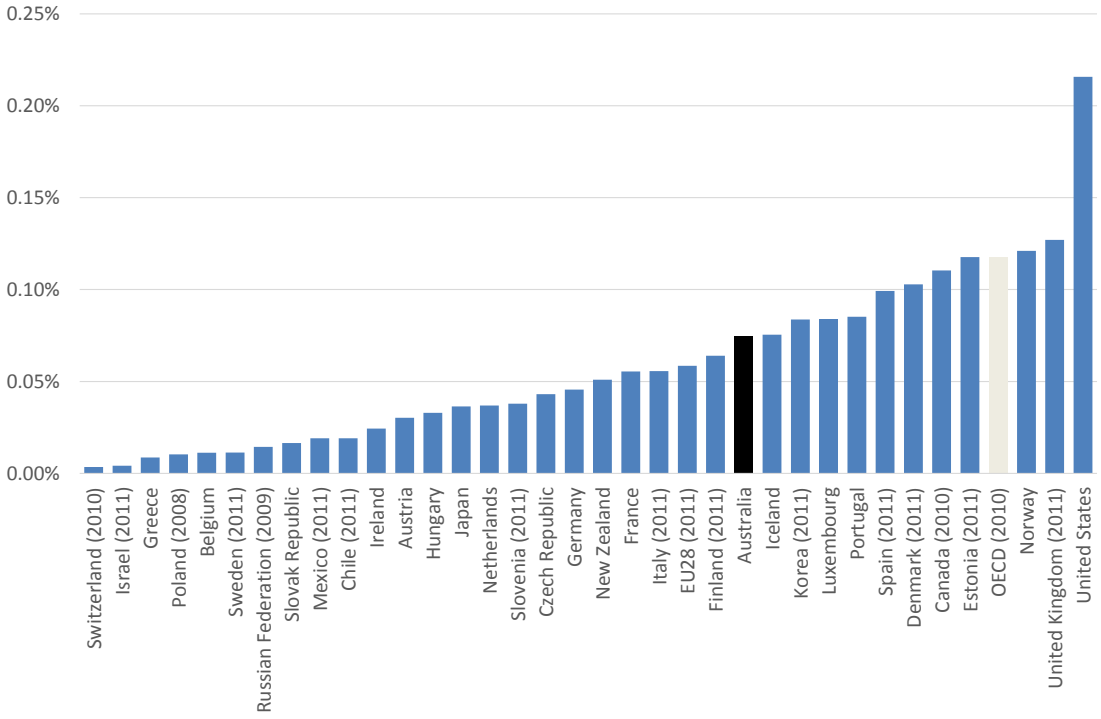
CSL, of course, supports increased funding of medical research, but that is not to say that the MRFF should be much larger; CSL is aware of the many demands on the public purse. Rather, it suggests that the MRFF should be used in a manner that fosters additional

[19] Research Australia (Sep 2014) *Australia's Medical Research Sector Backs the MRFF*, accessed 3 July 2015 at http://www.researchaustralia.org/news/australias-medical-research-sector-backs-the-mrff

[20] OECD (2011) *OECD Science, Technology and Industry Scoreboard 2011*. The figures for Australia were from 2008. The average share of GDP spent on R&D was 2.33%. Israel, Finland, Sweden, Korea, Japan, Denmark, Switzerland, United States, Germany, Austria and Iceland were ahead of Australia in the ranking.

private sector medical research, collectively raising Australia's spending on medical research above the OECD average. This indicates that the MRFF should be a major source of funding for translational research.

**Figure 5. Health R&D expenditure as a percentage of GDP (2012)**




**Source**: OECD Science, Technology and Industry Scoreboard 2013

## 4.2. The importance of translational research

The government has an important role in achieving a higher target level of expenditure on medical research, but so do commercial enterprises such as CSL. The willingness of the commercial sector to increase expenditure on medical research, particularly the clinical development stages of medical research, will depend upon the availability of candidate projects of sufficient quality to justify the large and risky investment in development.

Translational research includes: preclinical studies in relevant animal models of disease; *in vitro* and *ex vivo* studies using relevant tissues sampled from the target patient population; and toxicology studies, manufacturing and scale-up activities. They are fundamental steps before proof-of-concept studies can take place in patients. Translational research then extends into early stage human clinical trials. These R&D activities lie at the transition between the academic research sector and business R&D. It follows that an increase in

translational research would engender complementary and very likely larger amounts of post-translational medical research by the commercial sector.

CSL has previously identified[21] that Australia lacks resources and capability in translational research, and this inhibits the potential for Australia's health and medical research investment to be fully maximised. Because of the complexity and expense of translational activities through to proof-of-concept, many potentially valuable projects fail to attract the level of resource required to progress further. For example, CSL looks at over 100 new product opportunities each year. Of these, we choose 5-10% for full evaluation and fewer still for licensing. CSL has no doubt that greater government support for translational research would increase the pool of high quality projects in what is otherwise a somewhat thin market.[22]

The Strategic Review of Health and Medical Research, released in 2013, proposed the creation of a Translational Biotech Fund (TBF) to provide support for translational research. The TBF would bridge the funding gap that exists between the end point of NHMRC grants and private clinical research. The suggested size of the fund was $250m, a figure that CSL broadly agrees is appropriate.[23]

There is further compelling rationale for supporting translational research. It occurs early in the R&D process and therefore delivers, in relative terms, larger knowledge spillovers than later stage development. These spillovers can be expected to be greater still if government support encourages them to take place in collaborative enterprise between the academic research community and biotech firms. Indeed, CSL believes that one of the criteria that the MRFF should use in funding translational research is that the academic group has a credible and committed industry partner.

Accordingly, CSL recommends that the MRFF's should, in its steady state, allocate at least 20% of its available disbursements to translational research. That would amount to annual funding of around $200m per annum by the time the fund reaches $20bn.

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[21] CSL (March 2012) *Submission to the McKeon Strategic Review of Health and Medical Research.*

[22] The lack of depth in the market for viable post-translational projects has been cited elsewhere as a cause of similarly thin venture capital markets, and the lack of success from government measures targeted at support for venture capital. See, for example, National Endowment for Science, Technology and the Arts (2009) 'From funding gaps to thin markets UK Government support for early-stage venture capital,' Research report: September 2009 available at https://www.strath.ac.uk/media/departments/huntercentre/research/researchreports/NESTA_Report_Thin_Markets.pdf (last viewed 17 July 2014).

[23] Australian Government, Department of Health and Aging (2013) *Strategic Review of Health and Medical research (McKeon Review)*

### 4.2.1 Certainty of funding

Translational research is the riskiest and most costly element of the medical research pathway prior to clinical development. As such, translational research tends not to take place if there is uncertainty over funding for its expected duration. CSL believes that the funding model that underpins the MRFF should enable it to offer the relatively large (say $10m over the term of the translational research) and stable funding upon which translational research relies.

## 4.3. Funding the commercialisation of research and development

CSL notes that the MRFF legislation proposes a number of different prospective targets for funding, including corporations. Furthermore, the *Bill* defines medical innovation to include the 'commercialisation of medical research'.

Commercialisation is an essential stage in the development of new medicines. It describes the process of taking to the marketplace prospective products for which much of the technical risk has been resolved. Australia does not have a strong record of commercialising its R&D base, and this is a frequently expressed concern from, amongst other, the CSIRO, the Chief Government Scientist, and the Ministers of Industry, Innovation and Science. This has spawned piecemeal measures aimed at 'commercialising' Australia's research, with varying but generally limited effectiveness.

Commercialisation should largely be funded and undertaken by businesses because there are few knowledge spillovers and most of the economic gains accrue to the businesses themselves. Australia's commercialisation difficulties are not, in CSL's view, primarily due to a lack of government support for commercialisation; CSL ascribes Australia lack of success to other factors, touched upon in section 5.4.

Accordingly, CSL believes that the MRFF should be very cautious in supporting the commercialisation of research generally and the commercialisation of research by corporations specifically. There is a high risk that this type of funding will see no more success than previous commercialisation measures, and will in any case substitute for investment that businesses themselves should undertake. CSL does not therefore share the concern of some other commentators over proposed restriction on the MRFF funding for the commercialisation of medical research.[24]

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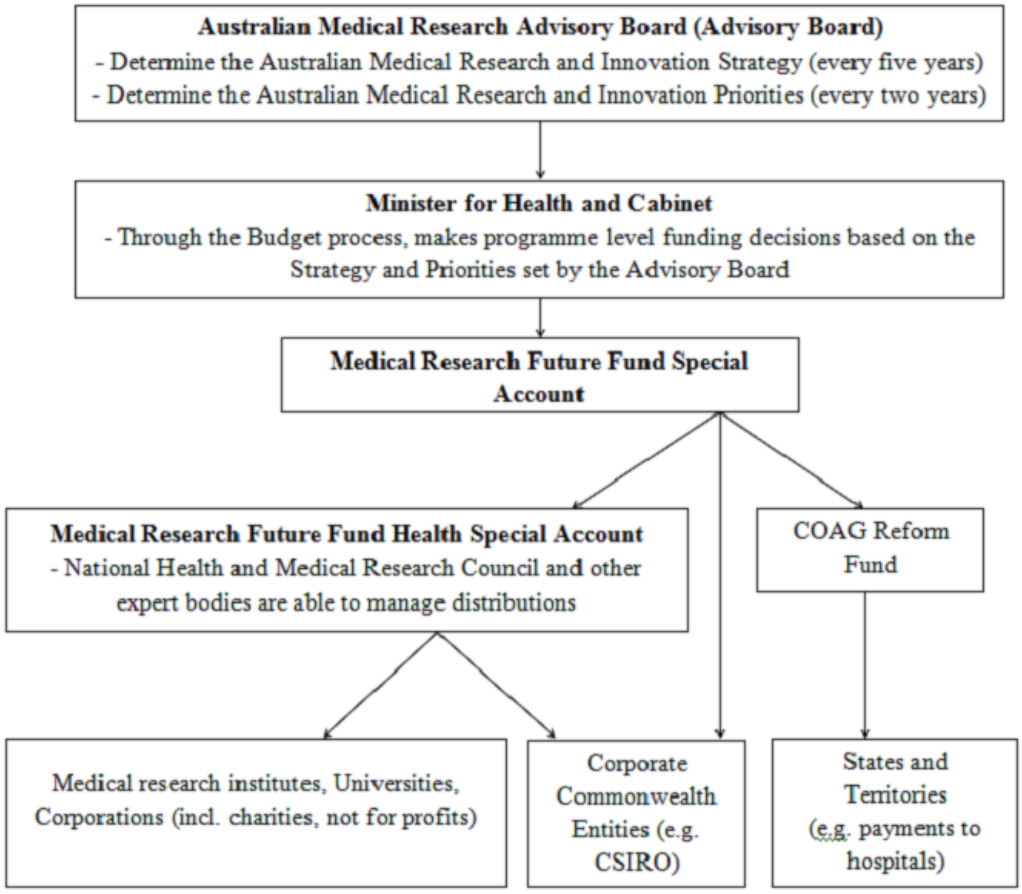
[24] See, for example, News.com.au (Jun 2014) *Sienna Cancer Diagnostics and Benitec attack proposed use of government's $20 billion medical research fund*, accessed 3 July 2015 at http://www.news.com.au/finance/economy/sienna-cancer-diagnostics-and-benitec-attack-proposed-use-of-governments-20-billion-medical-research-fund/story-fn84fgcm-1226941785144

## 4.4. Respective funding roles of the MRFF and NHMRC

The proposed governance arrangements for the MRFF are set out in Figure 6. Governance centres on an expert Australian medical research Advisory Board with appropriate expertise responsible for developing and publishing MRFF's strategy (on a five year basis) and priorities (on a two year basis).

**Figure 6. MRFF governance and disbursement arrangements**




CSL considers that five year intervals are appropriate for a funding body that is capable of providing longer-term funding. Decision-making mechanisms for the disbursement of funds from the MRFF will then be linked to the outlined strategy and priorities. As a prelude to forming its strategy, CSL would expect the Advisory Board to consult interested and expert parties in addition to having regard to NHMRC's national strategy.

While CSL recognises that the MRFF is a new initiative, it represents an opportunity to establish a funding source based on a substantial investment fund. It should therefore be able to support relatively long-term research teams and projects with stable funding commitments not subject to the short-term budget imperatives. In this light, CSL believes there are benefits in maintaining the complementarity between the MRFF and the

NHMRC such that the fund is not seen as and does not in practice become merely an arm of the NHMRC.

A number of research groups and public bodies expressed the view that the NHMRC would be the best body to administer it; CSL does not agree with this position. The governance model in which the expertise of the NHMRC is brought to bear through its *ex officio* membership of the Advisory Board is a better mechanism for ensuring that the MRFF and NHMRC operate in a complementary fashion while capitalising on their respective skills and experience.

CSL is somewhat concerned with the authority given the Finance Minister to debit the fund in favour of payments to the NHMRC. CSL recognises that this power would be subject to the direction of the Health Minister and would need to be consistent with the Strategy and Priorities. We also recognise the competencies of the NHMRC and other expert bodies in allocating funds to individual projects. Nevertheless CSL is concerned that this will have the practical result of coalescing the two sources of medical research funding.

CSL also notes that the legislation proposes to support a wide range of different mechanisms for distributing funds including, for example,

> …through the COAG Reform Fund, to States and Territories in order to support medical research infrastructure development. This may involve supporting infrastructure projects by hospitals, health services, universities or collaborative projects between state governments and medical research institutes. MRFF funding may also be made available to a Corporation. This could involve supporting research into the development of medicines or medical technologies (including personal health technologies) for commercial use.[25]

In each case 'the funding would only be available to the extent that the programmes are consistent with the Strategy and Priorities for medical research and innovation.' Nevertheless CSL is concerned that the practical result of this breadth of avenues is that the MRFF will end up meeting shortfalls in government funding to the medical sector that should properly be considered non-discretionary.

To mitigate these risks, CSL recommends that the Advisory Board be required to prepare a report every second year, attached to the Health Minister's report to Parliament, on compliance of disbursements with the MRFF's strategy and priorities, setting out how their disbursements have complemented rather than substituted for other relevant funding bodies.

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[25] Supplementary Explanatory Memorandum, 5.

# 5. Implications for government support

For the reasons set out in section 3 above, there are compelling grounds for government funding of R&D both generally, and specifically through the introduction of the MRFF. The Productivity Commission in its review of public support for innovation concluded that government support for business innovation was justified when it did so, and when that support resulted in additional R&D being undertaken.[26] CSL concurs with that view.[27]

CSL welcomes the MRFF which promises to substantially raise the value of Australia's medical research to the community. It should be considered, we believe, from a broader policy perspective comprising five main components.

## 5.1. Growth in the provision of basic science

Australia is at the world forefront in a number of areas of research in biological and human health research. This expertise has developed in part as a result of State and Commonwealth Government funding of basic science through the university system and the research institutes.

Basic science gives rise to substantial spillovers, which can be inter-generational in nature. Accordingly, basic science is likely to be under-supplied in the absence of government support. On that basis, government expenditure targeted at basic science is likely to remain highly productive and should remain a priority. The primary value of basic science derives not from the commercial value of individual projects, but from the foundations it lays for future research.

### 5.1.1 Skilled scientists

The biotech sector relies upon Australian universities and medical research institutes for its skilled Australian workforce. CSL would therefore welcome funding models for university science and technology that ensure the sector has a rich source of highly qualified scientists and engineers for both research and the work force. We also believe that Australia benefits from Australian trained scientists working in overseas markets. Most Australian scientists

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[26] Productivity Commission Research Report (9 March 2007) *Public Support for Science and Innovation*.

[27] For a more detailed discussion of the nature of the market failures that arise in R&D and the appropriate government responses to those failures see CSL (July 2014) *CSL Submission to the Senate Reference Committee Inquiry into Australia's Innovation System*. CSL has also addressed this issue in earlier public submissions including CSL (December 2006) *Submission to the Productivity Commission Research Study into Public Support for Science and Innovation in Australia;* CSL (April 2008) *Submission to the Review of the National Innovation System;* CSL (September 2008) *Response to the Review of the National Innovation System;* CSL (September 2009) *Response to Treasury's Consultation Paper "The new research and development tax incentive"* and CSL (March 2012) *Submission to the McKeon Strategic Review of Health and Medical Research*.

that work overseas choose to return to Australia at some stage in their career (often for family or lifestyle reasons), and return better trained and with valuable experience.

### 5.1.2 Access to IP and technology

CSL maintains its centre of excellence in early stage R&D in Australia in large part because of the high quality of IP that Australian institutions generate. CSL does not just benefit by acquiring patentable targets and molecules, but also from technologies independent of these such as new experimental processes and paradigms.

Continued and enhanced government support for Australian universities and medical research institutes would, in CSL's view, increase the supply of these essential inputs to biotechnology innovation, generating further knowledge spillovers, and further enhancing Australia's innovation system.

## 5.2. Translational research

Australia lacks resources and capabilities in translational research, and this inhibits the potential for Australia's health and medical research investment to be fully maximised. The role and importance of translational research are addressed in section 4.2 above. In CSL's view government funding plays a crucial role in this stage of the research cycle as medical research transitions from the academic sector into business. We identify this as a key role for the MRFF.

## 5.3. Business support for R&D

Governments in Australia have supported business R&D in the medical and pharmaceutical area through R&D tax offsets and by the provision of grants and direct funding.

### 5.3.1 The R&D tax offsets

R&D tax offsets provide the primary means of government support for private sector R&D in Australia. The 40% offset, for which CSL has in the past been eligible, has been a valuable source of support for CSL's Australian R&D, particularly in the area of new product development.

Ideally, government support for R&D should be confined to R&D that produces spillovers and that will increase as a result of the assistance. As a practical matter, it would not be sensible to appraise each business claim using these criteria. Since CSL believes that most business R&D produces some spillovers benefits (although these typically decline as the development moves close to market), the 45% refundable R&D tax offset for smaller firms and the 40 per cent non-refundable tax offset to larger firms (with no cap) represent a

reasonable balance that encourages R&D without an overly proscriptive definition of R&D activity.[28]

CSL is therefore concerned that the Tax *Superannuation Laws Amendment (2015 Measures No.3) Bill 2015* proposes to drop the refundable tax offset from 45% to 43.5% and the non-refundable tax offset from 40% to 38.5%, capped at $100m of expenditure. In CSL's view, these measures are inapt given the importance of R&D to economic growth. CSL is equally concerned that the continual review of and changes in R&D support arrangements makes long-term business investment in R&D more risky than it need be, making Australia a less attractive location for such investment.

In CSL's view, the aggregate level of expenditure in the Australian economy on R&D is already low by OECD standards, and lower than is needed to meet Australia's aspirations of becoming a leading innovative economy. Private sector R&D is essential to this goal. Weaker incentives for private sector investment in R&D, for example by reducing R&D tax offset and making future support for business R&D less certain, frustrates this goal. In the medical research sector, weaker incentives for business R&D will make Australian firms more reluctant to take forward promising medical research projects, weakening the overall medical research chain.

### 5.3.2 Direct support for investments

In 2008 the Pharmaceutical Industry Strategy Group ('PISG'), chaired by the then CEO of CSL, recommended 'a strategic investment fund program that would provide Government co-investment in strategic industry projects that transition the industry to a sustainable position and deliver enduring net benefit to Australia.[29]

CSL has received substantial support from State and Commonwealth governments that are similar to the support arrangements recommended by PISG, for example the Biotechnology Manufacturing and Privigen (immunoglobulin) Manufacturing facilities at Broadmeadows and the Biopharmaceutical Formulation Centre at Parkville. Some of these projects were 'footloose' in the sense that CSL had options to locate them at overseas sites (discussed in more detail in the following section). Collectively, these facilities enhance the Melbourne biotech cluster with enhanced R&D, biological manufacture and enhanced regulatory compliance skills, all of which can be expected to deliver significant spillover benefits over and above the benefits that CSL itself derives from them.

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[28] CSL believes that increasing the quantum of overseas expenditure eligible for the offsets would enhance the effectiveness of the concession by increasing incentives to undertake later stage development and commercialisation from Australia.

[29] Pharmaceuticals Industry Strategy Group Final Report/December 2008 (Commonwealth of Australia 2009).

## 5.4. Lack of competiveness as a location for commercialisation

In CSL's experience, Australia is not a competitive location from which to undertake the commercial development (including the advanced manufacturing) of products, even when those are derived to a significant degree from Australian research and development.

Australia has policy goals aimed at commercialisation of the results of its research base and has developed some notable pockets of success, but has yet to develop specialist globally competitive enterprises to replace traditional manufacturing. By and large, Australia is not an integral part of global supply chains. This is a frequent lament in Australia, from the CSIRO, the Chief Government Scientist, and the Ministers of Industry, Innovation and Science. This has spawned piecemeal measures aimed at 'commercialising' Australia's research, with varying but generally limited effectiveness. Advanced manufacturing in Australia, which is the key indicator of successful commercialisation of innovative products such as new medicines, has lagged the economy as a whole and, over the last five years or so, failed to add new jobs to the economy.[30]

One of the larger impediments to commercialisation of Australia's research base is Australia's uncompetitive corporate tax rate compared to its OECD peers. Australia's effective tax rate of 25.9% was the equal 7th highest in the OECD in 2013, above that of Italy (24.5%), Germany (24.4%) and Canada (18.6%). It has one of only seven effective marginal corporate tax rates for large businesses that has remained unchanged since 2005.

Countries such as the UK, US, Germany, Switzerland, Ireland and Singapore have non-tax attributes that make them desirable locations for the advanced manufacture of novel products, such as availability of skilled staff and closeness to major markets. Some also have considerably lower effective corporate tax rates than Australia, often no higher than 10%. By way of example, since 2013, the UK has reduced its corporate tax rate to 20% and has established a lower 10% rate for income derived from eligible patents under the so called 'Patent Box' tax concession, which would apply to most products of medical research.

CSL believes[31] that a preferential advanced manufacturing tax offering a lower corporate tax to advanced manufacturing derived from Australian research would be the single most effective measure in addressing the commercialisation challenge, and could be established without a substantial drain on government revenues.

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[30] Department of Industry 'Australian Industry Report 2014' http://www.industry.gov.au/industry/Office-of-the-Chief-Economist/Publications/Documents/Australian-Industry-Report.pdf October 2014

[31] See CSL (June 2015) *CSL submission to the Treasury in response to the "Re:think" tax discussion paper*.

## 5.5. Implications for the MRFF

The medical research sector in Australia is successful given the small share of GDP that it represents. CSL believes that government policy, tailored to the realities of medical research that aims to develop new medicines and new health practices could substantially raise the value of the sector to the Australian economy, and in so doing improve the health and wellbeing of the Australian community. Figure 7 provides a stylistic summary of government policy as it might apply to the medical research and development supply chain:

- state and Commonwealth governments continue to be the most important source of funds for education, basic science and basic research, to provide the basic building blocks upon which more targeted research relies and to ensure that there is a sufficient supply of skilled graduate scientists;

- governments also have the predominant funding role in the pre-translational stage of development (which the NHMRC refers to as the 'Create' stage);

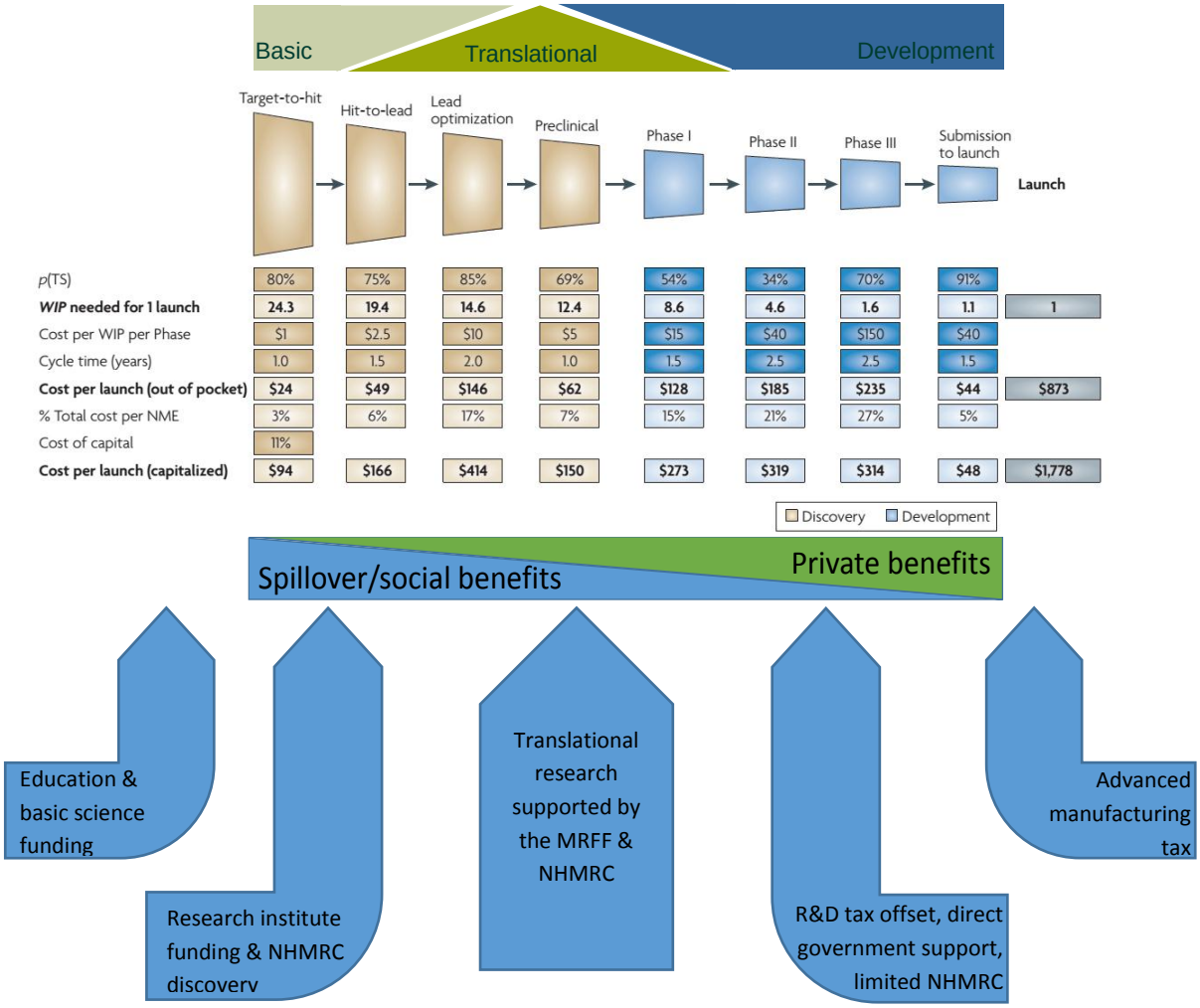
- the MRFF, while not exclusively directed at translational research can best enhance medical research in Australia by increasing the amount of translational research undertaken in Australia, complementing existing funding;

- an increasing role for private sector actors in the clinical development phase of medical research and development, with continued support through the R&D tax offset in recognition of the spillovers in this stage;[32] and

- measures, such as an advanced manufacturing tax to improve the competitiveness of Australia as a location for commercialisation of its research base, which would have the additional benefit of fostering greater commercial interest in the earlier stages of medical R&D.

[32] Recognising the need for some support for clinical trials from sources such as the NHMRC where there is medical need but a lack of commercial commitment.

**Figure 7. Tailored policy towards the medical R&D**



# 6. Conclusions

In May 2015, the Commonwealth Government proposed to establish the MRFF, designed to provide a significant and stable supply of funding for medical research in Australia.

CSL is a wholehearted supporter of the MRFF initiative which represents a visionary measure that could substantially enhance the medical research sector in Australia. It will increase the value of the Australian medical and pharmaceutical sectors to the Australian economy, and enhance the health and wellbeing of the community.

The MRFF has the potential to significantly enhance this sector by close to doubling government funding over the next decade. It should raise Australia's overall expenditure on medical research to around the average level of our OECD peers, close to the level of expenditure in the UK in terms of percentage of GDP.

CSL believes that medical research is disproportionately productive in economic, health and wellbeing terms and that Australia should therefore aspire to being well above the OECD average. There are, however, many calls on the public purse. This aspiration can therefore best be fulfilled if the MRFF is directed at translational research that is likely to recruit substantial additional and complementary research funding from the commercial sector. Accordingly, CSL recommends that the MRFF's should, in its steady state, allocate 20% of its available disbursements to translational research.

In terms of the specifics of the MRFF, CSL supports the proposed legislation. CSL recommends that the MRFF has a focus on projects that foster additional private sector investment in medical research, is cautious when it comes to funding commercialisation, and does not simply substitute for or become subsumed into other research funding bodies. The benefits that CSL perceives from the MRFF are dependent upon governments' continued commitment to funding existing avenues of support for medical research, not replacing them with the fund.

The MRFF should be seen as one component of a broader policy towards medical research and innovation. This should include funding for education and basic science, maintained funding for the NHMRC, increased funding for translational research through the MRFF, continued support for and commitment to business R&D by not eroding the current tax offsets, and urgent action to address Australia's lack of competiveness as a location for the manufacture of innovative products that derive from its research base.

## Submission details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