Medtech's role in a future innovaton and science led country

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Opening address, 12th annual Conference Medical Technology Association Australia (MTAA) National Conference

September 27, 2016

ATP

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The Australian Government has committed to making innovation a key element of its economic agenda and to creating an environment that provides clear pathways and incentives for Australia's business to innovate. Innovation is critical to economic development. Australia has strengths but also some challenges. Innovation Australia is an independent body, which was established by the Government to enhance Australia's innovation performance. Bill Ferris AC, Chair of Innovation Science Australia will discuss what changes are necessary for meaningful improvement in commercialisation.

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Introduction

Thank you for the introduction Gavin Fox-Smith … What a great title for the conference – 'The BluePrint for a Stronger MedTech Industry.' Over the years I have been involved in a number of ventures, like many of you, in the health and medical research sector. I'm not sure there is one simple blueprint for success, but I know the MTAA and its members are key players in identifying factors for a stronger industry.

ISA is an independent statutory board that includes people like the chief scientist, Dr Alan Finkel; Maile Carnegie, ex managing director, Google Australia and New Zealand, now at ANZ; venture capitalists Daniel Petre and Paul Bassat (co-founder of Seek); and Dr Chris Roberts, former Cochlear chief executive and ResMed non-executive director. We have just appointed two new members who will bring an international perspective to the group: Beth Comstock, Vice Chair of General Electric and Israeli author Saul Singer who co-wrote *Start-up Nation: The Story of Israel's Economic Miracle*.

Our remit is to advise government on all science, research, and innovation matters – from infrastructure to grants, tax incentives, and co-invest support programs. ISA also has a role in helping to implement the government's package of twenty-four measures that were outlined in the National Innovation and Science Agenda (NISA), announced by the Prime Minister.

A key deliverable for ISA is to develop a strategic plan for improving and enhancing Australia's innovation, science and research system that reaches out to 2030. This work is already under way with an audit of our existing innovation systems that will be provided to government in December 2016. We intend this to be a public document and its mapping will provide the base line from which our strategic plan will be developed with recommendations to Government by November 2017.

ISA's work isn't starting from scratch – recent initiatives in this space

Since NISA was announced last December, significant progress has been made with many measures already implemented and or well advanced. In launching the agenda, the government committed to undertaking a review of the R&D tax incentive (RDTI) programme, which is a very substantial part of the government's R&D investment; at least 30 per cent, equating to approximately $3 billion per year. This RDTI provides an important incentive for private sector research and development, and helps with cash flow for start-ups. The Government invited me, Alan Finkel and John Fraser to conduct what is colloquially known as the '3Fs review'.

Our recommendations seek to improve the performance of the programme and maximise its benefit to the nation. In particular, we want to encourage research that would otherwise not take place [known as the "additionality" principle]. One way to do this could be to encourage more collaboration by providing a premium credit for those businesses who link with our world class researchers.

Other significant initiatives already delivered include:

1. The new $500m Biomedical Translation Fund (BTF) has been announced with $250 million in government funding drawn from the Medical Research Future Fund. It will be matched by at least $250 million from private and institutional investors. Competitively selected private life sciences fund managers will manage it … their applications are currently under review.
   The BTF is a for-profit venture capital fund targeting investments in companies with projects at advanced pre-clinical and phase I and Phase II stages of development. The BTF is designed to assist biotechs and medtechs with the multiple 'valley of death' funding problems that hold back the commercialisation effort in our health and medical research sector. These investments are expected to require in the range of $5 million to $20 million per project. To access this $500m pool of venture capital, companies need to have active R&D projects in Australia … something for this audience to actively consider.

2. A new tax-based incentive for angel investors from July 2016 with a 20 per cent non-refundable tax offset for those investing up to $1m per annum. in start-ups, and a 10 year capital gains tax exemption for investments held at least 12 months. Also a significant potential solution to the early stage "valley of death".

3. New and less restrictive arrangements for venture capital limited partnerships (VCLPs) and early stage venture capital limited partnerships (ESVLCPs). Partners in new ESVCLPs will receive a 10 per cent non-refundable tax offset on capital invested during the year. The maximum fund size has increased from $100m to $200m, and there is no longer a requirement to divest from a company when its value exceeds $250m.

4. Funding for incubators and accelerators to strengthen the entrepreneurial ecosystem through the new $23m incubator support initiative, launched last week by Minister Greg Hunt; and five landing pads overseas (Berlin, Shanghai, Singapore, San Francisco, Tel Aviv) to help Australian entrepreneurs to test their ideas in key eco-systems and markets offshore.

5. And these NISA measures aren't the end of the story – last month at the AFR Innovation Summit held in Sydney, the Minister for Innovation, Greg Hunt, described these and other measures as part of a first "wave" of future innovation. He is already flagging NISA 2.0 focussing on ideas for additional investment in innovation, followed by NISA 3.0, which will focus on business simplification and implementing ISA's 2030 strategic plan.

All of these measures are directly relevant to our own home grown medtechs, and should encourage importers and their offshore suppliers to rethink how else they might more actively participate in building a stronger national medtech sector.

ATP Innovations, which is within a stone's throw of where I am standing, is the largest technology incubator in the Southern hemisphere. Since 2006 they have generated more than 400 skilled STEM jobs, launched over 700 products and overseen eight exits through trade sale or initial public offering. Of their current 70 residents, 17 are in the medtech sector. This includes new arrival Trimph a company that has a state of the art product for bone and tissue regeneration where the new tissue is grown inside the ultimate bioreactor: your own body. At room temperature, Trimph is liquid and can be injected into desired locations. But when the material heats to body temperature it forms an elastic gel that stays in place. The Trimph team are about to progress to human trials and will initially focus on dental applications. Despite being less than a year old, they already have a GMP- certified manufacturing facility in Sydney with potential to expand. Maybe Trimph will be an early candidate for the BTF?

ATP Innovations also house SpeeDx whose molecular diagnostic products can accurately target a large number of potential infectious agents in a single test. This is a small company that has licensed some its IP and successfully navigated TGA registration. They will soon have the world-first diagnostic product to detect *Mycoplasma genitalium* (a sexually transmitted bacterial infection).At the same time, the product provides information on its antibiotic resistance status; this could inform a more targeted treatment approach, limit inappropriate antibiotic use, and ultimately allow the patient to get better faster.

But what are the key success elements that allow these companies to pursue their commercialisation journeys? What **facilitates** the successful commercialisation of a great idea or discovery?

Facilitate

Knowing what levers have been pulled at state and federal level to support innovation is essential to creating and building an evidence-based system for the future. At the national level there are several successful programmes. They include the Medical Research Commercialisation Fund (MRCF), managed by Brandon Capital, which has been successfully operating since 2007. Its 50 member institutes, include Australia's leading medical research institutes and research hospitals. Within the Department of Industry, Innovation and Science Entrepreneurs' programme, there is also Accelerating Commercialisation (AC), which followed on from Commercialisation Australia. Its role is to encourage and assist small and medium businesses, entrepreneurs and researchers to find the right commercialisation solutions for their novel product, process or service. One of their success stories is ACT company My Health Test, which has a direct to consumer pathology test

service using proprietary home-based dry blood spot sample collection**.** Their revenue growth post funding is in the order of 300 to 400 per cent and they have a current valuation of between five and six million dollars from a 2013 zero start up base. Another AC recipient, imaging technology company Clarity pharmaceuticals – which are housed nearby at ATP Innovations - is developing next generation radiopharmaceuticals. Support provided to Clarity has helped fund a clinical trial of SARTATE, a new radiopharmaceutical for treating cancer.

At the state level there have been several initiatives like Uniseed in Queensland andthe NSW State government's medical devices fund that was set up in 2013, is also often mentioned in this context. It's a loan scheme where government is the last to get its money back if the SME is successful and becomes profitable. SpeeDx were 2014 recipients. The fund enabled them to expand their business, pivot from licensing to manufacturing, and double their staff. They now have over 30 staff - the additional skilled jobs are in R&D as well as production and manufacturing.

Regulation and innovation

These examples, and public discussion to date, have tended to emphasise invention-based innovation. But within the context of the wider definition – change that adds value, there are many other waysto facilitating innovation. For example, the ISA audit will inspect the impact of regulation in Australia to inform areas for simplification and improvement. We recognise that regulation affects innovators in different ways, depending on the sector, types of activity, current stage of development, and whether or not innovators are operating in or across our domestic and overseas markets.

Within the health sector, I'm aware that there are bottlenecks within key regulatory processes and that the 2015 Review of Medicines and Medical Devices Regulation provided a much-needed evaluation of industry's issues – with the effects of some recent changes yet to be felt. It has also been pointed out that Australian approvals are not just a requirement for sales in Australia but are an important prerequisite for endorsement in other countries; so the delay in local approvals has a global impact on commercialisation of Australian-developed devices.

As I'm sure you are aware, in the last fortnight the government has released a very encouraging response to this review that recommends greater flexibility in approval pathways . The timing of the response, many months after the review's final report, is indicative of the need for and value derived from ensuing stakeholder consultations because you are the ones best placed to judge whether implementing the recommendations will facilitate the import and export of superior medical technology products, services and processes to drive competitiveness, productivity, and profits. Equally, your ongoing engagement with government on what is and isn't working – either as individual businesses or through member organisations - provides an essential reality check. This is one way in which you each can **facilitate** a stronger medtech sector**.**

Individual action is good, but **co-ordination** is also required.

Ten years ago, Australia was a preferred clinical trials destination ahead of the United States, the United Kingdom, Germany, Japan, Singapore and India. Average costs of clinical trials were low,

the total amount of clinical trials taking place on a per-capita basis were high and a considerable percentage of clinical trials were being completed within the allocated time. Competition from Asia has since grown, as have trial costs – in part due to the strengthening dollar, and duplication and differing requirements between the various states and institutions are impacting heavily on our ability to meet sponsors' expectations.

The clinical trials landscape in Australia is very complex, and no single government or agency holds all the levers for change, nonetheless the federal government is working with states, territories and other stakeholders towards a nationally consistent approach. Priorities include streamlining ethics and governance, improving efficiency of recruitment and accruals, and strategically positioning Australia as a preferred location for performing clinical trials. The Council of Australian Governments (COAG) health council has agreed to consider new approaches to improve administrative efficiencies, better engage sponsors and improve trial start up times and outcomes. I know you have heard all this rhetoric before but I do believe progress is underway.

Although there is a significant economic value associated with Australia being a clinical trials destination, we also need to acknowldge the health benefit from the investigator - initiated or 'public-good' clinical trials which are non commercial and designed and driven by investigators actively engaged in providing healthcare. They can generate significant savings and improvements in health outcomes. Any improvements in the clinical trial processes will also serve to expand and enhance their impact.

And industry needs to be atthe forefront of this **co-ordination** task too. The MedTech and Pharma industry growth centre (aka MTP Connect) is one of six independent industry-led growth centres – an initiative that laid the foundation for last December's National Innovation and Science Agenda. MTP Connect represents all organisations in the sector that are directly involved in the research, development, manufacturing or market commercialisation of innovative products. Dr Bronwyn Evans is chair of the board and Sue MacLeman, former global head of commercial development at Mesoblast, is CEO. MTP Connect have recently released their draft ten-year sector competitiveness plan and are tasked with playing a coordinating role that will enable the sector to overcome the multi-faceted constraints and gaps that hinder its success – in addition to finding opportunities to address unnecessary or overly burdensome regulations. They have identified where they can act as an independent but collective voice, take direct action or fund projects to meet their goals that include encouraging the implementation of recommendations to streamline the clinical trial process. Certainly ISA's work will be influenced by this competitiveness plan and I'd suggest everyone in this room should carefully review and engage with MTP Connect on the path forward.

Collaborate

Coordination towards a common goal is one thing, but **collaboration** in reaching that goal is another key element to success. Numerous government reports and measures of innovation point to a need for better collaboration between business and publicly funded researchers, necessary for Australia to improve its ability to commercialise research discoveries.

This isn't the case for collaboration among researchers - despite Australia's geographic isolation, about half of our research publications list an international co-author. The National Health and Medical Research Council (NHMRC) reports that Australia contributes approximately three percent of the world's published biomedical research yet we constitute only 0.3 per cent of the world's population. And, in the Scientific American's Worldview scorecard that looks at biotechnology ranking of over 50 countries, Australia has jumped from 17th place in 2010 to hold one of the top five spots for the past three years. We are keeping company with USA, Singapore, Denmark, and New Zealand.

We are also one of the three biotech leaders when it comes to number of publicly traded companies, company revenue, and company market capitalization. And while we often hear about Cochlear, CSL and ResMed in the context of successful Australian medtech and biomedical companies, there are others such as Bionomics,* BlameySaundersHears,* Nanosonics, Sirtex and Starpharma*: three (*) of these companies are led by women (Deborah Rathgen, Elaine Saunders, Jackie Fairley) – unusual in this industry.

Last year MSD (known as Merck in US and Canada) bought shares in Bionomics, which is also part of the Cancer Therapeutics Cooperative Research Centre (CTxCRC). CRCs bring together industry and academic researchers and represent an important part of Australia's R&D endeavors. The CTxCRC has fifteen members including the National Cancer Centre Singapore and several global health companies. In January 2016, the CRC announced a licensing deal in excess of $15 million USD with MSD (Merck), to develop and commercialise new treatments for several cancers with an initial focus on blood disorders like thalassemia that if left untreated can lead to anaemia and death.

These industry-led and outcome focussed research partnerships are testament to the power of **collaboration.**

ISA has an evaluation oversight responsibility for the CRCs. In fact, over the last twenty-five years, 200 plus CRCs have been initiated and the program has generated a net economic benefit to the community, which has exceeded its costs by a factor of 3:1. We currently have 31 CRCs, including CRCs in areas that include cell therapy manufacturing and wound management innovation whose advisory committee includes a representative of Smith and Nephew, an MTAA member. It's another way you can enagage in mentoring and in supporting R&D.

CRCs and other collaborative efforts have also benefited from key national research infrastructure, like that supported under the National Collaborative Research Infrastructure Strategy (NCRIS), which includes mega facilities like the synchrotron (now part of ANSTO) and the Australian National Fabrication Facility (ANFF). The ANFF provides micro and nano fabrication facilities across its 21 member institutions and has been used by a UNSW research team to develop a microneedle patch that will allow patients to take their own blood sample, without the need for a doctor or nurse. For commercialisation, the team has partnered with Australian plastics manufacturer Romar Engineering and the Innovative Manufacturing Cooperative Research Centre.

ANFF has also already helped companies such as Queensland-based Vaxxas progress their discoveries towards market. Vaxxas are the developers of the Nanopatch - a needle-free vaccine delivery platform that is a safe and cost effective alternative to traditional vaccinations. It can eliminate the need for refrigeration and is a potential game changer for disease control in developing countries. Advanced instruments (such as the deep reactive ion etcher, photoplotter, hot embosser and soft lithography suite) were used to fabricate the microneedle arrays used in the technology. Vaxxas was established in 2011 with $15 million in venture capital funding – one of Australia's largest series A investments in a start-up.

My colleague, deputy Chair of ISA and chief scientist, Dr Alan Finkel is leading the expert working group in the development of the 2016 National Research Infrastructure Roadmap to strategically guide government investment in research facilities over the next ten years. This roadmap, along with ISA's audit, will feed into our 2030 strategic plan for Australian innovation, science and research – where we will work to identify the key factors for Australian success while considering future disruptive megatrends. In the medical technology and pharmaceuticals space these include precision medicines and personalised healthcare, consumer control, and data exchange and big data analytics.

We want to collaborate with you in developing this 2030 plan … our blueprint if you will. In the immediate future, you can participate in the consultations on MTP Connect's draft sector competitiveness plan by contacting the growth centre at info@mtpconnect.org.au. Next year, ISA will be embarking on broad consultations for our 2030 Plan – There will be call for written submissions and consultations of varying types and sizes. You can contact my office at oisa@industry.gov.au if you want an update on our plans.

Concluding remarks

I've outlined just a handful of examples of great discoveries and great commercial success stories in the sector. It is exciting and heartening to hear these stories, and part of ISA's role is to seek out key success elements that allow researchers and companies to pursue their commercialisation journeys.

In closing, a more innovative and entrepreneurial Australia will have far-reaching consequences for the economy and your bottom line. There are many ways for business to **contribute to and facilitate innovation:** through greater support for R&D including close collaboration with our PFRAs, participating in the relevant public consultations and policy development – the MTP Connect Plan and forISA's 2030 strategic plan, or by mentoring medtech startups. With improved regulatory regimes and investment incentives now being delivered we should expect to see MTAA members playing an important role in building up our own home-grown innovative medtech sector for a future Australia. I hope you and MTAA will continue to assist with all of this, and consider what you could do to strengthen and actively participate in our home-grown medtech capabilities.