What I want from Pharma: Medical Oncologist Explains

Associate Professor Gary Richardson is the Director of Oncology Clinics Victoria, Director of Cabrini Academic Haematology and Oncology Services and an Associate Professor of Medicine at Monash University. He previously held the position of Director, Department of Medical Oncology and Clinical Haematology at Monash Medical Centre. He is a Fellow of the Royal Australasian College of Physicians. Specialised Therapeutics sought his insights on medical and pharma interactions.

By Assc. Prof. Gary Richardson, Director of Oncology Clinics Victoria and Oncology Services and Assc. Prof. of Medicine, Monash University

Specialised Therapeutics' new business model can't be a bad thing, because interactions between pharma companies and the medical profession have definitely changed, thanks to the digital revolution.

In the old days when doctors saw pharmaceutical company representatives, it was all paper. That meant that part of a rep's role was to bring papers, show you evidence, outline details from a recent scientific meeting as well as spend some time selling the drug. Those days have gone, because everything is on the web

now. You get the alerts and the data is there. There are not that many practice-changing things that occur on a day to day basis and if there are, you will find out about it straight away.

What do I want when a pharma company representative comes to my office? I want information about new clinical trials and about drug access programs. I also want to know what's in the pipeline, what's coming to Australia and what we can do in the space we operate. I don't really want old information about drugs that are already available – I already know that information. What I would like is early information, that I may not yet have seen or been able to access. That kind of information is really good, but that is not so easy to get all the time.

(Under the Medicines Australia Code of Conduct), pharmaceutical representatives are prohibited from speaking openly and freely about access programs for medicines that are not yet approved for marketing in this country – despite the fact these drugs may be already approved and available overseas.

There needs to be a rethink. It is ridiculous that you can't discuss medicines that are 'off-label' or drugs that are potentially coming in the future. There seems to be a fear you will somehow break the rules. I find it insulting that authorities think you might be swayed by these sorts of discussions.

Consider the landscape around five years ago, when all the immunotherapy trials were being done in melanoma overseas. Abiding by the letter of the law, no-one in

Australia could discuss any of those medications with anyone, at all. You understand that a trial is going to come, and these drugs are being used overseas, but you are not allowed to talk about it. It just seems crazy, as not all oncologists attend overseas meetings or has seen an original presentation – particularly if it's not in their own area of expertise.

As a doctor, you should be able to make a decision whether a drug should be able to benefit any particular patient you have. The doctor has to make the decision to benefit the patient, because that's what we do.

In terms of other interactions with pharma, I have no problem with transparency reporting, (where pharmaceutical companies acknowledge payments to individual doctors for services or contributions towards them attending education activities, including flights and accommodation). But I do think it should be the same across all industries – it should be the same for politicians or lawyers. I am not worried if someone puts my name in the paper and notes that I've been paid (by a pharmaceutical company) to attend a meeting. The doctors that worry about these things the most I think, are the younger doctors. And particularly the ones that are still working in the public system, because it seems to me that they are very wary of pharma.

At the end of the day, working with pharma is a double edged sword. Pharmaceutical companies provide good drugs and sponsor clinical trials. The downside is that the industry as a whole, is largely perceived to be about money and many of the big pharma companies are beholden to shareholders.

What would I say to younger doctors who might be wary? At the end of the day, pharma companies are in the business of creating drugs that work. And there are some really amazing drugs that have been made. There are a lot of positives. And this move to remove financial incentives from reps based on volume of sales achieved takes away that pressure to sell and paves the way for a more open discussion."

*Associate Professor Gary Richardson spoke with Specialised Therapeutics in August 2017.

Herald Sun: 5 October, 2017

The Australian

By Sue Dunlevy 5 October 2017

Test rebate rejected: Outrage over breast cancer ruling

NO Medicare rebate will be offered for a breakthrough new test that could save thousands of breast cancer patients from debilitating chemotherapy.

The $4500 test, which can also identify aggressive breast cancers that do need chemotherapy, is subsidised in the United Kingdom, the United States, Canada and Europe. But the Medical Services Advisory Committee has rejected a rebate for the Oncotype DX test for a fifth time.

Critics say the best treatment will now be available only to the rich. Doctors fear low-income earners will never even be offered the test.

“It’s beyond belief they can be so hard-hearted — they must be a bunch of men,” said Kari Svensen, 71, of Sydney, who was able to avoid chemotherapy thanks to the test.

Wendy Dunstone, of Melbourne, was not going to have chemotherapy until the test showed her cancer was an aggressive type. She was only
able to afford the test thanks to an inheritance.

Explaining its decision, the MSAC said the test had only an incremental benefit over the usual care of women with breast cancer. And it raised doubts about the treatment’s cost-effectiveness, saying it was concerned the test could be performed in only one US laboratory.

Melbourne breast surgeon Dr Jane O'Brien said the MSAC was missing the point. The test was not about saving lives but about stopping the over-treatment of women with chemotherapy that made no difference, she said. The test, measuring the expression of 21 cancer-related genes, is performed on a small amount of tissue removed during a lumpectomy.

Study results show that of every 100 patients tested after being prescribed chemotherapy and hormone therapy, 65 would be switched to hormone therapy only. Of every 100 patients prescribed hormone therapy only, 15 would be switched to chemotherapy as well. Between 900 and 2000 Australians a year would benefit from funding of the test.

It would cost $3-$6 million per annum, but this would be offset by savings from reduced chemotherapy, making the net impact $1.5-$3.5 million. A spokesman for Health Minister Greg Hunt said the committee was independent and had made its decision based on expert advice.

Opposition health spokeswoman Catherine King said genomic testing for cancer was the way of the future, and governments needed to do more.

The Australian: 5 October, 2017

The Australian

By Sarah-Jane Tasker 5 October 2017

Patients Forced into Chemo: No Funds for

Breast Cancer Testing

Globally recognised technology that could spare thousands of Australian breast cancer patients from unnecessary chemotherapy will remain out of reach for many after the federal government refused to fund the expensive test.

The test, which provides a prognosis for early-stage breast cancer patients on the likelihood the cancer will recur, is reimbursed in the US, Canada, Britain and throughout Europe.

Specialised Therapeutics Australia has distributed the test here since 2014 at an out-of-pocket cost to patients of $4500, which it said was the lowest price available in the world.

More than 1000 Australian women and men diagnosed with breast cancer since 2014 have paid for the test, known as Oncotype DX.

Carlo Montagner, chief executive of Specialised Therapeutics, which applied to the government's medical services advisory committee for reimbursement of the test, said he was "dismayed and frustrated" by the latest rejection, which followed four previous failed applications.

It is believed that between 900 and 2000 Australian patients a year would benefit from the test if it was government-funded. It is estimated that funding the test would cost the government about $3 million in the first year, rising to $6m five years later. The test distributor said, that allowing for chemotherapy and drug cost savings, the net financial impact to the federal health budget would be between $1.5m for the first year and $3.5m
a year at five years.

"It seems that in Australia, only the 'haves' of our society can benefit from this cutting-edge technology.

"What a pity, in this age of personalised medicine and especially at a time when the government has acknowledged a commitment to innovation," Mr Montagner said.

He said his modelling showed that more than 250 Australian women every year, who could not afford to self-fund ODX, would endure unnecessary

chemotherapy without access to the test. The genetic test identifies breast cancer patients who could safely avoid chemotherapy by analysing the activity of specific cancer genes taken from a single sample of tumour tissue.

The advisory committee said it considered the incremental benefit of the ODX breast cancer testing over optimal care remained uncertain. It also found that uncertainty regarding the cost-effectiveness of ODX remained unresolved.

Jane O'Brien, a specialist breast surgeon at St Vincent's Private Hospital Melbourne, said the decision was unjustified, given it expected ODX to be compared with "usual care".

"The purpose of the test is to identify which women may be able to avoid chemotherapy," Dr O'Brien said.

"Therefore you're not expecting it to show better survival compared to usual care.

"What you're aiming to do is to safely avoid toxic therapies in women who don't need them."

Dr O'Brien said it was clear the test could result in health savings, given the cost of ODX would be less expensive than six months of chemotherapy.

Federal Government Rejects Funding Bid for Novel Breast Cancer Test That May Spare Women from Chemotherapy

Oncotype DX® breast cancer assay may spare thousands of women from chemotherapy

Medical Services Advisory Committee has now rejected five funding applications for Oncotype DX

Melbourne, Australia, 4 October 2017: THE Federal Government's peak advisory committee for Medicare funding has rejected calls from doctors, patients and the pharma industry to fund a novel breast cancer test that may spare thousands of Australian women from enduring unnecessary chemotherapy.

The Health Department's Medical Services Advisory Committee (MSAC) recommended against funding the expensive Oncotype DX breast cancer assay for Australian women – despite it being reimbursed and freely available to women in many other countries, including the United States, Canada, the United Kingdom and throughout Europe.

This genetic test identifies those women who could safely avoid chemotherapy, by analysing the activity of specific cancer genes taken from a single sample of tumour tissue. It is suitable for breast cancer patients who have hormone receptor positive, HER2 negative, early stage breast cancer, which is a common form of breast cancer affecting thousands of Australian women.

The test provides a prognosis of the likelihood the cancer will recur. It is also able to provide medical teams with predictive information, identifying tumours that would be more sensitive to chemotherapy.

Specialised Therapeutics Australia has made the test available in Australia since 2014 to those women who are able to afford the $4500 out of pocket cost. Since 2014, more than 1,000 men and women diagnosed with breast cancer have paid for an ODX test allowing them and their medical team to make a more informed decision about their treatment.

In the US, Canada, the UK and Europe, the Oncotype DX test is reimbursed, widely available and consistently shown to be cost-effective. It has spared many patients from enduring unnecessary and debilitating chemotherapy.

Respected Australian surgical oncologist and specialist breast surgeon, Professor Bruce Mann said he was "very disappointed" by the decision, noting the test had been shown to change treatment decisions in many cases. He said that most

frequently, it enabled patients to avoid chemotherapy. But sometimes, test results indicated that chemotherapy was the best treatment path.

“Many breast cancer patients simply cannot afford the high costs of this test and so are making treatment decisions without all potentially available information,” Professor Mann said.

“Having access to funded tests would allow limited health resources to be directed towards those who will benefit most.”

Australian breast surgeon Miss Jane O’Brien said that while the test frequently helped identify those women who could avoid unnecessary chemotherapy, it was also able to identify those for whom chemotherapy should be recommended.

“Without Oncotype, some patients may face the prospect of being under-treated,” she said.

“I have had patients who have taken the test and been advised to proceed with chemotherapy, when perhaps medical oncologists would have been confident in recommending anti-hormone therapy alone, based on the standard criteria that we have historically used. I think it is a great pity this test is not widely funded for all appropriate Australian patients.”

The Oncotype DX breast cancer assay measures the expression of 21 cancer-related genes to provide a Recurrence Score® result, a number between 0 and 100.

A low Recurrence Score result is associated with a better prognosis and the likelihood that there would be little to no benefit in being treated with chemotherapy. Conversely, a high result would indicate a poorer prognosis, however chemotherapy is likely to be effective and reduce the risk of recurrence.

The Oncotype DX breast cancer assay is suitable for women diagnosed with hormone-receptor positive, HER-2 negative breast cancer. The test is performed on tumour tissue removed during original surgery and patients are advised to have the test soon after surgery and before commencing follow up treatment.

The Oncotype DX test was developed by Genomic Health, Inc. (NASDAQ: GHDX) a world leading provider of genomic-based diagnostic tests that optimise treatment

for early stage cancer. The company is based in California in the USA.
The Oncotype DX breast cancer assay is made available in Australia by international biopharmaceutical company Specialised Therapeutics Australia at a cost of $4,500.

Specialised Therapeutics' Chief Executive Officer Mr Carlo Montagner said he was dismayed and frustrated by the latest MSAC decision, which follows five funding applications for Oncotype DX in Australia.

"This simply means that Australian women continue to be at a disadvantage," he said. "This test is widely available and reimbursed for women in most developed countries, including the United States and the United Kingdom.

"It seems that in Australia, only the 'haves' of our society can benefit from this cutting edge technology. What a pity, in this age of personalised medicine and especially at a time when the Government has acknowledged a commitment to innovation. Our belief in this technology is validated by clinical data and the experience of doctors and patients from around the world. We are lagging behind."

Specialised Therapeutics Australia will now seek to meet with health department authorities to reconsider the funding application.

Ends.

About the Specialised Therapeutics Group

The Specialised Therapeutics (ST) group of companies collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases in Australia, New Zealand and throughout South East Asia. ST is committed to making new and novel therapies available to patients around the world, with a

broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Further information can be found at www.STAbiopharma.com

About Oncotype DX®

The Oncotype DX portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumour in order to optimise cancer treatment decisions. The company's flagship product, the Oncotype DX Breast Recurrence Score® test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. With more than 800,000 patients tested in more than 90 countries, the Oncotype DX tests have redefined personalised medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com or www.MyBreastCancerTreatment.org.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimise cancer care, including addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ® Genomic Intelligence Platform™, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of Oncotype DX® gene expression tests that have been used to guide treatment decisions for more than 800,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ® Liquid Select™ test. The company is based in Redwood City, California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.

Guest Blog: Rare Cancers Australia chief Richard Vines discusses cancer drug access

Our company has enjoyed a long-standing relationship with Rare Cancers Australia, supporting this organisation's ongoing endeavour to provide all cancer patients with timely and affordable access to new cancer therapies. We are proud to introduce guest blogger Richard Vines, the CEO and co-founder of RCA, as he passionately but simply explains the need for change and how it can be achieved.

IN MY OPINION

By Richard Vines, Chief Executive Officer and Co-Founder Rare Cancers Australia

Consider this: There are two brothers and both are diagnosed with cancer. One has a rare tumour and one is diagnosed with melanoma. Both go to the same oncologist and both are prescribed the same immunotherapy drug. One brother

walks out paying $30 a month because the drug is PBS listed for melanoma, while the other one needs to find $10,000 per month.

Does that pass the ‘pub test’? But this scenario gets worse. We know that when a drug is listed on the PBS, the PBS does not pay pharma companies the official retail price because they have huge buying power and they can negotiate the best financial deal. This is normal and acceptable commercial behaviour. The rare cancer patient has already contributed his tax to help the Government pay for that drug’s broad accessibility for more common cancers, like melanoma. But then, he has to go and pay full retail price. So, you can see, the inequity just builds and builds.

In my role as CEO of Rare Cancers Australia (RCA), this scenario for patients is heartbreaking, and it is not uncommon. The frustration is palpable, it’s ongoing and I am seeing this with our patients every day. There are 240 acknowledged ‘rare cancers’, impacting thousands of patients in Australia.

These patients inevitably reach a point where they run out of PBS funded treatment options. Then, the affordability factor means they have nowhere to turn, despite the fact that there are often life-saving, or life-extending, medicines available. These patients – tax-paying Australians – are looking at prohibitive costs, of perhaps $6 – 8,000 a month.

The PBS System is one designed to carefully steward taxpayer funds with strict guidelines for evidence and cost-effectiveness. But in reality, the level and quantity of evidence required by the PBS is not attainable for rare and super rare cancers. This means that medicines invariably struggle to get reimbursed for these small patient populations. We need realism and flexibility.

I was talking to a mesothelioma patient the other day. The drug that he wants, or will need as a next step in trying to survive, is going to cost him $10,000 per month. He is about 55 years old and he can trace his disease back to a time when he was working in a factory at about 19 or 20 years old. The possibility of him getting any legal compensation is minimal however, and he wants an immunotherapy drug. We can't get him enrolled in a trial, because the selection criteria is really tight, so what option is he left with? Nothing. Should he re-mortgage his house and leave his family with fewer funds to buy himself some extra time?

There are drugs that are already available in this country and I call these medicines the 'low hanging fruit' in this whole debate. These medicines have been approved by the TGA for at least one common cancer type so we know that they are safe (within reasonable bounds) and that the supply chain has been verified. We also know that they are effective in rare cancers. Let's find a way to use them, for this mesothelioma patient and all the others.

To fix this we need everyone at the table, not just the Government but also the pharmaceutical industry, the clinical community, public servants and of course, patients and patient advocacy groups like ours.

For a start, the Federal Government needs to take a pragmatic approach. It must acknowledge that it is not always going to have all the evidence it needs to list a medicine for rare indications – it's just not possible, given the size of the patient populations we are dealing with. We have seen, and applaud, instances where Government authorities demonstrate this kind of flexibility

Take the recent case of Vorinostat. This medicine was TGA approved in 2009 for the treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) with progressive, persistent or recurrent disease subsequent to prior systemic therapies.

A subsequent PBAC submission was rejected for this rare indication due to 'unacceptably high and uncertain cost-effectiveness ratios.'

Advising the knock-back, the PBAC noted that the quality of data within the submission was extremely limited, due to small study sizes and heterogeneous, non-comparative data.

In 2016, we (RCA) worked with the company involved to invest in an additional analysis that would support a high quality resubmission.

The PBAC showed its flexibility in assessing this submission (e.g. allowing comparison to palliative care for the cost effectiveness analysis) and then, following successful price negotiations, Vorinostat was finally PBS listed on 1 July 2017.

This was a great outcome and something we, at RCA, are very proud of. Now I believe we must continue seeking new ways of collecting both trial and real world data. To do this, clinical trials especially Government-funded investigator trials need to have broader and wider inclusion criteria.

We would particularly like to see an allowance made so that 10% of places on all clinical cancer trials are reserved for rare cancer patients. This would not cost much, and could be done in such a way as to not detrimentally affect the main trial outcome, should the rare indications produce lower quality results. Companies and universities could do this tomorrow. Clinical trials are the best, safest and smartest way for cancer patients to access new and experimental therapies.

Government and industry also need to look at how they can make small changes, to ensure it is commercially attractive for industry to go to the effort and expense of applying for drug listings for small populations.

In our recent 'Rare Solutions' report we called for the introduction of multi-indication submissions as a means of allowing companies to apply for rare indications at the same time as common ones – thereby saving some of the inevitable double up that happens when applying for the same drug multiple times. We were very encouraged that the Health Minister announced, at the launch of our report, that he has instructed the chair of the PBAC to begin looking at mechanisms for pan-tumour applications, but we all need to work hard together to make this a reality.

Pharmaceutical companies can't just sit there with medicines on the shelf that might help rare cancer patients and not try to make these drugs available. Companies need to be assertive and get on the front foot. If they have a drug listed for breast cancer, then anything they can add on to that is a bonus. I say to them, 'Do a bit of extra work and open up other indications so that more patients

can access the treatment'.

And oncologists need to get active and advocate. At the end of the day, they are the people who have to look a patient in the eye and say, 'I am sorry, there is a drug that can help you but it is going to cost you $10,000 a month'.

Speaking generally, medical professionals are not traditionally political creatures, but when it comes to rare cancers, they need to be. Sometimes these doctors may just need to ruffle a few feathers to get a good outcome for the people whose lives are in their hands.

At the end of the day, who gets to decide a patient's treatment? It should be a patient's oncologist, not an economist. It's time to act.

For more information, please go to www.rarecancers.org.au

Inspire: Living Life with Breast Cancer August 2017

See below Specialised Therapeutics' inaugural edition of Inspire, a magazine for women living with breast cancer. To view this publication, move your mouse over the image below and click on the Click to read button.

Corporate Support: ST Supports

the GI Cancer Institute

ST is a longstanding supporter of the GI Cancer Institute, which saves lives by funding important research into gastro-intestinal cancers, including pancreatic cancer. In a few days, medical oncologist Dr Lorraine Chantrill will walk the Larapinta Trail in the Northern Territory to raise new funds. In this short video, she explains her mission and motivation.

Please click on the following video link to view the video.

The Australian: 25 July, 2017

The Australian

By Sarah-Jane Tasker 25 July 2017

New Push for Brain Cancer Drug

Leading neurosurgeon Kate Drummond has called on the Turnbull government to break the “bureaucratic mould” and approve reimbursement of a drug that prolongs the life of Australian brain cancer patients.

The debate on access to the drug was reignited after US senator John McCain was diagnosed with an aggressive brain tumour.

Australian regulators earlier this year knocked back a request to reimburse the drug, Gliolan, which has just been approved in the US. The drug, used across Britain and Europe as standard care, “lights up” the brain tumour, which helps the surgeon to remove as much of it as possible.

More than 600 Australian patients a year could benefit from use of the drug in brain surgery but Dr Drummond, a neurosurgeon at Royal Melbourne Hospital, said because Gliolan’s definition sat between a drug and a surgical instrument it fell into a “grey area” for regulators.

“It shows that every so often something comes up that doesn’t fit the bureaucratic mould but if it’s good for patients the government should break that bureaucratic mould and get it sorted,” she said. “It is a simple thing, we know that people live longer if we remove as much of the tumour as is safely possible before a patient goes on to have radiation and chemotherapy. Anything that can help that is important.”

Dr Drummond said the price of the drug in the overall cost of a brain tumour operation was small given the greater outcome achieved. “There are several things we can do to improve a patient’s outcome but one of the things that has been proven to increase the amount of tumour that you remove is to use Gliolan,” she said.

“Some public hospitals are just wearing the cost and it is the private patients who are suffering, because if it’s not listed, most insurers won’t cover it.”

New Zealand started funding the brain tumour visualisation drug for its public hospitals from June 1 and the number of patients benefiting from the technology has already jumped. Denis Strangman, whose wife died in 2011 — 11 months after being diagnosed with a brain tumour — raised the issue of Gliolan at his recent appearance before the Senate committee into funding for cancers with low survival rates.

“I gave them verbal and written evidence on how it should be supported in Australia,” Mr Strangman, who founded the International Brain Tumour Alliance, said. He said he hoped the committee would make a recommendation, when it

reported in November, to have the drug reimbursed to allow it to be more widely used in Australia to increase the quality of life of a patient and give them more time.

“The US regulator recently approved the drug and I wouldn’t mind betting that if McCain has surgery, he has surgery using that drug,” Mr Strangman said.

Will I Require Chemotherapy?

Wendy Dunstone was diagnosed with early breast cancer and chose to have her tumour tested using the genomic test, Oncotype DX to guide decisions on her treatment.

59 year old Wendy was preparing to embark on the ‘trip of a lifetime’ when a routine breast screening revealed a hidden tumour. “I was feeling the healthiest I had ever felt, probably ever in my adult life,” she recalls. “Then I got a phone call from BreastScreen saying, ‘We want you to come back for another look’. And that’s how it all started really.” Wendy underwent a lumpectomy. Subsequent pathology results revealed a 12 mm tumour that had not spread to lymph glands. In addition, it was found to be hormone receptor positive “although perhaps not as strongly as we would hope”, her surgeon Miss Jane O’Brien remembers. Before treatment decisions were made, Wendy decided to proceed with the Oncotype DX breast cancer assay, which examined tumour tissue from the original surgical specimen. The following video outlines her experience.

To view Wendy’s story, please click on the following video link.

Living with Pancreatic Cancer

Linda Wilson is an Australian mother, wife, grandmother and nurse who was diagnosed with pancreatic cancer five years ago. She had surgery, but was devastated when her cancer recurred. While she was given just months to live, she has steadfastly refused to abandon hope. She says, “I don’t consider I am dying from pancreatic cancer, I consider I am living with pancreatic cancer.” This is her story.

Please click on the following video link to view Linda’s story.