

Herald Sun: 8 April, 2016

HERALD SUN (MELBOURNE)

By Carlo Montagner 8 April 2016

PBS Price Cuts Cruel Pharma Innovation

Earlier this week, pharmaceutical companies across the country received a substantial financial penalty, as the federal government's Pharmaceutical Benefits Scheme cost-saving agenda took effect.

Under this plan, expected to save the government around \$3.7 billion over the next five years, all branded medicines listed on the PBS for five years or more will be available to the government at 5 per cent less than the originally agreed reimbursed price.

While taxpayers will see a difference in the price of many high-volume generics under this plan, the 5 per cent price reduction to prescribed specialty branded medicines will not result in taxpayers seeing any difference at the pharmacy counter.

That's because a patient's co-payment will remain the same regardless of what the government pays for the specialty medicine.

This decision will affect dozens of branded medicines and almost every pharmaceutical company in Australia. A 5 per cent price cut might seem insignificant, but in reality it will potentially slash millions of dollars from some companies' bottom lines.

Australia's pharma industry invests over \$1 billion every year in health and medical research, exports billions in manufactured goods and indirectly employs around 20,000 Australians. But behind the scenes, and what many Australians don't realise, is that pharmaceutical companies are innovators, educators and

philanthropists. They consistently fund clinical trials of new drugs that may change lives, educate the medical community about new technologies and provide millions of dollars in financial support to health programs.

Pharmaceutical companies also frequently support extensive compassionate programs enabling patients access to specialty medicines — not yet approved or reimbursed on the PBS — that might otherwise be unaffordable or unavailable. Not every drug makes it to market. For every innovative therapy that changes lives, there are hundreds that fail — in some cases, after many millions of dollars have been spent by pharma companies in development. This is not a waste. Many a brilliant discovery was made on the back of supposed failures. The reality is innovation is risk-laden, and the financial investment required is not for the faint-hearted.

Everyone I have worked with at global pharmaceutical companies, from lab researchers to senior executives, is striving to make a difference. They constantly balance the need for commercial viability against a genuine drive to innovate and bring new life-saving medicines and technologies to their communities. So while positive for the federal Budget, these latest PBS cost-saving measures pose an unprecedented commercial challenge for innovator pharma companies.

The prices of many drugs in Australia were originally negotiated at levels that result in some of the lowest prices in the world. Further, the opportunity to increase prices once a drug has been listed on the PBS is virtually non-existent. We wear the costs of any manufacturing price rises or any significant currency devaluations from the time a drug is listed — unlike private health insurers, for example, who are accustomed to achieving increases in excess of CPI each year. It is vital the risk companies take on behalf of all patients is financially supported.

This is the first forced price cut introduced by the government — we don't know if it will be the last. If prices are further reduced, there is a real possibility pharma companies will remove some specialty branded medicines from the PBS because it will not be commercially viable given the current pricing.

If this happens, cutting edge, life-saving drug therapies currently listed and being used to treat Australian patients may become unavailable and future breakthrough treatments may never be brought to Australia.

There is little doubt PBS pricing changes will impact innovation. Pharma companies will simply not have the same commercial incentive to include Australian sites in global studies of new drugs and technologies. I was relieved and emboldened by the Prime Minister's Innovation Statement. However, the reality is that to remain competitive and progressive, the pharmaceutical industry must be incentivised to continue investing in Australia. I ask the government to remember its commitment to innovation.

From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win

THE AUSTRALIAN 

SARAH-JANE TASKER | THE AUSTRALIAN | MARCH 19, 2016 12:00AM

From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win



Bozena Zembrzuski and Carlo Montagner reflect on their decision to found Specialised Therapeutics and bring Abraxane to Australia. Picture: Aaron Francis

After years working for big pharma in the US, Carlo Montagner and Bozena Zembrzuski risked their life savings to bring a leading cancer drug to Australia.

The two, who met at university, sold everything almost eight years ago — share portfolios and investment properties — and lived in rented accommodation when they returned to Australia to start their own pharmaceutical company, Specialised Therapeutics.

Montagner, who became chief executive, says he and his wife — parents to three children — took a risk on the Melbourne start-up. The early days of the business were a stark reminder of these risks.

The first drug they wanted to bring into Australia, Abraxane, developed to treat breast cancer, was originally rejected by the Pharmaceutical Benefits Scheme — the system under which the government subsidises the cost of medicine.

“I called my wife after I was told the PBS had rejected it and her first words were ‘we’re — ruined’,” Montagner says.

“I said we weren’t because ‘it is too good a drug not to get through, so let’s play it

through’.”

The couple, like most Australians, have watched friends and family battle cancer. Montagner’s father died last September from mesothelioma and the oncology expert says that, given his role, he is often approached by friends and family for advice on the deadly disease.

“When I receive a call from a friend for advice, it’s usually not for financial advice, so I generally tense up,” he says.

“For most patients given cancer diagnosis, and I went through this myself with my father last year, it’s just mind numbing, you don’t know where to turn and there’s a lot of information out there,” Montagner says.

The privately owned company — Montagner has no interest in attracting third-party investors — generated more than \$35 million in revenue last year but he says it isn’t just about money.

“I’m very passionate about this. I really do believe that this (Abraxane) is the chemotherapy that all Australian women should receive.”

Bringing a drug to the Australian market is usually reserved for those with deep pockets and time on their side. Drugs have to be licensed, which involves significant testing to secure the right local approvals. The testing needs to be done regardless of a drug’s use or approval in other jurisdictions.

Montagner tells *The Weekend Australian* the original financial risk they took as a family was worth it because he had a strong belief in Abraxane, which he had launched in the US in his previous role as president of the drug’s developer, Abraxis Bioscience.

Prior to the introduction of that drug into Australia in 2009, Montagner said breast cancer patients were using older chemotherapies that had been around for 20 years.

He says that today, Abraxane is one of the leading therapies for metastatic breast cancer and pancreatic cancer. Since the drug became available in Australia, more than 10,000 cancer patients have been treated with Abraxane.

The drug, which is now owned by US pharma Celgene, has been approved for

distribution in about 50 countries, including the US, Europe, Japan and India.

Montagner says the early take-up of the drug in Australia had exceeded their expectations “several fold”.

“We got caught in the first 18 months never really having enough stock,” he says.

“I couldn’t believe how quickly it was being adopted. We put the manufacturing plant in Phoenix under pressure ... the plant once pulled out all stops, working 24-7 for a week to make a batch for Australia because we were selling so much of it.”

Zembrzuski says while the company was started with some trepidation, they took the view that if it didn’t work, they would simply get jobs again.

“We had a lot of faith in all the training and experience we’d built up in our previous roles in Australia and overseas,” she says.

The company co-founder, who previously worked for global drug giant Novartis, says it’s a different dynamic to have a married couple as the bosses, which she said had the potential to go terribly wrong.

“We were very aware right from the start that being married should not cause any confusion or stress to people,” she says.

“If this was going to be a credible and professional venture then that couldn’t happen.”

Zembrzuski jokes that she was worried if she could take direction from her husband given he had taken on the CEO role. She says she decided to treat him at work as she would any of her previous managers.

“We both have strong opinions, are both self-motivated and have always worked for other people, never together,” she says. “But we bring different strengths to the table and we do complement each other.”

The company was originally started because Montagner says it was difficult to get a role in Australia that matched the remuneration he was accustomed to in the US as the president of a Nasdaq-listed biotech. He and his wife are passionate about conveying that they don’t take the success of the company for granted.

“We feel very lucky that we are able to provide for the kids and are our own bosses,” Zembrzuski says.

Teaching their three children, aged 9, 12 and 14, about giving and not just taking is central to the values they want to pass on as parents.

Montagner says that before they went to the US, they were like most Australians and saw people who sprouted philanthropic endeavours as “show-offs”.

“Then we went to the US and there it’s in the DNA of all successful people. We saw that and we completely changed our view and bought into the concept that people who do well and have the opportunity to give back should give back,” he says.

“Plus, we both grew up in working class families that didn’t have the opportunities to do what we do now, so the last thing we want is our kids to grow up in a privileged household where they became too materialistic and focused on themselves than others in greater need.”

The family started its philanthropic efforts with a \$1m donation to the Olivia Newton-John cancer research centre based at Melbourne’s Austin Hospital. They have also donated \$US250,000 (\$328,000) to build a trade school in East Timor.

Zembrzuski adds they are a “proud” Australian-owned company and while they will always maintain their head office in Melbourne, part of being entrepreneurial was looking at new options.

They expanded into Southeast Asia last year with the distribution of a drug to treat myeloma, a type of blood cancer.

“We aim to bring drugs to Australia and South East Asia that fulfil unmet medical needs,” Montagner says.

“We say no to drugs that don’t provide a unique benefit because then it becomes a pure marketing exercise if it doesn’t and we’re not interested in that.”

The company was founded on oncology drugs but it is also targeting haematology, urology and supportive care.

The rapid growth of Specialised Therapeutics has put it on the radar of larger companies but Montagner says he has no plans to sell.

“I love the fact we’re in a position where we can help others with some of the wealth we are generating and I love coming to the office each day and doing what we do. I see Rupert Murdoch and Warren Buffett ... what I take from them is they love what they do, it’s not a job, it’s what you do every day.”

The Australian: 19 March, 2016

THE AUSTRALIAN

By Sarah-Jane Tasker 19 March 2016

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Channel 10 News: November 2015

The following story appeared on Channel 10 News nationally following a PBS listing. Click to view.



Channel 9 News: November 2015

The following story appeared on Channel 9 News nationally following a PBS listing. Click to view.



Channel 7 News: November 2015

The following story appeared on Channel 7 News nationally following a PBS listing. Click to view.



Channel 7 Adelaide: November 2014

The following story appeared on Channel 7 Adelaide November 2014. Click to

view.



ABC News 24: January 2014

The following story appeared on the ABC in July 2014 announcing a PBS listing.
Click to view.



Today Tonight Channel 7 Network: May 2012

The following story appeared on the Channel 7 Network's current affairs program Today Tonight in May, 2012. Click to view.



Herald Sun: 17 September, 2011

HERALD SUN (MELBOURNE)

By Lucie van den Berg 17 September 2011

Olivia Has a Million Reasons to Smile

Olivia Newton-John had one million reasons to be happy yesterday when a Melbourne family made an unprecedented donation to her cancer centre that opens in June. But their generosity reduced the singer to tears.

"I'm so touched this morning, it's very overwhelming," she said. "To give an amount of \$1 million is incredible."

Carlo Montagner and Bozena Zembrzuski are urging others to follow in their philanthropic footsteps.

Last week entrepreneur Dick Smith accused rich Aussies of failing to open their hearts and wallets. The pair, who are founders of a pharmaceutical company, said their donation was a personal contribution inspired by their exposure to the healthcare world, their experience living in the US – where philanthropy is more prevalent and the knowledge that cancer affects so many people.

"We understand that not everyone can give \$1 million, but we just hope that just as we have been inspired by the action of others, perhaps this donation might inspire you to do the same," they said. "In our lifetime there is a very real possibility that you will be touched by cancer, as we have."

Newton-John's life was turned upside down when she was diagnosed with breast cancer. She shared her story with brain-cancer patient Steve Symons yesterday in the day oncology ward where the 26-year-old is undergoing chemotherapy for a brain tumour called medulloblastoma. He took his Carlton beanie off for her. "No one takes their hat off for me," the fellow Blues supporter laughed.

To donate to the Olivia Newton-John Cancer and Wellness Centre, call (03) 9496 5753 or visit www.oliviaappeal.com.

