One man's mission to make prostate cancer fix open to all

Jill Margo *Health editor* Feb 4, 2022 – 3.17pm

When business leader Laurie Cox AO ran out of options to treat his advanced prostate cancer, fortune smiled on him. He was offered an experimental treatment that became life-extending.

That was four years ago, and this nuclear treatment is now changing the way metastatic prostate cancer is managed. Although it worked beautifully for him, not all men who need it can get it.



'I have never had to look at a brick wall. I've been the beneficiary of progressive medical success and regard myself as very lucky,' says Laurie Cox Arsineh Houspian

The wealthy can pay for it, but it is not yet funded by Medicare or state government hospitals, making access difficult and inequitable.

Cox, who divides his life between Melbourne and Sorrento on the Mornington Peninsula, is keen for Australia to seize a unique opportunity and make this treatment accessible at an affordable price.

It is unique because two similar, smart molecules are available for use in this treatment. One is on patent and has been dubbed <u>"the billion-dollar molecule"</u> because of the revenue it is expected to generate.

As the other is off patent, a government funding stream could make this generic widely available.

Cox, 83, is a <u>former chair of the ASX</u>, the Transurban Group, the Potter Warburg Group in Australia and the Murdoch Children's Research Institute. He was an active executive until 2012 and for the next six years, he sat on boards.

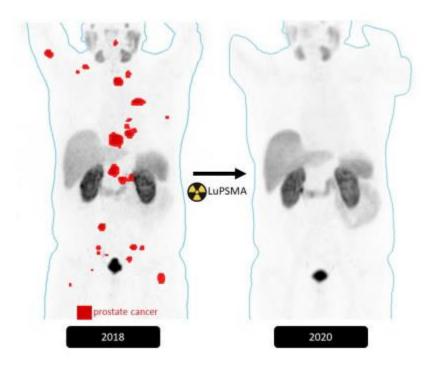
Today, he is still at his desk most days, running the family office, managing investments and doing some work for others – when he is not on the golf course.

"I've never made a song and dance about my condition, but I'm talking about it now, and I'm displaying my scans because this is an opportunity to get out in front, with a funding avenue to make this available to men who have no other options, and I'm hoping my experience might add something to the mix," Cox says.

He has spent 18 years managing his disease and as one treatment wore out, so another always appeared on the horizon.

"I have never had to look at a brick wall. I've been the beneficiary of progressive medical success and regard myself as very lucky.

"Yes, I'm aware of my cancer every day, but I keep looking forward, with confidence that those who look after me, will find the next thing I need."



Laurie Cox's PSMA PET scans before and after nuclear treatment showing complete disappearance of tumour metastases. Tumours recurred, and he had further successful treatment last year.

Treating the disease

Since his diagnosis in 2004, Cox has been through a robotic operation to remove his prostate, highdose focused radiation, and then 37 "shots" of other radiation. As an executive director of the Macquarie Group, he would take a tram to Epworth Hospital, have a shot and get the tram back.

"I'd be away from my desk for a couple of hours. I probably told somebody what was happening, but never made a formal disclosure because I was feeling fine."

Eventually, he outwore the usefulness of radiation and moved on to hormone therapy. A little later, another androgen medication was added.

When this drug combination was not enough to slow his cancer, he started chemotherapy. "It knocked the living daylights out of me and I only managed nine out of 10 cycles. It affected the nerves in my hands and feet and although it had some impact on my disease, it was not that much."

By 2018, he was in trouble again. His PSA (blood marker for prostate cancer) was rising and the cancer in his bones was painful. That is when the nuclear option appeared in Sydney.

So, every few months, he flew up to see Professor Louise Emmett, director of nuclear medicine at St Vincent's, who treated him on compassionate grounds, as an outpatient.

As all her trials were full, he had to pay the basic cost price for the generic molecule of \$5500 a cycle. The standard course is six cycles, although he would have more.

"We are still charging \$5500 per cycle at St Vincent's – but it is not a funding model we can continue long term. In private – it is \$10,000 per cycle," Emmett says.

Life-saving treatment

The treatment, called Lutetium-177 PSMA, or LuPSMA, does not work for everyone. Cox was never told, but without it, he would probably have had less than a year to live.

It took him into a new realm. Traditionally, drugs arrive at hospitals in cardboard boxes and are delivered into patients intravenously or orally. With nuclear medicine, they are "cooked-up" in radio-pharmacies within the hospitals, on the day they are needed.

As they develop, <u>nuclear treatments</u> are also driving the expansion of new-generation pharmacies in hospitals around the country.



'At one point, when his (Laurie's) PSA went right down, we waited almost a year for the next cycle, but COVID 19 intervened,' says professor Emmett. **Robert Catto**

LuPSMA treatment has two stages. First, a 3D whole body PET scan locates the cancer spread throughout the body. About 70 per cent of men are found suitable for treatment.

Next, the smart molecules are loaded with tiny nuclear warheads of lutetium 177. The molecules, known as PSMA, find the cancer cells and open their doors. Lutetium enters and destroys the cells from the inside.

Both PSMA molecules used in this treatment were developed in Germany. The patent to the "the billion-dollar" one is owned by pharmaceutical company Novartis.

The other was developed by academics who published it without seeking intellectual property protection. They released the molecule to the public and their generic product is now made up in hospital radio-pharmacies around the world.

Despite small differences, research shows they work equally well.



'LuPSMA would bring my PSA down to about zero, and it would lie there doggo for a while,' says Cox. Arsineh Houspian

Novartis has not applied for registration or funding for its agent in Australia yet, and because there is no big pharma to champion the generic, there is no funding to support it in a large clinical trial. In Australia, it is only used on compassionate grounds, as a last resort.

The only side effect Cox reports is a dry mouth at night, for which he takes medication. Like most men with prostate cancer, he watches his PSA levels carefully.

"LuPSMA would bring my PSA down to about zero, and it would lie there doggo for a while. Eventually, after a few months it would start to rise again, and I'd fly to Sydney for another cycle," Cox says.

"Louise used to get excited when she saw my cancer cells getting knocked off. There one minute, gone the next! But then, as I was enjoying such success, it wasn't working that well for two of my business associates who have since passed away."

Emmett says she can usually tell how well a man is likely to respond after the second cycle. "Laurie was having a really good response. At one point, when his PSA went right down, we waited almost a year for the next cycle, but COVID-19 intervened," Emmett says.

"He had his fifth cycle in 2020 and by the time he needed another, lockdowns and border closures made travel difficult. By then Melbourne's Peter MacCallum Cancer Centre was offering this as a clinical service and arrangements were made for him to be treated there."

Nuclear medicine physician-scientist, Professor Michael Hofman, who works closely with Emmett, took over. "Having completed <u>successful clinical trials</u>, we had this momentum and could open an off-trial access program at Peter Mac, at no costs to patients, thanks to philanthropic funding from the Prostate Cancer Foundation and the Peter Mac Foundation," Hofman says.

"The pandemic gave us a push because several men, who were responding well to treatment, had been travelling to Sydney and could no longer get there. There was a compelling need and Laurie became one of the first of patients to use the program.



'Over the past eight years, both agents have been used synchronously around the world and this is very unusual,' says Professor Hofman. Jesse Marlow

"Unable to access the Novartis agent, we used the generic. It was our first experience with it, and it was similar to the commercial product. Over the past eight years, both agents have been used synchronously around the world and this is very unusual.

"Globally, more men have probably been treated with the generic, so there's lots of experience with it, and we can use the evidence to cross pollinate."

Pricing signals

Hofman says the Novartis product is under review by the US Food and Drug Administration and approval is expected by July. There is no price yet, but there are signals.

In Switzerland, patients are not reimbursed and pay 21,000 Swiss Francs (\$32,000) a cycle. In the US, the price is expected to be even higher after FDA approval.

"Novartis is not bringing its agent to Australia in the short term and men can't wait until the company and government to come up with an agreeable price, particularly as we have an alternative," Hofman says.

"We are not opposed to synchronicity, but top prize is a funding stream for the generic, as soon as possible. This is urgent because hormone-resistant prostate cancer is lethal."

Both Hofman and Emmett describe Cox as an exceptional responder. After a cycle, his tumours disappeared completely, his pain went away, his scans became normal and his PSA sometimes was undetectable.

But eventually, all men progress. The cancer returns anywhere from a few to 18 months. "When it returns, we give another cycle," says Hofman, who will soon be giving Cox his ninth cycle.

Whenever Cox sees a clear scan, he reminds his doctors that the pressure is on them to keep achieving the same result.

Emmett says the Australian Association of Nuclear Medicine Specialists is advocating for better access and developing guidelines for the medical community, so it can be safely rolled out across the country.

The AANMS has also recommended the Australian Government urgently restore Medicare Benefits Schedule indexation for nuclear medicine after a 23-year freeze.

In its 2022-23 Pre-Budget Submission, the AANMS requested a government commitment to address the funding gap in nuclear medicine, to reduce out-of-pocket costs for consumers and ensure ongoing access to crucial nuclear medicine services.

President, Dr Geoff Schembri, says nuclear medicine is a crucial clinical tool that can both diagnose and treat a range of conditions including cancer, dementia, childhood illnesses, heart disease and thyroid disease.

"Australia is a recognised world leader in this field, but this is in jeopardy as inadequate funding undermines the speciality's ability to provide services and maintain important, ongoing research".