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Norman Swan: Welcome to an extended Health Report Special, with me, Norman Swan.

This program is about the cutting edge of high technology medicine: medical devices. Everything from artificial knees to intra-ocular lenses, to heart valves. There are thousands of medical devices on the market and their numbers and complexity grow each year. It's an immensely profitable business for companies whose worth can reach billions of dollars.

The story I'm about to tell you though, suggests that the regulation and monitoring of medical devices in Australia leaves a lot to be desired; that the organisation with the responsibility for devices, the Therapeutic Goods Administration, the TGA, the same one that had responsibility for Pan Pharmaceuticals, doesn't seem to have an adequate handle on what's going on and perhaps over-relies on what manufacturers tell them.

It's about how one woman's battle to discover what happened to her, which has cost her everything she owns, has uncovered information that arguably should have been discovered on her behalf by the TGA. It's an example of litigation which needn't have happened had the system worked properly.

It's a story where even though documented problems have been pointed out to the TGA, they've taken no action apart from correcting their records.

It's a story which also suggests complacency among surgeons who are under-reporting problems with devices.

I also warn you that this story is complicated, but that's often how authorities manage to escape accountability for their actions, or inactions.

Karen Carey Hazell is 42 and lives in Perth. She's a painter and sculptor and also runs a multimedia production unit.

Karen Carey Hazell: Probably started to get symptoms in my late teenage years, or my early 20s, and the symptoms were quite vague. A general weakness and fatigue, some breathlessness with exercise and then it progressed towards fainting.

Norman Swan: Karen's mitral valve wasn't working properly. It's called prolapse, and in most people it's harmless. In Karen though, it was more severe and tests suggested deterioration.

At one point, despite her cardiac history, Karen's problems with vision, and intermittent

weakness were misdiagnosed as multiple sclerosis.

Eventually she was told it was clots breaking off from her diseased valve. Now in her 30s, Karen's exercise capacity was falling. The option was valve repair but if that wasn't possible, the surgeon recommended a mechanical valve. Which is what happened. But it wasn't plain sailing.

Karen Carey Hazell: While I was in the hospital, I never got over the severe weakness; I was getting frequent dizziness with the room spinning that then resulted in vomiting. I found it very difficult to do the level of walking and things that you're supposed to do. So I guess I struggled to recover from the outset.

Norman Swan: The valve replacement surgery was in June 1996 and these symptoms, which were intermittent prior to surgery, now just didn't go away. And things didn't stay like that.

Karen Carey Hazell: No, the symptoms got much worse. In September of 1996, so three months after the surgery, I had an infarct to my left kidney. They said that a blood clot came from the heart valve and blocked the main artery into the kidney.

Norman Swan: Tell me the story.

Karen Carey Hazell: I just woke up one morning in incredible pain, it really, really hurt, and went into the hospital by ambulance. I was at home alone with my children, who were twin boys aged 7 at the time. So they called the ambulance for me. I was visited by a neurologist who explained to me that because I'd had the infarct into my kidney and spleen, essentially I was very lucky that those blood clots didn't go to the brain and cause a stroke. He explained that 25% of all blood that comes from the heart goes to the brain, so each time a clot goes off, you have a 25% chance that that clot will travel to the brain, and that he thought I was at significant risk of having another clot and then having a stroke, and that if I had a stroke that they would be assuming my care.

Norman Swan: How did you react to that?

Karen Carey Hazell: Well I didn't believe it. I guess I commented to the doctor at the time that being a blonde I wasn't using 25% of my blood flow to my brain, I was only using 12-1/2%, but I guess to put in context, the reason I didn't believe it is because I had cardiologists at the same time telling me that really the situation was under control, and the anticoagulation could be more readily controlled in the future.

Norman Swan: Karen was on an anti blood-clotting medication called Warfarin, which is essential if you have a mechanical heart valve. The records suggest her anti-coagulation level may have been low at that stage, something which was corrected.

But a few months later, the neurologist's warning was to be proved right.

Karen Carey Hazell: Yes, in March of 1997, so that was four months later, I woke up in the morning and showered and getting out of the shower found myself completely unstable. When I tried to walk, I wasn't able to direct the path that I was walking. I was very nauseous, vomiting, I had lost my co-ordination, I found it very difficult to use the phone, I was home alone, so it was quite difficult to dial the telephone to get assistance.

Norman Swan: And?

Karen Carey Hazell: And I went to hospital and the neurologist that I had met

previously took over my care and he diagnosed immediately the fact that there had been a stroke and it was definitely a clot coming off from the heart. Having a stroke was a huge shock to me, it sort of brought as a reality, the fact that I was life-threateningly ill and that if the situation didn't come under control, that there was a really good chance that I would die or have a catastrophic stroke.

Norman Swan: Karen had tests which ruled out that she had an inherent tendency to clot.

So here she was, wrongly diagnosed with multiple sclerosis, having a valve replacement which had made her worse, infarcted her kidney and spleen and risked her life with a stroke, after which she haemorrhaged because they'd added aspirin to her anti-coagulation, and then when you'd imagine things couldn't go downhill any more …

Karen Carey Hazell: In June of '97, three months after the first stroke, I was at my children's school, and actually had the stroke in the car park. I was collapsed for about 15 minutes before someone found me. I was then admitted by ambulance to hospital where they diagnosed another stroke and told me that definitely the valve would need to be removed.

Norman Swan: There is debate about whether this was an actual stroke or a transient ischaemic attack, a temporary stroke. Nonetheless, tests showed Karen had blocked some essential arteries to the back of the brain, so she was lucky not to have died or had a major disability.

This time there was no option. The mechanical valve had to be taken out and a pig tissue valve put in its place. This has less risk of clot formation. The replacement procedure was dangerous since there was clot on the original valve, but Karen came through.

Now the quest for answers began. And if nothing else, it shows how difficult and personally damaging this quest can be, creating needless resentment, anger and mistrust. All of which could have been prevented.

Now, I probably need to tell you a bit more about heart valves so you've clear picture.

The mitral valve sits on the left side of the heart between the upper pumping chamber and the lower one, that's the ventricle. The valve's purpose is to ensure that blood only flows forwards. And it does this by means of flaps, or leaflets. So when the ventricle contracts to push blood into the aorta, (that's the artery which carries blood around the body) the mitral valve's leaflets close together to form a seal to stop backflow.

Mechanical valves are made with a combination of metals and sophisticated materials to ensure durability and a smooth surface to avoid blood clots, thrombi, forming. When these clots do form, they can break off and embolise. That means they land in another organ, causing damage. That's what happened to Karen's kidney, spleen and brain. It's known as thrombo-embolism.

So let's go back to Sir Charles Gairdner Hospital in Perth in 1997. One of the cardiac surgeons at Karen's explant operation noticed there was excessive blood clot in the hinge mechanism of the removed valve. Karen's permission was sought to send the valve off for testing. She, like many people who've suffered a health care injury, wanted an explanation, so she approved, assuming an independent authority would do the job.

But that didn't happen. The valve was sent to the Australian distributor which sold the valve and which represented St Jude Medical, the US manufacturer. Karen tried to get

the valve back for independent testing and even used lawyers in the attempt. But the hospital told her they'd been informed it had already been sent back to the manufacturer in the United States. As you'll discover in a moment, unbeknownst to the hospital, the valve was still sitting in the Australian distributor's offices and was to do so for quite a few days.

Karen Carey Hazell: I still haven't been able to come to terms with the fact that the person that tests the valve is the party that has the largest vested interest. I would have thought that it needed to be tested by somebody independent. We were told that the valve wouldn't be returned, we were told that the manufacturer had an obligation under the Therapeutic Goods Act to have the valve properly tested and to report, and that that took precedence over my right to have the valve returned to me. That's not the truth. There is nothing in the Therapeutic Goods Act that removes the right of the owner of the valve to have the valve tested as they deem to be appropriate.

Norman Swan: Did you leave it there?

Karen Carey Hazell: I couldn't get the valve back and not only could I not get the valve back, but they indicated in writing that the testing of the valve is a destructive procedure. So it was likely that the valve was going to be destroyed by the testing procedure. So there was going to be nothing to get back. I later found out that the testing is not actually destructive, other than that the valve is dissembled. So the serial number that identifies the valve as being the one that was explanted from me, is imprinted under the sewing cuff of the valve, so when the valve is taken apart into its component parts, there's no way of demonstrating that each component was a component of the valve that was explanted from me.

Norman Swan: Because the serial numbers are not on all the different bits?

Karen Carey Hazell: That's right. There's only one serial number on one bit. So I took the view that there was little point in getting all of the components back in a box to have them tested, because we would never be able to tell whether or not they were actually the components that formed my valve.

Norman Swan: The correspondence indicates that the company wasn't prepared to report to Karen directly, only to her surgeon. The hospital gave Karen a copy of the company's report but she felt it wasn't accurate. For example, nowhere was the full extent of her complications mentioned, much less referred to as the reason for the valve having to be removed.

Karen Carey Hazell: So in producing a report on the testing of the valve that omitted the injuries that I suffered rang alarm bells in my head. The conclusion of the valve is that the cause of the thrombosis was unknown, and I felt that that wasn't an appropriate conclusion. The other main thing was that the surface of my valve had been viewed using ten times optical magnification. I mean I'm aware from studying High School biology as I'm sure other people are, that ten times optical magnification is a very low level of magnification to be looking at the mechanical surface of a valve where the issue is imperfections in the surface. There was one other matter where the report said that the testing had been conducted by an independent pathologist, and when I tried to contact that pathologist to ask him some questions about the testing, I was told by St Jude that he was their consultant and that if I had any questions, that I should address them to St Jude, and if they thought they were appropriate, they would pass them on to the pathologist.

Norman Swan: The situation was even more perplexing because after the operation, the

Head of Cardiothoracic Surgery at Sir Charles Gairdner Hospital in Perth had written a letter specifically asking the company to perform electron microscopy on the valve. Electron microscopy gives a finely detailed picture of the valve's surface. Yet it wasn't done and the valve was pronounced OK.

Karen started to wonder what was going on with the regulatory authorities, because she couldn't imagine she was the only person to have had a heart valve problem.

So she went to the Health Consumers Council of Western Australia for assistance. Its Executive Director was, and is, Michelle Kosky.

Michelle Kosky: Karen called in January 1998 about some events that had occurred to her.

Norman Swan: Now we should just declare a conflict of interest here.

Michelle Kosky: Of course.

Norman Swan: Karen has become the Chair of your Health Consumers Council, having been in a sense a supplicant to begin with.

Michelle Kosky: Karen has become a very important health advocate and health activist, absolutely.

Norman Swan: So carry on with the story.

Michelle Kosky: My first impression I suppose was of a very distressed young woman who'd undergone a catastrophic event in the health system, and I suppose for the Health Consumers Council it was an introduction to the whole world of medical and health devices.

Norman Swan: You hadn't dealt with that before?

Michelle Kosky: No, we hadn't had any issues, and it made me reflect that people are very ignorant about the processes that they can take to report such events to the appropriate authorities.

Norman Swan: So what was Karen asking of you?

Michelle Kosky: Well she didn't quite know how it all worked. She very rapidly learned, but she didn't really know that the Therapeutic Goods Administration regulated and monitored medical devices in Australia, and she just really didn't know about what her rights were in terms of access to information, and what actions she might take.

Norman Swan: The Health Consumers Council helped Karen with Freedom of Information requests to the TGA and another chapter of her story began to be revealed because there were more questions than answers in the TGA's documents.

One of the biggest was that the TGA had only one maybe two reports of valve problems relating to Karen's device on their files when from the published figures, with thousands of such valves implanted into Australians, there should have been hundreds just in the normal course of events.

You see, we're talking about mission critical devices which do occasionally go wrong just because of their artificial nature, although sometimes there can be defects which are

important to detect so manufacturers can improve their processes and doctors and patients be aware of any additional risks.

The international scientific literature suggests that each year someone has a mechanical valve in place there's between a 2% and 5% chance of thrombo-embolism each year, even with anti-coagulation.

A pig valve has a much lower risk.

So why would anyone choose a mechanical valve if you're looking down the barrel of up to a one in two chance of an event in ten years?

Professor Cliff Hughes, Head of Cardiothoracic Surgery at Royal Prince Alfred Hospital in Sydney.

Cliff Hughes: That's true. However, you need to put that in the background of the patient, that if they are left with their own valve, they are prone to even higher risks of those same complications. Most of the complications are minimised by the use of anti-coagulation, the drug we use at the moment is Warfarin, and with good control we can actually keep the incidence of complications down to about half a percent per year, and the majority of those are minor. But of course there is always the risk of a full blown stroke. But you have to balance that against the alternative, tissue valves, pig valves.

Norman Swan: And what are the problems there?

Cliff Hughes: Most of those patients can avoid having the anti-coagulant. But they wear out. Because they're a tissue valve and they're preserved, they fail, just like an old shoe when you keep bending it starts to crack, so the tissue valves can fail and there's about a 10% to 15% chance of that valve failing within about the same period of time, 10 to 15 years. And that can fail catastrophically and mean a very urgent operation under very difficult circumstances. So we are always balancing risks.

Norman Swan: And in someone like Karen's case where she would have to have a third operation?

Cliff Hughes: Well each time you have an operation the risks rise exponentially, that means they're greater between the second and third operation and they're even greater between the third and the fourth operation. It's technically more difficult to get back in because of the body's tendency to form adhesions.

Norman Swan: It's just after half past eight here on ABC Radio National and you're listening to an extended Health Report on whether the Therapeutic Goods Administration, the body responsible for our safety when it comes to medical devices, really has a handle on what's going on.

And you still have to ask why the TGA has only received one or two reports of problems when there should have been far more of this single make of heart valve, given its popularity.

Cliff Hughes for some years was also Chairman of the Device Evaluation Committee for the Therapeutic Goods Administration.

Cliff Hughes: Many of the problems that we see do not become apparent on pre-market evaluation because it's just not tested the way people use devices, just like motor cars on the Australian roads. So one of the important things is to have a post-market

surveillance as well as pre-market evaluation. So that if we start to see an increasing instance of problems, we recognise that early, and we can then investigate what could possibly be a critical incident.

Norman Swan: And that's the core of the story, it's post-marketing surveillance and whether we are actually doing that properly in Australia. There's only been one, perhaps two reports to the Therapeutic Goods Administration; how can that possibly be when up to 5% have a problem per annum. That means there must be hundreds of these valves out there that are having problems. We're not doing post-marketing surveillance properly in Australia.

Cliff Hughes: No, we're not. Post-market surveillance means that every device has a unique device identifier, that every patient that has a device implanted has that recorded on an electronic data base, and every time a problem is reported by a clinician or by a patient, that's also reported. Whenever a device is removed, that is automatically noted, and whenever a patient dies with a device in place, that is also automatically reported. Now that's an extensive electronic database which this country, in fact most countries in the world, don't have but desperately need. We do it for motor vehicles, we don't do it for heart valves.

Norman Swan: But why aren't cardiothoracic surgeons just doing the basic stuff, like they've got a problem, they report it to the TGA?

Cliff Hughes: Many people have had their valve in place and had a thrombo-embolic complication and if a surgeon sees that within his total experience of being say half a percent per year, then that's what he would expect.

Norman Swan: If a cardiothoracic surgeon has a patient with a clot, they're just assuming that the incidence is half to 1%, and they let it go through to the keeper. How is the public to be reassured there isn't a systematic problem with a valve and that everybody's just being overly complacent?

Cliff Hughes: Well firstly I think there are enormous numbers of studies which are admittedly isolated and institutional-based, looking at the performance of various valves. What we don't have is an automatic electronic continuous database which runs across all patients for all time.

Norman Swan: So what did Karen find out from her Freedom of Information requests from the TGA? Well, she found one document on their operating procedures which in effect told TGA officers that unless there was any reason to think otherwise, they had to rely on what manufacturers told them.

They also rely on manufacturers for most problem investigation although the TGA does reserve the right to examine devices itself.

Karen also got the reports sent by the valve's distributor to the TGA.

As far as we're able to ascertain, at no point did the distributor or St Jude Medical tell the TGA of the true nature of Karen's injuries. As a result the TGA only registered the event as a relatively minor incident and therefore presumably not worthy of intense attention.

The TGA only amended their records when Karen herself informed them of her injuries.

Another issue for Karen was that the patient information booklet from St Jude Medical,

which she was given after the operation, didn't mention the irreducible risk of thrombo-embolism. And while it told patients to seek medical care if there were problems with bleeding from the anti-coagulant, there were no such warnings about thrombo-embolism, an event with a significant chance of occurring. St Jude Medical claims the booklet isn't about risks, it's about lifestyle. Makes you wonder what could be more lifestyle limiting than a stroke and a dead kidney.

Karen felt there'd been sufficient gaps in St Jude's processes that they could be sued, but she didn't want to go down that track.

Karen Carey Hazell: Once it became obvious that there were some real patient safety issues, I felt very strongly that I wanted to use my case to see some improvement for other patients. One of the strategies that was available to me was to buy shares in St Jude, which gave me a different position in terms of being a shareholder rather than being a patient who had been injured. I then wrote to the directors of St Jude Medical, raising the issues that had been brought out into the open in relation to my case and the concerns that I had in relation to their procedures and the consequences in terms of patient safety. I told them that I was happy to provide all of my documents to them, I was quite happy to be very open about it, and I asked them to indicate that they would actually take some action in order to change the way that things were happening, and that that happen within a reasonable time frame.

Norman Swan: What, and you wouldn't take legal action?

Karen Carey Hazell: That's right. In the letter I said that provided they did that, that I would give up my right to legal action, because I didn't really want to be involved in a legal case, I just wanted to see that something was going to actually get better from what happened.

Norman Swan: And the reply from the directors of St Jude?

Karen Carey Hazell: Initially the reply was a great deal of silence, and then I received a letter from their lawyer saying that they were considering it, and then I received nothing more. So in the absence of any action, I commenced a legal action.

Norman Swan: The main reason for running this story on The Health Report is that the court case uncovered far more than anyone would otherwise have known, unless the TGA had done its own investigation. And it raises all sorts of issues about the TGA's relationship with manufacturers and distributors.

Both St Jude Medical and its Australian distributor knew of the full extent of Karen's injuries but, as I said before, it seems they never reported them to the TGA. In fact in September 1997 when St Jude Medical was closing their investigation, one of their officers wrote two documents on the same day. One was for internal consumption and the other for Karen's heart surgeon, a copy of which was sent by the distributor to the TGA as the final report. The internal document detailed Karen's injuries while the outside letter only told part of the story. The company says it assumed that her doctor would have known her problems so it was unnecessary to enumerate them.

Even so, there's a consistent pattern of minimising Karen's injuries when it comes to external communication.

Then there were the incident reports to the TGA from the sponsor, the company responsible for the valve in Australia, which at that time was its distributor, Getz Brothers.

Karen Carey Hazell.

Karen Carey Hazell: One of the purposes of the incident device reporting form is that the TGA get all of the information they need in order to conduct their investigation. In that form, the TGA asked whether or not the device is available for inspection, and the sponsor said that it was not available for inspection, that it had already been sent to St Jude Medical in America for testing. The form was dated 4th July, and I have information from the sponsor that shows that the valve was certainly with them until at least 21st July.

Norman Swan: In fact the valve almost certainly stayed in the distributor's office till 22nd July, the same day that another report was given to the TGA, again stating the valve had been sent back to America. In court, Getz Brothers said this was an oversight.

When the TGA asked Getz Brothers whether there was any previous experience of such incidents, the distributor answered No, when affidavits supplied to the court, while not specific, do suggest there have been many overseas, as you would have expected.

Karen's court case initially related to Failure to Warn about the risks of the valve, and in part focused on the patient information pamphlet.

Most litigation lawyers raise their eyes to the ceiling when they hear about Failure to Warn cases because they're notoriously hard for patients to win.

And sure enough, Karen lost with costs awarded against her. That was despite evidence from her expert witness, Dr Arthur Brandwood, which claimed that St Jude's Physician Reference Manual as presented in Australia at that time, was not up to date. This informs doctors about the risks of the product and presumably gives them background when they seek informed consent from their patients about a specific device. Dr Brandwood argued that around the time that edition of the manual was being prepared, there were about 29 papers which could have been included but weren't, some of which would have indicated a greater risk of thrombo-embolism.

The judge ruled this evidence wasn't relevant because doctors were aware of the risks, and didn't need such instruction.

But there was another part of the case. In June 2003, St Jude Medical informed Karen's lawyers that they had in fact carried out scanning electron microscopy on the valve, two years previously in 2001, and that it had found a chip on one of the valve leaflets near the hinge.

They claimed the defect hadn't been there when they examined the valve back in 1997.

As I said earlier, a surgeon who was present at the explant operation noted excessive clot in the hinges. St Jude's own pathologist didn't emphasise it quite that much but certainly noticed the clot around the hinges. He made no note of a chip, although if it had been present, it may have been hidden in the hinge.

Dr Brandwood, who specialises in device testing, also mentions a case where St Jude's pathologist had previously missed a chip under similar circumstances which had only been found later, also by electron microscopy.

To The Health Report's knowledge, neither St Jude Medical n or the distributor ever informed the TGA about this chip in Karen's valve. And we've no idea why it took

them two years to reveal it. The company claims it had no obligation to disclose the chip, given it was facing litigation.

No-one will ever really know what happened to this valve, whether the chip occurred post explant as argued by the company, or was there beforehand. Unfortunately a set of photographs taken by St Jude Medical prior to the electron microscopy didn't include a shot of this particular part of the valve. Dr Brandwood expressed surprise that they hadn't photographed all the surfaces in circumstances where the company knew there was to be litigation.

Even so, expert evidence, even by Karen's own expert, claimed that the original testing St Jude Medical had done in 1997 had been appropriate even though the scanning electron microscopy had not been performed then. Which may just mean that accepted testing standards aren't good enough when it comes to heart valves. St Jude Medical say they didn't follow the request of the Head of Cardiothoracic Surgery at Sir Charles Gairdner Hospital, when he asked them to perform electron microscopy, because St Jude was following its own protocols.

Karen also lost the part of the case concerning liability over the chip since the judge thought it more likely the chip occurred after the valve's removal.

We're not saying this type of valve is faulty or has a design flaw or anything that people who might have one in should be worried about. Because even if a chip had been proven to be present at the beginning, while St Jude may have been liable, it would have given them an opportunity to find out what might have gone wrong in manufacturing to ensure it didn't happen again.

It's the difference between pilot error and something fundamentally wrong with the aeroplane. And that's not what we're alleging.

The TGA knows all this now because Karen has informed them, but despite all these flaws in communication which led to no independent testing by the TGA, and an erroneous assumption that it wasn't a serious incident, they've taken no action against the distributor or the company.

Rita MacLachlan is Regulator for Medical Devices at the TGA. My first question to her was about their rules that TGA officers have to believe manufacturers unless they've good reason not to.

Rita MacLachlan: There is a level of trust here between the TGA and the sponsors and the manufacturers. The TGA can certainly undertake audits of Australian sponsors to ensure that they are complying with their conditions of registration.

Norman Swan: When was the last time you conducted such an audit?

Rita MacLachlan: Oh, those audits are conducted on an as-needs basis.

Norman Swan: So how many such audits have you completed?

Rita MacLachlan: Norman, I just can't give you that information at this point in time.

Norman Swan: In a situation where you know that 2%, 5%, 1%, whatever the figure is, of heart valves have thrombo-embolism, Getz said No, there's been no other experience of that, and they are representing the manufacturer as well. If you've got competent officers in the TGA, they would have known that was incorrect information. What

action did you take?

Rita MacLachlan: Norman, we depend on clinicians reporting adverse incidents to the company. If clinicians don't report those adverse incidents to the company, then the company is not able then to respond to the TGA. We have no jurisdiction over clinicians.

Norman Swan: So does that mean you're complacent about these thrombo-emboli?

Rita MacLachlan: No, the TGA is certainly not complacent about this.

Norman Swan: Did you check? It should have been surprising, given that your officer should have known the minimum rate of abnormalities, tens of thousands of valves have been put in, a lot of these particular valves have been put in around the world, they must have known there've been an irreducible number of problems with these valves and have nothing on Section 31 on a key form coming back to you, you're surely rather curious. I mean I have a handwritten note here with one of your officers, which has been discovered on Freedom of Information, saying TGA did not pick this up, this is embarrassing.

Rita MacLachlan: Norman, all I can say is that we depend on the integrity of the Australian sponsors. They are required legally to provide accurate information to us, and they in turn depend on information that is provided to them by clinicians.

Norman Swan: Well let's move on, because according to the information that again has been given to the TGA by Ms Carey Hazell, that all the material that went to you from the sponsor, suggested fairly minor problems in relation to the valve. You didn't ever receive from the sponsor a full description of Ms Carey Hazell's injuries, which are infarction to the kidney, infarction to the spleen, one definitely documented mid-brain stroke, and almost certainly a second one, and in fact it took Ms Carey Hazell to give you that information, and you had registered that as a temporary problem. Now isn't this a problem of information from the sponsor?

Rita MacLachlan: I can say that we're certainly disappointed in the information that was provided to us by the sponsor. However the information did come to us subsequently. We sought expert advice –

Norman Swan: But it was from the patient, not from the sponsor.

Rita MacLachlan: We have sought expert advice from the Chair of our Expert Committee, Professor Cliff Hughes at the time, and we then went in and we amended our analysis of the adverse incident report.

Norman Swan: What investigation did you do of the sponsor itself?

Rita MacLachlan: The investigations that we undertook concluded that there was no evidence to indicate the valve had malfunctioned.

Norman Swan: The issue is that you weren't given complete information by your sponsor, which suggests a flaw in your system. I mean what cross-checking do you currently and routinely perform on manufacturers and sponsors reports?

Rita MacLachlan: When we receive a serious adverse incident report, we get together a group of experts, first of all within the TGA. We will then go to the clinician that provided the report, if indeed a clinician provided the report, to seek extra information if

it's required. We then seek information from the company. Furthermore, we've established an expert sub-committee to look into all the adverse incident reports that the TGA receives, and this sub-committee meets every six weeks.

Norman Swan: But in this case the company had told you that the valve had been sent to America, so on your very first notification, you were told the valve had gone back to America, yet the valve was still in Australia for another two or three weeks, and you were told a second time when in fact the valve was only sent that day. Doesn't this indicate a problem that you could have had access to this valve if you'd wanted it? I mean do you ever examine these things yourselves?

Rita MacLachlan: Yes we do, Norman.

Norman Swan: And doesn't it concern you that this opportunity was denied you?

Rita MacLachlan: In this particular case, I certainly agree with you. We were advised that the valve was not available, that it had been sent back to the manufacturer, and subsequently we have learnt that this was not the case. That causes us a great level of concern.

Norman Swan: So what have you done about it with the sponsor?

Rita MacLachlan: Since that time, as soon as we are aware that there has been a particular problem with a heart valve, we are requesting that those heart valves come to the TGA.

Norman Swan: And yet we've had proposals on the table now for many years for a national tracking system for devices, and it's still not happened. Why?

Rita MacLachlan: The reason is, Norman, that to have a national tracking system, is outside of the powers of the TGA.

Norman Swan: But it's still not happened.

Rita MacLachlan: A lot is though happening, Norman. The Australian Council on Safety and Quality in Health Care has established a working group chaired by Professor Hughes, to look into how such a system would be put in place.

Norman Swan: Going back to this particular case, and it's an issue for the Therapeutic Goods Administration because you're responsible for safety, given that physicians and surgeons would rely on the information given by the company to doctors for informed consent, are you concerned that the company's physician reference manual at the date of Karen Carey Hazell's operation, did not have up-to-date information on risks?

Rita MacLachlan: I think that that is a cause for concern.

Norman Swan: Rita MacLachlan, the Regulator for Medical Devices in the Therapeutic Goods Administration.

Now, well-placed sources have told me that the laboratory division of the TGA has not been a happy place at times, and that's where the organisation does its own testing of medical devices.

I'm told that the TGA building in Canberra was designed for about 200 laboratory staff but I understand it's never held that many. I've been told, again by a well placed source,

that one of the key labs for device testing, the biomaterials lab, lost nearly half its staff in the late '90s, from 23 to 12. The TGA disagrees with these figures and denies that the numbers fell. My source confirmed the figures and was even prepared to give me names.

Is the TGA resourced enough for post marketing testing of problem devices? Rita MacLachlan again.

Rita MacLachlan: I'd be very confident that the TGA's resources in post-market surveillance in the laboratory are adequate for the TGA's post-marketing responsibilities.

Norman Swan: But I keep on getting told that the TGA just doesn't have the resources to do independent testing. If all these valves were reported, you wouldn't be able to cope.

Rita MacLachlan: I actually disagree. The TGA is perhaps the only regulator, key regulator, in the world that actually utilises its laboratories for adverse incident reporting.

Norman Swan: I understand that the TGA's income is very dependent on full fee recovery from sponsors and manufacturers. Doesn't that compromise your independence?

Rita MacLachlan: No, it certainly does not compromise our independence at all. If you look at what is happening with regulators around the world, all of them are moving to cost recovery operations.

Norman Swan: It doesn't mean that it's problem free though.

Rita MacLachlan: If you'd benchmark the TGA as an effective regulator, we come out right there at the top.

Norman Swan: But here is one case where you did not get the information that was accurate from the sponsor, and you seem to have taken no action.

Rita MacLachlan: In this particular case, Norman, our review and the expert advice that we obtained was that the appropriate actions had occurred.

Norman Swan: So were you ever informed there was a chip?

Rita MacLachlan: That information I've been provided with just, I think, within the last month or so, is information that was not provided to the TGA before, but I am advised that that information came from a laboratory analysis that was done by an independent person far more recently, and in preparation I think for this particular court case.

Norman Swan: No, it was done by a St Jude scientist and their internal scanning electron microscopy.

Rita MacLachlan: Certainly the information that we were provided by St Jude indicated that the appropriate checks had been made.

Norman Swan: We've got no national tracking scheme. How do we know there isn't a Pan Pharmaceuticals lurking here in the medical device industry somewhere? And these devices are much more mission critical than a jar of vitamin C.

Rita MacLachlan: The regulatory controls that are in place for high risk medical devices are commensurate with the controls that are in place worldwide. From our point of view, Norman, the outcome with the investigation with Karen Carey Hazell would have been the same.

Norman Swan: With all due respect, the outcome may not have been the same because a chip was discovered when eventually they did scanning electron microscopy, and no-one will ever know whether that chip was there at the beginning or it happened afterwards. If you had studied it and done scanning electron microscopy, the answer to that question might be known. And that would have helped St Jude in its manufacturing processes and it would have helped Karen Carey Hazell understand what was wrong with her valve, if indeed there was anything wrong.

Rita MacLachlan: The scanning electron microscopy was done at 11 times magnification, and the electron microscope at 11 times wouldn't have been any different to what had been found in the original observation.

Norman Swan: I'm sorry I don't understand you. Are you saying that their scanning electron microscopy was the same as optical?

Rita MacLachlan: I'm not saying that scanning electron microscopy is the same as optical, no, I'm certainly not.

Norman Swan: Nonetheless their scanning electron microscopy –

Rita MacLachlan: Look, I've got to say that for Karen Carey Hazell this has been a particularly tragic case, and I can certainly understand all the anguish that she has gone through, but from our point of view, the investigation followed the procedures that we had in place and we closed the actual incident report believing that nothing else could have been done.

Norman Swan: It's just that the average person listening to this, hearing you say this, thinks well you understand that in this situation of Karen Carey Hazell there are certain imponderables that you just don't know the answer to. But on several occasions the TGA has been given the wrong information by the sponsor or the company and OK, the outcome might not have been any different but the process was very wrong, and you're sounding quite relaxed about that.

Rita MacLachlan: I don't believe that the process was wrong. The heart valve was sent back to the manufacturer, the manufacturer undertook their analysis, they provided the evidence of that to us. We sought expert advice, the TGA did everything in its power to ensure that the investigation was closed out in the appropriate manner.

Norman Swan: Rita MacLachlan, the Regulator for Medical Devices in the Therapeutic Goods Administration. I did ask for an interview with the head of the TGA, Terry Slater, but was told he doesn't do interviews.

And here's cardiothoracic surgeon, Professor Cliff Hughes, and former Chair of one of their key committees.

Cliff Hughes: We can expect that all valves, all mechanical devices, whatever they are, are going to have a failure at some stage. There is no motor car that was built in 1911 that still runs reliably. So we need to expect that they will fail and therefore we need to monitor when they're about to fail, so we can offer our patients the best possible advice.

And that means a concerted, uniform database, which I think is quite possible electronically. We can do it using HIC data, we can do it using current medical record data that is used for ordering valves from the suppliers to hospitals and the like. It is possible to do.

Norman Swan: Given that you've been part of the TGA system, what's your view of what I think to the average listener would seem extraordinary. The Therapeutic Goods Administration in charge, this is the body that looked after Pan Pharmaceuticals, in the devices area, trusts the account of the manufacturer. So if something goes wrong, they seem quite happy for it to go to the manufacturer and to trust what the manufacturer says. There is no independent testing unless it's under extremely unusual circumstances.

Cliff Hughes: Yes, I think firstly that we are limited in the resources who can do the testing in this country. Of course relying on the manufacturer or the sponsor always raises a question of a conflict of interest, and the important thing is to have an audit process that shows that whatever is done to that particular valve is transparent, recorded and reported, and they're techniques I think that have to be developed between industry and regulators around the world.

Norman Swan: Do you think it's adequate at the moment?

Cliff Hughes: No, I don't. If we look at the airline industry whenever there's a plane crash there are a combined number of investigators which include the airline manufacturers, Boeing are often first on the scene, because they've got the expertise and they know their device. And they also want to know before anyone else does, why the device failed. I think it's true of manufacturers, they also want to know first. But we need to be assured that what they're doing is open and transparent and we're getting the right information.

Norman Swan: Karen Carey Hazell meanwhile owes hundreds of thousands of dollars in legal debts and costs and may well end up bankrupted. She's lost her family home, for what? To have uncovered what should have been known to the TGA. If the directors of St Jude Medical had taken her seriously and spoken to her about her concerns, they and she would probably have been spared a drawn out court case. However, the company claims that the course of events made a court case the only sensible option.

If you read the judgment, the judge seems to have taken the view that Karen has been almost vexatious in her pursuit of this case.

I asked Michelle Kosky of the Health Consumers Council whether that's the kind of person Karen, her Chair, is.

Michelle Kosky: No, it's interesting, isn't it, I see someone that's very at ease with herself in the world, not at all by nature vexatious or difficult, who has the courage to get up in conferences and talk about her experience and not be critical of the medical profession, but to remind us of our obligations to patients. I see someone that works hard, attends a lot of meetings, participates actively. So I see someone entirely different. That has been my experience of Karen.

Karen Carey Hazell: I became I guess, a consumer representative because it was quite shocking to me to realise that there were no good systems in place to ensure that what we get is what we expect to get. I guess I was one of the blind masses that go along believing that the health care system is probably one of the best in the world and that because we're in a country like Australia, we get the best of products and that everything is above board. It's been quite terrifying to have gone through this process

and have my blind sense of confidence undermined to such a degree where you feel that you probably need to go out there and actually do something about it. So I'm a consumer representative across several committees.

Norman Swan: What have you been told about your future?

Karen Carey Hazell: I will definitely need to have the tissue valve replaced. At that stage I'll be facing the third open heart surgery, and statistically a third open heart surgery has a mortality rate of 50%.

Norman Swan: Five-zero?

Karen Carey Hazell: Yes, five-zero. So it's going to be a 50-50 of whether or not I can make it through the surgery. That is made more dangerous by the fact that I have to remain anti-coagulated going into the surgery and always I have the issue of compromise blood flow to my brain, that there's always the risk of stroke.

Norman Swan: Karen Carey Hazell. We did ask for interviews with the distributor and St Jude Medical, but were declined, although some written answers were provided.

This has been The Health Report. I'm Norman Swan.

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