REPORT ON PROCEEDINGS BEFORE

PORTFOLIO COMMITTEE NO. 2 - HEALTH

USE OF PRIMATES AND OTHER ANIMALS IN MEDICAL RESEARCH IN NEW SOUTH WALES

CORRECTED

At Jubilee Room, Parliament House, Sydney on Tuesday 28 June 2022

The Committee met at 9:30.

PRESENT

The Hon. Greg Donnelly (Chair)

The Hon. Lou Amato

The Hon. Wes Fang

The Hon. Emma Hurst (Deputy Chair)

PRESENT VIA VIDEOCONFERENCE

Ms Abigail Boyd

The Hon. Chris Rath

* Please note:

[inaudible] is used when audio words cannot be deciphered
[audio malfunction] is used when words are lost due to a technical malfunction
[disorder] is used when members or witnesses speak over one another.

CORRECTED

The CHAIR: Welcome to the final hearing of the inquiry into the use of primates and other animals in medical research in New South Wales. I acknowledge the Gadigal people of the Eora nation, who are the traditional custodians of the land on which we are meeting today. I pay respect to Elders past, present and emerging. I also acknowledge and pay respect to any Aboriginal or Torres Strait Islander people joining us. Today we will hear from a number of stakeholders with an important perspective to share on the use of primates and other animals in medical research. I thank the witnesses for making the time to give their evidence to this inquiry. While we have many witnesses in person, some will be appearing via videoconference today. I ask for everyone's patience through any technical difficulties that we may encounter. I confirm that two members of the Committee will also be joining us remotely today over the internet. If participants lose their internet connection and are disconnected from the hearing, they are asked to rejoin the hearing by using the same link that has been provided by the Committee secretariat.

Before we commence I will make some brief comments about procedures. Today's hearing is being broadcast live via the Parliament's website. A transcript of today's hearing will be placed on the Committee's website when it becomes available. In accordance with the broadcasting guidelines, media representatives are reminded that they must take responsibility for what they publish about the Committee's proceedings. While parliamentary privilege applies to witnesses giving evidence today, it does not apply to what witnesses say outside of their evidence at the hearing. I therefore urge witnesses to be careful about any comments they may make to the media or to others after they complete their evidence.

Committee hearings are not a forum for people to make adverse reflections about others under the protection of parliamentary privilege. In that regard, it is important that witnesses focus on the issues raised by the inquiry terms of reference and avoid naming individuals unnecessarily. All witnesses have a right to procedural fairness according to the procedural fairness resolution adopted by the House in 2018. If witnesses are unable to answer a question and want more time to respond, they can take a question on notice. Written answers to questions taken on notice are to be provided within 21 days. The Committee may ask supplementary questions in writing after the hearing. Written answers to supplementary questions are to be provided within 21 days. If witnesses present in the room wish to hand up documents, they should do so through the Committee staff.

For those participating in today's hearing via videoconference, I ask them to state their name before they commence speaking, to speak directly into the microphone and to mute their microphones when they are not speaking. To aid the audibility of this hearing, I remind both Committee members and witnesses to speak directly into the microphones. Finally, would everyone please turn their mobile phones to silent for the duration of the hearing.

CORRECTED

Mr TROY SEIDLE, Vice-President, Research and Toxicology, Humane Society International, before the Committee via videoconference, affirmed and examined

Dr ROSEMARY ELLIOTT, President, Sentient, The Veterinary Institute for Animal Ethics, sworn and examined

Dr KATHERINE van EKERT, Vice-President, Sentient, The Veterinary Institute for Animal Ethics, affirmed and examined

The CHAIR: I welcome our first group of witnesses for our initial session. Mr Seidle, for our clarification, what part of the world are you joining us from?

TROY SEIDLE: I am in Toronto, Canada.

The CHAIR: Welcome. We are looking forward to your evidence. We know that you are all very busy and we appreciate you carving out some time to make yourselves available today. I invite the two organisations represented to make an opening statement. Mr Seidle, would you like to make an opening statement?

TROY SEIDLE: Good morning. Thank you to the Committee for the opportunity to provide feedback to this inquiry. I work for animals in science in Toronto, Canada, which sits in the traditional territory of many First Nations. While I am not in a position to speak to the situation for animals in laboratories in New South Wales specifically, I would be happy to address the Committee's questions from a more global perspective based on my nearly 30 years of experience in this field. It has been my pleasure to work alongside scientists, companies, regulators, policymakers and others for nearly three decades who share the view that a paradigm shift is needed in health research, safety science and education—a shift that positions human biology as the gold standard and prioritises funding and uptake of human-relevant, non-animal approaches.

The goal of medical research is to study and develop treatments for disease in humans, not in primates, dogs, mice or other animals. The same is true for the safety and efficacy assessment of new drugs, chemicals and other regulated products, aside from veterinary medicines. Yet when we look at the testing requirements enshrined in product safety regulations across the globe, and where so many of our health research dollars are invested, we see a nearly century-old paradigm that treats humans as 70-kilogram rodents. The Committee has previously heard that nearly 95 per cent of drugs entering human trials will fail and that the major causes of this failure are lack of effectiveness and poor safety profiles that were not predicted in animal tests.

How do we solve this problem? Throughout my career, I have served on a number of committees charged with the oversight of animal experiments and the promotion of the three-R principle of reduction, refinement and replacement of animals in laboratories. I have observed that these regulations often do little to advance the goal of full replacement, and this is evidenced by the steady increase in animal use in many countries around the world. In my view, policymakers can help by establishing new systems of accountability for publicly funded health research. They can require research funding bodies to objectively assess the human relevance and the likelihood of translational success of all proposed research; to reject and defund failing animal models; and, ultimately, to redirect this funding towards modern human biology-based approaches that have a greater likelihood of success. I am hopeful that this inquiry can be the beginning of the shift in paradigm for humans and animals alike.

The CHAIR: Thank you very much, Mr Seidle. I now move to the representatives from Sentient. As president, I assume that Dr Elliott will be making the opening statement? Thank you. If at this point you could unmute, that would be good.

ROSEMARY ELLIOTT: The nature of medical research conducted on non-human animals in New South Wales is shrouded in secrecy. What is actually done to these animals, and what is their fate? How many are bred and how many die or are killed, and how many are rehomed? During the first two days of public hearings for this inquiry, we have heard a lot of whitewashing phrases such as "highly regulated" and "compliant with standards" and the rigour of the Animals Ethics Committee process has been invoked. This shows remarkable confidence in a system that is stacked so far in favour of research that if a committee member has strong objections, they will be powerless to prevent the research being approved.

Given the mandatory confidentiality clauses, nobody will be any the wiser until one day someone questions how blatant cruelty, such as forced swim tests for up to 90 minutes, was ever allowed to proceed. This alarming lack of transparency extends to the crucial question of how effective is medical research using animals. The inquiry has heard evidence from researchers, chairs of various panels and animal welfare officers who have all assured us that using animals has produced life-saving vaccines and treatments that could not have been achieved without animal testing and most likely never will be.

The irony here given that we are talking about science is that this evidence has been based on opinion rather than scientific scrutiny. When medical research on animals is subjected to independent systematic reviews, regarded as the gold standard in evidence-based medicine, we see a very different picture—animal research is poorly predictive of human outcomes, unreliable and difficult to reproduce. This is due to a common pattern of methodological flaws, the effects of the laboratory environment and other variables on study outcomes, disparities between animal models of disease and human diseases, and inter-species differences in genetics and physiology.

These causes have not been amenable to change, and this explains the long history of research failures, including misleading safety studies even with the use of non-human primates. There is also the potential abandonment of effective therapeutics. Both are harmful to humans, as is the failure to develop more effective human-based research methods. Needless to say, the harms to research animals are profound. These animals suffer due to confined and often barren housing, the inability to express natural behaviours, exposure to noise and other stressors, regular handling and invasive procedures such as orogastric gavaging, and pain and distress from the infliction of injury such as spinal cord damage, burns or exposure to toxins or from debilitating genetic conditions or other conditions that have been induced, often with grotesque results. The end point for many is premature death, and the means of killing usually involves highly aversive CO2 inhalation.

A laboratory animal's experience is one of perpetual fear, vigilance, breathlessness, pain, nausea, hunger, discomfort, exhaustion, boredom, helplessness, frustration, terror, confusion and despair. This is hardly a life worth living. It is in the public interest to know this. The false dichotomy that it's either animal welfare or human health is an ongoing theme. This must be challenged because it silences debate around the real issue, which is that the suffering and needless death of sentient beings and the squandering of public funding to support this cannot be justified. Meanwhile, internationally, a cultural change in the scientific community is taking place. The US is set to end the FDA requirement for animal testing of new drugs. In 2021 the European Parliament voted overwhelmingly in favour of a resolution to phase out animal research in medical testing. The UK and some EU member states have national centres for the three Rs. The matter for us to address here is how Australian researchers can meet them in this movement.

The CHAIR: Thank you very much, Doctor. We are going to manually mute you at this end to stop the feedback occurring, which is disruptive. When it comes to you wanting to respond to a question, please put your hand up, if that would be agreeable to you, and we will unmute you. Thank you for those two opening statements. We will now move to questioning from Committee members.

The Hon. EMMA HURST: I'll start with Mr Seidle. You were talking a bit about this paradigm shift. I wondered, given that you are international, whether you have seen initiatives overseas that are actually working to replace the use of animals in experimentation.

TROY SEIDLE: Great question. Thank you. There are a number of initiatives that I could point to. In the interest of time, in the regulatory space I will speak to the OECD test guidelines program, which has developed a number of testing methods that are internationally harmonised. All of the countries around the OECD table have agreed regarding the scientific validity, meaning the relevance and reliability for a regulatory purpose, and these guidelines are used extensively in the chemical, cosmetic, pesticide, biocide and food sectors. We are seeing particularly what we will call the easy end points—skin and eye irritations, skin allergy—are largely fully replaced now, scientifically. We do still see a barrier in terms of the regulations in each of those sectors and in each of the countries around the world not being necessarily up to date with the state of the art, and that is—it partially answers your question in that the tools are available and the initiatives are there. There is a regulatory block.

What we are also seeing in the medical research area is the other scenario where it's not a regulation that says one must use animals to study cancer, for instance. It's simply an issue of the research funding. There are a number of substantial funding initiatives that we have seen, for instance, in the United States. The National Institutes of Health, the defence advanced product research agency, and the Food and Drug Administration have compiled substantial money for organ-on-a-chip development to look at safety testing as well as disease modelling. That is as simple as move the money away from what isn't working towards something that has a greater promise. That is where the lion's share of animals and laboratories are used. It's in the research space rather than testing. Tremendous power, as I said, lies in the hands of research funding agencies.

The Hon. EMMA HURST: I will move to both doctors from Sentient, Dr Elliott and Dr van Ekert. You are quite critical of—well, not critical of the animal ethics committees but the process of it. We have heard quite a bit of evidence in this inquiry.

We have heard complaints from animal care staff who say that there's no-one for them to complain to because each body is part of the animal research institution. We have also heard huge variabilities between animal ethics committees, where some will approve forced swim tests and others have ruled not to approve any of those experiments. Can I hear a little bit more about whether you think that animal ethics committee process is working

as it should be and what recommendations you think this Committee should be putting forward to fix the way the system is or isn't working?

KATHERINE van EKERT: I will answer because, Dr Elliott, I can't see your face. We do not think that animal ethics committees are working as well as they should. It's our understanding that they were set up to better bridge the gap between the public's interest in animal welfare and their interest in research and what's actually taking place. Unfortunately, though, that does not appear to be stacking up as planned. Despite the categories of animal ethics committees, it is still heavily stacked in favour of animal research. Just to clarify, you've got a veterinarian, you've got a researcher, you've got a general member of the public and you've got a member of the public with a vested interest in animal welfare.

I think it's fair to say that veterinarians involved in these animal ethics committees do, as we said in our submission, have a vested interest in the continuation of animal research, just by virtue of the fact that they're employed in that industry. It's just the nature of working within workplaces: You adopt a culture, and then you're generally in support of what's going on. Although, of course, they want to see animal welfare be maintained, we've also heard evidence that there are cases where a veterinarian's advice is overruled by the interests of the leading researchers. That in itself is concerning.

There's also a power imbalance. Think of a member of the public and an animal welfare person—a layperson, as it were—up against people who can be fairly intimidating: veterinarians with "doctor" in their name and researchers, who can also be intimidating people. These are powerful people in institutions. I would also offer the idea that there's probably a bit of a screening function too. Let's say you have a concern about the wellbeing of animals, you're working on these animal welfare committees and you're not finding that your voice is being adequately recognised. You're probably not going to choose to continue working there for too much longer. It's our opinion that they're heavily stacked in favour of animal research.

ROSEMARY ELLIOTT: Am I back?

The Hon. EMMA HURST: Yes. You're back, Dr Elliott.

ROSEMARY ELLIOTT: I was cut out of the meeting. I heard the beginning of what Dr van Ekert said. I agree with all of that. If she hasn't said it already, the institutional animal care and ethics committees are really a form of self-regulation, so they need to somehow be removed from the actual institutes that are doing the research. I feel that there's not enough separation. We also object to the mandatory confidentiality clauses that ethics committee members need. Can people hear me? I can't see myself.

The Hon. EMMA HURST: We can hear you.

The CHAIR: We can hear you.

ROSEMARY ELLIOTT: You can hear me. Can you see me?

The CHAIR: No.

The Hon. EMMA HURST: Yes.

The CHAIR: Yes and no. But keep talking.

ROSEMARY ELLIOTT: The mandatory confidentiality clauses are a big problem. We believe that there should be complete transparency to the public in terms of all ethics committee applications for the use of animals in medical research—all actions taken, complaints, the resolution of complaints et cetera. It feels like a very closed shop. We did hear evidence in the first two days of the hearings about things that were supported by animal ethics—the process itself is difficult. Although the process is similar to that of human ethics committees, where you need to reach a consensus and then, if not, a majority vote, I would argue that this doesn't really work with animals because when we look at the extreme treatment of animals in medical research—if one person objects to something like a forced swim test of 90 minutes, I think it shouldn't happen. But that person can be overridden. I'm concerned about the application of the process to the use of animals.

Ms ABIGAIL BOYD: Good morning. Thank you very much for appearing. I wanted to touch on something that came up in the first couple of days of hearings around there being a cultural problem within research institutions in relation to the use of animals in research. Firstly, do you agree that there is a cultural problem in terms of the attitude towards the use of animals in medical research? And does it differ, in your view, in Australia or New South Wales to other jurisdictions, such as the US and Europe? I will start with Mr Seidle.

TROY SEIDLE: I would say there's a lot of cognitive dissonance within this space. If we compare animal ethics to human research ethics, ideas like informed consent are treated as sacrosanct when we are dealing with human research and they go right out the window when we're talking about animal research. It's not a level

playing field, despite all of the paperwork that's attached to animal ethics reviews. The simple fact is if we take the three R commitments—reduce, refine and replace—within a protocol form, if I've applied for research funding, I've constructed an experiment and I'm using a mouse, a dog or a primate as a starting point, and then I get the protocol form and it says, "Is there a replacement for this procedure?", it is naive and disingenuous for any researcher or ethics committee to feel that there is going to be a one-to-one, off-the-shelf replacement that someone has already created that I will be able to substitute perfectly for the experiment that I just devised five minutes ago.

Yet that is absolutely the line of reasoning that these committees and funding agencies will go through. It's immediately "Tick, no replacement. The best we can do is reduce and refine." That is the status quo. That is so normalised. That is one of the many issues, until we can really confront how human-based research is designed and how we phrase and articulate research-testable hypotheses in a different way that do not use an animal model as step one.

Ms ABIGAIL BOYD: Thank you. Could I ask Dr Elliott for her response?

The Hon. EMMA HURST: I think she might've dropped out again, so you might want to ask—

The CHAIR: Dr van Ekert, are you able to respond?

KATHERINE van EKERT: Yes, it seems like she may have left the meeting. Is there a cultural issue? We would argue yes. It is our observation that it's probably fair to say that much of animal research is kind of existing within its own silo and often is not even translatable to human research. An example is the forced swim test, which was first developed in the seventies. A recent review paper by Dr Andrew Knight found that—it was examining how often forced swim tests were quoted in human medical papers. This is in the study of depression. The median number was zero, meaning that all of this research that is put into forced swim tests is not even used in human research.

A lot of animal researchers, they're very busy people. The primary objective often is publication—getting the papers in journals for academic progress within institutions. It just makes it really hard for them to look more broadly, both at the kind of research they're doing—they don't have sufficient time to undertake thorough, systematic reviews to figure out what has been done regarding their hypotheses and their research interests, how effective that research has been, in general—and then also just how effective that has been in the ultimate goal, which is in human work. So, yes, there is an issue with relying on animal researchers themselves to further our broad goal of developing good models for testing human disease. And then I guess we are carrying on this legacy that, as Dr Seidle said, was developed a good century ago—this legacy of at the time the best we had was animal models, we thought. But that is no longer the case, and I have every confidence that with additional funding put into alternative models that we will find even better things. Does that answer your question?

Ms ABIGAIL BOYD: It does.

The CHAIR: Thank you, Doctor. Sorry, Abigail, we now have to move to questions from—

Ms ABIGAIL BOYD: That's okay. Thank you.

The CHAIR: We may get a chance to return to you, hopefully. We now move to Government members. Would the Hon. Wes Fang like to start?

The Hon. WES FANG: Thank you, Chair. I will start with questions around efficacy. I have asked previous witnesses about the circumstances in which they might support animal testing, given they have a clear objection to it. Could I ask, either Dr Elliott or Dr van Ekert, under what circumstances would you be in a position to support animal testing, and how do you measure the thresholds that would allow you to permit that?

KATHERINE van EKERT: We are in support of animal testing where it is for the benefit of animals, which is not really relevant to this inquiry into the use of animals for medical research for human purposes. We are definitely in support of animal testing for veterinary medical research and also in the interests of species—like, observational studies, were it to, for example, help our understanding of improving endangered species research. In terms of the inquiry, where we are specifically looking at medical research for human interests, we are in support of research that works and, unfortunately, our current models using animals just have really low predictive values.

There are various citations I can share with you later, but anywhere from 90 to 95 per cent, on average, where animal research has been performed it subsequently fails at clinical trials—at human trials. That means either that it turns out that they are too toxic to use in humans or the drugs themselves that worked in a number of different animal species don't work in humans. That is one reason why we are opposed to use of animal research for this purpose, because it just doesn't work well. It has poor translatability to humans and, unfortunately, the

reason for that—well, there are a number of reasons, as Dr Elliott mentioned in our opening statement. There are methodological flaws which, historically, have plagued animal research.

Animals living in labs suffer chronic stress as a result of the environment, as a result of the way they are handled and the procedures they are subjected to, and that stress in itself impacts every system in the body. It impacts the nerve regeneration, it impacts genetic expression, it impacts their biochemistry. It impacts pretty much every research outcome we're looking at. I have got some great examples. A paper was examining aortic issues in mice, so they genetically engineered mice to develop aortic problems. Miraculously, those—so they were created, they had dodgy aortas and then as soon as they were transferred to large cages their aortic problems resolved. Similarly, research conducted to examine spinal disease in mice has found different responses to drugs depending on the type of flooring used in laboratory settings. So there are some really basic animal husbandry and handling things which are proving impossible to control for—

The Hon. WES FANG: I accept that. However, we heard some evidence during the previous hearings that things like the COVID vaccine would have taken a number of years more to roll out if we weren't permitted to test on animals. In that circumstance, I think it would be reasonable to say that there would be millions of human deaths which probably would have occurred in an unvaccinated population, had we had to wait a number of years more. Does that circumstance not warrant testing on animals?

KATHERINE van EKERT: That is a really difficult anecdotal scenario to answer because we just don't have a comparison. With scientific research you need a baseline to compare to, so you need a control—you need to have something that you do and then something that you don't do, so you have things to compare to. We don't have anything to compare animal research to in that scenario because regulations require the use of animals in research. We just don't know what could have been achieved without the use of animal research. Looking forward, the goal here and the goal with all research should be to find the most financially efficient and, as you mentioned from the time perspective, the most efficient means of achieving outcomes. We should be focusing on any model that is going to get us there. At least 90 per cent—in some types of research, Alzheimer's, for example, 99.6 per cent of all research performed does not translate in human trials. That is an awful amount of—like, estimates have at least $4 billion per drug in US billion dollars, whatever that is in Australian terms, to produce one new drug.

So I am with you; I am grateful for these COVID developments. But I would like to see how much better we could have done had we had access to non-animal models. And, thankfully, as we mentioned, the FDA—well, hopefully, assuming it passes the US Senate—it passed the House of Reps with an overwhelming majority vote in favour of a phase-out of our reliance on animal models to test these kinds of vaccines, to test drugs, as is the case in the European Parliament last year, so overwhelmingly vote in favour for no longer relying on these animal models. It is also my understanding with the COVID vaccination that human trials commenced in parallel to animal testing trials. So they had the information that they needed, they were comfortable proceeding with the human trials and it is my understanding that they were having to do the animal trials in parallel just for regulatory approval, not because they needed that information, necessarily, to inform the human responses.

The Hon. WES FANG: In relation to the last point that you made, given the high costs of animal testing and developing drugs, if you are correct that—I think you said 99.6 per cent of testing was not—

KATHERINE van EKERT: Specifically in Alzheimer's research.

The Hon. WES FANG: Why would pharmaceutical companies, which we know are driven by profit, still continue to do animal testing if it is so unreliable and not indicative of results that they can use to create profit?

KATHERINE van EKERT: I'm sure Dr Seidle can augment my response, given his knowledge of the international market. My understanding is that much of pharmacological research is conducted overseas. But current regulatory requirements are one of the key reasons. I will point to Europe. European Pharmacopoeia, which sets the standards for drug companies in Europe, announced that it will replace animal testing to detect fever-inducing compounds with a new non-animal test that uses human blood in a vial and detects antibody response—sorry, monocyte response. So there is a move away, and a big reason why they are still doing it is because the regulations are lagging behind the science.

TROY SEIDLE: I am happy to—

The Hon. WES FANG: Mr Seidle, you might be able to answer the last question that I have that came out of that. I think we would all like to move away from it; I don't think anybody thinks it's a great thing to do this. However, we don't have a replacement for it. Is it generally agreed that while the three Rs are a goal into the future, we're not there yet?

KATHERINE van EKERT: Was that directed at me?

The Hon. WES FANG: I will ask Mr Seidle to provide a response.

TROY SEIDLE: Sure, I am happy to. Again, it is a bit of a double standard in that there has to be a fully validated replacement approach in order to move away from something that we know scientifically has a far greater chance of failing than succeeding in relation to animal models. While I will not presume to speak for pharma companies, there are a number of publications that I could point to where those companies acknowledge that they have a business problem and they're working on—systematic reviews are the pinnacle of scientific scrutiny, but what can they use on a day-to-day basis to weed out animal models that are going to be to that 99.6 per cent Alzheimer's kind of scenario versus something that has a greater likelihood of translational efficacy.

I don't want to dodge the question but the simple reality is whether we are talking about animal or non-animal. If we don't understand the fundamental human biology that we are trying to predict in whatever system we choose, you're going to get a very high failure rate. And why don't we understand the fundamental biology? Because we're spending so much time and resources looking at mice, dogs and even primates. There are significant enough biological differences that wrong species often give the wrong result. We don't know; we have no way of predicting which experiment is going to give the correct result and which one will not. So we have this tremendous uncertainty that needs to be managed whichever kind of model system we use. But the simple reality is that if we don't apply some validation criteria or some quality control to animal experiments to level that playing field with non-animal, it's always going to be—maybe down the road we'll get to the three Rs, but not today. At the end of the day, are we willing to accept the 95 per cent failure rate for every new drug or can we do better? And at what point do we decide that we need to do better today?

The CHAIR: I indicate to the witnesses that I'm sure there will be some supplementary questions that were not asked in the relatively short period of time that we have had with you. Hopefully you will be agreeable to liaise with our secretariat over the answering of those supplementary questions, or questions that have arisen specifically from your evidence that we have not been able to ask you because of the time constraints. On behalf of the Committee, once again I thank you very much. We appreciate your submissions, which have been received and processed and which stand as evidence to the Committee—they are most helpful—and your oral evidence this morning.

(The witnesses withdrew.)

Dr DAVID MASON, Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching, before the Committee via videoconference, affirmed and examined

Mrs CATHY PITKIN, Deputy Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching, before the Committee via videoconference, on former affirmation

Dr MALCOLM FRANCE, Consultant Veterinarian and Board Member, Australian and New Zealand Council for the Care of Animals in Research and Teaching, before the Committee via videoconference, affirmed and examined

Ms KIRI COLLINS, President, Australian and New Zealand Laboratory Animals Association, before the Committee via videoconference, affirmed and examined

The CHAIR: Welcome to the next panel of witnesses. Thank you for your patience, everyone. It is challenging to have people in person and remote. But, nevertheless, we will do our best and deal with any matters that arise, if we need to do so. I will now invite opening statements. I am not sure how many opening statements are proposed. We have a limited amount of time, so do the witnesses from ANZCCART want to make one opening statement or more than one? If there is one, who will give it?

DAVID MASON: That would be me.

The CHAIR: Please proceed, Doctor.

DAVID MASON: ANZCCART is not an open advocacy organisation. Our vision is to be the leading source of information and advice concerning the ethical and scientific use of animals in research and teaching. The extent to which ANZCCART brings together the various stakeholders within our community through constructive and respective discourse on animal research is unique in Australia and New Zealand. There are a number of ways that currently ANZCCART has been supporting the three Rs, and I would like to highlight just three of these: our ComPass training program, our current research into the public perception of animals in research and teaching, and our commitment establishing an openness agreement in Australia, amongst others.

Our ComPass training modules, which are freely available, have been created by Professor Gail Anderson. This training platform and assessment tool, we believe, meets both the requirements of the code and also provides a framework for standardisation of training and assessment of AECs, researchers and students [inaudible] their understanding of obligations under the code. As of late June 2022 the overall user number has been nearly 5,000, with an individual overall completion rate of 71 per cent.

Our openness agreement commitment, led by board member Dr Malcolm France, has engaged a process of establishing an Australian-led commitment from all who are involved in animal research and teaching about being more open about the way in which they use animals as part of their research and teaching programs. A similar agreement has just been launched in New Zealand and is also in line with the UK Concordat. We have also just finished a period of public consultation about this project.

Lastly, in our current research led by Dr Rachel Ankeny, a specialist in public opinion polling, and Dr Alexandra Whittaker, ANZCCART has engaged a research team to accurately review the current public perceptions of the use of animals in research and teaching. We have no such similar objective research in Australia, possibly making this [inaudible] study. We aim to establish a broader understanding of the general public's view and look into their opinion on the use of animals in research and teaching. This is going to help to inform discussion and also support, in particular, category Ds to AECs. Finally, ANZCCART welcomes this review. We strongly support the three Rs of reduction, replacement and refinement and consider urgently how we can continue to support the world-leading, evidence-based, best-practice research, along with the consideration and needs of any animals involved in this work.

The CHAIR: Thank you very much. Doctor. I now invite Ms Collins, if she would like, to provide an opening statement.

KIRI COLLINS: My name is Kiri Collins. For background, I am an NSW TAFE-educated pathology technician by trade and the Head of Built Environment and Infrastructure, leading the delivery and operations of medical research-intensive environments, services and the teams that support them within the Randwick Health and Innovation Precinct. I am also the president of the Australian and New Zealand Laboratory Animals Association, currently serving my fourth term and seventh term as a member of the ANZLAA executive committee. ANZLAA is grateful to the Committee for the opportunity to participate in this inquiry and to give a meaningful voice to the laboratory animal science and welfare community that is charged with upholding high standards of health and welfare for animals.

ANZLAA is volunteer led, including myself, with over 800 members covering the full spectrum of professional expertise in the care and welfare of animals. New South Wales represents over 20 per cent of our membership, coming from world-class research institutes, universities and service providers. Examples of our expertise include animal care, technical skill, veterinary support, regulatory compliance and reporting training and the management of facilities and services.

ANZLAA promotes high standards of health and welfare and ethical conduct for animals involved in research and teaching through the free exchange of information within our community. We support cooperation between organisations and institutions to encourage and promote the implementation of the three Rs, including alternatives to animals, refinement of techniques and care strategies to improve the welfare of animals, and methodologies to reduce the numbers of animals in research whist ensuring the integrity and reproducibility in research.

ANZLAA's position is that the nature, purpose and effectiveness of the animal research in New South Wales is of high quality, demonstrated by a respect for animals, research integrity and outstanding performance of New South Wales research internationally. Whilst animal-based research in New South Wales provides a high-quality care environment for animals, there is always room to enhance the culture of continuous improvement in our regulatory environment, our research reproducibility, provision of funding support for the three Rs research, and renewed access to State-based quality training and education for the technical community.

This inquiry is a positive opportunity to work with the animal science and welfare community in establishing a safe and transparent environment for all who work in this industry to effectively communicate about our work, and to attract and retain the best and the brightest minds. These best and brightest have the potential to create meaningful advancements in both research and how effectively the industry communicates with our stakeholders, but we can only achieve this if New South Wales invests in and provides world-class environment in which we are to operate.

Although there are replacements for certain aspects of animal-based research and these are used as validated methods and availability are found, the ethical and medical ramifications of not being able to judiciously use animals in research before there is a scientifically valid way to replace all animals would be significant. It is not only treatments and cures for medical conditions that would be lost but learning about the fundamental processes in the body that we do not yet understand. We would like to acknowledge and thank the regulatory and welfare bodies and, most importantly, the medical research community of New South Wales for approaching decisions and actions in caring for and use of animals throughout their lifetime from a place of respect, dignity and scientific rigour. Again, I would like to extend my sincerest thanks to the Committee for this opportunity to speak. ANZLAA looks forward to working together to deliver the best possible outcomes for animals, medical research and the public.

The CHAIR: Thank you very much for that opening statement. Before we get underway with questioning, I acknowledge the submissions from the two organisations: ANZCCART's submission No. 234, and the Australian and New Zealand Laboratory Animals Association's submission No. 218. They provide valuable information to the inquiry, and I am sure, along with the opening statements, they will stimulate some questions, which we will now commence.

The Hon. EMMA HURST: Thank you all for coming today. I will start with Dr France. I wanted to ask about the ANZCCART openness agreement. Is that openness agreement at the moment entirely voluntary?

MALCOLM FRANCE: Yes, it is still in the development phase. It went out for public consultation earlier in the year, and that draft was based on the one that has been in place in the UK since 2014. It was developed and modified for the Australian environment by a working group convened by ANZCCART with quite, I think, significant representation from peak bodies, including funding bodies such as the NHMRC, Universities Australia, the Association of Australian Medical Research Institutes. Most recently, we have been joined by Humane Research Australia. We have tried to keep the representation on the working group as broad as possible. Ultimately—you are correct—the intention is, as it was in the UK, that the openness agreement would be a voluntary initiative for institutions to sign if they wished to.

The Hon. EMMA HURST: With the UK one, has there become an issue where some facilities just haven't signed on? Is that something that you think has happened in the UK and could potentially happen here?

MALCOLM FRANCE: I actually can't answer that question, I am afraid, as to whether—but I do know that in the UK a very large proportion of stakeholders have signed on: universities, private pharmaceutical companies, government bodies and medical funding bodies. It is quite diverse and in total about 120-something organisations, but I am afraid I can't answer what proportion of those organisations in those categories have not signed on.

The Hon. EMMA HURST: But there are some that haven't?

MALCOLM FRANCE: I don't know. I imagine it's possible, but I can't say. I would rather not give a misleading answer.

The Hon. EMMA HURST: Do you think, though, that this openness agreement eventually should become something that everybody signs on to for the sake of openness and transparency? There has been a lot of criticism that has come up in this inquiry about lack of openness and transparency. This seems like a step in the right direction. I am certainly not criticising the process of it, but do you think that it is something that at some stage each institution should be committing to?

MALCOLM FRANCE: I would like very much to see it get to the point where it is part of the culture that an institution involved in animal research signs the openness agreement or whatever instrument we eventually end up with. Should it be mandatory? I think it is much better that institutions engage in something like this willingly rather than being forced to do so. I would probably rather not speculate too much on whether it should be compulsory. I am encouraged by the support that these initiatives have had, not only the UK one but in other European countries and in New Zealand. Again, in New Zealand, I think all of their universities signed up as did quite a number of other organisations involved in medical animal-based research in one form or another.

The Hon. EMMA HURST: I know it's still in the development stage, but what kind of information is being proposed that members that sign up would publish, if you can give us a rough idea?

MALCOLM FRANCE: We are, again, in the interest of trying to get engagement from the research community, trying to keep that as open as possible. What we're really asking for is nothing more than that institutions are doing something to demonstrate greater openness and that year by year they are moving to a more and more open way of operating. What we've seen in the UK is a fair range of responses. Certainly there are organisations that are very proactive in their commitments to the openness agreement over there and are doing things like putting up videos—well, a lot more detail—and even open days in their organisations. I have to give credit—there is a small number of institutions in Australia that are already, and have been for quite a number of years, taking those sorts of initiatives, particularly, for example, Australian BioResources, which is the major mouse-breeding facility. They have a very open website with photographs of the cages and the rooms the animals are kept in, and they have had public open days in the days before COVID. There is quite a range, but the fundamental aim is to get institutions to commit to some form of greater openness. We'd like to give them some discretion in how they respond.

The CHAIR: Ms Abigail Boyd—

The Hon. EMMA HURST: Chair, I'm not sure if Ms Abigail Boyd is here.

The CHAIR: If she is not here, we'll continue with yourself.

The Hon. EMMA HURST: Thank you. I might move to Dr Mason. You note in your submission that you'd like to see more funding for alternatives in Australia, but you note that it shouldn't just be funding for development of alternatives but also the translation of those outcomes into mainstream research practice and upskilling of researchers and animal ethics committee members. Can you explain why funding for each of these is so important, perhaps starting with the translation of research and then talking about upskilling some of those AEC members? That was for Dr Mason.

DAVID MASON: [Inaudible]

The CHAIR: Dr Mason, if you could unmute yourself.

DAVID MASON: Sorry. I should know by now. When we're looking at this area of funding for research and, I guess, the translatability and how it would be supported, first and foremost we have got to make sure—and we do have a system in Australia where the animal ethics committees are reviewing each and every research project on their own merits. They're coming through and being assessed to actually make sure that they are meeting those three Rs and that there is an understanding from those committee members in terms of what the arriving group guidelines actually are and how they're going to be able to ensure that we are getting the best possible translatability from that research with the animals into human research outcomes potentially. In terms of funding and structures, what we're needing to see here is better support funding for ensuring that our AECs are actually trained and equipped and comfortable to ensure that they're actually able to understand their responsibilities under the code and also to be able to ensure that they've got the resources behind them to be able to enact the requirements under the code as well.

The Hon. EMMA HURST: We've heard—sorry, continue.

DAVID MASON: Go on. Sorry?

The Hon. EMMA HURST: Sorry, I interrupted you. Please continue.

DAVID MASON: We are definitely looking—I think there is always opportunity for increased funding when it comes to looking at how we can improve the three Rs and getting a better understanding of where animal research is being conducted and how we can continue to seek to improve it. We're looking to create a balanced and objective opinion. It's not just to say we should be doing it one way or the other but it's actually how can we get some understanding of where that research is going to be best conducted and how is it going to give us the best possible outcome?

The Hon. EMMA HURST: We've also heard quite a bit in this inquiry—there's been criticism from both sides of the fence in regards to the numbers of animals that are used in research and how that's being reported as one figure. Is part of good transparency a breakdown reporting of those numbers so that you've got categories such as the number of animals in observational research compared to biomedical research compared to agricultural research? Do you think that more detailed reporting like that would be supported? I know that that's something we've heard from both side of the fence, so I wanted to get your perspective as well.

DAVID MASON: From an ANZCCART perspective, that also falls into part of our openness understanding in terms of getting our institutions that are involved in animal research and teaching to actually provide a summary of what's involved. It is [audio malfunction] parts of Australia, we have—every State has got its own set of requirements and jurisdictions, and we don't have any consolidated way of actually getting a true understanding of the number of animals involved in research and teaching. There is certainly some bias that goes on with some of that reporting due to some of the observational study data that happens that can tend to push out a lot of those animal numbers that are involved.

The Hon. EMMA HURST: Going back to the AEC members, one suggestion that we've also had throughout this inquiry is getting training, particularly for category C and category D members. There was some real concern that there's a huge variability amongst animal ethics committees around their understanding of some quite difficult scientific pieces and that you might have one committee where the category C member is an expert in animal welfare but at another animal ethics committee it might be somebody that has volunteered for WIRES, for example. Do you think that, in an ideal world, we should be ensuring that there is some level of training or support for category C and category D members on animal ethics committees?

DAVID MASON: The short answer is yes. That's part of the reason why the ComPass training program and package was developed, because of an ongoing request from AEC members to have some standardised approach to training and support for their team members. Phase one of the ComPass training program actually addresses that completely, and its aim is to ensure that all members of the committee have got the tools and resources to actually fulfill their functions under the code. It includes the category Cs and category Ds and what that actually means for them. The second part of that is where our animal research project is coming in. That is certainly to try to provide those category D members with some understanding of what is the public perception so they've got that as a basis for their knowledge when they're actually applying that to the research.

The CHAIR: We will move now to Government members. I am wondering whether the Hon. Chris Rath may like to ask some questions, or I can move on to someone else.

The Hon. CHRIS RATH: Wes, did you have some questions?

The Hon. WES FANG: I'm happy to—

The CHAIR: That's fine. I didn't mean to put you on the spot, Chris. Just share it around.

The Hon. WES FANG: Ms Collins, I believe you were here when I was asking some questions earlier of the previous set of witnesses around the way in which they presented the correlation of results from animals to human results. They said that in 99.6 per cent of cases it didn't correlate. When I pushed the answer, I think they said it was in relation to stroke medicine or—

KIRI COLLINS: Alzheimer's—

The Hon. WES FANG: Yes.

The Hon. EMMA HURST: They did mention it the first time too.

The Hon. WES FANG: In your view, is that a reasonable presentation of the facts? Is that selective or is that a result that translates across animal testing regimes?

KIRI COLLINS: I think that has been presented that it is quite selective. I would say that I am not the appropriate expert that would be able to give comment on the extent of that. I would probably defer to the ANZCCART team that are on the line to be able to comment in further detail.

The Hon. WES FANG: I just wanted to give you the opportunity, to ask you first, because I did see you were there and I thought you might have had an opinion.

KIRI COLLINS: I appreciate that, thank you.

The Hon. WES FANG: But I will ask the witnesses online if they could also perhaps provide just a little bit of guidance as to how reflective those numbers might be across all animal testing regimes.

MALCOLM FRANCE: I can say that there is some variation depending on the type of disease and the body system that is under investigation. I think one also has to be cautious, though, to understand that the connection between research and, ultimately, new therapies is not a straight line. It is a very tortuous route. I think looking at translation of research in any field, whether it is medicine or anything else, is something that is very difficult, even in hindsight. I certainly could, if the Committee wished, on notice, send through a very interesting article that was published some time ago now that looked at a development of a drug and traced it back through the various papers that had been published and the scientists involved. Off the top of my head I can't remember the exact figures, but it was many hundreds of scientists and thousands of papers over the course of a century for the development of a single drug. So I think assessing the translatability of any form of research has to be done with great caution before judgements are made.

The Hon. WES FANG: Thank you. Do any of the other members perhaps have a view on this? I am seeing some shaking of heads. That is okay. The other aspect of the evidence that we heard this morning was that there are other means by which this testing can occur. We know that there are research facilities that are working on the replacement of animal testing by other means, whether it be an organ-on-a-chip or some of the other, I'll say, technical increases that we've had in this space. But do you have a view as to how effective those means are? Do they present issues themselves—if you are aware? Also, if animal testing was not a reliable indicator of the effect of a drug or a regime on humans, why is it that we do it?

MALCOLM FRANCE: Could I comment, Mr Fang?

The Hon. WES FANG: I would love you to. Thank you.

The CHAIR: Please, Doctor.

MALCOLM FRANCE: I think, looking at the utility of alternative methods, again, one has to look at the field of research in which they're being applied. A lot of the most successful alternatives have been taken up in the area of toxicology—that is, testing whether substances or new drugs could be poisonous. There are technical reasons why alternatives lend themselves very readily to that type of testing because it is very repetitive and very similar protocols are followed, yet in Australia there is a lot less of that sort of research done. We don't have the huge pharmaceutical R&D companies here, where they would be doing that testing, nor do we have the contract research organisations on the sort of scale that is found in the US and Europe.

So, unfortunately, that particular area where alternatives are readily taken up is not a big part of animal research in Australia. What we do have in Australia is a lot more basic research. This often is dealing with much more complex questions and complex systems, and, unfortunately, it makes it a lot more difficult to establish alternatives. That said, there are developments which are very promising and organoids—which are these mini 3D cell cultures—is one example where there is a lot of work starting to happen in Australia. But, again, we have to be realistic about the translatability of that. It could, at best, be quite a lot way down the track—if that answers your question.

The Hon. WES FANG: It does. The final point that I wanted to touch on before I pass to my other colleagues is we have heard in previous inquiries—not so much today—that things like the COVID vaccine that has been developed in recent times would potentially have taken up to two years or more to have been developed for rollout if we had not used animal testing. Would that be something that you think is a reasonable time frame that animal testing has allowed us to take off from the development? I know, obviously, there are different variations and different companies have done different things. But given the high death rates that we had from COVID, is it fair to say, one, that it has assisted and, two, we could have expected quite a number more human deaths had we not had that animal testing regime in place?

MALCOLM FRANCE: Will I comment again? Unless somebody else—sorry, I'll give somebody else a turn.

The Hon. WES FANG: I am looking for a volunteer.

MALCOLM FRANCE: I'll put up my hand again.

The CHAIR: Dr Mason, we'll start with you.

MALCOLM FRANCE: Sorry. David, did you want to answer?

DAVID MASON: No, I was going to say go for it, Malcolm. I think you're probably best placed to answer this one for us.

MALCOLM FRANCE: The technology that the so-called mRNA vaccines is based on was developed using animals and was well down the track. As to whether animal testing sped up the availability of the COVID vaccine specifically, I think it's really because there was already that foundation based on animal research directed towards other vaccines that the COVID vaccine could happen so quickly. And, of course, some of the speed with which that rollout occurred was also due to fast-tracking—but not cutting corners—various approval processes and other things not necessarily related to technical procedures, animal or non-animal.

The Hon. WES FANG: Thank you very much.

The CHAIR: Dr Mason, did you have anything you wanted to add? Or Mrs Pitkin?

DAVID MASON: No. I think [inaudible] stated there is, we have as an established process where animals are involved in the development of this research to date. But I think, looking forward, we need to continuously invest within Australia into one of those alternative methods and how we are going to continue to review, revise and refine the processes that are actually being involved. Do animals need to be involved into the future and do the number of animals that need to be involved in the future—what does that need to look like? I think there are some exciting pathways coming forward in terms of that technology and we need to keep reviewing and reflecting. That is part of ANZCCART's role to continue that dialogue and discourse within the scientific community to determine what is the best opportunity to provide that research with the outcome that we're looking for.

The CHAIR: Thank you. That is just about time, but there might be room for one more question. The Hon. Lou Amato, do you have a question?

The Hon. LOU AMATO: Yes. Part of the question might have been asked. To ANZCCART, I am not sure who is best to answer this question. First of all, thank you all for making yourselves available today. In your submission, on page 2, you mention:

> The contribution of animal science to medical research and human health over many decades has been substantial and led to many benefits and improvements regarding the health and well-being of people as well as animals themselves.

Could anyone elaborate a little bit more on that for me, please?

DAVID MASON: Cathy, do you want to talk about that one?

CATHY PITKIN: Sure. There have been many significant medical developments that have originated from animal research and, indeed, many improvements in the care and treatment of disease in animals themselves as a result of animal research. So not all animal research that's done is just for human benefit. There is actually a lot of animal research that's done which is about improving the wellbeing and the welfare of animals themselves.

The Hon. LOU AMATO: That's fantastic.

CATHY PITKIN: So that statement was really just acknowledging that there are both of those sorts of pathways.

The Hon. LOU AMATO: Okay. Thank you.

The CHAIR: Thank you very much. I have some questions. Perhaps if I could direct my questions, in the first instance, to Ms Collins. In your submission, Ms Collins, on page 1—if I can just take you to that page and the paragraph beneath the dot points on page 1, and particularly the final sentence, where it says:

> Finally, ANZLAA would like to draw the committee members' attention to our expertise, knowledge, and perspectives in demonstrating to the NSW Government where improvements are needed.

That also coincides with a comment you made in your opening statement about where improvements can be made and where they are needed. I invite you to elucidate on those particular areas. You can list them all as an exhaustive list or draw on some of the particular ones you think deserve some underlining.

KIRI COLLINS: As a general statement, the reference that we have made in our submission, and also in my opening statement today, reflects the need and the intent for the technical community to have a greater voice in the discussions about animal research in Australia. It has generally been accepted and discussed within the community that we need to have more opportunity, such as with inquiries like this, as well as working together with various funding bodies and agencies, to provide that expertise. Because we are a skill set that is incredibly important and fundamental to animal research, but we tend to have limited opportunity to give input where

required. Certainly when you reflect on what the responsibilities are within the code for the care and use of animals in research, there are really strong responsibilities and accountabilities that sit with the technical community for us to uphold. With that it also means that we have strong expertise and knowledge, and also the ability to effectively communicate and engage with medical researchers more generally about advancements in refinements and methodologies to be able to improve the use and number of animals in research.

The CHAIR: The key interface for the organisation, if I can paraphrase you, is representing the work done by individuals in the laboratories. Is that essentially the remit of the organisation?

KIRI COLLINS: Correct, yes. That is right: the technical community. There are the researchers themselves that are charged with having scientifically valid experiments that have merit and that are assessed by the various animal ethics committees. In partnership with those researchers, the technical and welfare community then supports them in the delivery of those programs of research. So it is the technical community who are looking after the day-to-day oversight and welfare of these animals in partnership with the researchers—as well as supporting them in education, training and further development that is required for the particular staff—and also make up portions of ethics committees and other forums as well to support that.

The CHAIR: The matter of the ethics committees as entities associated with animal research has come under some scrutiny over the course of this inquiry. We have had two days already and this is the third day, or half day. The suggestion has been made, if not explicitly then implicitly, that these operate as quite compliant bodies. The ethics committees are essentially, dare I say, pro-animal research and that is their default position. In terms of making animal ethics committees more robust, do you see that there is an enhanced role needed for the technical side of things to be better represented on the committees?

KIRI COLLINS: As a standard response I would say always. Certainly when it comes to the animal ethics committees, the facility managers, who I would also categorise as falling under the technical umbrella, are consulted and engaged with and, depending on the type of ethics committee, have a role to play on those committees. Certainly I would always be an advocate for that role expanding, but I would acknowledge that generally we are identified as subject matter experts that are consulted heavily by the animal ethics committees as well through those processes.

The CHAIR: You may not be able to give this answer off the top of your head, but you can take it on notice if you need to. In terms of the representation of the technical staff involved in animal research on animal ethics committees in Australia, as far as you are aware is that a high percentage of representation overall?

KIRI COLLINS: On the committees?

The CHAIR: Yes.

KIRI COLLINS: I would say no. Unless my colleagues can correct me, there is not an explicit category that caters to facility management or the general technical community being represented consistently across those forums. It is generally considered to be—

MALCOLM FRANCE: The code does include a category in addition to the four categories that the Committee would be aware of: A, B, C, and D. It is "should" rather than a "must", from memory, that there be representation from somebody with responsibility for the operation of the animal facilities. But I very much support Ms Collins' view that the perspective brought by the facility managers and the animal care staff is incredibly valuable to the point that I often describe the animal care staff, or the animal technicians, as the eyes and ears of the animal ethics committee because they are the ones who are in the animal facilities five days a week, or rostered on to weekends as well, and they know everything that happens. I think their feedback is extremely valuable to ethics committees. Most ethics committees take advantage of that, which is a positive.

The CHAIR: Dr France, can you elucidate on that point of the feedback to the animal ethics committees to make their performance more robust? How is that feedback done? As a general example, how are issues that might have arisen in the lab fed back to the committee for its consideration?

KIRI COLLINS: Certainly in my experience of working with animal ethics committees, the technical team works side by side with the researchers in the development of their applications to the ethics committees. We are providing guidance and support to them in pulling those applications together, and then also in the submission to the animal ethics committees as well. So we are engaged in that process and in the dialogue that the ethics committees are having directly with the researchers to be able to support the researchers in answering the questions that come back from the committee and also in giving responses back to the committee if those questions are directed to the technical staff. More often than not there are questions that come back from approvals that are very standard, and we do expect to see those, that are querying more so around the nature of the operations or

wanting to get further information about how the facility is operating or training requirements et cetera. This is where the technical staff will come in and support that process and give that information.

On a day-to-day basis generally the technical staff are working closely with either the ethics committee as required, depending on the institution, or the compliance division within the broader organisation under where the animal ethics committee sits. There is a direct relationship where we are meeting or conversing almost daily on the operations of our activity and also with our researchers as well. So the relationship that we have with the animal ethics committees, as far as ongoing conversation and input, is quite strong.

The CHAIR: I note the second to last paragraph on page 3 of your submission about what appears to be the withdrawal of—or the stopping of, for whatever reason—the TAFE course that was the qualification for persons wanting to work as an animal technician. Can you give the Committee a history of that? Is that something that has happened recently?

KIRI COLLINS: I would have to take that question on notice as far as the specific date.

The CHAIR: The timing of it, yes.

KIRI COLLINS: I do believe that the NSW TAFE course has now no longer been running for longer than five years. That specific course was discontinued mostly due to a lack of participants on the course. We are seeing that widespread across Australia now, that the numbers are getting less and less for that specific animal technology course. As a response to that, the various education providers are discontinuing this course. That means it then translates into a shortage of qualified staff within the workforce and the industry, and it then is becoming heavily reliant on the various institutions to be able to bridge that gap and provide that training.

The training that we provide across—I would say the majority or all of the facilities that I have come in contact with across New South Wales have a very extensive training program in order to access our animal facilities and then even more so for the technical staff that work in there. It can take anywhere between six to 12 months for a technician to actually be deemed as competent to be able to conduct work independently in these facilities because the training requirements we carry are of such a high requirement. We do have now quite a significant issue within New South Wales relating to staff shortages, and the NSW TAFE course gave very specific training to working within a laboratory with animals designated for research. Those qualifications and those particular course requirements—we cannot replicate those in any other courses. We have not seen that available in university degrees or in other TAFE courses as well.

The CHAIR: In terms of the curricula, that was in the TAFE course, which has been disbanded for whatever reason?

KIRI COLLINS: Yes, very laboratory animal-focused.

The CHAIR: Do you think there is a plausible argument for consideration of that particular qualification to be reinstalled?

KIRI COLLINS: Absolutely. We're at the point now where it has become very clear. Certainly, as a community, we did express our concerns about the closure of that course and the impact that it would have. Now, several years on, we are now seeing evidence of that impact with the low staff numbers that we have available and also the numbers that we have available for recruitment within various positions. So, yes, certainly that is an area of deep concern and of interest for the New South Wales community to have that course reinstated.

The CHAIR: Well, time has passed very quickly. I am sure Committee members will have some supplementary questions after they have read the Hansard of the evidence provided this morning. On behalf of the Committee, thank you all very much. The Committee's secretariat will liaise with you over the supplementary questions that arise. All the evidence today augments very nicely what was provided in your submission, so thank you very much.

(The witnesses withdrew.)

(Short adjournment)

Mr EDWIN BRACKENREG, Chief Executive Officer, Codex Research, affirmed and examined

Professor CHRISTOPHER LITTLE, Director, Raymond Purves Bone and Joint Research Laboratory, Kolling Institute, affirmed and examined

The CHAIR: Thank you, gentlemen, for coming along today. I will invite you now, if you wish to do so, to make an opening statement. From that, we can then move to questions from Committee members. If you are you comfortable with that proposal, Mr Brackenreg, I invite you to make an opening statement, if you wish.

EDWIN BRACKENREG: The validity of animal research is being increasingly questioned on scientific, ethical and economic grounds. Animal research fails to predict human outcomes in the majority of cases. In the past, there were no reasonable alternatives, hence the justification despite high failure rates, ethical concerns and the enormous resources needed for animal experiments. Advances in technology now enable better alternatives, fewer ethical issues, faster and cheaper experiments, greatly simplified infrastructure, safer human trials, and the hope of greater understanding of complex human diseases. However, the development of this sophisticated technology requires significant capital with long development cycles, in stark contrast to today's typical tech startup.

The US and Europe are global leaders, with substantial government funding, collaborative initiatives and relevant legislation driving change. An exemplar of success with government support was an FDA, NIH and DARPA initiative that saw a startup, Emulate Inc., spun out of a Harvard University organ-on-a-chip project. Emulate has raised $93 million to date in VC funding. A recent pre-print confirms that the human liver-on-a-chip can be vastly superior to animal models, correctly predicting human toxicity in 22 out of 27 small molecule compounds, all of which previously had passed preclinical animal studies, causing 208 patient fatalities and 10 liver transplants.

The liver-on-a-chip is predicted to be worth $3 billion annually in improved R&D productivity solely in predicting drug-induced liver injury. At Codex Research, we've been working with the University of Sydney to develop an in vitro model of vascular biology. The cardiovascular field, like many others, is plagued by promising therapies in preclinical studies—usually mouse experiments—that fail in clinical trials. Poor human outcomes can be attributed to rodent resistance to atherosclerosis and differences in blood flow dynamics, life span, metabolism and immune function. The device we are developing uses pumps, sensors and smart control algorithms to replicate human physiological conditions, with human cells yielding a superior model of vascular biology. We are working towards replicating patient-specific blood flow patterns using patient-derived cells, enabling studies that are not possible with animal experiments.

We make the following recommendations: first, for the New South Wales Government to institute a grant similar to the Medical Devices Fund targeting development of alternatives to animal experimentation—the global alternative testing market was worth $9 billion in 2020, predicted to reach $30 billion by 2030; second, to fund technology development infrastructure—the recently announced advanced manufacturing facility would be a good model for this; and third, to implement appropriate policy and legislation to help overcome the inertia of researchers, publishers and grant bodies that have their reasons for sticking with traditional experimental methods.

The CHAIR: Professor Little?

CHRISTOPHER LITTLE: I haven't prepared anything, but—

The CHAIR: Please, as you see fit.

CHRISTOPHER LITTLE: I come today both representing the Kolling Institute and also personally as both a veterinarian by training and an animal-based researcher or translational researcher. I have used a lot of animals in my own research in terms of both discovery research—looking at disease mechanisms—and also working with the pharmaceutical industry and others in terms of testing therapeutics. While, certainly, there has been, as Edwin said, failures in that process, there have been many successes—many successes that aren't, in fact, published. The current data on the success rates of animal research probably vastly underestimates its success for things where we find things that don't work and therefore don't progress through and cause harm.

Animal involvement in medical research has three main purposes. It does allow us to get insight into the progression of a disease, disease pathophysiology and to evaluate therapeutic interventions in the complex biology that, as of yet, we cannot replicate in vitro. Despite the current advancements in that space, the in vitro technologies still have failures of being able to fully mimic the complex, day-to-day, minute-by-minute regulation that occurs in an in vivo system. However, as with Edwin, I do believe what we need to do is be better and smarter at how we do in vivo animal research. It won't work for all diseases, and there are some where, perhaps, we should

immediately be looking for alternatives. But we can be smarter and better about understanding how predictive models are, how we improve their predictability and how we improve their translation.

In fact, despite the current dogma that animal research fails, a recent meta-analysis looking at translation of animal research across medicine suggested somewhere in the vicinity—depending, again, on the disease—of between 70 per cent and 90 per cent translational success. That's actually very successful. As of yet, in vitro models don't have any proven validity. I think there is a stepwise process that will happen. I think all of us would not want to go to animal research as the first step. But in that stepwise process of better in vitro models that mimic the pathophysiology, and then better selected in vivo models that are predictive, that's currently, and will remain for the foreseeable future, the ideal model for health research and medical research.

The Hon. EMMA HURST: Thank you both for coming. I'd like to start with Mr Brackenreg. I want to talk about the funding for people who are developing alternatives. We've had a lot of discussion during this inquiry about the fact that alternatives sometimes simply aren't available in Australia for some of that research. I am just wondering how much of that is because there is a lack of funding available for the development of those alternatives? If there is a lack of funding, is that affecting the growth of that industry to actually replace animals in research?

EDWIN BRACKENREG: Our experience is that it is quite difficult to get funding to work on this sort of in vitro technology here in Australia. We have been successful. The project that we're currently running in conjunction with the University of Sydney has been funded by the IMCRC—that is the Innovative Manufacturing CRC. They aren't related to the health field at all but, because we came to them with a project where we said we were going to work on a high-tech device and try to make that high-tech device here in Australia, they agreed to fund our project. That has allowed us to set up this collaboration with the University of Sydney. This is a matched grant, and we didn't get any money out of it for Codex. The money went to the lab at Sydney university. That has been absolutely vital for the work so that we could validate our iterated prototypes as we made these prototypes. That is a very expensive process if you have to pay for it yourself; however, instead of money coming into Codex to help us develop it, we actually spent $1 million of our money matching our half of the grant that was required, to give that money to the lab to continue that research.

As you can imagine, developing this sort of technology is very expensive. It's also quite risky. We are really in early days in developing this sort of technology. We've been doing animal experiments for literally thousands of years. Some of the earliest recorded writings were about experiments that were done on animals as humans tried to learn about human biology from thousands of years ago. The animal research ecosystem has a very long head start on what we have. There is a lot of funding that goes into experiments as a part of that ecosystem. It's quite normal for researchers to apply for a grant, to put that application into a funding body and to include in that grant an animal study as part of their project, and for the granting body to look at it and go, "Yes, that's what's needed," approve the grant and that gets funded.

All of that money then goes through the researchers and then into the ecosystem that provides the animals and provides the infrastructure for animal research. There is very little of that at the moment in terms of sophisticated in vitro replacements for animal studies. This is significantly different from the normal day-to-day in vitro studies where cells are put in a Petri dish. Researchers do that every day as well. But the sort of sophisticated technology that's required to raise this to the next level where we hope to replace animal studies, that is a whole different ball game, and there isn't a lot of funding towards that sort of work.

The Hon. EMMA HURST: Do you think that if there's a lack of funding and a lack of support for the development of alternatives, we will lose researchers and startups to other countries? On the flip side, is it an important economic opportunity for New South Wales to actually start funding the development of these alternatives here in Australia?

EDWIN BRACKENREG: I think it's a fantastic opportunity. As I said, it's still early days. That means that there is a ground-floor opportunity. Industry and venture capitalists these days tend to lean towards investing in the typical tech startup, which is usually a software startup with short business cycles and short development cycles. All you need is for someone to come up with a great idea, and off they go and develop some piece of software that implements that great idea and away they go. That's quite attractive to VCs. They can see a return on their investment potentially only a few years away. The development of this sort of technology, however, can take many years before you see the results.

Venture capitalists tend to see it as high risk. In other words, they don't understand the technology and they don't understand much about biology. They know a lot more about software and how to write that, so they tend to shy away from investing in this sort of industry. It may require some government pump priming to get an industry like this off the ground but, because this is early days, we are still at the ground level. Developing a hub here in New South Wales would be an outstanding opportunity to develop a hub of high-value jobs and of very

attractive research positions that could attract researchers and high-value workers into NSW. I think it would be an excellent opportunity for the New South Wales economy.

The Hon. EMMA HURST: You mentioned that you did get a matched grant, but it wasn't from the health field. Is that because it's almost unheard of that someone would get a grant developing an alternative from the health field?

EDWIN BRACKENREG: There are a few grants that we've looked at within the health field. The Medical Devices Fund grant that I mentioned as an example of a good grant is one of them. That specifically is for medical devices. Our device may one day, hopefully, be a medical device, but right now it's a research device and a research tool that we would put forward as a replacement for animal studies as an improvement on in vivo research methodology, so we don't qualify for that grant. Other grants that we've looked at and applied for, we also have not been—we simply don't match the requirements of those grants.

Ms ABIGAIL BOYD: Good morning to you both. I would like to start my questioning with Professor Little. I am just looking at your submission where you say, "There would be more harm and risk to public health if animal models were not used." I think that is one of the arguments that has been, perhaps, given a little bit more—too much in my view—focus in this inquiry; the idea that because in the past animal research has produced results that have been really good for humankind, therefore, we have to keep using it or there is a requirement to continue using animals in research forevermore. Clearly that is not the case. Can I just clarify your position on that? Is your position that, in the current context of what is available to use as an alternative, we need to keep using animals in research to the extent that we do? Or do you envisage that we will always have to use animals in research?

CHRISTOPHER LITTLE: Thank you for the question. I think, first of all is to say that I actually support everything that Edwin just said. I do think in the current context, yes, we don't have a viable alternative for the majority of diseases and health conditions we want to do research on. The translational utility and validity isn't there at the moment for these higher-tech animal replacement technologies. Do I think that they will lead to a reduction in animal use in the future? Yes, I hope so. As a veterinarian I hope so and as a humanitarian I hope so. Do I think that they are likely to replace everything? I suspect they won't. I suspect, like animal models, there are some that are very useful and predictive for certain diseases and some that aren't as good for diseases. Animal models of stroke have been notoriously bad. Animal models of other diseases have been much better. So I think for some diseases we will probably continue to need to use animals.

That may be for things that are even perhaps on the more controversial end of animal use, which is to understand and to study pain. Chronic pain is one of the major conditions in its own right and as part of other disease conditions which affect society. We have all heard about the opioid crisis and we have our own opioid crisis in Australia because of poor pharmaceuticals and ways to treat chronic pain. Pain is not simply a cell-based response. It's a psychosocial response that occurs in terms of how we perceive that change in nerve cell function. That's not something that I think—pain and chronic pain—we will be able to do in vitro, no matter how sophisticated our fluidics and cell culture systems are. So I suspect for some diseases we will continue to need to use animals.

I think we should do it smarter. I have written lots of papers on and I think we need our animal models to be better and more predictive, and I think in funding the research that I would fully support that we fund to try for Edwin and others to improve the in vitro models and their predictability. They will need to go alongside existing animal models to in fact show that they are at least as good or better. Because we can't throw away everything now and say, "Well, we won't do animal research because there are ethical issues with it," because right now that would be detrimental. It would stop development.

Ms ABIGAIL BOYD: Yes, and I don't think anyone—well, maybe somebody is suggesting that, but I don't think that's been suggested in this inquiry. In terms of getting us to that point where we are reducing significantly the numbers of animals that are being used in research and where it is really only the research that definitely requires animals still, how do we get to that point? Do you think that is something that has to require government intervention or can it be something that the industry itself can encourage?

CHRISTOPHER LITTLE: I think as researchers we can encourage it, but we are slaves to our funding. So, just as Edwin, I have to apply for all of my research funding through usually government-based but also philanthropic agencies and others. We are slaves to what we can get funded. So that "simple"—I use that in inverted commas—comparative research that would head us in that direction to reduce animal numbers to find out which models are better, to find out which diseases this particular model is predictive of or which phenotype or cluster of patients it's predictive of, that's difficult to get funded. And it's not just difficult for Edwin to get funded from an in vitro basis; that's difficult to get funded in vivo. To say, "I would like to do a study that improves predictability and ultimately will reduce the number of animals we use, or we'll stop using them for this disease"—

really hard to get funded. So I think government could intervene in all of that. But remembering that a lot of the funding we apply for is Federal Government funding anyway. So government, at the moment, is not intervening in that direction and I think it would be great if it did.

Ms ABIGAIL BOYD: Thank you. I am not sure if I have any time left, but if I do—

The CHAIR: You have 17 seconds. Go for it.

The Hon. WES FANG: I am happy to provide a bit of ours.

The CHAIR: Please proceed, Abigail.

Ms ABIGAIL BOYD: I was going to ask Mr Brackenreg if he has any contribution on those questions also.

EDWIN BRACKENREG: Yes. I agree that governments have a part to play, that the majority of research funding does come from the Federal level but State governments certainly have a role in applying pressure to Federal governments to get on board with the idea of funding this sort of research, and that it's important for industry players. If we can't sell our devices to researchers then we can't make money and we can't continue to reinvest in increasingly developing the technology. The only way we can sell our devices to researchers is if the researchers can get grant funding for it. Researchers don't generally have a war chest of money sitting around to spend on some cool gadget that comes along that industry introduces to them. The only way they can get money to buy an in vitro device is to write a grant application and have that grant application approved—then they have the money to buy the in vitro device. Until that happens, we don't really have a market to sell into.

I think governments certainly have a role to play in influencing granting bodies to look to make decisions to fund this type of research, but also publishers. So publishers also will only publish the papers that they like. Publishers are a private enterprise who make quite nice tidy little profits out of their existing model. Their existing model is, generally, when a researcher submits a piece of work the publisher will invariably look to see an animal study tying it all together at the end of research before they're interested in publishing it. So I think government can certainly play a role in influencing that as well.

I'd just like to mention that the US Government is in the process—it looks very much like it will go through—of passing a thing called the FDA Modernization Act at the moment, which removes the mandatory element of doing animal studies for drug trials. This has passed the lower House with an enormous majority, including 176 Republicans in favour, every Democrat in favour and only 28 Republicans voting against it in the lower House. It's a bill that's sponsored by both a Republican and a Democrat and it's currently passed the Senate Committee to put it into a package of legislation before being put to the floor on the Senate. It looks very likely that this will pass. So this will remove the mandate that requires animal studies before drugs can be put to human trials. This is in the US. The EU is passing similar legislation as well.

The Hon. WES FANG: What I've taken away from this inquiry so far is that both sides seem to be very good at selective data. That is, "We'll present this as supporting our case"—for example 99.6 per cent, which was highlighted in the first session of the inquiry—"but it was related to one aspect of testing." The other side obviously have a different view and they will be selective about the data that they put forward. In relation to the ability of devices to supplement testing and provide reliable accurate data, things like liver toxicity sound very reliable. I'm interested in the broader scale of testing. At the moment, given the whole regime that we do for testing on animals, how much technology do we have that can supplement that full regime? And how long do you think it would be before we are able to replace all animal testing? Is that even feasible?

EDWIN BRACKENREG: You're asking me, I presume?

The Hon. WES FANG: The philosophical parts are probably for both of you. But, yes, I'm asking you about the replacement component of it.

EDWIN BRACKENREG: As I said, right now there is growing interest in developing this technology globally and it is, I believe, a growing market. Therefore, I believe New South Wales should try to jump in in the early days and develop a capability that will benefit New South Wales economically and scientifically. I see this sort of technology as quite a parallel with the silicon chip technology that we've been developing over the last 50 years. I've lived through that process. I purchased my first Apple IIe computer in the 1980s. It was a machine that you could play around with. It was a hobby machine, and no business would ever look at buying an Apple IIe to do anything with because it was fun for hobbyists to play with but its utility was quite limited. However, that industry continued to develop and after probably 10 years, businesses started to buy computers and they found them to enormously increase their productivity. Now, of course, 40 years later we live a world in which silicon chip devices are absolutely ubiquitous on every desk and no-one would ever consider having a job that didn't have a computer involved in some way.

I believe this in vitro technology will probably follow a similar pathway. If we get in at the early days, we will be part of an ecosystem that develops some technologies that today may seem like science fiction in exactly the same way as the very commonplace laptops that I see on the desks around me would have been absolute science fiction when I bought my first desktop computer. I can't answer the question as to whether or not in vitro testing will completely replace what can be done with animal experimentation. But I am extremely confident that if we invest in building and developing this technology, in exactly the same way that computers have massively increased productivity in the workplace this in vitro technology will, in time, massively increase our capability in terms of medical research.

CHRISTOPHER LITTLE: I don't see this as a combative thing. I fully agree with that. I think we should be trying to develop it and we should be trying the in vitro technologies and replacement, reduction and refinement technologies for animal research to improve that stepwise process. My goal is not to be an animal researcher; my goal in medical research is to find treatments for human and—as a veterinarian—also, in the One Health approach, for animal conditions. I will use whatever means I can that are the best ways for me to do that. If at the moment I think that's animal-based research then that's what I will end up using. If for some conditions and somewhere along the line that becomes an in vitro model, I will gladly use that. Because the end goal is improved health, and however we can get to that is what we should be aiming for. I think funding and developing all those things, if that's a stepwise and parallel process, is what we should be aiming for.

The Hon. WES FANG: Lou or Chris, do you have anything?

The Hon. LOU AMATO: No, that was a logical answer.

The CHAIR: One of the challenges that's exercising some of our minds was picked up quite nicely at the bottom of page 1 and going over to page 2 in the Kolling Institute submission. In terms of the research, it states:

> In this discovery pathway, the need for animal models is critical, as the committee would appreciate, it is often unethical, arguably immoral and potentially dangerous to conduct experiments on human subjects without initial experiments in animal models to demonstrate safety and efficacy.

With respect to that statement, I get the sense that—and I say this respectfully—some of those who are pursuing the change of moving away from animal experimentation rapidly don't seem to be turning their minds to that, at the end of the day, if we have a starting point that we didn't have to have animal experimentation at all—in other words, we're starting with a blank sheet of paperer—in 2022 we wouldn't go there to start. But we are where we are at this point in time. I would argue that it is still critical to accept the proposition that you would not want to have a movement towards experimenting on human beings; I think that's probably an agreed statement. How do we not move away from the understanding that we don't ever want to contemplate experimenting on human beings in any way, shape or form but, at the same time, move at a more accelerated rate away from animal experimentation? I suppose it's the ultimate question, the way in which we can accelerate the movement away without compromising that principle. Do you have thoughts about our thinking around how we should address that? This is the overarching question, isn't it?

EDWIN BRACKENREG: I would say that is the overarching question. I think the starting point is to look at this sentence, change very little and say, "often unethical, arguably immoral and potentially dangerous to conduct experiments on human subjects without initial experiments using some technology that demonstrates safety and efficacy". There's no need to specify animal models in there, which is what the FDA modernisation Act is all about. It's saying, "Why specify that animal models have to be used to do this if we can find alternatives?" At the moment the debate outside of that sentence is do we have alternatives? The answer is not a lot, but we have a lot of people who believe that with investment, time and government assistance we can develop more and more alternatives so that you can leave out the animal and put in some technology, and more and more that won't involve animals.

The CHAIR: Do you think it would default to that position if you removed the reference to the animals?

EDWIN BRACKENREG: I don't know that it would default to that position if you took away animals. As I said, we have been experimenting on animals for a very long time and it has built up this whole ecosystem and a massive amount of infrastructure. I think the previous witness was someone who looked like they worked in or around animal facilities. There are a lot of these animal facilities and there are a lot of people who work in them; there are a lot of publishers that, as I said, expect to see animal studies in the papers that are presented to them for publication; and there are a lot of granting bodies that expect to see animal studies put into the grant applications. There is little expectation from any of those groups to see alternatives replacing animal studies. So simply removing "animal" from this sentence and not taking any further action would probably not produce very much change because there is a lot of inertia in the system—"this is the way we've done it; let's just keep doing it the way that works for us"—at all levels, from researchers to publishers to granting bodies. I think it would require

proactive intervention to develop an attitude that we need to proactively move away from animal models towards some technological replacement.

CHRISTOPHER LITTLE: Again, I don't disagree with that statement at all. I think at the moment it's about saying, "At the moment, we don't have that." Ultimately, what we want is to have things that are predictive—highly predictive—of therapeutic efficacy and safety in human and animal patients. At the moment, that's the animal experimental model system. If we can develop technologies that reduce that need—as I have said, I'm not sure it will replace it entirely—that's a desirable aim, but they would have to be validated. All of these things, the 2,000 years plus of animal experimentation, have not only developed an infrastructure but have developed a predictive knowledge base within that as to what is useful in comparative medicine and what is not. You would have to develop that with the in vitro technologies. There would be failures and mistakes in there of saying, "We know this is predictive for that. This model is not predictive—turns out that failed and we did have patient problems," just as we have with animals. I think it is about developing methodologies, be they technologies or animal models, that are better and that are predictive. I think that's desperately what we're trying to do. I think all of us want to improve health.

The CHAIR: Can I put that question back to you? I suppose that's really what we're contemplating: How do we move things along? The remit of this particular inquiry is for the New South Wales Parliament. Obviously, we have autonomy in terms of what we do as a Parliament and, indeed, the government of the day in what it's able to do with respect to law-making. The funding primarily—not exclusively but primarily—for research in Australia, particularly in these areas, is from the Commonwealth through the channels that you are aware of. I'm wondering if I could ask this open-ended question to both you gentlemen: From the point of the State of New South Wales—the State itself, the Parliament and the government of the day, whoever it might be—what do you think it can do to help move things along without compromising this fundamental position about not wanting to contemplate experimenting on human beings?

EDWIN BRACKENREG: I think very simple things that could be considered by the New South Wales Government would be implementing a specific grant along the lines of the Medical Devices Fund, which is an excellent grant in that it doesn't require matched funding from the industry partner. It's a good amount. You can be granted up to, I believe, $5 million for any given project. You can go and apply for a grant on multiple occasions up to that limit of $5 million. You can go and get a grant to progress your technology to the next level, and then go and get a further grant subsequently a year later or two years later or whatever and continue until you have that money. I guess the disadvantage of the grant is that it's designed to be paid back. If the project becomes profitable—and only if the project becomes profitable—then the grant money is paid back, and then it's available to be given to someone else. That's something the New South Wales Government can do.

The Advanced Manufacturing Research Facility being recently announced that's going to set up a hub for bringing advanced manufacturing knowledge and connecting academia with industry out in western Sydney—I have only just been recently made aware of that. It looks to be an amazing program that the New South Wales Government is putting up something along those lines, and possibly even working in collaboration with the AMRF, as developing the technology. If we're going to actually develop and manufacture the technology itself here in New South Wales, you will need to do advanced manufacturing, but to validate your prototypes it would be good to have a hub that connects bioscience and biomedical researchers with industry, as opposed to just the manufacturing researchers with industry. That could work hand in hand with the AMRF. That would, I think, attract a lot of attention into New South Wales.

The other recommendation, I guess, is a little bit more airy-fairy. It would simply be if the New South Wales Government had a policy in place of trying to advance the technology—because we are building this nascent industry here in New South Wales, let's advocate for that sort of technology—every time we meet with the Federal Government, we just say to them, "Hey, when you're doing research funding, you guys really need to consider funding more this sort of in vitro technology rather than just sticking with animal models and just doing what we've been doing." So that would be more collaborative. If the Government has this as a policy—this is what we're going to do; we're going to develop these technologies here in New South Wales—then all the Ministers of the Government, Opposition members and crossbenchers who agree with the policy would be out there advocating as much as they could. They could possibly be attending scientific conferences, and saying, "Look, we think that the New South Wales Government likes the idea of researchers, publishers and granting bodies globally getting on board with this idea of developing in vitro technologies rather than just sticking with animal models all the time."

The CHAIR: Professor Little, do you have any thoughts from New South Wales' point of view?

CHRISTOPHER LITTLE: I agree, again, with that comment. I think it does need to be about supporting research and supporting comparative research. That initial step will still be comparison with the

existing models and their validity. I think the advanced manufacturing facility—the New South Wales Government is also investing in the medical research hub at Sydney University near RPA as well. Again, that's a biomedical research area—a hub—that could be bringing together technologies with biological researchers and classic biomedical researchers, using existing in vitro and animal models, to try to develop that. Again, it's having a policy where you might be driving that comparison, because the initial thing will be a comparative. You will have to develop the technologies and you will need to compare that to the existing predictive models, and that will need to happen to show that they have validity. Having that policy and that infrastructure in place, I think, would be really important.

The sad truth about medical research, full stop, is we do what we can to get funded. Part of it will be about trying to set aside some funding for it. It might be changing the Medical Devices Fund to have a specific category for developing in vitro technologies rather than a widget that's going to treat such and such. It might be having a separate category of that and putting it aside and saying, "We want, as a policy, to use some of the existing funding that we have to develop the in vitro technologies because we believe in that." It may not necessarily be more funding. Ideally, I would love there to be more funding. It might be hiving off some of that to specifically support an objective of the New South Wales Government.

The CHAIR: Gentlemen, on that note, thank you both very much for coming along today. Your submissions were most helpful. They have been received, processed and stand as evidence to the inquiry. You have also come today and provided oral evidence, which sits nicely on top of that, and of course the answers to the questions that we posed to you. I'm sure there will be some supplementary questions that will flow from having given your evidence and members reading the transcript and wanting to follow that up. The Committee secretariat will be involved in doing that. On behalf of the Committee, thank you very much. It's much appreciated.

(The witnesses withdrew.)

The Committee adjourned at 11:59.