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Use of primates and other animals in medical research in New South Wales

Report 59

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Portfolio Committee No. 2 - Health

Use of primates and other animals in medical research in New South Wales

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Use of primates and other animals in medical research in New South Wales

"October 2022".

Chair: The Hon. Greg Donnelly MLC

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Terms of reference

That Portfolio Committee No. 2 - Health inquire into and report on the use of primates and other animals in medical research in New South Wales, and in particular:

(a) the nature, purpose and effectiveness of medical research being conducted on animals in New South Wales, and the potential public health risks and benefits posed by this research;

(b) the costs associated with animal research, and the extent to which the New South Wales and Federal Government is commissioning and funding the importing, breeding and use of animals in medical research in New South Wales;

(c) the availability, effectiveness and funding for alternative approaches to animal research methods and technologies, and the ability of researchers to meet the 3 R's of Replacement, Reduction and Refinement;

(d) the ethical and animal welfare issues surrounding the importing, breeding and use of animals in medical research;

(e) the adequacy of the current regulatory regime regarding the use of animals in medical research, particularly in relation to transparency and accountability;

(f) overseas developments regarding the regulation and use of animals in medical research; and

(g) any other related matters.

The terms of reference were self-referred by the committee on 3 December 2021.[1]

[1] *Minutes*, NSW Legislative Council, 3 December 2021, p 2963.

Committee details

Committee members		
The Hon Greg Donnelly MLC	Australian Labor Party	*Chair*
The Hon Emma Hurst MLC	Animal Justice Party	*Deputy Chair*
The Hon Lou Amato MLC	Liberal Party	
Ms Abigail Boyd MLC*	The Greens	
The Hon Wes Fang MLC	The Nationals	
The Hon Aileen MacDonald MLC**	Liberal Party	
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* Ms Abigail Boyd MLC substituted for Ms Cate Faehrmann MLC from 27 April 2022 for the duration of the inquiry. Ms Abigail Boyd MLC was a participating member from 2 February 2022 to 26 April 2022.

** The Hon Aileen MacDonald MLC replaced the Hon Chris Rath MLC as a substantive member of the committee from 16 August 2022. The Hon Chris Rath MLC replaced the Hon Shayne Mallard MLC as a substantive member of the committee from 29 March 2022. The Hon Shayne Mallard MLC replaced the Hon Natasha Maclaren-Jones MLC as a substantive member of the committee from 25 January 2022.

Secretariat

Erin Pynor, Principal Council Officer

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Tina Mrozowska, Administration Officer

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Chair's foreword

In this inquiry the committee had to grapple with important questions relating to how individuals and institutions conduct themselves in relation to the way they think about and undertake research for medical purposes with respect to the use of animals including non-human primates. It was clear from the contributions of inquiry participants that the idea of intentionally causing harm or killing animals for gratuitous purposes or just for the sake of it is, as it should be, considered abhorrent and completely unacceptable. At the same time, the committee heard that the use of animals for the purpose of medical research, that involves in some cases them being harmed or even killed, has and continues to advance medical science that has unquestionably produced extraordinary health benefits for humankind over a long period of time.

It is clear that the medical research landscape is rapidly changing particularly with respect to the development and application of computer and information technology. The committee received evidence of medical and health advances for both humans and animals informed by non-animal research techniques including growing human cells in vitro, using organ-on-a-chip technology and the application of 3D culture systems in drug screening and bioprinting organs including skin. Evidence received from medical research experts regarding these developments was positive and optimistic. Indeed, their evidence suggested that there was an opportunity for New South Wales to lead the nation, championing a national three Rs (Replacement, Reduction and Refinement) centre to create highly skilled jobs in medical research, development and manufacture of cutting-edge technological alternatives.

However, at this point in time it appears that it is more accurate to describe the emerging methods as adjuncts to, rather than alternatives or substitutes to the use of animals in medical research. The opportunity to take further concrete steps to implement the three Rs was found by the committee to be persuasive. The committee did identify two specific medical research experiments - the use of rodents in the forced swim test and the smoking tower test - that it concluded were particularly harmful and accordingly, has recommended that the conduct of them be rapidly phased out.

The issue of transparency regarding medical research was raised by many inquiry participants who work with and advocate for animals. The committee heard a view that the general public had a right to know about the nature and extent of the use of animals in medical research in New South Wales, particularly as much of this research is publicly funded. On the other hand, a number of medical researchers expressed concerns about the potential impact, if all the details of their work were released into the public domain. Noting the concerns expressed by institutions, the committee concluded that there was a need for enhanced transparency, improved nationally consistent reporting requirements and appropriate resourcing for the inspection and audit activities that will ensure research institutions comply with existing and future regulatory requirements.

This inquiry generated considerable public interest and engagement, with the committee receiving a number of submissions and conducting three public hearings. The committee is grateful to inquiry participants including – individuals, NGOs, academics, institutions and research bodies - for their evidence and insights. The committee was impressed by the integrity and commitment of veterinarians, animal care professionals and rehoming establishments who work with animals used in medical research. Equally, the committee acknowledges and appreciates the seriousness in which those engaged in medical research are concerned about animal welfare. The committee has made recommendations that encourage animal ethics committees to continue to draw on the invaluable knowledge and expertise of veterinarians on how to best care for animals used in medical research.

As well as thanking all participants, I extend my gratitude to fellow committee members for the collegiate way in which they participated in this inquiry. Their willingness to consider and challenge the respective positions of this nuanced policy debate was much appreciated. I thank the committee secretariat for their most capable assistance. It is our hope that the evidence documented and the commentary provided in this report will both help inform the NSW Government's consideration of these matters and facilitate discussions at the national level that will prompt positive developments with respect to the welfare of animals used in medical research.

The Hon. Greg Donnelly MLC
Committee Chair

Recommendations

Conduct of inquiry

The terms of reference for the inquiry were self-referred by the committee on 3 December 2021.

The committee received 880 submissions and 22 supplementary submissions.

The committee held three public hearings at Parliament House in Sydney.

Inquiry related documents are available on the committee's website, including submissions, hearing transcripts, tabled documents and answers to questions on notice.

Chapter 1 Public health benefits and effectiveness

Evidence of medical advancements for human beings, secured over a long period time, that would not have been possible without using animals in medical research were cited by numerous inquiry participants, highlighting a considerable health public health benefit that must be balanced against animal welfare considerations. This chapter details the prevailing view of the medical research community that animals remain essential to their work because the less established, but emerging alternatives cannot yet provide the same public health benefit.

A countervailing view is explored that opposes the use of animals in medical research on ethical grounds and questions whether the use of animals predicts human outcomes as accurately as is claimed by the medical research community. Proponents of this view told the committee that fundamental cultural change is needed to shift conventional reliance on the use of animals and to propel the development of alternatives.

Advancements in public through the use of animals in medical research

1.1 Contributions to the inquiry by researchers explained why animals are used in medical research, including the small but significant role played by non-human primates (hereafter, 'primates'). The committee was also told by researchers of the benefits of using animals in medical research through advancements in public health. While alternatives to the use of animals in medical research are being developed, the committee heard from some participants that there is a lack of effective non-animal alternatives at present.

Purposes of using animals in medical research

1.2 The committee heard that the use of animals in medical research serves two essential purposes:

- to test the safety of drugs (toxicology), vaccines, medical devices and therapies before human clinical trials
- to advance scientific knowledge (referred to as discovery, fundamental or basic research).[2]

1.3 The NSW Government provided evidence about the use of animals in medical research in this state:

> Within NSW, the conditions being researched in health establishments are predominantly common conditions facing the community. Some globally important neglected diseases and/or rare conditions, in which there is research expertise locally, are also subject to research.
>
> …
>
> NSW has particular expertise in the study of the effects of age, both at the newborn and the older age end of the spectrum and has contributed important advances to understanding the effects of age and pregnancy-related changes in the physiology of humans and animals. The common conditions are responsible for robbing our

[2] Submission 226, Association of Australian Medical Research Institutes, p 2.

> community of hundreds of thousands of productive and healthy years of life annually and adding significantly to the demands on our health system for acute and chronic care.[3]

1.4 In some cases, the use of animals in medical research is 'about improving the wellbeing and the welfare of animals themselves'. According to Mrs Cathy Pitkin, Deputy Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching:

> 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.[4]

1.5 One example of medical research of benefit to animals is in vitro fertilisation (IVF) technology created for humans being used to help 'native species, including the now endangered koala'.[5]

1.6 The committee heard that toxicology research, often regulated by standardised tests, 'is not a big part of animal research in Australia'.[6] Led by pharmaceutical companies overseas, it is an area of early focus for the replacement of animal methods. Dr Malcolm France, Consultant Veterinarian and Board Member, Australian and New Zealand Council for the Care of Animals in Research and Teaching, told the committee that the focus in Australia is on basic research:

> 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.[7]

1.7 An example of the use of animals in basic research towards curing children's cancer was discussed by Dr Ted Rohr, Director Research Ethics and Compliance Support at the University of New South Wales, detailing that:

> We take extracts from a tumour that a child has, a hard-to-treat tumour, we transplant that into a mouse and we use all the current treatments that are possible to test on the mouse, so that we can apply that treatment to that particular child or future children who have that specific cancer.[8]

1.8 The development and validation of COVID-19 vaccinations and drugs was referred to as a recent example of how animals is 'crucial' to medical research by Professor Anthony Cunningham AO, NSW and ACT Branch Chair, Australian Academy of Health and Medical

3 Submission 239, NSW Government, pp 2-3.

4 Evidence, Mrs Cathy Pitkin, Deputy Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching, 28 June 2022, p 13.

5 Evidence, Professor Brian Kelly, Pro Vice-Chancellor (Research), University of Newcastle, 1 June 2022, p 12.

6 Evidence, Dr Malcolm France, Consultant Veterinarian and Board Member, Australian and New Zealand Council for the Care of Animals in Research and Teaching, 28 June 2022, p 12.

7 Evidence, Dr France, 28 June 2022, p 12.

8 Evidence, Dr Ted Rohr, Director Research Ethics & Compliance Support, University of New South Wales, 1 June 2022, p 16.

Sciences.[9] The committee heard Professor's Cunningham's view that 'we would not have had COVID vaccines within a year if we had not had primate research'.[10] Australian researchers, while not ultimately developing a successful vaccine, stated that imported Syrian hamsters and primates provided effective models for their research in the validation of elsewhere-developed messenger ribonucleic acid (mRNA) vaccines.[11] Distinguished Professor Annemarie Hennessy, Deputy Chair of the Animal Research Review Panel and Director, Australian National Baboon Colony, explained the level of comfort that could be offered to human trial participants globally by first conducting trials in primates:

> … some 200,000 human subjects stepped up to be part of the research that would enable the global vaccine to go forward. But how much more comforting to be able to go to those 200,000 volunteers and say, "This has been tested in a few dozen macaques." It was done in non-human primates, but in a way that enabled the next step to go much more quickly.[12]

1.9 Ms Rachel Smith, Chief Executive Officer of Humane Research Australia, presented a counterpoint that the fast-tracking of COVID vaccines was not only due to medical research on animals: 'it was not just animals that got to the vaccine, it was also cell cultures, computer modelling' and organoids.[13] Further, Professor Peter Schofield AO, board member of the Association of Australian Medical Research Institutes, stated that non-animal testing had resulted in important discoveries, noting that 'non-animal testing said that [the anthelmintic drug] ivermectin could reduce the impact of the virus in cell culture'.[14]

1.10 Moreover, the committee heard that human trials of COVID vaccines ran in parallel with animal trials, suggesting researchers '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'.[15] Ms Smith explained the considerable workload and resources involved in identifying the correct animals for testing vaccines, and suggested that developing non-animal methods ahead of time would facilitate rapid responses to future pandemics:

> … trying to establish which animals, then, could contract COVID—trying to genetically modify animals so that they can be receptive to COVID, so that we can then test on them—whereas if we can spend time and money investing in non-animal methods which can be validated, then we can have them prepared if we do have another

9 Evidence, Professor Anthony Cunningham AO, NSW and ACT Branch Chair, Australian Academy of Health and Medical Sciences, 16 May 2022, p 2. See also Evidence, Professor Philip O'Connell, Executive Director, the Westmead Institute for Medical Research, 16 May 2022, p 22.

10 Evidence, Professor Cunningham AO, 16 May 2022, p 4.

11 Evidence, Professor Cunningham AO, 16 May 2022, p 2.

12 Evidence, Distinguished Professor Annemarie Hennessy, Deputy Chair, Animal Research Review Panel and Director, Australian National Baboon Colony, 1 June 2022, p 53.

13 Evidence, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 16 May 2022, p 14.

14 Evidence, Professor Peter Schofield AO, Board member, Association of Australian Medical Research Institutes, 16 May 2022, p 25.

15 Evidence, Ms Smith, 16 May 2022, p 16; Evidence, Dr Katherine van Ekert, Sentient - The Veterinary Institute for Animal Ethics, 28 June 2022, p 6.

> epidemic, rather than panicking and thinking, "What animal can we test it in? What animal can we try and recreate the symptoms in?"[16]

Research using primates

1.11 In NSW, primates are kept and bred for research at the Australian National Baboon Colony, which is 'maintained, managed and financially supported by Sydney Local Health District… The total Australian National Baboon Colony expenditure funded by the District for the 2021–22 financial year was $0.762 million.'[17]

1.12 The NSW Government described primates research as 'having the highest impact in terms of validating and establishing safety of important new therapies'.[18] Professor Philip O'Connell, Executive Director of the Westmead Institute for Medical Research, emphasised their 'small but important role in translating discoveries in lower order animals into therapies in humans', explaining that:

> Their similarities to humans in terms of receptor-ligand compatibility and development means that [primates] have a special place in neuroscience research, immunology, vaccine development, pregnancy and gene therapy. For all these diseases, there are examples of non-human primate research yielding results that translated successfully into better patient care.[19]

1.13 Despite its frequent discussion in relation to COVID-19 vaccines, medical research on primates was described as making up 'only about 0.3 per cent of animal research worldwide'.[20]

1.14 The use of primates was opposed by submitters including the RSCPA, who noted:

> Primates stand out among other taxa for their flexibility in how they respond to the world around them and their highly sophisticated and complex social and cognitive capacities. Therefore, meeting their needs in the research setting with the consequent spatial and social restrictions and limitations on choice and control is inevitably fraught. Therefore, it is difficult to ensure that these animals in a research setting can experience a good quality of life. It is on this basis that the RSPCA opposes the use of primates for research.[21]

1.15 Humane Research Australia agreed, noting that:

> Primates are genetically the closest living creatures to humans. Their sentient ability is thought to be very similar to ours, as primates have complex social interactions. In contrast, a laboratory setting is far removed from the natural habitat. The average laboratory cage of the rhesus macaque is 7 million- fold smaller than their natural home range…The animal welfare impacts associated with their advanced abilities are

16 Evidence, Ms Smith, 16 May 2022, p 15.

17 Responses to questions on notice, Budget Estimates 2021–2022 (Portfolio Committee No. 2 – Health (Health and Medical Research), 7 September 2022, p 31.

18 Submission 239, NSW Government, p 3.

19 Evidence, Professor O'Connell, 16 May 2022, p 22.

20 Evidence, Professor Cunningham AO, 16 May 2022, p 4.

21 Submission 222, RSPCA, p 8.

> profound in a research setting, where they may associate previous negative experiences such as invasive procedures with future occurrences.[22]

1.16 Acknowledging this, Associate Professor Roger Garsia, Chair, Sydney Local Health District Animal Ethics Committee, explained the high threshold for their use in research and the efforts of researchers to maximise the amount of scientific information obtained from each animal:

> … effectively the threshold for the use of non-human primates is that this experimental work could not be done effectively in anything other than a non-human primate and that it is a necessary step to advance an important field of medical research. To give a sense, in our work that we supervise with non-human primates, the numbers of animals that are used are very few because each animal is studied so intensively to try and generate the maximum amount of information. Some of the animals will participate in a number of protocols, some of which are observational, behavioural et cetera, right through to experiments which might be involved in transplantation or something which is a very major impact intervention.[23]

1.17 Associate Professor Garsia explained that the beneficiaries of this research are numbered at 'hundreds and thousands of people in this country, let alone internationally' because testing 'in a subhuman primate' directly precedes 'the administration into human volunteers'.[24]

1.18 Veterinarian and animal welfare researcher Professor Andrew Knight presented a different view that studies and systematic reviews have shown that 'research on primates for the normal purposes—which is attempting to test drugs, vaccines and so on, intended for human patients—unfortunately is not sufficiently reliable or predictive enough for human beings to be of very much use'.[25] One reason given was the logistics of gaining access to primates and the resulting small sample size, and a result 'this research has not been reliably and consistently useful in helping us to advance important human healthcare objectives'.[26]

1.19 Humane Research Australia agreed with this position, noting that:

> It has been argued that primate research is essential to advance human health. Indeed, this is a common assumption due to their close genetic relationship to humans. Yet, we are separated by 25 million years of evolution. There are major anatomical, genetic, dietetic, environmental, toxic, and immune differences. Systematic reviews of primate research indicate that the perceived benefits to humans are overstated and that non-human 13 primate models have provided disappointing contributions toward human medical advancements.[27]

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22 Submission 204, Humane Research Australia, p 12.

23 Evidence, Associate Professor Roger Garsia, Chair, Sydney Local Health District Animal Ethics Committee, 1 June 2022, p 58.

24 Evidence, Associate Professor Garsia, 1 June 2022, p 58.

25 Evidence, Professor Andrew Knight, private individual, 1 June 2022, p 39.

26 Evidence, Professor Knight, 1 June 2022, p 39.

27 Submission 204, Humane Research Australia, p 8.

Public opposition to the use of animals in medical research

1.20 This inquiry received hundreds of submissions which included evidence from individual members of the public expressing their concerns around the ethics of the use of animals in medical research. The specific animal welfare concerns highlighted in submissions are discussed further in Chapter 2 of this report.

1.21 Individual submission authors provided a range of ethical reasons for their opposition to the use of animals in medical research, including:

- the sentience of animals and their ability to experience pain, loneliness, fear, and love[28]
- the similarity of humans to animals, and unfair treatment of them as having lives worth less than human lives[29]
- the inability of animals to advocate for themselves[30]
- the stress of capture, transportation, handling, confinement and living conditions.[31]

1.22 The ethical issues of using animals for medical research were also drawn out in the submission from Mr David Yazbek:

> Animals are sentient beings, just like us. But unlike us, they have no choice as to whether they are experimented upon or live or die. Their lives are totally dependant on the kindness of humans. Animals deserve kindness, empathy and compassion. They do not deserve to live perpetually in cages being experimented upon in any manner. They certainly do not deserve to feel fear as a result of people.[32]

1.23 These concerns about the ethics of the use of animals in experimentation were echoed by animal protection organisations. The Animal Defenders Office observed that:

> Accountability and transparency in the animal medical research industry is minimal, to the point where it is questionable whether the industry can say it has a social licence to do what it does. Time and again we speak to members of our community who have no idea that animals are used for research in Australia. They think it does not happen here and that it was something that happened in the distant past but not anymore. They have wrongly assumed that we and science itself have progressed and moved beyond such antiquated methods.[33]

1.24 Sentient also raised concerns about the experience of animals used in medical research:

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28 Submission 177, Mrs Moira Ferres, p 1; Submission 492, Ms Juliet Green, p 1; Submission 288, Ms Simone Cooper, p 11; Submission 118, Ms Rae-lee Diamond, p 1; Submission 139, Ms Michelle Gable, p 2; Submission 198, Miss Dearne Leeden, p 1; Submission 418, Mr David Yazbek, p 1.

29 Submission 190, Vivien Smith, p 1; Submission 164, Ms Yvette Agardy, p 1; Submission 156, Ms Holly Norton, p 1; Submission 54, Mrs Maria Ilardo, p 1.

30 Submission 64b, Mrs Rachel Sussman, p 1.

31 Submission 288, Ms Simone Cooper, p 3; Submission 278, Ms Janice Haviland and Mr Martin Derby, p 2; Submission 636, Mr Steven Ackling, p 1; Submission 795, Name suppressed, p 1.

32 Submission 418, Mr David Yazbek, p 1.

33 Evidence, Ms Tara Ward, Solicitor, Animal Defenders Office, 16 May 2022, p 38.

> 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.[34]

1.25 In addition to ethical issues, individual submitters opposed medical research using animals on various other grounds:

- it is largely government-funded (and by extension should have social licence)[35]
- animals are physiologically and genetically different to humans, making results unreliable[36]
- alternatives are increasingly available that are cheaper, faster, and more accurate'[37]
- medical research on animals can facilitate disease transmission from animals to humans[38]
- the demand for research subjects can encourage illegal wildlife trading (for example, one individual suggested that 'primates are often snatched from their natural environment and sent to laboratories in a time when all global wildlife is being severely depleted).'[39]

Benefits of using animals in medical research

1.26 A strong and repeated position from medical researchers who made submissions and provided oral evidence to the inquiry was that animals remain essential to their work, which aims to improve human health and treat disease.[40] Professor O'Connell stated that:

> Without animal research, our understanding of disease would be severely diminished, the introduction of new therapies severely curtailed and an unreasonable burden and risk will be placed on vulnerable people who will either have their medical needs unmet or face an increased risk when new, inadequately tested therapies are put for clinical trials without thorough evaluation.[41]

1.27 Professor Brian Kelly, Pro Vice-Chancellor of Research at the University of Newcastle told the committee that the university's health and medical research 'studies have a clear aim: to help people live better, healthier lives', expanding that:

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34 Evidence, Dr Rosemary Elliot, President, Sentient, the Veterinary Institute for Animal Ethics, 28 June 2022, p 3.

35 See, for example: Submission 14, Mr Emmanuel Nulty, p 1; Submission 650, Ms Teresa Romanovsky, p 1; Submission 681, Mrs Zoe Schmidt, p 1; Submission 687, Name suppressed, p 1.

36 See, for example: Submission 30, Ms Wormald, p 1; Submission 57, Ms Donna Monaghan, p 1.

37 Submission 425, Denisa Jalloh, p 1.

38 Submission 669a, Ms Anthea Von Staerck, p 1, Submission 61, Name Suppressed, p 1.

39 Submission 748, Name suppressed, p 1.

40 Submission 239, NSW Government, p 2; Evidence, Professor Schofield AO, 16 May 2022, p 21; Evidence, Professor Kay Double, Professor of Neuroscience and Chair of the Animal Ethics Committee at the University of Sydney, 1 June 2022, p 11; Evidence, Professor Wayne Hawthorne, Chair, Animal Ethics Committee, Western Sydney Local Health District, 1 June 2022, p 2; Evidence, Professor Kelly, 1 June 2022, p 12; Evidence, Professor Cunningham AO, 16 May 2022, p 2.

41 Evidence, Professor O'Connell, 16 May 2022, p 22.

> We also know that animal studies are leading to better treatments for conditions such as stroke, mental illness, asthma, COVID-19 infection, chronic pain and a range of cancers. Animal models are carried out in combination with other technologies to help us better understand and treat disease. They do not perfectly mimic what happens in the human body, but neither do molecular methods, cell cultures or clinical trials for that matter. Animals do, however, provide an essential degree of guidance and confidence that enables subsequent clinical testing to proceed more safely.[42]

1.28 Professor O'Connell cited the 'unprecedented increase in life expectancy in this country' as evidence of benefits of our current approach to medical research.[43]

Current alternatives cannot fully replace animal research

1.29 The prevalent view presented by medical researchers as expressed by Professor Cunningham AO was that 'current alternatives cannot fully replace animal research'.[44] Professor Robert Brink, Pillar Director in Translational Science, Garvan Institute of Medical Research shared the view that:

> For many purposes, there is no current alternative to the use of animal models basically because the complexity of living beings is such that we cannot model that computationally or outside the living being. We believe that, for the time being—and as far as we can see—animal models will be essential for advancing medical research.[45]

1.30 Professor Schofield AO pointed to the consequences of research without animals, particularly that 'the failure rate in clinical trials would be much higher and far more dangerous for humans because we would then be making humans the guinea pigs'.[46] Specific examples of where animal models were critical to the delivery of human health outcomes were provided, including:

- researching a cure for type one diabetes, [47] including pancreas and islet transplantation[48]
- 'organ transplants… made possible through research with animals, which has allowed for the development and constant improvement of the surgical and pharmacological techniques that are now routinely employed'[49]
- developing better therapies for fibrotic liver disease[50] and new stem cell therapies for heart failure[51]

42 Evidence, Professor Kelly, 1 June 2022, p 12.

43 Evidence, Professor O'Connell, 16 May 2022, p 27.

44 Evidence, Professor Cunningham AO, May 2022, p 2.

45 Evidence, Professor Robert Brink, Pillar Director in Translational Science, Garvan Institute of Medical Research, 16 May 2022, p 21.

46 Evidence, Professor Schofield AO, 16 May 2022, p 21.

47 Submission 240, JDRF Australia, p 1.

48 Submission 209, The Westmead Institute for Medical Research, p 1.

49 Submission 226, Association of Australian Medical Research Institutes, p 1.

50 Submission 209, The Westmead Institute for Medical Research, p 1.

51 Submission 209, The Westmead Institute for Medical Research, p 1.

- using small animals (rodents) to understand biological mechanisms and developing novel treatments for mental health, including developing new interventions and biomarkers being trialled in patients with depression and cancer[52]
- implanting and growing a cancer patient's tumour in a cohort of mice and subjecting the mice to chemotherapeutic treatments to assess efficacy[53]
- using gene editing of mice models to interrogate and find treatments for rare genetic diseases in human patients[54]
- primate models that accurately model Hepatitis B are key to further therapeutic development to benefit the 360 million people globally affected.[55]

1.31 Professor Cunningham AO gave evidence that if Australia had to reduce animal testing 'we would have to rely on results from other jurisdictions and internationally'.[56]

1.32 At the same time, Professor Brink identified an encouraging trend which is that 'we are using fewer and fewer animals all the time. And what we do use them for – the impact is much higher than it used to be'.[57]

1.33 Professor Schofield AO assured the committee that 'if there were effective non-animal alternatives … medical researchers would use them'.[58] However, Mr Edwin Brackenreg, Chief Executive Officer of technology company Codex Research presented a different view, asserting there are alternatives to using animals, but the technology requires significant capital investment and long development cycles:

> 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.[59]

1.34 There was evidence from both research and animal advocates alike that more needs to be done to develop and move towards alternatives.

Questioning the efficacy of animal research, and need for alternatives

1.35 Evidence from some inquiry participants questioned the effectiveness of the use of animals in medical research. These submitters supported a cultural shift towards human-relevant data

52 Submission 215, Neuroscience Research Australia, p 1.

53 Submission 219, Garvan Institute of Medical Research, p 3.

54 Submission 219, Garvan Institute of Medical Research, p 3.

55 Submission 223, Australian Academy of Health and Medical Sciences, NSW Branch, p 2.

56 Evidence, Professor Cunningham AO, 16 May 2022, p 3.

57 Evidence, Professor Brink, 16 May 2022, p 36.

58 Evidence, Professor Schofield AO, 16 May 2022, p 21.

59 Evidence, Mr Edwin Brackenreg, Chief Executive Officer, Codex Research, 28 June 2022, p 16.

derived from alternative approaches to medical research, challenging conventional views on the necessity of using animals. While accepting that alternative methods require development, it was argued that it is essential medical science harnesses technology and explore non-animal methods, for ethical reasons and to achieve more accurate results. In support of the efficacy of alternatives, the committee was directed to a number of other countries that have committed to phase out the use of animals in medical research. Further details regarding this are provided later in the chapter.

Accuracy of results from animal research

1.36 Despite evidence from the medical research community that testing on animals is essential to medical research, the committee heard evidence that challenged success rates of the use of animals in medical research. For example, Mr Brackenreg of Codex Research expressed the view that 'animal research fails to predict human outcomes in the majority of cases'.[60] Mr Troy Seidle, Vice-President, Research and Toxicology, Humane Society International expressed a similar view that:

> 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.[61]

1.37 Humane Research Australia also argued that 'the benefits [of using animals] are overstated, and that superior methods based on human-biology are much needed to progress human health in the modern era'. They explained that:

> Although even a single significant advancement is to be applauded, it must be considered in the context of a great number of failed cases, which indicate the unreliable and ineffective nature of animal models. It would be prudent to seek more consistently successful models that could produce a higher rate of significant contributions.[62]

1.38 In response to questions taken on notice, Sentient – The Veterinary Institute for Animal Ethics shared insights from a journal article about how the conditions in which animals are held in laboratories can affect research outcomes:

> Laboratory procedures and conditions exert influences on animals' physiology and behaviors that are difficult to control and can ultimately impact research outcomes and impede extrapolation to humans. Animals in laboratories are involuntarily placed in artificial environments, usually in windowless rooms, for the duration of their lives. Captivity and the common features of biomedical laboratories—such as artificial lighting, human-produced noises, and limited space and lack of environmental

60 Evidence, Mr Brackenreg, Codex Research Pty Ltd, 28 June 2022, p 16.

61 Evidence, Mr Troy Seidle, Vice-President, Research and Toxicology, Humane Society International, 28 June 2022, p 7.

62 Submission 204, Humane Research Australia, p 3.

enrichment—can prevent species typical behaviors, causing distress and abnormal behaviors among animals.[63]

1.39 Sentient added that animals 'are also exposed to social stressors, whether this is isolation or aggressive interactions between conspecifics'.[64]

1.40 The committee was provided specific examples where animal models had a 'low translation rate' in basic research,[65] particularly in relation to:

- cardiovascular diseases because of species differences, including in hemodynamics, lifespan, lipid metabolism and immune function, and the difficulty replicating human cardiovascular disease parameters in animal models including cardiac arrythmias, heart failure and resistant hypertension[66]
- neurodegenerative diseases (brain disorders) including Alzheimers,[67] schizophrenia and autism. Drugs have cured these conditions in mice but none have worked in humans[68]
- stroke[69]
- vaccines, particularly monoclonal antibodies and CRISPR RNAs which are so specific for human target genetic sequences that responses are often not representative in animal models, not even in primates.[70]

1.41 Codex Research presented a view that the use of animals in basic research is not effective in tackling 'the biggest disease burdens on society currently', particularly cardiovascular and neurodegenerative diseases.[71]

1.42 An example given by Sentient - The Veterinary Institute for Animal Ethics in relation to rodent research was that 'the reliance on "CRAMPED" animals — cold, rotund, abnormal, male-biased, enclosed and distressed — could help explain the current low success rates'.[72]

1.43 Professor Wojciech Chrzanowski, Professor of Nanomedicine, University of Sydney, and Science Advisor, Medical Advances Without Animals Trust (MAWA) highlighted the inconsistency of results from animals when laboratory conditions vary:

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63 Ashya Aktar, 'The Flaws and Human Harms of Animal Experimentation', Cambridge Quarterly of Healthcare Ethics (2015), issue 24, p 408, accessed 18 October 2022 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/pdf/S0963180115000079a.pdf>.

64 Answers to questions on notice, Sentient - The Veterinary Institute for Animal Ethics, received 1 August 2022, p 8.

65 Evidence, Ms Smith, 16 May 2022, p 12.

66 Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, pp 1-2.

67 Evidence, Dr van Ekert, 28 June 2022, p 6.

68 Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, pp 3-4.

69 Evidence, Professor Christopher Little, Director, Raymond Purves Bone and Joint Research Laboratory, Kolling Institute, 28 June 2022, p 18.

70 Evidence, Professor Christopher Little, Director, Raymond Purves Bone and Joint Research Laboratory, Kolling Institute, 28 June 2022, p 18.

71 Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, p 3.

72 Answers to questions on notice, Sentient - The Veterinary Institute for Animal Ethics, 1 August 2022, pp 7-8.

> In one of the examples with animals, if you house the animals into different houses, the results are actually completely different. Even sometimes when you house them in the same house but in two different corners, your result will be different. So how do you normalise it, and how do you know that your result is actually correct or not? The microbiomes are different.[73]

1.44 In relation to toxicology or drug discovery, the committee heard evidence that 'nearly 95 per cent of drugs entering human trials will fail': a failure rate attributed to 'lack of effectiveness and poor safety profiles that were not predicted in animal tests'.[74] Dr Katherine van Ekert, Vice President of Sentient - The Veterinary Institute for Animal Ethics explained that failure rates include circumstances where the trial drugs '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'.[75]

1.45 By conducting systematic reviews, Professor Knight identified 'a certain set of flaws within medical research' that uses animals, spanning design, assessment and conduct of research and its reporting in scientific journals.[76] His conclusion is that the lack of scientific scrutiny applied to the use of animals in medical research is 'limiting the reproducibility and the reliability of this research and, consequently, the ability to produce the hoped-for benefits in terms of human healthcare advancements', inferring:

> … it is very clear that although there are some benefits and some links, the level is unfortunately much lower than is usually hoped for, and often what is expected, and is in fact very low overall. It's a method that we can use, but the efficiency of this method or this tool for achieving that public healthcare objective is very, very poor.[77]

1.46 Professor Knight called for an increased focus on how often animal research actually produces hoped-for benefits,[78] a view echoed by Sentient – The Veterinary Institute for Animal Ethics, which explained how conducting secondary research upfront can reduce repetition and reduce 'alarming failure rates', outlining that:

> Systematic reviews can help researchers and clinicians keep up with literature by summarising a large body of evidence and helping to explain differences among studies on the same question. Meta-analysis is the statistical method used to combine results from relevant studies, and the resultant larger sample size provides greater reliability of the estimates of a treatment effect. Systematic reviews and meta-analyses of experimental investigations can clarify whether and how translation from animal to clinical research could progress and can provide a unique opportunity to review the appropriateness of the animal models used.[79]

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73 Evidence, Professor Wojciech Chrzanowski, Professor of Nanomedicine, University of Sydney, and Science Advisor, Medical Advances Without Animals Trust (MAWA), 1 June 2022, p 27.

74 Evidence, Mr Seidle, 28 June 2022, p 2.

75 Evidence, Dr van Ekert, 28 June 2022, p 5.

76 Evidence, Professor Knight, 1 June 2022, p 41.

77 Evidence, Professor Knight, 1 June 2022, p 41.

78 Evidence, Professor Knight, 1 June 2022, p 41.

79 Answers to questions on notice, Sentient - The Veterinary Institute for Animal Ethics, 1 August 2022, p 6.

1.47 Ms Smith of Humane Research Australia was among those advocating for thorough scrutiny of whether the research method is likely to make 'a tangible difference', rather than simply 'justifying the research because of the severity of the disease'.[80]

Cultural change towards exploring alternatives to using animals

1.48 The need for a cultural shift in medical research, considering the use of animals and alternatives, was repeated many times in evidence to the inquiry.[81] The use of animals was described as 'entrenched'[82] and 'prevalent within academia industry and regulatory agencies'.[83] Discussing a 2020 paper titled 'Are researchers moving away from animal models as a result of poor clinical translation in the field of stroke', Ms Smith's evidence drew attention to:

> … a bias towards animal research by grant funders, peer reviewers and journal editors; the wish to avoid sunk costs invested in animal research infrastructure; and the economic drivers of those gaining from animal research, such as suppliers of animals or equipment.[84]

1.49 Professor Knight told the committee that 'the current culture of how animal research is designed, conducted and reported has produced such a low level of benefits in light of the resources that have been invested in it that a paradigm change is clearly warranted', arguing for funding to be redirected to 'more promising and justifiable fields of research and health care'.[85] The funding of medical research is discussed further in Chapter 2 of this report.

1.50 Considering the culture of animal testing within the medical research community, Dr Suzanne Fowler, Chief Science Officer at RSPCA Australia told the committee:

> In Australia, there is not really a culture to go, "You know what? There might be a better way. Maybe there is a better way."…We need a big push and a big incentive and a massive jolt for this industry to go, "You know what? We can't keep doing it that way. Maybe I need to do a parallel study, which still might use animals, but I could validate that organ on a chip technology or micro organoids could get me similar results or could give me the same building blocks to build knowledge on."[86]

1.51 Professor Chrzanowski described 'inertia and some resistance' in the research community, but expressed optimism about the possibilities and uptake of alternatives to animal models:

> I think if we have some spectacular successes showing that it works, maybe this would drag more people behind. But definitely what I see at the university, maybe with slightly

80 Evidence, Ms Smith, 16 May 2022, p 16. See also Answers to questions on notice, Sentient - The Veterinary Institute for Animal Ethics, 1 August 2022, p 2.

81 Evidence, Ms Sarah Margo, Solicitor, Animal Defenders Office, 16 May 2022, p 44; Evidence, Ms Smith, 16 May 2022, p 10; Evidence, Dr Suzanne Fowler, Chief Scientific Officer, RSPCA Australia, 16 May 2022, p 45; Evidence, Professor Knight, 1 June 2022, pp 38 and 42; Evidence, Mr Seidle, 28 June 2022, p 2.

82 Evidence, Ms Tara Ward, Solicitor, Animal Defenders Office, 16 May 2022, p 43.

83 Evidence, Ms Smith, 16 May 2022, p 10. See also: Evidence, Dr Fowler, 16 May 2022, p 40.

84 Evidence, Ms Smith, 16 May 2022, p 10.

85 Evidence, Professor Knight, 1 June 2022, p 38.

86 Evidence, Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia, 16 May 2022, p 45.

> younger academics—there is definitely a strong push towards the alternatives and the better models. They give a lot of chances and more opportunities for fundamental discoveries, which you cannot do in the animal models. The fundamental discovery drives the outcome and drives the commercialisation. Without the fundamentals, we cannot do anything.[87]

1.52 'Sometimes it takes a few researchers, who build a culture and perpetuate it to the rest', in Professor Chrzanowski's experience.[88]

1.53 Evidence that cultural change is underway was provided by Ms Smith who described 'increasing recognition of the limitations of animal models in scientific literature and by innovative companies embracing new approaches'.[89] Ms Sarah Margo, Solicitor, Animal Defenders Office, expressed an optimism in this regard, suggesting 'we can absolutely move towards reducing our reliance on animals, regardless of what the status quo right now and today is'.[90]

Human-relevant, non-animal approaches

1.54 Mr Seidle of Humane Society International described the necessary cultural change as 'a shift that positions human biology as the gold standard and prioritises funding and uptake of human-relevant, non-animal approaches',[91] expanding in answers to the committee's questions that 'years of research and innovation have delivered a suite of powerful and commercially available predictive tools' which are superior to the use of animals in medical research.[92]

1.55 Humane Research Australia explained that its advocacy for human-relevant data 'does not mean we are advocating for testing on humans-or unwilling humans. It just means using human-relevant data. So, using human cells and then creating 3D models, or organised from human-relevant material'.[93] Professor Knight hypothesised that 'human cell cultures, simulations and epidemiological studies are more likely to produce benefits for actual human beings'.[94]

1.56 The cultural change needed extends to the academic publication of medical research in Australia, according to Professor Alastair Sloan, Professor of Tissue Engineering and Dental Biology, and Science Advisor at MAWA. He provided a specific example of presenting a 'great piece of research around antimicrobial coatings of implants' to a scientific journal and being told "you must put it into an animal model". He explained his contrary view that testing the coatings in animals 'would provide no additional useful data' as 'the oral microbiology, the flora of the human mouth, is different to any animal model system you would want to use'.[95] As well as

87 Evidence, Professor Chrzanowski, 1 June 2022, p 29.

88 Evidence, Professor Chrzanowski, 1 June 2022, p 25.

89 Evidence, Ms Smith, 16 May 2022, p 10. See, for example, Submission 202, CK Cell Technologies Pty Ltd, p 1; Submission 225, Codex Research Pty Ltd, pp 1-4.

90 Evidence, Ms Margo, 16 May 2022, p 44.

91 Evidence, Mr Seidle, 28 June 2022, p 2.

92 Answers to questions on notice, Mr Seidle, 21 August 2022, p 1.

93 Evidence, Ms Smith, 16 May 2022, p 15.

94 Evidence, Professor Knight, 1 June 2022, p 41.

95 Evidence, Professor Alastair Sloan, Professor of Tissue Engineering and Dental Biology Science Advisor, Medical Advances Without Animals Trust, 1 June 2022, p 27.

discussing biological differences, he explained that animal models provide less reproducibility than non-animal model systems:

> If you're developing a therapeutic, like I am, an animal system gives you one animal, one time point—or one animal, one dose point—whereas model systems can give you multiple dose points and multiple time points and are highly reproducible. It means when you ultimately get to the top of the pyramid and transition into a true preclinical environment, you are asking the right questions, very specific questions, and the need for animals, if at all, becomes very, very low. That is the journey we should be looking to progress to.[96]

Better results might be achieved by using alternative methods

1.57 The committee was interested to hear examples of innovative approaches to medical research that are starting to improve human health without the use of animals. Some examples include:

- innovations in personalised medicine: 'taking a patient's cells and recreating certain parts of the person's physiology in a dish to test whether treatments are effective or not' for them.[97] For example researchers in the Netherlands grew mini guts from patient cells to successfully predict which cystic fibrosis patients respond to which drugs[98]
- an 'organ-on-a-chip methodology' which identified that 80 per cent of a sample of 27 drugs were toxic to humans after passing animal testing; 208 human fatalities and 10 liver transplants would have been prevented if the technology had been available and used[99]
- a liver chip that could have detected the hepatoxicity of inarigivir, a trial drug treatment for hepatitis B which led to the death of a patient during phase II clinical trials after woodchuck, rat and mouse tests suggested the safety and efficacy of the drug[100]
- 3D culture systems which can achieve better characterisation of pathological mechanisms, also making them suitable for drug screening for human neurodegenerative diseases[101]
- a 3D bioprinting company in South Korea that produces successful skin replacement for burns victims, moving from one bioprinter to hundreds of bioprinters within five years.[102]

1.58 Professor Chrzanowski gave evidence that in his field of respiratory health, alternatives to animal research 'are the only option for us'. He explained:

> … in reality, there are only two models that represent human physiology—but pathophysiology very poorly—which are baboons and sheep. If we have to do 100 samples, imagine how many animals would be sacrificed and what the ethical application of this is. For any other model—the small animal or rodent model—the correlation to human physiology and a translation to clinical trials is zero. Absolute zero. There are

96 Evidence, Professor Sloan, 1 June 2022, p 27.

97 Answers to questions on notice, Medical Advances Without Animals Trust, p 5.

98 Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, p 6.

99 Evidence, Ms Smith, 16 May 2022, p 19.

100 Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, p 6.

101 Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, p 2.

102 Evidence, Professor Chrzanowski, 1 June 2022, p 30.

> different aerodynamics, a different number of lobes, different cells—no cilia, no mucus.[103]

1.59 Professor Chrzanowski elaborated that in vitro (outside the body) research allows 'in depth' and reproducible study, but qualified that whole organs cannot be represented in vitro: 'you can do the small airways, you can do the upper airway, the trachea—you can create certain parts of the physiology. But this is not an entire lung. That is the limitation'.[104]

1.60 The committee heard that alternative models to the use of animals have considerable benefits including reproducibility, reliability and rapidity. Professor Chrzanowski presented a view that:

> The alternative models…mimicking structures of human physiology—are really great options because we can build a lot of them. What that means is that we can create hundreds of models and do the high-throughput screening. They are reproducible; they are reliable. On top of this, they allow rapid screening and they also allow us to take the cells directly from the patients, which means that we can create a model of each of the individual patients for personalised medicine.[105]

1.61 When asked what incentives exist for large pharmaceutical companies to invest in research into alternatives to animal testing, Professor Cunningham AO answered 'to improve their vaccines', explaining that mice are not 'the exact equivalent of humans' and:

> If we can develop models that use human-discarded tissues, then obviously that provides a much greater understanding of how these vaccines might work in humans and how they might be improved – the side effects of them and their efficacy.[106]

1.62 Professor Chrzanowski gave evidence of the existing investment in alternatives by pharmaceutical companies including Roche and AstraZeneca, and defence organisations including DARTA and DSD, 'because they know that the animal models don't work for them'.[107]

Alternative methods require development

1.63 Despite the optimistic view presented by some inquiry participants, a number of witnesses experienced in the use of animals to conduct medical research expressed the need to exercise caution around exclusive reliance on new methods. For example, Professor Christopher Little, Director of the Kolling Institute's Raymond Purves Bone and Joint Research Laboratory, told the committee 'as of yet, in vitro models don't have any proven validity', describing that a 'stepwise process' would probably follow to improve them.[108] Professor Little expressed an openness to whichever methods achieved results, telling the committee:

> 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

103 Evidence, Professor Chrzanowski, 1 June 2022, p 21.

104 Evidence, Professor Chrzanowski, 1 June 2022, p 24.

105 Evidence, Professor Chrzanowski, 1 June 2022, pp 21–22.

106 Evidence, Professor Cunningham AO, 16 May 2022, p 6.

107 Evidence, Professor Chrzanowski, 1 June 2022, p 2.

108 Evidence, Professor Little, 28 June 2022, p 17.

> 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.[109]

1.64 Dr Christopher McCarthy, Chair, Animal Care and Ethics Committee, University of Newcastle told the committee 'I think I speak on [behalf of] all researchers – the day we don't need to use any animal models would be a good day'. He qualified that, for example, in relation to smoke inhalation research 'my understanding is that the researchers do not have an alternative that would remove the animal model'. [110]

1.65 The efficacy of particular new technologies was considered, including by Professor Schofield AO who contended that 'Stem cell technology has still got a long way to go' and offers 'potential, but not fulfilled delivery'.[111] Considering whether 3D printing would overcome animal research, Professor O'Connell commented 'I think in some instances it will, but it is hard for me to see that it would exclusively in the next 10 or 15 years'.[112]

1.66 Considering the economic implications of moving away from the conventional methods, Professor Cunningham AO cautioned that if New South Wales introduced more stringent regulations around using animals in research, big corporations 'would go elsewhere'.[113] Ms Smith presented a different view, stating 'it could be counter argued that if we are not facing new methods of technology here, then our researchers could be going overseas to follow that path'.[114]

Transition plans to phase out some types of animal research

1.67 MAWA Trust described 'huge global interest in non-animal technologies'.[115] The committee heard that a number of other countries have committed to phase out the use of animals in medical research.[116] For example:

- The Netherlands will phase out some types of research by 2025 using a transition plan.[117]
- The European Parliament voted overwhelmingly in favour of a resolution to phase out animal use for research, testing, and education, adopting an action plan in 2021.[118]

109 Evidence, Professor Little, 28 June 2022, p 20.

110 Evidence, Dr Christopher McCarthy, Chair, Animal Care and Ethics Committee, University of Newcastle, 1 June 2022, p 13.

111 Evidence, Professor Schofield AO, 16 May 2022, p 23.

112 Evidence, Professor O'Connell, 16 May 2022, p 25.

113 Evidence, Professor Cunningham AO, 16 May 2022, p 6.

114 Evidence, Ms Smith, 16 May 2022, p 17.

115 Answers to Questions on notice, MAWA Trust, p 4.

116 Evidence, Ms Margo, 16 May 2022, p 44.

117 Evidence, Ms Smith, 16 May 2022, p 17.

118 Answers to questions on notice, Sentient - The Veterinary Institute for Animal Ethics, 1 August 2022, p 16; Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, p 1; Submission 214, NSW Young Lawyers, pp 14-15.

- The United States Congress is considering a bill[119] that 'broadens the scope of acceptable preclinical models for drug development, enabling researchers to test a drug's safety and efficacy using more advanced and human-relevant methods.'[120]
- New Zealand's Animal Welfare Act 1999 prohibits research on primates unless approved by the Director-General.[121]
- The UK in 2004 responded to a House of Lords Select Committee report on Animals in Scientific Procedures by establishing a national 3Rs centre (discussed further in Chapter 5).[122]
- China in 2020 banned export of primates, including for medical research.[123]
- Brazil and South Korea have "mandatory alternatives" requirements: it is illegal for a company to conduct animal experimentation if a non-animal approach is available.[124]

Committee comment

1.68 The committee received insightful evidence about the use and value of both animal and non-animal methods used for medical research purposes. While progress of using non-animal methods expands and will continue to do so, the majority of the committee is of the view at this point in time, for various aspects of medical research, there is still an imperative to use animals.

1.69 Given that the aims of medical research are to provide humans with the most effective medical treatment and care, the committee was persuaded a strategy must be adopted at both a governmental level and by individual research institutions, maintaining the reliance on animal methods for only so long as necessary before their progressive replacement with alternatives is possible.

119 FDA Modernization Act of 2021, HR2565 introduced to the House of Representatives on 15 April 2021 and S.2952 introduced into the Senate on 7 October 2021.

120 Answers to questions on notice, Codex Research Pty Ltd, 18 August 2022, p 5.

121 Submission 245, Animal Defenders Office, p 15.

122 Submission 245, Animal Defenders Office, p 15.

123 Submission 205, European Animal Research Association, p 3.

124 Submission 220, Humane Society International Australia, p 7.

Chapter 2 Ethical and welfare issues

The view that intentionally harming and causing pain and suffering to animals is unacceptable underpinned many of the contributions made to this inquiry. This was expressed most strongly by animal welfare organisations and individuals. From research organisations and government representatives, the committee heard the range of ethical considerations that underpin decisions about using animals in medical research, including the question of whether using animals is justified by potential benefits to human health.

This chapter sets out a brief overview of the multifaceted ethical and animal welfare issues raised in evidence, with a specific focus on stakeholder views expressed about two particular experiments, the forced swim test and smoking tower procedures. The views documented here set the foundation for the more specific aspects of the regulatory structure explored in the subsequent chapter of this report.

Ethical opposition and justification for the use of animals for medical research

2.1 The committee heard contrasting views about the use of animals in medical research spanning the following positions:

- the use of sentient animals in medical research cannot be justified ethically[125]
- the use of animals is a necessary part of developing effective therapies for humans.[126]

2.2 Stakeholders such as the Australian Veterinary Association (AVA) discussed the interdependent relationship between animals and humans. The AVA shared their Policy Statement which provides that:

> Animals are sentient beings that are conscious, feel pain, and experience emotions2. Animals and people have established relationships for mutual benefit for thousands of years.
>
> Humans have a duty of care to protect animals. Where a person does not meet his or her obligations to animals in his or her care, animals may suffer. When this happens, the law must be able to adequately intervene to enforce compliance and prevent suffering.
>
> Animals have intrinsic value and should be treated humanely by the people who benefit from them. Owned animals should be safe from physical and psychological harm. They need access to water and species-appropriate food and shelter and should be able to fulfil their important behavioural and social needs. They must receive prompt veterinary care when required and have as painless and stress-free a death as possible.
>
> Animals can be used to benefit humans if they are humanely treated, but the benefit to people should be balanced against the cost to the animal. They should not be used in direct combat or for purposes where suffering, injury or distress is likely to be caused.[127]

125 For example, Evidence, Dr Rosemary Elliott, President, Sentient – The Veterinary Institute for Animal Ethics, 28 June 2022, p 3.

126 For example, Evidence, Professor Kay Double, Professor of Neuroscience, Chair of Animal Ethics Committee, University of Sydney, 1 June 2022, p 11.

127 Submission 242, Australian Veterinary Association, p 3.

2.3 The ability of animals to feel and perceive and their inability to consent to their use in medical research were explored by inquiry participants including Ms Tara Ward, Solicitor at the Animal Defenders Office who outlined that:

> For many who are concerned about the use of sentient animals who have not consented to this kind of experimentation, there are serious ethical concerns about this that are not justified and cannot be justified from a utilitarian balancing act. Just as we draw the line and would not experiment on humans in that situation, even if it guaranteed a quicker and better outcome, I would say that we do not experiment on any sentient creature where we have not got their consent.[128]

2.4 The Kolling Institute provided their view that without using animals, humans could be exposed to dangerous experiments:

> … 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.[129]

2.5 In addition, the Association of Australian Medical Research Institutes submitted that 'the welfare of animals used in research is of the highest concern to those working in medical research'.[130] As an example, the Garvan Institute of Medical Research outlined some of the education and training measures taken to ensure animals are cared for during medical research:

> Animal welfare is a continuously evolving area that indicates commitment by the industry in ensuring high standards of animal care. Animal ethics committee members, animal care staff as well as researchers undergo continuing education to upskill and upgrade their knowledge. Training requirement[s are] mandatory, rigorous and involve dedicated learning and practice.[131]

2.6 In this regard, the care taken by the laboratory animal science and welfare community to 'approach all decisions and actions in caring for and use of animals throughout their lifetime from a place of respect and dignity'[132] was made clear by the Australia and New Zealand Laboratory Animals Association.

Research causing significant harm to animals

2.7 Inquiry participants presented strong objections to medical research practices that cause significant physical and psychological harm to animals. In this section the committee examines two particular research experiments that are said to cause such extreme harm: the forced swim test and the smoking tower.

128 Evidence, Ms Tara Ward, Solicitor, Animal Defenders Office,16 May 2022, p 43.

129 Submission 227, Kolling Institute, pp 1-2.

130 Submission 226, Association of Australian Medical Research Institutes, p 4.

131 Submission 209, Garvan Institute of Medical Research, p 5.

132 Submission 218, Australia and New Zealand Laboratory Animals Association, p 2.

Procedures with particularly serious consequences

2.8 A particularly emotive aspect of participants' discussion of the use of animals in medical research was evidence of practices that cause significant physical or psychological harm to animals. Dr Rosemary Elliott, President of Sentient - The Veterinary Institute for Animal Ethics, described 'profound' harm to all research animals, explaining that 'a laboratory animal's experience is one of perpetual fear, vigilance, breathlessness, pain, nausea, hunger, discomfort, exhaustion, boredom, helplessness, frustration, terror, confusion and despair.'[133]

2.9 The Animal Defenders Office submitted that they are particularly concerned about animals being used in invasive procedures and research that may even lead to their lives being terminated:

> Current categories of invasive animal research procedures include 'major surgery with recovery', 'major physiological challenges', and 'death as an endpoint' (ie where researchers do not intervene to kill the animal before certain levels of suffering are reached). In 2020 in NSW more than 58,400 animals were reportedly used for these three procedures. There are serious ethical concerns about using animals in research where they will not only suffer but have their lives terminated.[134]

2.10 In a similar vein, Dr Elliott outlined the suffering that animals experience in the course of medical research, which in some cases lead to their deaths:

> 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 CO_2 inhalation.[135]

2.11 Professor Andrew Knight, a veterinary professor of animal welfare and ethics, highlighted the specific animal welfare concerns around primates, and the 'sorts of characteristics may place primates at particular risk of suffering when subjected to invasive research in confinement within these environments':

> … they have particularly advanced cognitive, psychological and social characteristics, which means that it is particularly problematic when they are confined in relatively small environments where they are not able to exercise their full, natural behavioural repertoire. The disruption of their social networks is also important. These factors create a particular set of stressors, which may be less commonly experienced by other species. One characteristic, for example, is their long memories. They have the ability to remember that certain people—as in, laboratory technicians—certain tools and certain procedures may be associated with pain and stress, and to anticipate those occurring in the future.[136]

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133 Evidence, Dr Rosemary Elliott, President, Sentient - The Veterinary Institute for Animal Ethics, 28 June 2022, p 3.

134 Submission 245, Animal Defenders Office, p 6.

135 Evidence, Dr Elliott, President, 28 June 2022, p 3.

136 Evidence, Professor Andrew Knight, 1 June 2022, p 38.

2.12 Numerous submissions from private individuals drew attention to specific and serious animal welfare concerns that they said occurred in the course of medical research. The submissions suggested that most of these alleged practices and consequential harms occurred in Australia, and some were identified as occurring in New South Wales. Prominent examples are highlighted below:

- Primates
  - 'macaque monkeys had their skulls drilled into and electrodes inserted into their brains … to measure their attention spans'[137]
  - macaque monkeys had their spinal cords partially severed resulting in paralysis on one side - one monkey was described as being unable to stand up, with both of its left limbs flaccid[138]
  - monkeys sliced 'open from neck to groin while they are tied down and still alive'[139]
  - pregnant baboons induced with pre-eclampsia[140]
  - primates subjected to 'electric shock experiments'[141]
  - monkeys addicted to drugs[142]
  - marmosets used 'to take electrophysiological readings from their brains before they were killed with an overdose'[143]
- Companion animals
  - 'Dogs being forced to inhale poisonous gases'[144]' or force-fed pesticides[145]
  - kittens blinded[146]
  - cats and ferrets having 'hard plastic tubes are forced down the[ir] delicate throats' to train doctors in intubation[147]
  - rabbits starved from water and food for experimentation, and housed in cages not bigger than their size for experiments such as muscle cramping[148]
  - rabbits and guinea pigs subjected to:
    - the Draize Test which involves dripping chemicals into their eyes or rubbing them onto their shaved skin, without any pain relief,' a toxicity test that can lead to scarring, blindness, and death[149]
    - the LD50 Test to test the dosage of a substance necessary to cause death where 'researchers hook the animals up to tubes that pump large amounts of the test product into their stomachs until they die, which may take days or

137 Submission 272, Name suppressed, p 2.
138 Submission 277, Mrs Janet Allan, pp 2-3.
139 Submission 448, Mrs Francine Horne p 1.
140 Submission 259, Ms Mary Ann Gourlay, p 4.
141 Submission 444, Mrs Jennifer Valentine, p 1.
142 Submission 289, Mrs Sofia Debus, p 1.
143 Submission 158, Name suppressed, p 1.
144 Submission 448, Mrs Francine Horne p 1.
145 Submission 288, Ms Simone Cooper, p 10.
146 Submission 289, Mrs Sofia Debus, p 1.
147 Submission 289, Mrs Sofia Debus, p 1.
148 Submission 258, Ms Cheryl Forrest-Smith, p 5.
149 Submission 139, Ms Michelle Gable, p 1.

even weeks of prolonged suffering. Animals often suffer from vomiting, paralysis, convulsion, internal bleeding, and diarrhea during this time'.[150]

- Rodents
  - rats 'fed a fast-food diet of pies, lamingtons, and dim sims to investigate linkages with obesity'[151]
  - rodents having weights dropped on their heads to cause traumatic brain injury'[152]
  - mice and rats undergoing skull surgeries, burns, and spinal surgeries and 'provided with post-procedural pain relief only about 20 percent of the time'[153]
  - overbreeding of mice, rats and guinea pigs by institutions and culling them in the hundreds when they are not needed[154]
- Livestock
  - lambs shaken to death 'to prove whether shaking alone is sufficient to produce brain injury and mortality, or whether additional head impact is required'[155]
  - pigs given silicone breast implants[156]
  - pregnant sheep fed alcohol[157]
  - live pigs burned to test methods of wound healing.[158]

2.13 In addition, in relation to companion animals, Humane Research Australia advised that healthy greyhounds are used 'for heart surgery experiments, terminal blood donation, and to test dental implants and deep brain stimulation devices'.[159]

2.14 The committee notes that while these alleged practices may not have occurred in New South Wales, Ms Lisa Craig, a former animal care manager at research facilities in Australia and the United States, provided evidence that concerning practices may be close to home when she commented 'I have encountered things in Australia that I have been quite shocked by.'[160]

2.15 The next section considers in greater detail two particular uses of mice in medical research, reflecting the extent of evidence received about them and the concerns raised in this evidence.

150 Submission 139, Ms Michelle Gable, pp 1-2.

151 Submission 258, Ms Cheryl Forrest-Smith, p 6. See also: Evidence, Ms Smith, 16 May 2022, p 17.

152 Submission 253, Ms Josephine Velte, p 1.

153 Submission 288, Ms Simone Cooper, p 3.

154 Evidence, Ms Lisa Craig, 16 May 2022, p 48.

155 Submission 277, Mrs Janet Allen, p 5.

156 Submission 277, Mrs Janet Allen, p 5.

157 Submission 277, Mrs Janet Allen, p 5.

158 Submission 23, Name suppressed, p 1.

159 Submission 204, Humane Research Australia, p 13.

160 Evidence, Ms Craig, 16 May 2022, p 49.

Forced swim test and the smoking tower

2.16 The committee was encouraged by inquiry participants to look in detail at two 'particularly invasive types of research'[161] involving rodents, the forced swim test and use of a smoking tower in inhalation research (also referred to as the 'smoking model' or 'smoking mice'). As an indicator of the strength of inquiry participants' views, Ms Craig described these two uses of animals in medical research as leading to 'the most horrific welfare issues I have seen.'[162]

2.17 Several inquiry participants called for the forced swim test and smoking tower procedures to be banned outright in New South Wales.[163] Humane Research Australia advised that some Animal Care and Ethics Committees had prohibited these tests.[164]

2.18 The background to each use is explained in the following case studies, with a selection of participants' views set out beneath.

Case study A: The forced swim test

The forced swim test was developed in 1978 and has been used for decades in neurobiology research and drug studies, including to evaluate antidepressants. The test (shown in Figure 1) involves placing a mouse or rat in a transparent cylinder of lukewarm water where they swim and attempt to climb the walls of the cylinder before becoming immobile and floating. The animals are generally removed after a set time, but some animals die after the test from aspirating water.[165]

The test is grounded in theory that animals that spend more time floating (and less time swimming or attempting to escape) are feeling helpless and that this indicates depression or anxiety. There is a correlation between the efficacy of some antidepressants and the outcomes of the test.[166] However, there have been questions raised as to whether this test is a good model for a complex, chronic condition like human depression, as contradictory evidence has shown that floating is a learned and adaptive behaviour that saves energy and is beneficial for survival.[167]

The test has been used in research at the Macquarie University and the University of Wollongong. Following a review at the University of Wollongong, the test is now only used

161 Evidence, Ms Smith, 16 May 2022, p 12.

162 Evidence, Ms Craig, 16 May 2022, p 49.

163 See, for example: Submission 204, Humane Research Australia, p 14; Submission 220, Humane Society International Australia, p 5; Submission 245, Animal Defenders Office, p 8; Submission 262, Sentient - The Veterinary Institute for Animal Ethics, p 5.

164 Answers to questions on notice, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 29 June 2022, p 5.

165 Submission 204, Humane Research Australia, pp 10–11; Submission 222, RSPCA, pp 8–9.

166 *In camera* evidence, Witness A, 16 May 2022, p 4, published by resolution of the committee.

167 Submission 222, RSPCA, p 9. See also Submission 204, Humane Research Australia, pp 10-11; Evidence, Dr Sarah Toole, Animal Welfare Officer & Veterinarian, University of Wollongong, 1 June 2022, pp 3-4; *In camera* evidence, Witness A, 16 May 2022, p 4.

with the aim of comparing it to alternative testing methods.[168] Macquarie University has also publicly stated it will not use the forced swim test.[169] The test has been decommissioned by several global pharmaceutical companies, including Bayer, Johnson & Johnson, Pfizer and AstraZeneca.[170]

Figure 1 Rodent struggling in beaker of water

Source: Submission 258, Cheryl Forrest-Smith, p 4.

2.19 The committee heard largely negative views of the swim test among inquiry participants. Ms Rachel Smith of Humane Research Australia pointed to 'growing evidence that it is not actually an accurate screening tool for antidepressants and many pharmaceutical companies are no longer using that because of that lack of validity'.[171] Likewise, Professor Knight gave evidence grounded in literature reviews that the forced swim test does not provide enough useful data and is detrimental to animal welfare and should no longer be undertaken:

> What we found by studying forced swim tests published in the scientific literature is that unfortunately the results of this research were almost never actually cited by clinically focused papers aimed at tackling major depressive disorder and other important psychiatric disorders in human beings. This research, if it was cited, tended to be cited by other animal research. But human, clinically focused research was continuing almost in a parallel world without making very much use of this forced swim test data whatsoever. It is not achieving its intended objectives scientifically, in terms of contributing to combating those major human diseases. It has a particularly severe animal welfare impact. So, based upon the harm benefit analysis that this research is meant to be complying with, it should not be proceeding.[172]

168 Evidence, Dr Toole, 1 June 2022, pp 3-4.

169 Letter, Dr Karolyn White, Director, Research Ethics and Integrity, Deputy Vice-Chancellor (Research), Macquarie University to Dr Trunnell, Senior Scientist, Science Advancement and Outreach, PETA, 6 September 2022, published by PETA, <www.peta.org/wp-content/uploads/2022/09/macquarie-university-letter-to-peta.pdf> accessed 18 October 2022.

170 Submission 245, Animal Defenders Office, p 7.

171 Evidence, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 16 May 2022, p 12.

172 Evidence, Professor Knight, 1 June 2022, p 39.

2.20 Commenting on the forced swim test, Witness A encouraged 'more time and effort put into asking deeper questions and not just taking the [test's] application at face value'.[173]

2.21 Humane Research Australia submitted that there were suitable alternatives available to the forced swim test, particularly using human tissues, cells or mathematical and computer models of human systems.[174]

2.22 The committee understands that a number of Australian research institutions have made public commitments that they will not use animals in the forced swim test, notably:

- The University of Adelaide[175]
- The University of South Australia[176]
- Macquarie University[177]
- Griffith University.[178]

2.23 Dr Sarah Toole, Animal Welfare Officer and Veterinarian at the Wollongong University highlighted to the committee some of the university's welfare concerns about the forced swim test:

> We have had some adverse events with that particular test. We had quite a few rats that were large, male rats that had been housed in conventional laboratory housing for a number of months. When they were in the forced swim test, we had some drownings occur… We had these incidents where the rats didn't die straightaway. Basically, it was aspiration of water that wasn't detected. The rats subsequently died, after the test. It was confirmed by post-mortem examination and histopathology on the lungs. Those issues were brought to the attention of the committee. The committee reviewed some videos of that test and subsequently decided that they would only allow that test if it was being used in parallel with an aim to look at alternatives to that test.[179]

Case study B: The smoking tower

Forced smoke inhalation research exposes mice to cigarettes or other hazardous inhalants and observes the physical effects that follow. Smoking towers ensure nose-only or head-only exposures by placing mice in small chambers (see Figure 2). Mice are forced to breathe in

173 *In camera* evidence, Witness A, 16 May 2022, p 4.

174 Submission 204, Humane Research Australia, p 11.

175 Nationwide News Pty Ltd, 'University of Adelaide bans inhumane testing' (9 September 2020), www.news.com.au/technology/science/animals/university-of-adelaide-bans-inhumane-animal-testing/news-story/60a995cffaa6b313696fd63de3d68abd .

176 PETA Australia, 'The University of South Australia Bans the Forced Swim Test' (22 April 2022), https://www.peta.org.au/news/the-university-of-south-australia-bans-the-forced-swim-test/ .

177 PETA Australia, 'Victory for Mice! Macquarie University Bans Notoriously Cruel Lab Test' (8 September 2022), https://www.peta.org.au/news/macquarie-uni-forced-swim-test/ .

178 Humane Research Australia, 'Forced Swim Test at Australian Universities' (4 September 2020), https://www.humaneresearch.org.au/forced-swim-test-at-australian-universities/ .

179 Evidence, Dr Sarah Toole, Animal Welfare Officer and Veterinarian, Wollongong University, 1 June 2022, pp 3–4.

smoke for a minimum of one hour, twice a day for five days a week, for up to 18 weeks. In whole-body exposure, the animals are immersed in the smoke without being restrained.[180]

The National Health and Medical Research Council advised that, across Australia, there were nine active funded projects involving the use of smoke inhalation experiments to develop and test treatments for asthma, emphysema or lung cancer, or to understand the mechanism of chronic obstructive pulmonary diseases,[181] a condition that the University of Newcastle estimates that about 1.5 million Australians suffer from.[182] For example, projects at the University of Newcastle and the Centenary Institute at the Royal Prince Alfred Hospital sought to reproduce chronic obstructive pulmonary disease in the mice, and then test treatments.[183]

The University of Newcastle advised that 127 mice were experimented on in the 12 month period up to May 2022.[184] Between 2018 and 2021, 91 mice at the University of Newcastle died in connection with the use of the smoking tower in inhalation experiments. In October 2021, the university stopped using its inhalation device and subsequently decommissioned it.[185]

Figure 2 nose-only exposure of mice to inhalants in a 'smoking tower'

Source: Submission 220, Humane Society International Australia, p 5.

2.24 The committee heard evidence that smoke inhalation research can lead to important outcomes for public health. The prevalence of smoking, bushfires, wood smoke and particulates in our current environment was emphasised by Associate Professor Roger Garcia, Chair, Sydney Local Health District Animal Ethics Committee. His evidence outlined how Animal Ethics

180 Submission 204, Humane Research Australia, p 10; Submission 244, Ms Paula Wallace, pp 1-2.

181 Answers to questions on notice, Ms Prue Torrance, Executive Director, Research Quality and Priorities, National Health and Medical Research Council, 22 July 2022, p 1.

182 Evidence, Dr Christopher McCarthy, Chair, Animal Ethics and Care Committee, University of Newcastle, 1 June 2022, p 14.

183 Submission 204, Humane Research Australia, p 10.

184 Evidence, Dr McCarthy, 1 June 2022, p 18.

185 Evidence, Dr Christopher McCarthy, Chair, Animal Care and Ethics Committee, University of Newcastle, 1 June 2022, pp 14-15; Answers to questions on notice, Prof Brian Kelly, Pro Vice-Chancellor (Research), University of Newcastle, 22 July 2022, pp 6-7.

Committees seek to balance the benefits of insight into significant human health issues and the animal welfare impacts of individual experiments.[186]

2.25 Recent use of smoking towers by the University of Newcastle was explained in evidence by Professor Brian Kelly, Pro Vice-Chancellor of Research, stating that the goal had been to increase 'our collective understanding of how respiratory illness develops, so we can find better treatments for patients'.[187] Chair of the Animal Care and Ethics Committee at the University of Newcastle, Dr Christopher McCarthy presented views that:

- translational benefits of the research from mice to humans had been 'shown and proven'[188]
- researchers did not have an alternative that would provide the same benefits.[189]

2.26 At the same time, Dr McCarthy explained that the animal ethics committee had made a number of recommendations to the university to improve the animal welfare impact of the smoking tower and minimise unintended deaths from mice 'turning' in the tower's tubes:

> Within my time as both a category A member and chair, we have made many reinforced recommendations to the researchers, and all of those have been enacted. So as far as cooling in the units, the mice have also now been placed—and, for several years now, warmed both prior and post any of the procedures that are occurring. Any animals that are seen to be turning in the tubes—both those towers are monitored at all times and so researchers are able to identify those animals and remove them immediately. There have been no deaths from turning of mice in the last few years that I've been involved as chair of the committee.[190]

2.27 On the other hand, the high welfare impact of using mice in smoking tower research led a number of witnesses to conclude that the test is not justified by its human health outcomes and should be stopped.[191] Dr Fowler of RSPCA Australia outlined how the method of conducting the experiment does not consider animal wellbeing:

> … not only is the animal—in most cases, a mouse—being exposed to smoke being forced into its lungs, but there is also the feeling of not being able to escape the environment. The ongoing stress of that and the fact that they are repeatedly exposed to that day after day, generally five days a week, Monday to Friday, because that is what is convenient for the research student. Straightaway, it is convenient for the research student or the research paradigm but not necessarily convenient for the animal, and that is not taken into consideration. [192]

186 Evidence, Associate Professor Roger Garcia, Chair, Sydney Local Health District Animal Ethics Committee, 1 June 2022, p 59.

187 Answers to questions on notice, Prof Brian Kelly, Pro Vice-Chancellor, Research, University of Newcastle, 22 July 2022, p 7.

188 Evidence, Dr Christopher McCarthy, Chair, Animal Care and Ethics Committee, University of Newcastle, 1 June 2022, p 15.

189 Evidence, Dr McCarthy, 1 June 2022, p 13.

190 Evidence, Dr McCarthy, 1 June 2022, p 14.

191 Evidence, Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia, 16 May 2022, p 40; Evidence, Professor Andrew Knight, 1 June 2022, p 40.

192 Evidence, Dr Fowler, 16 May 2022, p 40.

2.28 Along the same lines, Ms Craig drew on her 'extensive experience' with the smoking tower to outline the distress suffered by the animals, including hypothermia, withdrawal symptoms and an instance of mass culling 'when the researcher has decided that the progress of the study is not going the way they expected or intended'. [193] Ms Smith of Humane Research Australia highlighted the 'whole range of adverse reactions to that from death and suffocation trying to escape the tube'. [194]

2.29 Witness A described the use of the smoking tower as 'very problematic' from a veterinary and scientific point of view, and its impact 'extremely severe', as on top of inducing severe, chronic lung disease in mice, it introduces 'severe restraint and confinement'.[195] Noting that its use 'has been approved for many years by an animal ethics committee', they queried why a more evidence-based approach had not been taken in considering research applications:

> There are veterinarians on that animal ethics committee, and I cannot understand why they have not picked up on some of the fundamental flaws in the original paper that described the technique. Perhaps they only look at the document placed in front of them, which would be the application from the researcher. They do not necessarily have the time to go back to the primary literature.[196]

2.30 Several stakeholders queried the necessity of using smoking towers even if smoke inhalation research is needed, given the availability of whole-body smoke exposure which mitigates some of the severe animal welfare impacts. Professor Wojciech Chrzanowski, representing the Medical Advances Without Animals Trust, highlighted that it is a regulatory requirement to use less invasive methods:

> One of the problems with this technique is that if you look at the regulatory code, it makes it very clear that if there is a less invasive technique that can be used to achieve the same scientific outcomes then the less invasive technique should be used. We do have an alternative to the nose-only smoke exposure technique, namely whole-body exposure, in which animals are placed, often in groups, in a chamber. You avoid not only the welfare impact of the tight confinement or constraint, but you also avoid the uncontrolled scientific variables arising from the stress response. The animals will still be stressed in a whole body chamber exposure method, but it will be substantially less than what would be occurring in the very tight restraints.[197]

2.31 Professor Chrzanowski was among members of the scientific community who expressed doubt that results from any smoking inhalation research using mice would help us understand human disease due to the biological differences between our species:

> The main problem is that the lungs in rats and mice do not represent at all the physiology in humans—zero. The other thing is that smoking is very different to humans than to animals. You cannot give a cigarette directly to the mouth of an animal. It is the same if you would like to develop the treatment, you cannot use the same devices. You cannot use the puffer for asthma to the animal because the mouth is not fitting there. Physiologically it's very different… Hallmarks of the disease in the small

193 Evidence, Ms Craig, 16 May 2022, p 48.

194 Evidence, Ms Smith, 16 May 2022, p 12.

195 *In camera* evidence, Witness A, 16 May 2022, p 3.

196 *In camera* evidence, Witness A, 16 May 2022, p 4.

197 *In camera* evidence, Witness A, 16 May 2022, p 4.

> animals in the rodent models are very different to the hallmarks of the disease in humans. If you would like to develop a treatment or even study physiology of this disease, there's actually no way of doing this properly.[198]

2.32 Ms Smith of Humane Research Australia expressed disappointment at recent smoking tower use by the University of Newcastle despite reports that 'members of their own animal ethics committee—for many years… have been objecting to that'. Ms Smith made the point that unlike the requirement to test therapeutics on animals before conducting clinical trials, it is not mandatory to use animals in basic research or discovery experiments like smoke inhalation, and that methods with reduced animal welfare impact could be pursued.[199]

2.33 Ms Sarah Margo, Solicitor, shared the ADO's observation that 'big pharmaceutical companies, are voluntarily moving away from using these kinds of tests and setting a precedent in other parts of the world where these are no longer accepted or considered necessary or justifiable', noting that the 'same voluntary commitment has been made by a selection of universities in Australia'.[200]

Potential changes to approval requirements

2.34 The committee heard calls for changes to approvals for research using the forced swim test and the smoking tower to ensure that the highest possible level of scrutiny is applied. For example:

- Dr Fowler of the RSPCA recommended 'special provisions if you are going to do such high impact studies'[201]
- Professor Andrew Knight argued 'the research needs to be especially justifiable in order to be proceeding. It needs to be particularly good scientific quality and the likelihood of benefits should be very high in order for there to even be a case'[202]
- Witness A recommended 'the highest possible stringency' be applied to approving the forced swim test and the smoking test, similar to the LD50, Draize tests and research on primates: 'not just a recommendation from an animal ethics committee but also independent evaluation from a veterinary animal welfare science point of view'.[203]

2.35 At a state level, the Chair of the New South Wales Animal Research Review Panel (ARRP) indicated that the forced swim test and smoking procedure had come to the ARRP's attention, with a view to deliver a guideline recommendation on their use. In reference to the guideline on the forced swim test, Professor Phillips explained that:

> … we have undertaken a survey of the institutions in New South Wales in terms of their use of forced swim tests and smoking procedure... We are at the moment collating that

198 Evidence, Professor Wojciech Chrzanowski, Professor of Nanomedicine, University of Sydney, and Science Advisor, Medical Advances Without Animals Trust, 1 June 2022, p 24. See also: Evidence, Dr Fowler, 16 May 2022, p 40; Evidence, Professor Knight, 1 June 2022, p 40.

199 Evidence, Ms Smith, 16 May 2022, p 12.

200 Evidence, Ms Sarah Margo, Solicitor, Animal Defenders Office, 16 May 2022, p 40.

201 Evidence, Dr Fowler, 16 May 2022, p 40.

202 Evidence, Professor Knight, 1 June 2022, p 40.

203 *In camera* evidence, Witness A, 16 May 2022, p 4.

> information, and we are also looking to review the literature around the forced swim test and identify what the debate is, with the welfare considerations and also with the research outcomes associated with it. That's the work that is currently in progress, and it is something that ARRP hasn't quite landed on yet, but it is something that we are hoping to finalise with a guideline recommendation in the next six months.[204]

2.36 Providing further detail on the review of the forced smoking procedure, Professor Phillips stated:

> … we have undertaken a review of the forced smoking procedure and we are in the process of finalising a guideline associated with that. When that guideline has been approved by ARRP and falls to submission and publication by the DPI through the ARRP website and with the institutions and informing researchers, one of the groups we are going to circulate that guideline to is the NHMRC.[205]

2.37 At the Commonwealth level, the committee heard that funding for the forced swim test is being considered by the National Health and Medical Research Council (NHMRC). Ms Prue Torrance, Executive Director, Research Quality and Priorities, commented 'we have had that particular one brought to our attention and our animal welfare committee will be looking at it to see whether it is something where we need to be doing anything specific to provide any further guidance on NHMRC-funded research using those tests'.[206]

2.38 The committee heard evidence that suggests that the ARRP's proposed guideline intends to increase reporting requirements around the use of the forced swim test and smoking tower. ARRP Chair Professor Phillips advised:

> … we have also made the reporting around smoking a higher level. It will have to be reported by institutions in their annual report to their governing body, which the ARRP will also review, which will increase the level of transparency around that and will also report it at a higher level of invasiveness than what it would have been reported and required before. We are then going to look to review that process in 12 months.[207]

Committee comment

2.39 The committee received strong evidence from the eminent representatives of the medical research community who appeared before us. They told the committee that the use of animals is unfortunate but necessary, and they would welcome the day animal testing is no longer required. The majority of committee members acknowledge that the use of animals in medical research is justifiable on public health grounds, provided the animals are treated humanely.

2.40 Cruelty to animals is abhorrent and cannot be justified in any context. The committee is concerned by allegations of cruelty to animals in the guise of medical research benefitting humans.

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204 Evidence, Professor Jacqueline Phillips, Chair, Animal Research Review Panel, 1 June 2022, p 55.

205 Evidence, Professor Phillips, 1 June 2022, p 56.

206 Evidence, Ms Prue Torrance, Executive Director, Research Quality and Priorities, National Health and Medical Research Council, 1 June 2022, p 47.

207 Evidence, Professor Phillips, 1 June 2022, p 56.

2.41 The committee heard compelling evidence that suggests that on some occasions, the harm to animals occasioned by some medical research is greater than the human health benefits gained. The use of the forced swim test and the smoking tower appear to be two such examples.

2.42 We distinguish here between the smoking tower and smoke inhalation research involving whole body exposure. The smoking tower is singled out for comment because of its profound impacts on animals.

2.43 The committee is heartened by evidence that the ARRP is considering these procedures in detail with a view to providing clearer guidance to research organisations about their use and reporting requirements. It is also encouraging that a number of institutions have voluntarily and openly committed to cease using the forced swim test in particular. However, the committee has concluded that voluntary commitments and a guideline are not sufficiently stringent measures given the severity of the animal welfare impacts.

2.44 New South Wales strives to be at the forefront of the ethical and humane treatment of animals. The committee finds merit in rapidly phasing the forced swim test and smoking tower out of use in medical research. Accordingly, we recommend that the NSW Government consider how best to bring to an end to the use of these two tests in New South Wales.

Recommendation 1

That the NSW Government take steps to ensure the forced swim test and smoking tower test are rapidly phased out of use in medical research in New South Wales.

Chapter 3 Regulating the use of animals in medical research

This chapter explains how the use of animals in medical research in New South Wales is regulated and sets out views on the adequacy of the regulatory system. Animal Ethics Committees (AECs) are a key component of the regulatory regime and were the focus of significant evidence to the inquiry. The committee heard calls for AECs to be more representative and accountable. Inquiry participants also singled out audits and inspections as a cause for concern and called for more regular and robust arrangements.

Overview of the animal research regulatory regime

3.1 The NSW Government is responsible for the regulation of animal use in medical research in New South Wales. The major elements of the current framework are legislation, a national code of practice – *Australian Code for the Care and Use of Animals for Scientific Purposes* (hereafter, the Code), and regulatory oversight by the Animal Research Review Panel and the Department of Primary Industries. Each is outlined briefly below, concluding with a summary of views on the performance of the regulatory system.

Legislation

3.2 The use of animals for research and teaching in New South Wales is regulated by the *Animal Research Act 1985* (hereafter, the Act) and the Animal Research Regulation 2021 (hereafter, the Regulation), which incorporate requirements of a national code of practice. The Act prescribes standards for the protection and welfare of animals used in connection with animal research, using a system of enforced self-regulation, with community participation.[208]

3.3 The Act provides a framework for the regulation of animal research, which consists of:

- a licensing and accreditation system for the conduct of research or the breeding or supply of animals for research
- animal care and ethics committees (hereafter, AECs) that approve and supervise research using animals
- an Animal Research Review Panel (hereafter, the ARRP) to oversee animal research and animal care and ethics committees, and advise the Minister on relevant matters
- inspection of research facilities
- prosecutions for offences.[209]

3.4 Establishments carrying out animal research, or supplying animals for use in research, must be accredited and licensed under the Act. Authorisation to carry out animal research can be issued

208 Animal Ethics Infolink, 'Animal Research Act', https://www.animalethics.org.au/legislation/animal-research-act .

209 *Animal Research Act 1985,* pts 2, 3, 4, 5, 6.

to individuals by accredited establishments or by the Secretary of the Department of Regional NSW, if recommended by an AEC.[210]

3.5 A person may be fined and/or imprisoned for committing an offence under the Act, including unlawfully carrying out animal research, and unlawfully keeping or supplying animals for animal research.[211] Any harm to animals that is not approved under the Act can be prosecuted under the *Prevention of Cruelty to Animals Act 1979*.[212]

Regulatory oversight

3.6 The Department of Primary Industries (DPI) within the Department of Regional NSW is the regulator responsible for accreditation, licensing and compliance under the Act.[213] The Secretary of the Department of Regional NSW shares the ability to authorise animal research with accredited research establishments, and makes accreditation decisions based on advice from the ARRP. [214]

3.7 The Minister for Agriculture appoints the 12 members of the ARRP and the Act specifies that they must be divided equally between industry (university and pharmaceutical representatives), animal welfare representatives and ministerial appointments.[215]

3.8 The ARRP audits and inspects individual research facilities at least every four years[216] and conducts annual performance reviews of animal ethics committees.[217] It also investigates complaints about animal research establishments, which are then reported to the Secretary of the Department of Regional NSW for further action.[218]

3.9 The ARRP has responsibility for all New South Wales AECs and 'support[s] AECs in performing their duties'. [219] AECs appointed under the Act supervise the research carried out by accredited research establishments and licensed animal suppliers.[220] AEC functions include:

- reviewing project applications and approving only those projects that are ethically acceptable and conform with the Code
- terminating any research that it considers has deviated from its approval

210 Submission 239, NSW Government, p 8; Submission 228, Children's Medical Research Institute, p 3.

211 *Animal Research Act 1985*, pt 5.

212 *Animal Research Act 1985*, pt 5; *Prevention of Cruelty to Animals Act 1979*, s 24(1)(e).

213 Secretary of Regional NSW, Animal Research Instrument of Delegation 2020 under the *Animal Research Act 1985*, 21 August 2020, s 3(1).

214 Submission 239, NSW Government, p 8.

215 *Animal Research Act 1985*, s 6(2).

216 Submission 228, Children's Medical Research Institute, p 3; Submission 223, Australian Academy of Health and Medical Sciences, NSW Branch, p 4; Submission 239, NSW Government, p 8.

217 Submission 239, NSW Government, pp 8-9; Submission 227, Kolling Institute, p 4.

218 Submission 239, NSW Government, p 9.

219 NSW Department of Primary Industries, 'Animal Research Review Panel Annual Report 2020–21', www.animalethics.org.au/__data/assets/pdf_file/0006/1388121/Annual-Report-2020-21.pdf .

220 *Animal Research Act 1985*, s 13.

- reviewing activities associated with the care and management of animals in facilities, and approving only those projects that are ethically acceptable and conform with the Code
- conducting follow-up reviews of approved projects and activities
- monitoring the care and use of animals in medical research
- responding to unexpected adverse events and non-compliances
- approving an institution's guidelines for the care and use of animals in medical research
- undertaking inspections and audits of facilities that use animals in medical research
- providing advice and recommendations to institutions and reporting on operations.[221]

3.10 The composition of AECs is complex, and like the ARRP structure, seeks to represent and balance a range of different viewpoints. The Act provides that at least one committee member must be independent of animal research and relevant institutions. Under the Code, each AEC must include one person from each of the following four categories, with members from categories C and D making up at least one-third of all members present:[222]

- Category A – a person with qualifications in veterinary science
- Category B – a suitably qualified person with substantial and recent experience in the use of animals for scientific purposes or teaching
- Category C – a person with demonstrable commitment to and experience in furthering the welfare of animals who is not associated with the institution or currently involved in the use of animals in scientific or teaching activities (where possible, endorsed by an animal welfare organisation)
- Category D – a person not associated with the institution, who has never been involved in the use of animals in scientific or teaching activities.[223]

3.11 In addition to the mandatory requirements, the Code advises that to 'function effectively', institutions 'should appoint to the animal ethics committee a person responsible for the routine care of animals within the institution' and 'may appoint additional members with skills and background of value to the animal ethics committee '.[224]

3.12 The Code suggests that decisions by AECs be made on the basis of consensus, defined as 'all members accept the final decision, even though it may not be an individual's preferred option'.[225]

221 National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 26.

222 Submission 217, The University of Sydney, p 6; National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 20.

223 Submission 217, The University of Sydney, p 6; National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 20.

224 National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 20.

225 National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 20.

However, if consensus cannot be reached after exploring ways of modifying a project, the majority rules.[226]

3.13 Each application to an AEC to undertake research using animals must:

- justify the use of animals and address the 3Rs (Replacement, Reduction and Refinement), including why non-animal alternatives are not suitable
- outline the impacts of the research project on animals, and how these would be minimised (such as through environmental enrichment and pain relief).[227]

3.14 In response to questioning about the stages in the life of an average research proposal, the committee received the following answer from Professor Robert Brink, Pillar Director in Translational Science, Garvan Institute of Medical Research :

- a researcher would have an idea
- they would apply for funding through a grant funding agency or the NHMRC
- the grant application phase would screen out proposals that are 'clearly unethical'[228]
- if funded, the researcher applies to their AEC 'with a detailed proposition about what exactly you are going to do and why you are doing it'[229]
- the ARRP may reject the proposal or ask additional questions: "Have you considered this? What does this mean?"
- if approved, the researcher would start the experimental work.[230]

3.15 According to Professor Philip O'Connell, Executive Director, Westmead Institute for Medical Research, the system allows those with the appropriate expertise, namely the AECs 'that know the researchers and know the conditions' to take a central role in regulating the use of animals in medical research.[231] Professor O'Connell explained that 'your work is audited by your ethics committee and the ethics committee is then audited by DPI, and, in the case of primates, by several other bodies as well.[232] Dr Peter Johnson, a retired veterinarian and former DPI inspector, used the term 'monitored self-regulation' to describe the same system.[233]

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226 National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 26; Submission 227, Kolling Institute, p 4; Submission 232, Western Sydney Local Health District, p 4.

227 Submission 239, NSW Government, p 9; Submission 227, Kolling Institute, p 4; Submission 217, The University of Sydney, p 6; Submission 231, The University of Newcastle, p 1; Submission 233, Western Sydney Local Health District (Animal Ethics Committee), pp 1-2.

228 Evidence, Professor Robert Brink, Pillar Director in Translational Science, Garvan Institute of Medical Research Brink, 16 June 2022, p 30.

229 Evidence, Professor Brink, 16 June 2022, p 30.

230 Evidence, Professor Brink, 16 June 2022, pp 30–31.

231 Evidence, Professor Philip O'Connell, Executive Director, the Westmead Institute for Medical Research, 16 May 2022, p 33.

232 Evidence, Professor Philip O'Connell, Executive Director, the Westmead Institute for Medical Research, 16 May 2022, p 29.

233 Evidence, Dr Peter Johnson, 1 June 2022, p 36.

Code of Practice

3.16 The *Australian Code for the Care and Use of Animals for Scientific Purposes* is a prescribed national code of practice under the Animal Research Regulation 2021. The Code provides an ethical framework for animal research and teaching through mandated standards and best practice guidelines. The Regulation prescribes that the following aspects of the Code must be complied with:

- details of animal research project applications
- membership of AECs
- AEC decision making.[234]

3.17 The Code sets out principles that apply to investigators, institutions, animal carers and AECs, and all those involved in the care and use of animals for scientific purposes, including:

- using animals only when it is justified
- supporting the wellbeing of the animals involved
- avoiding or minimising harm to those animals
- applying high standards of scientific integrity
- applying the 3Rs at all stages:
  - *replacement* of animals with other methods
  - *reduction* in the number of animals used
  - *refinement* of techniques to alleviate or minimise potential pain and distress and enhance animal welfare[235]
- subjecting the care and use of animals to ethical review, approval and monitoring by an AEC
- balancing the potential effects on the animals with the potential benefits. [236]

3.18 The Code applies throughout the animal's lifetime, and includes provisions in relation to:

- acquisition
- transport
- breeding
- housing
- husbandry
- project use

234 *Animal Research Regulation 2021*, regs 8, 21(2), Sch 2 reg 8.

235 Submission 239, NSW Government, p 9.

236 National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 9.

- post-use.[237]

Research with additional regulatory requirements

3.19 Research using primates requires additional justification and is subject to more regular inspections, including to comply with the National Health and Medical Research Council's *Principles and guidelines for the care and use of non-human primates for scientific purposes*.[238] Professor O'Connell explained that 'you have to put forward a good rationale for why you are using non-human primates' and that the approval process would normally involve three ethics committees, for example, local, hospital and university. In addition:

> It then has to go to DPI for it to look at… Then it goes to an NHMRC non-human primate research committee …. and then there is the Animal Research Review Panel of DPI. When it has been through all that, you can start. In our experience, all of the ethics committees and all of the research committees personally inspected the facilities, looked at the record keeping and looked at the research.[239]

3.20 Particularly invasive tests must meet additional requirements before they can be approved by an AEC:

- the LD50 test, which involves administering a substance to animals to determine the dose that will lead to a predetermined death rate (normally 50 per cent). Approval of LD50 tests for product testing requires the Minister's concurrence, with a recommendation for approval from the ARRP
- the Draize test, which applies a substance to the eye of an animal to determine its irritancy, can only be approved for the sole purpose of establishing that a prophylactic or therapeutic substance intended to be applied to eyes is not an irritant.[240]

3.21 Lethality tests, such as the LD50 test, have additional reporting requirements, requiring accredited research establishments to:

- keep records (for seven years) of all lethality tests that are approved by its AECs[241] in relation to:
  - the species of animal concerned
  - the number of animals concerned
  - the type of procedure
  - the justification for the approval of the lethality test

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237 National Health and Medical Research Council (2103), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), pp 1 and 9; Submission 217, The University of Sydney, p 6; Submission 214, NSW Young Lawyers, p 7.

238 Submission 239, NSW Government, p 10; Submission 226, Association of Australian Medical Research Institutes, p 8.

239 Evidence, Professor O'Connell, 16 May 2022, pp 31–32.

240 *Animal Research Act 1985* ss 26(4)(a)-(b), 3(1) (definitions of 'Draize test' and 'LD50 test'); Submission 139, Ms Michelle Gable, p 1.

241 *Animal Research Act 1985*, s 56A(1).

  - changes or modifications being developed, if any, to replace the need to carry out the lethality test.[242]
- give a copy of the record to the ARRP within one month of the relevant reporting period (calendar year).[243]

3.22 The records provided to the ARRP about lethality tests may be made available to the public.[244]

Views on the adequacy of regulation

3.23 The committee heard a range of views about the adequacy of the regulatory environment surrounding the use of animals in medical research in New South Wales.

3.24 The medical research community on the whole was supportive of the current system. For example, Professor O'Connell expressed support and warned against increasing the regulatory burden on their operations, saying 'it takes a fair bit of time to get through that whole process':

> We believe that the current regulatory framework is comprehensive and rigorous within a mandated good governance framework and does not need to be changed. It is our opinion that further additional regulation will adversely impact productivity and cost without any improvement in animal welfare.[245]

> If you look at the ethics approval in general, even for clinical trials—if you ask researchers what the problem is, it is getting through all the bureaucracy to strike a blow in anger, to use a paraphrase. Basically that gets more and more onerous as each year goes by… You would have to put forward an argument for why you felt additional regulation would improve that welfare.[246]

3.25 On the other hand, the committee notes that Professor Robert Brink, Pillar Director in Translational Science, Garvan Institute of Medical Research, described the level of regulation as 'not onerous', highlighting the ability to have a 'fair hearing' within the AEC structure.[247]

3.26 Professor Schofield AO, Board member, Association of Australian Medical Research Institutes, explained his understanding of the high level of trust in research institutions inherent in the deregulated system and the responsibilities that come with it:

> The research community is afforded a wide privilege by the parliaments of Australia to enable the use of animals in research, and our obligation is to reciprocate by doing that when it is appropriate and justified, under approval, and adhering to the three Rs. That

242 *Animal Research Regulation 2021*, reg 23.

243 *Animal Research Act 1985*, s 56A(2).

244 *Animal Research Act 1985*, s 56A(3).

245 Evidence, Professor O'Connell, 16 May 2022, p 22.

246 Evidence, Professor O'Connell, 16 May 2022, p 33.

247 Evidence, Professor Robert Brink, Pillar Director in Translational Science, Garvan Institute of Medical Research Brink, 16 May 2022, p 27.

> is the societal compact that we have. We in the research community have to both adhere to our side of that bargain and also be willing to accept the consequences of deviation.[248]

3.27 Professor Schofield AO went so far as to express confidence that: 'Do Australian standards and New South Wales standards conform to the best standards around the world? I think the answer is yes'.[249]

3.28 However the committee heard contrasting evidence that the regulatory system performs poorly. Ms Rachel Smith, Chief Executive Officer of Humane Research Australia told the committee that 'the system of self-regulation is far from robust'.[250]

3.29 The Animal Defenders Office also expressed concern about the regulatory framework:

> The regulatory framework in NSW covering animal research is what is known as 'enforced self-regulation'. That is, while the legislation sets out requirements for carrying out the research, it is largely left to the industry itself to ensure the requirements are followed, and there is minimal oversight or intervention by external enforcement agencies (eg government departments). Researchers are required to obtain AEEC approval, but AEECs are established by the research institutions themselves and dominated by industry participants. There is little to no public reporting of research refused or modified by AEECs, or outcomes of AEEC inspections of institutions and laboratories, or AEEC or institutional responses to unexpected adverse events. Complaints are rare and prosecutions for non-compliance with regulatory requirements are even rarer. Self-regulation also carries a high risk of perceived and actual conflicts of interest as it depends on research institutions monitoring their compliance with regulatory requirements through their own AEECs.[251]

3.30 Other inquiry participants including the RSPCA[252] and the Animal Defenders Office[253] identified numerous areas for improvement.

3.31 Witness A, who has a long career adjacent to medical research, gave evidence that:

> … the regulatory framework is very good in principle. What concerns me is how it is being implemented in practice. True, some institutions make a very commendable effort to achieve best practice in both the spirit and the letter of the regulations, but overall I see deficiencies, which have concerned me increasingly in recent years. If I had to suggest a unifying cause, it is a weakening of the regulatory bodies charged with overseeing the regulations in this country.[254]

3.32 Another inquiry participant with 30 years' experience in animal care cited extremely concerning animal welfare breaches. When questioned whether these were due to the current regulations

248 Evidence, Professor Peter Schofield AO, Board member, Association of Australian Medical Research Institutes, 16 May 2022, p 34.

249 Evidence, Professor Schofield AO, 16 May 2022, p 29.

250 Evidence, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 16 May 2022, p 10.

251 Answers to supplementary questions, Animal Defenders Office, 4 July 2022, p 6.

252 Submission 222, RSPCA, pp 11-12.

253 Submission 234, Animal Defenders Office, pp 9-14.

254 *In camera* evidence, Witness A, 16 May 2022, p 3, published by resolution of the committee.

not being enforced, or deficiencies in the regulatory system itself, she responded: 'I think it comes down to absolute inadequacy in regulations.'[255]

3.33 The RSPCA raised particular concern about the guidelines for the care and housing of animals used for experimentation, noting that many of the guidelines are over 20 years old and in need of updating:

> Animals in a research setting are generally maintained in controlled and contained environments. Most species used, including dogs, cats, rodents and primates, are social animals and their needs and natural behaviours are best supported when housed with others of the same species. In many circumstances, research requires animals to be isolated which can restrict the opportunities for them to engage in positive natural behaviours. Other aspects of the research environment restrict natural behaviour including the opportunity to forage, exercise and meet other highly motivated biological needs which can impact on their ability to live a good life. It has also been proven that maintaining good animal welfare leads to better quality scientific outcomes…
>
> Although the guidelines are now given mandatory effect by way of license conditions, to create regulatory certainty, the practice guidelines should be given force by being prescribed as a code or standard by the regulation. Many of these guidelines have not been reviewed in more than 20 years. They should be reviewed in the process of being prescribed.[256]

3.34 A number of inquiry participants also called for a review of the Code, which has not been updated since 2013.[257]

Animal ethics committees

3.35 AECs are a key component of the regulatory system. The committee heard varying views on their performance: many inquiry participants praised the work of animal ethics committees, while others suggested that they need to become more representative and accountable.

Performance of animal ethics committees

3.36 Many inquiry participants presented the view that the performance of AECs is 'very robust'.[258] Asked whether he considered AECs were doing a good job, Professor Cunningham AO drew on 20 years of 'stringency' in being 'quizzed' by the 'lay, animal welfare and veterinary representatives on those committees'.[259]

3.37 Professor Cunningham AO explained that 'part of the brief' of an AEC is 'to understand the consequences of the research', asking questions like: 'Is this highly valuable research? Is it well done? Is it excellent? Is it the sort of research that would justify using animals of any type?' and

255 Evidence, Ms Lisa Craig, 16 May 2022, p 50.

256 Submission 222, RSPCA, p 7.

257 Submission 222, RSPCA, p 13; Submission 204, Humane Research Australia, p 16.

258 Evidence, Ms Cathy Pitkin, Executive Manager, Social Responsibility and Ethics, Commonwealth Scientific and Industrial Research Organisation, 1 June 2022, p 48.

259 Evidence, Professor Cunningham AO, 16 May 2022, p 9.

then undertaking to 'quiz the researchers very carefully about how the research is going to be used and the future significance'.[260]

3.38 Professor Brink, drawing on his experiences, including as chair of an AEC, said that AECs were doing a good job:

> Animal experimentation is very highly regulated and overseen independently by the animal ethics committees, which run through the various research institutes. It is very clear that only research which absolutely requires animals is approved by these ethics committees and research cannot take place without their approval.[261]

3.39 Dr Tanya Stephens, Animal Welfare and Ethics Committee Member, Australian Veterinary Association presented a view that in her experience, AECs operate 'very well' and democratically, highlighting that it is open to members of the public to 'have a say in experimentation' through membership on a committee:

> Anybody can apply to sit on animal ethics committees. They are not detached from the real world. If you want to sit on one, you can get a list where there are vacancies and you can apply. This is why they were established, and they do play a really important role there for the community to make sure.[262]

3.40 Associate Professor Roger Garsia, Chair, Sydney Local Health District Animal Ethics Committee, explained that the 'live process' allows for the committee and researchers to work together to refine and improve protocols for research that would use animals, explaining:

> It is not uncommon to defer an approval to the next meeting and in between meetings to do quite a lot of work with the researchers. Sometimes it is a matter of them giving much more detail about what they are doing. Very often they have considered some of the additional aspects that they haven't written, and people then are much more comfortable approving a protocol where they are sure that the experience in the international experience with this model is such or that the value of the work is such, because ethics committees are trying to always do this balance. We are depriving animals of liberty. We need to balance that by, again, medical and scientific knowledge.[263]

3.41 Dr Susan Maastricht, Animal Welfare and Ethics Committee Member, Australian Veterinary Association, echoed this, asserting that some requests to use animals in medical research receive the response "no, you can't do it" from AECs, but more commonly, they are told "no, that's not sufficient. The welfare of the animals is not being addressed. We see the benefit. We see what you're trying to do, but you can't do that for the welfare of the animals. The impact is far too great."[264] In her view, the 'back and forth' allows opportunities for 'animal welfare vets to

260 Evidence, Professor Cunningham AO, 16 May 2022, p 8.

261 Evidence, Professor Brink, 16 May 2022, p 21.

262 Evidence, Dr Tanya Stephens, Animal Welfare & Ethics Committee Member, Australian Veterinary Association, 1 June 2022, p 36.

263 Evidence, Associate Professor Roger Garsia, Chair, Sydney Local Health District Animal Ethics Committee, 1 June 2022, pp 56–57.

264 Evidence, Dr Susan Maastricht, Animal Welfare and Ethics Committee Member, Australian Veterinary Association, 1 June 2022, p 35.

be involved in the design process'.[265] The role of animal welfare vets is discussed further in Chapter 4.

3.42 Dr Stephens' experience was also that discussions about alternatives to animal research are 'always' discussed, including when 'research projects have been knocked back'.[266] By contrast, Ms Tara Ward of the Animal Defenders Office gave a different perspective based on her experience on an AEC:

> From my perspective as a Category C member of a university AEEC for over 5 years, the current system is not working when it comes to requiring researchers to consider alternatives. While researchers are required to address the issue on their research project applications, they frequently copy and paste standard wording stating that there are no alternatives currently available but that they are monitoring the literature. The AEEC can do nothing about this, short of asking further questions on each individual protocol and asking the researcher to provide details.[267]

3.43 The Animal Defenders Office suggested that their consideration of alternatives could be strengthened by a change to protocol forms used in AEC deliberations to avoid a system in which:

> … the status quo is absolutely entrenched. There is very little evidence of moving beyond that, so external incentives are required. That could be as little as changing the way protocol forms are drafted, to force researchers to give more than just standard words: "We have to use animal models now because there is no alternative, but we are monitoring the literature."[268]

3.44 Medical Advances Without Animals (MAWA) Trust raised concerns that animal ethics committees can be compromised by the current typical process, whereby funding is allocated to an animal research project prior to receiving ethics approval:

> AEC members also advise that timing can be important as once a proposal is presented to an AEC, it often has funding approval and that issues regarding animal ethics are among the last to be considered. In other countries there is ethical screening before funding decisions are made which avoids the problem of researchers, faculties and institutions having so much invested by the time the AEC is required to assess whether alternatives have truly been investigated. AEC members have said that they feel immense institutional pressure at times to approve projects despite their reservations.[269]

Strengthening animal ethics committees

3.45 Some inquiry participants questioned whether all AECs perform to the same high standard. Ms Lisa Craig, a long-term animal care manager, highlighted the 'wide range of ethics committee

265 Evidence, Dr Maastricht, 1 June 2022, p 35.

266 Evidence, Dr Stephens, 1 June 2022, p 33.

267 Answers to supplementary questions, Animal Defenders Office, 4 July 2022, p 4.

268 Evidence, Ms Tara Ward, Solicitor, Animal Defenders Office , 16 May 2022, p 42.

269 Submission 351, MAWA Trust, p 8.

processes and procedures', observing 'some institutions are more inclined to do the right thing. Other institutions are quite questionable at times'.[270]

3.46 Witness A presented a view that 'things are falling through the cracks', citing nose only smoke exposure experiments as an example of a protocol with 'fundamental flaws' that are not picked up or addressed during AEC deliberations.[271]

3.47 Professor Andrew Knight presented a high-level criticism of whether ethical review bodies provide adequate scientific scrutiny of research:

> It has been said that animal researchers are sometimes scientific giants but ethical infants … they may be very intelligent and expert in a particular area but unfortunately not in the crucial area of subjecting this research … to scientific scrutiny adequately. There have been uncritical assumptions that this research is likely to produce the sorts of key societal benefits that have been so often claimed in applications to grant committees, to ethical review bodies and even to journals. That needs to stop.[272]

3.48 Professor Knight also argued that more needs to be done to encourage pre-registration of animal research, and publication of negative findings:

> To ensure that all such evidence is publicly available, greater efforts must also be made by researchers and editors to publish negative results. Studies that fail to show a treatment effect are often considered less interesting and are, consequently, less likely to be published. The subsequent exclusion of such results from systematic reviews leads to overestimations of treatment efficacy and partly explains the widespread failures in humans of treatments apparently efficacious in animals. Within the field of human studies, clinical trial registers allow researchers to learn about existing and prior clinical trials, including those with negative outcomes, before results are formally published. A similar international initiative to register animal studies and their results is warranted.[273]

3.49 The RSPCA also expressed support for requiring the publication of negative results, to improve transparency in the industry:

> RSPCA recommends that all animal studies should be pre-registered on a central database, of which there are already many available, to ensure full reporting of study details and to encourage reporting of negative results to ensure this information becomes available at the end of the study. Most registries have an option to place an embargo on the pre-registered study for up to five years, after which time the details of the study become automatically publicly accessible. There is currently little incentive in Australia for researchers to publish negative findings. This leads to the risk of replication of studies by various researchers which could be avoided if there was a requirement to publish negative findings and make this data widely available. Without this requirement, there is likely to be publication bias.[274]

3.50 In relation to this issue, Professor Anthony Cunningham AO of the Australian Academy of Health and Medical Sciences alerted the committee to the government's online register for

270 Evidence, Ms Craig, 16 May 2022, p 48.

271 *In camera* evidence, Witness A, 16 May 2022, p 4.

272 Evidence, Professor Andrew Knight, 1 June 2022, p 43.

273 Submission 250, Professor Andrew Knight, p 4.

274 Submission 222, RSPCA, p 3.

clinical trials while acknowledging the difficulties in publishing negative findings in other publications:

> One of the reasons why clinicaltrials.gov was set up was to ensure that all trials were registered and negative results were registered as well. Researchers like me often find ways to publish data that includes negative results as well, so you can publish the negative results side by side with the positive results. But I agree with you: It is very difficult to get journals to accept a pure negative study.[275]

3.51 The composition of AECs was queried by some witnesses as leading to power imbalance[276] and bias towards the use of animals in medical research, with adverse consequences for the welfare of animals. Dr Rosemary Elliott, President of Sentient - The Veterinary Institute for Animal Ethics, described 'a system that is stacked so far in favour of research that if a committee member strongly objects, they will be powerless to prevent the research being approved'.[277] Vice President Dr Katherine van Ekert explained that:

> 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.[278]

3.52 Some inquiry participants also raised concerns about the fact that research projects could be approved despite objections from members of AECs. For example, in relation to the smoking tower experiments, Humane Research Australia stated that:

> …it is very disappointing to see the University of Newcastle continue to use this method and for students to continue to be using that method there when, members of their own animal ethics committee— for many years, we have information that they have been objecting to that, but it is still continuing.[279]

3.53 Humane Research Australia elaborated that 'the research was seemingly allowed to continue despite the objections as approvals were made without consensus and relentless bullying, intimidation and refusals to act on the concerns raised led to AEC members with objections resigning'.[280]

3.54 Professor Jacqueline Phillips, Chair of the Animal Research Review Panel, cited relevant provisions of the *Australian code for the care and use of animals for scientific purposes* to provide clarity around what should happen if a consensus is not reached:

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275 Evidence, Professor Anthony Cunningham AO, Australian Academy of Health and Medical Sciences, 16 May 2022, p 7. See also: Evidence, Professor Robert Brink, Pillar Director, Translational Science, Garvan Institute of Medical Research, 16 May 2022, p 35; Evidence, Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia, 16 May 2022, p 41.

276 Evidence, Dr Katherine van Ekert, Vice President, Sentient - the Veterinary Institute for Animal Ethics, 28 June 2022, p 4.

277 Evidence, Dr Rosemary Elliott, President, Sentient - The Veterinary Institute for Animal Ethics, 28 June 2022, p 2.

278 Evidence, Dr van Ekert, 28 June 2022, p 4.

279 Evidence, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 16 May 2022, p 12.

280 Answers to supplementary questions, Humane Research Australia, 29 June 2022, p 10.

> I was going to clarify from the code. It is actually a provision in there—this is 2.3.11 in the code—that if consensus is still not achieved after, as you have described, discussion and attempt to resolve their differences and exploring with applicants ways of modifying the activity or the project, "the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.[281]

3.55 The problems identified as flowing from the current composition and conduct of AECs included:

- where multiple ethics committees, institutions or researchers are involved, assumptions are mistakenly made that someone else has gone through the ethics approval process.[282]
- 'research being conducted without an animal ethics committee approval', which continued after complaints were made[283]
- a 'potential conflict of interest' in that 'the chair of that panel has always been somebody who comes from an animal research background', comparing that it is a 'better arrangement' when the chairs are not animal researchers[284]
- animal researchers and laboratory technicians 'have a vested interest in the continuation of animal research, just by virtue of the fact that they're employed in that industry'[285]
- veterinarians' advice can be 'overruled by the interests of the leading researchers'[286]
- lay committee members and animal welfare representatives can become intimidated by 'powerful people in institutions' including veterinarians and researchers, reporting that 'if they made a complaint about an animal research facility, they were no longer taken to view the actual facility'[287]
- committee members experienced 'harassment and bullying and fear of speaking out because of other members on the animal ethics committee or in the research institution', including fearing the consequences of sharing photos and footage under their confidentiality agreements[288]
- those concerned with animal welfare may not be 'adequately recognised' within research institutions and choose to leave the workplace.[289]

3.56 To address some of these shortfalls, Witness A proposed measures to improve the operation of AECs by upskilling staff and providing relevant guidance material, proposing:

- regular training for members of AECs

281 Evidence, Professor Jacqueline Phillips, Chair, Animal Research Review Panel, 1 June 2022, p 57.
282 Evidence, Ms Smith, 16 May 2022, p 11.
283 Evidence, Ms Smith, 16 May 2022, p 11.
284 *In camera* evidence, Witness A, 16 May 2022, p 8.
285 Evidence, Dr van Ekert, 28 June 2022, p 4.
286 Evidence, Dr van Ekert, 28 June 2022, p 4.
287 Evidence, Ms Smith, 16 May 2022, p 11.
288 Evidence, Ms Smith, 16 May 2022, p 11.
289 Evidence, Dr van Ekert, 28 June 2022, p 4.

- two-yearly symposiums for AEC members that had been hosted by the Department in the past, commenting that 'I think the last one of those was about five years ago'
- evidence-based guidelines for animal care 'which are now out of date by up to 15 years'.[290]

3.57 Similarly, Medical Advances Without Animals in recognising that there was 'insufficient education and training for researchers and Animal Ethics Committee (AEC) members, and therefore insufficient knowledge of alternative animal replacement methods', suggested that there should be funding for 'education and training in alternatives for students, researchers and AEC members to increase awareness, knowledge and expertise in animal-free methods and technologies.'[291]

3.58 Responding to questions about the discontinuation of regular seminars for AEC members, the NSW Government advised:

> Animal Ethics seminars, run by NSW DPI and the ARRP approximately every two years until 2015, were discontinued due to resourcing requirements.
>
> • As part of their strategic plan, ARRP identified webinars as an effective method to engage with industry to protect and promote the welfare of animals used in research and teaching.
>
> • ARRP and DPI have committed to hosting 3 education and awareness webinars for the Animal Research community in 2022.
>
> o Webinar 1: Research animal research rehoming (held 31 May 2022)
>
> o Webinar 2: Research application statistics (planned for July 2022)
>
> o Webinar 3: Ethical decision making (planned for Nov 2022)
>
> • Webinar 1 on Research animal rehoming was very well attended with 126 participants.
>
> • Feedback was extremely positive - 80% of respondents indicated they felt more informed to start rehoming program discussions or expand the current rehoming program at their establishment.
>
> • Webinar recordings have been circulated to participants and published on Animal Ethics Infolink as an ongoing educational resource.[292]

Audit and inspection functions

3.59 As noted previously, the ARRP is responsible for auditing and inspecting individual research facilities at least every four years and annual monitoring the performance of their ethics committees. Witness A told the committee that independent inspection of research establishments, one of the core functions of the regulatory system, had 'failed' and required urgent attention:

290 *In camera* evidence, Witness A, 16 May 2022, p 8.

291 Submission 351, Medical Advances Without Animals Trust, pp 14–15.

292 Answers to questions on notice, Department of Primary Industries, 27 July 2022, p 6.

> In New South Wales I feel the regulatory body—although the people themselves are doing their level best, I think it has failed in one of its most core responsibilities, which is the independent inspection of institutions as accredited animal research establishments. I assume that is a reflection of declining resourcing, but it is something that I believe is in urgent need of attention.[293]

3.60 The committee heard evidence that audits and inspections were now conducted by bodies other than the ARRP. Dr Sarah Toole, Animal Welfare Officer & Veterinarian at the University of Wollongong, described the practice of institutions cross-auditing each other:

> In 2021 ARRP was unable to conduct our audit due to resourcing shortages but approved an arrangement whereby we audited another institution and members of that institution audited the University of Wollongong. Whilst we believe both institutions conducted the audits with the required rigour of an independent audit, we feel that additional funding and resources should be directed towards the regulator so that it can conduct this important process.[294]

3.61 Reflecting on the previous practice of audits and inspections led by the regulator, Dr Maastricht observed that 'there was something quite meaningful about the fact that a regulator and the people from that group were coming in to do those inspections'.[295]

3.62 Witness A told the committee of their concerns at the practice of institutions conducting inspections 'quid pro quo':

> … we have arrangements where we have two institutions doing a quid pro quo: "I will inspect your facilities. You will inspect mine." To me, that is a fundamental conflict of interest. A major university that I know of recently had its independent external review conducted by a single individual remotely. COVID is not an excuse.[296]

3.63 Witness A identified further regulatory gaps in relation to the outsourcing of audit and inspection functions, namely:

- 'failing to conduct the audits themselves' and allowing institutions to 'bring in a consultant or somebody you think is suitably qualified, that will be good enough'
- reducing the frequency of audits to three years from four (the minimum mandated in the Code)
- changing from audits conducted by inspectors who 'were highly qualified, experienced people' who 'were taken much more seriously than they have been in recent years'.[297]

3.64 The Animal Defenders Office also expressed a number of concerns about the audit and inspection process:

293 *In camera* evidence, Witness A, 16 May 2022, p 3.

294 Evidence, Dr Sarah Toole, Animal Welfare Officer & Veterinarian, University of Wollongong, 1 June 2022, p 3.

295 Evidence, Dr Maastricht, 1 June 2022, p 37.

296 *In camera* evidence, Witness A, 16 May 2022, p 8.

297 *In camera* evidence, Witness A, 16 May 2022, p 9.

> Carrying out pre-arranged inspections of research institutions every 3-4 years is manifestly inadequate to monitor the care of the many (often thousands) of animals kept at an institution…The ADO submits that unannounced inspections at least once a year would be the minimum that would be required to give a basic level of assurance that an institution is complying with animal welfare requirements.[298]

3.65 To address deficiencies in the audit and inspection process, a number of inquiry participants called for greater resourcing for the ARRP.[299]

3.66 The committee asked Mr Greg Vakaci, Director Compliance and Integrity Systems, DPI, to respond to evidence questioning the integrity of audits and inspections. Mr Vakaci advised that the department in conjunction with the ARRP still conducts audits if required on a risk-based approach, increasing the frequency of audits where needed.[300]

3.67 Commenting further on the risk-based approach, Dr John Tracey, Deputy Director General, Biosecurity and Food Safety at DPI told the committee:

> I think the key point about the risk-based approach here also allows a greater focus where we see higher risk or where the panel sees higher risk in relation to that. It actually is a much stronger way forward. As we're progressing, it's getting stronger and stronger in relation to that.[301]

Committee comment

3.68 Many representatives of research institutions and AECs who appeared before the committee expressed a nuanced understanding that operating in a deregulated system requires adherence to accountability requirements in relation to their activities and rigorously evaluating their own processes. The committee heard compelling evidence that many AECs are operating well and make the welfare of animals their primary consideration. However, we are concerned with evidence that not all AECs are operating with the same rigour. It is in the interests of public health and the well-being of animals used in experimentation, as acknowledged by the medical research community, that every AEC operates with the same high level of rigour and operating standards.

3.69 Steps to improve the operation of AECs should start with the upskilling of their members, including members of the public who give considerable of their time and energy to participate in committee deliberations. There is a wide variability in members' background, ranging from lay members of the public to career scientists. The committee is pleased to hear that the ARRP has reinstated regular training for AEC members. The committee recommends that at least three in-person seminars be held every year with the ability for online participation. We also recommend that induction training be developed for all new committee members, to be delivered in person with the ability for online participation.

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298 Answers to supplementary questions, Animal Defenders' Office, 4 July 2022, p 6.

299 Evidence, Dr Johnson, 1 June 2022, p 36; Evidence, Dr Toole, 1 June 2022, p 3; Evidence, Dr Maastricht, 1 June 2022, p 34.

300 Evidence, Mr Greg Vakaci, Director Compliance and Integrity Systems, Department of Primary Industries, 1 June 2022, p 62.

301 Evidence, Dr John Tracey, Deputy Director General, Biosecurity and Food Safety, 1 June 2022, p 62.

Recommendation 2

That the NSW Government deliver at least three in-person seminars with the ability for online participation every year for members of animal ethics committees and develop in-person induction training with the ability for online participation and ensure all animal ethics committee members receive adequate training about the availability of alternatives.

3.70 There are legitimate community expectations for transparency around the use of animals in medical research. Ongoing audits and inspections by the regulator are the pillars of accountability and make a significant contribution to openness. The committee was surprised to hear that audits and inspections are not required to be conducted by ARRP inspectors but can be done on a 'quid pro quo' basis across institutions. Research facilities and their ethics committees need to be subject to rigorous oversight to ensure they uphold the requirements of the Code and regulatory framework. Any diminution in the rigour of audits and inspections is unacceptable, including the move to decrease the frequency of audits from three to the minimum four years. We recommend the reinstatement of audits by inspectors employed by the Department of Primary Industries on a three-yearly basis, and that funding to the department be increased to enable the ARRP to effectively perform its audit and inspection functions.

Recommendation 3

That the New South Wales Government increase funding to the Department of Primary Industries within Regional NSW to effectively resource the audit and inspection functions of the Animal Research Review Panel and reinstate three-yearly audits of animal research facilities as soon as practicable, to be conducted by inspectors employed by the department.

Chapter 4 Improvements to animal care and greater transparency in medical research

The first half of this chapter identifies specific measures to improve the welfare of animals used in medical research. It begins with a discussion of the standards of animal care in New South Wales, followed by suggestions for improvement including an expanded role for veterinarians, as well as training for those caring for research animals. Next, the chapter considers how to improve the lives of animals by rehoming them once they exit medical research.

The second half of the chapter considers how to achieve greater transparency around the use of animals in medical research. This includes providing a voice to animal care staff and veterinarians, protection for whistleblowers and effective complaints measures. Reporting is vital to transparency, and in particular consistent national reporting of the number of animals used in medical research.

Improving standards of animal care

4.1 The committee heard some evidence about poor standards of animal care in certain research institutions in New South Wales. Inquiry participants gave evidence that improvements in animal welfare could be driven by giving veterinarians a more prominent role in medical research and ensuring high quality and consistent training for animal care staff and medical researchers.

Standards of animal care in New South Wales

4.2 The committee received limited evidence commenting specifically on the standards of care for animals used in medical research in New South Wales. In this regard the committee drew on evidence from Ms Lisa Craig, a long-term animal care manager with 30 years' experience across academia, industry and government.[302] Ms Craig commenced her career in the United States and then moved to Australia, working at four facilities in New South Wales and Queensland, and has also been engaged in other Australian facilities as a member of the Association for Assessment and Accreditation of Laboratory Animal Care.[303]

4.3 Ms Rachel Smith, Chief Executive Officer, Humane Research Australia commended Ms Craig on coming forward and described the challenges faced by animal care staff in speaking out about welfare concerns:

> I was quite surprised to see a public submission because we receive very similar reports but they are usually anonymous or the people that provide the report are very cautious of the information being provided because they fear for their jobs … I think it is very brave of that individual to come forward.[304]

4.4 Ms Craig encapsulated the view that the humane and respectful treatment of animals must be given the highest priority: 'it is of utmost importance that when animals are used in research it

302 Evidence, Ms Lisa Craig, 16 May 2022, p 47.

303 Evidence, Ms Craig, 16 May 2022, p 49.

304 Evidence, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 16 June 2022, p 11.

is done with the utmost care and respect for the animals and their welfare'. However, Ms Craig informed the committee that she had witnessed the opposite at some medical research institutions:

> I have been engaged in institutions where previous staff have been neglectful in managing care of animals, or improperly trained, or lacked knowledge around the appropriate care of those species. That has resulted in things such as bumblefoot in guinea pigs or mouldy water bottles. [305]

4.5 Ms Craig also highlighted a number of other concerning animal welfare issues from her time working in animal research institutions:

> I have personally witnessed a significant number of animal welfare issues. This includes the removal of toes and tail tipping of adult animals, animals not being given appropriate anaesthesia and analgesia, mass culling of animals as researchers are not happy with preliminary data from them, animals used in horrific inappropriate smoke inhalation studies, animal fasted for excessive periods of time, severe and significant overproduction of animals.[306]

4.6 Ms Craig also raised concerns around wastage and excess breeding:

> Breeding of animals for research, including commercially available animals, occurs at institutions across Australia, resulting in significant overproduction and culling of excess animals. This includes mice, rats, and guinea pigs.[307]

4.7 These concerns were echoed by the RSPCA:

> Where animal breeding is undertaken within institutions this must be well managed by highly trained and competent staff. The risk of overbreeding is significant with students often tasked with managing their own breeding colonies with minima l training and oversight in doing so. Well run facilities have their own breeding manager who is tasked with ensuring overbreeding does not occur and that best practice is undertaken to avoid wastage of animals. Wastage occurs when animals are bred in numbers in excess of need, and then not utilized but killed and disposed. To prevent wastage, institutions must be required to track and report breeding and usage statistics relevant to individual strains of animals and the reasons for any wastage.[308]

4.8 Ms Craig expressed concern about the poor standards of expertise around laboratory animal science in Australia and the 'over-reliance' on researchers to oversee the care of animals:

> Unfortunately, professionalism in lab animal science in Australia is lacking. That includes access to lab animal science in medicine education. Australian regulations leave the authority and responsibility for animal care and welfare with the chief investigator. Veterinarians, paraprofessionals and professional lab animal science involvement in research is not prioritised and research is over-reliant on researchers who lack expertise in animal care and welfare, including the principles of lab animal science in medicine. Even the Animal Research Review Panel does not include expertise in lab animal

305 Evidence, Ms Craig, 16 May 2022, p 49.

306 Submission 251, Ms Craig, p 3.

307 Submission 251, Ms Craig, p 3.

308 Submission 222, RSPCA, p 6.

> science in medicine, nor representatives from those of us directly involved in the daily care and management of animals for research.[309]

4.9 Expanding on this point, Ms Craig told the committee that despite her experience as an animal facility manager, she could not override what a researcher deemed to be appropriate animal care:

> So one of my struggles as an animal facility manager is that I do not have authority to determine how animals are managed. It is the researchers, and it requires researcher approval to determine the care and management of the animals. So if I say a cage should be changed every two weeks and the animal researcher says, "No, it should be changed once a week", then I have to allow that researcher's requirements….
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> …
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> … there is a lot of conflict in what a researcher believes is the appropriate care and management but what actual science says is the appropriate care and management of an animal in research. It is not your pet; you cannot change the food and water as you see fit. That does have significant impacts on the variability of the experiment and the ultimate outcomes.[310]

4.10 Ms Craig concluded that in her experience, 'animal care programs are generally the last priority on the budget'.[311]

4.11 The greater role of veterinarians in medical research institutes in the United States was identified by Ms Craig as driving higher standards of animal care, unlike in Australia where the primary researcher has responsibility for animal welfare outcomes:

> In the US, for one, the US regulations require that … adequate veterinary care is in place at all institutions. The veterinarian has the ultimate authority for animal welfare and responsibility. The veterinarians are much more engaged and involved in the development of the procedures and protocols around animal use. The veterinarians are much more involved in the ethics or animal care and use review programs. There is extensive staffing and expertise in live animal science and medicine, so animal facility managers may have a masters degree in laboratory animal science. Those programs are just simply not available in Australia. Veterinarians in the US may have much more extensive training and education and experience of live animal science than our average welfare officers.[312]

4.12 Noting that a veterinarian is required to sit on every AEC, Ms Craig told the committee that the 'veterinarian member does not have to have any experience, does not have to have ever practised, only must have the qualification that allows them to be registered in Australia'.[313] Witness A also observed that veterinarians on AECs may not be experienced in the use of animals in medical research:

> Not all of those vets, in my opinion, have relevant experience. You get vets who have a dog-and-cat practice at the local suburb. That is great, but that requires slightly

309 Evidence, Ms Craig, 16 May 2022, p 49.

310 Evidence, Ms Craig, 16 May 2022, p 40.

311 Evidence, Ms Craig, 16 May 2022, p 49.

312 Evidence, Ms Craig, 16 May 2022, p 49.

313 Evidence, Ms Craig, 16 May 2022, p 53.

> different experience and background to managing anaesthesia in mice or those sorts of things. [314]

Role of veterinarians

4.13 Inquiry participants called for the role of veterinarians to be expanded to ensure that animals used in medical research are looked after with the highest standards of care. Dr Susan Maastricht, veterinarian and Animal Welfare and Ethics Committee Member of the Australian Veterinary Association explained the benefits of veterinarians being more involved in medical research using animals:

> Our training is about animals and understanding animals—all about them, not just their health and wellbeing but the environment in which their whole of life is actually given the greatest merit and benefit. It is just something that we carry with us. It is part of our integral training that we bring, and it would be such a unique opportunity for New South Wales, who has led the way in this space. It would be lovely to see New South Wales do something really meaningful to provide opportunities for veterinarians to receive further training and to get employment in areas such as this.[315]

4.14 In particular, inquiry participants recommended that all medical research institutes be required to employ a veterinarian on staff to facilitate improvements in animal welfare. Witness A recommended that institutions be required to 'employ a veterinarian or person with similar qualifications', predicting that 'you would see better animal welfare and you would see better-quality science, and ultimately greater support for social licence'.[316]

4.15 Dr Sarah Toole is an animal care officer at the University of Wollongong as well as a veterinarian. Dr Toole agreed that 'all institutions should have a veterinarian on staff', above the requirement in the Code that 'there has to be a program of veterinary care and somebody with either veterinary or other appropriate qualifications responsible for veterinary care'.[317]

4.16 The committee was told that Western Sydney University and the Western Sydney Local Health District employ animal care officers who are trained veterinarians.[318] Professor Wayne Hawthorne, Chair of the AEC at the Western Sydney Local Health District, elaborated that this officer was only one of a number of vets employed at these two facilities, including veterinary anaesthetists, and that in his opinion this is 'integral to research projects'.[319]

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314 *In camera* evidence, Witness A, 16 May 2022, p 9, published by resolution of the committee.

315 Evidence, Dr Susan Maastricht, Animal Welfare & Ethics Committee Member, Australian Veterinary Association, 1 June 2022, p 37.

316 *In camera* evidence, Witness A, 16 May 2022, p 5.

317 Evidence, Dr Sarah Toole, Animal Welfare Officer & Veterinarian, University of Wollongong, 1 June 2022, p 6.

318 Evidence, Professor Wayne Hawthorne, Chair, Animal Ethics Committee, Western Sydney Local Health District, 1 June 2022, p 6; Evidence, Professor Kevin Dunn, Pro Vice-Chancellor Research, Western Sydney University, 1 June 2022, p 6.

319 Evidence, Professor Hawthorne, 1 June 2022, p 6.

Training for researchers and animal care staff

4.17 In addition to an expanded role for veterinarians, the committee heard that there is a need to address a shortage of appropriately trained animal care staff. Ms Kiri Collins, President, Australian and New Zealand Laboratory Animals Association, described 'a shortage of qualified staff within the workforce and the industry',[320] partly due to the discontinuation of the TAFE course on animal care, leading to a reliance on training by research institutes:

> That specific course was discontinued mostly due to a lack of participants … 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 NSW TAFE course gave very specific training to working within a laboratory with animals designated for research … we cannot replicate those in any other courses.[321]

4.18 Describing the training that animal care staff receive from medical research institutes, Ms Collins said:

> 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. [322]

4.19 Ms Collins concluded by calling for the TAFE course to be reinstated:

> Certainly, as a community, we did express our concerns about the closure of that course and the impact that it would have … [T]hat is an area of deep concern and of interest for the New South Wales community to have that course reinstated.[323]

4.20 The medical research community also recognised the importance of animal care staff trained not just by institutions but through accredited training programs. Professor Peter Schofield AO, Board member, Association of Australian Medical Research Institutes, recommended that the government 'work with stakeholders to develop accredited training standards and training programs for staff working with animals in research'.[324]

4.21 Commenting on the discontinuation of the TAFE course, Ms Craig said:

> The TAFE program in New South Wales is gone, so where do you get animal care staff that have any training in animal care? So we are bringing them in and we are training them on the ground, and it is difficult.[325]

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320 Evidence, Ms Kiri Collins, President, Australian and New Zealand Laboratory Animals Association, 28 June 2022, p 15.

321 Evidence, Ms Collins, 28 June 2022, p 15.

322 Evidence, Ms Collins, 28 June 2022, p 15.

323 Evidence, Ms Collins, 28 June 2022, p 15.

324 Evidence, Professor Peter Schofield AO, Board member, Association of Australian Medical Research Institutes, 16 May 2022, p 21.

325 Evidence, Ms Craig, 16 May 2022, p 53.

4.22 The committee heard that appropriate training was needed not just for animal care staff, but for researchers. Explaining the training requirements for researchers using animals in medical research, Professor Kevin Dunn, Pro Vice-Chancellor Research, Western Sydney University, told the committee:

> … a researcher in this area needs to have training in animal care. Some of that training might be at a very basic level, and for students at lower levels. Animal care, husbandry, principles, three Rs principles—all of those sorts of things. That's essential. Deeper levels of training around other types of experiments, invasive procedures, would be attached to where the research was necessary or where the research was involved.[326]

4.23 To address shortfalls in researcher's animal care expertise, Dr Maastricht recommended 'improving competency training of researchers and involving institutional or facility veterinarians in assessing the competencies of researchers to undertake procedures on animals.'[327]

4.24 While additional training was clearly required for researchers and animal care staff, the inclusion of honours students in animal research raised its own set of concerns. Mr Peter Adamson, a former AEC member, said that in his experience 'much suffering is inflicted on animals by students so that they can submit research to gain Honours degrees and PhDs'.[328] Humane Research Australia also highlighted some of their reservations about the use of honours students, noting that:

> It establishes a [precedent] of using animals in research, does not equip students with skills needed to peruse advanced new approach methodologies, and is wasteful of animal lives in the projects where outcomes are known and the animals are simply used to demonstrate existing knowledge, which could be taught by other methods. There is also the potential of animal welfare impact if the students are not adequately trained or experienced. To reduce the number of animals used and bring about a change in future generations of researchers, HRA recommend that honours students are prohibited from using animals. This would also encourage supervisors to expand the research methodologies they use.[329]

Rehoming of animals used in medical research

4.25 Inquiry participants pointed to the rehoming of animals used in medical research as a means to improve the lives of animals after they had been used in medical research.

4.26 The *Australian Code for the Care and Use of Animals for Scientific Purposes* states that after animals have been used for research, AECs can make provisions for them to be rehomed 'wherever possible', and in particular, where the research impact on the animal has been minimal and the animal's condition and behaviour indicates introduction to a new environment would have

326 Evidence, Professor Dunn, 1 June 2022, p 3.

327 Evidence, Dr Maastricht, 1 June 2022, p 31.

328 Submission 252, Mr Peter Adamson, p 1.

329 Answers to supplementary questions, Humane Research Australia, 29 June 2022, pp 11–12.

minimal impact on the animal's wellbeing.[330] Several animal welfare organisations proposed that this requirement be made mandatory, rather than voluntary.[331]

4.27 Beagle Freedom Australia is one of two significant not-for-profit organisations that rehomes animals used in research – it has rehomed 'hundreds' of dogs and cats since 2013. The other major rehoming organisation, Liberty Foundation, has rehomed around 420 animals since 2017 including dogs, cats, rabbits, guinea pigs, rats, mice and fish. Between 2019 and 2020, 30 dogs and 75 cats were rehomed by research establishments based in New South Wales.[332]

4.28 Ms Paula Wallace, Director, Liberty Foundation noted that despite rehoming being enshrined in the Code, rehoming had only become more commonplace in recent years. Ms Wallace believed that rehoming was a more ethical approach than euthanasia or sending the animal to another research facility but was concerned that cost and convenience was leading to an unfortunate fate for animals used in research:

> … money and convenience … should not be driving factors in deciding the fate of animals used in research. They should not be euthanased because it is considered to be easier.[333]

4.29 The foundation highlighted the benefits of rehoming for research institutions, which included an improved reputation, better risk management and alignment with public views. The benefits of rehoming for an animal's wellbeing were also outlined:

> … they will have the opportunity to live out their natural lives, as well as experience an environment different from that of the institutional context, free from scientific intervention, where the care and services are available to enable them to lead an enriching existence.[334]

4.30 Representing the views of medical research institutes, Professor Schofield AO, advised that he was supportive of animal rehoming initiatives 'to the extent that it is possible'.[335]

4.31 In 2020, the ARRP introduced its voluntary 'Research Animal Rehoming Guidelines' to support 'responsible homing practices to optimise rehoming success'.[336] The Animal Defenders Office and Beagle Freedom called for these guidelines to be made mandatory. Beagle Freedom's Co-Founder, Ms Nikki Steendam explained their organisation's difficulties in convincing research

330 National Health and Medical Research Council (2013), *Australian code for the care and use of animals for scientific purposes*, 8th Edition (updated 2021), p 67.

331 See, for example: Submission 236, Tree of Compassion Incorporated, p 4; Submission 241, Beagle Freedom Australia, p 6; Submission 262, Sentient - The Veterinary Institute for Animal Ethics, p 5; Answers to questions on notice, Ms Paula Wallace, Director, Liberty Foundation, 22 July 2022, p 7.

332 Answers to questions on notice, Ms Paula Wallace, Director, Liberty Foundation, 22 July 2022, pp 5-6.

333 Evidence, Ms Paula Wallace, Director, Liberty Foundation Australia, 1 June 2022, p 22.

334 Submission 213, Liberty Foundation Australia Limited, p 4.

335 Evidence, Professor Schofield AO, 16 May 2022, p 33.

336 NSW Department of Primary Industries, 'Animal Research Review Panel Guideline 27: Research Animal Rehoming Guidelines: For establishments and individuals involved in the care and use of animals for research and teaching in NSW' (December 2020), p 8.

facilities to release its animals to them, and advised that the guideline's voluntary nature meant that it was not being followed.[337]

4.32 There were stakeholders who called for funding for rescue organisations that are performing the work of rehoming animals used in research institutions. For example, Liberty Project stated that:

> For the rehoming movement for ex-research animals to expand and become sustainable at scale, we believe industry and government must work together with rehoming organisations, most importantly, by providing funding and other support…it should not be left to the charitable sector to pay for rehoming of animals from government-owned or -run research facilities as is currently taking place.[338]

The call for funding was also supported by the Animal Defenders Office.[339]

4.33 Several animal welfare organisations also called for mandatory retirement ages for dogs and cats used in research.[340] Liberty Foundation observed hundreds of cats and dogs being retained for use in other research projects after their experiments, and was concerned about the cumulative impact on animals remaining in research for extended periods of time and how this would impact their ability to be rehomed at a later date.[341]

4.34 In May 2022, the Hon Emma Hurst MLC introduced the Animal Research Amendment (Right to Release) Bill 2022, which would amend the Act to create mandatory obligations on institutions to take reasonable steps to ensure the rehoming of cats and dogs used in medical research and to generally limit the use of cats and dogs to three years.[342] In June 2022, the Legislative Council passed the bill. On 13 October 2022, the bill passed the Legislative Assembly with amendments. At the time of writing this report, the amendments are awaiting consideration in the Legislative Council.[343]

A voice for those involved in animal care

4.35 Staff involved in the day-to-day care of animals used in medical research have high level expertise that should be listened to in legislative and policy discussions. Those involved in animal care should be able to make formal complaints without fear, whether as written complaints to AECs or complaints under whistleblower laws.

337 Evidence, Ms Nikki Steendam, Co-Founder, Beagle Freedom Australia, 1 June 2022, p 23; Submission 245, Animal Defenders Office, p 13.

338 Answers to supplementary questions, Liberty Project, 22 July 2022, p 6.

339 Submission 245, Animal Defenders Office, p 13.

340 See, for example: Submission 262, Sentient - The Veterinary Institute for Animal Ethics, p 5; Submission 204, Humane Research Australia, p 14.

341 Submission 213, Liberty Foundation Australia Limited, p 5.

342 *Hansard*, NSW Legislative Council, 18 May 2022, pp 6500–6502 (Emma Hurst).

343 Parliament of New South Wales, Animal Research Amendment (Right to Release) Bill 2022, https://www.parliament.nsw.gov.au/bills/Pages/bill-details.aspx?pk=3969 .

Providing a voice to veterinarians and animal care staff

4.36 Dr Susan Maastricht in her capacity as Animal Welfare and Ethics Committee Member, Australian Veterinary Association (AVA), told the committee that 'veterinarians are key experts in animal health and welfare, so it is important for our views to be heard on any animal welfare legislative or policy amendments.'[344] Dr Maastricht called for additional funding and for veterinarians to have a voice in discussions on animal welfare issues:

> … there are some other elements that need additional funding. I think, to be frank, the regulator could do with more resources … I think there is some real merit in them being able to do what they need to do and to give more opportunities for veterinarians to participate on ARRP, in the DPI and in this particular sector. I think that would be fantastic.[345]

4.37 The AVA recommended that a veterinarian be appointed to the ARRP to ensure that veterinary science was given sufficient prominence:

> Currently there is no requirement for a member of the veterinary profession to be included on ARRP although it may happen simply because a ministerial or Vice Chancellors Committee nominee is a veterinarian. It is the opinion of the AVA that this is a gap that needs to be addressed. A panel with the responsibilities outlined will benefit from the presence of at least one member with qualifications, knowledge and skills in veterinary science. A nominee provided by the Australian Veterinary Association would ensure that this inclusion could be achieved with the most appropriate representative.[346]

4.38 In a similar way to veterinarians, Ms Collins representing laboratory technicians and animal care workers, emphasised 'the need and the intent for the technical community to have a greater voice in the discussions about animal research in Australia':

> … 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 … 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.[347]

4.39 Ms Collins observed that 'generally we are identified as subject matter experts that are consulted heavily by the animal ethics committees as well through those processes' and described their collaborative role working with researchers in developing applications and submissions to the AEC and responding to AEC operational and technical questions.[348]

4.40 Dr Malcolm France, Consultant Veterinarian and Board Member, Australian and New Zealand Council for the Care of Animals in Research and Teaching, added that he would describe the animal care staff or animal technicians, as the 'eyes and ears' of the animal ethics committee:

344 Evidence, Dr Maastricht, 1 June 2022, p 31.

345 Evidence, Dr Maastricht, 1 June 2022, p 35.

346 Submission 242, Australian Veterinary Association, p 9.

347 Evidence, Ms Collins, 28 June 2022, p 13.

348 Evidence, Ms Collins, 28 June 2022, p 14.

> … 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.[349]

Whistleblowers and complaints to Animal Ethics Committees

4.41 Complaints are another means for those involved in the use of animals in medical research to voice their concerns, using whistleblower protections or through writing to AECs.

4.42 Ms Smith told the committee that whistleblowers in the medical research community fear coming forward: '… when we speak to anonymous providers of that information, they are fearful that they have signed confidentiality agreements as being part of the AEC or that if they were to share photos or footage, it could be linked to them.[350] Ms Sarah Margo, Solicitor, Animal Defenders Office concurred and said that job security and a person's reputation within the industry could stop them from coming forward.[351]

4.43 The committee heard that disclosures might not be protected by whistleblower laws. Ms Margo told the committee that section 56 of the Act 'in our legal opinion, actually stymies any of the efforts of whistleblowers and does not offer any kind of protection for someone who should wish to disclose some kind of contravention under the Act'.[352] Her colleague Ms Tara Ward, also a Solicitor, went on to explain that disclosures could potentially be protected by the Public Interest Disclosures Act but it would only apply to whistleblowers from universities, and even then that Act only protects disclosures made by public officials about corrupt conduct.[353]

4.44 In relation to complaints to AECs, Witness A brought a particular example to the committee's attention. They wrote to an AEC to make a complaint about the approval of a particular research application. Witness A said they were disappointed in the investigation and response:

> I wrote to the animal ethics committee of the institution and got a response back which, I have to say, surprised me. This is not typical of all institutions, but I was concerned that it would happen at all. I suggested that the committee might want to have another review of the application to ensure that it met best practice, and I was told that that would contravene the committee's review procedure because approval was given under the terms of best practice at the time …
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> There was a discussion at the animal ethics committee to which I was not party, and that concerned me as well. The argument was that I had a conflict of interest. I cannot see why I would have had a conflict of interest … I felt the investigation was underwhelming and lacked the sort of commitment I would have expected and the sort of commitment that I have seen at other institutions.[354]

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349 Evidence, Dr Malcolm France, Consultant Veterinarian and Board Member, Australian and New Zealand Council for the Care of Animals in Research and Teaching, 28 June 2022, p 14.

350 Evidence, Ms Smith, 16 May 2022, p 11.

351 Evidence, Ms Sarah Margo, Solicitor, Animal Defenders Office, 16 May 2022, p 39.

352 Evidence, Ms Margo, 16 May 2022, p 39.

353 Evidence, Ms Tara Ward, Solicitor, Animal Defenders Office, 16 May 2022, p 39.

354 *In camera* evidence, Witness A, 16 May 2022, p 7.

Reporting requirements

4.45 Research institutes are subject to various reporting requirements in relation to their use of animals in medical research. Despite this, inquiry participants gave evidence that there is insufficient transparency around the use of animals in medical research, and the data that is published makes it difficult to fully understand the types and amount of research done on animals in New South Wales and Australia. They called for consistent national reporting to address gaps in data collection and publication.

Reporting and calls for greater transparency

4.46 Accredited establishments working with animals are required to report on their activities: under the Regulation, they must submit annual reports to the NSW Government, including the number of animals used, negative impacts on animal wellbeing, adverse outcomes and steps taken to implement the 3Rs.[355] Animal use statistics are published on the Department of Primary Industries' Animal Ethics Infolink website.[356]

4.47 Inquiry participants called for greater transparency around the use of animals in medical research.[357] Ms Ward gave evidence that the Animal Defenders Office 'would urge the New South Wales Government to commit to improving transparency by requiring increased public reporting about animals used in medical research'.[358]

4.48 Humane Research Australia described the publication of animal use statistics as 'commendable' and a contributor towards accountability, while calling for further detailed information to be made available.[359] Humane Research Australia made a number of recommendations to improve transparency, including:

- providing details on the numbers of animals bred but not used for medical research and which were killed instead
- CCTV cameras in research facilities
- permitting media and animal welfare organisations to visit primary breeding colonies
- publication of ministerial approvals for lethal doses
- greater scrutiny of undergraduate and postgraduate animal use
- a mandatory requirement in the Code for research institutes to publish their annual reports and summaries of external reviews/inspection reports
- requiring the fate of all species used in research to be reported.[360]

355 Submission 239, NSW Government, pp 1 and 9; Submission 217, The University of Sydney, p 7.

356 Submission 239, NSW Government, p 9.

357 Evidence, Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia, 16 May 2022, p 39; Evidence, Ms Smith 16 May 2022, p 13.

358 Evidence, Ms Ward, 16 May 2022, p 38.

359 Submission 204, Humane Research Australia, p 16.

360 Submission 204, Humane Research Australia, pp 14–16.

4.49 The Animal Defenders Office also expressed support for improved reporting of animal use statistics, particularly in relation to the reporting the 'fate of animals':

> Reporting on the fate of animals is mandatory only for domesticated dogs and cats used in research. Reporting is voluntary for all other animal groups. This is unacceptable from a transparency standpoint…Furthermore, there is no ethical justification for requiring reporting on cats and dogs but not other species. The ADO submits that reporting on the fate of all animals should be mandatory.[361]

4.50 Transparency around reporting was also supported by the medical research community, as noted in evidence by Professor Anthony Cunningham AO, NSW and ACT Branch Chair, Australian Academy of Health and Medical Sciences: 'the academy also supports transparent reporting of the use of animals in research'.[362] Dr Ted Rohr, Director Research Ethics and Compliance Support, University of New South Wales, informed the committee that reporting of animal usage should be 'meaningful':

> From my view the critical part is the meaning of collecting statistics. It is one side to collect numbers; it is another side to produce information for the public, for the informed public, so they get what they want. I think this should be constructed by academics in the social sciences who are familiar with thxese types of surveys, rather than by a regulator saying, "Give us this number", or "Give us that number", because that doesn't translate to the public understanding what these numbers mean.[363]

Consistent national reporting

4.51 Alongside calls for greater transparency, a number of inquiry participants spoke of the desirability of uniformity in the regulation and reporting of the use of animals in medical research throughout Australia.[364] For example, Dr Maastricht said the AVA is 'advocating for better harmonisation and standardisation across jurisdictions for annual animal use statistics and animal research legislation, particularly calling for uniform Commonwealth legislation aligned to the Australian code for the care and use of animals for scientific purposes'.[365]

4.52 Dr Rohr told the committee that consistent national reporting would increase transparency by contributing to more informed public understanding of the statistics, and suggested the national Office of the Gene Technology Regulator as a potential model for such national reporting:

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361 Submission 245, Animal Defenders Office, pp 12–13.

362 Evidence, Professor Anthony Cunningham AO, NSW and ACT Branch Chair, Australian Academy of Health and Medical Sciences, 16 May 2022, p 11.

363 Evidence, Dr Ted Rohr, Director Research Ethics & Compliance Support, University of New South Wales, 1 June 2022, p 20.

364 See, for example: Submission 217, The University of Sydney, pp 8-9; Submission 234, Australian and New Zealand Council for the Care of Animals in Research and Teaching, p 3; Evidence, Professor Kay Double, Professor of Neuroscience, Chair of Animal Ethics Committee, University of Sydney, 1 June 2022, pp 11 and 19-20; Submission 242, Australian Veterinary Association, pp 3 and 10; Submission 212, Western Sydney University, p 3; Submission 213, Liberty Foundation Australia, p 8; Submission 237, CSIRO, p 3.

365 Evidence, Dr Maastricht, 1 June 2022, p 31.

> We have differences between States and our research is at least national, but even more so international. I think at the moment we don't have an Australia-wide focus on reporting. On that idea of transparency, we have to report different statistics to different States and then they get reported differently to the public and the legislation differs between States. The Office of the Gene Technology Regulator works very well from what I and my colleagues can see. That would be an idea.[366]

4.53 A particular concern with the reporting structure is the requirement to report data from observational studies in the same way as the number of animals used in medical research. The committee was told that this can skew public opinion and understanding of the actual number of animals used in medical research. According to Dr David Mason, Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART), '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'.[367]

4.54 Dr Christopher McCarthy, Chair, Animal Ethics Committee, University of Newcastle, explained how the numbers can be inflated by referring to an observational study of frogs that required the counting of tadpoles:

> We had some amazing research in conservation of the bell frog in Newcastle, which has been decimated due to a fungus called chytrid. We had to count the tadpoles. There are hundreds of thousands. The numbers that are being published … these are animals being observed, not acted upon. It really does inflate those numbers substantially.[368]

4.55 Another example was provided by Professor Kay Double, Professor of Neuroscience and Chair of Animal Ethics Committee, University of Sydney, who described how fish swimming past a camera could be counted in the number of animals reported:

> Let me give you an example. If someone is doing purely observational research, so they are doing research on, for example, a fish species, and they are only looking to see where the fish are and how many there are, they set up cameras and they are watching the fish swim past a camera. If they have 60,000 fish that swim past that camera, they count those as being animal use. If those animals then turn around and swim back the other way, we don't know whether they are the same animals or not, but they would then be recounted, so that would be 120,000 fish that would be used as animal research usage.[369]

4.56 Professor Double observed that 'it is very difficult to really get a grasp on the scope of animal use in Australia compared to other countries'.[370] Professor Double advised that other countries do not include observational statistics in their reporting on the number of animals used in medical research, and called for nationally consistent reporting legislation to address this issue:

366 Evidence, Dr Rohr, 1 June 2022, p 19.

367 Evidence, Dr David Mason, Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching, 28 June 2022, p 11.

368 Evidence, Dr Christopher McCarthy, Chair, Animal Ethics Committee, University of Newcastle, 1 June 2022, p 20.

369 Evidence, Professor Double, 1 June 2022, pp 19-20.

370 Evidence, Professor Double, 1 June 2022, pp 19-20.

> Inconsistent reporting of research animal activities in different States and Territories, and including all animals involved in biomedical, veterinary, wildlife, environmental research and teaching, significantly distorts animal research statistics in Australia. Other countries report only animals directly used in biomedical research. This could be addressed by a harmonised national reporting system embedded in legislation, as seen in the EU and the UK.[371]

4.57 The committee was informed that, in recognition of 'legitimate community expectations for transparency', ANZCCART is currently leading a national initiative to develop an Openness Agreement on Medical Research in Australia. The aim is to 'improve openness and public understanding of animal research' and 'enable well-informed public discussion'.[372] This step aligns with developments in other countries:

> This follows a similar approach being adopted overseas. The first openness agreement was launched in the UK in 2014 and others are now in place in Spain, Portugal, Belgium, France, Germany, The Netherlands and New Zealand. Openness agreements are also under development in several other countries including the USA and Switzerland.[373]

4.58 ANZCCART said that the Openness Agreement is being revised following a public consultation process and feedback from institutional and community stakeholders. The intention is to finalise the Agreement and invite organisations to sign up later in 2022.[374]

4.59 Professor Double called for the Australian Government to provide appropriate resourcing to ANZCCART to support administration of the Openness Agreement:

> We also recommend that the New South Wales Government urge the Federal Government to improve resourcing of ANZCCART to deliver support and administer an openness agreement to facilitate greater transparency, community confidence and the social licence that we currently receive for animal research.[375]

4.60 The committee notes that ANZCCART's principal sponsors are the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Royal Society Te Apārangi (RSNZ), Universities Australia (UA), State Government Departments responsible for the management of animal welfare legislation and their members as well as receiving annual contributions from professional organisations.[376]

4.61 Humane Research Australia welcomed the draft Openness Agreement as a means to 'encourage research institutes to be more open'. However, they noted that 'it is non-binding and in its

371 Evidence, Professor Double, 1 June 2022, p 11.

372 Submission 234, Australian and New Zealand Council for the Care of Animals in Research and Teaching, p 4.

373 Submission 234, Australian and New Zealand Council for the Care of Animals in Research and Teaching, p 4.

374 Submission 234, Australian and New Zealand Council for the Care of Animals in Research and Teaching, p 4.

375 Evidence, Professor Double, 1 June 2022, p 11.

376 Submission 234, Australian and New Zealand Council for the Care of Animals in Research and Teaching, p 1.

current format, there is no obligation on regulators to report on their performance in meeting greater transparency'.[377]

Committee comment

4.62 The committee is concerned at claims that standards of animal care may be variable across institutions. While only one witness provided direct evidence of witnessing cruelty inside a research facility, the perspective that was offered by Ms Lisa Craig was reinforced by evidence from Humane Research Australia, who stated that her experience 'really echoes some of the information we have, which ranges from members of the public that served on AECs and felt they were completely intimidated'.[378]

4.63 The evidence presented shows that in some cases standards fall short of community expectations for the respectful and humane treatment of all animals. The committee reiterates in the strongest terms that the use of animals in medical research is justifiable on public health grounds only if animals are treated humanely.

4.64 The committee notes the serious issues raised by some witnesses regarding the current regulatory framework, including but not limited to, overbreeding of animals, issues regarding pre-registration and publication of negative results from animal research experiments, the participation of honours students in medical research using animals and the standards for housing and care of animals in research facilities. The committee was also concerned to hear evidence about non-disclosure obligations imposed by the *Animal Research Act*, and the limited protections afforded to whistleblowers. The committee recommends that the NSW Government investigate opportunities for reform and undertake a review of the *Animal Research Act* with regards to the issues raised in this inquiry.

Recommendation 4

That the NSW Government investigate opportunities for reform and undertake a review of the *Animal Research Act 1985* considering the issues raised in this inquiry, including but not limited to the:

- overbreeding of animals
- need to encourage pre-registration and publication of negative results of medical research involving animals
- issues concerning honours student undertaking medical research using animals
- housing and care of animals used in medical research
- need for protections for whistleblowers who seek to raise concerns about the treatment of animals used in medical research.

4.65 The committee concludes that the employment of veterinarians in all research institutes, and the appointment of a veterinarian with appropriate expertise to AECs, are key to driving improvements in animal welfare outcomes. We recommend that the NSW Government engage

377 Submission 204, Humane Research Australia, p 14.

378 Evidence, Ms Smith, 16 May 2022, p 11.

with the Australian Government at a ministerial level to advocate for priority review of the Code, to require veterinarians appointed to AECs to have the appropriate skills to oversight the conduct of medical research using animals, and that medical research institutes be required to employ a veterinarian.

Recommendation 5

That the NSW Government engage with the Australian Government at a ministerial level to advocate for priority review of the *Australian Code for the Care and Use of Animals for Scientific Purposes*, to ensure that:

- veterinarians with appropriate expertise are appointed to animal ethics committees
- research institutions be required to employ a veterinarian.

4.66 The ARRP as the body with oversight of the use of animals in medical research in New South Wales must have the benefit of expertise in veterinary science. We concur with the Australian Veterinary Association that a member of the Panel must be an experienced veterinarian and recommend that the *Animal Research Act 1985* be amended to ensure that one member is selected by the Minister from a panel nominated by the Australian Veterinary Association.

Recommendation 6

That the NSW Government amend the *Animal Research Act 1985* to provide that one member of the Animal Research Review Panel shall be a person selected by the Minister from a panel of qualified persons nominated by the Australian Veterinary Association.

4.67 The discontinuation of the TAFE course on animal care may be another factor contributing to the variability of animal welfare standards across institutions, as well as leading to staff shortages. It is important that there be accredited training of animal care staff to achieve consistency and uphold the highest standards of animal welfare.

Recommendation 7

That the NSW Government commit to the reinstatement of the TAFE training course on animal care.

4.68 The committee is concerned that animals are being unnecessarily euthanised after being used in medical research. Many cats and dogs in particular may be able to be rehomed, particularly if they are still young and have had a relatively normal and caring upbringing. Not enough research institutions are actively seeking rehoming options for these animals, or responding to offers made by dedicated rehoming organisations.

4.69 Existing obligations to rehome animals are voluntary. The committee considers that requirements must be imposed on research institutes to actively seek out rehoming

opportunities, and recommends that the ARRP's 'Research Animal Rehoming Guidelines' be strengthened into a mandatory model.

4.70 The committee notes that while the Animal Research Amendment (Right to Release) Bill 2022 appears likely to pass through the NSW Parliament there is potential to expand rehoming efforts in the animal research space. The committee supports investigation of opportunities to provide support to organisations who are doing the work of rehoming animals used in medical research.

Recommendation 8

That the NSW Government commit to a mandatory model for rehoming animals used in medical research, building on the Animal Research Review Panel's 'Research Animal Rehoming Guidelines' and investigate opportunities to provide support to animal rescue organisations who rehome animals used in medical research.

4.71 The gaps and in some cases inconsistencies of reporting requirements around the use of animals in medical research contribute to public confusion about the use of animals in medical research. Both researchers using animals in medical research and animal advocacy organisations expressed concerns to the committee about the adequacy of reporting of statistics on animals used in medical research in New South Wales. The committee therefore calls on the NSW Government to consider the reporting of these statistics.

Recommendation 9

That the NSW Government consider the reporting of statistics surrounding animals used in medical research, including but not limited to:

- publishing an annual list of accredited animal research establishments, and the species of animals they use in medical research
- reporting on the total numbers of animals bred (but not ultimately used) for medical research
- requiring the fate of all species used in research to be reported
- the separate reporting of animals used in observational studies.

4.72 It does not make sense to the committee that observational studies of wildlife are reported in the same way as medical research using animals. This anomaly, which is not the case overseas, hampers informed public debate. This is a clear example of the benefit of nationally consistent reporting requirements. We recommend that the NSW Government work with the Australian Government at a ministerial level to advocate for nationally consistent reporting requirements on the use of animals in medical research. These reporting requirements should provide for the separate and discrete reporting of animals involved in observational studies, to ensure that the public has a meaningful understanding of the numbers of animals used in medical research.

Recommendation 10

That the NSW Government engage with the Australian Government at a ministerial level to advocate for nationally consistent reporting requirements on the use of animals in medical research including the separate and discrete reporting of animals involved in observational studies.

4.73 The ANZCCART Openness Agreement is a welcome step towards greater transparency around the use of animals in medical research. The committee did not receive evidence on whether ANZCCART is resourced appropriately to administer the Openness Agreement. We therefore recommend that the NSW Government take steps to ascertain if this is the case, and if not, liaise with the Australian Government to ensure appropriate funding.

Recommendation 11

That the NSW Government liaise with the Australian and New Zealand Council for the Care of Animals in Research and Teaching to ensure appropriate funding of the administration of the Openness Agreement on Medical Research in Australia and explore opportunities to ensure all research institutions sign up to this Agreement.

Chapter 5 Funding medical research: using animals and alternatives

5.1 This chapter continues the discussion commenced in Chapter 1, where the committee examined:

- the limitations of medical research using animals
- the need for cultural change towards innovative non-animal methods
- the benefits of human-relevant data
- evidence that better results might be achieved using alternative methods
- transition plans in place to phase out some types of medical research using animals.

5.2 The committee is persuaded that alternative methods are worth developing in New South Wales to ensure that we have the best possible information to inform medical treatment in this state. This chapter discusses traditional funding pathways available to medical researchers and proposes a new dedicated funding pathway that would nurture and expand the nascent industry in New South Wales.

Role of state and federal agencies

5.3 Responsibility for funding medical research largely lies with the National Health and Medical Research Council (NHMRC). The state government also provides some funding—including for research into alternatives, as outlined in the next section—although it was difficult to determine the extent. Funding to cover the cost of using animals in medical research is also provided largely by medical research establishments.

How is medical research funded?

5.4 The committee heard that research proposals are funded from a combination of 'Federal and State dollars', requiring researchers to apply for and be selected for grants that rarely cover the full extent of a research project using animals.[379]

5.5 Professor Peter Schofield AO, Board member, Association of Australian Medical Research Institutes, clarified that beyond grant funding, 'the individual researcher would be paying for the supply and delivery ... The institutions cover the housing and maintenance of those animals, typically, once they are on site, often with a per-cage charge for room cleaning and the like'.[380]

379 Evidence, Professor Peter Schofield AO, Board member, Association of Australian Medical Research Institutes, 16 May 2022, p 28.

380 Evidence, Professor Schofield AO, 16 May 2022, p 28.

Federal funding for medical research

5.6 Federally, the NHMRC provides significant grant funding for health and medical research and training. Over the five years from 2016 to 2020, the council provided 366 grants totaling $335.6 million to New South Wales institutions where animal use was being proposed.[381] Professor Philip O'Connell, Executive Director, the Westmead Institute for Medical Research, made the point that NHMRC grants are very competitive, estimating 'a success rate of less than 10 per cent to get an NHMRC grant'.[382]

5.7 Professor Schofield AO responded to questioning about the NHMRC application process that 'increasingly NHMRC have a very well-tested … system of peer review, independent peer review and panels'.[383]

5.8 The committee heard a view that NHMRC grants should be extended to cover animal care, recognising the considerable cost of keeping animals in the appropriate environment. Animal care professional Ms Lisa Craig, a long-term animal care manager, explained that well-resourced animal care—while expensive—would actually improve the consistency of research outcomes by minimising variables:

> … when NHMRC funds grants that involve animal research, they need to have sufficient funding for the animal care … The NHMRC grant should come with the requirement that the researcher does some genetic monitoring of their animals, does microbiome monitoring of their animals, to ensure that the results are consistent and that they can then explain or investigate any inconsistencies. It is rigorous science, and it is expensive.[384]

5.9 The NHRMC does not provide dedicated funding for research projects that are focussed on alternatives to animal models or enhancing the 3Rs, but this 'would be assessed on its merits against all of the others'.[385] In evidence, the Ms Prue Torrance, Executive Director, NHMRC explained that the onus is on researchers to consider whether the method proposed is best practice and grounded in evidence before applying to the NHMRC, stating:

> There are a whole series of processes that should happen well before an application is received by us wherein the researcher is taking responsibility for considering whether the method meets best practice, considering all relevant aspects of, say, species-specific biology, physiology and behaviour; considering the best available scientific evidence, including international evidence and the potential adverse impact on the wellbeing of animals used and any strategies they might need to minimise adverse impacts. There are responsibilities in the code for the researchers, and the investigators themselves, to be considering all of that before they even propose to use the test.[386]

381 Submission 238, National Health and Medical Research Council, pp 1-2.

382 Evidence, Professor Philip O'Connell, Executive Director, the Westmead Institute for Medical Research, 16 May 2022, p 29.

383 Evidence, Professor Schofield AO, 16 May 2022, p 24.

384 Evidence, Ms Lisa Craig, 16 May 2022, p 54.

385 Evidence, Professor Schofield AO, 16 May 2022, p 29.

386 Evidence, Ms Prue Torrance, Executive Director, Research Quality and Priorities, National Health and Medical Research Council, 1 June 2022, p 46.

5.10 The NHMRC has contributed to the body of information available about the importance of alternatives. Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia, drew the committee's attention to 'the Orima *Survey on the replacement, reduction and refinement of the use of animals for scientific purposes in Australia*' commissioned by the NHMRC in 2017, commenting that 'lack of funding' was found to be a 'potential blocker' to the use and development of non-animal methods.[387]

5.11 While the NHMRC funds animal research classed as discovery or basic research, the Therapeutic Goods Administration is the federal government agency relevant to the acceptance of drugs and vaccines developed through clinical trials using animals, gatekeepers of a small but significant income stream for some Australian research institutions and pharmaceutical companies. The requirement for all new drugs and vaccines registered by the TGA to have been tested on animals[388] was critiqued by some inquiry participants, who drew the committee's attention to policy developments in the United States and the European Union, which are considering relaxing this requirement to allow alternative methods to validate new drugs before they enter the market.[389]

5.12 Professor Schofield AO and Dr Di Evans, Senior Science Officer, RSPCA Australia[390] made the case for any regulatory adjustment at the federal level in Australia to be supported by government funding so that drug development can safely rely on the data from non-animal methods. According to Professor Schofield AO:

> So that would be something that I think governments would need to fund because they are asking their regulators to adopt alternative standards that they consider would provide safety to the community. So, yes, we can get there, but I think that would have to be government supported so that there was an evidence base for the regulators. The pharmaceutical companies, who are putting forward submissions, would then mirror their data according to what the regulators want and need.[391]

State funding for medical research

5.13 Regrettably, the committee was not able to gain an understanding of the extent to which the NSW Government funds medical research using animals at present or historically. The committee asked representatives of the Department of Primary Industries to take on notice a question on the state government funding that goes into medical research using animals. In response, the NSW Government emphasised that there is no dedicated stream available to fund alternatives to medical research using animals, but did not elucidate on the amount of funding provided to animal-based research more generally. Based on the answer, the committee understands that:

387 Evidence, Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia, June 2022, p 45.

388 Submission 239, NSW Government, p 2.

389 See, for example: Evidence, Dr Katherine van Ekert, Vice President, Sentient – The Veterinary Institute for Animal Ethics, 28 June 2022, p 6; Evidence, Mr Edwin Brackenreg, Chief Executive Officer, Codex Research Pty Ltd, p 19; Submission 236, Tree of Compassion, p 4; Submission 245, Animal Defenders Office, p 15; Submission 351, Medical Advances Without Animals Trust, p 13.

390 Evidence, Dr Di Evans, Senior Science Officer, RSPCA Australia, 16 May 2022, p 46.

391 Evidence, Professor Schofield AO, 16 May 2022, p 26.

- while the NSW Government uses taxpayer money to fund the use of animals in medical research, this funding is not separately recorded or reported and therefore the total amount is unclear[392]
- NSW Ministry of Health, through the Office for Health and Medical Research, funds a number of grant programs in Advanced Therapeutics, a field which increasingly uses non-animal testing methods such as organoids and tissue explants
- DPI does not currently provide funding for targeted development of alternatives to animal use in research, but all projects must provide evidence that alternatives have been considered and their non-use justified
- projects undertaken by DPI have identified and implemented alternatives to live animals, for example replacing live fish with autonomous sensors and using environmental DNA (eDNA) to determine the presence of animals.[393]

'Alternatives are the way of the future'

5.14 Building on discussion in Chapter 1 about the necessity, and indeed, the benefits of exploring alternatives to the use of animals, the committee was interested to hear participants' views about how to stimulate this developing industry. The consistent message received was that there needs to be incentives available to use alternatives, rather than a 'tick-box' requirement to have considered them, and a sharing of information on a national scale to harness existing knowledge and maximise investments already made.

5.15 A number of witnesses recalled the recommendations of the Senate inquiry into animal experimentation which recommended dedicated funding for alternatives channeled through a national centre for the 3Rs of replacement, reduction and refinement.[394]

Greater incentives for alternatives research

5.16 The case for greater investment in the use of alternatives, the key pillar of the 'replacement' limb of the three Rs, was made by advocacy organisations. The RSPCA considered that Australia had made 'limited progress' in meaningfully implementing the 3Rs over recent decades.[395] The MAWA Trust suggested it was internationally acknowledged that 'replacement' had been 'neglected'.[396] Humane Research Australia believed that the alternatives field in Australia was underdeveloped in comparison with Asia, Europe, or the United States.[397]

392 Answers to questions on notice, Budget Estimates 2019-2020, Portfolio Committee No. 2 – Health (Health and Medical Research), Further hearing 12 March 2020, p 8.

393 Answers to questions on notice, Department of Primary Industries, 27 July 2022, pp 5-6.

394 Submission 204, Humane Research Australia, p 1; Submission 247, Animal Liberation, pp 3-4, Submission 351, Medical Advances Without Animals Trust, p 5.

395 Submission 222, RSPCA, p 5; Submission 351, Medical Advances Without Animals Trust, p 15.

396 Submission 351, Medical Advances Without Animals Trust, p 15.

397 Submission 204, Humane Research Australia, p 8.

5.17 Some inquiry participants agreed that there was inadequate funding, describing a 'paucity' or 'dearth' of funding for 3Rs research.[398] Both the University of Sydney and the Association of Australian Medical Research Institutes noted that there were currently no 3Rs initiatives funded by the Australian Government.[399] According to Ms Sarah Margo, Solicitor at the Animal Defenders Office:

> Many jurisdictions overseas have already accepted that alternatives are the way of the future, regardless of how long it takes us to get there. In terms of moving towards that, what we need to see in New South Wales is investment and dedication and funding in the alternative space.[400]

5.18 Professor Kay Double, Professor of Neuroscience and Chair of the Animal Ethics Committee at the University of Sydney elaborated on the lack of government funding for alternatives and advocated for a dedicated funding stream:

> The problem there is that we do not have funds available specifically for three Rs research in Australia—that is, from the State or Federal governments ... the success rates for competitive funding from the NHMRC currently is 8 per cent. Those are all going to be research projects which are not specifically towards the three Rs.
>
> … researchers know that they will not get those [alternatives research projects] funded because there are no specific funds for it. What we really need is a system for sufficient funding to really enable three Rs research to occur.[401]

5.19 Acknowledging the need to continue to use animals 'at the moment in certain pathways', Dr Fowler was among witnesses who explained why a lack of incentives to using animal entrenches the status quo:

> The problem is that there is a sincere lack of incentive for those very researchers you spoke to earlier today to work out, "Is there truly an alternative in this?" They might go, "Can I do this immune study without using an animal?" And they go, "Well, no. It's an immune study. I need the entire animal to be able to do this; therefore, that is my answer on the ethics form and that is how I am going to proceed." At the moment, there is no incentive for us to say to a researcher, "Actually, there is this new study that was done overseas, where it is well funded, and I would like you to do a parallel study that uses the animals and uses this new methodology, and see if you can get the same results or the same amount of data out of this."
>
> …there is no look beyond their blinkers to say, "Actually, maybe I could do a systematic review," or, "Maybe I could invest in big data and look at very large cohorts of human data to see if there are results I could get there." There is no incentive and they do not get funding to do that type of work.[402]

398 Submission 217, The University of Sydney, p 5; Submission 226, Association of Australian Medical Research Institutes, p 7; Submission 242, Australian Veterinary Association, p 7.

399 Submission 217, The University of Sydney, p 5; Submission 226, Association of Australian Medical Research Institutes, p 7.

400 Evidence, Ms Sarah Margo, Solicitor, Animal Defenders Office,16 June 2022, p 44.

401 Evidence, Professor Kay Double, Professor of Neuroscience, Chair of the Animal Ethics Committee at the University of Sydney, 1 June 2022, p 18.

402 Evidence, Dr Fowler, 16 May 2022, p 45.

5.20 Dr Fowler argued that in addition to a lack of attention to the replacement 'R', refinement could be further incentivised to overcome 'blocks', explaining:

> I also think there are blocks for trying to do refinement, because if you say to someone, "There is a pain relief that you could use to make sure that the research is not of such a high impact to the animal," they need to validate that the pain relief is not going to change their results. They need to do a side by side study, and that is going to cost them more money with limited access to grant funds. And so, to make this sort of change happen, you need to give incentives to researchers to do so.[403]

5.21 Assertions about a lack of state government funding for alternatives research were countered in Budget Estimates by Dr Antonia Penna, Executive Director, Office for Health and Medical Research, NSW Health, who suggested that the NSW Government indirectly provided significant funding for animal alternatives, through its funding of research institutions:

> … we fund a lot of medical research institutes at the moment to support their infrastructure. Quite a few of them provide alternatives around organoids and so forth … Whereas we don't specifically fund, we support institutes that actually do that. I think we lead this quite significantly, not only in Australia, there is no doubt about that.[404]

Establishing a centre of excellence for alternatives in New South Wales

5.22 Many inquiry participants strongly advocated for an animal alternatives-focused research centre to be established in Australia, which could provide significant benefits to the state if based in New South Wales.

5.23 Humane Research Australia advocated for the development of an 'Australian Centre for the Development and Validation of Alternatives' that would develop, refine and validate alternatives to animal-based research.[405] This concept was supported by several other inquiry participants, including the RSPCA, Association of Australian Medical Research Institutes, AVA, the MAWA, Sentient and the Animal Defenders Office, with some believing that the scope of the centre should also incorporate the other two Rs – reduction and refinement.[406]

5.24 Humane Research Australia cited several countries that had established dedicated alternatives research centres, and many inquiry participants particularly highlighted the successes of the 'National Centre for the Replacement, Refinement & Reduction of Animals in Research' (known as 'NC3Rs'), based in the United Kingdom.[407] Each year, the NC3Rs awards prizes, project

403 Evidence, Dr Fowler, 16 May 2022, p 45.

404 Evidence, Dr Antonia Penna, Executive Director, Office for Health and Medical Research, NSW Health, Budget Estimates 2022-2023: Portfolio Committee No. 2 – Health (Examination of proposed expenditure for the portfolio area: Health), 7 September 2022, p 77.

405 Submission 204, Humane Research Australia, pp 8-9.

406 Submission 222, RSPCA, p 5; Submission 226, Association of Australian Medical Research Institutes, p 10; Submission 242, Australian Veterinary Association, p 7; Submission 351, Medical Advances Without Animals Trust, p 15; Submission 245, Animal Defenders Office, pp 5-6; Submission 262, Sentient – The Veterinary Institute for Animal Ethics, p 4.

407 Submission 204, Humane Research Australia, pp 17-18; Submission 212, Western Sydney University, p 2; Submission 217, The University of Sydney, p 4; Submission 222, RSPCA, p 5; Submission 226,

grants and PhD scholarships for 3R research; it also provides educational materials for researchers and advice to government and other bodies.[408]

5.25 Professor Alastair Sloan, Science Advisor, Medical Advances Without Animals Trust, outlined how the establishment of the NC3Rs had shifted UK researchers' attitudes around the use of alternatives, and believed that New South Wales could follow suit and lead a cultural shift in Australia:

> … in 2006, you were getting 10, 15 or 20 [NC3Rs] applications. You then go up to 2019, 2020 and 120 or 130 applications. You can see how that has shifted the culture.
>
> …
>
> New South Wales can show leadership and that leadership leads to significant step change in culture or practice, suddenly you are getting a whole collection of researchers in New South Wales winning highly competitive but excellent grant projects that actually drive things forward.
>
> …
>
> You almost send a shockwave across the sector and the biomedical research sector that way. So I think someone should take a step change and leadership to show quite dramatically—and it could be done quite quickly—that that leadership, that decision-making, this focus, whether it be funding or direction or awards, whatever it may be, is making a step change. Then I think other States will want to follow suit. Certainly from a Federal point of view, the Federal Government and your NHMRCs will start to go, "Okay, we need to take notice of this." I think someone has to plant the flag and show significant leadership. It should nudge everybody else to go in the same direction.[409]

5.26 MAWA advocated for a world-class innovation precinct or discovery centre to be established in New South Wales to develop multidisciplinary scientific skills in alternatives. Professors Sloan and Chrzanowski outlined the opportunity to attract industry partners to establish world class manufacturing capabilities and attract researchers from across Australia.[410] They argued loss of jobs from the reduction in the use of animals in medical research would be more than made up for in new jobs in replacement and refinement technology development.

5.27 Responding to a question at a Budget Estimates hearing about whether an alternatives centre should be established in New South Wales, the Hon Brad Hazzard, Minister for Health, suggested that it would be funded by the Australian Government, rather than the NSW Government:

Association of Australian Medical Research Institutes, p 10; Submission 228, Children's Medical Research Institute, p 3; Submission 351, Medical Advances Without Animals Trust, pp 6, 11 and 12.

408 Submission 217, The University of Sydney, p 4; Submission 226, Association of Australian Medical Research Institutes, p 10; Submission 351, Medical Advances Without Animals Trust, p 6.

409 Evidence, Prof Alastair Sloan, Science Advisor, Medical Advances Without Animals Trust, 1 June 2022, p 28.

410 Answers to questions on notice, Ms Sharyn Watson, Executive Director, Medical Advances Without Animals Trust, 19 August 2022, p 9; Evidence, Prof Chrzanowski, 1 June 2022, p 30; Evidence, Prof Sloan, 1 June 2022, p 30.

> … that sort of research would be across the whole of Australia, so it would be Federal government funding rather than State government funding for that type of research.[411]

5.28 The Animal Defenders Office acknowledged that a national approach was preferable, but believed the creation of an interim state institution would be beneficial.[412]

5.29 While a national approach in Australia is preferable, the Animal Defenders Office supports the creation of an interim state institution for the advancement of non-animal alternatives and technologies in New South Wales. At the very least, the NSW Government should allocate meaningful funding to programs and grants aimed at reducing the numbers of animals used in medical research. These measures would demonstrate New South Wales' commitment to the principle of replacement and would help define a timeline for phasing out the use of animals in medical research.[413]

Committee comment

5.30 In the committee's view, there is an opportunity for New South Wales, as a significant participant in medical research, to be at the forefront of developing alternatives to the use of animals. We heard compelling arguments for funding to be allocated specifically to alternative approaches. Rather than seeing this as an extra outlay for the state of New South Wales, it would appear that this dedicated funding stream would lead to long-term savings by reducing the reliance on the resource-intensive use of animals. Not only that, such funding could strengthen the state economy by attracting the best and brightest scientists to New South Wales.

5.31 While the NSW Government cannot act alone, the committee is convinced that the wealth of expertise available in this state leaves us well placed to be the engine room behind a centre for excellence to nurture the 3Rs and administer expanded funding for alternatives research throughout Australia. By committing upfront to constructing an innovation precinct in New South Wales, the state would be able to take the lead about how best to maximise the efficiency and ethics of medical research with a view towards ending the use of animals in medical research.

Recommendation 12

That the NSW Government commit funding to enable the establishment and operation of a national flagship 3Rs research centre in the state.

5.32 The committee notes that while it is clear the NSW Government provides funding towards the use of animals in medical research, it was difficult for the committee to confirm precisely how much funding had been allocated. When public money is being spent, it is important that there be transparency and accountability. The committee recommends that the NSW Government

411 Evidence, The Hon Brad Hazzard, Minister for Health, Budget Estimates 2022-2023: Portfolio Committee No. 2 – Health (Examination of proposed expenditure for the portfolio area: Health), 7 September 2022, p 77.

412 Submission 245, Animal Defenders Office, p 5.

413 Submission 245, Animal Defenders Office, p 5.

report annually on both the amount of government funding being given to the use of animals in medical research, and the amount of funding given to the development of alternatives.

Recommendation 13

That the NSW Government report annually on the amount of government funding given to the use of animals in medical research and funding given to the development of alternatives.

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Appendix 2 Witnesses at hearings

Date and location	Name	Position and Organisation
Monday 16 May 2022 **Room 814-815** **Parliament House, Sydney**	Professor Anthony Cunningham AO *(via videoconference)*	NSW State Branch Chair, Australian Academy of Health and Medical Sciences, NSW Branch
	Ms Rachel Smith	Chief Executive Officer, Humane Research Australia
	Professor Peter Schofield AO	Board member, Association of Australian Medical Research Institutes
	Professor Robert Brink	Pillar Director in Translational Science, Garvan Institute of Medical Research
	Professor Philip O'Connell	Executive Director, The Westmead Institute for Medical Research
	Ms Sarah Margo *(via videoconference)*	Solicitor, Animal Defenders Office
	Ms Tara Ward *(via videoconference)*	Solicitor, Animal Defenders Office
	Dr Suzanne Fowler *(via videoconference)*	Chief Science Officer, RSPCA
	Dr Di Evans *(via videoconference)*	Senior Science Officer, RSPCA Australia
	Ms Lisa Craig *(via videoconference)*	Private individual
	Witness A	
Wednesday 1 June 2022 **Room 814-815** **Parliament House, Sydney**	Professor Wayne Hawthorne	Chair, Animal Ethics Committee, Western Sydney Local Health District
	Professor Kevin Dunn	Pro Vice-Chancellor Research, Western Sydney University
	Dr Sarah Toole *(via videoconference)*	Animal Welfare Officer & Veterinarian, University of Wollongong
	Professor Kay Double	Professor of Neuroscience / Chair of Animal Ethics Committee, The University of Sydney

Date and location	Name	Position and Organisation
	Dr Susan Maastricht	Director, Research Integrity and Ethics Administration, The University of Sydney
	Dr Ted Rohr	Director Research Ethics & Compliance Support, University of New South Wales
	Dr Christopher McCarthy	Chair, Animal Care and Ethics Committee, University of Newcastle
	Professor Brian Kelly	Pro Vice-Chancellor (Research), University of Newcastle
	Professor Alastair Sloan *(via videoconference)*	Science Advisor (Professor of Tissue Engineering and Dental Biology, University of Melbourne), Medical Advances Without Animals Trust (MAWA Trust)
	Professor Wojciech Chrzanowski	Science Advisor (Professor of Nanomedicine, University of Sydney), MAWA Trust
	Ms Paula Wallace *(via videoconference)*	Director, Liberty Foundation Australia
	Ms Nikki Steendam *(via videoconference)*	Co-Founder, Beagle Freedom Australia
	Ms Tam Burke *(via videoconference)*	Co-Founder, Beagle Freedom Australia
	Dr Tanya Stephens	Animal Welfare and Ethics Committee Member, Australian Veterinary Association
	Dr Peter Johnson	Private individual
	Dr Susan Maastricht	Animal Welfare and Ethics Committee Member, Australian Veterinary Association
	Professor Andrew Knight *(via videoconference)*	Private individual
	Ms Prue Torrance *(via videoconference)*	Executive Director, Research Quality and Priorities, National Health and Medical Research Council (NHMRC)

Date and location	Name	Position and Organisation
	Ms Mary Bate *(via videoconference)*	Assistant Director, Ethics and Integrity Section, Research Quality and Priorities, NHMRC
	Ms Cathy Pitkin *(via videoconference)*	Executive Manager Social Responsibility and Ethics, CSIRO
	Dr Jack Steele	Director, Science Impact and Policy, CSIRO
	Dr John Tracey	Deputy Director General, Biosecurity & Food Safety, Department of Primary Industries (DPI)
	Mr Greg Vakaci	Director Compliance and Integrity Systems, DPI
	Dr Kim Filmer	Chief Animal Welfare Officer, DPI
	Associate Professor Roger Garsia	Chair, Sydney Local Health District Animal Ethics Committee
	Professor Jacqueline Phillips	Chair, Animal Research Review Panel
	Distinguished Professor Annemarie Hennessy	Deputy Chair, Animal Research Review Panel; Director, Australian National Baboon Colony
Tuesday 28 June 2022 **Jubilee Room** **Parliament House, Sydney**	Mr Troy Seidle *(via videoconference)*	Vice President, Research & Toxicology, Humane Society International
	Dr Rosemary Elliott *(via videoconference)*	President, Sentient – The Veterinary Institute for Animal Ethics
	Dr Katherine van Ekert *(via videoconference)*	Vice President, Sentient – The Veterinary Institute for Animal Ethics
	Mr David Mason *(via videoconference)*	Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART)
	Mrs Cathy Pitkin *(via videoconference)*	Deputy Chairperson, ANZCCART
	Dr Malcolm France *(via videoconference)*	Board member and Convenor of the Openness Agreement, ANZCCART
	Ms Kiri Collins	President, Australia and New Zealand Laboratory Animals Association

Date and location	Name	Position and Organisation
	Mr Edwin Brackenreg	Chief Executive Officer, Codex Research Pty Ltd
	Professor Christopher Little	Director Raymond Purves Bone and Joint Research Laboratory, Kolling Institute
	Witness B	
	Witness C	

Appendix 3 Minutes

Minutes no. 50
Friday 3 December 2021
Portfolio Committee No. 2 - Health
Macquarie Room, Parliament House, Sydney, 9.02 am

1. Members

Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Ms Faehrmann
Mr Fang (until 9.11 am and from 10.50 am)
Mr Khan (from 9.04 am)
Mrs Maclaren-Jones (from 9.04 am until 10.19 am, and then from 11.19 am until 11.40 am)
Mr Secord

2. Correspondence

The committee noted the following items of correspondence:

Received

- 2 December 2021 – Letter from Ms Hurst, Ms Faehrmann and Mr Secord requesting a meeting of Portfolio Committee No. 2 to consider a proposed self-reference into the use of primates and other animals in medical research in New South Wales.

3. Inquiry into health outcomes and access to health and hospital services in rural, regional and remote New South Wales

3.1 Livestream and recording of hearing

Resolved, on the motion of Mr Secord: That the committee agree to record the hearing, and that this recording be placed on the inquiry webpage as soon as practicable after the hearing.

3.2 Public hearing

The committee proceeded to take evidence in public.

Witnesses were admitted to the hearing room and via video link.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witness was sworn and examined:

- Ms Jenny Lovric, Manager, Community Engagement & Partnerships - Aboriginal Legal Service, Just Reinvest (*via videoconference*)

The evidence concluded and the witness withdrew.

The following witnesses were sworn and examined:

- Ms Catherine Henry, Spokesperson, Australian Lawyers Alliance *(via videoconference)*
- Ms Kathy Rankin, Policy Director – Rural Affairs & Business Economics & Trade, NSW Farmers Association (*via videoconference*)
- Ms Sarah Thompson, Member of the NSW Farmers Rural Affairs Policy Committee, NSW Farmers Association (*via videoconference*)

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Dr Edward Johnson, President, Services for Australian Rural and Remote Allied Health (*via videoconference*)
- Ms Catherine Maloney, Chief Executive Officer, Services for Australian Rural and Remote Allied Health (*via videoconference*)
- Ms Leanne Evans, Senior Policy & Relations Advisor, Exercise and Sports Science Australia (*via videoconference*)
- Mr John Stevens, NSW State Chapter Co-Chair, Exercise and Sports Science Australia (*via videoconference*)

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Dr Kristin Bell, Chair, Specialist Training Program Committee and Chair, QEC Regional Training Network, The Royal Australian and New Zealand College of Ophthalmologists (*via videoconference*)
- Associate Professor Ashish Agar, Chair, Reconciliation Action Plan Working Group, The Royal Australian and New Zealand College of Ophthalmologists (*via videoconference*)
- Dr Michael Jonas, President, Australian Dental Association – NSW Branch
- Dr Sarah Raphael, Advisory Services Manager, Australian Dental Association – NSW Branch

Dr Bell tendered the following documents:

- M J Burton et al, 'The Lancet Global Health Commission on Global Eye Health: vision beyond 2020', The Lancet (2021)
- J Huang-Lung, B Angell, A Palagyi, H R Taylor, A White, P McCluskey, L Keay, 'The true cost of hidden waiting times for cataract surgery in Australia', Public Health Research & Practice (2021)
- Document entitled 'Proposal Brief: RANZCO Regionally Enhanced Training Network (RETN)' including two appendices
- Document entitled 'National Health Reform Agreement (NHRA) Long-term Health Reforms Roadmap'
- Document entitled 'The Outback Eye Service: Saving sight in the West' prepared by Ideology Consulting.

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Ms Catherine Lourey, Commissioner, Mental Health Commission of NSW (*via videoconference*)
- Dr Justine Hoey-Thompson, Member, The Royal Australian and New Zealand College of Psychiatrists (*via videoconference*)
- Professor David Perkins, Director and Professor of Rural Health Research, Centre for Rural and Remote Mental Health (*via teleconference*)
- Dr Hazel Dalton, Research Leader and Senior Research Fellow, Centre for Rural and Remote Mental Health (*via videoconference*)

The evidence concluded and the witnesses withdrew.

The public hearing concluded at 3.08 pm.

3.3 Tendered documents

Resolved, on the motion of Mr Secord: That the committee accept and publish the following documents tendered during the public hearing:

- M J Burton et al, 'The Lancet Global Health Commission on Global Eye Health: vision beyond 2020', The Lancet (2021), tendered by Dr Bell.
- J Huang-Lung, B Angell, A Palagyi, H R Taylor, A White, P McCluskey, L Keay, 'The true cost of hidden waiting times for cataract surgery in Australia', Public Health Research & Practice (2021), tendered by Dr Bell.

- Document entitled 'Proposal Brief: RANZCO Regionally Enhanced Training Network (RETN)' including two appendices, tendered by Dr Bell.
- Document entitled 'National Health Reform Agreement (NHRA) Long-term Health Reforms Roadmap', tendered by Dr Bell.
- Document entitled 'The Outback Eye Service: Saving sight in the West' prepared by Ideology Consulting, tendered by Dr Bell.

4. Consideration of terms of reference

The Chair tabled the letter proposing the following self-reference:

That Portfolio Committee No. 2 - Health inquire into and report on the use of primates and other animals in medical research in New South Wales, and in particular:

(a) the nature, purpose and effectiveness of medical research being conducted on animals in New South Wales, and the potential public health risks and benefits posed by this research;

(b) the costs associated with animal research, and the extent to which the New South Wales and Federal Government is commissioning and funding the importing, breeding and use of animals in medical research in New South Wales;

(c) the availability, effectiveness and funding for alternative approaches to animal research methods and technologies, and the ability of researchers to meet the 3 R's of Replacement, Reduction and Refinement;

(d) the ethical and animal welfare issues surrounding the importing, breeding and use of animals in medical research;

(e) the adequacy of the current regulatory regime regarding the use of animals in medical research, particularly in relation to transparency and accountability;

(f) overseas developments regarding the regulation and use of animals in medical research; and

(g) any other related matters.

Ms Hurst moved: That the committee adopt the terms of reference.

Question put.

The committee divided.

Ayes: Mr Donnelly, Ms Faehrmann, Ms Hurst, Mr Secord.

Noes: Mr Fang, Mr Khan.

Question resolved in the affirmative.

5. Conduct of the inquiry into the use of primates and other animals in medical research in New South Wales

5.1 Proposed timeline

Resolved, on the motion of Ms Faehrmann: That the committee commence the inquiry on 1 February 2022.

6. Adjournment

The committee adjourned at 3.15 pm, until Tuesday 1 February 2021, Jubilee Room, Parliament House, Sydney (public hearing for health outcomes and services in regional, rural and remote NSW inquiry).

Vanessa O'Loan
Committee Clerk

Minutes no. 51
Tuesday 1 February 2022
Portfolio Committee No. 2 - Health
Jubilee Room and via Webex, 9.01 am

1. Members

Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Mr Amato
Ms Faehrmann
Mr Fang
Mr Mallard (from 9.04 am)
Mr Secord

2. Change of membership

The committee noted that Mr Mallard replaced Mrs Maclaren-Jones as a substantive member of the committee from 25 January 2022, and that Mr Kahn, who was substituting for Mr Amato for the duration of the inquiry into health outcomes and access to health and hospital services in rural, regional and remote New South Wales, resigned from the Legislative Council on 6 February 2022.

3. Previous minutes

Resolved, on the motion of Mr Secord: That draft minutes nos. 49 and 50 be confirmed.

4. Correspondence

The committee noted the following items of correspondence:

Received

- 9 November 2021 – Email from Witness L, to the committee, providing additional information regarding the Far West Local Health District
- 15 November 2021 – Letter from Mr David Shoebridge MLC, to the Chair, regarding correspondence received by the Public Accountability Committee from the Hon Mark Latham MLC and the Hon Brad Hazzard MP, Minster for Health and Medical Research about the application of Public Health Orders and isolation requirements
- 8 December 2021 – Email from Dr Allan Molloy, to the secretariat, regarding the implementation of best practice COVID and extreme event safety rapid recovery protocols and requesting to be called as a witness at a Health outcomes and services in regional, rural and remote NSW inquiry hearing
- 15 December 2021 – Email from Ms Marion Collier, to the secretariat, recounting her experience at Mudgee Hospital in 2011
- 24 December 2021 – Email from Dr Allan Molloy, to the Chair, providing additional information about the cancellation of the proposed pilot of the Recovery App and reiterating his request to appear as a witness
- 7 January 2022 – Email from Ms Christine Corby OAM, Chief Executive Officer, Walgett Aboriginal Medical Service, to the secretariat, providing an overview of the support required by the Walgett Aboriginal Medical Service to ensure it continues to provide culturally appropriate care to the community in Walgett and its surrounds
- 17 January 2022 – Letter from Mr Trevor Rowe, to the Chair, requesting that the committee consider hearing evidence from an independent patient advocate as a witness at a Health outcomes and services in regional, rural and remote NSW inquiry hearing.

Resolved, on the motion of Mr Fang: That the committee keep the following correspondence confidential, due to sensitive and/or identifying information regarding third parties, and potential adverse mention:

- Email from Witness L dated 9 November 2021
- Email from Ms Collier dated 15 December 2021

- Email from Dr Allan Molloy dated 24 December 2021

5. Inquiry into the use of primates and other animals in medical research New South Wales

5.1 Closing date for submissions
Resolved, on the motion of Ms Hurst: That the closing date for submissions be 31 March 2022.

5.2 Stakeholder list
Resolved, on the motion of Ms Faehrmann: That:

- the stakeholders on the attached list be invited to make a submission
- members have two days to nominate additional stakeholders to make submissions and that the committee agree to the stakeholder list by email, unless a meeting of the committee is required to resolve any disagreement.

5.3 Hearing date
Resolved, on the motion of Ms Hurst: That the committee hold two hearings and set aside one additional reserve hearing date in May/June 2022, the dates of which are to be determined by the Chair after consultation with members regarding their availability.

6. Inquiry into health outcomes and access to health and hospital services in rural, regional and remote New South Wales

6.1 Public submissions
The committee noted that the following submission was published by the committee clerk under the authorisation of the resolution appointing the committee: submissions nos. 630a, 717-719.

6.2 Attachments to submissions
Resolved, on the motion of Mr Fang: That the committee authorise the publication of attachment 1 to submission no. 630a.

6.3 Changes to submission publication status
Resolved, on the motion of Mr Fang*:* That submission 201 be made fully confidential, at the request of the submission author.

6.4 Answers to questions on notice and supplementary questions – Public hearing
The committee noted the following answers to questions on notice and supplementary questions were published by the committee clerk under the authorisation of the resolution appointing the committee:

- Ms Jamelle Wells, Private citizen, received 15 October 2021
- Ms Liz Hayes, Private citizen, received 15 October 2021
- Ms Alecka Miles, Chair - Rural, Remote and Community Paramedicine Special Interest Group, Australasian College of Paramedicine, received 15 October 2021
- Mr Jerry Yik, Head of Policy and Advocacy, The Society of Hospital Pharmacists of Australia, received 18 October 2021
- Dr Susie Lord, Board member, Faculty of Pain Medicine , Australian and New Zealand College of Anaesthetists (ANZCA), received 15 October 2021
- Ms Majella Gallagher, Relationship Manager, Can Assist, received 10 November 2021
- Ms Annie Miller, Director, Cancer Information and Support Services, Cancer Council, received 10 November 2021
- Dr Alex Stephens, Director of Research, Northern NSW Local Health District, and Chair, NSW Rural Health Research Alliance, received 3 November 2021
- Cr Paul Maytom, Mayor, Leeton Shire Council received 10 November 2021
- Mrs Linda McLean , Branch Agriculture & Environment Officer, Country Women's Association of NSW – Hillston branch, received 9 November 2021
- Dr Michael Holland, Co-founder, ONE - One New Eurobodalla hospital, received 2 November 2021
- Ms Catherine Hurst, Private citizen, received 10 November 2021

- Ms Stacey O'Hara, Committee member, Murrumbidgee Aboriginal Health Consortium, received 20 October 2021
- Dr Geoffrey Pritchard, Private citizen, received 8 November 2021.

6.5 Livestream and recording of hearing

Resolved, on the motion of Mr Amato: That the committee agree to record the hearing, and that this recording be placed on the inquiry webpage as soon as practicable after the hearing.

6.6 Public hearing

The committee proceeded to take evidence in public.

Witnesses were admitted via video link.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witnesses were sworn and examined:

- Mr Stewart Dowrick, Chief Executive, Mid North Coast Local Health District (via videoconference)
- Dr Richard Tranter, District Medical Director for Integrated Mental Health and Alcohol & Other Drugs, Mid North Coast Local Health District (via videoconference)

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Ms Kay Hyman, Chief Executive, Nepean Blue Mountains Local Health District (via videoconference)
- Ms Eloise Milthorpe, Acting Director Planning, Nepean Blue Mountains Local Health District (via videoconference)
- Professor Steevie Chan, Acting District Director Medical Service, Central Coast Local Health District (via videoconference)

The following witness was examined on their former oath/affirmation:

- Ms Scott McLachlan, Chief Executive, Central Coast Local Health District (via videoconference)

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Ms Margaret Bennett, Chief Executive, Southern NSW Local Health District (via videoconference)
- Dr Liz Mullins, Executive Director of Medical Services, Southern NSW Local Health District (via videoconference)

Mr Secord tabled the following document:

- Response to Ryan Park MP – Petition – Eurobodalla Hospital, 22 December 2021.

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Ms Margot Mains, Chief Executive, Illawarra Shoalhaven Local Health District (via videoconference)
- Ms Margaret Martin, Executive Director Clinical Operations, Illawarra Shoalhaven Local Health District (via videoconference)
- Ms Caroline Langston, Executive Director, Integrated Care, Mental Health, Planning, Information and Performance, Illawarra Shoalhaven Local Health District (via videoconference)
- Ms Amanda Larkin, Chief Executive, South Western Sydney Local Health District (via videoconference)

The evidence concluded and the witnesses withdrew.

The public hearing concluded at 3.32 pm.

6.7 Tendered documents

Resolved, on the motion of Mr Secord: That the committee accept and publish the following documents tabled during the public hearing:

- Response to Ryan Park MP – Petition – Eurobodalla Hospital, 22 December 2021, tabled by Mr Secord.

7. Adjournment

The committee adjourned at 3.33 pm until Wednesday 2 February 2022, Jubilee Room, Parliament House, Sydney and via Webex (public hearing for health outcomes and services in regional, rural and remote NSW inquiry).

Vanessa O'Loan
Committee Clerk

Minutes no. 56
Friday 29 April 2022
Portfolio Committee No. 2 - Health
Room 1043, Parliament House, Sydney, 9.34 am

1. Members

Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Mr Amato (via Webex)
Ms Faehrmann
Mr Farlow (substituting for Mr Rath, from 1.00 pm)
Mr Fang
Mr Rath (via Webex until 1.00 pm)
Mr Secord

2. Change of membership

Committee noted that Mr Rath replaced Mr Mallard as a substantive member of the committee from 29 March 2022.

3. Previous minutes

Resolved, on the motion of Ms Faehrmann: That draft minutes nos. 51 and 52 be confirmed.

4. Correspondence

The committee noted the following items of correspondence:

Received

- 3 February 2022 – Letter from Ms Caroline Langston, Executive Director, Integrated Care, Mental Health, Planning, Information and Performance, Illawarra Shoalhaven LHD, to the Chair, providing clarification to her evidence during the Health outcomes and services in regional, rural and remote NSW hearing 1 February 2022
- 4 February 2022 – Letter from Mr Roy Butler MP, Member for Barwon to the Chair, regarding maintenance of Broken Hill Airport
- 8 February 2020 – Email from Dr Hazel Dalton, Research Leader and Senior Research Fellow, Centre for Rural and Remote Mental Health, to the secretariat, informing the committees about a white paper authored by Dr Tonelle Handley on behalf of the Centre for Innovation in Regional Health about end of life care in regional and rural New South Wales

- 30 March 2022 – Letter from Mr David Shoebridge MLC, to the Chair, regarding correspondence received by the Public Accountability Committee from Dr Winston Cheung and others in relation to the pandemic's impact on the health care system
- 27 April 2022 – Email from the Office of Ms Cate Faehrmann, to the secretariat, advising that Ms Boyd will substitute for Ms Faehrmann for the duration of the inquiry into the use of primates and other animals for medical research in NSW
- 28 April 2022 – Email from the Office of Minister Sam Farraway MLC, to the secretariat, noting Mr Farraway's non-participation in the health outcomes and access to health and hospital services in rural, regional and remote New South Wales inquiry.

Resolved, on the motion of Mr Fang: That the Chair, on behalf of the committee, after the Federal election write to the Commonwealth Minister for Infrastructure, Transport and Regional Development, the New South Wales Minister for Women, Minister for Regional Health and Minister for Mental Health, the Hon. Bronnie Taylor MLC and Cr Tom Kennedy, Mayor, Broken Hill Council alerting them to the issues at Broken Hill Airport as raised by Mr Butler and encouraging them to work together to resolve the issues as soon as possible.

5. Inquiry into health outcomes and access to health and hospital services in rural, regional and remote New South Wales

5.1 Clarifications to evidence

Resolved, on the motion of Mr Secord:

- That the committee authorise the publication of the following correspondence:
  - Email from Ms Caroline Langston, Executive Director, Integrated Care, Mental Health, Planning, Information and Performance, Illawarra Shoalhaven Local Health District, dated 3 February 2022, correcting an error in evidence made during the hearing in Sydney on 1 February 2022
- That the committee authorise the addition of footnotes to the evidence of Ms Langston reflecting her clarification of evidence.

5.2 Answers to questions on notice and supplementary questions – Public hearing

The committee noted the following answers to questions on notice and supplementary questions were published by the committee clerk under the authorisation of the resolution appointing the committee:

- Ms Christine Corby OAM, Chief Executive Officer, Walgett Aboriginal Medical Service, received 6 December 2022
- Cr Ian Woodcock, Mayor, Walgett Shire Council, received 7 January 2022
- Mr Carl Grant, Chief Executive Officer, Bila Muuji Aboriginal Corporation Health Service, received 14 January 2022
- Mr Umit Agis, Chief Executive, Far West Local Health District, received 21 January 2022
- Ms Betty Kennedy, Enrolled Nurse, New South Wales Nurses and Midwives' Association, received 17 February 2022
- Mr Greg Sam, Chief Executive Officer, Royal Flying Doctor Service of Australia (South Eastern Section), received 17 February 2022
- Dr Justine Hoey-Thompson, Member, The Royal Australian and New Zealand College of Psychiatrists, received 22 December 2021 and 11 January 2022
- Ms Leanne Evans, Senior Policy & Relations Advisor, Exercise and Sports Science Australia, received 11 January 2022
- Dr Hazel Dalton, Research Leader and Senior Research Fellow, Centre for Rural and Remote Mental Health, received 14 January 2022
- Professor David Perkins, Director and Professor of Rural Health Research , Centre for Rural and Remote Mental Health, received 8 February 2022
- Ms Catherine Lourey, Commissioner, Mental Health Commission of NSW, received 14 January 2022

- Ms Kathy Rankin, Policy Director – Rural Affairs & Business Economics & Trade, NSW Farmers Association, received 17 January 2022
- Ms Jenny Lovric, Manager, Community Engagement & Partnerships - Aboriginal Legal Service, Just Reinvest, received 19 January 2022
- NSW Health, received 23 March 2022
- NSW Health, received 28 March 2022

5.3 Report deliberative and reporting date

Resolved, on the motion of Ms Hurst: That the committee report by 5 May 2022, with the report deliberative to take place on a 29 April 2022.

5.4 *****

6. Inquiry into the use of primates and other animals for medical research in NSW

6.1 Treatment of short submissions from individuals

Committee noted that the inquiry has received approximately 900 submissions, the majority of which are from individuals and are less than half a page in length. Many are a few short lines as observed with the first 110 submissions circulated to the committee.

Resolved, on the motion of Ms Faehrmann: That the committee:

- define a 'short' submission from an individual as being half a page or less in length
- collate and process any 'short', and non-confidential submissions into a single document for publication on the website
- process and publish all other submissions, that is, those from organisations and more substantive individual submissions as normal.

7. Adjournment

The committee adjourned at 3.08 pm until Monday 16 May 2022, Macquarie Room, Parliament House, Sydney (public hearing for the use of primates and other animals in medical research New South Wales inquiry).

Vanessa O'Loan
Committee Clerk

Minutes no. 57
Monday 16 May 2022
Portfolio Committee No. 2 - Health
Room 814/815, Parliament House, Sydney at 9.17 am

1. Members present

Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Mr Amato
Ms Boyd
Mr Fang
Mr Moselmane (substituting for Mr Secord from 2.15 pm) (until 3.59 pm)
Mr Rath
Mr Secord (until 1.30 pm) (*via videoconference*)

2. Apologies

3. Change of membership

The committee noted that Ms Boyd substituted for Ms Faehrmann from 27 April 2022 for the duration of the inquiry into the *Use of primates and other animals for medical research in New South Wales*.

4. Previous minutes

Resolved, on the motion of Ms Hurst: That draft minutes nos. 56 be confirmed.

5. Correspondence

The committee noted the following items of correspondence:

Received

- 31 March 2022 – Confidential letter – Submission author, to the Chair, offering to meet with the committee *in camera*.
- 27 April 2022 – Email – Ms Cate Faehrmann MLC, to the secretariat, advising that Ms Abigail Boyd MLC will be substituting for Ms Faehrmann from 27 April 2022 for the duration of the inquiry into primate/animal medical research.
- 4 May 2022 – Email – Dr Greta Ridley, Head of Research Office, Children's Medical Research Institute, to the secretariat, declining the invitation to appear at the hearing on 16 May 2022.
- 11 May 2022 - Email - Ms Georgie Dolphin, Program Manager - Animal Welfare, Humane Society International (HSI), to the secretariat, advising that HSI is unable to appear at the hearing on 16 May 2022, and offering to appear instead on 1 or 28 June 2022.

Sent

- None

Resolved, on the motion of Mr Amato: That the committee keep the correspondence received on 31 March 2022 from an individual, offering to appear at a hearing in camera, confidential, as per the request of the author.

6. Inquiry into the use of primates and other animals in medical research in NSW

6.1 Public submissions

The committee noted that the following submissions were published by the committee clerk under the authorisation of the resolution appointing the committee: submission nos. 46, 202, 204-207, 209, 211-215, 217-226, 228-232, 234-240, 242, 243 and 245-250.

6.2 Partially confidential submissions (name suppressed)

The committee noted that the following submission was partially published by the committee clerk under the authorisation of the resolution appointing the committee: submission no. 233.

Resolved, on the motion of Mr Secord: That the committee keep the following information confidential, as per the requests of the authors: names and/or identifying and sensitive information in submissions no. 233.

6.3 Partially confidential submissions (sensitive information)

The committee noted that the following submissions were partially published by the committee clerk under the authorisation of the resolution appointing the committee: 241 and 251.

Resolved, on the motion of Mr Secord: That the committee keep the following information confidential, as per the request of the authors: sensitive information in submissions nos. 241 and 251.

6.4 Confidential submissions

Resolved, on the motion of Mr Amato: That the committee keep submission nos 38, 104, 192, 203, 216, 227 and 251a confidential, as per the request of the authors.

6.5 Allocation of questioning

Resolved, on the motion of Mr Fang: That allocation of time for questioning be in the hands of the Chair.

6.6 *In camera* evidence

Resolved, on the motion of Mr Fang: That the evidence of the following witness be heard in camera: Witness A**.**

6.7 Recording of hearings

Resolved, on the motion of Mr Rath: That the committee agree to record all hearings for the inquiry, and that these recordings be placed on Parliament's YouTube channel as soon as practicable after the hearings.

Resolved, on the motion of Ms Hurst, that Ms Lisa Craig be invited to give evidence for 45 minutes (until 4.00 pm on 16 May 2022).

6.8 Public hearing

The witness was admitted.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witness was sworn and examined:

- Prof Anthony (Tony) Cunningham, NSW State Branch Chair, Australian Academy of Health and Medical Sciences, NSW Branch *(via videoconference)*

The evidence concluded and the witness withdrew.

The following witness was sworn and examined:

- Ms Rachel Smith, Chief Executive Officer, Humane Research Australia

Ms Smith tendered the following document:

- All-Party Parliamentary Group for Human Relevant Science, 'Bringing Back the Human: Transitioning from Animal Research to Human Relevant Science in the UK' (March, 2022).

The evidence concluded and the witness withdrew.

The following witnesses were sworn and examined:

- Prof Peter Schofield AO, Board member, Association of Australian Medical Research Institutes
- Prof Robert Brink, Pillar Director in Translational Science, Garvan Institute of Medical Research
- Prof Philip O'Connell, Executive Director, The Westmead Institute for Medical Research

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Ms Sarah Margo, Solicitor, Animal Defenders Office *(via videoconference)*
- Ms Tara Ward, Solicitor, Animal Defenders Office *(via videoconference)*
- Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia *(via videoconference)*
- Dr Di Evans, Senior Science Officer, RSPCA Australia *(via videoconference)*

The evidence concluded and the witnesses withdrew.

The following witness was sworn and examined:

- Ms Lisa Craig *(via videoconference)*

The evidence concluded and the witness withdrew.

6.9 *In camera* hearing

The committee proceeded to take *in camera* evidence.

Persons present other than the committee: Committee secretariat, AV contractors and Hansard reporters.

Witness A was sworn and admitted.

The evidence concluded and the witness withdrew.

The hearing concluded at 4.46 pm.

6.10 Tendered documents

Resolved, on the motion of Mr Amato: That the committee accept and publish the following document tendered during the public hearing:

- All-Party Parliamentary Group for Human Relevant Science, 'Bringing Back the Human: Transitioning from Animal Research to Human Relevant Science in the UK' (March, 2022), tendered by Ms Smith.

7. Other business

8. Adjournment

The committee adjourned at 4.46 pm, until Wednesday 1 June 2022, 9.15 am.

Erin Pynor
Committee Clerk

Minutes no. 58
Wednesday 1 June 2022
Portfolio Committee No. 2 - Health
Room 814/815, Parliament House, Sydney at 9.03 am

1. Members present

Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Mr Amato (*via videoconference*, until 12.30 pm, and from 5.05 pm)
Ms Boyd (until 2.45 pm, and from 4.55 pm)
Mr Fang
Mr Rath

2. Apologies

Mr Secord

3. Previous minutes

Resolved, on the motion of Mr Rath: That draft minutes no. 57 be confirmed.

4. Correspondence

The committee noted the following items of correspondence:

Received

- 17 May 2022 – Email – Witness A, to the secretariat, providing a link to an international database that allows researchers to publish outlines of proposed studies
- 26 May 2022 – Email – Animal Ethics Committee of Western Sydney Local Health District, to the secretariat, withdrawing the request for their submission no. 233 to be 'name suppressed'
- 26 May 2022 – Email – Animal Ethics Committee of Western Sydney Local Health District, to the secretariat, withdrawing the request for parts of their submission no. 233 to be kept confidential.

5. Inquiry into the use of primates and other animals in medical research in NSW

5.1 Update on processing of individual submissions

The committee noted the circulation of 85 public submissions and two confidential submissions by private individuals that are either over 250 words or have attachments, and that approximately 750 'short' submissions (less than 250 words) will be distributed in a collated document by Friday 3 June 2022.

5.2 Public submissions

The committee noted that the following submissions were published by the committee clerk under the authorisation of the resolution appointing the committee: submission nos. 64, 64a, 64b, 124, 126, 139, 150, 163, 168, 177, 198, 208, 244, 252-254, 256-265, 267, 267a, 268-271, 273, 274, 276-285, 287-289, 291, 293, 296, 297, 298, 298a, 299-301, 303-306, 308-314, 316, 318-321 and 323.

5.3 Acceptance of revised submission no. 351

Resolved, on the motion of Mr Fang: That the committee accept and publish the revised submission no. 351 from MAWA Trust received on 26 May 2022.

5.4 Removal of confidentiality for submission no. 233

Resolved, on the motion of Ms Boyd: That the committee publish submission no. 233 from the Animal Ethics Committee of Western Sydney Local Health District in full, including the author's name.

5.5 Partially confidential submissions (name suppressed)

Resolved, on the motion of Mr Amato: That the committee keep the following information confidential, as per the requests of the authors: names and/or identifying and sensitive information in submission nos. 107, 266, 272, 275, 286, 290, 294, 295, 302, 307, 315, 317, 322 and 324-327.

5.6 Partially confidential submissions (adverse mention)

Resolved, on the motion of Mr Rath: That the committee authorise the publication of submission no. 255, with the exception of potential adverse mention which is to remain confidential.

5.7 Confidential submissions

Resolved, on the motion of Mr Fang: That the committee keep submission nos. 298 and 328 confidential, as per the request of the authors.

5.8 Allocation of questioning

Resolved, on the motion of Mr Fang: That allocation of time for questioning be in the hands of the Chair, with time equally allocated between government, opposition and cross bench.

5.9 Declaration of interest

Ms Hurst made the following declarations in relation to witnesses on the hearing schedule:

- Dr Peter Johnson was the Inspector in the Animal Welfare Unit at the time Ms Hurst served as a member of the Animal Research Review Panel
- Ms Hurst served as a member of the Animal Research Review Panel alongside Professor Jacqueline Phillips and Distinguished Professor Annemarie Hennessy.

5.10 Public hearing

The public hearing commenced at 9.17 am.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witnesses were sworn and examined:

- Prof Wayne Hawthorne, Chair, Animal Ethics Committee, Western Sydney Local Health District
- Prof Kevin Dunn, Pro Vice-Chancellor Research, Western Sydney University
- Dr Sarah Toole, Animal Welfare Officer & Veterinarian, University of Wollongong (via videoconference)

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Prof Kay Double, Professor of Neuroscience / Chair of Animal Ethics Committee, The University of Sydney
- Dr Susan Maastricht, Director, Research Integrity and Ethics Administration, The University of Sydney
- Dr Ted Rohr, Director Research Ethics & Compliance Support, University of New South Wales
- Dr Christopher McCarthy, Chair, Animal Care and Ethics Committee, University of Newcastle
- Prof Brian Kelly, Pro Vice-Chancellor (Research), University of Newcastle

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Prof Alastair Sloan, Science Advisor (Professor of Tissue Engineering and Dental Biology, University of Melbourne), Medical Advances Without Animals Trust (MAWA Trust) (via videoconference)
- Prof Wojciech Chrzanowski, Science Advisor (Professor of Nanomedicine, University of Sydney), MAWA Trust
- Ms Paula Wallace, Director, Liberty Foundation Australia (via videoconference)
- Ms Nikki Steendam, Co-Founder, Beagle Freedom Australia (via videoconference)
- Ms Tam Burke, Co-Founder, Beagle Freedom Australia (via videoconference)

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Dr Tanya Stephens, Animal Welfare and Ethics Committee Member, Australian Veterinary Association
- Dr Peter Johnson

The following witness was examined on their former oath/affirmation:

- Dr Susan Maastricht, Animal Welfare and Ethics Committee Member, Australian Veterinary Association

The evidence concluded and the witnesses withdrew.

The following witness was sworn and examined:

- Prof Andrew Knight (via videoconference)

The evidence concluded and the witness withdrew.

The following witnesses were sworn and examined:

- Ms Prue Torrance, Executive Director, Research Quality and Priorities, National Health and Medical Research Council (NHMRC) (via videoconference)
- Ms Mary Bate, Assistant Director, Ethics and Integrity Section, Research Quality and Priorities, NHMRC (via videoconference)
- Ms Cathy Pitkin, Executive Manager Social Responsibility and Ethics, CSIRO (via videoconference)
- Dr Jack Steele, Director, Science Impact and Policy, CSIRO

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Dr John Tracey, Deputy Director General, Biosecurity & Food Safety, Department of Primary Industries (DPI)
- Mr Greg Vakaci, Director Compliance and Integrity Systems, DPI
- Dr Kim Filmer, Chief Animal Welfare Officer, DPI
- Assoc Prof Roger Garsia, Chair, Sydney Local Health District Animal Ethics Committee
- Prof Jacqueline Phillips, Chair, Animal Research Review Panel
- Dist Prof Annemarie Hennessy, Deputy Chair, Animal Research Review Panel; Director, Australian National Baboon Colony

Ms Hurst tendered the following document:

- Return to order for papers, 3 June 2021, Notes from AEC meeting, Department of Regional NSW, Document SO52_1626.00000106

The evidence concluded and the witnesses withdrew.

The hearing concluded at 5.17 pm.

6. Adjournment
The committee adjourned at 5.32 pm, *sine die*.

Erin Pynor
Committee Clerk

Minutes no. 59
Thursday 9 June 2022
Portfolio Committee No. 2 - Health
Members' Lounge, Parliament House, Sydney at 2.30 pm

1. Members present
Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Mr Amato
Ms Boyd
Mr Fang
Mr Rath
Mr Secord

2. Apologies

3. Previous minutes
Resolved, on the motion of Mr Amato: That draft minutes no. 58 be confirmed.

4. Correspondence
The committee noted the following items of correspondence:

Received

- 30 May 2022 - letter from Ms Marita Cowie AM, Chief Executive Officer, Australian College of Rural & Remote Medicine, to the Chair, seeking to be included in the proposed rural palliative care taskforce

Resolved, on the motion of Mr Secord: That the Chair, on behalf of the committee, write to the Hon. Brad Hazzard, Minister for Health, the Hon. Bonnie Taylor MLC, Minister for Women, Minister for Regional Health and Minister for Mental Health and NSW Health alerting them to the request from Ms Cowie, Chief Executive Officer, Australian College of Rural & Remote Medicine.

5. Inquiry into the use of primates and other animals for medical research in NSW

5.1 Public submissions
The committee noted that the following submissions were published by the committee clerk under the authorisation of the resolution appointing the committee: submission nos. 1, 4-9, 11, 12, 14, 17, 20-22, 24, 26, 30, 32, 34, 35, 37, 39-45, 51-54, 57-60, 62, 67, 68, 73-79, 81-85, 88, 89, 95-103, 106, 109, 110, 115-119, 125, 129, 130, 130a, 131, 133, 135, 136, 138, 140, 141, 143-145, 148, 149, 153, 154, 156, 162, 164, 166, 167, 170, 171, 173, 175, 178, 180-183, 185, 186, 188, 190, 191, 193, 194, 196, 197, 199-201, 352-370, 370a, 370b, 371-386, 386a, 387-389, 389a, 390-403, 403a, 404-444, 444a, 445-485, 487-499, 499a, 500-504, 504a, 505-537, 537a, 538-554, 554a, 555-562, 562a, 563-655, 655a, 656-664, 664a, 665-669, 669a and 670-683.

5.2 Partially confidential submissions (name suppressed)
Resolved, on the motion of Mr Fang: That the committee keep the following information confidential, as per the requests of the authors: names and/or identifying and sensitive information in submissions no. 2, 3, 10, 13, 15, 16, 18, 19, 23, 25, 27, 28, 31, 33, 36, 47-50, 56, 61, 63, 65, 66, 69-72, 80, 86, 87, 90-94, 105, 108,

111-114, 120-123, 127, 128, 132, 134, 137, 142, 146, 147, 151, 152, 155, 157-161, 165, 169, 172, 174, 176, 179, 184, 187, 189, 195, 684-707, 707a, 708-733, 733a and 734-880.

5.3 Partially confidential submissions (potential adverse mention)
Mr Fang moved: That the committee authorise the publication of submissions no. 29 and 486, with the exception of potential adverse mention which is to remain confidential, as per the recommendation of the secretariat.

Question put.

The committee divided.

Ayes: Mr Amato, Mr Donnelly, Mr Fang, Mr Rath, Mr Secord.

Noes: Ms Boyd, Ms Hurst.

Question resolved in the affirmative.

5.4 Confidential submissions
Resolved, on the motion of Mr Rath: That the committee keep submission nos 329-350 confidential, as per the request of the authors.

5.5 Additional hearing
Resolved, on the motion of Ms Boyd: That the committee hold a final half-day hearing into the Use of primates and other animals in medical research on 28 June 2022.

6. Other business

7. Adjournment
The committee adjourned at 2.43 pm, until 9.15 am, 28 June 2022 (Hearing – Inquiry into the Use of Primates and Other Animals in Medical research in New South Wales).

Madeleine Foley
Committee Clerk

Minutes no. 61
Tuesday 28 June 2022
Portfolio Committee No. 2 - Health
Jubilee Room, Parliament House, Sydney at 9.18 am

1. Members present
Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Mr Amato
Ms Boyd (*via videoconference*)
Mr Fang
Mr Rath (*via videoconference*)

2. Apologies
Mr Secord

3. Previous minutes
Resolved, on the motion of Mr Amato: That draft minutes nos. 59 be confirmed.

4. Correspondence
The committee noted the following items of correspondence:

Received

- 14 June 2022 – Email – Jamie Snashall, Head of Government Relations, Medicines Australia, to the secretariat, declining the invitation to appear at the hearing on Tuesday 28 June 2022.
- 17 June 2022 – Confidential email – Organisation A, to the secretariat, accepting the invitation to appear at the hearing on 28 June 2022, requesting to meet with the committee *in camera*.
- 18 June 20222 - Confidential email – Witness A, to the secretariat, providing proposed redactions to *in camera* transcript for 16 May 2022 hearing, to enable partial publication.
- 22 June 2022 – Email – Mr Quoc Nguyen, Project Officer, Kolling Institute, to the secretariat, advising that the Kolling Institute submission can be made publicly available.
- 22 June 2022 – Confidential email - Witness A, to the secretariat, confirming that a redacted version of an *in camera* transcript provided to the witness can be published.

Sent

- 15 June 2022 – Letter (sent via email) from the Hon Greg Donnelly MLC to Commonwealth Minister King, New South Wales Minister Taylor and Cr Kennedy regarding Broken Hill airport.
- 15 June 2022 – Letter (sent via email) from the Hon Greg Donnelly MLC to Minister Hazzard, Minister Taylor and NSW Health regarding the request from Ms Cowie, Chief Executive Officer, Australian College of Rural & Remote Medicine.

Resolved, on the motion of Ms Hurst: That the committee keep the correspondence received on 17 June 2022 from Organisation A, requesting to appear at a hearing *in camera*, confidential.

Resolved, on the motion of Ms Hurst: That the committee keep the correspondence received on 18 June 2022 from Witness A, providing proposed redactions to in camera evidence, confidential.

Resolved, on the motion of Ms Hurst: That the committee keep the correspondence received on 22 June 2022 from Witness A, confirming that a redacted version of the *in camera* transcript for 16 May 2022 can be published, confidential.

5. Inquiry into the use of primates and other animals in medical research in NSW

5.1 Removal of confidentiality for submission no. 227

Resolved, on the motion of Mr Fang: That submission no. 227 be published in full, including the author's name.

5.2 Publication of a partially confidential *in camera* transcript

Resolved, on the motion of *Ms Boyd*: That the committee authorise the publication of the partially confidential in camera transcript from the hearing on 16 May 2022, as agreed with Witness A.

5.3 Allocation of questioning

Resolved, on the motion of Mr Amato: That allocation questions be in the hands of the Chair, with time equally allocated between government, opposition and cross bench.

5.4 *In camera* evidence

Resolved, on the motion of Mr Fang: That the evidence of the following witnesses be heard in camera: Witness B and Witness C.

5.5 Public hearing

The public hearing commenced at 9.29 am.

The witnesses were admitted.

The Chair made an opening statement regarding the broadcasting of proceedings and other matters.

The following witnesses were sworn and examined:

- Mr Troy Seidle, Vice President, Research & Toxicology, Humane Society International *(via videoconference)*
- Dr Rosemary Elliott, President, Sentient – The Veterinary Institute for Animal Ethics *(via videoconference)*
- Dr Katherine van Ekert, Vice President, Sentient – The Veterinary Institute for Animal Ethics *(via videoconference)*

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Mr David Mason, Chairperson, Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) (*via videoconference*)
- Mrs Cathy Pitkin, Deputy Chairperson, ANZCCART (*via videoconference*)
- Dr Malcolm France, Board member and Convenor of the Openness Agreement, ANZCCART (*via videoconference*)
- Ms Kiri Collins, President, Australia and New Zealand Laboratory Animals Association

The evidence concluded and the witnesses withdrew.

The following witnesses were sworn and examined:

- Mr Edwin Brackenreg, Chief Executive Officer, Codex Research Pty Ltd
- Prof Christopher Little, Director Raymond Purves Bone and Joint Research Laboratory, Kolling Institute

The evidence concluded and the witnesses withdrew.

The public hearing concluded at 12.00 pm.

5.6 *In camera* hearing

The committee proceeded to take *in camera* evidence.

Persons present other than the committee: Committee secretariat and Hansard reporters.

The following witnesses were sworn and examined:

- Witness B
- Witness C

The evidence concluded and the witnesses withdrew.

The hearing concluded at 12.48 pm.

6. Adjournment

The committee adjourned at 12.50 pm, *sine die*.

Erin Pynor
Committee Clerk

Draft minutes no. 70
Monday 17 October 2022
Portfolio Committee No. 2 - Health
Room 1043, Parliament House, Sydney at 10.03 am

1. Members present

Mr Donnelly, *Chair*
Ms Hurst, *Deputy Chair*
Mr Amato
Ms Boyd *(via videoconference)*
Mr Buttigieg *(substituting for Mr Secord from 2.07 pm)*
Mr Fang
Mr Graham *(substituting for Mr Secord from 12.00 pm to 2.07 pm)*
Mrs MacDonald *(from 12.38 pm)*
Mr Rath *(substituting for Mrs Mac Donald from 10.00 am to 11.00 am)*
Ms Sharpe *(substituting for Mr Secord from 10.00 am to 12.00 pm)*

2. Apologies
Mr Secord

3. Previous minutes
Resolved, on the motion of Mr Amato: That draft minutes nos. 68 and 69 be confirmed.

4. Correspondence
The committee noted the following items of correspondence:

Received

- 27 September 2022 – Email – attachments from Professor Paul Middleton, Director, South Western Emergency Research Institute, providing a written summary of his verbal briefing to the committee, a published journal article comparing access block in Australian jurisdictions that was flagged during the meeting, and an embargoed report on the prevalence of access block in Australian emergency departments.
- 13 October 2022 – Letter from Mr Donnelly, Ms Faehrmann and Mr Secord, requesting a meeting of Portfolio Committee No. 2 to consider a proposed self-reference into a matter arising from Budget Estimates relating to the COVID-19 classification of the Minister for Health, the Hon Brad Hazzard MP.

5. Inquiry into the impact of ambulance ramping and access block on the operation of hospital emergency department in New South Wales

Resolved, on the motion of Ms Hurst: That the committee publish the written summary of Professor Middleton's verbal briefing to the committee.

6. Inquiry into the use of primates and other animals in medical research in NSW

6.1 Partially confidential submissions (name suppressed)
Resolved, on the motion of Mr Fang: That the committee keep the following information confidential, as per the requests of the authors: names and/or identifying and sensitive information in submission nos. 55 and 321.

6.2 Confidential submissions
Resolved, on the motion of Mr Fang: That the committee keep submission nos. 210 and 292 confidential, as per the requests of the authors.

6.3 Correspondence from in camera witness
Resolved, on the motion of Mr Fang: That the committee keep the correspondence from Witness A dated 17 May 2022.

6.4 Answers to questions on notice
The committee noted that the following answers to questions on notice were published by the committee clerk under the resolutions appointing the committee:

- answers to questions on notice from Prof Robert Brink, Pillar Director in Translation Science, Garvan Institute of Medical Research, received 16 June 2022
- answers to questions on notice from RSPCA Australia and RSPCA NSW, received 22 June 2022
- answers to questions on notice Australian Academy of Health and Medical Sciences, NSW Branch, received 24 June 2022
- answers to questions on notice from Prof Peter Schofield AO, Board member, Association of Australian Medical Research Institutes, received 27 June 2022
- answers to questions on notice from Ms Rachel Smith Chief Executive Officer, Humane Research Australia, received 29 June 2022
- answers to questions on notice from Prof Kevin Dunn, Pro Vice-Chancellor Research, Western Sydney University, received 4 July 2022

- answers to questions on notice from Prof Philip O'Connell, Executive Director, Westmead Institute for Medical Research, received 4 July 2022
- answers to questions on notice from Ms Tara Ward, Managing Solicitor (Volunteer), Animal Defenders Office, received 4 July 2022
- answers to questions on notice from Dr Peter Johnson, received 4 July 2022
- answers to questions on notice from Prof Andrew Knight, received 15 July 2022
- additional information from Prof Andrew Knight, received 15 July 2022
- additional information from Dr Malcolm France, Board member and Convenor of the Openness Agreement, Australian & New Zealand Council for the Care of Animals in Research and Teaching, received 18 July 2022
- answers to questions on notice from Ms Nikki Steendam, President, Beagle Freedom Australia, received 20 July 2022
- answers to questions on notice from Dr Sarah Toole, Animal Welfare Officer and Veterinarian, University of Wollongong, received 21 July 2022
- answers to questions on notice from Dr Susan Maastricht, Director, Research Integrity and Ethics Administration, University of Sydney, received 22 July 2022
- answers to questions on notice from Prof Brian Kelly, Pro Vice-Chancellor (Research), University of Newcastle, received 22 July 2022
- answers to questions on notice from Ms Paula Wallace, Director, Liberty Foundation, received 22 July 2022
- answers to questions on notice from National Health and Medical Research Council, received 22 July 2022
- additional information from Prof Wayne Hawthorne, Chair, Animal Ethics Committee, Western Sydney Local Health District, received 27 July 2022
- answers to questions on notice from Department of Primary Industries, received 27 July 2022
- answers to questions on notice from Dr Rosemary Elliott, President and Dr Katherine van Ekert, Vice President, Sentient, received 1 August 2022
- answers to questions on notice from Mr Edwin Brackenreg, Chief Executive Officer, Codex Research, received 18 August 2022
- answers to questions on notice from Ms Sharyn Watson, Executive Director, Medical Advances Without Animals Trust, received 19 August 2022
- answers to questions on notice from Mr Troy Seidle, Vice President, Research & Toxicology, Humane Society International, received 21 August 2022
- answers to questions on notice from the Australian and New Zealand Laboratory Animals Association, received 6 September 2022.

6.5 Consideration of Chair's draft report

The Chair submitted his draft report, entitled *'Use of primates and other animals in medical research in New South Wales'*, which, having been previously circulated, was taken as being read.

Chapter 1

Resolved, on the motion of Ms Hurst: That paragraph 1.1 be amended by:

a) inserting 'by researchers' after 'Contributions to the inquiry'

b) omitting 'The committee was told of the benefits' and inserting instead ' The committee was also told by researchers of the benefits'

c) inserting 'from some participants' after 'the committee heard'.

Resolved, on the motion of Ms Hurst: That paragraph 1.8 be amended by:

a) omitting 'numerous contributors' and inserting instead 'Professor Anthony Cunningham AO, NSW And ACT Branch Chair, Australian Academy of Health and Medical Science'

b) omitting 'critical' and inserting instead "crucial"

c) inserting 'See also:' in footnote 9, before 'Evidence, Professor Philip O'Connell, Executive Director, the Westmead Institute for Medical Research, 16 May 2022, p 22.

Resolved, on the motion of Ms Hurst: That the following paragraph be inserted after the heading 'Research using primates':

"In NSW, primates are kept and bred for research at the Australian National Baboon Colony, which is 'maintained, managed and financially supported by Sydney Local Health District … The total Australian National Baboon Colony expenditure funded by the District for the 2021-22 financial year was $0.762 million." [FOOTNOTE: Responses to questions on notice, Budget Estimates 2021–2022 (Portfolio Committee No. 2 – Health (Health and Medical Research)), 7 September 2022, p 31.]

Resolved on the motion of Ms Hurst: That paragraph 1.13 be amended by

a) omitting "the extreme difficulty of meeting their physical and behavioural needs in a research environment' and inserting instead:

'Primates stand out among other taxa for their flexibility in how they respond to the world around them and their highly sophisticated and complex social and cognitive capacities. Therefore, meeting their needs in the research setting with the consequent spatial and social restrictions and limitations on choice and control is inevitably fraught. Therefore, it is difficult to ensure that these animals in a research setting can experience a good quality of life. It is on this basis that the RSPCA opposes the use of primates for research. [FOOTNOTE: Submission 222, RSPCA p 8]

b) inserting the following paragraph:

'Humane Research Australia agreed, noting that:

Primates are genetically the closest living creatures to humans. Their sentient ability is thought to be very similar to ours, as primates have complex social interactions. In contrast, a laboratory setting is far removed from the natural habitat. The average laboratory cage of the rhesus macaque is 7 million- fold smaller than their natural home range (40). Primate research is particularly contentious, presenting a clear ethical dilemma of using animals with high cognitive abilities, a long lifespan, and well-developed social structures as mere 'tools for research'. The animal welfare impacts associated with their advanced abilities are profound in a research setting, where they may associate previous negative experiences such as invasive procedures with future occurrences.' [FOOTNOTE: Submission 204, Humane Research Australia, p 12]

c) inserting a new paragraph from the sentence starting with 'Acknowledging this …'

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 1.15:

'Humane Research Australia agreed with this position, noting that:

It has been argued that primate research is essential to advance human health. Indeed, this is a common assumption due to their close genetic relationship to humans. Yet, we are separated by 25 million years of evolution. There are major anatomical, genetic, dietetic, environmental, toxic, and immune differences. Systematic reviews of primate research indicate that the perceived benefits to humans are overstated and that non-human 13 primate models have provided disappointing contributions toward human medical advancements' [FOOTNOTE: Submission 204, Humane Research Australia, p 8]

Resolved, on the motion of Ms Hurst: That paragraph 1.16 be amended by omitting 'numerous' before 'medical researchers'.

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 1.23:

'There was evidence from both research and animal advocates alike that more needs to be done to develop and move towards alternatives.'

Resolved, on the motion of Ms Hurst: That paragraphs 1.24 – 1.28 be moved after paragraph 1.18.

Resolved, on the motion of Ms Hurst: That paragraph 1.24 be amended by omitting 'Moves to replace the use of animals in medical research with alternatives align with the views expressed in a number of submissions received from private individuals'. and inserting instead:

'This inquiry received hundreds of submissions which included evidence from individual members of the public expressing their concerns around the ethics of the use of animals in medical research'.

Resolved, on the motion of Ms Hurst: That paragraph 1.25 be amended by inserting 'Individual' before 'submission authors'.

Resolved, on the motion of Ms Hurst: That paragraph 1.26 be omitted.

Resolved, on the motion of Ms Hurst: That the following new paragraphs be inserted after paragraph 1.27:

'These concerns about the ethics of the use of animals in experimentation were echoed by animal protection organisations. The Animal Defenders Office observed that:

> Accountability and transparency in the animal medical research industry is minimal, to the point where it is questionable whether the industry can say it has a social licence to do what it does. Time and again we speak to members of our community who have no idea that animals are used for research in Australia. They think it does not happen here and that it was something that happened in the distant past but not anymore. They have wrongly assumed that we and science itself have progressed and moved beyond such antiquated methods. [FOOTNOTE: Evidence, Ms Tara Ward, Solicitor, Animal Defenders Office, 16 May 2022, p 38]

Sentient also raised concerns about the experience of animals used in medical research:

> 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.' [FOOTNOTE: Evidence, Dr Rosemary Elliot, President, Sentient, the Veterinary Institute for Animal Ethics, 28 June 2022, p 3]

Resolved, on the motion of Ms Hurst: That paragraph 1.29 be amended by:

a) inserting 'some' before 'inquiry participants'

b) omitting 'outside the medical research community'

Resolved, on the motion of Ms Hurst: That paragraph 1.30 be amended by omitting: 'Submitters argued:

- 'animal research fails to predict human outcomes in the majority of cases'
- 'there are significant enough biological differences [between humans and animals] that wrong species often give the wrong result'
- 'the benefits [of using animals] are overstated, and that superior methods based on human biology are much needed to progress human health in the modern era'
- 'laboratory procedures and conditions exert influences on animals' physiology and behaviours that are difficult to control and can impact research outcomes'.'

and the following new paragraphs be inserted instead:

'For example, Mr Brackenreg of Codex Research expressed the view that 'animal research fails to predict human outcomes in the majority of cases'. Mr Troy Seidle, Vice-President, Research and Toxicology, Humane Society International expressed a similar view that:

> 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.

Humane Research Australia also argued that 'the benefits [of using animals] are overstated, and that superior methods based on human-biology are much needed to progress human health in the modern era'. They explained that:

> Although even a single significant advancement is to be applauded, it must be considered in the context of a great number of failed cases, which indicate the unreliable and ineffective nature of animal models. It would be prudent to seek more consistently successful models that could produce a higher rate of significant contributions.

'In response to questions taken on notice, Sentient – The Veterinary Institute for Animal Ethics shared insights from a journal article about how the conditions in which animals are held in laboratories can affect research outcomes:

> Laboratory procedures and conditions exert influences on animals' physiology and behaviors that are difficult to control and can ultimately impact research outcomes and impede extrapolation to humans. Animals in laboratories are involuntarily placed in artificial environments, usually in windowless rooms, for the duration of their lives. Captivity and the common features of biomedical laboratories—such as artificial lighting, human-produced noises, and limited space and lack of environmental enrichment—can prevent species typical behaviors, causing distress and abnormal behaviors among animals.' [FOOTNOTE: Ashya Aktar, 'The Flaws and Human Harms of Animal Experimentation', Cambridge Quarterly of Healthcare Ethics (2015), issue 24, p 408, accessed 18 October 2022 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/pdf/S0963180115000079a.pdf>.]

'Sentient added that animals 'are also exposed to social stressors, whether this is isolation or aggressive interactions between conspecifics'. [FOOTNOTE: Answers to questions on notice, Sentient - The Veterinary Institute for Animal Ethics, received 1 August 2022, p 8.]

Ms Hurst moved: That paragraph 1.59 be amended by:

a) omitting 'insightful' and 'and value'

b) omitting 'there is a general consensus that at this point in time, for various aspects of medical research, there is still an imperative to use animals.' and inserting instead 'there is a recognition that more needs to be done in the alternatives space'.

Question put.

The committee divided.

Ayes: Ms Hurst, Ms Boyd.

Noes: Mr Donnelly, Mr Amato, Mr Fang, Ms Sharpe.

Question resolved in the negative.

Resolved, on the motion of Ms Boyd: That paragraph 1.59 be amended by omitting 'there is a general consensus' and inserting instead 'the majority of the committee is of the view'.

Ms Hurst moved: That paragraph 1.60 be amended by omitting 'maintaining the reliance on animal methods for only so long as necessary before their progressive replacement with alternatives is possible.' and inserting instead 'to move towards alternatives as quickly as possible'.

Question put.

The committee divided.

Ayes: Ms Hurst, Ms Boyd.

Noes: Mr Donnelly, Mr Amato, Mr Fang, Ms Sharpe.

Question resolved in the negative.

Chapter 2

Resolved, on the motion of Ms Hurst: That paragraph 2.1 be amended by:

a) omitting 'creatures' and inserting instead 'animals'

b) omitting 'without their consent' after 'medical research'.

Resolved, on the motion of Ms Hurst: That paragraph 2.4 be amended by omitting 'On the other hand, the Kolling Institute provided a different view' and inserting instead 'The Kolling Institute provided the view'.

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 2.12:

'In addition, in relation to companion animals, Human Research Australia advised that healthy greyhounds are used for 'heart surgery experiments, terminal blood donation, and to test dental implants and deep brain stimulation devices'' [FOOTNOTE: Submission 204, Humane Research Australia, p 13.]

Ms Sharpe left the meeting.

Mr Graham joined the meeting.

Resolved, on the motion of Ms Hurst: That paragraph 2.13 be amended by:

a) omitting 'animal welfare officer' and inserting instead 'animal care manager at research facilities'

b) omitting 'anecdotal' before 'evidence'

Resolved, on the motion of Ms Hurst: That the second paragraph of Case Study A be omitted: 'The test is grounded in theory that animals that spend more time floating (and less time swimming or attempting to escape) are feeling helpless and that this indicates depression or anxiety. Indeed, there is a correlation between the efficacy of some antidepressants and the outcomes of the test. However, some contradictory evidence has shown that floating is a learned and adaptive behaviour that saves energy and is beneficial for survival', and the following new paragraph be inserted instead:

'The test is grounded in theory that animals that spend more time floating (and less time swimming or attempting to escape) are feeling helpless and that this indicates depression or anxiety. There is a correlation between the efficacy of some antidepressants and the outcomes of the test. However, there have been questions raised as to whether this test is a good model for a complex, chronic condition like human depression, as contradictory evidence has shown that floating is a learned and adaptive behaviour that saves energy and is beneficial for survival.' [FOOTNOTE: Submission 222, RSPCA, p 9. See also Submission 204, Humane Research Australia, pp 10-11; Evidence, Dr Sarah Toole, Animal Welfare Officer & Veterinarian, University of Wollongong, 1 June 2022, pp 3-4; *In camera* evidence, Witness A, 16 May 2022, p 4.]

Resolved, on the motion of Ms Hurst: That the third paragraph of Case Study A be amended by inserting after 'the test is now only used with the aim of comparing it to alternative testing methods':

'Macquarie University has also publicly stated it will not use the forced swim test.' [Letter, Dr Karolyn White, Director, Research Ethics and Integrity, Deputy Vice-Chancellor (Research), Macquarie University to Dr Trunnell, Senior Scientist, Science Advancement and Outreach, PETA, 6 September 2022, published by PETA, <www.peta.org/wp-content/uploads/2022/09/macquarie-university-letter-to-peta.pdf> accessed 18 October 2022]

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 2.21:

'Wollongong University highlighted to the Committee some of their welfare concerns about the forced swim test:

> We have had some adverse events with that particular test. We had quite a few rats that were large, male rats that had been housed in conventional laboratory housing for a number of months. When they were in the forced swim test, we had some drownings occur… We had these incidents where the rats didn't die straightaway. Basically, it was aspiration of water that wasn't detected. The rats subsequently died, after the test. It was confirmed by post-mortem examination and histopathology on the lungs. Those issues were brought to the attention of the committee. The committee reviewed some videos of that test and subsequently decided that they would only allow

that test if it was being used in parallel with an aim to look at alternatives to that test' [FOOTNOTE: Evidence, Dr Sarah Toole, Animal Welfare Officer and Veterinarian, University of Wollongong, 1 June 2022, pp 3-4]

Ms Hurst moved: That paragraph 2.37 be amended by:

a) omitting 'cannot ignore the overwhelming body of' and inserting instead 'received'

b) omitting 'the eminent representatives of' before 'the medical research community'

c) omitting 'We concur that the use of animals in medical research is justifiable on public health grounds, provided the animals are treated humanely' and inserting instead 'We recognise that all inquiry participants want to see an end of the use of animals in experimentation and a move toward alternatives'.

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Amato, Mr Donnelly, Mr Fang, Mr Graham.

Question resolved in the negative.

Resolved, on the motion of Mr Fang: That paragraph 2.37 be amended by:

a) omitting 'cannot ignore the overwhelming body of' and inserting instead 'received strong'

b) omitting 'We concur that the use of animals in medical research is justifiable on public health grounds, provided the animals are treated humanely' and inserting instead 'The majority of committee members acknowledge the use of animals in medical research is justifiable on public health grounds, provided the animals are treated humanely'.

Resolved, on the motion of Ms Hurst: That paragraph 2.40 be amended by omitting 'some of which can be mitigated by instead using whole of body exposure' and inserting instead 'on animals'.

Resolved, on the motion of Ms Hurst: That:

a) paragraph 2.42 be amended by:

   i. omitting 'should strive' and inserting instead 'strives'
   ii. omitting 'in medical research' after 'treatment of animals'
   iii. inserting 'rapidly' before 'phasing'

b) Recommendation 1 be amended by inserting 'rapidly' before 'phased out'.

Chapter 3

Resolved, on the motion of Ms Hurst: That paragraph 3.9 be amended by:

a) omitting 'receiving regular reports in relation to the projects approved'

b) omitting 'overlap considerably with the ARRP but they perform the following on an institutional rather than system wide level' and inserting instead 'include'.

Resolved, on the motion of Ms Hurst: That paragraph 3.14 be amended by:

a) omitting '• the ARRP oversees the AEC's decision-making, providing 'rigorous oversight with feedback from all the members'. The ARRP may reject the proposal or ask additional questions: "Have you considered this? What does this mean?"

b) omitting '• the ARRP responses go back to the AEC who 'considers that and decides whether or not to approve the protocol" and

c) inserting instead '• the AEC may reject the proposal or ask additional questions: "have you considered this What does this mean?"

Mrs MacDonald joined the meeting.

Resolved, on the motion of Ms Hurst:

a) That paragraph 3.28 be amended by inserting the following new paragraph after 'far from robust':

'The Animal Defenders Office also expressed concern about the regulatory framework:

> The regulatory framework in NSW covering animal research is what is known as 'enforced self-regulation'. That is, while the legislation sets out requirements for carrying out the research, it is largely left to the industry itself to ensure the requirements are followed, and there is minimal oversight or intervention by external enforcement agencies (eg government departments). Researchers are required to obtain AEEC approval, but AEECs are established by the research institutions themselves and dominated by industry participants. There is little to no public reporting of research refused or modified by AEECs, or outcomes of AEEC inspections of institutions and laboratories, or AEEC or institutional responses to unexpected adverse events. Complaints are rare and prosecutions for non-compliance with regulatory requirements are even rarer. Self-regulation also carries a high risk of perceived and actual conflicts of interest as it depends on research institutions monitoring their compliance with regulatory requirements through their own AEECs.' [FOOTNOTE: Answers to supplementary questions, Ms Tara Ward, Solicitor, Animal Defenders Office, 4 July 2022, p 6]

b) That the following new paragraphs be inserted after paragraph 3.30:

'The RSPCA raised particular concern about the guidelines for the care and housing of animals used for experimentation, noting that many of the guidelines are over 20 years old and in need of updating:

> Animals in a research setting are generally maintained in controlled and contained environments. Most species used, including dogs, cats, rodents and primates, are social animals and their needs and natural behaviours are best supported when housed with others of the same species. In many circumstances, research requires animals to be isolated which can restrict the opportunities for them to engage in positive natural behaviours. Other aspects of the research environment restrict natural behaviour including the opportunity to forage, exercise and meet other highly motivated biological needs which can impact on their ability to live a good life. It has also been proven that maintaining good animal welfare leads to better quality scientific outcomes…
>
> Although the guidelines are now given mandatory effect by way of license conditions, to create regulatory certainty, the practice guidelines should be given force by being prescribed as a code or standard by the regulation. Many of these guidelines have not been reviewed in more than 20 years. They should be reviewed in the process of being prescribed.' [FOOTNOTE: Submission 222, RSPCA, p 7]

'A number of inquiry participants also called for a review of the Code, which has not been updated since 2013.' [FOOTNOTE: Submission 222, RSPCA, p 13; Submission 204, Humane Research Australia, p 16]

Resolved, on the motion of Ms Hurst: That paragraph 3.38 be amended by:

a) Inserting the following after 'have been knocked back':

'By contrast, Ms Tara Ward gave a different perspective based on her experience on an AEC:

> From my perspective as a Category C member of a university AEEC for over 5 years, the current system is not working when it comes to requiring researchers to consider alternatives. While researchers are required to address the issue on their research project applications, they frequently copy and paste standard wording stating that there are no alternatives currently available but that they are monitoring the literature. The AEEC can do nothing about this, short of asking further questions on each individual protocol and asking the researcher to provide details'. [FOOTNOTE: Answers to supplementary questions, Animal Defenders Office, 4 July 2022, p 4.]

b) Omitting 'however' after 'Animal Defenders Office'

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 3.38:

'Medical Advances Without Animals raised concerns that animal ethics committees can be compromised by the current typical process, whereby funding is allocated to an animal research project prior to receiving ethics approval:

> AEC members also advise that timing can be important as once a proposal is presented to an AEC, it often has funding approval and that issues regarding animal ethics are among the last to be considered. In other countries there is ethical screening before funding decisions are made which avoids the problem of researchers, faculties and institutions having so much invested by the time the AEC is required to assess whether alternatives have truly been investigated. AEC members have said that they feel immense institutional pressure at times to approve projects despite their reservations.' [FOOTNOTE: Submission 351, Medical Advances Without Animals Trust, p 8.]

Resolved, on the motion of Ms Hurst: That the following new paragraphs be inserted after paragraph 3.41:

'Professor Knight also argued that more needs to be done to encourage pre-registration of animal research, and publication of negative findings:

> To ensure that all such evidence is publicly available, greater efforts must also be made by researchers and editors to publish negative results. Studies that fail to show a treatment effect are often considered less interesting and are, consequently, less likely to be published. The subsequent exclusion of such results from systematic reviews leads to overestimations of treatment efficacy and partly explains the widespread failures in humans of treatments apparently efficacious in animals. Within the field of human studies, clinical trial registers allow researchers to learn about existing and prior clinical trials, including those with negative outcomes, before results are formally published. A similar international initiative to register animal studies and their results is warranted.' [FOOTNOTE: Submission 250, Professor Andrew Knight, p 4.]

'The RSPCA also expressed support for requiring the publication of negative results, to improve transparency in the industry:

> RSPCA recommends that all animal studies should be pre-registered on a central database, of which there are already many available, to ensure full reporting of study details and to encourage reporting of negative results to ensure this information becomes available at the end of the study. Most registries have an option to place an embargo on the pre-registered study for up to five years, after which time the details of the study become automatically publicly accessible. There is currently little incentive in Australia for researchers to publish negative findings. This leads to the risk of replication of studies by various researchers which could be avoided if there was a requirement to publish negative findings and make this data widely available. Without this requirement, there is likely to be publication bias.' [FOOTNOTE: Submission 222, RSPCA, p 3.]

'In relation to this issue, Professor Anthony Cunningham AO of the Australian Academy of Health and Medical Sciences alerted the committee to the government's online register for clinical trials while acknowledging the difficulties in publishing negative findings in other publications:

> One of the reasons why clinicaltrials.gov was set up was to ensure that all trials were registered and negative results were registered as well. Researchers like me often find ways to publish data that includes negative results as well, so you can publish the negative results side by side with the positive results. But I agree with you: It is very difficult to get journals to accept a pure negative study.' [FOOTNOTE: Evidence, Professor Anthony Cunningham AO, Australian Academy of Health and Medical Sciences, 16 May 2022, p 7. See also: Evidence, Professor Robert Brink, Pillar Director, Translational Science, Garvan Institute of Medical Research, 16 May 2022, p 35; Evidence, Dr Suzanne Fowler, Chief Science Officer, RSPCA Australia, 16 May 2022, p 41.]

Resolved, on the motion of Ms Hurst: That the following new paragraphs be inserted after paragraph 3.42:

'Some inquiry participants also raised concerns about the fact that research projects could be approved despite objections from members of AECs. For example, in relation to the smoking tower experiments, Humane Research Australia stated that:

> it is very disappointing to see the University of Newcastle continue to use this method and for students to continue to be using that method there when, members of their own animal ethics committee— for many years, we have information that they have been objecting to that, but it is still continuing.' [FOOTNOTE: Evidence, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 16 May 2022, p12.]

'Humane Research Australia elaborated that 'The research was seemingly allowed to continue despite the objections as approvals were made without consensus and relentless bullying, intimidation and refusals to act on the concerns raised led to AEC members with objections resigning" [Answers to supplementary questions, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 29 June 2022, p 10.]

'Professor Jacqueline Phillips, Chair of the Animal Research Review Panel, cited relevant provisions of the *Australian code for the care and use of animals for scientific purposes* to provide clarity around what should happen if a consensus is not reached:

> I was going to clarify from the code. It is actually a provision in there—this is 2.3.11 in the code—that if consensus is still not achieved after, as you have described, discussion and attempt to resolve their differences and exploring with applicants ways of modifying the activity or the project, "the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion." [FOOTNOTE: Evidence, Professor Jacqueline Phillips, Chair, Animal Research Review Panel, 1 June 2022, p 57.]

Resolved, on the motion of Ms Hurst: That paragraph 3.43 be amended by omitting 'members of the public' and inserting instead 'lay committee members'.

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 3.44:

'Similarly, Medical Advances Without Animals in recognising that there was 'insufficient education and training for researchers and Animal Ethics Committee (AEC) members, and therefore insufficient knowledge of alternative animal replacement methods', suggested that there should be funding for 'education and training in alternatives for students, researchers and AEC members to increase awareness, knowledge and expertise in animal-free methods and technologies.' [FOOTNOTE: Submission 351, Medical Advances Without Animals Trust, pp 14-15.]

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 3.50:

'The Animal Defenders Office also expressed a number of concerns about the audit and inspection process:

> Carrying out pre-arranged inspections of research institutions every 3-4 years is manifestly inadequate to monitor the care of the many (often thousands) of animals kept at an institution. […] The ADO submits that unannounced inspections at least once a year would be the minimum that would be required to give a basic level of assurance that an institution is complying with animal welfare requirements.' [FOOTNOTE: Answers to supplementary questions, Ms Tara Ward, Solicitor, Animal Defenders Office, 4 July 2022, p 6.]

Ms Hurst moved: That paragraph 3.54 be amended by:

a) Omitting 'many AECs' and inserting instead 'while some AECs'

b) Omitting 'and make the welfare of animals their primary consideration. However' and inserting instead 'there was variability among AECs'

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Amato, Mr Donnelly, Mr Fang, Mr Graham, Mrs MacDonald.

Question resolved in the negative.

Mr Graham left the meeting.

Mr Buttigieg joined the meeting.

Resolved, on the motion of Ms Hurst: That Recommendation 2 be amended:

a) by inserting 'with the ability for online participation' after 'in-person seminars'

b) by inserting 'with the ability for online participation' after 'in-person induction training'

c) by inserting at the end 'and ensure all animal ethics committee members receive adequate training about the availability of alternatives'

Resolved, on the motion of Ms Hurst: That paragraph 3.56 be amended by omitting 'the highest standards of animal welfare' and inserting instead 'the requirements of the Code and regulatory framework'.

Resolved, on the motion of Mr Fang: That Recommendation 3 be amended by inserting 'as soon as practicable' after 'audits of animal research facilities'.

Chapter 4

Ms Hurst moved: That paragraph 4.1 be amended by omitting 'some' before 'evidence'.

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Amato, Mr Buttigieg, Mr Donnelly, Mr Fang, Mrs MacDonald.

Question resolved in the negative.

Resolved, on the motion of Mrs MacDonald: That paragraph 4.1 be amended by omitting 'some' and inserting instead 'certain'.

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 4.4:

'Ms Craig also highlighted a number of other concerning animal welfare issues from her time working in animal research institutions:

> I have personally witnessed a significant number of animal welfare issues. This includes the removal of toes and tail tipping of adult animals, animals not being given appropriate anaesthesia and analgesia, mass culling of animals as researchers are not happy with preliminary data from them, animals used in horrific inappropriate smoke inhalation studies, animal fasted for excessive periods of time, severe and significant overproduction of animals.' [FOOTNOTE: Submission 251, Ms Lisa Craig, p 3.]

Resolved, on the motion of Ms Hurst: That the following new paragraphs be inserted after paragraph 4.4:

'Ms Craig also raised concerns around wastage and excess breeding:

> Breeding of animals for research, including commercially available animals, occurs at institutions across Australia, resulting in significant overproduction and culling of excess animals. This includes mice, rats, and guinea pigs.' [FOOTNOTE: Submission 251, Ms Lisa Craig, p 3.]

'These concerns were echoed by the RSPCA:

> Where animal breeding is undertaken within institutions this must be well managed by highly trained and competent staff. The risk of overbreeding is significant with students often tasked

> with managing their own breeding colonies with minima l training and oversight in doing so. Well run facilities have their own breeding manager who is tasked with ensuring overbreeding does not occur and that best practice is undertaken to avoid wastage of animals. Wastage occurs when animals are bred in numbers in excess of need, and then not utilized but killed and disposed. To prevent wastage, institutions must be required to track and report breeding and usage statistics relevant to individual strains of animals and the reasons for any wastage. [FOOTNOTE: Submission 222, RSPCA, p 6.]

Resolved, on the motion of Ms Hurst: That paragraph 4.13 be amended by omitting 'employed there' and inserting instead 'employed at these two facilities'.

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 4.20:

'While additional training was clearly required for researchers and animal care staff, the inclusion of honours students in animal research raised its own set of concerns. Mr Peter Adamson, a former AEC member, said that in his experience 'much suffering is inflicted on animals by students so that they can submit research to gain Honours degrees and Ph.D's.' [FOOTNOTE: Submission 252, Mr Peter Adamson, p 1.] Humane Research Australia also highlighted some of their reservations about the use of honours students, noting that:

> It establishes a precent of using animals in research, does not equip students with skills needed to peruse advanced new approach methodologies, and is wasteful of animal lives in the projects where outcomes are known and the animals are simply used to demonstrate existing knowledge, which could be taught by other methods. There is also the potential of animal welfare impact if the students are not adequately trained or experienced. To reduce the number of animals used and bring about a change in future generations of researchers, HRA recommend that honours students are prohibited from using animals. This would also encourage supervisors to expand the research methodologies they use. [FOOTNOTE: Answers to supplementary questions, Ms Rachel Smith, Chief Executive Officer, Humane Research Australia, 29 June 2022, p 11.]

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 4.27:

'There were stakeholders who called for funding for rescue organisations who are performing the work of rehoming animals used in research institutions. For example, Liberty Project stated that:

> For the rehoming movement for ex-research animals to expand and become sustainable at scale, we believe industry and government must work together with rehoming organisations, most importantly, by providing funding and other support… it should not be left to the charitable sector to pay for rehoming of animals from government-owned or -run research facilities as is currently taking place.' [FOOTNOTE: Answers to supplementary questions, Ms Paula Wallace, Director, Liberty Project, 22 July 2022, p 6.]

'The call for funding was also supported by the Animal Defenders Office.' [FOOTNOTE: Submission 245, Animal Defenders Office, p 13.]

Resolved, on the motion of Ms Hurst: That paragraph 4.29 be amended by omitting 'and it was introduced into the Legislative Assembly for concurrence' and inserting instead:

'On 13 October 2022, the bill passed the Legislative Assembly with amendments. At the time of writing this Report, the amendments are awaiting consideration in the Legislative Council.'

Resolved, on the motion of Ms Hurst: That paragraph 4.31 be amended by omitting 'additional funding for veterinarians' and inserting instead 'additional funding and for veterinarians'.

Resolved, on the motion of Ms Hurst: That paragraph 4.43 be amended by inserting at the end:

'• Requiring the fate of all species used in research to be reported'

Resolved, on the motion of Ms Hurst: That the following new paragraph be inserted after paragraph 4.43:

'The Animal Defenders Office also expressed support for improved reporting of animal use statistics, particularly in relation to the reporting the 'fate of animals':

> Reporting on the fate of animals is mandatory only for domesticated dogs and cats used in research. Reporting is voluntary for all other animal groups. This is unacceptable from a transparency standpoint. […] Furthermore, there is no ethical justification for requiring reporting on cats and dogs but not other species. The ADO submits that reporting on the fate of all animals should be mandatory.' [Submission 245, Animal Defenders Office, p 13.]

Resolved, on the motion of Ms Hurst: That paragraph 4.56 be amended by omitting 'The committee acknowledges that the evidence of single inquiry participants is not always credible and persuasive. However' and inserting instead 'While only one witness provided direct evidence of witnessing cruelty inside a research facility'.

Ms Hurst moved: That paragraph 4.57 be amended by omitting 'The committee reiterates in the strongest terms that the use of animals in medical research is justifiable on public health grounds only if animals are treated humanely' and inserting instead 'The Committee strongly believes the inhumane treatment of animals in medical research would be unjustifiable'.

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Amato, Mr Buttigieg, Mr Donnelly, Mr Fang, Mrs MacDonald.

Question resolved in the negative.

Resolved, on the motion of Ms Hurst: That the following new paragraphs be inserted after paragraph 4.57:

> 'The Committee notes the issues raised by some witnesses regarding the current regulatory framework, including but not limited to, overbreeding of animals, issues regarding pre-registration and publication of negative results from animal research experiments, the participation of honours students in animal research and the standards for housing and care of animals in research facilities. The Committee was also concerned to hear evidence about non-disclosure obligations imposed by the Animal Research Act, and the limited protections afforded to whistleblowers. The Committee recommends that NSW Government investigate opportunities for reform and undertake a review of the Animal Research Act 1985 with regards to the issues raised in this Inquiry.'
>
> **'Recommendation X**
> That the NSW Government investigate opportunities for reform and undertake a review of the Animal Research Act 1985 with consideration of the issues raised in this Inquiry, including but not limited to:
>
> - The overbreeding of animals
> - The need to encourage pre-registration and publication of negative results of experiments involving animals
> - The issues concerning honours student undertaking animal research experiments
> - The housing and care of animals used in animal experimentation
> - The need for protections for whistleblowers who seek to raise concerns about the treatment of animals used for experimentation'

Ms Hurst moved:

- That a new paragraph be inserted after paragraph 4.57: 'The committee also notes that a number of witnesses raised concerns about the adequacy of the *Australian code for the care and use of animals for scientific purposes*, which has not been updated since 2013. We therefore recommend the NSW Government engage with the Australian Government on a ministerial level to advocate for a priority review of the Code.'
- That Recommendation 4 be moved after paragraph 4.57 and Recommendation 4 be amended by omitting:
  'to ensure that:
  • veterinarians with appropriate expertise are appointed to animal ethics committees

• research institutions be required to employ a veterinarian.'

- That paragraph 4.58 be amended by omitting 'engage with the Australian Government at a ministerial level to advocate for priority review of the Code' and inserting instead 'take steps to amend the *Animal Research Act 1985*'.
- That a new recommendation be inserted after paragraph 4.58:

Recommendation

That the NSW Government amend the *Animal Research Act 1985* to ensure that:

• veterinarians with appropriate expertise are appointed to animal ethics committees

• research institutions be required to employ a veterinarian.

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Amato, Mr Buttigieg, Mr Donnelly, Mr Fang, Mrs MacDonald.

Question resolved in the negative.

Mr Fang moved: That Recommendation 7 be amended by omitting 'commit to' and inserting instead 'consider'.

Question put.

The committee divided.

Ayes: Mr Amato, Mr Fang, Mrs MacDonald.

Noes: Ms Boyd, Mr Buttigieg, Mr Donnelly, Ms Hurst.

Question resolved in the negative.

Ms Hurst moved:

- That a new paragraph be inserted after paragraph 4.62: 'The committee notes that while the Animal Research Amendment (Right to Release) Bill 2022 appears likely to pass through NSW Parliament there is potential to expand rehoming efforts in the animal research space. The committee also notes the need to provide funding and support to organisations who are doing the work of rehoming animals used in medical research.'
- That Recommendation 7 be amended by inserting ', and investigate opportunities to provide funding and support to animal rescue organisations who rehome animals used in research' after 'Research Animal Rehoming Guidelines'.

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Amato, Mr Buttigieg, Mr Donnelly, Mr Fang, Mrs MacDonald.

Question resolved in the negative.

Mr Buttigieg moved:

- That a new paragraph be inserted after paragraph 4.62: 'The committee notes that while the Animal Research Amendment (Right to Release) Bill 2022 appears likely to pass through NSW Parliament there is potential to expand rehoming efforts in the animal research space. The committee supports investigation of opportunities to provide support to organisations who are doing the work of rehoming animals used in medical research.'

- That Recommendation 7 be amended by inserting ', and investigate opportunities to provide support to animal rescue organisations who rehome animals used in medical research' after 'Research Animal Rehoming Guidelines'.

Question put.

The committee divided.

Ayes: Ms Boyd, Mr Buttigieg, Mr Donnelly, Ms Hurst

Noes: Mr Amato, Mr Fang, Mrs MacDonald

Question resolved in the affirmative.

Resolved, on the motion of Ms Hurst: That paragraph 4.63 be amended by omitting 'the unfortunate perception that medical research institutes have something to hide' and inserting instead 'public confusion about the use of animals in medical research.'

Resolved, on the motion of Ms Hurst: That a new committee comment and recommendation be inserted after the first sentence of paragraph 4.63:

'Both researchers using animals in medical research and animal advocacy organisations expressed concerns to the committee about the adequacy of reporting of statistics on animals used in medical research in New South Wales. The committee therefore calls on the NSW Government to consider the reporting of these statistics.

Recommendation

That the NSW Government consider the reporting of statistics surrounding animals used in medical research, including but not limited to:

• publishing an annual list of accredited animal research establishments, and the species of animals they experiment on

• reporting on the total numbers of animals bred (but not ultimately used) for animal research

• requiring the fate of all species used in research to be reported.

Resolved, on the motion of Mr Buttigieg: That the recommendation inserted after paragraph 4.63 be amended by inserting a final dot point: 'the separate reporting of animals used in observational studies.'

Resolved, on the motion of Ms Hurst: That paragraph 4.63 be amended by omitting 'These reporting requirements should exclude animals involved in observational studies' and inserting instead 'These reporting requirements should provide for the separate and discrete reporting of animals involved in observational studies'.

Resolved, on the motion of Ms Hurst: That Recommendation 9 be amended by inserting ', and explore opportunities to ensure all research institutions sign up to this Agreement.'

Chapter 5

Resolved, on the motion of Ms Hurst: That paragraph 5.13 be amended by inserting a new dot point at the start of the list: 'While the NSW Government uses taxpayer money to fund animal research, this funding is not separately recorded or reported and therefore the total amount is unclear.' [FOOTNOTE: Answers to questions on notice, Budget Estimates 2019-2020, Portfolio Committee No. 2 – Health (Health and Medical Research), Further hearing 12 March 2020, p 8]

Resolved, on the motion of Ms Hurst: That a new paragraph be inserted after paragraph 5.28:

'While a national approach in Australia is preferable, the ADO supports the creation of an interim state institution for the advancement of non-animal alternatives and technologies in New South Wales. At the very least, the NSW Government should allocate meaningful funding to programs and grants aimed at reducing the numbers of animals used in medical research. These measures would demonstrate New South

Wales' commitment to the principle of replacement and would help define a timeline for phasing out animal use in medical research.' [Submission 245, Animal Defenders Office, p 5]

Resolved, on the motion of Ms Hurst: That paragraph 5.29 be amended by:

- omitting 'The opportunity' and inserting instead 'In the committee's view, there is an opportunity'
- omitting 'is not lost on the committee'.

Resolved, on the motion of Ms Hurst: That paragraph 5.30 be amended by inserting 'with a view towards ending the use of animals in medical research' after 'the state would be able to take the lead about how best to maximise the efficiency and ethics of medical research'.

Mr Fang moved: That Recommendation 10 be amended by omitting 'commit funding to enable' and inserting instead 'promote'.

Question put.

The committee divided.

Ayes: Mr Fang, Mrs MacDonald.

Noes: Ms Boyd, Mr Buttigieg, Mr Donnelly, Ms Hurst.

Question resolved in the negative.

Ms Hurst moved: That a new committee comment and recommendation be inserted after Recommendation 10:

The committee notes that while it is clear the NSW Government provides funding towards the use of animals in medical research, it was difficult for the committee to confirm precisely how much funding had been allocated. When public money is being spent, it is important that there be transparency and accountability. The committee recommends that the NSW Government report annually on both the amount of government funding being given to the use of animals in medical research, and the amount of funding given to the development of alternatives.

Recommendation

That the NSW Government report annually on the amount of government funding given to the use of animals in medical research and funding given to the development of alternatives.

Question put.

The committee divided.

Ayes: Ms Boyd, Mr Buttigieg, Mr Donnelly, Ms Hurst.

Noes: Mr Fang, Mrs MacDonald.

Question resolved in the affirmative.

Ms Hurst moved: That a new committee comment and recommendation be inserted after Recommendation 10:

The committee notes that all inquiry participants expressed the view that they would like to get to the point where animals are no longer being used for experimentation. This goal will not be achieved without government leadership and support, including the need for funding towards the development of more alternatives to the use of animals in experimentation. With that in mind, the committee recommends the NSW Government seek to develop a plan on how we can transition away from animal use and towards the use of the alternatives.

Recommendation

That the NSW Government seek to develop a plan on how we can transition away from animal use and towards the use of the alternatives.

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Buttigieg, Mr Donnelly, Mr Fang, Mrs MacDonald.

Question resolved in the negative.

Ms Hurst moved: That a new committee comment and recommendation be inserted after Recommendation 10:

> Given the significant concerns raised in this inquiry about the routine cruelty inflicted on animals in research facilities, as well as the serious questions about the scientific validity of studies involving animals for human medical research, the Committee has serious reservations about the continued use of animals in experimentation. The Committee also believes that with a Government focus towards alternatives, the transition away from animals in experimentation can be achieved much faster. We therefore recommend the NSW Government commit to ending the use of animals in experimentation
>
> **Recommendation**
> That the NSW Government end the use of animals in medical research.

Question put.

The committee divided.

Ayes: Ms Boyd, Ms Hurst.

Noes: Mr Buttigieg, Mr Donnelly, Mr Fang, Mrs MacDonald.

Question resolved in the negative.

Resolved, on the motion of Mr Fang:

- The draft report as amended be the report of the committee and that the committee present the report to the House;
- The transcripts of evidence, submissions, tabled documents, answers to questions on notice and supplementary questions, and correspondence relating to the inquiry be tabled in the House with the report;
- Upon tabling, all unpublished attachments to submissions be kept confidential by the committee;
- Upon tabling, all unpublished transcripts of evidence, submissions, tabled documents, answers to questions on notice and supplementary questions, and correspondence relating to the inquiry, be published by the committee, except for those documents kept confidential by resolution of the committee;
- The committee secretariat correct any typographical, grammatical and formatting errors prior to tabling;
- The committee secretariat be authorised to update any committee comments where necessary to reflect changes to recommendations or new recommendations resolved by the committee;
- Dissenting statements be provided to the secretariat within 24 hours after receipt of the draft minutes of the meeting;
- The secretariat is tabling the report on Friday 21 October 2022.

7. Adjournment

The committee adjourned at 4.16 pm, *sine die*.

Madeleine Foley
Committee Clerk

Appendix 4 Dissenting statements

The Hon Emma Hurst MLC, Animal Justice Party

This Inquiry has exposed the shocking reality of what goes on behind closed doors in animal research facilities in NSW.

While this Inquiry Report has made some important recommendations – including the need to ban forced swim and smoking tower experiments, require mandatory rehoming of animals used for experimentation, increase reporting and transparency requirements and establish funding for alternatives to animal alternatives in NSW – it does not go far enough and clearly does not accurately reflect the evidence we received at the Inquiry.

I am utterly dismayed that the Labor party refused to support several important amendments to this report.

The most shocking was that the Labor party did not support a recommendation that the Government develop a plan on how we can transition away from animal use, and towards the use of alternatives – or to bring about an end to the use of animals in experimentation. This was a position held by every stakeholder who gave evidence at the inquiry. Researchers do not want to continue to use animals in experimentation when there are alternatives available – but the Labor party and the NSW Government made it clear in this Inquiry that they won't be supporting the industry to achieve this goal, and won't even support a proposal to develop a plan to be able to achieve this.

Labor's refusal to support this amendment speaks volumes. Not only are they ignoring animal protection organisations and the research industry, but they are clearly taking a stance that animal welfare does not matter.

The other bizarre position taken by the Labor Party was a refusal to support the consideration of funding to rescue groups who rehome animals used in medical experimentation. This is unjustifiable.

While all parties supported a recommendation to require mandatory rehoming of animals in research, neither Labor nor the NSW Government were willing to support an Animal Justice Party recommendation to call for funding for these animal rescue groups who do the work. This is yet another example of how the NSW Government is willing to take advantage of volunteer-run, charitable animal rescue groups, without properly funding them. It appears that the Labor party are now taking a similar position of refusing to recognise the hard work of animal rescue volunteers and rejecting mere considerations around funding their life saving work. I am disgusted that the Labor Party would side with the Government on these essential initiatives to save animals.

Aspects of the report are clearly one-sided, and do not reflect the views of all members of the Committee. My attempts to make the report reflect a more balanced position were rejected, which was surprising to me given this is not the experience I have had in other Committees where there is generally more of a willingness to work together to reach a Committee consensus. For example, I do not agree with the Committee comments in this Inquiry Report that 'there is an imperative to use animals' for medical research, or that 'the use of animals in medical research is justifiable on public health grounds, provided the animals are treated humanely'.

To the contrary, we received evidence at this Inquiry, from expert researchers and scientists, that the use of animals in experimentation has major limitations, often leads to inaccurate results, and is actually holding back the development of more accurate and effective scientific methods that could advance human and animal health. We also heard that animals in this industry are not treated humanely – and in fact, are subject to routine cruelty, from the artificial laboratory conditions they are forced to spend their lives in, to the painful experiments that are conducted on these sentient beings, to their ultimate deaths.

At times, I feel the language in this Report tries to water down evidence given by highly esteemed expert witnesses, by including qualifying language such as 'some' when describing their evidence. Other areas of the report attempted to inflate evidence given by witnesses with an opposing view. In many instances, attempts to make the report a fair and accurate representation of the evidence received were rejected by the Government and Labor party representatives. To put it bluntly, this was a shameful display of failing to remain impartial and reflect the evidence received.

The Animal Justice Party also sought to include a recommendation seeking a review of the Australian code for the care and use of animals for scientific purposes, which has not been updated since 2013. This review was called for by animal protection organisations, including RSPCA Australia, however it was not supported by other members of the Committee.

Lastly, the Labor party seem to have failed to understand the legislative framework regarding animal protection in NSW, rejecting an amendment to make changes to expand the role of vets under the *Animal Research Act 1985* (NSW). Instead, they supported a recommendation calling for the Federal Government to take action on this issue, when NSW can easily amend its own legislation to more swiftly deal with the issues raised at the inquiry. This is a sad attempt to deflect from taking real action, and in doing so, the NSW Government and the Labor party have failed to support both vets and animals in NSW.

I am deeply disappointed by the failures of this report to accurately reflect the shocking evidence that we heard. There is a great deal of change desperately needed in this space, and this Report does not go far enough.