Submission No 214

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

Organisation: NSW Young Lawyers

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THE LAW SOCIETY OF NEW SOUTH WALES
young LAWYERS

Submission on the inquiry into the use of primates and other animals in medical research in New South Wales

31 March 2022

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THE LAW SOCIETY OF NEW SOUTH WALES
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The NSW Young Lawyers Animal Law Committee (**Committee**) makes the following submission on the inquiry into the use of primates and other animals in medical research in New South Wales (**Inquiry**)

NSW Young Lawyers

NSW Young Lawyers is a division of The Law Society of New South Wales. NSW Young Lawyers supports practitioners in their professional and career development in numerous ways, including by encouraging active participation in its 15 separate committees, each dedicated to particular areas of practice. Membership is automatic for all NSW lawyers (solicitors and barristers) under 36 years and/or in their first five years of practice, as well as law students. NSW Young Lawyers currently has over 15,000 members.

The Committee comprises a group of over 400 members interested in animal protection laws regulating the treatment of animals. The Committee aims to raise awareness and provide education to the legal profession and wider community, while increasing understanding about the importance of protecting animals from abuse and neglect. A common theme amongst Committee members is a passion and desire to use their legal skills and the law to improve protections for animals.

The Committee welcomes the opportunity to make a submission on the Regulations, and makes comment on sections (a), (d), (e) and (f) of the Inquiry's Terms of Reference.

Summary of Recommendations

1. Serious consideration ought to be given to narrowing the useability of animals in research - or, potentially, eliminating it, at least in certain fields – given the limited translatability of the results to human use and the significant harm it causes to animal subjects.

2. In many cases in which harm is caused to animals in the name of research for perceived human benefits, the potential or sought benefit does not justify the harm inflicted on the animals involved. In those cases, such research should not be permitted.

3. The Australian Code for the Care and Use of Animals for Scientific Purposes ought to be clearly worded to effectively minimise harm on animals used in medical research.

4. More robust public disclosure obligations ought to be introduced to the current regulatory regime.

5. Clearly worded legislation and policies ought to be introduced to ensure that the 3R principles are seriously and rigorously applied and enforced.

6. Clearly worded legislation and policies ought to be introduced to ensure the transparency, oversight and enforcement to the importation of (in particular) primates used in research.

7. A clear requirement to avoid unnecessary pain, harm and/or suffering ought to be incorporated into the legislative regime.

8. The Committee supports a directive to structurally facilitate the use of non-animal testing alternatives, with a view of phasing out animal testing for scientific purposes in the near future.

(a) The nature, purpose and effectiveness of medical research being conducted on animals in New South Wales

Animal experimentation is relied upon by the medical research community. Results from animal experimentation aim to develop knowledge regarding human physiological and pathological processes. This translates to testing the efficacy of pharmaceutical products (vaccines, drugs) before it can be deemed safe for human use and consumption.[1] There appears to be an assumption in the medical research community that the use of animal models is predicative of positive health outcomes in humans. This assumption may not be sound, however, given that there are key physical and biological differences between animals and humans which impact the overall reliability of animal models.[2] By way of example:

- Mice are typically used in efforts to find a cure for cancer. However, mouse models used in animal research testing carcinogenicity were orally given (or injected) with a carcinogen to induce cancer for the purposes of finding a cure for cancer.[3] While the mice were cured of the cancer, it has not worked in humans.[4]

- Large scale testing on chimpanzees has been used in efforts to find an effective vaccine for preventing HIV/AIDS. However, when they were initially infecting chimpanzees with the HIV virus, they did not experience influenza-like symptoms as humans do, and as such, their use in the research was proven to be unnecessary and unhelpful.[5] Recent alternate research developments have rendered chimpanzees largely unnecessary as research subjects.[6]

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[1] '*Assessed listed medicines evidence guidelines* (Version 1.1, August 2018) 9. Application and approval processes', *Australian Department of Health – Therapeutic Goods Administration* (Webpage, 19 August 2018) <https://www.tga.gov.au/book-page/9-application-and-approval-processes>.
[2] Peter Radan, 'Antivivisection and Charity' (2013) 35(3) *Sydney Law Review*, 535; Andre Menache and Ray Greek, 'Systematic Reviews of Animal Models: Methodology versus Epistemology' (2013) 10(3) *International Journal of Medical Sciences*; Peter Tatchell, *Why Animal Research is Bad Science* (New Statesman, 2004), 18-9; Annalea Pippus, Lawrence A Hansen and Ray Greek, 'The Nuremberg Code Subverts Human Health And Safety By Requiring Animal Modeling' (2012) 13(16) *BMC Medical Ethics*.
[3] Annapoorni Rangarajan and Robert A Weinberg, 'Comparative Biology Of Mouse Versus Human Cells: Modelling Human Cancer In Mice' (2013) 3(12) Nature, 952-9; Kenneth R Hess, 'Statistical Design Considerations In Animal Studies Published Recently In Cancer Research' (2011) 71(2) *Cancer Research*, 625.
[4] Ibid.
[5] Robert C Jones, 'A Review of the Institute of Medicine's Analysis of using Chimpanzees in Biomedical Research' (2013) 20(2) *Science and Engineering Ethics*, 481-504; Andre Menache and Ray Greek, 'Systematic Reviews of Animal Models: Methodology versus Epistemology' (2013) 10(3) *International Journal of Medical Sciences*; Lena J Gamble and Qiana L Matthews, 'Current Progress In The Development Of A Prophylactic Vaccine For HIV-1' (2010) 5 *National Center for Biotechnology Information*.
[6] Bruce M. Altevogt, Diana E. Pankevich,

- TGN 1412, an immunomodulatory drug, caused "catastrophic systemic organ failure" in the volunteers it was injected into in 2006. No such effect was found during previous research on rats, mice, rabbits and non-human primates.[7]

- A vaccine, first tested on animals, was found to expose women to increased risks of developing stroke and breast cancer.[8] This was not found in the mice or non-human primates on whom it was first tested.[9]

While chemicals, pharmaceuticals and procedures can have one effect in animals, the outcome can be very different (and, at times, damagingly so) to humans. These are only a few examples among many which exemplify the difficulty in drawing conclusions about what will happen to humans based on results from animal-based research.

Common experimental methods include invasive procedures and blood sampling.[10] Generally this involves testing new chemicals on animals 'eyes, down their throats or on their sensitive exposed skin.[11] It has also been consistently shown that rabbits, guinea pigs and mice are subjected to the negative side effects of untested chemicals.[12]

Furthermore, psychological experiments are used extensively by the medical research community. These also have significant health impacts upon the animals being tested; for example, isolating primates led to them engaging in harmful behaviours, such as self-mutilation, biting and ripping out their hair.[13] The stress of being confined for the purpose of animal experimentation causes these animals to suffer from anxiety and physical declines in health.

The Committee submits that the consequences of experimentation upon the physical and mental welfare of animals are unacceptable. The above indicates that more harm than good is derived from it, especially given

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Marilee K. Shelton-Davenport, and Jeffrey P. Kahn (eds), *Chimpanzees in Biomedical and Behavioural Research, Assessing the Necessity* (The National Academy Press, 15 December 2011).
[7] Akhtar, Aysha, 'The Flaws and Human Harms of Animal Experimentation' (2015) 24 *Cambridge Quarterly of Healthcare Ethics* 407–19 ('The Flaws and Human Harms Article').
[8] The Flaws and Human Harms Article (n 7).
[9] Ibid
[10] Andrew Knight, *The Costs and Benefits of Animal Experiments* (Palgrave Macmillan, 2011), 42.
[11] The Flaws and Human Harms Article (n 7) 407–19.
[12] Ibid
[13] McLeod, S. A, 'Attachment theory' (2017) *Simply Psychology*.<https://www.simplypsychology.org/attachment.html>.

the significant limitations on translating the results from animals in a controlled laboratory setting to the human population.

Specifically, approximately 89% of novel drugs fail human clinical trials, with about one-half of these failures caused by unanticipated human toxicity.[14] This shows the lack of efficacy in animal testing with regards to the accurate prediction of toxicity-related failures in humans.[15] Further, a 2006 review of 76 animal studies found that only 37% were ever replicated in humans and about 18-20% were actually contradicted in humans.[16]

Moreover, the Committee submits that available alternatives to animal research are often a more sophisticated way to attempt to address a particular scientific question, and are often more efficient and accurate than the means they replace.[17] Human clinical studies, such as for micro-dosing purposes, can be used whereby (voluntary) human participants are given 'low quantities of a drug to test the effects on the body on the cellular level without it affecting the entire human body.[18] Further examples of alternatives include using human stem cells for basic research, or in vitro (test tube) research using human tissue.[19] Other effective alternatives include using cell, tissue and organ engineering which can be used for testing drug toxicity; or using human bodies donated to science for the purposes of sourcing information about the human body, disease processes and other medical questions.[20] With these options available, the Committee queries the utility of most, if not all, animal use in research.

[14] Gail A. Van Norman, MD, 'Limitations of Animal Studies for Predicting Toxicity in Clinical Trials' (2019) 4(7) *JACC Basic Transl Sci*, 845–854.
[15] Ibid.
[16] Ibid; Ri Scarborough, 'Why animal trial results don't always translate to humans', *Medical Express* (Webpage, 30 August 2017) <https://medicalxpress.com/news/2017-08-animal-trial-results-dont-tohumans.html>.
[17] Katrina Sharman, 'Opening the Laboratory Door: National and International Legal Responsibilities for the Use of Animals in Scientific Research' (2006) 2 *Journal of Animal Law*, 67; David DeGrazia, 'The Ethics of Animal Research: What are the Prospects for Agreement?' (1999) 8(1) *Cambridge Quarterly of Healthcare Ethics*, 28
[18] Peter Tatchell, *Why Animal Research is Bad Science* (New Statesman, 2004), 19.
[19] Jean Greek and Ray Greek, 'Is The Use Of Sentient Animals In Basic Research Justifiable?' (2010) 5(14) *Philosophy, Ethics, and Humanities in Medicine*, 12; David DeGrazia, 'The Ethics of Animal Research: What are the Prospects for Agreement?' (1999) 8(1) *Cambridge Quarterly of Healthcare Ethics*, 28.
[20] Peter Tatchell (n 15) 19; David DeGrazia (n 16) 28; Jean Greek and Ray Greek (n 20) 12.

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

Sentience and suffering

Up to 7 million animals are used annually in research, testing and teaching in Australia.[21] Many of those experience some degree of pain or stress either due to the experiments for which they are used or due to the environments in which they are kept.[22]

Britain's 2002 Animal Procedures Committee's report on the laboratory use of primates acknowledged that "...there are serious ethical and animal welfare concerns regarding the use of primates in experiments, and considerable public disquiet with regard to such use. These concerns are also likely to increase as more is discovered about their advanced cognitive faculties, complex behavioural and social needs, and the difficulties of satisfying these in a laboratory environment."[23]

The Australian Code for the Case and Use of Animals for Scientific Purposes (**Code**) is a guide developed by the National Health and Medical Research Council (**NHMRC**) for those involved in using animals for scientific (including medical) research. The Code is established on principles of minimising harm, maintaining scientific integrity, and only using animals when considered justifiable.[24]

The Committee submits that the use of animals for medical research does not allow for harm to be minimised in many cases. Much of the wording of the Code uses terminology such as "where possible", "where appropriate", and "in consultation with," which leave considerable room for interpretation[25] and are difficult to enforce.

The Committee submits that the use of animals for medical research is not justifiable. For an experiment to pass an 'ethics test', researchers must prove that the potential benefits to humans outweigh the impact on the

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[21] 'Animal Experiments. Get educated.', *Animal Liberation Queensland* (Web Page, 2002) <https://alq.org.au/animal-experiments>.
[22] 'Australian supplier of lab animals to close, sparking fresh debate about use of mice and rats in research', *The Guardian* (Web Page, 9 July 2021) <https://www.theguardian.com/australia-news/2021/jul/09/australian-supplier-of-lab-animals-to-close-sparking-fresh-debate-about-use-of-mice-and-rats-in-research>.
[23] Animal Procedures Committee, *Report of the Animal Procedures Committee for 2002* (Report, 2002) at 24.
[24] National Health and Medical Research Council, 'Australian Code for the Care and Use of Animals for Scientific Purposes – 8th Edition', *Commonwealth of Australia* (Web Page, 1 June 2021) <www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes>.
[25] 'Scientific research on primates: what do we owe animals like us?', *The Conversation* (Web Page, 5 February 2013) <https://theconversation.com/scientific-research-on-primates-what-do-we-owe-animals-like-us-11673>.

animals involved.[26] There are ethical and scientifically superior alternatives that are more relevant and predictive for humans (as touched on above), such as:

- Non-invasive imaging technology such as MRIs and CAT scans
- Epidemiology (the study of human populations)
- Human clinical studies
- Human cell and tissue cultures
- Microdosing (in which humans are given very low quantities of a drug to test the effects on the body on the cellular level, without affecting the whole-body system)
- Mathematical and computer-based databases and models
- Stem cell and genetic testing methods
- In vitro (test tube) techniques.[27]

The research industry is profit-driven

The animal research industry is a commercial, for-profit one, resulting in a strong economic incentive for researchers, breeders, suppliers, and pharmaceutical companies who derive financial benefits from animal research, to continue their current practices. Laboratories and affiliated universities also have an incentive to retain the funding they receive for animal research, housing, and maintenance grants.[28]

The Committee submits that the profit-driven nature of the medical research industry means that there is a conflict of interest when considering if medical research is "justifiable" as required by the Code, and whether harm can ever be minimised to achieve acceptable animal welfare standards.

Ethical issues regarding importation

[26] 'Australia's secret primate experiments', *Animals Australia* (Web Page, 8 December 2021) <https://animalsaustralia.org/latest-news/australia-secret-animal-experiments/>.
[27] 'Animal Experiments. Get educated.'(n 21)..
[28] 'Animal Experiments. Get educated.' (n 21)..

Humane Research Australia estimates that between 2000 and 2009, at least 648 non-human primates were imported into Australia for research purposes. Many breeds of this species are considered critically endangered due, in most part, to habitat destruction and illegal poaching.[29] Pigtail macaques imported from Indonesia, for instance, are threatened by the destruction of their habitat, and by pollution.[30] While Australia has a policy against importing wild-caught animals, a lack of accountability throughout the importation process makes the policy almost impossible to enforce.[31]

Transportation causes profound negative and lasting effects on the primates. It is proven to cause serious psychological harm on top of the suffering already endured in the cruel capture and removal from habitat and family groups. Individual animals are separated into single cages for medical investigations and quarantine a few weeks before the journey.[32] The animals are then transported singly as cargo in small, cramped crates, usually too small to allow them to stand up, and travel as cargo where they may become ill or die in transit while for others anxiety and stress can lead to infection and the onset of disease.[33]

Australia's travel guidelines

There is a lack of oversight in the transporting of primates to Australia, especially given the inappropriate conditions and the harm a long-haul flight inflicts on an animal. There is no specific requirement that any transport code be adhered to other than the *Environment Protection and Biodiversity Conservation Act 1999*, however it only "requires that the transport of live animals be done in a humane way". It is unclear who is responsible for the animals' welfare once they are in transit from the country of export. The NHMRC Guidelines make no specific allowance for travel time or frequency of feeding or watering and veterinary intervention and treatment essential for animals in physical distress is impossible to provide during air transit.[34]

The international transport of live specimens must comply with the International Air Transport Association Live Animal Regulations. These regulations are the worldwide standard for commercial airlines to ensure all

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[29] 'Australia's secret primate experiments' (n 26).
[30] Scientific research on primates: what do we owe animals like us? (n 25).
[31] 'Australia's secret primate experiments' (n 26).
[32] Sentient The Veterinary Institute for Animal Ethics and Barristers Animal Welfare Panel, Submission No 56 to Senate Standing Committees on *Environment and Communications, Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015* (2015) 1-2.
[33] Cruelty Free International, Submission No 48 to Senate Standing Committees on *Environment and Communications, Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015* (2015).
[34] Parliament of Australia, *Australian Greens' Dissenting Report (Report on the Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports for Research) Bill 2015)* 2015, para 1.75 ('*Australian Greens' Dissenting Report*')

animals are transported safely and humanely by air. However, the IATA is a trade organisation, meaning their regulations are not a worldwide standard for ensuring all animals are transported safely and humanely by air.[35]

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

Disclosure

The Committee submits that a system of mandatory public disclosure regarding the number and species of animals used, the aims of the research, the procedures employed, justification why alternatives could not be used, and the outcomes for those animals ought to be introduced.[36]

Presently, animal experimentation in NSW is subject to a system that relies too heavily on self-regulation under the *Animal Research Act 1985* (**ARA**).[37] This system does not incorporate adequate independent assessment and imposes very little accountability upon the industry.[38]

Despite the large number of animals involved in medical experimentation and the fact that most of such research is funded by taxpayers through the NHMRC, most of these experiments remain secretive and avoid public scrutiny.[39] For instance, details of ethical assessments made by the Animal Ethics Committees (**AEG**), which operates under NHMRC's code, remains largely unavailable to the public.[40]

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[35] Ibid, para 1.73.
[36] Monika Merkes and Rob Buttrose, 'Scientific research on primates: what do we owe animals like us?' *The Conversation* (Webpage, 5 February 2013) <https://theconversation.com/scientific-research-on-primates-what-do-we-owe-animals-like-us-11673>; *Australian Greens' Dissenting Report* (n 34).
[37] 'Animal Experimentation in Australia: the Horrifying Reality', *Animal Justice Party* (Webpage) <https://nsw.animaljusticeparty.org/animal-experimentation-in-australia/>.
[38] Ibid.
[39] Ibid; Monika Merkes and Rob Buttrose, 'The elusive ethics of animal ethics committees', *The Conversation* (Webpage, 20 November 2012) <https://theconversation.com/the-elusive-ethics-of-animal-ethics-committees-10056>; Merkes and Buttrose, 'Scientific research on primates: what do we owe animals like us?' (n 36).
[40] Monika Merkes and Rob Buttrose, 'The elusive ethics of animal ethics committees' (n 39); Denise Russell, 'Why Animal Ethics Committees Don't Work', *Between the Species* (2012).<https://digitalcommons.calpoly.edu/cgi/viewcontent.cgi?article=2002&context=bts>.

The Committee further submits that more robust requirements regarding financial disclosure to the public ought to be introduced.

Firstly, although the NHMRC is funded by taxpayers, animal testing has been recognised by scientists as costly, time-consuming, and not very effective.[41] If this is the case, then clear, publicly available details and explanations are needed to ensure accountability and that the allocation of those public resources can be justified.[42]

Second, many elements of animal experimentation remain highly profitable and globally active.[43] If the industry is to draw on public funding, while also agitating the public interest in the maintenance of animal welfare standards and legislation, the Committee submits that financial disclosure is necessary to ensure that any unnecessary cruelty in pursuit of those (in some cases derived from public funding) financial gains does not escape scrutiny.

Finally, such disclosure may be necessary at times to enhance the independence of independent members of AEGs, which is arguably lacking in the present.[44] This is of particular concern when maintaining transparency among research facilities is hampered by:

A) failures to maintain adequate care for animals' needs as only been noticed, highlighted and responded to with legal enforcement in cases where significant resources (e.g. Court-related fees and investigative costs) and lengthy processes have been engaged;[45] and

B) facilities being unwilling to divulge information on the basis that they constitute trade secrets – in the Committee's view an insufficient rationale in the context of (sometimes publicly funded) animal welfare and cruelty considerations. Although the *Industrial Chemicals Act 2019* (Cth) restricts animal testing on chemicals that are intended to be used in cosmetics, it does not address chemicals in household cleaning products which are nonetheless found in many cosmetic products.[46] The new law does not

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[41] Animal Experimentation in Australia: the Horrifying Reality (n 37); Katrina Sharman, 'Opening the Laboratory Door: National and International Legal Responsibilities for the Use of Animals in Scientific Research' (2006) 2 *Journal of Animal Law*, 67; David DeGrazia, 'The Ethics of Animal Research: What are the Prospects for Agreement?' (1999) 8(1) *Cambridge Quarterly of Healthcare Ethics*, 28.
[42] Ibid.
[43] Animal Experimentation in Australia: the Horrifying Reality (n 37); *Australian Greens' Dissenting Report* (n 34), para 1.47.
[44] Monika Merkes and Rob Buttrose, 'The elusive ethics of animal ethics committees' (n 39); Denise Russell (n 40).
[45] *See,* for example *Australian Rickettsial Reference Laboratory Foundation v Director General, Department of Trade and Investment, Regional Infrastructure and Services (NSW)* [2013] NSWADT 226.
[46] 'Ban on the use of animal test data for cosmetics', *The Department of Health* (Webpage, 05 July 2021) <https://www1.health.gov.au/internet/main/publishing.nsf/Content/ban-cosmetic-testing-animals>; Animal

apply to chemicals that can be used for other purposes, along with cosmetics. Animal protection organisations such as Humane Society International and Humane Research Australia are concerned that companies planning to introduce a new chemical for cosmetics could attempt to bypass the new law by submitting a new chemical application as 'multi-use', such as for cleaning products, together with cosmetics.[47] In the Committee's view, this is a significant loophole in the Federal legislation which ought to be closed through further drafting and amendment.

The 3R principles established under the Code espouse Replacement (i.e. replacing animals in research with non-animal options where possible), Reduction (of the number of animals involved in research, provided the harm to those animals is not then increased) and Refinement (of the techniques and methods used so as to improve welfare outcomes and reduce harm and suffering).[48] However, there is a lack of oversight and compliance in this area.[49] It also does not ensure best practice.[50]

In the Committee's view, clearly worded legislation and policies by the State as well as regulatory bodies including NHMRC ought to be introduced to ensure that the 3R principles are seriously and rigorously applied and enforced by not only the actual research process itself, but also in the decision-making processes and in the granting of permits to import primates and monitoring their compliance.[51]

The Committee would also extend these comments on transparency, oversight and enforcement to the importation of (in particular) primates used in research, whose provenance is not generally ensured or closely interrogated, such that the risk of importing wild-caught animals is not at all remote.[52]

The Committee also submits that a clear requirement to avoid unnecessary pain, harm and/or suffering ought to be incorporated into the legislative regime.

While such matters are generally provided for in the (potentially soon-to-be-amended) *Prevention of Cruelty to Animals Act 1979* (**POCTA Act**), there is an exemption to many of the offences in that Act for cases where

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Experimentation in Australia: the Horrifying Reality (n 37); Be Cruelty-Free Australia, Submission No 15 to Senate Community Affairs Legislation Committee, Inquiry into *Industrial Chemicals Bill 2017* and related Bills, 14 June 2017, 2.
[47] Be Cruelty-Free Australia (n 46).
[48] *Australian Greens' Dissenting Report* (n 34), para 1.25.
[49] Ibid.
[50] *Australian Rickettsial Reference Laboratory Foundation v Director General, Department of Trade and Investment, Regional Infrastructure and Services* (NSW) [2013] NSWADT 226; *USA in Mississippi State University and the IAMS Company v PETA* (No 2006 – CA – 02120 –SCT).
[51] *Australian Greens' Dissenting Report* (n 34) para 1.23;Monika Merkes and Rob Buttrose, 'Scientific research on primates: what do we owe animals like us?' (n 36).
[52] *Australian Greens' Dissenting Report* (n 34)*, paras 1.41 – 1.59.*

the ARA has been complied with. In that interplay between the two statutes, a requirement to even acknowledge, let alone address, animal welfare is lost.

By comparison, section 18 of the *Animal Welfare Act 1985* (SA) (**SA Act**) explicitly requires adequate premises and facilities for animal care and handling as well as adequate veterinary attention to animals subject to licensed animal research. While only a minor element of what the Committee considers ought to be incorporated into the NSW research legislation, it shows how steps can be taken to start to address (in this case quite basic) needs.

Section 25 of the SA Act also requires that the use of the animal be essential for the particular purpose and that persons intend to conduct the research have appropriate experience and qualifications.

A requirement to avoid unnecessary or unreasonable harm would better reflect the purported intention of animal welfare legislation in NSW (and, if the views of the research industry and the Codes that exist within are to be accepted, the intention of the animal research industry and its governance) and remedy a shortcoming that has arisen between the ARA and the POCTA Act.

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

While there are a number of countries that have banned all cosmetic testing on animals, including Australia, the use of animals in medical research is still widely permissible.[53] There are currently no countries which have enforced a blanket ban on both primate[54] and non-human animal experimentation. In 2006, Austria became and remains the only country to ban the use of any testing on all non-human apes (chimpanzees, orangutans, gorillas, bonobos and gibbons).[55]

New Zealand, the United Kingdom and the European Union have a partial ban on experimenting on non-human great apes (hominids[56]). New Zealand granted legal personhood to great apes in 1999 and amended their *Animal Welfare Act 1999* to state that no person may carry out any research, testing, or teaching involving

[53] Animal Experimentation in Australia: the Horrifying Reality (n 37).
[54] A primate includes apes, monkeys and humans.
[55] Animal Experimentation in Australia: the Horrifying Reality (n 37).
[56] A hominid is a member of the family Hominidae, the great apes: orangutans, gorillas, chimpanzees and humans.

the use of a non-human hominid unless such use has first been approved by the Director-General.[57] The Director-General must not give approval unless they are satisfied that the use of the non-human hominid in the research, testing, or teaching is in the best interests of the non-human hominid[58]; or that the use of the non-human hominid in the research, testing, or teaching is in the interests of the species to which the non-human hominid belongs and that the benefits to be derived from the use of the non-human hominid in the research, testing, or teaching are not outweighed by the likely harm to the non-human hominid.[59]

The Committee submits that consideration should be given to the effect of importing certain breeds of primates used for testing. The European Union have recorded breeds of Asian primates used for testing being taken and bred from monkeys taken from the wild, as opposed to being bred in captivity in European countries. These have been described as "lucrative operations...[that] may serve to 'launder' wild-caught monkeys" to sell as captive-bred to the research industry, and which "appear[s] to have resulted in their disappearance even from legally protected areas".[60] This is particularly concerning when 70% of primates in Asia are already listed as threatened with extinction.[61]

In 2010 the EU adopted a Directive on the protection of animals used for scientific purposes which firmly centres the principles of the 3 R's: replacement, reduction, refinement[62]. The Directive sets an ultimate goal of entirely replacing the use of animals for scientific purposes. Currently, there are a limited number of research purposes for which animals are allowed to be used such as basic research,[63] applied research into human and animal diseases and cures, the protection of species and the environment, and education and training.

In 2013, a further Directive was adopted which aimed at improving animal welfare by requiring that scientific procedures involving animals can only take place following a detailed submission of the planned study/studies and subsequent approval by the Health Products Regulatory Authority (HPRA) on the basis of a favourable harm/benefit analysis. There are also a number of reporting requirements such as the use of each animal and the severity experienced by the animal.

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[57] *Animal Welfare Act 1999* (New Zealand), s 85(1) ('*AWA* NZ').
[58] Ibid s 85(5)(a).
[59] *AWA* NZ (n 57)s 85(5)(b).
[60] Ardith A. Eudey, 'The Crab-Eating Macaque (Macaca fascicularis): Widespread and Rapidly Declining' (2008) 23(1) *Primate Conservation* 129, 1.
[61] 'IUCN Red List 2008: Threatened Primates by Family and Region', *IUCN/SSC Primate Specialist Group,*(Web page) < http://www.primate-sg.org/summary_primate_threat_status/>.
[62] 'EU regulations on animal research', *European Animal Research Association* (Web page) <http://www.eara.eu/animal-research-law>; 'Animals used for scientific purposes', *European Commission* (Web page) <https://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm>.
[63] 'Basic research' refers to studies of a fundamental nature, which are designed to add knowledge about the structure, functioning or behaviour of organisms.

In September 2021, the EU Parliament voted in favour of accelerating plans to phase out the use of animals in research, regulatory testing and education. This was done with the understanding that there need to be structures set up to validate and accept alternative methods for animal testing.[64]

The Committee supports the implementation of an immediate ban for any testing on non-human hominids and primates, and a directive to structurally facilitate the use of non-animal testing alternatives, with a view of phasing out animal testing for scientific purposes.

Concluding Comments

NSW Young Lawyers and the Committee thank you for the opportunity to make this submission. If you have any queries or require further submissions please contact the undersigned at your convenience.

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[64] 'European Parliament resolution of 16 September 2021 on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education', *European Parliament* (Web page, 16 September 2021) <https://www.europarl.europa.eu/doceo/document/TA-9-2021-0387_EN.html>; 'MEPs demand EU action plan to end the use of animals in research and testing', *European Parliament* (Web page, 2021) <https://www.europarl.europa.eu/news/en/press-room/20210910IPR11926/meps-demand-eu-action-plan-to-end-the-use-of-animals-in-research-and-testing>.