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

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The Hon Greg Donnelly, BEc MIR MLC – Chair Inquiry into the use of Primates and other Animals in Animal Experiments in New South Wales Portfolio Committee No.2 – Health Parliament House Macquarie Street SYDNEY NSW 2000

Via Inquiry website

31 March 2022

Dear Mr Donnelly,

Letter of support for the submission by *Humane Research Australia (HRA)* to the Inquiry into the use of Primates and other Animals in Animal Experiments in New South Wales

Humane Society International (HSI) Australia welcomes the opportunity to provide this letter to express our full support for the submission by *Humane Research Australia (HRA)* to the inquiry into the use of primates and other animals in medical research in New South Wales (NSW).

We have more than 25 years' experience in Australia working to achieve an ecologically sustainable and humane world for animals. We have been a long-term supporter of the work by HRA, a not-for-profit organisation advocating scientifically valid and humane non-animal methods of research, and we value their expertise and advocacy in this area of animal protection.

Globally, HSI is working to achieve a paradigm shift in health research and safety science that would see human biology as the gold standard, and experiments on animals replaced by human-based micro-physiological, computational, and other non-animal approaches. HSI's global Research & Toxicology program is spearheading two high-impact collaborations – Animal-Free Safety Assessment (AFSA) and Biomedical Research for the 21st Century (<u>BioMed21</u>) – to bring together scientific, corporate and other stakeholders from across the globe to advance our shared vision of a human-focused approach to chemical and product safety and health research.

As stated in HRA's submission, Australia is cited as one of the highest users of animals in research globally¹, with New South Wales typically reporting usage of more than two million animals each year. HSI Australia shares HRA's concerns that despite these alarming statistics, the Commonwealth, State and Territory Governments are still failing to improve transparency and move towards non-animal testing methods despite recommendations made following a 1989 inquiry² into animal experimentation. The committee made these recommendations, among others, more than 30 years ago, which are still yet to be implemented:

- 1) That the Commonwealth, State and Territory Governments publish annually accurate and comprehensive information on the extent and forms of animal experimentation conducted within their respective jurisdictions;
- 2) That the Commonwealth establish a separate fund for research into the use of alternatives to animal experiments.

HSI Australia supports the recommendations detailed by HRA addressing the Terms of Reference, and below we restate them and include further comments of our own:

(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;

HSI Australia believes that artificially inducing symptoms of a human disease in healthy animals does little to replicate the actual disease being studied. HSI Australia supports and reiterates the following recommendations as set out by HRA:

- Extensive independent report evaluating the impact of animal-based research in NSW to be commissioned.
- Retrospective assessments of animal research to be mandatory as a condition of funding and made public.
- Grant evaluation reports to be made public for all publicly funded research.
- Animal care and ethics committee applications for animal-based research to be made public, to enable scrutiny of the proposed cost/benefit assessment.
- Statistics of adverse drug responses to be made public.
- Clinical trial failure rates to be made public.

¹ Taylor, K. and Alvarez, L. R. (2019) 'An Estimate of the Number of Animals Used for Scientific Purposes Worldwide in 2015', *Alternatives to Laboratory Animals*, 47(5–6), pp. 196–213. doi: 10.1177/0261192919899853. <u>https://journals.sagepub.com/doi/full/10.1177/0261192919899853</u>

² Animal Experimentation. Report by the Senate Select Committee on Animal Welfare (1989): <u>https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Significant_Reports/animalwelfarectte/animalexperimentation/index</u>

- Greater scrutiny of basic research using animals.
- Pre-registration of all animal experiments to prevent duplication (see <u>www.preclinicaltrials.eu</u> and <u>www.animalstudyregistry.org</u> for examples)
- (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;

HSI Australia supports the recommendations outlined by HRA, namely that:

- A consistent process be introduced for publicly funded research to record expenditure that involves the use of animals that is accessible to the public.
- The expenditure for the development and validation of non-animal methods (we are not aware of the existence of any such funding programs in NSW currently) is also recorded and reported against.

(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;

HSI Australia supports the suggestions outlined by HRA, namely recommending:

- An ongoing, federally funded research funding stream for the development of non-animal based scientific testing.
- A commitment to developing an Australian Centre for the Development and Validation of Alternatives.
- State and territory funding for the development of non-animal based scientific testing via incentives such as awards, scholarships or research grants.
- Training for journal and grant peer reviewers in non-animal methods.
- All applications to animal ethics committees to provide evidence that alternatives have been sought such as systematic reviews.
- To encourage more progressive thinking than the 3Rs this is missing the 'Relevance R' and simply maintaining the status quo.

HSI Australia supports HRA's suggested 5Rs to replacement:

- 1. Recognise failing preclinical models and discontinue funding
- 2. Redirect funding to human-predictive research methods
- 3. (Re)train scientists in non-animal research methods
- 4. Redesign university curricula to focus on non-animal approaches
- 5. Resolve to phasing out animal use in science, with defined timetable and metrics

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

HSI Australia believes it is unacceptable to cause suffering to animals during research procedures, particularly those that cause significant harm such as forced inhalation research and the forced swim test currently being conducted in New South Wales.

Forced Inhalation Research:

The University of Newcastle and the Centennial Institute are currently conducting inhalation research³ with mice exposed via nose-only or whole-body exposure to cigarettes or other hazardous inhalants. Despite validated *in vitro* and *in silico* technology being available to transition to human-relevant inhalation research, animal models are still frequently used in inhalation toxicology such as these mice in NSW.

There are severe animal welfare outcomes and likely ongoing suffering caused by this invasive research, which subject mice to smoke inhalation experiments for several weeks. The vast physiological differences between mice and humans also means there would be significant limitations to the research and the validity of its outcomes. HSI Australia is strongly opposed to this research as a means of studying local toxicity and associated disease in humans.

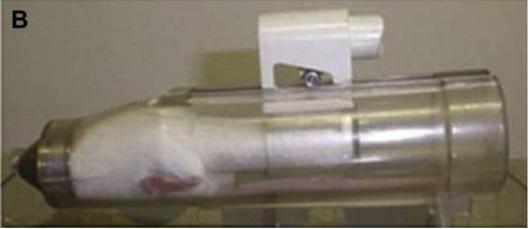


Photo credit: Copyright © Elsevier. Emma L. Beckett *et al* (2013) Image shows a mouse used in forced inhalation testing, nose-only dosing, retrieved from: A new short-term mouse model of chronic obstructive pulmonary disease identifies a role for mast cell tryptase in pathogenesis, *Journal of Allergy and Clinical Immunology*, Volume 131, Issue 3, <u>https://doi.org/10.1016/j.jaci.2012.11.053</u>. (<u>https://www.sciencedirect.com/science/article/pii/S0091674912026425</u>)

³ N Anderson (2021) Optimising inhalation research: Transitioning to human-relevant science. <u>https://www.humaneresearch.org.au/wp-content/uploads/2021/11/Optimising-inhalation-research-transitioning-to-human-relevant-research.pdf</u>

The following images show how these chambers are set up with multiple chambers added to a smoking tower.



Photo credit: HRA, https://www.humaneresearch.org.au/forced-to-smoke/

Forced Swim Test:

Animals such as mice or rats are forced to swim in a cylinder of water during the forced swim test. After some time attempting to escape, they tend to eventually stop struggling and float. They are deemed to be more 'depressed' when they spend more time floating.

A research publication sourced by HRA confirmed that Macquarie University and the University of Wollongong have used this test recently for research on antidepressants. But the forced swim test has been found to be less predictive than chance at determining if a compound would have antidepressant efficacy in humans. Many of the world's top pharmaceutical companies have stated that the forced swim test does not teach us anything reliable about human depression. HSI Australia strongly opposes these forced swim tests.

Primate Research:

As HRA has shared in their submission, 53 primates were used in research in NSW in 2019, according to the Annual Use in Research Statistics Report. 31 of these were used to research human or animal biology, six for human or animal welfare, and 16 for stock breeding. HRA's investigations indicate that most primate research conducted in NSW relates to studies into preeclampsia, diabetes and vision/cognition.

HSI Australia supports HRA's position that the special status granted to great apes on the grounds of moral reasoning should not exclude other primates from the same protection. Non-human primate models have provided disappointing contributions toward human medical advancements, as demonstrated by the references in the HRA submission. HSI Australia is also strongly opposed to the use of dogs and cats in research in NSW, with <u>opinion polls</u> commissioned by HRA in 2018 revealing a similar public consensus.

HSI Australia supports HRA's recommendations to:

- Prohibit the use of forced inhalation research in NSW legislation.
- Prohibit the use of the forced swim test in NSW legislation.
- Commit to a phase-out of primate research.
- Commit to a phase-out of research using dogs.
- Commit to a phase-out of research using cats.
- Introduce mandatory rehoming of suitable dogs and cats used in research (current rehoming guidelines are voluntary).
- Introduce a mandatory retirement age for dogs and cats used in research of 6.
- Fate of all species used in research to be reported.

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

The severe lack of transparency concerning medical research is one of HSI Australia's major concerns. Details of the type of research currently taking place, reasons for it, and the outcomes and so-called benefits remain hidden from public view. It is no wonder then that the usefulness and legitimacy of such research is so often the subject of public debate. This is even more hypocritical when it is the public who are theoretically benefitting from this medical research. Such secrecy ultimately damages the sector itself by promoting a lack of trust and suspicion of the unknown. HSI Australia strongly believes that the whole process from including the process and approval procedures, and results, should be routinely available for public opinion.

HSI Australia supports HRA's recommendations to:

- Publish adverse incident statistics.
- Make list of license holders publicly available.
- Provide details on the numbers of animals bred, but not used, for medical research, instead being killed for no purpose.
- CCTV cameras in research facilities.
- Ability to visit primate breeding colony for media and animal welfare organisations, in accordance with biosecurity measures.
- Ministerial approvals for lethal dose tests to be made public.
- Plain language non-technical summaries of research projects.
- NSW Government to call for a revision to the 2013 National Code. The code currently specifies that research institutes should 'consider making available all annual reports and summaries of external reviews/inspection reports'. We recommend that this should be mandatory.
- Greater scrutiny of undergraduate and postgraduate animal use.

- Consideration of a national body for animal ethics reviews. The equivalent for human ethics is <u>Bellberry</u>, which provides streamlined scientific and ethical reviews of human research projects across the country.

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

HSI's global research & toxicology program works through intergovernmental bodies such as the OECD to accelerate global adoption of modern non-animal testing methods, and through our network of country offices to have these new approaches taken up through national regulations. Their efforts have been instrumental in securing "mandatory alternatives" requirements in Brazil and South Korea, whereby it is illegal for a company to conduct animal experimentation if a non-animal approach is available. HSI is also supporting training in developing countries to help companies and government authorities transition to modern nonanimal methods.

Last month HSI/Europe handed over a 155,000-strong petition demanding action by the EU Commission to phase animal use out of European science and chemical safety regulations. Nearly 10 million animals are used in experiments in EU laboratories annually and this number has remained relatively unchanged in the last decade. In the longer-term, an Action Plan is needed to put the EU on a sustained path to fully end its reliance on animals in biomedical research, toxicology and education. This can be achieved through strategic shifts in science funding and investments in non-animal approaches, modernised regulatory frameworks across product sectors, and other targeted initiatives involving stakeholders. Recently conducted opinion polls confirm that EU citizens prioritise ending animal experiments, with nearly three quarters agreeing that the EU should set binding targets and deadlines to phase out testing on animals.

Polling in South Korea also showed that almost 82% of respondents want to see the 21st National Assembly session demonstrate legislative support for alternatives to animal testing, which includes approaches such as human organ-mimics and tests using human-derived cells instead of experiments on mice, monkeys, and dogs. The nationwide opinion poll conducted by <u>independent polling</u> company Realmeter, and commissioned by HSI/Korea, came just a month after official statistics published by the Ministry of Agriculture, Food and Rural Affairs revealed a total of 3,712,380 animals used for testing in 2019. New federal legislation has since been proposed in South Korea that would prioritise funding for human biology-based approaches in biomedical research.

(g) any other related matter

The fact that more than 90% of drugs found to be safe and effective during animal testing ultimately fail in human trials, according to the National Institutes of Health (NIH), serves as a clear indication of the significant shortcomings of animal research. Tackling human diseases by researching on animals is not working. For effective approaches for new drug discovery, science is increasingly moving away from animal models and applying human-relevant technologies. This direction benefits both animals and humans.

In conclusion, HSI Australia wants to see an end to the use of primates and other animals in medical research due to a number of factors including the suffering and negative welfare outcomes of the animals concerned, the high mortality rates, the lack of transparency of research in Australia, and the questionable benefits achieved.

HSI Australia appreciates the opportunity to comment on this inquiry and is grateful to HRA for their valued expertise and advocacy in this area of animal protection. We hope the recommendations outlined contribute towards a significant reduction in the use of primates and other animals in medical research in NSW.

Yours sincerely

Georgie Dolphin Program Manager – Animal Welfare Humane Society International Australia