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Hon. Greg Donnelly
Chair of Portfolio Committee No.2 Health
Legislative Council
Parliament of New South Wales
Macquarie Street, Sydney NSW 2000

**RE: Additional information for the response to
“Inquiry into the use of primates and other animals in medical research in New South Wales”**

Dear Hon. Greg Donnelly and Committee members,

This letter to the parliamentary inquiry into the use of primates and other animals in medical research in New South Wales, is lodged as additional information of note to the committee for consideration.

In attending the inquiry, I thought that with the title of “Inquiry into the use of primates and other animals in medical research in New South Wales” the use of non-human-primates (NHPs) in research would have been raised at the time that I attended the inquiry. However, to my surprise at NO time did anyone raise the issue of the use of NHP’s with me. As one of the few researchers in Australia using NHP’s for cutting edge research, and as the world expert and President of the International Xenotransplantation Association, I thought that there would have been some questions directed to the use of NHP’s.

I was disappointed that I could not share our world-class, cutting-edge research that has been changing the face of the world in transplantation and helping many thousands of patients in NSW and Australia. Our NHP facilities have been a focus of many reviews and received considerable commendation on the extraordinary care and focus on the overall health and wellbeing of our animals, and the research projects they are part of. Commendation has come from both within Australia from various bodies including the ARRP, JDRF and other research funding agencies and overseas institutions who have sent their own researchers to our institution for training and to ask for help to design their own facilities.

I also wanted to make the point known that the Honourable Ms Emma Hurst has in fact attended our campus on two occasions as a member of the ARRP committee to inspect our facility and animals. On these visits she viewed the NHP facility and several research NHPs for some time, complimenting us on how well our animals were, how well they were cared for and what an amazing facility we have for their housing and care. The facility is at the leading edge of Australian standards and above the global standards in housing for NHPs used in medical research anywhere in the world.

I also wanted to draw the committee’s attention to the fact that for the use of NHPs, there are additional levels of scrutiny, oversight, and regulation, as is appropriate. The Animal Ethics Committee (AEC) oversees all NHP protocols. As background to the extremely rigorous oversight of NHP protocols, there are several AECs that oversee these protocols. All protocols that utilise NHP’s

are reviewed and approved by multiple animal ethics committees that are separate and independent. For example, when an AEC application comes to the Western Sydney Local Health District (WSLHD) AEC it must first have been oversighted by the AEC of Royal Prince Alfred Hospital, who oversight the National Baboon colony. Subsequently, it must also be approved by the University of Sydney AEC and the WSLHD AEC which report directly to the ARRP on these matters. Additionally, there is also oversight from the NHMRC non-human primate (NHP) committee that has responsibility for NHMRC funded projects using NHPs under the “principles and guidelines for the care and use of non-human primates for scientific purposes”, ensuring the rigorous and multiple independent reviews of any application, for any project utilising NHP’s.

Additionally, as outlined in our earlier response to the inquiry, in NSW Animal Ethics Committees (AEC’s) oversight and promote the ethical, humane, and responsible care and use of animals for scientific purposes on all active animal research projects for the many researchers and projects as legislated by the Animal Research Act 1985 No 123 and Animal Research Regulation⁽¹⁾. They also work to the Australian Code for the Care and Use of Animals for Scientific Purposes⁽²⁾. As such in NSW the AEC’s provide significant oversight, and this ensures that all animal protocols are undertaken in a humane and ethical manner as per the Code⁽²⁾. The process of review and the Code were developed over decades to provide the best ethical use and care for animals in research in NSW and Australia, where we have some of the highest level oversight of animal research in the world due to the Australian Code for the Care and Use of Animals for Scientific Purposes⁽²⁾ and appropriate legislation. Many researchers in Australia including myself feel that the legislation is appropriate and provides significant cover for research to be undertaken in a very ethical and scientific manner. Researchers in Australia place significant onus on ethics and undertake research with significant care and respect for the animals within the projects.

Of great concern is if animal research, at any level, is stopped in NSW or Australia then it may well be that these projects will be shifted overseas where they will be undertaken in significantly less regulated or legislated jurisdictions, such as in Asia. Due to increasing legislation in some other countries there is a shift in where research is being undertaken. An example of this is where this is due to several countries limiting the use of Non-Human-Primates (NHP’s), with several larger Asian countries now establishing huge biotech and animal research infrastructure to undertake these research projects. This is occurring from both big pharma and many biotech researchers that require to undertake animal research and don’t have access to it, due to over restrictive regulations in their own countries, such as the UK.

This catering for external research projects is becoming significantly commercialised, and, in these Asian countries, there are limited and very poorly legislated animal welfare and research animal regulations, as compared to Australia.

I have been able to see this firsthand for myself over many years, visiting both China and Korea where there are many Biotech and research hubs being developed. Both countries have significant use of non-human primates in their work, which has expanded significantly over the past few years. I most recently was asked to provide a state-of-the-art lecture at the 2022 International Symposium of the Korean Association for Laboratory Animal Sciences (KALAS) in July, where there were more than 1,300 participants and many private companies exhibiting their products and animal research facilities.

I attach several photos below of one of the exhibition halls at this meeting for your information to see the significant number of company exhibitors using both small animals and NHP’s in their contracted work.



The obvious issues herein are that if animal research in any form moves to another country, or countries, then there may be very limited ethical oversight, nor regulations, for these projects and specifically for the ethical care of the animals. The standard of animal ethics from our own country can NOT be applied there, nor can the appropriate assurance of standard of care to undertake these projects. Additionally, to ensure the research results we would be concerned to use this data to provide applications for advancement of this work to clinical trials.

Even the simplest forms of care may not necessarily be adhered to in these countries. For example, non-human-primates are held in extremely small cages for extended periods of time and do not have access for exercise, sunlight or even appropriate environmental enrichment. Additionally, the way in which the animals are handled, restrained, have injections given, samples collected, biopsied or operated on would be of a much lower standard of care than is undertaken in Australia. The lack of any or all of these can provide undue stress to these animals and as such the integrity of the work being performed is less reliable than is done in a normalised relaxed and caring environment. The overall poorer conditions may well cause stressor effects such as overwhelming release of the stress hormones such as Cortisol, Catecholamines including adrenaline and norepinephrine, as well as Vasopressin, and Growth hormone, which in turn effects the experimental outcomes. We do not have such issues in our facilities or under our protocols and we always ensure the best of standards and care for any research animals.

Additionally, the validity of these experiments may also be questioned due to the lack of overall research governance, data acquisition, data retention, appropriate standards, use of appropriate equipment, sample collection, sample analysis, and data sharing. Again, meaning that to base our applications to move forward with clinical trials would be called into question both on a clinical level as well as a regulatory level. As President of the International Xenotransplantation Association, and as a reviewer of scientific journal submissions, I have rejected several scientific research papers from China and other countries. My decision to reject these scientific papers and the medical advances they report have been based on the inability to accurately verify the data, but more so on the lack of validatable ethical oversight of the animals used to obtain the results. As scientists, we must always apply the most appropriate ethical oversight and best standard of care of animals and patients in the quest for medical advancement.

In NSW the AECs are responsible for approving and monitoring research within Accredited Animal Research Establishments. Regular inspections of these facilities are undertaken by the AEC and the Department of Primary Industry Inspectors (Specialist Veterinarians). They assess all animals actively involved in medical research studies, the research facilities in which the animals are housed, and any work are undertaken.

In these overseas countries there are no inspection of facilities or projects, there is no provision for appropriately legislated cage sizes, dimensions, or characteristics (such as lighting, temperature and humidity control, night day temperature and light cycle) for facilities for animals in which they are

contained. All of these elements are provided in Australian animal facilities due to the adherence of, and due to, the Australian Code for the Care and Use of Animals for Scientific Purposes⁽²⁾.

We acknowledge that it is essential that the New South Wales government have appropriate legislations which efficiently supports and regulates animal research. However, these legislations and regulations should not be increased to become overwhelmingly stifling of research or findings. By restricting the ability of surgeons, researchers and clinicians, the advances in medical sciences and in developing lifesaving treatments for our patients will be dramatically delayed, reduced and potentially stalled. We wish to be able to provide the most appropriate, up to date, ethical, safe and effective health care to our patients.

Please to contact me if you need any further information.

Yours sincerely

Professor Wayne Hawthorne

References:

1. NSW Government. Animal Research Act 1985 No 123. In: Legislation NSW. 2022. <https://legislation.nsw.gov.au/view/html/inforce/current/act-1985-123#>
2. Council NH&MRC. Australian code for the care and use of animals for scientific purposes / Australian Government, National Health and Medical Research Council, Australian Research Council. 8 ed: Canberra, ACT : National Health and Medical Research Council : Universities Australia : CSIRO, July 2013.; 2013.