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Senate Committee

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CRICOS Provider No. 00120C

Re: Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015

Disclaimer: The views expressed herein are solely those of the author (BAL), not the ANU or any other ANU employee or associate

Potential Conflicts-of-Interest: BAL is a scientific advisor to Humane Research Australia (HRA), and also acts as an advisor to the ANU Animal Ethics Committee on the 3Rs and alternatives to animals in scientific research. BAL's own biomedical research endeavours are animal-free and actively employ replacement alternatives to explore fundamental medical research problems.

Dear Senators and Committee Members,

Thank you very much for this opportunity to comment and provide input into the above cited Senate Bill concerning the ban of live (non-human) primates into Australia for research purposes.

In general, I agree with the view presented that there is no need to continue with the importation of live non-human primates (NHP) into Australia for research (including pre-clinical drug toxicology evaluations), most particularly those captured in the wild prior to importation. As stated in the Senate documents, Australia has three NHP-breeding facilities from which to source animals for research.

I would like to add further comment to the wider issue of animals in biomedical research, as raised in the Second Reading speech delivered on 17th September 2015, for example -

Page 7116 – *“The Bill does not ban the use of primates for research per se – the Greens acknowledge this is a separate issue that requires rigorous challenge and examination. There are three government-funded facilities in Australia that breed primates for research ...”*

Page 7117 – *“... which includes the trade in monkeys to supply the booming biomedical and pharmaceutical research industry ...”*

And further:

Page 7117 – *“There is considerable clinical evidence that much animal-based research correlates poorly with the human response. This is confirmed by scientific reviews that show correlations between the results of animal experimentation and human outcomes are negligible, expensive and unnecessary. Most animal*

experiments do not translate to clinical trials, are not validated, minimally cited, and use methodologies that render findings as unreliable”.

On page 7118, the Senator correctly points to a number of alternative techniques that can be used together or separately as biomedical research methods/techniques to replace animals in medical research; the Ames test is a good example of a current, validated animal-free test that replaced an existing animal toxicology test. Animal toxicity testing for botulism toxin is being replaced by an innovative neuronal cell culture system, and the European Centre for the Validation of Alternative Methods (ECVAM) has developed approximately 50 animal replacement alternatives for toxicology testing – in short, this is a dynamic area of pure and applied research with advances made regularly, particularly for toxicology (drugs, cosmetics etc.) and by extension into biomedical (discovery) and pre-clinical research.

There is increasing recognition (via systematic review and meta-analyses of previous research) of the poor predictive capacity of animal studies to inform human physiology and pathology, and hence disease processes and potential interventions. This has been explored primarily for mice, which continue as the favoured animal system for fundamental research. Similar meta-analysis, to my knowledge, has not been conducted for NHPs, and review of the evidence via Internet search reveals the expected division of opinion depending on whether one is engaged in NHP research or in animal welfare.

Thus far the “*Review of Research Using Non-Human Primates*” (the “Bateson Review”), which was released in 2011, stands as a prominent review into the utility and efficacy of NHPs to inform human biology and medicine; interestingly this review has been subsequently subjected to significant criticism, particularly for not being “scientific” enough in its investigations (Ray Greek, Lawrence A Hansen and Andre Menache, *Medicolegal and Bioethics*, 2011:1 3–22). In short therefore, the specific question of NHPs as models for human disease has not been as thoroughly explored as for rodents.

The larger question of non-human animals in biomedical research continues, with the weight of evidence suggesting, as summarised by the Senator in her submission of the 17th September 2015, that they are unreliable as predictors of human health and disease (In a personal communication, the Director of the *Center for Alternatives to Animal Testing* (CAAT) in Baltimore, the United States, says that animal models have a “ ... 90 – 95% failure rate ...”, that being failure to translate into human benefit).

For further discussion of animals in biomedical research, please refer to a Commentary I wrote last year for *MJA Insight* – this article contains embedded links to a number of other resources that have assessed these questions. The link is: <https://www.mja.com.au/insight/2015/14/brett-lidbury-animal-instincts>

Australia must embrace these questions of non-human animals in research and testing, as a priority, to ensure the best possible outcomes in terms of biomedical research translation into tangible human health benefit, based on evidence and not longstanding traditions or cultures. A national centre similar to the *National Centre for the 3Rs* (NC3Rs) in the United Kingdom would be a good start, to stimulate Australian progress in modernising our already excellent performance in scientific enquiry.

Many thanks for considering my submission.

Yours sincerely

Brett A. Lidbury