

12 February 2016

Committee Secretary
Senate Standing Committees on Environment and Communications
PO Box 6100,
Parliament House
Canberra ACT 2600

Dear Committee,

Inquiry into the Environment Protection and Biodiversity Conservation Amendment (Prohibition of Live Imports of Primates for Research) Bill 2015

Thank you for the opportunity to present to you on Friday 5th February concerning the importation of primates for research.

We acknowledge that Humane Research Australia is opposed to significant vested interests and fierce competition from those who wish to retain the right to use animals in research. We therefore very much welcomed the opportunity to have been able to present the case on behalf of primates used in experiments and importantly for the more expeditious advancement of medical research by the use of non-animal alternatives.

As agreed during the session, we attach the following documentation:

- Replacing Primates in Medical Research An expert report by: Dr Hadwen Trust / FRAME / St Andrew Animal Fund.
- Maternal parity affects neonatal survival rate in a colony of captive bred baboons the
 research paper which documents the deaths of baby baboons (torn in two, decomposed
 etc).
- Incidence of lymphoma in a captive-bred colony of hamadryas baboons the research paper referred to in recent media.

We'd also like to take this opportunity to comment on some of the points raised in the submissions and at the hearing.

Perceived necessity of primate use

It is often argued that the use of primates has been instrumental in the development of major medical breakthroughs. The facts¹ show that while animals are widely used for medical research, they are far from being an appropriate model, and certainly could not be accurately credited for any medical 'breakthrough'. The genetic, anatomic and metabolic differences between humans and other animals mean that any data obtained from animal tests cannot be translated to humans with sufficient accuracy. Even when genetically modified, there is no single animal model that can accurately mimic the complex human situation. There are far too many unknown variables that cannot all be accounted for.

Two examples provided in the submissions, and raised by Professor Bourne (including in his <u>open</u> <u>letter</u> on *Speaking of Research*'s website), were the development of the Polio Vaccine and Deep Brain stimulation as a treatment for Parkinson's Disease. These claims are misrepresentative of the historical records.

With regards to the polio vaccine, monkey experiments were involved in its development, however:

- Polio is contracted through the digestinal tract in humans but through the respiratory system in monkeys.
- The original vaccine (having been 'successfully' tested on monkeys) resulted in numerous human deaths and paralysis. Then even further experiments (on monkeys) led to development of a nasal treatment which caused permanent olfactory damage to human children.
- In 1941, Dr Albert Sabin studied human autopsies to disprove the nasal theory and stated: "...prevention was long delayed by the erroneous conception of the nature of the human disease based on misleading experimental models of the disease in monkeys"
- Finally, in 1949, Nobel Laureate John Enders grew the virus in tissue cultures. However he did use monkey tissue which unfortunately resulted in a virus (SV4O) jumping the species barrier to humans. It is now grown in human cell culture outside the human body (and could have been originally).

(Source: Safer Medicines)

More recently, deep brain stimulation for sufferers of Parkinson's disease is often credited to the terribly cruel work with MPTP (1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine).)- treated monkeys, developed after the serendipitous discovery of symptoms of parkinsonism in young drug addicts

Look Back in Anger – What Clinical Studies Tell Us About Preclinical Work Thomas Hartung, Altex 30, 3/13 (http://altweb.jhsph.edu/altex/30_3/FFTHartung.pdf)

¹ "For all indications, 95% of drugs that enter clinical trials do not make it to the market, despite all promise of the (animal) models used to develop them."

Submission 1 - Supplementary Submission

exposed to the narcotic contaminant. Yet the practice has actually been used to treat sufferers since the 1940's - many years before the first ever description of the MPTP-primate model ever existed.²

It is interesting that reference to Hansaard indicates Bourne cited the genetic similarities between humans and other primates as reason for us to use them in research yet contradicted this position when asked about chimpanzees.

Professor Bourne: "Primates share approximately 95 per cent of human genes and a number of anatomical and physiological similarities. For this reason primates are critical to biomedical research targeting the cause, progression, prevention and treatment of a wide variety of diseases."

Senator Rhiannon: "Considering their genome is much closer to ours than the macaques, marmosets and the other primates that we are using, do you think that we should still be using chimpanzees?"

Professor Bourne: "No. And I am going to take that argument to the fact that you are suggesting that everything that we need to decipher from medicine is all about the genetics. If we wanted a 100 per cent correlation between primate and human genetics, that is all about the human. This is not a linear relationship."

In summary, primates have been used throughout history in crude and invasive experiments, but the fact that they were used in the process does not imply nor logically follow that they were a necessary part of the development of medical treatments. FDA data previously referred to showing that 95% of drugs successfully tested on animals failed when translated to humans actually implies the opposite: medical research succeeds *in spite of* animals being used in testing. It also raises the question of how many drugs that failed animal tests may have passed alternative testing regimes on human-like models and therefore been successful in human trials.

NHMRC support of animal research

It was disappointing to hear Professor Anne Kelso speak so favourably of animal experiments when perhaps the CEO, as well as the NHMRC itself, should remain impartial on such an issue.

Prof. Kelso confirmed the extremely high failure rate of drugs tested on animals but advised that a very large number of drugs also failed during the pre-clinical (animal trials).

Kelso: "The great majority of new drugs and treatments that are developed do not make it through the multiple steps of assessment before they go into human trials"

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² Burns RS *et al.* 1983. A primate model of parkinsonism: selective destruction of dopaminergic neurons in the pars compacta of the substantia nigra. PNAS 80:4546.

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It would be useful to know what percentage of drugs which failed those animal tests actually worked in humans. Tamoxifen³ is an example of this - currently widely used in the treatment of breast cancer yet failed in animal tests. It raises the logical question of whether medical research has inadvertently disregarded a potential cure for cancer or any other major illness?

The futility of animal tests was discussed in depth by Dr Andre Menache in his testimony. HRA considers that not only are animal (and in particular, primate) experiments unnecessary, they are also dangerously misleading and are wasting precious resources including tax payer funds which could be diverted to research methods that are more predictive of human outcomes and therefore more likely to result in genuine human cures.

Allowing the importation of primates for research purposes contravenes the 3R's principle which includes the requirement to reduce and replace animals, and the implementation of a ban would therefore be a prudent but small step toward a more humane and scientifically-valid research ethos.

Thank you again for the opportunity to present our case. If there is any further information you require we will be happy to provide it.

Yours sincerely,

Helen Marston Chief Executive Officer, Humane Research Australia

³ The propensity for Tamoxifen to cause tumours in rats was not discovered until the drug had been on the market for many years. Had this been discovered during preclinical trials it would have been abandoned. http://www.huffingtonpost.com/aysha-akhtar/animal-experiments b 4209541.html