## To: Portfolio Committee No. 2 – Health

## From: Troy Seidle, Humane Society International

Re: Responses to supplementary questions arising from 28 June 2022 inquiry into use of primates and other animals in medical research in New South Wales

## Date: 25 July 2022

1. You stated in your submission that in order to promote alternatives, we need "strategic shifts in science funding and investments". Can you explain what you mean by this, and explain how these "strategic shifts" can promote alternatives?

The goal of medical research is to understand the fundamental biological mechanisms in humans that underlie normal development and functioning (i.e. health), as well as how these mechanisms can be perturbed, leading to adverse health outcomes (i.e. disease), in order to inform preventive and therapeutic interventions to alleviate human suffering. However, the reality in much of the world today is that research involving animals continues to receive a substantial proportion of medical research funding, despite the increasingly recognized limitations of the animal model paradigm in delivering relevant and predictive surrogates for human biology and disease.<sup>1</sup> At the same time, years of research and innovation have delivered a suite of powerful and commercially available predictive tools (e.g. human pluripotent stem cell models,<sup>2</sup> organoids,<sup>3</sup> organs-on-chips<sup>4</sup> and computational systems biology models<sup>5</sup>). These state-of-the-art tools can more directly emulate human biology and disease<sup>6</sup> because they are built using healthy and diseased cells and tissues from human donors, as compared to the creation of artificial disease models in other animal species (e.g. by manipulating their genetics, through surgery, infection, trauma or other harmful intervention), which seldom if ever provides a clinically relevant or translatable recapitulation of human biology or disease.<sup>7</sup>

Recognizing that the primary driver for animal-based research is <u>funding</u>, it follows that meaningful progress toward the replacement of animals in medical research is unlikely until the governmental and philanthropic funders of such research come to acknowledge the limitations of animal models and regard human biology-based approach as the cornerstone of medical research going forward.<sup>8</sup> This recognition must then be reflected in all strategic science priorities, funding calls, and awarded grants – a process that would naturally lead to the redirection of funding away from animal models with low human predictivity/translation and towards more predictive, human-relevant tools and approaches.

<sup>&</sup>lt;sup>1</sup> <u>https://www.forbes.com/sites/forbestechcouncil/2022/05/26/the-fallacy-and-future-of-preclinical-drug-development/?sh=2b09b3d25041</u>

<sup>&</sup>lt;sup>2</sup> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3343213/</u>

<sup>&</sup>lt;sup>3</sup> https://www.nature.com/articles/s41580-020-0259-3#:~:text=1%3A%20Comparison%20of%20organoids %20with,%2Dderived%20xenografts%20(PDX).

<sup>&</sup>lt;sup>4</sup> <u>https://emulatebio.com/organ-chips</u>

<sup>&</sup>lt;sup>5</sup> <u>https://en.wikipedia.org/wiki/Modelling biological systems</u>

<sup>&</sup>lt;sup>6</sup> <u>https://www.businesswire.com/news/home/20191106005813/en/Liver-Chip-Predicts-Human-Toxicity-that-was-Undetected-in-Animal-Studies-for-Drugs-Halted-in-Clinical-Trials</u>

<sup>7 &</sup>lt;u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594046/</u>

<sup>&</sup>lt;sup>8</sup> <u>https://www.mdpi.com/2076-2615/12/7/863/htm</u>

2. During this inquiry, we've received evidence of cruelty happening at research facilities in Australia – for example, animals not receiving proper analgesia, mass killings from excess breeding stock, animals having their tails and toes cut off. Do you see a link between incidents of cruelty like this, and a lack of transparency in the animal research industry? If so, how are the two related? Can you explain how transparency could help ensure incidents like this will reduce in occurrence? Are there other changes that will help reduce cruelty incidents?

While I concur that many of the incidents described are unquestionably cruel from an animal's perspective, it should be recognized that many of these are in fact generally accepted and routine practices within the "animal science" community. Overbreeding to maintain colonies of genetically modified mice and other animals, and the "culling" of "surplus", is common across the globe, including countries with arguably the strongest legislative protections for animals in laboratories.<sup>9</sup> The same is true of toe- and tail-clipping<sup>10</sup>, retro-orbital bleeding<sup>11</sup>, use of restraint devices<sup>12</sup>, and countless other painful, invasive or otherwise distressing routine procedures, including common killing methods such as asphyxiation with carbon dioxide gas<sup>13</sup>, neck-breaking<sup>14</sup> and decapitation by guillotine<sup>15</sup>.

From my perspective, these and other horrors come hand in hand with the "laboratory animal" paradigm. Lack of transparency is a symptom rather than a root cause, nor is greater transparency in itself a remedy – although I am supportive in principle of calls for increased documentation of the harms that animals in laboratories experience and the actual medical, scientific and societal benefits (or lack thereof) arising from experiments, and making this information readily available to the public. However, a more direct approach to addressing these institutionalized cruelties is laid out in my reply to the preceding question, which is to redirect research funding away from animal use. A top-level political commitment to substantially redirect public (taxpayer) research funding away from harmful animal use in favour of modern, human-centered approaches. Reducing the scale of animal use should not only lead to a proportionate reduction in incidents, but also an increase in human-relevant research results – a win-win for humans and animals alike.

3. A witness at this inquiry said that in some countries overseas, only animals used in biomedical research are recorded in animal research statistics. By contrast, in NSW, the total number of animals used in research is reported as one statistic, but includes the number of animals used in all types of research e.g. farmed animal research, veterinary research, observational research as well as biomedical research, so it can be difficult to determine precisely how many animals are used for biomedical research only. There has been some suggestion that NSW should only report on animals used in biomedical research (and no reporting on the use of animals in other types of research) – would you support this, or do you think it would be better for the reporting to simply clarify how many animals are used for each type of research (e.g. biomedical research, farm animal research, etc)? Can you explain what the issues are if we stopped reporting the use of some animals in experimentation?

While statistical reporting, like other transparency measures, is not a panacea to the complex challenges posed by the use of animals in science, the more robust and granular the statistics, the better able policy makers and other stakeholders will be to objectively monitor and evaluate trends (including progress toward the oft-stated commitment to reduce, refine and ultimately replace the use of animals) and propose evidence-based interventions. The European Commission's common framework for statistical reporting and content is an example of a granular and robust transparency mechanism that I could recommend for NSW<sup>16</sup>. I would caution against further consolidation – or omission – of categories of animal use from government reporting. A decision to not collect and/or to omit entire categories of animal use would result in an under-reporting of animal use, which could at best be

<sup>&</sup>lt;sup>9</sup> <u>https://www.hsi.org/news-media/home-office-stats-animals-071918/</u>

<sup>&</sup>lt;sup>10</sup> <u>https://research.wayne.edu/iacuc/rodenttailclipping</u>

<sup>&</sup>lt;sup>11</sup> <u>https://web.jhu.edu/animalcare/procedures/retro-orbital.html</u>

<sup>&</sup>lt;sup>12</sup> <u>https://www.lomir.com/animal-restraints/</u>

<sup>&</sup>lt;sup>13</sup> <u>https://www.frontiersin.org/articles/10.3389/fvets.2020.00411/full</u>

<sup>&</sup>lt;sup>14</sup> <u>https://en.wikipedia.org/wiki/Cervical\_dislocation</u>

<sup>&</sup>lt;sup>15</sup> <u>https://www.wpiinc.com/var-2645-rodent-guillotine</u>

<sup>&</sup>lt;sup>16</sup> <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D0569&from=EN</u>

construed as misleading the public, acting in opposition to the goal of transparency, and at worst shielding selected categories of animal use from public scrutiny. Further consolidation of reporting categories could also be seen as a step backwards from a transparency perspective.

4. We heard from an animal care technician during this inquiry who had worked in the US and here in Australia. She highlighted that in the US, if there are welfare issues, there is an independent welfare body someone can complain to with the authority to investigate. She had major concerns that the same did not occur here in Australia – that the oversight body was the institution itself (or the Animal Research Review Panel which is still part of the research industry) with no independent and separate regulatory oversight. Do you have concerns about this state of regulation of animal research in NSW? Do you think the 'self-regulation' system we have is problematic, and will continue to lead to animal protection issues?

Self-regulation is akin to the fox guarding the henhouse – and when the activity being regulated involves inflicting harm and death upon other sentient beings, the presence of "welfare issues" should come as no surprise. It is possible that an independent welfare body could be successful in preventing or remediating some of the incidents reported during this inquiry. However, it should be recognized that from an objective "animal suffering" standpoint, there may be little difference between an authorized procedure (e.g. acute inhalation toxicity test prescribed by Australia's federal regulatory authority for pesticides<sup>17</sup>, in which animals are confined in full-body restraint tubes and forced to inhale extreme concentrations of a pesticide chemical for up to 6 hours – without sedation or pain relief – to identify the dose that kills 50%) and a reportable incident of cruelty. It is likely that the former (routine/authorized cruelties) far outnumber the latter (isolated incidents of cruelty). I note this both for perspective and to highlight the need to government authorities at different levels to better align regulatory safety and animal protective standards to resolve conflicts that currently exist.

<sup>&</sup>lt;sup>17</sup> <u>https://apvma.gov.au/node/905</u>