

Email submission to [mckeonreview@secretariat.com.au](mailto:mckeonreview@secretariat.com.au)

Dear Sir / Madam,

## **Strategic Review of Health and Medical Research in Australia**

Humane Research Australia is a not for profit organisation that challenges the use of animals in research and promotes the use of more humane and scientifically valid alternatives. We welcome this opportunity to comment on a review which we consider to be of utmost importance to the future health of Australians.

### **A snapshot of human health**

According to the Australian Bureau of Statistics, there were 141,070 deaths registered in 2010.<sup>1</sup>

The Australian Institute of Health and Welfare released a report “Australia’s Health 2012.” In it, they list the following major chronic diseases:

| <b>Cause of death</b>    | <b>No. of Male deaths</b> | <b>%</b> | <b>No. of female deaths</b> | <b>%</b> |
|--------------------------|---------------------------|----------|-----------------------------|----------|
| Coronary heart disease   | 12,047                    | 16.7     | 10,476                      | 15.3     |
| Cerebrovascular diseases | 4,514                     | 6.2      | 6,706                       | 9.8      |
| Lung cancer              | 4,791                     | 6.6      | 3,025                       | 4.4      |
| Colorectal cancer        | 2,253                     | 3.1      | 1,812                       | 2.6      |
| Diabetes                 | 2,120                     | 2.9      | 2,050                       | 3.0      |

*Source: AIHW National Mortality database. Leading underlying causes of death, all ages, specific causes, 2009.*

After considering the associated risk factors of these diseases, an earlier report of theirs concludes that:

- More than 85% of adults are not consuming enough vegetables
- One in two adults are not getting sufficient physical activity
- Almost 50% of adults are not consuming enough fruit
- Around 21% of adults smoke tobacco.<sup>2</sup>

Each of these risk factors can be eliminated, meaning that the current leading causes of death are largely preventable.

### **Financial burden on our health care system.**

Cardiovascular disease takes up \$7.9 billion of our health care resources (11%), with the major component being hospital care.<sup>3</sup> The associated risk factors include tobacco smoking, high blood pressure, high cholesterol, physical inactivity, excess weight, poor diet and excessive alcohol use. In fact, almost every category of chronic disease in Australia, including

<sup>1</sup> <http://www.abs.gov.au/ausstats/abs@.nsf/Products/6E41A607F5A48705CA2579C6000F741D?opendocument>

<sup>2</sup> Chronic Diseases and Associated Risk Factors in Australia, 2006. Australian Institute of Health & Welfare.

<sup>3</sup> Australian Institute of Health and Welfare 2012. Australia’s health 2012. Australia’s health series no.13. Cat. no. AUS 156. Canberra: AIHW.

cerebrovascular disease, diabetes, osteoporosis, colorectal cancer and even depression has the same or similar associated risk factors.

Added to these healthcare costs is the publicly funded \$780 million in grant money (much of which is used to fund animal experiments) awarded to researchers by the NHMRC in 2012<sup>4</sup> in an attempt to cure these ailments.

HRA questions why, if we can greatly reduce the incidence of these diseases through lifestyle modification, do we persist with research to cure these ailments, and at the same time subject millions of animals to often painful experiments?

We have other ways of addressing these issues:

**Prevention** – education about smoking, healthy eating, exercise, safe sex.

**Rehabilitation** – for users of drugs and alcohol, which would subsequently decrease the rate of depression and suicide.

**Improved traffic conditions** - driving skills, road conditions, signage and policing of speeding and drug and alcohol users would help reduce the road toll. On average, four to five people are killed every day in crashes on Australian roads. A great many more are seriously injured and permanently incapacitated. In addition to the burden of personal suffering, the monetary cost of road crashes is an estimated \$15 billion annually (1996 data).<sup>5</sup>

Higher investment into these strategies collectively has the potential for saving many more lives than medical research could ever achieve.

If our government is truly concerned about achieving a healthy society then our taxes would clearly be better utilised on the above. A healthier society would also be far less of a burden on our hospital and health care systems.

### **Wastage of research dollars**

In an attempt to rid our society of many illnesses, researchers often turn to animal experiments to find cures or treatments for the (largely preventable) diseases that plague us. When we consider some of the research that has been publicly funded however, we might question the relevance of this 'research' to the improvement in human health. Recent examples include:

- Breast implants in pigs
- Feeding junk food and marijuana to rats
- Administering alcohol to pregnant sheep
- Shaking baby lambs to death<sup>6</sup>

This is just a small number examples to illustrate the blatant absence of sufficient regulation and ethical scrutiny of how our valuable resources are being wasted.

We consider that an essential strategy would be to shift the focus toward health education and lifestyle choices in order to reduce the burden on our healthcare system. It seems absurd that public funding is used to research disease (on the wrong species) whilst we already have the

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<sup>4</sup> NHMRC research funding dataset 2010-2019.

<sup>5</sup> Australian Transport Safety Bureau ([http://www.atsb.gov.au/publications/2006/Road\\_safety\\_in\\_Aust.aspx](http://www.atsb.gov.au/publications/2006/Road_safety_in_Aust.aspx))

<sup>6</sup> <http://www.humanereseach.org.au/case-studies/>

capacity to heal many people who are sick and dying of preventable illnesses due to lack of education and under-resourcing of hospitals and medical staff.

### **Utility of animal experiments**

Even when we consider research that is more directly related to improving human health and therefore perhaps more justified, animal experimentation is not the most efficacious approach. As mentioned on page 28 of the consultation paper, pre-clinical and early clinical trials have been dubbed “Valley of Death #1 and #2 as these stages of development are difficult areas to attract funding. This is because they are the highest risk investment, due mostly to the inefficacy of currently used preclinical testing – animal tests!

Species differences – anatomical, genetic and metabolic differences make animals inappropriate models for human medicine. 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.

According to Food and Drugs Administration (U.S. regulatory authority), nine out of ten drugs deemed successful through animal tests, fail in human clinical trials. Any other industry that boasts a 90% failure rate would be considered absurd. This not only questions the efficacy and very base argument for using animals, but critically raises the question about all the drugs that failed in animals which might have worked in humans. How many discarded cures for cancer?

Researchers are now acknowledging the limitations of animal use but argue that drugs and medical interventions need to be tested in an entire living system. The problem is that they are using the wrong system. Considering the differences that occur on the metabolic, genetic and molecular levels, when applied to an entire biological system those intricate differences become exponential. Pre-clinical testing needs to be conducted in such a way that eliminates the risk of species differences and is instead directly applicable to humans.

There are also cases of safe and efficacious human pharmaceuticals that would not pass rigorous animal testing because of severe or lethal toxicity in some lab animal species. The common cancer drug Tamoxifen, for example, has the opposite effect on several species by promoting oestrogen rather than blocking it, as it does in humans.

Stress in the animal can be caused by routine laboratory procedures, handling, transportation, restraint, even light/dark cycles can affect the emotional and physiological wellbeing of an animal and this can in turn affect scientific outcome due to variations in hormones and pathology. So if such differences can occur between members of the same species with the same genetic make up then isn't it logical that those variances would become exponential when extrapolating data to an entirely different species?

Today, science is studying diseases and drug responses on a very different level than in the 1800s and early 1900s. In the past, science was looking at traits and functions that were largely shared among species thus animals were used as surrogate humans. Science is currently studying disease and drug response at the level where the differences between individual humans are of critical significance.

### **The need for alternative research**

There has been no mention throughout the consultation paper about the need for the development and validation of non-animal methodologies, yet it is imperative that these

avenues are explored further. Animals are not accurately predictive of human outcomes, so we need a better model. Using a model that 'best approximates' the problem is simply not good enough.

In drug testing for example, there are now harmless scientific technologies such as microfluidic chips and microdosing. Not only do these techniques analyse the effects of drugs on an entire living system, they analyse a human living system, eliminating error caused by species differences and resulting in data that is relevant to humans. Whilst no model is perfect, a battery of human-specific methodologies in pre clinical testing is far more predictive than depending on data from another species

Systematic reviews conducted in the areas of toxicity testing and biomedical research have shown that alternatives are far more predictive of human outcomes than data obtained from animals.

Overseas researchers have government funded institutions dedicated to the development and validation of alternative methodologies. The Australian government needs to show a commitment to the development and validation of non-animal methodologies.

### **Summary**

In conclusion, HRA acknowledges the importance of medical research, but considers that the health of Australians would be dramatically improved if greater resources were put into health education to reduce the incidence of illness, and also into our healthcare system to ensure that sufficient hospital beds, medical and nursing staff are available to enable the treatment of disease and illness which we already have the knowledge and capacity to treat. Only then will sufficient financial resources be available for further research – which must then be species-specific.

Additionally, as part of the review, HRA would like to see included:

- A commitment by the Australian government to invest higher resources into the development and validation of alternative methodologies (to using animals).
- Greater transparency and accountability of all research by institutes using animals by making publicly available all annual reports and summaries of external reviews.
- Establishment of an independent body which would enable the oversight, consistency and regulation of all aspects of animal research

Thank you again for the opportunity to comment on this review. Should you require any further information on any issue raised in this submission please do not hesitate to contact the undersigned. In addition we would be more than happy to meet to discuss this review and our response in further detail.

Yours sincerely,

Helen Marston  
Chief Executive Officer