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ADVOCATES FOR
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Giving voice, taking action

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Dear Ms Gibson,

**ADVOCATES FOR ANIMALS' RESPONSE TO
SCIENCE AND INNOVATION STRATEGY FOR SCOTLAND: CONSULTATION PAPER**

Advocates for Animals (Advocates) would like to make the following general response to the consultation relating to the use of animals in experiments in Scotland and the development and promotion of humane alternatives.

Animal experiments in Scotland

A disproportionately large amount of the total British animal experimentation is conducted in Scottish laboratories. Home Office figures show that in 2005 a total of 408,794 regulated procedures were carried out on animals in Scotland - 14.1% of the GB total of 2.9 million experiments.

In the year 2005, 267,960 mice, 56,993 fish, 49,284 rats, 7,854 birds, 5,294 sheep, 3,016 rabbits, 2,944 guinea pigs, 1,308 dogs, 941 pigs, 864 Old World primates, 774 hamsters, 238 amphibians, 69 horses and other equids, 46 New World primates and 4 cats were used in experiments in Scotland.

Scientifically misleading

In addition to the ethical concerns about experiments using animals, the scientific community is itself increasingly questioning the validity of this type of research. In fact, many believe that such techniques are acting as a restraint and hindering the progress of modern science. A British Medical Journal article concluded that animal studies should not be conducted until their validity to clinical medicine has been assessed.

The Home Office has stated that it has not commissioned or evaluated any formal research on the efficacy of animal experiments and that it has no plans to do so. It is paradoxical that the deaths of millions of animals through experimentation in laboratories is a legal requirement, when the validity of the legally required experiments has never been established.

Drug Discovery World states: "It is well known that the rat, dog and sometimes non-human primate models used for toxicological testing often do not predict human response, and thus drug failures occur during clinical development or even later due to unanticipated

*adverse effects in humans.*¹ In fact, Adverse Drug Reactions are one of the western world's biggest killers, accounting for tens of thousands of deaths every year, and an estimated 15% of all hospital admissions.

As the tragic high-profile clinical trial of TGN1412 demonstrated, non-human animals are inappropriate models to predict a drug's safety in humans and can in fact be dangerously misleading. A near-fatal reaction in the six healthy human volunteers humans despite the fact that non-human primates had shown no ill-effects after being given huge doses of the drug. Adverse drug reactions are now one of the western world's biggest killers, accounting for tens of thousands of deaths every year, and an estimated 15% of all hospital admissions. Many newly approved drugs are either withdrawn or relabelled due to unpredicted side effects in humans. All of these drugs are deemed safe through experimentation on animals.

A recent report funded by the NHS examined the concordance between results derived from human clinical trials and the corresponding results from animal experiments for six different medical treatments. The NHS decided to commission the systematic review 'Testing treatments on animals: Relevance to humans' after the Home Office, in 2004, stated that it had never studied whether or not the results from animal experiments can be reliably applied to human medicine. The results highlighted that animal experiments could be misleading and inaccurate when results were relied on in human medicine.

The reality is that science has progressed *despite* experiments on animals, not *because* of them.

Billions of pounds continue to be expended on futile research using animals with only a small fraction of the money dedicated to modern, effective, humane, non-animal research. Advocates believes that the UK Government and Scottish Executive should invest in developing and promoting alternatives to using animals and work towards ending all animal experiments - for the good of both human and non-human animals.

With constantly increasing public concern regarding animal experimentation and a political desire to reduce its level, the future of toxicity testing and medical research lies in the development of humane alternatives to replace the use of animals in these experiments.

Replacing animal experiments in Scotland

It is the failure to develop and validate modern non-animal tests that perpetuates the reliance on out-dated animal experimentation. We believe that Scottish scientists should be leading the way in developing such modern, reliable and effective alternatives, with a view to establishing Scotland as the world leader in such technologies. Such an initiative could be initiated and supported by the Scottish Executive.

Rather than carrying out more vivisection that other countries, Scotland should be leading the way in developing and promoting alternatives worthy of a supposedly compassionate and forward-thinking country in the 21st century.

The following quotes from a wide range of authoritative sources illustrate the breadth of support for the development of alternatives to using animals in experiments:

In 2002, the House of Lords Select Committee on Animals in Scientific Procedures recommended that a national centre should be established to progress the Three Rs (replacing, refining and reducing animal experiments). It stated that: *"The principal justification for such a centre is that all sides of the debate on animal procedures say that animals are highly imperfect models. It will be for the benefit of science, and ultimately of*

¹ *Drug Discovery World* (Winter 2004/2005)

*human health, if better methods of research and testing could be developed...The development of scientifically valid non-animal systems of research and testing is important, not just to improve animal welfare, but to provide substantial benefits for human health*² In response, the Government agreed and added that *"...alternative methods are often, in reality, 'advanced methods' broadening the scope and overcoming some of the limitations of existing animal models."* and *"Replacement methods, such as in vitro screening and computer modelling, can be more reliable, quicker, more efficient and cost effective than animal models".*³

At the launch of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), the then Minister Caroline Flint explained: *"Placing the lead responsibility with the Office of Science and Technology emphasises that the 3Rs, humane experimental techniques, and the development of advanced research methods are part of the mainstream United Kingdom science base. It also acknowledges that Department's leading role in signalling both the financial and scientific benefits of such developments."*⁴

A recent report on the use of primates in research discussed the use of alternatives for medical research and toxicology and stated that *"The considerable promise in this field should compel bodies that fund biological or medical research to take every opportunity of supporting research directed at developing alternative approaches."*

The new REACH (Regulation, Evaluation and Authorisation of Chemicals) legislation states specifically that one of its aims is the *"promotion of alternative methods for assessment of hazards of substances"* and that *"the development of these alternatives should be prioritised in future EU research."*⁵

The Royal Commission on Environmental Pollution (RCEP) reviewed new EU proposals to test and control hazardous chemicals. In supporting non-animal testing approaches, the RCEP wrote *"...rapid progress in genomics and proteomics, in combination with the ever-increasing power of bio-informatics, creates a unique opportunity to improve the predictive power of safety assessments by offering a more effective way to identify toxic hazards."*

The report of the UK Associate Parliamentary Group for Animal Welfare on the use of animals in vaccine testing stated: *"Alternative methods of testing are urgently needed to stop animals suffering in tests of this kind. Indeed, there is a need for more reliable and consistent tests, and alternative methods can and should be superior to the testing methods on animals that are currently in use."*⁶

Novo Nordisk drug company is contributing to EU-wide research to develop and use computer simulations in drug development. A spokesperson said *"We hope that in the future biosimulation will enable us to develop drugs faster and cheaper while at the same time relatively reducing the number of experimental animals and human trials."*⁷

² Select Committee on Animals in Scientific Procedures, vol. 1 – Report, 2002, HL Paper 150-I, p 39 and p 26.

³ Government Reply to the Report of the House of Lords Select Committee on Animals in Scientific Procedures, Session 2001-2002. Presented to Parliament by the Secretary of State for the Home Department, January 2003, p 4 and p 7. Cm. 5729.

⁴ Statement by Caroline Flint, 21 May 2004: The use of animals in scientific procedures: Government plans to establish a national centre for research into the reduction, refinement and replacement (the 3Rs) of animal use and animal welfare.

⁵ *The use of non-human primates in research*. A working group report chaired by Sir David Weatherall FRS FmedSci. December 2006.

⁶ The Associate Parliamentary Group for Animal Welfare report, 2005: The use of animals in vaccine testing for humans.

⁷ EU biosimulation project gets underway. Scrip 17 December 2004.

New molecular techniques for studying DNA, gene activity and biomarkers are revolutionising studies of human populations in understanding health and illness. As the Dr Hadwen Trust for Humane Research says, *“Traditional epidemiology has already underpinned many life-saving public health policies. The new molecular toolbox is dramatically improving epidemiology’s ability to clarify links between exposure and effect, whether in terms of disease, treatments or toxicity, in the species of interest – as well as replacing experiments on animals.”*⁸

The government’s Health and Safety Laboratory is investing considerable funds and effort in the development of computer models (called PBPK models) to improve chemical risk assessment. They write *“The ability to integrate in vitro data into PBPK models enhances the value, and aids the interpretation, of many in vitro techniques proposed as alternatives”* to animals in toxicology research.⁹

There is clearly a huge and growing commercial world market for alternatives to using animals in experiments. The European Commission has established a new partnership with industry to push forward ways to reduce animal use in testing. Launching this partnership, the Vice President of the Commission, Gunther Verheugen, said *“A coordinated approach would finally demonstrate that research in the development of alternatives is not only beneficial for animal welfare but also encourages the development of new markets for these methods... Alternative methods have the potential to increase the credibility and accuracy of tests as well as the safety of human beings. In fact, sometimes human cell models are better at predicting human health effects than the animal model... The development and validation of new methods and strategies will also increase competitiveness of European industry. The alternative method developed to replace the so-called rabbit pyrogen test for bacterial impurities in drugs has proved a major commercial success, and has a world-wide market volume of 200 million Euro.”*

Conclusion

We believe that there are strong moral, scientific and economic arguments in favour of Scotland developing, validating and promoting cutting-edge alternatives to the use of animals in experiments. We urge the Scottish Executive to take the lead in establishing Scotland as a world-leader in this field of science.

Yours sincerely



ROSS MINETT
Director

Information included in these comments was kindly provided by Dr Gill Langley MA PhD (Cantab) MIBiol CBIol, Science Director, Dr. Hadwen Trust for Humane Research. (www.scienceroom.org).

⁸ Combined tactics: the new epidemiology, 2005: In: The Dr Hadwen Trust Science Review 2005, p19-20.

⁹ HSL web pages, 2006: www.hsl.gov.uk/capabilities/pbpbk.htm

Annex B

RESPONDENT INFORMATION FORM: SCIENCE AND INNOVATION STRATEGY FOR SCOTLAND

Please complete the details below and return it with your response. This will help ensure we handle your response appropriately. Thank you for your help.

Name: *ROSS MINETT, DIRECTOR, ADVOCATES FOR ANIMALS*

Postal Address: *10 QUEENSFERRY ST, EDINBURGH, EH2 4PS.*

1. Are you responding: (please tick one box)

(a) as an individual go to Q2a/b and then Q4

(b) **on behalf of** a group/organisation go to Q3 and then Q4

INDIVIDUALS

2a. Do you agree to your response being made available to the public (in Scottish Executive library and/or on the Scottish Executive website)?

Yes (go to 2b below)

No, not at all We will treat your response as confidential

2b. **Where confidentiality is not requested**, we will make your response available to the public on the following basis (**please tick one** of the following boxes)

Yes, make my response, name and address all available

Yes, make my response available, but not my name or address

Yes, make my response and name available, but not my address

ON BEHALF OF GROUPS OR ORGANISATIONS:

3 The name and address of your organisation **will be** made available to the public (in the Scottish Executive library and/or on the Scottish Executive website). Are you also content for your **response** to be made available?

Yes

No We will treat your response as confidential

SHARING RESPONSES/FUTURE ENGAGEMENT

4 We will share your response internally with other Scottish Executive policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for the Scottish Executive to contact you again in the future in relation to this consultation response?

Yes

No

