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From the Rt Hon Alan Johnson MP
Secretary of State for Health



Your Ref: 01090802

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Tessa

23 MAR 2009

Thank you for your letter of 4 March enclosing an example of correspondence you have received from a number of your constituents about Early Day Motion 569 on the use of animals in the testing of medicines and the Safety of Medicines Bill 2009.

The Department of Health agrees that the most reliable methods of testing drugs should be used to reduce the need for animal based research.

The current approaches to drug development, involving an integrated programme of non-clinical testing and clinical trials, have been developed on a scientific basis for over 30 years. Your constituents may be interested to know that, in that time, animal experiments have faced, and continue to face, rigorous scientific evaluation. There is now an extensive list of guidelines on how best to conduct a range of toxicological studies. Scientific journals frequently publish articles questioning the way animals are used as surrogate humans, as well as suggesting ways to improve testing strategies. There are also various groups carrying out research on the efficiency of animal testing. For example, the Safety Working Party of the European Medicines Evaluation Agency collaborates with other scientists in America and Japan through the International Congress on Harmonisation to try to establish standardised methods for testing pharmaceutical products.

Appropriate animal research plays an important role in providing vital safety information for potential new medicines, and there is a rigorous procedure in place concerning the use of any animal in the discovery and development of new medicines.

To obtain a licence for a medicinal product, applicants need to comply with relevant European pharmaceutical legislation. This includes defining the toxicological profile of the product in animal studies, in order to evaluate its safety before humans are exposed to it. Once the pharmacological, pharmacokinetic and toxicological profile of a product has been evaluated in animals, it is then tested in humans.

Many animal studies are designed to provide reassurance before proceeding to human trials, because some aspects of the toxicological assessment of products

cannot be adequately assessed in man. For example, the assessment of the carcinogenic potential and of reproductive effects of new medicines relies on the results of animal studies, for both ethical and practical reasons.

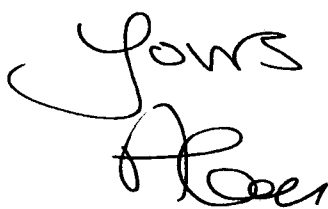
It is extremely regrettable that some people are hospitalized every year as a result of being treated with prescription medicines, but all drugs have some risks attached to their use, even after they have been tested in animals and in clinical trials involving humans.

The Government has made a commitment to minimising the use of animal testing, and to encouraging the development of other in vitro methods in place of animal testing. A National Centre for the Replacement, Reduction and Refinement of Animals in Research (NC3Rs) was established in May 2004, with an initial annual budget of £696,000. In 2008, up to £2.6million was available for research grants and this figure is estimated to increase to just over £5million by 2010/2011. The NC3Rs brings together stakeholders in academia, industry, Government and animal welfare organisations to facilitate the exchange of information and ideas, and the translation of research findings into practice that will benefit both animals and science. The Centre's mission is to advance and promote the replacement, reduction and refinement of research and testing using animals (3Rs), by:

- working with regulators on the acceptance of alternative methods;
- supporting high-quality research that advances the 3Rs; and
- providing advice and guidance on the 3Rs and animal welfare to the scientific community.

The Centre will make an annual report to the Minister for Science and Technology on its activities. More information on the activities of the NC3Rs is available on their website www.nc3rs.org.uk.

I hope this reply reassures your constituents that the Government is committed to ensuring the safety of medicines for patients.

A handwritten signature in black ink, appearing to read 'Alan Johnson', written in a cursive style.

ALAN JOHNSON