The granting of project licences is governed by section 5, which provides that a project licence shall not be granted unless the Secretary of State is satisfied:

- that the programme is to be undertaken for one of the purposes listed (subsection 3),
- that it is not reasonably practicable to achieve the purpose except by the use of animals (subsection 5), and
- that the procedures to be used are those that minimise the numbers and suffering of the animals involved consistent with the results sought (subsection 5) (emphasis added).

The terminology of section 5 in my view suggests both:

- that there is no underlying presumption in favour of the granting of project licences, and
- that the onus is borne by those seeking a licence to establish to the Secretary of State's satisfaction that each of the prescribed criteria is met.

Cost/benefit analysis

The Secretary of State, moreover, is under a clear obligation to "weigh the likely adverse effects on the animals concerned against the benefit likely to accrue as a result of the programme" (subsection 4). The ASPA thus requires in effect that no animal be subject to a procedure unless, and until, an assessment has been made of two factors, namely:

- the likely benefit that might arise from the procedure, and
- the likely adverse effects on the animals who are to be subjected to the procedure.

The ASPA requires then a cost/benefit analysis – as to whether the likely benefit outweighs the likely adverse effects. The phrases "likely benefit" and "likely adverse effects" each incorporate two elements, one quantitative and the other predictive. The Secretary of State accordingly is required to determine not only the degree of anticipated benefit/suffering, but also the predictability of such benefit/suffering.

It is a prerequisite of the application of the ASPA that protected animals are subjected to experimental or other scientific procedures "which may have the effect of causing [them] pain, suffering, distress or lasting harm". In reality, the suffering of animals in laboratories is almost inevitable, and it is the other side of the equation – the benefit likely to accrue, that is variable.

The benefit likely to accrue must be for one or more of the purposes listed in section 5(3). Whereas the purposes include animal beneficiaries, in practice the majority of animals are used for the benefit likely to accrue to humans (although there are some infamous exceptions, e.g. "metabolic" experiments conducted on cats and dogs on behalf of pet food manufacturers). Accordingly, in practice, the cost/benefit analysis that the Secretary of State is required to conduct is between human benefit, both as to significance and predictability, and the adverse effects on the animals involved.

Recalling that it is a prerequisite of the grant of a licence that benefit and predictability of benefit outweigh the adverse effects, and bearing in mind that the latter in practice is almost inevitable, it might reasonably be anticipated that no licence would ever be granted unless and until the Secretary of State was satisfied both as to the significance to human health and well-being of the benefit sought, and as to its predictability. It is in the context of research purportedly for human benefit, however, that questions regarding the legality of vivisection in practice are most readily discerned.

Significance of benefit

It is a popular perception that animals are used only for important medical research. Project licences, however, are sought for such purposes as the development of personal and household products, weapons testing[8] and other purposes of minor, or

[8] The Home Office has adopted a policy against granting licences for "offensive" weapons testing, but "non-offensive" weapons testing continues.

highly questionable, "benefit" to anyone. Furthermore the level of suffering inflicted on the animals involved is often extreme. In so-called "safety" tests, for example, animals are force-fed or injected with enormous doses of various substances such as washing detergents, toilet cleaners, air fresheners, glues, paints, dyes, pesticides, herbicides, solvents and the like.

As stated above, there is no presumption in favour of granting a licence, and those seeking to obtain one accordingly bear the burden of presenting evidence sufficient to satisfy the Secretary of State that the likely benefit outweighs the adverse effects on the animals used. In view of the minor or questionable benefit of many of the purposes for which licences are sought, it is difficult to imagine how those seeking a licence in such cases could discharge that burden. It is even more difficult to imagine how the Secretary of State conducting the cost/benefit analysis required by the ASPA could grant such licences. This, nevertheless, is what has happened and continues to happen.

Predictability of benefit

Even assuming that the potential benefit is of genuine significance, the Secretary of State is also required to assess the predictability of such benefit. Predictability is the *sine qua non* of science – an indispensable condition. A test that cannot be replicated, and is not predictive of outcome (see below), simply has no place in scientific methodology. Without predictability, one strays out of the realms of science and into that of hope and belief – more commonly associated with faith, rather than science (or, indeed, law).

There has, however, never been an evaluation of the ability of animal experimentation to predict outcome (beneficial or deleterious) in humans. Whereas there is much anecdotal "evidence" of instances in which the outcome of animal testing has been reflected in subsequent human application, these are merely examples of coincidence rather than evidence of predictability. By way of illustration, regard the "litmus test".

Litmus paper turns blue in an alkaline solution, and red in an acid. This effect is wholly reliable and is thus of scientific value in terms of indicating the pH of the solution in question. If, however, litmus paper only sometimes turned red in acid and blue in alkali, and on other occasions turned a random and unpredictable colour in either acid, or alkali, the archetypal litmus test would loose entirely its value as a scientific tool. It would not be until further, different tests had been conducted that it could be ascertained whether the information provided by the litmus test had in fact been accurate. Conducting the litmus test would thus have rendered no usefully predictive information because no reliance could be placed on it in predicting the acidity/alkalinity of a substance of unknown pH.

If animal experimentation had any value as a scientific methodology, it would resemble the real litmus paper rather than the hypothetical (and useless) one described in that illustration. There is, however, no clear and irrefutable evidence that animal experimentation is capable of being reliably predictive of benefit (or detriment) to humans. Consider the following:

- In March 2004, Caroline Flint MP, responding on behalf of the Home Secretary to a question asked by Mike Hancock MP, stated that the Home Office had not commissioned or evaluated any formal research on the efficacy of animal experiments, and had no plans to do so.[9]

- According to a report in the British Medical Journal,[10] 5% of all hospital admissions are due to adverse

[9] Written parliamentary question No 148, 25 March 2004.

[10] Pirmohamed, M., "Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients", *British Medical Journal*, Volume 329, July 2004, pp. 15-19.

reactions (ADRs) to prescription drugs, and 2% of those admitted actually die, i.e. more than 10,000 people a year die because of ADRs (more than three times the number killed in road traffic incidents). It is the fourth leading case of preventable death in the UK, and the cost to the NHS is estimated at nearly £500 million a year.

- Dr Richard Klausner, Director of the National Cancer Institute (NCI), has stated: "The NCI believes we have lost cures for cancer because they were ineffective in mice."[11]

- Aspirin causes birth defects in most animals experimented on in laboratories,[12] and Paracetamol is toxic to cats.[13]

- The development of the polio vaccine was delayed for some 25 years. As Dr Albert Sabin, the inventor of the vaccine, explained: "prevention [of polio] was long delayed by the erroneous conception of the nature of human disease, based on misleading experimental models of the disease in monkeys".[14]

- Alexander Fleming abandoned penicillin as an antimicrobial when it proved ineffective on rabbits, only to try it serendipitously – and successfully – in desperation on a critical human patient a decade later.[15] He later admitted that misleading results from animal testing almost prevented the discovery of the entire field of antibiotics.

- No one has ever been able to demonstrate, through animal experiments, that inhaling tobacco smoke – no matter in what quantities or concentrations – causes lung cancer.[16]

- The arthritis drug Vioxx, withdrawn in 2004, appeared safe in animals but is estimated to have killed up to 60,000 people worldwide.[17]

Conclusions

In the absence of any scientific evaluation of the efficacy of animal testing in predicting benefit to humans, the likelihood of benefit to humans is at best an unknown quantity and at worst a deficit.

There are thus no objective and independent criteria against which the Secretary of State could assess the likelihood of benefit in relation to a particular project licence application.

In the absence of such assessment, the Secretary of State cannot be satisfied, in conducting the cost/benefit analysis required by the ASPA, that the likely benefit outweighs the likely adverse effects on the animals.

As such an analysis is a precondition to the grant of a project licence, no such licence should be granted in accordance with the ASPA.

In the absence of a project licence, the cruelty inflicted on animals involved in vivisection is contrary to the PAA.

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[11] *LA Times*, 6 May 1998.
[12] Menache, A., *Animal Experiments, Bad Ethics, Bad Science*, March 2005, p.1.
[13] Ibid.
[14] Statement before the Subcommittee on Hospitals and Health Care, Committee on Veterans' Affairs, House of Representatives, USA, 26 April 1984, serial No 98-48.
[15] Greek, C.R., MD & Greek J.S., DMV, *Specious Science: How Genetics and Evolution Reveal Why Medical Research on Animals Harms Humans*, 2002, p. 107.
[16] Colby, L.A., *In Defence of Smoking*, 1999, Chapter 9, "Smoking Animals"– referring to evidence given in a lawsuit brought in 1998 by the State of Minnesota against tobacco companies during which experts for both the plaintiff (the State) and the defendants (the tobacco companies) agreed that, despite many animal inhalation experiments over a period of many years, all of the experiments had failed (see www.lcolby.com/b-chap9.htm).
[17] *The Sunday Times*, 21 August 2005.