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Animal Aid

Question 1: What is your view about the use of animals in research?

Animal Aid believes that it is morally wrong to capture, incarcerate or experiment on any animal for the benefit of humans or any other animals. In the case of animal experimentation for the purposes of biomedical research, even the supposed justification (ie. benefit to people) is not supported by evidence. On the contrary, animal experimentation is positively harmful to human health (as demonstrated by voluminous evidence) and should cease immediately.

Research involving animals does not provide information that is relevant to human medicine because the data cannot be transferred to humans with any degree of reliability. In fact, studies of the predictability of animal experiments consistently show them to be worse than random guesswork. For example, in one paper[i] which reviewed drugs whose toxicity to humans caused their withdrawal from the market (1960-1990) only 4 out of 24 cases were predictable from animal data. In another review[ii] only 6 of 114 human toxicities had animal correlates.

Many drugs, which have been safety-tested in animals, go on to cause serious side-effects, including death, in people. Adverse drug reactions are the fourth leading cause of death in the Western world, killing over 100,000 people every year in the US alone[iii]. Clearly, the animal tests are failing to protect people.

Hazardous chemicals have long been passed as 'safe' on the basis of tests on animals, thereby giving consumers a false sense of security and causing them to be exposed to dangerous substances without due protection. Two glaring examples are cigarette smoke and cholesterol, both of which were claimed to be safe long after human epidemiological data had shown otherwise. Probably no two mistakes have cost as many lives.

When animals are used as 'models' of human disease, patients suffer as well as animals. For example, dozens of treatments for stroke have been developed in animals but none of them has been successful in humans - in fact, they have harmed patients in clinical trials. We have **lost cures for cancer** because of experiments on animals, according to the US National Cancer Institute.

20 years and vast amounts of resources have been wasted on misleading AIDS research in animals. The first vaccine, Aidsvax - based on success in chimpanzees, was pronounced a failure this year - having failed to protect the 8,000 high-risk volunteers in the trial.

Your other questions about the acceptability of using animals presuppose that animal experimentation is scientifically valid but if, as we maintain, it is not - those questions are merely hypothetical.

Question 2: What are your views about the use of genetically modified animals in research?

There are welfare problems specific to transgenic animals. These fall into two major categories: (a), the production of transgenic (GM) strains, and (b), the compromised welfare suffered by the transgenic animals once they are produced.

Regarding point a), the level of 'wastage' of animals in the production of GM strains is phenomenal: when new genes are injected into an embryo, the proportion of resulting animals who take up the gene can be as low as 1% - the other unwanted 99% are destroyed. In addition, for every GM animal produced, as many as 300 'donor' and 'recipient' animals undergo hormonal injections (which can cause painfully enlarged ovaries); major surgery to implant the embryos; and death, as soon as the required embryos are retrieved from them. Most of these animals are not even recorded in the HO statistics, as they have not undergone an officially recognised 'procedure'. This is despite having been confined in a small, barren cage, forcibly mated, and killed as soon as they have given birth to the offspring for which they were merely a disposable vessel.

Regarding point b), the 'successfully modified' animals (generally identified by cutting off and examining the tips of their tails) will suffer in a variety of ways. They will suffer the intended effects of their gene insertion/deletion. This might be a disorder supposedly analagous to the human ailment being modelled, or it will be the loss of organs and/or their functions, as a result of one or more genes being 'knocked out' in order to discover their function. The effects of this cannot be predicted in advance. Researchers can guess, for example, that knocking out a receptor gene for thrombin (a blood-clotting enzyme) in mice will affect their control of blood coagulation. But only by creating the animals can they discover that such a deletion causes half of the altered embryos to bleed from multiple sites so that they die in the womb.[iv] Other mice have been accidentally produced with no legs or with only one eye.[v]

In addition to these intended defects, a significant proportion of transgenic animals also suffer invisible, internal abnormalities, which may go completely undetected, which may manifest themselves in subsequent generations, and which are entirely unexpected and unpredictable results of the imprecise and uncontrollable insertion of the transgene into the genome of the host. For example, 'giant' mice were given a human growth hormone gene to make them bigger than normal. But they also suffered unplanned-for liver and kidney damage, grossly deformed hearts, spleens and genitalia, together with high infant mortality and a shortened life-span.[vi]

The whole concept of modelling diseases on the basis of their genetic component alone is fundamentally flawed. There is indeed a genetic element to our susceptibility to many diseases, but our genes are not an automatic ticket to illness or health. Other factors such as diet, lifestyle and environmental pollution are far more important in determining whether or not we will succumb to a particular disease at a particular time. Most of us are carrying the genes for a variety of serious diseases but are not suffering from them. This is because these 'disease genes' are not switched on unless triggered through, for instance, exposure to cigarette smoke, a high-fat diet or some other environmental risk factor. Even if one identical twin suffers from a particular disease, the other twin usually does not, showing that genes alone are not enough to cause disease.[vii] (Except, of course, inherited disorders like cystic fibrosis.)

Even when scientists think they have a 'good model' it is difficult to determine how much its attributes are due to its genes or to environmental factors. Wildly differing results have been found to occur in different laboratories using the same strains of animal in the same procedures.[viii]

Scientists claim there are good mouse models of cystic fibrosis but none of the 'CF mouse' strains accurately models the human condition, in which the major symptoms are excess mucus in the lungs, leading to lung infections. The mice, in contrast, suffer principally from bowel disorders and are clearly not a very helpful model of the disease.[ix]

This type of research is accelerating at such an alarming rate that it has already reversed the steady decline in animal usage which has been so hard won over the past 20 years. Just because the animals are mainly mice, does not mean they have no need for proper care and protection: mice are sentient mammals and, as such, deserve to be treated as more than just 'fuzzy test-tubes'. Neither must they be viewed as a 'practice run' before moving on to higher mammals of supposedly greater utility. Andi, the first GM monkey, has already been created in America amid preposterous claims of valuable future models of all kinds of human diseases. ANDi was the only survivor of 224 eggs and 40 implanted embryos who had incorporated the experimental gene (a fluorescence gene from a jellyfish), but even he failed to *express* the gene as expected. The idea that multiple genes for complex diseases can be inserted into monkeys and controlled to turn on or off at the right times, in the right places and to the right extent is clearly pie in the sky, or 'monkeyshine', as the Editor of New Scientist called it.[x] We must recognise that this agenda is being driven by very powerful business interests and not by purported therapeutic need.

Legal protection for GM animals is inadequate and changes in the law are required in order to afford them due consideration. This is, not least, because their use, certainly on its current scale, was not foreseen when that legislation was introduced. Even the Home Office recognised this inadequacy and, in 1999, published guidance notes for project licence applicants intending to create or use GM animals. These notes stipulate, for example, that mice should be at least five weeks old before they can be superovulated by repeat hormone injections - a

week after which they will be killed for egg/embryo harvesting. The notes also specify a maximum of 0.5cm tail-tip removal, or a maximum 15% of total blood volume removal by tail-bleeding for DNA-typing. However, DNA can be typed by faecal or saliva-sampling: clearly these more humane methods should be mandatory. The massive wastage of animals as 'failures' should be prohibited. There are methods (including breeding from homozygous lines and ensuring more accurately targeted transgene insertion) that achieve much greater levels of success and these should be mandatory. Equally significant is that the Home Office notes still classify the production and maintenance of GM animals as 'mild' severity procedures. Yet, as we have seen, the consequences of transgenesis cannot be predicted and often seriously compromise the welfare of the resulting animals.

Altering the genetic material of animals raises a whole host of ethical, moral and religious questions:

- Changing the genetic make-up of an animal compromises its essential nature and fails to respect its unique identity. To many people it is also indefinably 'un-natural'.
- Deliberately designing animals to suffer, as disease models inevitably do, is morally repugnant.
- GM animals are more than likely to suffer in unexpected ways as well as in the ways intended by their manipulators. Altering animals' genes without knowing the consequent harm they will suffer raises fresh ethical problems.
- Because researchers want to protect their 'inventions', each of many thousands of GM animal strains are 'owned' by private patent-holders, who sell them as just so much laboratory equipment. The very idea of patenting life, particularly sentient life, is abhorrent to many.
- A moral dilemma that applies equally to all animal research is this: who are we to decide whether the potential benefits to mankind outweigh the costs to the animals? This 'dilemma' should be resolved, however, when policy-makers understand that the oft-quoted 'potential benefits' are much more usually potential harms to human beings themselves, from bogus and misleading animal results.

Recent research in transgenic mice has demonstrated that the hazards of genetic modification can be completely unexpected and extremely serious: attempts to engineer a contraceptive vaccine, instead produced a deadly virus which killed all the animals in the experiment. The implications for a major bio-hazard within or beyond the research community are chilling to contemplate.

Animal Aid considers the costs inherent in transgenic animal research will always outweigh the supposed benefits, which are exaggerated beyond the bounds of credibility.

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Question 3: What is your view about the use of alternatives?

Proponents of animal experiments claim that medical progress would cease without them. In reality, precisely the opposite would be the case, with immeasurable benefits flowing from the development and application of superior non-animal techniques, a wealth of which we already have at our disposal. The truth is, enormous improvements have been made in the diagnosis and treatment of many diseases, thanks to advances in technology that have nothing to do with animal experimentation. These methods should not be regarded as “alternatives” to animal research as that term implies the animal methods work, which they do not. They have never even been validated. Some of the reliable and productive methods which have yielded knowledge, treatments and cures for human diseases are listed below:

MRI, CAT and PET scanners, for example, allow detailed analysis of the brains and other organs of conscious patients without surgery or even discomfort. Scanning techniques are becoming ever more sophisticated, one impressive new advance being voxel-based morphometric analysis (VBM). 'This is the first opportunity to link brain development and function with the actions of a specific gene', said a leading neurologist. 'The technique will allow accurate measurement of neurological disease progression and the effects of drug therapy.' [xi]

New tissue and organ culture techniques provide human material for analysing disease processes and testing new therapies. At a stroke, interspecies differences that have plagued biomedical research for decades are eliminated. After all, 'the only universal model for a human is other humans.' [xii] British pharmaceutical company Pharmagene tests drugs exclusively on human tissue with the philosophy, 'If you have information on human genes, what's the point of going back to animals?' [xiii]

Computer modelling is a sophisticated way to analyse and design the molecular structure of drugs to target specific receptors. For example, the protease inhibitors given to patients with HIV were designed by computer and tested in human tissue cultures and mathematical and computer models, bypassing animal tests because of the urgent need.[xiv] Research teams around the world are working on a 'virtual human',[xv] which is designed to predict drug metabolism and metabolite interaction with any given organ - information that animal models will never be able to provide.

Autopsy studies are immensely valuable: 'Virtually the whole of modern medical knowledge was created through the study of autopsies.' [xvi] There is still much more to be learned.

Clinical (patient) research and clinical trials of drugs and other therapies are very powerful tools, shaping treatment decisions for individual patients and advancing the standards of medical care. So long as they are conducted responsibly they can make enormous contributions to medical progress. It is imperative that new treatments and medications are tested carefully on patients to

establish efficacy, after all the in vitro and other tests have been conducted to ensure minimum possible risk. Microdoses of drugs can be administered to volunteers and safely tracked through the body using PET scanners, giving valuable information that animals could never provide. Clinical trials would be safer for participants if the animal testing stage was removed. 'It is impossible to establish the reliability of animal data until humans have been exposed.' [xvii] 80% of medicines fail in Phase 1 clinical trials because they are not safe for people[xviii] - even though they have successfully completed safety testing in animals.

Technological improvements continue to be made, and provide potential for substantial medical advancement. It is claimed that human stem cells may be able to repair and even replace damaged organs in the future. Genetic screening could allow medicines to be better tailored to individual patients, thus potentially eliminating many harmful side-effects responsible for so many deaths as described above.

'Alternative' therapies have become much more widely-accepted in recent years with the public turning increasingly to non-allopathic therapies, based on a holistic model of health and disease, whereby the focus is on strengthening and nourishing the body's immune defences rather than making a 'self-destructive' high tech war on pathogens, tumours and the like.

Disease prevention offers the greatest hope for the 'big three' killers - heart disease, cancer and strokes. All the evidence for the major risk factors (smoking, high-fat diets, lack of exercise, etc.) has come from epidemiological (population) studies of people and their lifestyles. Prevention is always better than cure, and as far as illnesses such as AIDS are concerned, prevention is not just better than cure - it is the only cure. **Epidemiology** has taught us how the AIDS virus is transmitted and how we may combat it. Combined with genetic, clinical, *in vitro* and *in silico* research, epidemiology is a very powerful tool whose scope is virtually unlimited.

The results of a ten year multicentre evaluation of *in vitro* cytotoxicology, published in the August 1999 edition of *Toxicology in vitro*, demonstrated that using human tissues to predict human hazard is more accurate than any protocol involving animals or their tissues. The leader of the research group, Dr. Bjorn Ekwall, stated; 'Not only do these non-animal tests have a higher precision than traditional tests, the main advantage of this approach is improved understanding of toxic events.' For example, TRAIL was a promising new cancer drug that appeared to be safe and effective when tested on mice and monkeys, but tests on human liver cells in culture showed it to be highly toxic. The drug would have caused considerable damage or liver failure had it been given to patients.

A wide range of current and future non-animal research methods are being developed by the Dr. Hadwen Trust for Humane Research, the Lord Dowding Fund for Humane Research, FRAME and the Humane Research Trust. As you will no doubt be receiving submissions from them I shall not go into detail here.

The future for medical research is indisputably to use human models for human diseases. At a stroke, inter-species differences, which have plagued biomedical research for

decades, would be eliminated. The reliability of safety prediction in drug testing would be substantially improved, with a concomitant saving of lives, as mentioned in the response to Question 1.

Question 4: What is your view about ethical issues relating to the use of animals in research?

Animal experiments have had a substantially negative cost benefit for human health, as shown by the examples we gave in our response to Question 1. Patients and volunteers are endangered in clinical trials and consumers are exposed to hazardous substances because 'safety testing' in animals is meaningless for humans. Clearly, animal experimentation is unethical for people as well as for animals and so the question as to how much suffering should be allowed in return for benefits to people becomes a nonsense.

Your background notes (p19) point out that almost everyone believes that it is wrong to make animals suffer without reason. We have shown that using animals for toxicity testing and as disease models is not a scientifically justifiable reason to make animals suffer.

On p20, you ask if medical research would be slowed down without animal experimentation, but we argue that precisely the opposite would be the case. The main effect of animal experimentation is to slow down medical research by leading researchers up endless blind alleys. Cancer, diabetes, heart disease - all these diseases and more are ‘cured’ in mice every week - yet how many human cures do we have to show for it?

It is very clear that all animals are capable of suffering pain, fear and distress. It has recently been proven (again!) that even fish feel pain. Broiler chickens have been shown to self-administer analgesics when given the opportunity. There is abundant evidence that animals suffer during research - not only from the 'procedures' but also from the stress of isolation, incarceration, handling, social deprivation, and other insults. There is certainly no need for further 'research' into this area - what is needed is more transparency about the reality of laboratory life for animals so that the public (people whose empathy is intact!) can judge for themselves whether animal experimentation is acceptable. The issue is for society to decide - and in order to make a decision, society must be in possession of all the facts.

Very recent research has demonstrated animals' self-awareness. A team from the University of Buffalo, New York, the University of Montana and Georgia State University report in the December issue of Behavioural and Brain Sciences that bottlenose dolphins and rhesus monkeys are capable not just of thinking, but of "metacognition"; evidence of sophisticated cognitive self-awareness.

Ethics committees are incapable of making objective decisions about the acceptability of animal experiments, as proven in a survey which showed that they

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will approve experiments at their own institution which they would reject at another![xix]

Opinion polls consistently show that a majority of the public opposes animal experimentation[xx], unless they are primed with loaded questions which effectively manipulate them into making the artificial choice between the life of a baby and that of a few rats. This was the tactic employed by the CMP poll cited on p19.

Question 5: What is your view about the UK regulations on research involving animals in the UK?

Section 5(5) of ASPA states that 'an experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of the animal, is reasonably and practically available.' This reveals the extreme weakness of the enforcement of the Act because, were it properly enforced, Section 5(5) would ensure NO use of animals because there is ALWAYS another method which would, in fact, be MORE scientifically satisfactory. This is because the animal model is scientifically invalid for extrapolation to humans, as we have already explained.

The cost-benefit assessment; the central pillar of the Act, has failed completely in its supposed function of preventing futile use of animals: the costs to animals are not given due weight; the costs to people are given no weight! and the supposed benefits are not subject to any objective or scientific assessment of validity. All licence applicants claim their experiment will advance medical knowledge and help towards treatment of a particular disease, but how many of those claims have ever been realised?

Regulations are extremely inadequately enforced, partially because the Inspectorate is so understaffed. 25 inspectors to oversee the conduct of more than 14,000 licence-holders is utterly inadequate. Also, the presumption of the Inspectorate is in favour of animal experimentation: even the House of Lords Select Committee on Animals in Scientific Procedures acknowledges that the Inspectorate is not independent, and should be submitted to external review. Their Report recommended that *"The Home Office Inspectorate should be subject to periodic review, by a body other than the Inspectorate itself".* The House of Lords' Report goes on to comment that *"the current attitude of the Inspectorate and the Home Office is insufficiently self-critical… "* and that *"the Home Office would rather distance itself from problems than be proactive in finding and providing solutions."* The Report concludes that *"the independence of the inspection process and the independence of policy review, centre on the monitoring of the Inspectorate… The independence of the Inspectorate is important if the public is to have confidence in the regulatory system…".*
The majority of the Inspectors are previous animal research licence-holders. Such people cannot possibly afford due weight to the physical and, in particular, the psychological suffering of animals because the level of empathy required to do is unattainable for anyone who finds animal experimentation justifiable. Animal suffering should clearly be assessed by independent animal welfare professionals.

Breaches of ASPA or other welfare recommendations are not dealt with seriously at all. Undercover investigations have exposed extreme suffering and bad practice at HLS, Harlan Hillcrest and Cambridge University within the recent past, but all the offences have been brushed aside by the Home Office as minor one-off incidents not requiring disciplinary action, let alone prosecution - even where the law has been broken. For example, the researchers who deafened and killed mice at Cambridge University last year with loud music and amphetamines, outside of their project licence authorisation, received nothing more than a ticking-off. In fact, there has never been a prosecution of a vivisector under ASPA, despite abundant evidence of serious malpractice and breaches of the law.

This lack of impartiality and lack of enforcement mean we have a system of virtual self-regulation by the research community. Principal Planning Inspector Stuart Nixon, who conducted the recent public inquiry into Cambridge University's proposed primate center, said in his report: "...*those objecting see a system, which is arguably self-perpetuating by way of peer review involving many also involved in similar research. As for licensing/grant applications, while many overseeing this process are not directly involved in animal research today, the scrutiny process is not seen as transparent. From the lack of information and evidence placed before me, I see no reason to disagree".*

Question 6: What do you think about the information that is available to the public about research involving animals?

Details of the majority of experiments (especially those conducted by commercial companies) are not published. Nor is there an opportunity to view applications for project licenses submitted to the Home Office. This is a serious deficiency, given the evidence indicating that licenses continue to be granted for animal research that is unduly cruel, frivolous or repetitious.

Animal Aid believes information about animal experiments should be subject to the new Freedom of Information legislation to enable real assessment of the validity or otherwise of animal research. Anonymised license applications should be published so that advocates for laboratory animals and, indeed, the wider public can actively challenge laboratory animal suffering before it has taken place. It is the public's right to know and to challenge what is being done in their name and with their money.

Genuine issues of commercial confidentiality could be comfortably resolved within a climate of maximum openness. At present, companies involved in carrying out or commissioning animal experiments can assert a right to confidentiality, to the detriment of public health, as well as to animal welfare.

Section 24 of ASPA is an extreme provision by any standards. Not only does it impose a potential two year prison sentence on persons disclosing virtually any

information obtained during the 'exercise of [their] functions', but even the Secretary of State is ensnared by the secrecy requirement. Disclosure to parliament - about wrongdoing, for instance - is prohibited, thus making proper ministerial accountability impossible.

The House of Lords' Report recommends that *"Section 24 of the 1986 Act should be repealed. Specific justification should then be made for each class of information that needs to be kept confidential, such as the identity of researchers and matters of commercial confidentiality and intellectual property".*

The Report goes even further, saying; *"The debate currently centres around what information should be released and made public. We consider that this approaches the question from the wrong direction. There should be a presumption in favour of complete openness, and consideration should then be given as to what information should remain confidential. This would be in line with the provisions of the Freedom of Information Act 2000."*

Animal experiments have for too long been conducted in a climate of secrecy, the justifications for which relate principally to claims for the need for commercial confidentiality and the need to protect the personal safety of individual researchers. Neither of these justifications is plausible. The personal security of researchers would be advanced by a climate of openness, although such a climate would oblige those engaged in animal experiments to seek to convince the general public as to the legitimacy of their activities.

The sweeping away of the secrecy enacted for reasons of 'commercial confidentiality' would be beneficial both to the animal victims of laboratory research and to the general public, who require a right of access to information relating to their own health.

It is worth reiterating, finally, that the secrecy habit pre-dates any fear of animal rights militancy. In 1965, the government's Littlewood Committee Report on Animal Experiments noted that there had been an '...appearance of secrecy about the practice of animal experimentation' and that Home Office inspectors 'have tended to discourage laboratory authorities from inviting individuals or the Press to enter animal houses'.

In 1974, guidance notes compiled by the Research Defence Society and the Home Office recommended researchers to 'aim at a closed community in a self-contained unit with private lift or entrance(s) for staff... not overlooked or, if so, fitted with opaque windows... Premises selected and prepared for experimental animal usage should ideally be in a quiet place undisturbed by traffic and out of sight of the general public and afforded minimal publicity.'

In other words, the paraphernalia of secrecy is in place not to defend vivisectors from an 'extremist minority' but from the majority of the British public, that majority having declared themselves to be against animal experiments on both moral and scientific grounds. [20]

In a recent debate in the House of Lords (17th Oct 03), Lord Lucas said that one of the "principle causes of animal terrorism" was the way information was withheld from the public. He said, "We are not allowing any legitimate democratic discussion of these matters and we should not be surprised when that causes ulcers to erupt on the body politic".

As a final point, Animal Aid does indeed believe that medicines that were developed using research with animals should be labelled to inform people of this fact. The label should be in the form of a government health warning, to the effect that if the medicine is new and thus has not been subject to long-term human exposure, patients should be wary of it and consider using older, tried and tested medicines instead, because the safety information obtained in animal tests has not yet been verified by large-scale human usage and is likely to be found wanting.

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[xx] A May 1999 New Scientist MORI poll revealed that 64 per cent of those questioned oppose vivisection. The level of opposition was confirmed by another MORI poll, published in September 1999 and this time commissioned by Novartis. This showed a 69 per cent disapproval of vivisection. Animal Aid commissioned a poll from NOP in May 1998, which showed a majority of adults aged 14-35 opposed animal experiments on the grounds that the results could not be reliably applied to people. Animal Aid-commissioned NOP polls conducted in April 2003 revealed that 52% of respondents regarded experiments on primates as morally unacceptable. Only 40% said they were acceptable - the remainder fell into the Œdon¹t know¹ or

Œrefused[1] category. When asked whether they believed that results from primate experiments could be reliably applied to people, 43% said they could not, whilst 44% said they could. Amongst the younger age groups, a clear majority regarded such tests as scientifically unreliable.

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