

Europeans *for* Medical Progress

Newsletter Summer 06

Europeans for Medical Progress is a non-profit research and educational institute dedicated to improving human health by modernising biomedical research. We focus on rigorous scientific analysis of animal experimentation to assess the balance of help or harm to human health. We oppose animal modelled research as a method for seeking cures and treatments for human disease based on overwhelming scientific evidence that findings from animal models cannot be reliably extrapolated to humans. When such findings are extrapolated to humans, patients, consumers and research volunteers are harmed and medical progress is hampered. We communicate the urgent need to focus on methods of research that truly serve the interests of patients, rather than corporate finances.

Our educational work functions as a separate charity: EMP Trust.

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INSIDE THIS ISSUE:

- Important media coverage
- Clinical trial fiasco
- Asterand shows the way
- The evidence mounts
- Consequences of medicine without a firm evidence-base
- Winning hearts and minds
- Desperate tactics of opponents
- Government double-speak
- EMP's director back to health

Winning the argument

EMP has been involved in a number of recent debates with members of Pro-Test, the pro-vivisection campaign group founded in January by 16-year-old Laurie Pycroft. Pro-Test claims to have science on its side, yet when asked for evidence that animal testing is vital to medicine, they merely assert that it is 'self-evident' and that anyone who disagrees is irrational or 'anti-science'. Proclaiming to uphold science itself, no less, they should surely welcome an independent scientific evaluation of the effectiveness of animal testing, in order to vindicate their stance. Strangely, they are determined to prevent such an evaluation and have employed a smear campaign against EMP to lobby MPs who support an evaluation to change their minds (see Desperate tactics of opponents). In our view, campaigning against scientific scrutiny of any aspect of scientific practice justifies the label 'anti-science'.

On March 15th, EMP's science director, Dr Jarrod Bailey debated with Pro-Test's Iain Simpson in the House of Commons. Iain Simpson made a case that humans are superior to animals and therefore it is acceptable to use them for our benefit – though he made no convincing case that animal research is, in fact, beneficial.

On May 17th, Sheffield University Debating Society hosted a debate between Dr Bailey and Kristina Cook of Pro-Test in front of an audience of over 100 people. Despite the presence of many Pro-Test supporters in the audience, the motion was carried that: **"This house believes that animal testing is detrimental to human health and should be abolished."** Dr Bailey received the following email from a member of Sheffield's academic staff: *"Dear Dr Bailey, I attended the recent debate on the validity of vivisection, held by the University of Sheffield Debating Society, and would like to congratulate you on the result. I thought you made an excellent case, and defended yourself superbly against the rather malicious (in my opinion) and personal attacks by both Kristina Cook and members of the audience."*

On May 5th, Oxford University's Isis magazine hosted a debate between Kathy Archibald, director of EMP, Oxford neurosurgeon and Pro-Test spokesperson Professor Tipu Aziz, Mel Broughton of SPEAK ('The Voice for the Animals') and Laurie Pycroft, founder of Pro-Test. A transcript of the debate was published in Isis magazine and will be available at www.isismagazine.org.uk. Suffice to say, no cogent scientific case for



Isis debate in Oxford photo credit Isis Magazine

animal testing was made, though Professor Aziz made some extraordinary assertions, such as “Microdosing is not used by drug companies because it’s irrelevant.” It would be interesting to hear GSK, or any pharmaceutical company pass comment on that, following their substantial investment in the technology.

Kathy Archibald pointed out that Vioxx had killed up to 140,000 people, to which Professor Aziz responded “that’s not bad, when you consider how many people benefited from the drug.” While we agree that there’s no such thing as a safe drug, EMP believes that drugs could and should be safer than Vioxx, the drug with the highest fatality record in history.

Pro-Test state on their website that “Every medical advance and all future cures will flow from animal research. Fact - not opinion.” Never mind the fact that the Advertising Standards Authority ruled in October that a similar claim made by the Association of Medical Research Charities was misleading and should not be repeated. Pro-Test’s observation that “there is reason and fact on one side of this debate, and anti-reason and pure emotion on the other” is quite right: the irony is that they have their labels the wrong way round. We look forward to further debates with Pro-Test – the more exposure of the depths of their understanding of science, the better!

The BBC invited EMP to participate in a special Newsnight debate in Oxford on July 27th, which was televised that night. Kathy Archibald was asked to be a key panellist in a Question Time style debate. During many discussions with the producers, we expressed our concern that this debate should not be presented in the way the BBC has always portrayed the issue before: as an ‘emotion versus reason’ impasse, which ignores the perspective of scientists who challenge the dogma that animal experimentation is indispensable to medical progress. We were reassured many times that this perspective would be well represented and that the programme would be scrupulously balanced.

What transpired, however, was a stage-managed ‘debate’ focused on extremism, whose direction had clearly been decided in advance and which merely re-hashed the same clichéd and irresolvable arguments we’ve been hearing for years. Sadly the BBC’s utterly transparent bias on this issue destroyed any prospect of dialogue which might have moved the debate forward and was a blatant attempt to portray those who oppose animal experimentation as deluded, irrational and misanthropic. The explosive issue at the heart of this controversy – the question of whether animal experimentation actually benefits humans – and the denial of scientific scrutiny of that question by the Establishment, will have to wait for a future programme by a neutral broadcaster: we won’t be holding our breath.

Important media coverage

The BBC is not alone: other media coverage of the animal testing issue continues to be spectacularly one-sided. For example, in a two-month period between February and April this year, the Guardian ran 12 articles to the effect that we’d all be dead if not for animal testing and anyone who disagrees is misinformed and anti-science; and only one opposing article, entitled “We’re not terrorists, and we’re not against progress.” This excellent piece by Sharon Howe, who has since founded VERO (Voice for Ethical Research at Oxford) was clearly provoked by the deluge of unreasoned criticism and also by the accusation that opponents of the Oxford animal laboratory are obstructing cures for Parkinson’s and other diseases and denying patients their only source of hope. Sharon Howe’s mother suffers from Parkinson’s disease and, as she points out, “No one could be keener to see a cure for Parkinson’s.” EMP confronted the Guardian with their unbalanced record and was very pleased to secure an article entitled “It’s time to test the testers” which is available on our website. We were also delighted to have an article (a right of reply to an attack on EMP by Tipu Aziz) in the last Oxford Student newspaper of term – again, available on our website. On July 1st, the lead letter in New Scientist was ours:

The MRC and Wellcome Trust’s claim that “many medical advances would have been impossible without experiments on monkeys” (Upfront, 10 June) is simply not true. Their new report claims that benefits from primate research include the polio vaccine and treatments for stroke and Parkinson’s disease, though not a single reference is provided to support those claims.

In contrast, a scientific review of primate research (<http://www.curedisease.net/reports/index.shtml>) citing almost 100 references, shows that monkey experiments delayed the polio vaccine and have failed to produce a single successful treatment for stroke. Deep brain stimulation for Parkinson’s disease is, in fact, a triumph of human clinical observation; not primate experimentation, as an excellent New Scientist article explained (‘The Parkinson’s fix’, vol 183, issue 2457, p40).

There are serious scientific objections to primate experimentation, whose track record is abysmal. 80 AIDS vaccines (50 preventive, 30 therapeutic, according to the NIH) have failed in human trials, following success in primates. TGN1412 failed spectacularly in humans, despite ‘proof of safety’ in monkeys, while tests in human tissue could have averted this fiasco. Scientific justification for such a controversial practice must be demonstrated, not merely asserted without substantiation.

We had many letters published in national and regional newspapers and gave a number of radio interviews, both national and regional. Dr Bailey also appeared on BBC News 24.

Clinical trial fiasco

In March, a spotlight was thrown on the business of clinical trials and the transition from animal tests to human tests, when a phase 1 drug trial being conducted at Northwick Park hospital went horribly wrong, leaving six young men in intensive care with multiple organ failure. The drug, TGN1412, was a monoclonal antibody, designed to calm the immune system in order to help treat leukaemia, multiple sclerosis and rheumatoid arthritis. It had been shown to be safe in animals (cynomolgus macaque monkeys) and authorisation for its administration to the volunteers was given on that basis, which is the standard procedure for clinical trial authorisation. The volunteers' dose was calculated by dividing the animals' dose by an estimated 'safety factor' of 500, again a routine procedure, based on 'allometric scaling factors' no more scientific than educated guesswork. Had a microdose study been conducted, the volunteers would have received a dose approximately 80 times smaller, which may not have had such devastating consequences. The RDS (Research Defence Society) intimates that the actual dose used was a 'microdose' simply because it was 1/500th of the monkey dose, though this description is incorrect and does not satisfy the European Medicines Agency's definition of a microdose.

The young men's plight has been widely reported all over the world, with vivid descriptions of their agony and their appearance as 'elephant men'. Ryan Wilson, the worst affected, is still in hospital awaiting the loss of his fingers and toes. A recent report by immunologist Professor Richard Powell indicates that most of the victims are showing early signs of lymphatic cancer and are likely to suffer a range of premature autoimmune disorders.

The Medicines and Healthcare products Regulatory Agency (MHRA) and the companies involved maintain that this disaster was entirely unpredictable, though Ryan Wilson's solicitor says that "this disaster was bound to happen." Many experts in the field concur with the headline in the Times; "Tests on animals create a false sense of security." Professor Greg Winter, of the Laboratory of Molecular Biology in Cambridge – a key figure in the development of monoclonal antibodies 20 years ago – said it was wrong to make too many assumptions based on animal experiments. According to Dr Camilo Colaco, chief scientific officer of Immunobiology Ltd in Cambridge, "The more we learn about the immune system, the more we realise that the mouse is not a good model for humans." In fact, scientists in Germany have just discovered that mice have a

second thymus, though they have always been used in immunological studies under the assumption that they have one thymus. Concerning the Northwick Park tragedy, Dr David Glover, former chief medical officer of Cambridge Antibody Technology, said "I believe from the basic science it was predictable." Indeed, Asterand plc, the world's leading human tissue company, offers a human tissue array test which would have predicted the severe reactions. Currently, though, animal tests are required by regulators before clinical trials can go ahead, while tests such as Asterand's are not.

The Expert Scientific Group convened by the Government to examine the design of phase 1 clinical trials in the wake of the disaster has issued an interim report which makes several recommendations to improve safety. One recommendation is to calculate safe starting doses in a more scientific manner. They acknowledge that: "Traditional approaches (based on toxicological effect in animal studies) may not be appropriate for calculating doses to administer these drugs ['novel biological molecules'] in first in man studies. Because of the different mode of action of these drugs (and the fact that animal studies do not appear adequately to predict the likely effect in humans) a different basis (eg lack of biological effect) should be used."

Another recommendation is that: "Industry and regulators should consider ways to collect and share information on unpublished pre-clinical studies and phase one trials, to both protect public health and prevent unnecessary duplication of drug development and trials. Although there is a newly created EU database of suspected, unexpected, serious adverse reactions to drugs in trials, there is currently no access to information about drug development nor trials that were halted for safety reasons in the past, nor any international data source."

Asterand shows the way

Asterand plc, formed in January 2006 by the merger of Pharmagene plc and Asterand, Inc. is a leading supplier of high quality human tissue and tissue-based services whose mission is to help the drug and diagnostic industry develop new products and move them into clinical trials faster at less cost and with more confidence. They supply high quality, ethically-sourced human tissue via a global network of over 100 sites. From their newsletter; "Phase Zero Quarterly" July 2006:

Why Use Human Tissues In Research:

- Getting a drug from discovery to market is hugely expensive; realistically, the cost can only be reduced by increasing the efficiency of the process.

- Experience has shown that this will not be achieved while we rely so heavily on data from experimental (ie non-human) species, even 'humanised' versions.
- Rationally, the case for the use of human tissue at all stages of discovery and development is inarguable.
- Reluctance to use human tissues is usually based on perceptions of cost, unacceptable time scales and poor reproducibility. However, nothing is more expensive than studies that mislead. Today, access to human tissues is very much improved, and reproducibility is addressable simply by conducting appropriately designed and powered studies.
- There is no substitute for relevance.

Asterand's Dr Robert Coleman explains: "An enthusiasm for established, available animal models in the face of evidence of their unsuitability for purpose is commonplace. PhaseZERO™ is a collection of human tissue-based capabilities designed to introduce the human element into drug research. In seemingly uniquely human diseases where there is no useful animal model, such as cystic fibrosis, there is little point in utilising animal models at all to provide proof of concept, and work would be better directed towards PhaseZERO™ studies on, for example, human lung epithelial cells *in vitro*."

According to Asterand's founder and CEO, Randal Charlton, "With the mapping of the human genome, everyone needs different kinds of tissue to develop the therapies that will cure the four thousand genetic diseases that afflict mankind." Last December, the Economist, a major international business magazine, described bio banks like Asterand as "the new central banks of medicine." The magazine pointed out that "no major drug can be developed without good tissue-based research." In July, Asterand signed a deal with Mitsui Corporation; one of the largest corporations in the world. "The Japanese pharmaceutical market is a major developer of new drugs," says Randal Charlton. "The use of human tissue in preclinical research can shorten the drug development process. However, Japanese drug research companies have limited access to high quality samples and data and this creates an opportunity for Asterand. We can meet the demand through our world bio-bank and our global network of hospitals that provide ethically consented samples and data for approved research."

EMP was delighted to meet Randal Charlton in Oxford for the Newsnight debate, in which we were so disappointed that he was not given an opportunity to speak.

Mr Charlton is keen to alert the investing public to what Asterand is doing and to enlist their support. If ethical investors wish to support initiatives that will enable the replacement of animal tests by superior tests employing human tissue, they could help accelerate the process by buying shares in companies like Asterand. Such financial backing would enable Asterand and other such companies to offer their expertise to the boardrooms of every drug discovery company in the world and could make massive positive changes in the way new drugs are discovered and developed. Financial reward could be attractive too: according to Dr James Crawford of the University of Florida College of Medicine, "Archived tissue is worth its weight in diamonds."



The evidence mounts

Six recent studies funded by the NHS set out to quantify the relevance to humans of testing treatments on animals. They were conducted by a team of researchers from the Universities of Edinburgh and Birmingham and the WHO Collaborative Center in Maternal and Child Health in Argentina, led by Dr Pablo Perel and Professor Ian Roberts of the London School of Hygiene and Tropical Medicine. The studies ("Testing treatments on animals: Relevance to humans") examined the concordance between systematic reviews of human clinical trials with those of systematic reviews of the corresponding animal experiments.

Treatments for patients should be based on high quality, reliable evidence which is relevant to humans. Where treatments are based on animal research, it must be established that the findings are applicable to humans, in order to avoid endangering human health and wasting resources. Sir Iain Chalmers, one of Britain's leading experts on evidence-based medicine, notes that; "In applied fields like health care, failure to prepare scientifically defensible reviews of relevant animal and human data results not only in wasted resources but also in unnecessary suffering and premature death."

Disturbingly, in these studies, the reviewers found that many of the animal experiments had been poorly conducted, and furthermore, in many instances, the animal research could not be analysed properly due to shoddy reporting of the numbers of animals used and

the statistical methods employed to arrive at the authors' conclusions. Where a clear prediction could be derived, the findings in animals correlated clearly and unambiguously with those in humans in only one instance, that of the use of bisphosphonates to prevent osteoporosis in post-menopausal women. Even here, the authors noted that research in animals continued well after effectiveness was established in humans and that long-term clinical studies and post-monitoring clinical experience in humans, not more animal research, will be more relevant for clinical practice.

In four of the six interventions, the animal studies did not clearly predict the human outcome. In a review of the use of Tirilazad in the treatment of stroke, the animal data clearly predicted improvements in outcome, while in humans the treatment increased the risk of disability or death.

Another review concerned the administration of corticosteroids to patients with serious head injuries, which has been standard practice for 30 years. According to many animal studies, the treatment should have improved the chance of survival. However, a clinical trial involving 10,000 patients was abandoned early when it became clear that the drugs increase the risk of death by 20% within two weeks of treatment. Dr Stefan Sauerland of the University of Cologne estimated that, worldwide, 10,000 people may have been killed by the drugs.

These reviews strongly support the necessity of an evaluation of the efficacy of using animal data to predict human responses for a much wider range of diseases and treatments. Indeed, not to do so is both unethical and unscientific.

The full report is available at www.pcpoh.bham.ac.uk/publichealth/nccrm/publications.htm

The consequences of medicine without a firm evidence-base

A survey published in May (*Archives of Internal Medicine*, 166: 1021) found that, in the US, a fifth of drugs were prescribed for 'off-label' uses, ie. for treating conditions for which the drugs were not approved by the regulator, the FDA. Then the team looked at whether these off-label uses had scientific support, in the sense of having been proven to be effective in controlled clinical trials or at least fairly large observational studies. The team found that three-quarters of the off-label prescriptions had little or no scientific support.

One example of the potential consequences is what happened in the 1980s when doctors prescribed drugs approved to treat severe irregular heartbeat to patients with mild irregular heartbeat. When clinical trials

were eventually carried out in people with mild arrhythmias, they showed that, contrary to all expectations, the drugs doubled or tripled the risk of death. It was later concluded that the heart drugs had killed 50,000 people.

Dr Raymond Woosley, whose team led the clinical trials, said; "It amazes me that you can get on the internet and find out how many suitcases an airline lost this month, but you cannot find out how many people were harmed by a medication." He thinks doctors should record poor drug outcomes in a national computer network that would flag up common problems. This summer, a computer system is being tested in Scotland, which will alert doctors in six surgeries if they prescribe a medicine to children off-label. The system will suggest approved alternatives and record the doctor's decision. If successful, the software will be tried in hundreds of Scottish surgeries. New Scientist magazine observes that vigorous improvements in surveillance of drug prescriptions, and of what happens to the patients who receive them, are essential to drag drug prescribing towards a more evidence-based footing. Dr Randall Stafford, an epidemiologist at Stanford University in California who led the survey published in May, plans to calculate the financial cost of all the new drugs prescribed off-label in the US to people who might not benefit from them at all, in the hope that a mountain of wasted dollars might finally spur some action.

Clearly, better information about drug effects in humans is required before marketing. Post-marketing drug surveillance also has an important role to play. As Dr Marc Berger, Merck's Vice President for Outcomes Research commented; "We have a dearth of information to really know the full risks and benefits of our drugs, not just when they're approved but even years after they've been approved."

The British Medical Association urged doctors to be more vigilant over drug side-effects. Their report in May highlighted the fact that more than a quarter of a million patients are admitted to hospital in the UK each year because of harmful side-effects of drugs.

The FDA admitted in July that several thousand prescription and over-the-counter medicines – including cough medicines, painkillers, sedatives and anti-inflammatory drugs – have never been certified as safe and effective. Even when drugs have been approved, consumers cannot be confident they are safe: Vioxx being a prime example. An anonymous survey of scientists at the FDA published in July by The Union of Concerned Scientists, elicited disturbing comments such as "There is a remarkable amount of pressure to find 'creative' ways to approve problematic drugs."

Consumers International – the world federation of consumer organisations – published a report in June charting the scale of illicit practices by drug companies in the UK and across Europe. The report concludes that drug companies are endangering public health through widescale marketing malpractices, ranging from covertly attempting to persuade consumers that they are ill to bribing doctors and misrepresenting the results of safety and efficacy tests on their products.

Just days later, Sir Iain Chalmers accused the pharmaceutical industry of “blatant scientific misconduct” in an article in the *Journal of the Royal Society of Medicine* (June 29th). He said “If you hide or sweep under the carpet evidence that may be important in informing treatment decisions, that is not just unscientific, it is unethical.” He called for much stricter regulation of the pharmaceutical industry, which endangers patient’s lives by burying bad news from drugs trials.

A study published in June (*Annals of Internal Medicine* 2006;144: 901-12) revealed that 4,000 of the 5,000 deaths related to asthma each year in the US may be due to the drugs rather than the disease itself. The culprit is the long-acting beta agonists, such as salmeterol, contained in products such as blockbuster asthma drug Advair. Researchers from the University of Dundee have found that a specific genetic variant causes salmeterol to be ineffective; giving a sound rationale for personalised prescribing of such risky medicines.

A study presented in February at the annual conference of the American Association for the Advancement of Science showed that children given smaller doses of drugs whose effects have been tested only on adults (which is standard practice) are at greater risk of harmful side effects because the proportions of proteins in the body that control their effectiveness change as children age. Nine out of ten drugs given to newborn babies and 50 per cent of those given to children of all ages have not been tested to ensure that they are appropriate. Studies show that under-18s suffer up to three times more side effects than adults.

Children as young as five have suffered strokes, heart attacks, hallucinations and convulsions after taking drugs to treat attention deficit hyperactivity disorder. Cases in Australia include the sudden death of a seven-year-old, and a five-year-old who suffered a stroke after taking Ritalin.

Professor Graeme Miller and colleagues at the Australian General Practice and Classification Centre in Sydney found that up to two million Australians had reported an adverse drug event to their GP in the last six months, with almost half rated moderate to severe. He said that drug companies conducting trials had to

bear some of the blame for putting drugs on the market without fully gauging the frequency or severity of their side effects.

All of these examples serve to illustrate the futility of studying human diseases and their treatments in animals other than humans. Clearly, our attention should be focused on studying the genetic and other differences between individuals that allow some people to succumb to disease or adverse drug reactions while others do not.

So many technologies allow us to do this today; notably DNA chips, which enable the practice of personalised medicine and the identification of single nucleotide polymorphisms (‘snips’) which correlate with variations in drug response and disease susceptibility.

A new technology called the ‘Smart Petri Dish’ can detect subtle changes in the size and shape of human cells which help to predict responses to drugs. Professor Sangeeta Bhatia explains; “This type of sensor could help us predict human liver responses without patient exposure. This is important because we know that the enzymes that metabolise drugs – the P450 family – are very different in animals and humans. This is one of the reasons many drugs clear animal testing but end up toxic in patients.”

Winning hearts and minds

A large proportion of the public seems to be aware that technologies are available today that render biomedical research on animals obsolete – or at least, not as indispensable as we are often led to believe. The biggest poll on animal testing ever conducted was a Sky News survey in May 2006, in which 51% of almost one million voters said they were not in favour of animal testing. Another Sky News poll, in March, asked ‘Do we need animal testing?’ to which 78% of nearly 56,000 people voted no.

Pro-vivisection campaigners, including Pro-Test and the RDS, frequently claim majority public support for animal testing but this is clearly not the case. We are heartened that people are becoming more informed about the issue and less easily swayed by misleading propaganda in support of animal testing, despite its prevalence. We will continue to acquaint people with the truth whenever we have the opportunity to do so.

Shelly Willetts, communications director of EMP, gave talks to packed audiences at the YAOH festival in Bristol and the Quaker Society AGM in London. Dr Bailey spoke to the Green Party spring conference and to Nottingham University medical school. Kathy Archibald gave a public talk in Bishop’s Stortford, which was splendidly introduced by the local mayor.



We attended the Primary Care Conference in Birmingham where, once again, we were delighted by the level of interest and warmth of the welcome we received from doctors, nurses and other healthcare professionals. Virtually everybody we spoke to agreed with our concerns and fully supported our efforts to achieve an evaluation of the effectiveness of animal testing in biomedicine.

Desperate tactics of opponents

Early Day Motion 92 'Animal Testing of Drugs' has attracted 248 MPs to sign in support of an independent scientific evaluation of the use of animals as surrogate humans in drug safety testing and medical research. This is a phenomenal level of support, representing almost half of the MPs eligible to sign EDMs in parliament. EDM 92 has been among the top 20 most-signed EDMs for several months. Many thanks to all our supporters who have helped to achieve such impressive parliamentary endorsement.

If you have not already asked your MP to sign, please contact us for a pre-written postcard to send as soon as possible: the EDM will close in November, so this is our last opportunity to garner political support for such a momentous evaluation.

Pro-Test has been lobbying their supporters to write to MPs who have signed EDM 92 and ask them to remove their signature. The RDS has sent a derogatory diatribe about EMP to every MP, asking them not to sign EDM 92, or to remove their signature. Evan Harris, the liberal democrat MP for Oxford West and Abingdon, tabled an opposing EDM (1850) to try to divert signatories from EDM 92. This tactic has not been very successful, so Dr Harris has now tabled an amendment to EDM 92 itself. His 'amendment' is a complete reversal of the substance of EDM 92; stating that "this House recognises that medical research using animals is currently both essential and valuable"; attempting to discredit EMP; and claiming that "there have already been numerous independent inquiries into animal research and its efficacy

including by a House of Lords Select Committee, the Animal Procedures Committee and the Nuffield Council on Bioethics, all of which have concluded that the use of animals in medical research and drug safety testing is valid and - at present - necessary."

In fact, an independent scientific inquiry into the efficacy of animal research has never been attempted. The House of Lords Select Committee on Animals in Scientific Procedures was a lay committee, whose focus was largely on legislation, public information and ethics. They clearly did not attempt the rigorous and exclusively scientific analysis suggested by EDM 92. They did, however, acknowledge 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 human health, if better methods of research and testing could be developed."

The Animal Procedures Committee 'inquiry' was not an evaluation of the efficacy of animal research but a review of the cost-benefit assessment employed during the authorisation of animal experiments. It concluded that "it is clear that there is a need for more efforts to assess the value of animal toxicity tests in predicting effects in humans" and that "assessment of scientific validity is thus an essential precursor to cost-benefit assessment per se." Our point exactly.

The Nuffield Council on Bioethics inquiry was into "The **ethics** of research involving animals." They concluded that "it would be desirable to undertake further systematic reviews and meta-analyses to evaluate more fully the predictability and transferability of animal models."

The Government freely admits that it "has not commissioned or evaluated any formal research on the efficacy of animal experiments and has no plans to do so."

EDM 92 seeks an assessment of the relative efficacy of each of the available methods for establishing drug safety to establish which combination of them is most predictive for humans and therefore ensures the best protection of human safety. As animal tests are currently our chief safety screen before new drugs are tested on people, it is only reasonable to compare them against a battery of the new technologies that are now available, including microdosing, microfluidics and human DNA chips. Nothing of the kind has been attempted before. In the light of recent drug catastrophes, such an evaluation is surely the only responsible course of action. Attempting to sabotage such a vital evaluation is extraordinary and begs the question of the motivation behind such sabotage.

Pro-vivisectionists are apparently so desperate to conceal the rational, scientific case against animal testing that they are increasingly demonising scientists who dispute their dogma as ‘animal rights activists masquerading as scientists’ – an accusation they have levelled against EMP many times. The most striking thing about this campaign of vilification is that, rather than engage with our scientific dialogue and provide scientific evidence of their own, they resort to invective and innuendo: the last refuge of those who have no argument in their own defence. Yet the burden of proof is clearly on pro-vivisectionists to convince sceptics – who include 248 MPs and 83% of GPs: hardly an ignorant or extremist minority.

This issue must be judged on facts, not rhetoric. The only way to settle the matter is through an independent and transparent scientific evaluation, which all sides should welcome – unless they fear the outcome.

Government double-speak

Tony Blair signed the ‘People’s petition’ in favour of animal research in May, saying that “There is no alternative for the foreseeable future to using animals if we are to see the full benefits of scientific advances.” In the absence of evidence to support that statement, he employs the common tactic of equating animal research with medical research, thus dismissing all opponents as enemies of medical progress.

Four UK research centres, involving six universities, have been awarded more than £11 million to regenerate training in animal research skills for undergraduate, postgraduate and postdoctoral scientists. This award of mainly public money has been made in response to the identification of a ‘skills gap’ in mammalian biology thought to be caused by a decline in animal physiology education. The awards were made in June with Science Minister Lord Sainsbury’s backing. He said; “The UK is a world leader in medical research and it is essential that we train the next generation of researchers in practical animal research skills so that we can maintain our position.” The problem with this statement is that there is no evidence to suggest that animal research is indispensable to maintaining our position. Lord Sainsbury says that “we all benefit from the vital, life-saving research that takes place in this country.” Nobody disputes that fact but whether we benefit from animal research is a very different question – and one which the Government is at pains not to address.

Andy Burnham, Minister for Delivery and Quality at the Department of Health said in a parliamentary debate on May 23rd; “In recent times, research using animals has led to new treatments and therapies for

many conditions including stroke.” This is an extraordinary claim, considering the fact that there are still no successful drug treatments for stroke, other than one drug (tPA) which was found to be successful in human clinical trials without prior animal studies.

Mr Burnham went on to say that the Northwick Park hospital incident “demonstrated the danger of putting people into early clinical trials when there has not been sufficient animal research.” This claim defies logic and contradicts the many experts in the field who assert that the monkey tests created a false sense of security and could never have predicted the catastrophe, while tests in human tissue could have done.

Evan Harris proposed that medicines should be labelled ‘tested on animals’ to make the public realise that medicines are “only available through research and testing on animals.” Andy Burnham responded that “it has been suggested that some people may be deterred from taking medicines—and there is a financial cost to the NHS of doing so.” Clearly, if people were deterred from taking medicines because they wish to avoid animal-tested products, there are serious implications for their health, which EMP considers more serious than a financial loss to the NHS.

The fact is, animal testing is not responsible for our medicines, which would be safer and more effective if they were tested using more modern and relevant technologies. If the Government introduces such a labelling scheme, it will invite well-deserved legal censure for making such a fraudulent and damaging claim.

EMP’s director back to health

Kathy Archibald has been unwell for some time, owing to an islet-cell tumour in her pancreas. We are very happy to report that surgery was successful and Kathy is making an excellent recovery. Fortunately, her treatment was based on experience from previous patients (naturally!) though if it had been based on what we know of the condition in animals, surgery would have been futile as the disease is invariably fatal.

In a recent study published in the *Proceedings of the National Academy of Sciences* (14th Feb 2006; 103(7): 2334-2339), Professor Per-Olof Berggren of the Rolf Luft Center for Diabetes Research at the Karolinska Institute in Sweden announced; “Our major finding is that human pancreatic islets have a unique architecture, and work differently than rodent islets...We can no longer rely on studies in mice and rats. It is now imperative that we focus on human islets. At the end of the day, it is the only way to understand how they function.”