# Europeans for Medical Progress Trust

### Newsletter Summer 07

**Europeans for Medical Progress Trust** is a registered charity: 1039411. We focus on rigorous scientific analysis of animal experimentation to assess the balance of help or harm to human health. We aim to protect human health by promoting human-specific medical research. We seek to educate the public, scientists, the media and the Government about the sophisticated biomedical research techniques that enable genuinely fruitful study of human biology.

Europeans for Medical Progress is an independent, not-for-profit organisation of scientists dedicated to improving human health by modernising biomedical research. There is alarming evidence that animal experiments provide results that, when applied to humans, can prove misleading or fatal. These tests exhaust precious research funding, waste valuable time, produce ineffective solutions, and delay progress toward human cures.

Help us put patients before profits

Europeans for Medical Progress/ Europeans for Medical Progress Trust PO Box 38604 London W13 0YR 020 8997 1265 info@curedisease.net www.curedisease.net

### **INSIDE THIS ISSUE:**

- Welcome Dr Clotworthy
- Talks and debates
- Meeting at Italian Parliament
- Primate research reports
- Animal testing is it worth it?
- Medical research in the news
- EMP news: EDM 92
- ITV more balanced than BBC
  Submission to Duff report on phase one clinical trials
- Conservative Party Health
  Policy Submission
- Green Party conference

# **Our film: Safer Medicines**

Tony Benn, patron of EMP Trust, launched *Safer Medicines* at a reception in the House of Commons on April 25th. We are immensely grateful to Ruth Winstone, Officer of the House of Commons, for sponsoring our reception, which was a very successful launch to what we hope will be an equally successful film.

*Safer Medicines* is available free at www.curedisease.net and via podcast, or DVD for only £5. The film contains no images of animal testing. This landmark short (half hour) film showcases state-of-the-art approaches to ensuring that drugs in the future will be safer than they have been in the past. World leading scientists from industry and academia present their vision for the future of drug development – with a focus on *human* biology.

Randal Charlton, founder of Asterand, the world's leading human tissue company and Dr Bob Coleman, Senior Scientific Consultant to Asterand, explain how crucial it is to focus on human tissue in drug discovery and development. Dr Greg Baxter, co-founder of Hurel Corporation, introduces the exciting concept of microfluidics. Dr Quin Wills, co-founder of SimuGen, explains what can be achieved with DNA chips in conjunction with advanced mathematical models of how human genes respond to drugs. Professor Denis Noble of Oxford University and a key founder of the Physiome project shows the value of virtual organs such as the virtual heart. Professor Colin Garner of York University and founder of Xceleron describes how microdosing offers a revolutionary approach to drug testing.

Mat Fraser, actor and Thalidomider, argues powerfully that better means to assess drug safety are needed. Tony Benn shows that the case for a scientific evaluation of animal tests for drug safety is unarguable and should be a priority.

"Most MPs and nearly all GPs agree that animal tests must prove their worth: people's lives are at stake. This





Prof Colin Garner Mat Fraser



Prof Denis Noble



**Rt Hon Tony Benn** 



**Randal Charlton** 



Dr Bob Coleman



Dr Greg Baxter



Dr Quin Wills

important film shows that methods are available that promise to reduce the alarming toll of serious adverse drug reactions for the benefit of humanity." **Tony Benn** 

In light of recent drug disasters, such as Vioxx and Northwick Park, *Safer Medicines* proposes solutions to an urgently pressing problem.

We hope that this film – the first of its kind anywhere in the world – will help to show people that there are technologies available that could prove beneficial to patients and consumers as well as the pharmaceutical industry and to laboratory animals at the same time. Many of us have been simply unaware that such sophisticated methods are available and have been persuaded to believe that animal tests are the best or only method we have. We are offering free copies of the film to MPs and hope that it will help to encourage the Government to give this important issue the attention it deserves.

### Action

Watch the film at www.curedisease.net. The film contains no images of animal suffering. Order DVD copies – *only £5!* – for family and friends, your GP and your local secondary school, college or university.

Please ask your MP to watch the film, emphasising its important and positive public health message. A brief sample letter is available on our website.



Dr Margaret Clotworthy

### Dr Clotworthy joins EMP Trust

EMP Trust is flourishing since the arrival of Dr Margaret Clotworthy as our full-time Science Consultant. Margaret is a cell biologist who gained her PhD from Cambridge University. She has experience of developing *in vitro* models

to test treatments for eczema and psoriasis and has worked on cancer therapies in cell culture lines for the pharmaceutical industry. We are delighted to welcome her to the Trust.

### Talks and debates

Dr Clotworthy has already undertaken a number of talks across the country, which have been very well received. An audience of students and staff at Anglia Ruskin University was riveted and asked many excellent and probing questions. Members of the audience at the Green Party autumn conference were so inspired that they requested future talks at their own institutions.

We are particularly pleased to have had the opportunity to speak at two of the UK's growing network of Café Scientifiques: "committed to promoting public engagement with science and to making science accountable." Margaret spoke at the Café Scientifique in both Brighton and Bristol, where the organiser commented that she "gave everyone plenty of food for thought" – precisely the purpose of Café Scientifique.

A talk to the sixth form at Ramsey Abbey College, Huntingdon generated an excellent discussion, as did presentations to the public in London, Nottingham and Bridgewater.

A debate hosted by Greenspeak in Brighton provided a lively exchange, as did a debate with Pro-Test at the London School of Economics in January. Margaret Clotworthy and EMP Trust's director, Kathy Archibald, were invited to debate Professor John Stein and Iain Simpson of Pro-Test. About 50 students and members of the public attended, and we were delighted when a show of hands at the end indicated that two people had changed their minds after hearing the debate.

In contrast to our opponents, the EMP Trust presentations made extensive use of evidence from the scientific literature, centring on the question of whether animal tests benefit humans – as is always assumed. The origins of many of our current treatments were also discussed, and the more sophisticated means by which we hope new drugs will be tested in the future. You can listen to all four speakers on our website.

Debate at London School of Economics



In November, Dr Clotworthy attended 'Risk 2006' – a risk management conference organised by Patients for Patient Safety, part of the World Alliance for Patient Safety. Doctors, nurses and other healthcare professionals at the conference were very interested in our work and overwhelmingly supportive of our aims.

# **Meeting at Italian Parliament**

The 14<sup>th</sup> December saw an exciting meeting to celebrate the life & work of Professor Pietro Croce, pathologist and author of the influential book "*Vivisection or science*", held in a building of the Italian Parliament in Rome. The presence of a translator meant that everybody could profit from listening to speakers from the UK, France and of course, Italy.



Dr Jarrod Bailey

Dr Jarrod Bailey (also Science Consultant to EMP Trust) and Dr Margaret Clotworthy were invited to attend, and Dr Bailey spoke convincingly of the problems that arise from reliance on animal tests to safeguard human health, especially with respect to their use in safety testing for new medicines. He then discussed some of the newer methods now available,

such as microdosing, and told the audience about the success of Early Day Motion 92, which called for an independent scientific evaluation of the merits of animal versus a battery of the newer, human-based tests for predicting the effects of drugs in humans.

Professor Claude Reiss, President of the French scientific committee Antidote Europe, set out an excellent case for adopting newer methods, and elaborated especially on the theme of toxicogenomics, or the use of the latest genetic technologies, to test new drugs for safety, an area in which he has particular expertise.

The meeting was well attended by politicians and the media, who eagerly listened to all the presentations, including several by members of the scientific committee Equivita and other Italian organisations. The Director of WWF Italy, Fulco Pratesi, spoke of their support for the implementation of more accurate non-animal methods when assessing the risks posed by chemicals. The Italian Minister for the Environment eloquently stated his support for the replacement of animal tests with more relevant methods.

We are grateful to the Director of Equivita, Fabrizia Pratesi, for inviting us to the meeting and look forward to continued collaboration with our European counterparts in the future as we strive to modernise toxicological testing for all our benefit.

## **Primate research reports**

The Weatherall Report, which purported to be an independent scientific review of the necessity for the continued use of non-human primates in medical research, was released in December. It is available at www.nhpstudy.com. Predictably, the report concluded, with few exceptions, that primate research should continue. Yet the Chair of the review Committee, Sir David Weatherall, just happens to be Emeritus Regius Professor of Medicine at Oxford University – currently the centre of fierce controversy over the building of its new animal laboratory – he could hardly have concluded otherwise!

Unfortunately, the report contains glaring inaccuracies, including a claim that deep brain stimulation as a treatment for Parkinson's disease was discovered in monkeys when in fact it was discovered and pioneered in human patients.

To its credit, the report did recommend that the major UK funding bodies should constantly review the need for nonhuman primate research and measure its overall impact on scientific and medical advances. Specifically, they should undertake a systematic review of the outcome of all the primate research they have funded over the past ten years.

Chimpanzee Research: An Examination of its Contribution to Biomedical Knowledge and Efficacy in Combating Human Diseases
February 2007
Major Contributors: (in alphabetical order)
Jarrod Bailey, Ph.D. Project R&R: Release and Restitution for Chimpanzees in US Laboratories, Boston, MA
Jonathan Balcombe, Ph.D. Physicians Committee for Responsible Medicine, Washington, DC
Andrew Knight B.Sc., BVMS Animal Consultants International, London, UK
Reviewers and Other Contributors :
Lawrence D'Antonio, Ph.D.
Debra Durham, Ph.D.
Arna nda Greena II, Ph.D.
Annie Hall
Comminiand by <b>Projet R&amp; R: Ritease and Restitution for</b> Chimpanene in U.S. Laboratories a campige of the No England AnK-Visite from Society, Backon, MA Copyright © 200°. Now England AnK-Visite from Society

Fortuitously, a new study by Dr Jarrod Bailey and colleagues, commissioned by Project R&R: Release and Restitution for Chimpanzees in US Laboratories – a campaign of the New England Anti-Vivisection Society – has done just that for chimpanzee research in the ten years between 1995 and 2004. The

study found that the 95 studies examined (randomly selected from a pool of 749 published papers) contributed "*little, if at all, to tangible human clinical progress and practice.*" The study is available to read on our website.

Neurosurgeon Dr Marius Maxwell wrote a scathing critique of the Weatherall report, which can be viewed on our website. He commented: "As a practicing neurosurgeon and neuroscientist with three decades of research behind me, I know only too well that non-human primate research has contributed little, if anything, to the treatment of patients with neurological disorders. The great strides in our understanding and ability to treat such disorders have resulted from human studies. If we want medical progress, we must focus on humans, not monkeys, using today's sophisticated scanners and other state-ofthe-art techniques."

Dr Maxwell also had an article published in the Guardian in February (again available via our website), which concluded: "All the genetic manipulations and wishful thinking in the world will not turn a monkey into a human being. It is time for animal experimenters to admit this and to start pursuing research methods that will help – not harm – desperate human patients."



# Animal testing – is it worth it?

In our last newsletter we commented on the release of an NHS-

commissioned review, investigating the degree to which animal studies predicted the outcome of six major treatments in humans, two of which were withdrawn as a result of harm to patients. The reviewers found that animal studies clearly failed to predict the effects in humans in two cases, leading to thousands of deaths, whilst in a further two cases the animal studies did manage to predict the correct outcome. In the final two cases the results were inconclusive. This study was published in the *British Medical Journal* on 27<sup>th</sup> January in a themed issue entitled "Animal testing – is it worth it?"

The team's additional finding that many of the animal studies were poorly conducted and badly written up was blamed in some circles for the poor applicability of the animal studies, rather than it being a fault inherent in the use of animal models. However, a citation study by Drs Hackam and Redelmeier, published in the *Journal of the American Medical Association* (11<sup>th</sup> October 2006) which examined how well only the most highly cited, best quality animal research translated into human treatments, found that only about a third managed to do so. Indeed, the authors saw fit to warn those who conduct clinical research (with humans) to expect "*poor replication of even high-quality animal studies.*"

Furthermore, a citation study by Dr Lindl and colleagues, published in *Alternatives to Animal Experiments* in March 2005 (now available at www.animalexperimentfacts.info) examined how successfully animal research conducted at three German universities in the early 1990s has translated into the clinic. They found that in every case, even where the animal research was cited by clinical researchers, the ideas verified by the animal work failed to be confirmed in humans. The question posed by the BMJ begins to look more and more rhetorical.

The BMJ study prompted an online response by Professor Janusz A Jankowski of the Radcliffe Infirmary, University of Oxford, who wrote in a letter entitled 'Animal models of human disease; of mice and menace' (BMJ, 31<sup>st</sup> January): "This article is timely as it highlights the unsatisfactory surrogate of many animal model systems for human disease...while some surrogate in vivo [animal] models may inform on the mechanisms of human as well as animal disease many others are potentially a menace and may actually slow our progress."

Two responses by Kathy Archibald were also posted on the *BMJ* website: these can be viewed in the 'published letters' section of our website.

### Medical research in the news Powerful MRI scanner

In November, Nottingham University unveiled the biggest brain scanner in the UK. 30 years ago, Sir Peter Mansfield pioneered MRI scanning at Nottingham, for which he won the Nobel prize in 2003. Current top-of-the-range scanners utilise a 3 tesla magnet but this latest machine boasts a 7 tesla magnet, weighing 40 tonnes and producing a magnetic field 140,000 times that of the Earth's. It promises the most detailed images yet of the brain, as well as intricate real-time imaging of thought processes that can be used to study mental illnesses such as schizophrenia. Project leader Professor Peter Morris notes: "We can look down at a lower scale than we have been able to before...We think there is a very real opportunity to study some of the neurodegenerative diseases and their effects on the brain." Sir Peter Mansfield added; "Medically there's been a huge advance."

#### Autism research

Meanwhile, the world's first purpose-built brain imaging centre for the study of autism spectrum disorders is to be opened at Oxford University. MEG (Magnetoencephalographic) scanners allow researchers to view brain activity whilst a particular task is performed, showing how brain activity is changing from one moment to the next. Professor Anthony Bailey, leader of the autism research group, explains; "The scanner is silent and safe, children and adults can sit upright, and researchers are able to sit next to them, making it a stress-free experience. Imaging the brain allows us to compare the brain activity of someone with autism to that of someone without autism. The new centre will transform our research into the brain basis of autism."

### **Mini-livers**

Researchers at Newcastle University have grown tiny sections of human liver from stem cells derived from umbilical cord blood. Eventually, the team speculates that their method could create liver tissue suitable for transplantation. But a more immediate application for the 'mini-livers' would be in testing the safety of new drugs, in which the liver plays a crucial role. The researchers have founded a company called ConoStem to develop this work further.

#### Breast and colon cancer genes mapped

In September, US cancer researchers announced the discovery of nearly 200 mutated genes implicated in breast and colon cancer, which together make up one-fifth of all cancer diagnoses worldwide. The team analysed more than 13,000 genes from tumour tissues taken from 11 patients with breast cancer and 11 patients with colorectal cancer. Dr Victor Velculescu of Johns Hopkins University's Kimmel Cancer Centre said; "It looks like each cancer has about 100 different genes that are mutated, at least 20 of which are thought to be important for the tumour's progression."

Ed Yong, of Cancer Research UK, commented: "These newly identified genes could provide rich hunting grounds for scientists looking for new ways of treating or detecting cancers. In the future, scientists hope to be able to tailor plans for preventing or treating cancer to each person's individual genetic profile. Studies like this can help us to accomplish this goal."

In April, researchers in Switzerland and Germany found that a test for one particular oestrogen receptor gene could help doctors identify breast cancer patients who would be particularly likely to respond to antioestrogen therapy, such as tamoxifen.

# Blind children denied treatment due to misleading animal research.

Animal studies, such as infamous experiments involving sewing kittens' and infant monkeys' eyelids shut, have led clinicians to believe for decades that visual deprivation early in life results in permanent functional blindness. However, a paper published in the journal *Psychological Science* in December reported that a girl in India blinded from birth by cataracts, which were not removed until she was 12, eventually regained almost normal vision. Thanks to this dramatic discovery, blind children over the age of seven may now be offered surgery that was previously thought hopeless. Researchers at the Massachusetts Institute of Technology have launched 'Project Prakash' to try to reach some of the 450,000 blind children in India, some of whom may be treatable after all.

### \$1 billion clinical trial crash

In December Pfizer, the world's biggest pharmaceutical company, terminated worldwide clinical trials of its intended blockbuster heart drug, torcetrapib, in which it had invested \$1 billion, sending shockwaves around the entire industry. The drug designed to reduce heart risk turned out actually to increase it, with 82 deaths among people in the trial taking the drug versus 51 deaths among people in the same trial who were not taking the drug.

Had the drug been successful, it would probably have been the largest-selling pharmaceutical in history, generating several billion dollars a year. Some heart specialists had predicted that the drug would not work or may harm people. Many of their doubts were assuaged, however, by reassuring 'proof of principle' studies in rabbits, which contradicted worrying human studies.

All of which goes to show how important it is to rigorously assess safety and efficacy for humans early on in drug development, in order to avoid devastating and expensive late-stage failures like torcetrapib. Better to fail in clinical trials than after marketing (like Vioxx) but better still to fail in phase zero – before human beings are put at risk and huge amounts of money and hope have been invested. The loss to Pfizer represents not just reduced profits for shareholders but also has a human face: Pfizer is now laying off 10% of its workforce – which comprises 10,000 people.

Another would-be blockbuster drug, this time developed by AstraZeneca for stroke patients, was abandoned in October when positive results in animals failed to translate into humans. Dr Robert Matthews wrote in the First Post: *"The wonder was that anyone found the failure surprising. Tests on animals have led to around 100 drugs being thought potentially useful for stroke; not one has proved effective in humans. You don't need to be a balaclavawearing animal rights activist to question the value of animal studies in this area of medical research."* 

A comment by Dr Janet Woodcock, Chief Medical

Officer of the US Food and Drug Administration, is apposite here; "Study in people early in the process is going to decrease human exposure to compounds that ultimately fail – which right now is the majority of them."

# Successful pilot study of virtual clinical trial software.

Biosimulation company Optimata's 'virtual patient technology' allows for an unlimited number of 'virtual trials' to be carried out on a wide range of dosages and varied patient populations. The new software is the fruit of 20 years of research and currently specialises in cancer drug trials. A pilot project with Eli Lilly assisted in the clinical trial design of a novel anti-cancer compound and will now be expanded into additional drug candidates. Guy Malchi, Chief Executive Officer of Optimata explained; "We can expedite a no-go decision before a pharma company spends a lot of time and money and raises the hopes of patients that you'll be able to help them."

# Human metabolism recreated in lab

Researchers from the University of California reported in January in the *Proceedings of the National Academy of Sciences* that they have created a 'virtual' model of all the biochemical reactions that occur in human cells. Study leader Professor Bernhard Palsson said; "*The new tool we've created allows scientists to tinker with a virtual metabolic system in ways that were, until now, impossible, and to test the modelling predictions in real cells.*"

Metabolomics and metabonomics is a burgeoning field in which biochemical markers in bodily fluids are examined to find patterns that might indicate a disease or health problem. Most diseases have a subtle but distinctive 'metabolic signature' which may in the future enable doctors to check a patient's metabolic profile against a database of known disease profiles, providing a quick diagnosis, perhaps even before symptoms have started to appear.

### Toward an evidence-based toxicology

In October, Dr Sebastian Hoffmann and Professor Thomas Hartung of the European Centre for the Validation of Alternative Methods (ECVAM) authored a paper in the journal *Human & Experimental Toxicology* entitled '*Toward an evidence-based toxicology*.' They suggest following the lead of evidence-based medicine and taking the opportunity presented by the forthcoming REACH (Registration, Evaluation and Authorisation of Chemicals) legislation to review the toxicological toolbox.

They point out that most toxicological tests in use today, especially animal tests, lack a thorough assessment of their performance characteristics, ie, their relevance and reliability and that "some astonishing limitations of the predictive value of such tests can be calculated."

This echoes Professor Hartung's comment that such tests are "simply bad science" in an editorial in Nature (November 10th, 2005), which observed that "the toxicology tests on which regulators rely are stuck in a time warp, and are largely based on wasteful and often poorly predictive animal experiments."



Encouragingly, the Belgian Senate is considering calling for a feasibility study to assess the potential of a toxicogenomics centre to fulfil Belgium's obligations under REACH. Professor Claude

**Professor Claude Reiss** 

Reiss, President of the Antidote Europe scientific committee, was invited to present evidence of the capabilities of toxicogenomics to the Senate in February. He explained that it would be logistically impossible to ascertain the risks of all the chemicals to be tested under REACH using animal tests – as current regulations require – because not only are the results unreliable for human beings but they are also far too expensive and far too slow. Conversely, a toxicogenomics centre using the approach proposed by Antidote Europe would enable all of the chemicals to be tested at a fraction of the cost and in a matter of months rather than decades.

#### Pioneering carcinogenicity test

Gentronix, a company founded by researchers at The University of Manchester, has launched GreenScreen HC: a test using human cell cultures to identify cancer-causing substances. The engineered human cell line glows green when exposed to genotoxins. This is the first test accurate enough for use early in the drug discovery process; being both highly specific and sensitive. As well as its reliability, the test is fast, delivering results after only 48 hours. The standard rodent bioassay for carcinogenicity, in contrast, takes two years and is so unreliable that its results have been widely acknowledged for years to be meaningless.



### Easy fundraising for EMP Trust

There are various easy ways to help raise money for EMP Trust, some of them at no cost to you! Charity Flowers

(www.charityflowers.co.uk) is the UK's only flowers by post service wholly owned by a charity and where all the profits are donated to charitable causes. They deliver a fabulous range of flowers from Guernsey, so you can also be safe in the knowledge that your gift is not exploiting workers or the environment in developing countries. You can choose from over 170 charities to receive 15% of the price of your order and we are pleased to say that EMP Trust is now one of them. Please quote code EMPT on orders.

Everyclick.com is an internet search engine with a difference – it donates half its revenues to charity. You can raise money for EMP Trust just by searching the web! Please see our website for details of how you can use Everyclick to support EMP Trust without it costing you, or us, a penny.

EMP Trust is also registered through MissionFish with eBay for Charity, so that anyone who chooses to sell any items through eBay can donate a portion (your choice) of the proceeds to the Trust.

Please consider leaving a legacy to EMP Trust in your will. Because the Trust is tax-exempt, and because we have no expensive overheads (all our office space is donated without charge), 100% of your legacy will go towards our vital work. The Trust's work is only possible because of a generous legacy that we are so grateful to have received last year – but all of that donation has now been allocated and we are in urgent need of further funding. Your support is invaluable and is truly appreciated.

# Europeans *for* Medical Progress

# **Early Day Motion 92**

EDM 92 closed in November with an astonishing 250 signatures – representing a *majority* of MPs who are eligible to sign EDMs! This phenomenal show of parliamentary support for an evaluation of the 'fitness

for purpose' of animal tests for ensuring drug safety cannot be ignored. We are maintaining pressure on the Government to make sure the concerns of so many MPs, as well as GPs and the public, are acted upon. EMP Trust's new film, *Safer Medicines*, will be very valuable in that regard.

# **ITV more balanced than BBC**

True to form, in November the BBC broadcast a programme which was widely advertised as a neutral and balanced 'documentary' on the subject of animal experimentation and the controversial new Oxford laboratory in particular. '*Monkeys, Rats and Me'* by Adam Wishart transpired to be a grossly distorted and biased piece of pro-vivisection propaganda.

EMP's director, Kathy Archibald, was filmed at length for the programme but her contributions were edited out before transmission. The end result was a programme full of wild claims for the medical benefits of animal experimentation, which were not challenged and were presented as facts. Once again, the claim was made that treatments such as deep brain stimulation (DBS) for Parkinson's disease and dystonia would not have been possible without experiments on monkeys, despite the fact that DBS was actually pioneered in patients, not monkeys.

The BBC's persistent bias on this subject is astonishing and breaches its own clear obligation to remain impartial and to cover all sides of a story factually and fairly. EMP complained to the BBC and received the same standard dismissal letter that was sent to many other complainants. We complained again and are still waiting for a response, which was promised by March 5<sup>th</sup> and then by March 21<sup>st.</sup> Our letters of complaint can be viewed on our website.

ITV's Central News programme's discussion of animal testing and the Oxford lab was much more balanced in comparison. Kathy Archibald was invited to be one of the guests in a live debate, where studio guests had the opportunity to put questions to the Prime Minister. Laurie Pycroft of Pro-Test, Professor Aziz of Oxford University and Dr Gill Langley of the Dr Hadwen Trust for Humane Research were the other pertinent guests.

Kathy asked Tony Blair if he would authorise a scientific comparison of animal tests for drug safety with a battery of the latest human-based tests, as a majority of MPs would like him to do. In response, the Prime Minister said that *"I'm told that unless we have experiments on animals we can't make progress on Alzheimer's disease, Parkinson's and other diseases...If* 

*this research is going to save human lives, we have a duty to do it.*" Which misses the point we are seeking to address – that all-important question: "if."

# Submission to Duff report on phase one clinical trials

In December, the Government published the final report of the Expert Scientific Group on phase one clinical trials, chaired by Sir Gordon Duff, which was set up in response to the Northwick Park clinical trial catastrophe.

EMP's submission to the consultation was published in the report. In summary, our recommendation was that the clinical relevance of safety tests in animals should be reviewed, since such important clinical decisions as whether to proceed with the trial of TGN1412, for example, are based upon it. We believe that volunteers in clinical trials deserve better protection than 'proof of safety' in animals, which – as thalidomide, eraldin, opren, clioquinol, isoprenaline, rezulin, Vioxx, TGN1412, etc. should have taught us – means very little for humans.

Dr Sally Burtles of Cancer Research UK was one of many scientists who gave oral evidence to the Expert Group. In her presentation, she acknowledged; "We do trials in people because animal models do not predict what will happen in humans."

In March, another report on phase one clinical trials was published by a working party of the Royal Statistical Society. This report criticised the use of animal data to provide assurances that the much smaller doses given to the volunteers would be safe and recommended that in future, tests should be done on human cells in test-tubes to try to work out safe doses for such biological agents.

### **Conservative Party Health Policy Submission**

In November, EMP submitted a document outlining the urgent case for an independent scientific evaluation comparing the ability of the current system of animal tests to predict the response of humans to a new drug with that of a battery of the newest techniques, including tissue culture, microfluidics, DNA chips, computer modelling and microdosing. We hope that as a result the Conservative Party will recognise the implications for human health of remaining shackled to the old-fashioned regulatory regime of the past, when better technologies are available, and make an evaluation a key part of their election manifesto. We also contacted the Conservative Animal Welfare Group, and were delighted when Roger Baker MRCVS, Chairman (Policy), indicated that the Group wholeheartedly supports our call for an independent review.

# **Green Party Conference**

In addition to Dr Clotworthy's talk, EMP had a stand at the Green Party's autumn conference in Hove. The level of interest in our work was overwhelming and several valuable contacts were made.

The Green Party is committed to ending animal experimentation, making it the only party with such a radical and progressive approach to the protection of public health and safety.

The Green Councillors in Oxford have been coming under intense pressure over their position on this issue, due to the controversy surrounding the new laboratory under construction there. Margaret Clotworthy met with them to explain how EMP Trust would answer some of the questions with which they are regularly challenged.

It is always a pleasure and inspiration to meet with Dr Caroline Lucas MEP, who, we are delighted to say, is a great supporter of EMP and a patron of the Trust.



Dr Margaret Clotworthy and Dr Caroline Lucas at the Green Party Conference September 2006