

Safer Medicines Campaign

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Welcome to our joint Safer Medicines Campaign/Safer Medicines Trust newsletter.

Kathy Archibald
Director

Safer Medicines Campaign is an independent organisation of scientists and doctors whose aim is to ensure the best methods are used to assess the safety of medicines. We campaign for sophisticated human biology-based tests to be compared with the animal tests currently required by law. A million Britons are hospitalised by medicines every year, costing the NHS £2 billion. We believe 21st Century science can do better.

Our educational wing, Safer Medicines Trust, is a registered charity: Number 1039411

Help us put patient safety first

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House of Lords conference

On 20th October 2009, Lord McColl CBE, Conservative Shadow Minister for Health, Professor of Surgery and Fellow of the Royal College of Surgeons, hosted a conference at the House of Lords entitled: **Human tissues are invaluable for medical research – how can we make them more available?**

The meeting was co-sponsored by Safer Medicines Trust and specialist human tissue companies Biopta and Asterand.

The aim was to bring together key academics and leaders from the transplant and tissue banking communities, along with the pharmaceutical industry, regulators and politicians, to positively shape the future of human tissue access in the UK.

Ethically donated human tissue helps pharmaceutical companies to create safer, more effective medicines. Yet such research is hindered by insufficient access to human tissue, much of which is incinerated in hospitals, rather than being made available to researchers.

Newsletter Spring 2010

Eye-opening presentations (see p3) on the life-saving value of human tissue and on successful initiatives to maximise this precious resource were followed by a lively discussion described by Lord McColl as 'the best we've ever had' in that particular venue. The presentations and the discussion are available to play via www.safermedicines.org/humantissue.

Radio 4's *You and Yours* programme covered the conference the following day with two interviews which can be heard via the same web address. We were also delighted with coverage both before and after the event in the parliamentary *House Magazine*, as well as in the scientific journals *Cell and Tissue Banking* and *Alternatives to Laboratory Animals*.

There was overwhelming enthusiasm amongst those present to tackle the obstacles to greater use of human tissue, which all agreed is an urgent goal. A working party has since been established, with a view to addressing a range of problems identified at the conference.



From left: Dr Margaret Clotworthy, Science Director, Dr Bob Coleman, Science Advisor, Kathy Archibald, Director, Professor the Lord McColl, CBE

Human tissue EDM



'Making medicines safer and speeding up the testing of new drugs are highly important aims for the Government to pursue, and I will continue to push this agenda in Parliament.'

Jo Swinson (Lib Dem) MP has tabled Early Day Motion 212: Access to human tissue for health research, calling on the Government to do more to help researchers gain access to tissue samples which might otherwise go to waste.

Safety of Medicines EDM – phenomenal success

Thank you to everyone who encouraged your MP to sign Early Day Motion 569 in support of The Safety of Medicines (Evaluation) Bill which was, sadly, not afforded parliamentary time for debate. You helped to achieve a truly remarkable demonstration of support in favour of such a momentous evaluation. EDM 569 was the joint 10th most-signed of all 2,421 EDMs in the last parliamentary session, with a phenomenal **243 signatories!**



'I will do everything I can to hasten the comparison called for in the Safety of Medicines (Evaluation) Bill. We must move safety testing into the 21st century, for all our sakes.'

Dr Bob Spink (Independent) MP has re-tabled the Safety of Medicines Early Day Motion in the current parliamentary session as EDM 29:

That this House believes that the safety of medicines should be established by the most reliable methods available in order to reduce the large and increasing toll of serious adverse drug reactions; and calls on the Government to initiate an unprecedented comparison of currently required animal tests with a set of human biology-based tests, to see which is the most effective means to predict the safety of medicines for patients.

The time to evaluate animal tests has surely come. With adverse drug reactions increasing (a study in the October issue of the journal *Pediatrics* reports that more than half a million US children suffer side effects every year) and the output of new medicines decreasing, while their costs spiral ever upwards, it has never been more important to assess the methods used to test drug safety.

ACTION

Please write to your MP **before** the Easter recess on March 31st, to ask them to sign both EDM 212 and EDM 29. Please take the opportunity to thank them if they signed EDM 569. You can find out who signed via our website or contact us by email, letter or phone.

We suggest that you write something very brief, for example as follows:

Please sign EDM 29, which calls for an unprecedented comparison of currently required animal tests with a set of human biology-based tests, to see which is more predictive of safety for patients and EDM 212, which calls for better access to human tissues for medical research.

EDM 29 does not seek to ban any animal tests but merely to assess them scientifically.

A million Britons are hospitalised by prescription medicines every year, costing the NHS £2 billion (Sarah Boseley, *the Guardian*, 3rd April 2008).

These figures must be improved. There is evidence that human biology-based technologies may be more predictive of safety for humans: hence the need for a scientific comparison.

Given the volume of letters MPs receive, we believe brevity is paramount! MPs are only obliged to respond to their own constituents, so it is crucial to include your full address and postcode.

Reaching the public

2009 was exceptionally successful in terms of raising the profile of our concerns about the validity of animal testing in the media and amongst politicians and scientists. We had articles published in *the Guardian*, the *Telegraph*, the *North West Gazette*, the Green Party publication *GreenWorld*, lifestyle magazine *Lifescape*, the Scientists for Global Responsibility newsletter and *Regulatory Affairs Journal Pharma*.

Dr Clotworthy made a strong scientific case for comparing the relative merits of the animal model with human biology-based methods on BBC1's *Inside Out* programme. She will feature in 'On The Edge' (www.EdgeMediaTV.com), Sky Channel 200 at 7pm on March 18th and April 29th.

We drew attention to the inadequacies of animals in medical research, particularly as compared with the latest human biology-based methods, in our submissions to the Academy of Medical Sciences study 'Animals containing human material' and the Home Office's public consultation on the revision of the laws governing the use of animals in laboratories.

We are very grateful to FRAME for publishing the proceedings of our Speed and Safety in Drug Discovery conference at the Royal Society. Copies can be purchased from us and from FRAME. Details and links may be found on our website.

We are delighted to have a version of our film, Safer Medicines, with French subtitles available on our website. Many thanks to Antidote Europe, from whom DVDs are available.

We are deeply grateful for legacies left to us by generous and far-sighted supporters Sheila Carson, Jane Higgins, Valerie Kneebone and Michael Sutcliffe, whose gifts are enabling us to work towards their shared vision of sophisticated human focused medical research for the benefit of all.

Summary of House of Lords presentations



'Our unswerving reliance on animal tests for safety and efficacy in humans does not stand up to rigorous evaluation. It is now time to move towards more human focused testing for human medicines.'

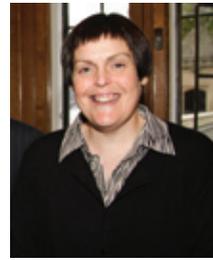
The opening presentation by **Dr Bob Coleman**, consultant to the pharmaceutical industry and advisor to Safer Medicines Trust, emphasised the crucial importance of using human tissues. Results from other species simply do not reliably translate to the clinic, as evidenced by the 92% failure rate of potential new drugs in clinical trials. He pointed out the serious gaps in supply of certain types of fresh tissue, such as nerve tissues, and posited that a system to obtain non-transplantable organs from organ donors is essential to meet research needs.

'Living human tissues can be used to really predict how a drug is going to behave in patients.'



Dr David Bunton, co-founder and CEO of Biopta Ltd, reiterated the vital role that human tissues play in drug development, and elaborated on some of the remarkable ways in which even minute skin biopsies can be put to good use evaluating the impact of new

compounds on blood pressure, for example. He explained how some drugs are far more active in human tissues than in tissues from animals. If only animals (or their tissues) are tested, this can lead to medicines being given at dangerously high doses, or in the loss of medicines that would be valuable in people.



'The sky is the limit, beyond animal research, when it comes to human tissue engineering.'

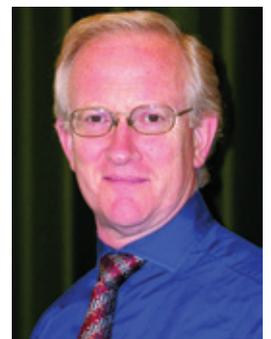
Dr Kelly BéruBé, who heads the Lung & Particle research group at Cardiff University, inspired everyone with a presentation on the development of physiologically representative human 'micro-lungs' and how these are already being used to inform drug development, as well as to assess environmental hazards.



'Our aim is to develop new drugs to treat human disease, so using human tissue is an obvious way to go.'

Iain Dougall from AstraZeneca elaborated further on the use of human tissues in drug development for respiratory disorders, where they play an essential role. It was clear from his presentation, as well as comments from the floor, that the use of human tissues is highly regarded by pharmaceutical companies but would not become more widespread until supply issues were resolved.

'If you really want to study human disease, you've got to study the human. Don't try studying something else as a surrogate, however tempting it might look because it's easier – you're going to get the wrong answer.'



Professor Chris Foster of the University of Liverpool, a pathologist exonerated by the Alder Hey inquiry, illustrated the essential role of pathologists in clinical research. His explanation of the need for improved recognition and funding of pathology departments, which collectively constitute the largest human tissue repositories and a tremendous but under-appreciated and utilised resource, clearly resonated with the hospital-based delegates present.



'Patients want this [surplus tissue donation for research] to happen and they are surprised to learn that it is not actually being used for research purposes.'

Jane Hair, Deputy Director of the NHS Greater Glasgow and Clyde Bio-repository, gave a valuable insight into the need to recoup costs while ensuring that all researchers with worthy projects have access to the necessary tissues. Despite the encouraging finding that most patients consent if asked, a recent audit uncovered that only 5% of surgical patients in Glasgow were being asked to consent to the use of their surplus tissues in research. They are now examining whether the use of IT to ensure that consent is requested and recorded at admission will improve this figure.



'The fact that we are licensed and ethically approved is quite attractive to research groups because they don't have to go through that whole process themselves.'

Sandie Martin, founder and Head of not-for-profit Ethical Tissue, Bradford, highlighted the valuable role of tissue banks with 'Ethical Approval Status' in minimising paperwork for researchers by obviating the need for them to obtain individual project approval.

'The benefits of human tissue for research are vast. Donor families are happy to know in many cases that these tissues can be made available for research if not transplantable.'



Dolores Baldasare from the US International Institute for the Advancement of Medicine (IIAM) gave a fascinating presentation on how her organisation manages to coordinate the collection and distribution of non-transplantable organs throughout the USA and beyond. IIAM liaises between the donor family, hospitals and researchers, and works with around 50 organ procurement organisations to provide tissues for research around the world.

In the US, would-be donors have a legal right to donate their organs and tissues for research, transplantation, education or therapy. In the UK there is no equivalent legislation, which means that non-transplantable organs are rarely consented for research or education. Surely the US system is one we should emulate, in order to give people the opportunity to make such valuable and life-saving donations if they wish to do so – which a majority of people clearly do.



'I was very impressed with the idea that you change things bottom-up and the idea of patient power too'

Lord McColl concluded the conference by echoing the call made by Professor Gerry Thomas of Imperial College London and the Wales Cancer Bank, that we should harness patient power to overcome bureaucratic hurdles and 'just do it'.

Medical Research in the News



Tamiflu revelations

In June 2009, the World Health Organisation declared swine flu a pandemic, which triggered the stockpiling of antiviral drugs and vaccines in many countries, including the UK, that are now trying to offload £billions worth of surplus stocks.

A cross party group of Council of Europe parliamentarians has accused pharmaceutical companies of using scare tactics to influence governments:

'They have made them squander tight healthcare resources for inefficient vaccine strategies and needlessly exposed millions of healthy people to the risk of unknown side effects of insufficiently tested vaccines.'

The UK government stockpiled over 30 million doses of Tamiflu, based on claims by Roche, the manufacturer, that it reduces complications of flu (including bronchitis and pneumonia) by 67% in otherwise healthy people.

But a joint investigation by the British Medical Journal (BMJ) and Channel 4 News, plus an independent review by the Cochrane Collaboration, based on evidence available so far, revealed that the benefits of Tamiflu in reducing complications, as claimed, appear to be vanishingly small.

The investigation uncovered a catalogue of secrecy and restricted access to crucial trial data, which speaks volumes about the lack of transparency in drug evaluation and how health policy is decided.

Interestingly, the US drug regulator, the Food and Drug Administration (FDA) says that Tamiflu has not been shown to reduce complications, while the European Medicines Agency (EMA) concludes that it does.

'The current system [for assessing drug safety and effectiveness] isn't working. Worse than that, it gives a false sense of security.... Why should the public have to rely on detective work by academics and journalists to patch together the evidence on such a potentially important drug? When vast quantities of public money, and large amounts of public trust, are placed in drugs, the full data must be accessible for scrutiny by the scientific community'
– Dr Fiona Godlee, Editor, BMJ.

Ref: BMJ 8th December 2009 and 12th January 2010.



Publication bias kills

Tragically, the example of Tamiflu and the suppression of crucial data is by no means an isolated case. Biased reporting and non-reporting of clinical trials is a major problem in medicine, distorting evidence about whether a treatment is helpful or harmful and harming and even killing untold numbers of patients as a consequence.

Leading medical journals announced in 2005 that they would only publish trials registered in advance, to prevent subsequent cover-ups. But a new study reveals that companies are still failing to properly register a majority of trials. Of those that are registered, a third are later manipulated to substitute outcomes that did not favour the drug in question with positive findings on a different outcome instead.

Dr Ben Goldacre quotes the astonishing example of all the published studies where one non-steroidal anti-inflammatory drug was compared to another: *'In every single trial, the sponsoring company's drug was either equivalent to, or better than, the drug it was compared to: all the drugs were better than all the other drugs. Such a result is plainly impossible.'*

Clinical trials *'have become the primary marketing tools of pharmaceutical companies'*
– Dr David Healy, Cardiff University.

The *Oncologist* medical journal reported that drug companies published fewer than 6% of all the clinical studies they undertook to test their drugs. Bad results in the other 94% are buried simply by failing to publish them.

'Scientists since Galileo have realised you can't be a scientist without data' – Aubrey Blumsohn, whose concerns about access to Procter and Gamble's research data on the osteoporosis drug risedronate cost him his job as senior lecturer in metabolic bone medicine at Sheffield University and led him to abandon his career as a clinical researcher.

A study in November's *Archives of Internal Medicine*, aimed at preventing another Vioxx by uncovering side effects more quickly after a drug is marketed, proposes a constantly updated public database that could be analysed freely by independent researchers.

'There is this kind of dogma in medicine that you shouldn't use any drug for the first seven years after it's released, because it takes that long to figure out its harms and benefits' – Dr. Michael Steinman, assistant professor of medicine, University of California, San Francisco.

References: *Journal of the American Medical Association* 2009;**302**(9):977
BMJ 2009;**339**:4949
The Oncologist 2008;**13**:925
BMJ 2009;**339**:5293
New York Times, 23rd November 2009

Let's see the animal data too

All of the above is a damning indictment of the system that is supposed to ensure our medicines are safe and effective. It is unarguable that governments should mandate ready access to the raw data behind any analyses used to license and market a drug.

That *must* include animal data, since crucial decisions, such as whether to proceed to clinical trials and whether the drug might cause cancer or birth defects are based on demonstrated safety in animals. Yet, as we know from Northwick Park, even safety in monkeys at enormous doses does not guarantee safety in humans. In fact, a seminal study in the *Journal of the Royal Society of Medicine* (2008;**101**:95) shows that even safety in both dogs and monkeys provides no prediction of any value that the drug will be safe for humans.

Alarming, despite all the above-mentioned flaws in reporting of clinical research, it is still of a far higher standard than the reporting and conduct of animal research, as stroke research group Camarades (www.Camarades.info) has found: *'This lack of advanced scientific methods leaves many questions about the value of animal research unanswered'*
– Professor Michael Bracken, Yale University.

A large systematic survey published in November 2009 found serious omissions in reporting of data and in strategies to reduce bias in results. Only 12% of the animal studies used randomisation, only 14% used blinding and only 8% gave the raw data. The National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), which co-funded the study, concluded that serious efforts are needed to improve both the quality of experimental design and the quality of reporting of biomedical research using animals. They commented: 'The entire scientific community is reliant on published experiments being appropriately designed and carried out, and accurately and transparently reported, as this has implications for the scientific validity of the results... and the suitability of these animal studies for translation into clinical trials.'

Sir Iain Chalmers, of the James Lind Library, Oxford, and Professor Paul Glasziou, of the Centre for Evidence-Based Medicine, University of Oxford, wrote in a study published in *The Lancet* (374, 9683: 86, 4th July 2009) that over half of clinical trials are designed without reference to previous research on the same question. This causes duplication of effort and exposure of patients and research volunteers to avoidable risks. They conclude that inadequate planning, design, reporting and publication of studies probably waste between 50% and 85% of global research funds (of over US\$100 billion).

As Sir Iain Chalmers has said before (in a presentation to the Scottish Wellcome Trust Clinical Research Facility, 30th June 2005): '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.'

Animal data used to justify claims that a drug is safe should be open to full scientific scrutiny, just as all data from human trials should be. The best way to evaluate the effectiveness of animal tests for drug safety is to compare their results with subsequent real-world outcomes in patients and consumers. The Safety of Medicines (Evaluation) Bill and a series of Early Day Motions, which we have initiated, call for that comparison to be conducted, alongside a comparison of the performance of the latest human biology-based tests, to see which methods are superior.

Support for our proposal is substantial and growing amongst MPs, biotech companies, the human tissue research community and – crucially – major pharmaceutical companies. Getting the comparison conducted is an urgent priority, which it is high time the Government recognised.

Reference: Kilkeny, C *et al*, PLoS ONE 4(11): e7824.

Epilepsy *in vitro*



Researchers at Newcastle University have observed spontaneous epileptic activity in brain tissue removed from patients during surgery as part of their treatment. Thanks to this breakthrough, they have discovered why traditional drugs which target chemical release from nerve cells are ineffective in almost a third of patients: the signals which send these patients' brains haywire are electrical rather than chemical.

Although brain disorders are notoriously difficult to mimic in the lab, this sort of insight could only be obtained by looking at real patients, rather than animal 'models'. Now scientists have high hopes that they will be able to find effective drugs to help such patients – of whom there are an estimated 45 million worldwide – so that they will no longer have to resort to surgery.

'Until now we have only been able to mimic epilepsy using experimental animal models but this can never give you a true picture of what is actually going on inside the human brain in epilepsy'
– Dr Mark Cunningham, Institute of Neuroscience, Newcastle University.

Reference: ScienceDaily.com, 1st December 2009

Clinical trials in a dish

'It feels like we're on the cusp of a revolution. This is a breakthrough – to take human cells and use them to make the tissue involved in the disease'
– Dr. George Daley, Associate Director of the Stem Cell Institute at Children's Hospital Boston and Co-Chairman of Iperian's scientific advisory board.

Scientists have taken skin cells from a patient with a rare heart disorder and turned them into heart cells. The skin cells, which are obviously much safer & easier to extract than heart cells, are specially treated so that they become stem cells – the cells which eventually give rise to all the cells in the body. These

are then 'reprogrammed' in the lab so that they turn into heart cells with the same problem seen in the patient. Thus scientists have an endless, safe & ethically obtained supply of defective human cells. They can be used to study the basic biology of the disease, and perhaps most promisingly of all, to design and test new drugs.

Around the world, skin cells have also been turned into muscles, nerves, kidney, liver & other organs from patients with devastating genetic diseases. John Walker, CEO of Ipiorian, a company which develops & uses these cells to discover treatments, believes that using human cells instead of animals will not only give more accurate results, but could also cut the time taken to get drugs to patients by years.

Reference: *Forbes Magazine*, 5th October 2009

A whole (human) system

Leeds-based Kirkstall has developed an advanced commercially available cell culture system which links human cells from different organs of the body together to form a 'quasi vivo' mimic of the human body. Drugs can be added to the 'body' and the complex interactions between the different 'organs' observed. For example, the liver is crucial to drug metabolism, and the effect of the drugs' metabolites on a variety of organs can be determined simultaneously. The result is a more accurate – and economical – model of what will happen in people, and they are currently working hard to validate it.

Kirkstall believes that barriers to the adoption of sophisticated human biology-based techniques are regulatory rather than technological, as regulatory agencies have simply grown accustomed to relying on animal test data.

US company, Hurel (*Human-relevant*) has developed a system designed to achieve similar results, and spoke at our Speed & Safety in Drug Discovery conference at the Royal Society in 2008 (see their presentation at www.drugtestingconference.com). By eliminating the time, money and potential inaccuracies associated with animal testing, Hurel estimates their test could shave \$100 million off the roughly \$1 billion cost of developing a new drug.

Reference: outsourcing-pharma.com, 20th October 2009

Toxichip

A 3 year project, called Toxichip, is being funded by the European Union to develop two types of biochip: one using bacteria engineered to change colour in the presence of dangerous chemicals in the environment, and one for the toxic assessment of chemicals using cultured human cells. The latter chip will find use, not only in evaluating chemicals for environmental risk,

but also in looking at drug safety. The chip will allow cellular responses to drugs (or chemicals) to be assessed in combination, which is important as many patients need to take more than one drug at a time, and people may be exposed to many agents simultaneously in the environment. By incorporating microfluidic, electronic and computer technologies, the aim is to produce chips that can be used quickly, simply and cheaply to assess the risks posed by new drugs or chemicals more accurately than animal tests.

Reference: RTÉ News 30th November 2009

Superior human tissue

In another example of innovative UK companies rising to the challenge of developing human biology-based tests, University of Oxford spin-out Zyoxel is using bioreactor technology to grow human tissues in environments closer to those the cells experience in the body.

'Recent research has shown our technology can be used to culture more realistic cancer tissue for testing, offering a powerful new tool for cancer drug discovery programmes'

– Prof Cui, University of Oxford & Zyoxel technology co-inventor.

This boosts test accuracy, cuts drug development times & potentially slashes costs by at least 10%. As Zyoxel CEO Dr Tim Hart estimates that failure to detect toxicity early in drug development costs the industry about £5 billion each year, the impact could be huge. The company's advances have not gone unnoticed as far afield as China, where a company keen to have such technology on-board has invested £1million to help fund test development.

Reference: *Oxford Mail*, 19th July 2009

Cancers catalogued

Scientists have unlocked the entire genetic code of two of the most common cancers – skin and lung – identifying 90% of the mutations in two human cancer cell lines. Not only will these 'mutational signature' maps pave the way for blood tests to spot tumours far earlier, they will also yield new drug targets, says the Wellcome Trust team.

'This is a landmark moment in cancer research. From this moment on, this is going to be our expectation for what we want to know about individual cancers – it resets our ambitions for cancer'

– Professor Michael Stratton FRS, Wellcome Trust and Institute of Cancer Research.

Reference: TheScientist.com, 16th December 2009

ACTION

Leaflets

If you can help by distributing our leaflets we will be delighted. Donations to help with postage and printing costs will be greatly appreciated.



Newsletters

Please order further copies of this newsletter to distribute if you can.

DVDs

Watch *Safer Medicines* on our website or buy a copy: **only £5!** If you know any secondary school teachers or lecturers please encourage them to ask us for a free copy. An order form is on our website.



Petition

Sign our petition in support of an independent and transparent scientific evaluation of the use of animals in drug safety testing

- on our website
- on our petition sheet – which you can print from our website or order by email, post or telephone
- on the form below.

Please return all petitions to us by 1st May 2010

Name	Address	Phone No. (optional)

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If you want to see real progress towards a future where medical research is based on studying humans rather than animals, please give generously today.



Booklets

Order *A Critical Look at Animal Experimentation*: a booklet examining the impact of animal experimentation on research into cancer, AIDS, neurological disorders and others, as well as outlining more valid human-based methods of research.

Please copy this section or cut it off and return to us – thank you

Please tick if you wish to see an independent scientific evaluation of animal tests for drug safety

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- Please tick if you are eligible and wish to *gift aid* your donation to the Trust (*only* the Trust is eligible for gift aid).

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