

Safer Medicines Campaign

PO Box 62720, London SW2 9FQ - Tel: 020 8265 2880 - info@safermedicines.org - www.safermedicines.org

New Bill launched - MPs urged to act

The **Safety of Medicines (Evaluation) Bill 2009** was launched in January to tackle the escalating problem of adverse drug reactions by requiring an unprecedented scientific comparison of testing methods.

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. Sophisticated methods of safety testing are now available but the law still demands animal tests. It is time to challenge this forty year old requirement’

– Safer Medicines Campaign patron and former Minister of Technology, the Rt Hon Tony Benn.

There is alarming evidence that animal tests are failing to protect us:

- Six young men at Northwick Park hospital were almost killed by a drug they were given because it had been ‘proved safe’ in monkeys.
- Arthritis drug Vioxx killed tens of thousands of people after being ‘proved safe’ in mice, rats, rabbits, dogs and monkeys.
- 92% of new drugs fail in human trials, following success in animal tests.

- Many studies show that animal tests – even in both dogs and monkeys – are **no more predictive for humans than tossing a coin:** e.g. Journal of the Royal Society of Medicine 2008; 101: 95, British Medical Journal 2007; 334: 197.

Tests frozen in time

‘Some animal tests haven’t changed in 60 years. The tests are frozen in time. This is not science. Science is always moving ahead’ – Professor Thomas Hartung, Head of the European Centre for the Validation of Alternative Methods (Washington Post, 12th April 2008).

‘It’s slow. It’s expensive. We are not rats and we are not even other primates’ – Dr Francis Collins, Director, US National Human Genome Research Institute (Reuters 14th February 2008).

Time to test animal tests

The Government and the pro-animal testing lobby claim that there have been four inquiries into animal testing – but none has measured its effectiveness at predicting drug safety.

In fact, all four inquiries actually called for its scientific evaluation:

The (2002) House of Lords Select Committee on Animals in Scientific Procedures workshop on toxicity testing concluded: ‘the reliability and relevance of all existing animal tests should be reviewed as a matter of urgency.’

The (2003) Animal Procedures Committee inquiry concluded: ‘it is clear that there is a need for more efforts to assess the value of animal toxicity tests in predicting effects in humans.’

The (2005) Nuffield Council on Bioethics inquiry concluded: ‘it would be desirable to undertake further systematic reviews and meta-analyses to evaluate more fully the predictability and transferability [i.e. the scientific value] of animal models.’

The (2006) Weatherall Committee also concluded that ‘debate on the use of non-human primates in research would benefit from more systematic information on its overall impact on scientific and medical advances.’

The best model for humans is human

‘We do trials in people because animal models do not predict what will happen in humans’

– Dr Sally Burtles, Cancer Research UK (Expert Group on Phase One Clinical Trials (Duff) report, 7 December 2006).

Key to solving the problem of predicting how drugs will affect patients is a shift of focus from animal studies towards human biology. This was the theme of an **international scientific conference** at the Royal Society in November 2008: Speed and Safety in Drug Discovery – see www.drugtestingconference.com.

Leading scientists agreed that the best model for human drug development is human beings. They offered a breathtaking array of technologies to test the safety of medicines in a human context.

Comparison needed

Since animal tests are currently our chief safety screen before drugs are tested in people, it is only reasonable to compare them with today’s advanced human biology-based methods.

How can we do this? By taking a set of drugs which have already been widely used in patients – so we know the problems they can cause – and running them through a suite of the latest tests. Comparing these results with the results we already have from animal tests will reveal which methods are most predictive for humans.

The Safety of Medicines (Evaluation) Bill 2009, tabled by a cross-party group of MPs, calls on the Government to conduct this unprecedented scientific comparison.

Dr Ian Gibson MP (Labour), Mike Hancock CBE MP (Liberal Democrat) and David Amess MP (Conservative) have also tabled Early Day Motion 569 in support of the Bill.



‘It is astonishing that animal testing has never been scientifically evaluated. The process is long overdue.’
Mike Hancock CBE MP



‘If replacing animal tests could benefit drug safety, who could fail to be happy?’
David Amess MP



‘These impressive technologies deserve a fair trial, to see if they could do a better job of protecting patients.’
Dr Ian Gibson MP

ACTION!

Your help in persuading MPs to sign EDM 569 is **vital!** A phenomenal 250 MPs signed EDM 92 in 2006, thanks to *your* encouragement.

Please help us put pressure on the Government by achieving even greater support for EDM 569 – **send our postcard to your MP today** or write to them at: House of Commons, London SW1A 0AA.

Contact us at the address above for further copies of this sheet or postcard.

PUTTING PATIENT SAFETY FIRST (formerly Europeans for Medical Progress)

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Which would you trust



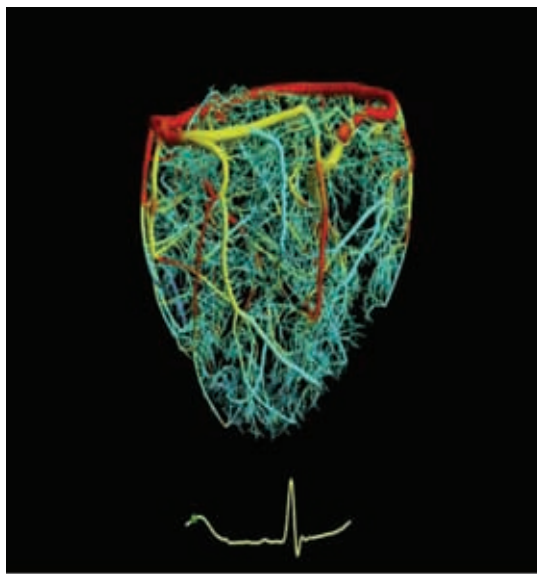

to protect your health?

Tests in mice, rats, rabbits and dogs indicated that painkiller Vioxx protects the heart – yet it killed many thousands of people through heart attacks and strokes.

Isn't it time to compare animal tests with today's scientifically developed human biology-based methods to test the safety of medicines?

Please support the Safety of Medicines (Evaluation) Bill

Safer Medicines NOW



Early Day Motion 569

That this House believes 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 upon the Government to initiate an unprecedented comparison of currently required animal tests with a set of human biology-based tests, as required by the Safety of Medicines (Evaluation) Bill 2009, to see which is the most effective means to predict the safety of medicines for patients.

Human biology-based methods

In 2007, the US National Research Council called for the replacement of animal tests for environmental toxicity with **'more efficient *in vitro* tests and computational techniques.'**

The Safety of Medicines (Evaluation) Bill requires animal tests to be compared with some of these methods, including:

Human tissue

New drugs can be tested in ethically donated human tissues relevant to the disease in question. Companies such as Asterand, Biopta and Aeirtec work exclusively with human tissue because it is more relevant than animal tissue. VaxDesign creates mini immune systems from human blood samples, to test vaccines in a whole population without exposing a single person.

See, e.g. www.asterand.com, www.biopta.com, www.aeirtec.com, www.vaxdesign.com, www.apredica.com

DNA chips

Glass slides the size of a postage stamp, where thousands of genes can be monitored simultaneously for their response to a new drug. Toxicity can be predicted more accurately than with current methods, in dramatically reduced time and at greatly reduced cost.

See, for example, www.SimuGen.co.uk

Microfluidics chips

Small glass slides with tiny compartments, each containing a sample of tissue from different parts of the body. The compartments are linked by microchannels through which a blood substitute flows. The test drug is added to the blood substitute and circulates around the device; mimicking what goes on in the body on a micro scale.

Hurel (**H**uman **r**elevant) is pioneering this field. See www.hurelcorp.com

Computer modelling

Virtual organs predict the effects of one or more drugs in humans rapidly and accurately. Virtual patients allow treatments to be tailored to the individual. The 'virtual human' project is an international collaboration to improve our ability to predict, diagnose and treat disease.

See, e.g. www.entelos.com, www.physiome.org, www.vph-noe.eu, www.optimata.com

Microdosing

An exciting new method of testing drugs safely in humans at an earlier stage. Microdosing relies on one of the most sensitive measuring devices ever invented, so sensitive that it could detect a litre of liquid diluted in all the oceans of the world! Its accuracy at predicting human metabolism is unsurpassed.

See, for example: www.xceleron.com, www.vitaleascience.com

