Putting patient safety first

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Safer Medicines Trust

Safer Medicines Campaign

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Since 1968, the Government has required new medicines to be tested in animals. But 9 out of 10 drugs that pass animal tests are unsafe or ineffective in humans. For example:

- Six young men at Northwick Park hospital were almost killed by a drug they were given because it had been 'proved safe' in monkeys.
- Painkiller Vioxx killed many tens of thousands of people after being 'proved safe' in mice, rats, dogs and monkeys.

It's time to test animal tests

It is time to compare animal tests with today's advanced human biology-based methods *(see over).*

How can we do this? By taking a set of drugs which have already been 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 (Ten Minute Rule) Bill presented 20th July 2010

to tackle the crisis of adverse drug reactions by requiring an unprecedented 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)

Please sign EDM 475

"If replacing animal tests could benefit drug safety, who could fail to be happy?"
Co-sponsor David Amess MP (Conservative)

"We must move safety testing into the 21st century for all our sakes."
Co-sponsor Bob Russell MP (Liberal Democrat)

"These impressive technologies deserve a fair trial, to see if they could do a better job of protecting patients."
Co-sponsor Paul Flynn MP (Labour)

"More reliable methods will benefit everyone. A national strategy to replace outdated animal tests is urgently needed to improve the safety of medicines."
Co-sponsor Dr Caroline Lucas MP (Green)

"It is astonishing that animal testing has never been scientifically evaluated. This process is long overdue."
Co-sponsor Mike Hancock CBE MP (Liberal Democrat)

The best model for humans **is human**

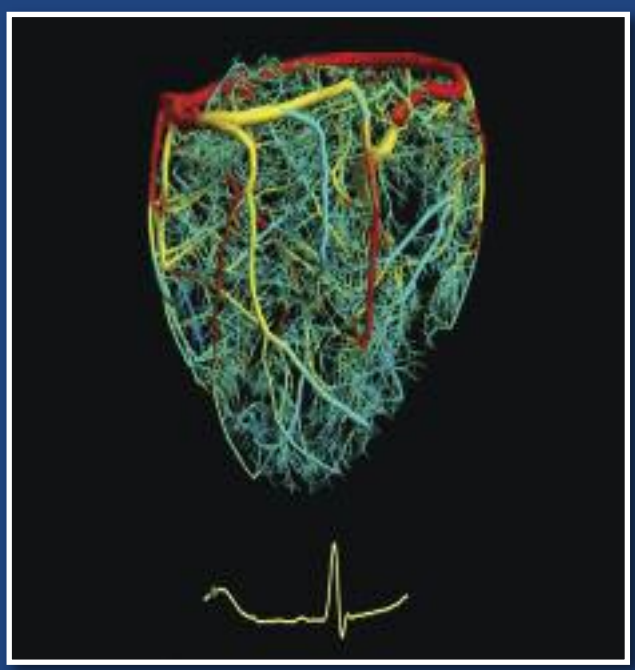
"For too long we have used animal models for human disease. In the clinic, we treat patients, and therefore the most appropriate model is the human." **Professor Gerry Thomas, Hammersmith Hospital and Imperial College, London and Director of Scientific Services, Wales Cancer Bank**

"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." **Dr Bob Coleman DSc, co-founder of Pharmagene, now Asterand, and Pharmaceutical Industry Consultant**

"An increased focus on human biology when developing drugs produces safer medicines, faster and cheaper." **Dr Katya Tsaioun, founder and CEO, Apredica**

"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 DSc, MRCS, FRC-Path, University of Liverpool**

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.**



Four inquiries...

There have been four inquiries into animal testing in recent years – but none has measured its effectiveness at predicting drug safety. In fact, all four inquiries actually called for animal testing to be evaluated scientifically:

- 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."**

"It's slow. It's expensive. We are not rats and we are not even other primates."
Dr Francis Collins, Director US National Institutes of Health (Reuters 14th February 2008).

Early Day Motion 475

"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 a comparison of currently required animal tests with a set of human biology-based tests, as proposed in 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 Bill will require animal tests to be compared with some of these methods, including:

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Human tissue

New drugs can be tested in ethically donated human tissues relevant to the disease in question. Companies such as Asterand, Biopta and Sistemic 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: www.asterand.com, www.sistemic.co.uk www.biopta.com, www.vaxdesign.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: www.SimuGen.co.uk, www.affymetrix.com**

Microfluidics chips

Glass slides with tiny compartments, each containing tissue from different parts of the body. The compartments are linked by microchannels through which a blood substitute flows. The test drug circulates around the device; mimicking what goes on in the body on a micro scale. Hurel (**Hu**man **rel**evant) and Kirkstall are pioneering this field. **See: www.hurelcorp.com, www.kirkstall.org**

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: www.entelos.com, www.physiome.org, www.vph-noe.eu, www.optimata.com, www.simcyp.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: www.xceleron.com, www.vitaleascience.com**

"Some animal tests haven't changed in 60 years. The tests are frozen in time. This is not science. Science is always moving ahead."
Dr Thomas Hartung, Chair for Evidence-Based Toxicology, Bloomberg School of Public Health (Washington Post, 12th April 2008).

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