Which would you **trust** to **protect** your **health?**

Medicines are still tested for safety in animals - yet high-tech tests based on human biology are far more accurate.

Words by Kathy Archibald

For ten years I have studied the divergent ways in which humans and animals respond to diseases and their treatments. Four years ago, I had cause to celebrate that divergence, when I was diagnosed with insulinoma: a rare pancreatic tumour. Searching the internet produced an abundance of information on insulinoma in ferrets, in whom surgery is futile as the disease is always fatal. Fortunately, humans are different and I was lucky enough to be cured by surgery. But I was glad that my decade of study spared me from trusting that what happened in an animal 'model' of my disease would also apply to me!

Unfortunately, the Government does believe that what happens in animal models also applies to patients. This is why they insist that all new

medicines must be tested for safety in animals before they can be tested in volunteers and patients in clinical trials. The idea is that animal tests will weed out any dangerous drugs and thus spare people from being used as guinea pigs.

Sadly, the reality is very different. For every 100 medicines that enter clinical trials, after extensive animal tests have indicated that they should be safe, only eight are actually effective and safe enough to be marketed. This means that for every eight drugs deemed safe, volunteers and patients in clinical trials are exposed to 92 that are either unsafe or ineffective.

In the infamous clinical trial at Northwick Park hospital three years ago, six young men were almost killed by a drug which they were given because it had been shown to be safe in monkeys – even at a dose 500 times higher than theirs.

Clearly, monkeys did not predict how the drug would affect humans. In fact, no animal tests can predict how any drug will affect humans, despite this being the rationale for their use. No published evidence exists that shows animal tests are predictive for humans, while abundant published evidence exists that shows they are not. Many scientists have acknowledged for many years that animal tests are about as predictive as tossing a coin. A study published in the Journal of the Royal Society of Medicine in February 2008 showed that tests in both dogs and monkeys are no more predictive than tossing a coin.

Meanwhile, a million Britons are hospitalised by prescription drugs every year, costing the NHS £2 billion. We do not suggest that animal tests are solely responsible for these shocking figures but it is undeniable that better methods of assessing drug safety are urgently needed.

The good news is that, thanks to tremendous advances in science and technology, there is now a dazzling array of technologies available to test the safety of medicines in a human context.

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 report, 7 Dec 2006).

Safer Medicines Trust, the charitable wing of our organisation, recently hosted an international scientific conference at the Royal Society, at which leading scientists agreed that the best model for human drug development is human beings. Key to solving the problem of predicting how drugs will affect patients is a shift of focus from animal studies towards human biology. The eminent speakers demonstrated the superior predictive ability of their methods and how they are constantly being improved still further.

Time to test animal tests

Astonishingly, the effectiveness of animal testing has never been compared with these newer methods, despite the fact that all four much-quoted inquiries into animal testing in recent years called for an assessment of the value of animal tests. Now, in co-operation with Safer Medicines Campaign, a cross-party group of MPs has launched The Safety of Medicines (Evaluation) Bill, calling for an unprecedented comparison of animal tests for drug safety with human biology-based methods. MPs from the three main parties have tabled Early Day Motion 569 in support of the Bill.

Your help in persuading MPs to sign EDM 569 is vital! Please send our postcard to your MP today. For all our sakes, we must move safety testing into the twenty first century. ■

Kathy Archibald is the founder and director of Safer Medicines Campaign, a not-for-profit patient safety organisation of doctors and scientists whose concern is whether animal testing, today, is more harmful than helpful to public health and safety.
Visit: www.safermedicines.org
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Human biology-based methods

In 2007, the US National Research Council called for the replacement of animal tests 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. Asterand, Biopta and Aeirtec work exclusively with human tissue. VaxDesign creates mini immune systems from human blood samples, to test vaccines in a whole population without exposing a single person.
Visit: www.asterand.com, www.biopta.com, www.aeirtec.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.
Visit: www.SimuGen.co.uk

Microfluidics chips

Small glass slides with tiny compartments with a sample of tissue from different body parts. The compartments are linked by microchannels through which a blood substitute flows. The test drug is added to the substitute and circulates around the device, mimicking what goes on in the body on a micro scale. Hurel (Human relevant) is pioneering this field. **Visit: 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.
Visit: www.entelos.com, www.physiome.org, www.vph-noe.eu, www.optimata.com

Microdosing

An exciting method of testing drugs safely in humans at an earlier stage. It relies on a measuring device 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.
Visit: www.xceleron.com, www.vitaleascience.com

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.