



Keep the directive that protects research animals

Losing legislation that has animal welfare at its core would not just jeopardize science, it is also likely to lead to a drop in standards, argues Kay Davies.

I have spent years meticulously trying to understand the disease process in Duchenne muscular dystrophy (DMD) and using that information to develop treatments. DMD is one of the most devastating childhood genetic disorders in the world. There is currently no effective treatment, so there is a huge unmet clinical need. Every so often, we get an unexpected finding that leads us to a new approach to therapy. One of our discoveries has led to clinical trials of a candidate treatment. This drug is promising because it targets the underlying cause of the disease.

Between the painstaking cell-line analysis and trials in humans there is a crucial step: validation of our theories in mice. Our work in cell lines, although useful, gives no indication of how effectively a treatment will combat the disease in crucial muscles such as the diaphragm and heart, given that most patients die from either respiratory or cardiac defects.

Even though personal experience as a scientist teaches me that, as things stand, no progress can be made in improving human health without animal research, the decision to use animals should never be taken lightly. It is extremely important that the research is highly regulated and that we have an open and honest discussion about it. As with all research, experiments involving animals should not proceed without the broad consent of society.

It is for this reason that I am worried about the Stop Vivisection European Citizens' Initiative. The Italian-based initiative wants to scrap animal research in Europe by repealing a European directive that protects animals used for science. It has gathered more than one million signatures, and so gets to present its case next week to the European Parliament, which is largely composed of new members.

The directive was introduced in 2010 after a long and considered process of debate with a wide range of groups, and came into full effect in 2013. It is ambitious legislation that requires the raising of welfare standards across the continent, and obliges licensed researchers to adopt the '3Rs': reduction, refinement and replacement.

My lab in Oxford, UK, has to renew its licence to carry out research in animals from the local committee every five years, with a review halfway through. Welfare is an extremely important concern. We have found that the best way to continually improve standards is for my research team to work closely with animal-house staff to explain the experiments being carried out and why they are being done. In this way, those who look after the animals every day understand what effects the animals might be experiencing, and can therefore tailor their care.

All funders, including the European

Commission, want as few animals as possible to be involved in research. This is not always easy, because doing experiments with too few animals can be just as damaging as using too many. If the results are not significant because the sample sizes are too small, then the work and the animals have been wasted. We need to justify, in statistical terms, the appropriate number of animals.

In my view, technology is continually helping us to reduce the number of animals needed. Already in my lab, we are developing imaging technology that enables us to monitor the response to candidate drugs in mice, so experiments can be shorter, less invasive and use fewer animals. Other advances, such as tissue engineering, stem-cell technology and computer modelling, also show promise for refining the use of animals and providing potential alternatives. On this score, the

directive has placed further duties on the European Centre for the Validation of Alternative Methods, a body that makes sure that substitute methodologies are at least as reliable as equivalent methods using animals. Since 1990, it has validated more than 30 such alternatives.

Removal of the directive would be a significant step backward both for animal welfare in the European Union and for Europe's leading role in advancing human and animal health. Biomedical researchers have a duty to continue trying to develop treatments, and there is always what I think of as a 'tipping point' between our confidence in our experimental findings and starting human trials. We want treatments to be available for humans as soon as possible and, as we develop alternative testing techniques, this

will shift further and further towards being possible with very little experimentation in animals. It would be wonderful to see the day when we can do experimental medicine in small groups of patients without validation in animals first, but we are not there yet. It is simply too great a risk to patients.

There are always going to be those who disagree with animal research, and the scientific community must show where, perhaps unexpectedly, we share common ground. Like those who disagree entirely, we do not want animals to be used in research forever, and we must make our thinking behind the 3Rs and alternatives better understood. The directive makes a massive contribution to animal welfare, and allows experiments that are necessary to realizing the medical benefits of my research and that of countless other European scientists. Abolishing it would not be good for basic science, medical progress or animal welfare. ■

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