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The Science

Species differences play a major role in holding back medical progress, there is problematic translation of animal results to humans. It is proven that 92% of drugs that show promise in animal tests fail to reach the clinic and benefit patients. The majority of these failures are cited as 'due to adverse effects' and 'lack of efficacy in humans'. A clear example would be in predicting liver toxicity. The latest human liver-on-a-chip technology alone is estimated to be worth $3 billion annually to the pharmaceutical sector due to increased R&D productivity. We are told testing requires a whole biological system; however, this is perpetuating the use of animals while completely ignoring the differences between species systems. We must do something else entirely. A laboratory environment, in itself, causes significant stress, making data even less translatable to humans.

A 2015 investigation concluded that between 50 and 89% of all preclinical research, is not reproducible, animal experimentation is implicated as a serious problem area. US, EPA government scientists recently carried out vast analyses of huge datasets of animal studies on thousands of chemicals. The findings pointed clearly to both poor reproducibility and predicative value for humans. Furthermore, genetically modified (GM) animals have also failed to translate to human biology and or to reflect the human situation being researched in many areas including Multiple Sclerosis, Oncological studies, Muscular Dystrophy, Diabetes, and many neurodegenerative diseases including Alzheimer's and Parkinson's. In fact, major scientific breakthroughs in disease areas such as diabetes and breast cancer have relied on studies of human patients; they would not have been possible if the scientists had used animals for their research.

Global Regulator expectation is that two animal species, rodent and non-rodent, be used for safety/toxicity testing, before progression to human clinical trials. Use of dogs and non-human primates (NHPs) have been shown to add just 2% and 0.4% respectively to the weight of evidence of existing probabilities that new drugs might be safe. This negligible contribution is statistically insignificant to safety assurances, and causes massive needless animal suffering and death, increased monetary costs and also time delays to product development.

In the USA the FDA Modernization Act 2.0 has now been enacted into law, this removes the 83 year old mandate to use animals and gives the option to use NAMs. Scientific development will be accelerated overseas whilst the UK delays in making change. There is formidable and irrefutable published evidence to immediately stop using animals in scientifically bogus tests.

New Approach Methodologies/Non Animal Methods (NAMs)

NAMs are human-specific techniques that represent superior science. They are designed to provide results that are much more human relevant. They are not hampered by the non-predicative translation of one species to another. Game changing examples are organ-on-a-chip/micro-physiological systems technology and micro-dosing. NAMs are not a choice between an animal life or a human loved one, they provide an opportunity to use superior, cutting edge new approaches that are specific to humans making them more accurate.

The Government claims that the Animals in Scientific Procedures Act (ASPA 1986, revised 2012) protects animals used for science. ASPA states 'the principle of replacement is the principle that, wherever possible, a ***scientifically satisfactory*** method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure.' Further, the Government repeatedly states that animals are only used as a last resort principle and that their use is only permitted where no alternative exists. We know this is simply not the case. In practice a 'scientifically satisfactory' method is interpreted as one that has undergone regulatory approval

and validation, thus creating an additional layer of compliance that is not explicitly required by the legislation. UK Law is routinely overridden by a global Regulator expectation (the FDA Modernization Act 2.0 should remove this). ***Animal use has never been validated/approved, and is certainly not scientifically satisfactory.*** The UK's scientific leaders are in broad agreement with a NAMs roadmap for chemical safety, however engagement from the policy and regulatory government departments is lacking and needs to be stepped up for a UK REACH.

It is currently scientifically satisfactory to replace and/or abandon ALL animal research immediately. Not only are there current NAMs replacements, but there is also the complete opposite, research that involves human volunteers, within a rigorous ethical framework ensuring the safeguarding of participants.

Independent NAMs specialist committee and Project Licences (PPL)

At no stage from project conception by the animal researcher to Animal Welfare Ethical Review Body (AWERB) to the Home Office Inspectors or purely administrative, tick box, new licencing team are PPLs reviewed by a NAMs specialist. There is no requirement to provide evidence that replacement options have been thoroughly investigated. Instead a view can simply be stated that the research outcome requires animal use. Even if Inspectors are consulted, most, if not all, come from an animal research background and thus are biased from the outset. Inevitably animal procedures will be approved where non-animal methods do exist. The last PPL application to be rejected was one in 2012, data is not held prior to 2011.

We propose that the Home Office adds an advisory independent committee, comprising of specialists in various NAMs, as a step in the pathway to review PPL applications prior to the granting of Home Office approval. For every proposed, and actual, use of animals - given the time to pull evidence together - they could demonstrate that (a) the odds of the findings in animals being sufficiently and reliably human relevant are slim, and (b) that using human-specific methods would give more reliable, robust results. With the exception of s24 ASPA, this would require no change in existing legislation. If the government has a genuine commitment to making the UK a centre of excellence for science, this simple adjustment could put us right at the forefront of disease research allowing multiple drugs that do not make it past animal use to be accurately assessed for the human system and to make a difference to the patients that need them.

If the government is serious about moving on from, and avoiding, animal use in science, and using NAMs superior science, they would facilitate this. NAMs Specialists are ready to give their time voluntarily.

The Statistics and Ethics

In 2021, there were 3.06 million scientific procedures on living animals carried out in GB. Additional statistics, last published in 2017, revealed 1.81 million non-GA animals were bred for scientific procedures but were killed or died without being used in regulated procedures. These additional statistics should be published annually. Data is misleading without the inclusion of up to £2 million more animal deaths, many of which are surplus 'stock.'

There is a strong ethical case for replacing animals with modern, human relevant, innovative methods. Dogs, for instance, have sentience, thoughts, feelings and cognition comparable to that of a 3 year old child.

The Regulators – Animals in Science Regulation Unit (ASRU)

During 2021, there were just 22.69, full time equivalent, Home Office inspectors. Lack of regulatory oversight, combined with the sheer number of animals held in laboratories, means that shocking welfare violations occur.

ASRU annual reports for 2019-2021 were published on 26th October 22. Non-compliance cases show a significant increase (2018–28 to 2021–61) despite inspections reducing from 470 in 2019 to 214 in 2021.

Remedial action, in almost all cases, is a letter or inspectors advice. Non-compliance falls under systems relying on self-reported or whistleblower testimony, leading to a worrying lack of oversight by the regulatory authority. The reality is neither the Home Office Animals in Scientific Regulation Unit (ASRU) or the public know what is happening behind those closed doors. The self reported non-compliance cases will be just the tip of the iceberg. Additionally, ASRU is fully funded by those it regulates leading to a conflict of interest and lack of independence.

Sadly, the cruel treatment of animals within laboratories continues under the falsehood that the ASRU regulation of ASPA, provides adequate protection for laboratory animals. In February 22, Chris Sherwood, CEO of the RSPCA, resigned from the ASRU change programme steering committee, citing lack of confidence in this Regulator. The regulated community and wider stakeholders also have expressed concerns that there was inadequate consultation in the regulatory reform that was implemented in July 2021.

Financial

In 2019, the UK government's gross expenditure on research and development (R&D) was £ 38.5 billion. Around 40%, £ 15.4 billion, is spent on basic research which uses many animals and is largely publicly funded. The annual budget of the NC3Rs is around £10 million, of which around £ 6.375 million is for NAMs development. This equates to 0.016%, yet the Government claim to actively support and fund the development of NAMs. ***Funding must be on a scale that reflects the urgency and importance of this issue.*** In the existing animal research paradigm, novel drugs take 10 -15 years to reach the market at a cost of over £1.5 billion.

Section 24 the ASPA Secrecy clause

A consultation to review s24 of ASPA was undertaken in mid 2014. The results remain unpublished due to a delay because of a lack of a policy unit to manage the work. This clause prevents stakeholders from reviewing documents, including project licences. Requests for information under the Freedom of Information Act 2000 are also largely exempted mainly by s38 (health and safety), s41 (confidentiality), s36 (prejudice to effective conduct of public affairs). The sector remains shrouded in secrecy and is certainly not transparent as is claimed.

Commercial Breeders (Marshall BioResources and Envigo)

ASPA and its Code of Practice sets out minimum guidelines, not even best practice for the care, transit, housing and killing of research animals. Both of the commercial breeding companies in the UK have a well-documented history of international animal abuse. A high profile Envigo site in the USA was recently closed due to gross welfare violations. The USA permits research animals to have rights to within their welfare regulations, unlike the UK, that explicitly excludes research animals from both the sentience bill and the Animal Welfare Act. ASRU actively supports these companies and permits them to operate beyond the reach and oversight of the public, deeming them to be low-risk. Inspections are minimal, announced, brief and increasingly carried out virtually.

At MBR Acres Ltd in Huntingdon, beagle puppies are bred for the research industry in conditions reflecting an industrial scale puppy factory with over 1,200 dogs on site at any one time. The dogs are left unattended 20 hours a day at weekends and 16 hours a day during the week. Once the staff have left only security remains patrolling the outside areas, they have no access to the sheds where the dogs are kept. Establishment standard condition 4 refers only to ‘adequate care and accommodation’ appropriate to the species. The number of staff reduced from 41 in 2017 to 24 in 2021. A veterinary surgeon and care staff should be on site 24/7, this is a basic welfare need.