Safety of medicines and the use of animals in research

We are concerned about the misleading claims made by Kathy Archibald and colleagues in their Correspondence (June 4, p 1915).[1]

The main claim made is that more medicines are failing, that adverse drug reactions have increased, and that these problems are caused by inadequacies in the medicines development process. They blame an "over-reliance of the pharmaceutical industry on the use of animals to predict drug behaviour in man".[1]

It is essential for all doctors, patients, regulators, and the bioscience sector globally that new medicines are safe and effective. Sound and sophisticated science is used at all stages of research into health and disease, and in the development of new treatments. Animal research and testing is a small but vital part of this effort, and does not represent, in any sense, "over-reliance".

Animal research and testing is essential for understanding normal and disease processes. In the preclinical development of new treatment candidates, animals are crucial for understanding their pharmacokinetics and pharmacodynamics, and for detecting unforeseen toxic effects. The identification of developmental and carcinogenic hazards is particularly reliant on continued animal testing, since such effects would not become evident in patients for many years.

Nobody is permitted to use animals where there is a viable alternative.[2] All parties support the significant investment in the search for alternatives to animals in research and ways of improving their welfare and reducing the numbers used. The UK leads in this area.[3] The global pharmaceutical industry is also making strides to encourage harmonisation of international regulatory requirements to minimise animal testing wherever possible.[4]

The UK's Medicines and Healthcare Products Regulatory Agency has acknowledged that non-animal testing is used wherever possible, but adds that "at present there are no laboratory methods available to totally replace animal testing of medicines" (personal communication).

99% of drug candidates discovered at the beginning of the process are indeed eliminated, most during early research phases, but this is a necessary part of the process of demonstrating efficacy as well as safety.[5] More relevant is the success of the vast majority of medicines approved for market by the regulators. Only a very small number—estimated at less than 1%—are subsequently withdrawn owing to serious side-effects.

93% of people admitted to hospital with an adverse drug reaction have a type A response. This means that the side-effects are predictable and could have been avoided if the medicine had been taken according to its prescribing information, or if the prescriber had been aware of other medicines being taken by the patient.[6] Most adverse drug reactions are, therefore, avoidable rather than the result of inadequacies in the drug development process.

Millions of people are alive today thanks to medical advances. Despite these efforts there are still diseases without adequate treatments—eg, dementia, many cancers, and heart failure. We all need to strive to improve every step of the development process, but this does not mean we should tear up a tried and tested process that has helped so many patients. Very recently, research on mice, stem cells, and a new polypeptide drug showed how the heart might be able to repair itself.[7] It is difficult to see how this advance could have been achieved without animal research.

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