The European Commission’s Opinion Backing Use of Non-Human Primates in Research is Flawed

Scientific advisors to the commission have disregarded evidence of past failings and the achievements of new technologies, say Margaret Clotworthy, Robert Coleman and Kathy Archibald.

A recent opinion of the European Commission’s Scientific Committee on Health and Environmental Risks (SCHER) that supports the use of non-human primates (NHPs) in biomedical research is scientifically flawed. It fails to evaluate in a critical manner the contributions to biomedical science that the committee assumes are made by NHP research and simply disregards proof of the contribution that human biology-based methods are now able to make.

The opinion, handed down in January, concluded that for many areas of biomedical research, there are, at present, no valid alternatives that would allow for a discontinuation in the use of NHPs. SCHER’s brief was to provide independent scientific information on the current status of possible replacements for NHPs. Yet the committee conspicuously fails to challenge its own assumption that NHP research is inherently efficacious – despite being presented with highly significant evidence to the contrary – and ignores the achievements of new technologies. The opinion also raises questions as to whether SCHER was suitably qualified to carry out the remit of the brief.

There are published several large-scale systematic reviews of NHP research that cast considerable doubt on the reliability and utility of NHPs for combating human diseases yet the opinion fails to reflect this.

SCHER concludes that the use of NHPs is essential in a number of important areas of research, including: safety testing of pharmaceuticals; the development of vaccines and therapies for infectious diseases such as HIV/AIDS; and the development, and testing, of treatments for neurological disorders such as Parkinson’s disease.

However, no convincing case has been made for the value of NHPs in any of these areas of research. Moreover, there is powerful evidence of the unsuitability of NHP use in many cases.

On the drug safety testing front, 67% of NHP use is for testing pharmaceuticals. Yet there are no published data that show that toxicity tests in NHPs are predictive of human outcomes. On the other hand, a paper published in 2008 concerning a much-quoted study of the predictivity of dogs for testing of pharmaceuticals; the development of vaccines and therapies for infectious diseases such as HIV/AIDS; and the development, and testing, of treatments for neurological disorders such as Parkinson’s disease.

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According to John Xuereb, director of the Cambridge Brain Bank Laboratory and the Wolfson Brain Imaging Centre (both based at the University of Cambridge in the UK)10: “Alzheimer’s, Parkinson’s and other neurodegenerative diseases occur in humans and it is in human tissue that we will find the answers to these diseases.” Over 700 interventions have been published showing efficacy in animal stroke models. Of these, around 150 have been tested and been found to be ineffective in human stroke studies – sometimes harming patients20. Many scientists would agree with the statement by David Wiebers of the Mayo Clinic in the US that21: “Over-reliance upon such animal models may impede rather than advance scientific progress in the treatment of this disease.”

Meanwhile, there has been a veritable explosion of imaging techniques, from magnetoencephalography and electroencephalography, through positron emission tomography and functional magnetic resonance imaging, to magnetic resonance spectroscopy, transcranial magnetic stimulation and diffusion tensor MRI. These techniques and many more have advanced our understanding of the human brain in health and disease far more than studies of NHPs. Ultimately, it is through study of the human brain that treatments for human neurological disorders will be found.

The SCHER opinion is exceptionally defensive of the use of NHPs. It says that “other species provide demonstrably unsatisfactory models in crucial respects”, but it fails to recognise that NHPs often suffer the same limitations. The opinion is unjustifiably critical of microdosing and extraordinarily dismissive of the US National Academy of Sciences report on “Toxicity testing in the 21st century”. This report, published in 2007, called for replacement of animal tests by “more efficient in vitro tests and computational techniques”. However, SCHER concludes that this pertains only to chemicals and has no relevance for pharmaceuticals.

**Was SCHER the wrong body?**

We believe that SCHER was the wrong body to be entrusted with this important brief. Its mandate covers non-medical health and environmental safety issues. In our opinion, its members have insufficient relevant expertise and their independence is compromised, since many of them are current or former animal researchers. The commission says that some of SCHER’s members have a relevant background in pharmacology and that experts involved in drafting the opinion work both with animals and with other methods such as human epidemiology, in vitro and computational methods. It also says that SCHER is the most appropriate framework for providing advice on alternatives to animal testing and that its working group included several external experts with a suitable profile covering all the relevant areas of expertise.

However, since the purpose of the opinion was to assess the ability of new technologies to replace NHPs in specific research areas, the working group should have had expertise in those new technologies. Given the wholly inadequate treatment of the current status of technologies that we believe are indisputably superior to the use of NHPs in many cases, we maintain that insufficient expertise in those areas was available.

At a hearing hosted by SCHER on 6 November 2008, senior representatives of both the UK government and a major industrial user of NHPs warned that the opinion would not be taken seriously if it were as one-sided as the draft opinion had been. Furthermore, suitably qualified scientists nominated by groups opposing the use of NHPs were refused permission to attend the meeting. The Safer Medicines Campaign was not even invited, contrary to claims that all contributors to the consultation were invited to participate.

In the absence of evidence to the contrary, we question SCHER’s opinion that the use of NHPs is essential for testing pharmaceutical products, including vaccines and neuroprotective agents, for either safety or efficacy. We believe that the effectiveness of tests in NHPs should be measured against the latest human-specific technologies before pronouncements can be made concerning which types of tests are indispensable.

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