

New Zealand White rabbit, the beagle dog and the cynomolgus monkey. Because these animals have been traditionally used, there is substantial accumulation of historical data. Given this extensive historical data, there is some concern that use of a different animal model could delay approval of a new drug—even if another animal is a better model. It is unfortunate that the idea that ‘we have always done it this way’ becomes more important than the scientific reality of which animal is most appropriate as a model. A statement confirming that there is a large amount of historic data to support the use of a specific animal may be included, but it should not be the sole basis for justification.

Laboratory animal veterinarians are trained to identify appropriate animal models and should be consulted when a proposal is being developed. As veterinarians, we owe it to the animal and the study to use our education and training to support the best science. That fact that we have always done studies one way or another does not mean that is the best way. Adequate justification for the use of any animal, be it rodent or non-rodent, should be provided in all protocols. Inclusion of a specific justification and an accompanying literature search utilizing appropriate terms might have convinced Madela and prevented the citation.

1. Animal Welfare Act and Animal Welfare Regulations. 9 CFR.
2. Russell, W.M.S. & Burch, R.L. *The Principles of Humane Experimental Technique* (Methuen and Company, London, 1959).

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A word from USDA, FDA and OLAW

In response to the issues raised in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA/APHIS/AC), the Food and Drug Administration (FDA) and the Office of Laboratory Animal Welfare (OLAW) offer the following clarification and guidance:

The Animal Welfare Act and regulations (AWR) and the PHS Policy require research facilities to ensure that procedures involving animals will avoid or minimize discomfort, distress and pain to the animals^{1,2}. Toxicological studies are considered research procedures that may cause more than slight or momentary pain or distress to the animals involved. As such, the principal investigator must consider alternatives (e.g., replacement with a species of a lower phylogenetic order or using alternative methods as suggested in FDA test guidance documents regarding the use of *in vitro* methods). The written narrative description of the methods and sources used to determine that alternatives were not available must be provided to the IACUC¹. In non-clinical studies, FDA may provide guidance on the use of rodent and non-rodent species in toxicological evaluations. When determining the appropriateness of a non-rodent species, consideration should be given to selecting a species of the lowest phylogenetic order that will yield the most informative data.

The rationale for involving animals, and the rationale for the appropriateness of the species to be used, as required in each research protocol by the AWR and the PHS Policy, may be developed from the information gathered in the search for alternatives^{1,2}. This detailed explanation enables the IACUC to ensure that animal pain and distress are minimized, unless otherwise scientifically justified. It is the IACUC’s responsibility to review and confirm that a sound, objective and logical reason has been provided for each of these required elements prior to approving the use of animals for the research proposal³.

The USDA inspector has the authority and duty to enforce the Animal Welfare Act and the regulations. Any noncompliant item could result in an inspection report citation, with further action taken as warranted.

1. Animal Welfare Act and Animal Welfare Regulations. 9 CFR, Chapter 1, Subchapter A – Animal Welfare: Part 2 Regulations. §2.31(d)(1)(i-ii) and §2.31(e)(2).
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* IV.C.1.b. and IV.D.1.b. (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals – Frequently Asked Questions*. Protocol Review, Question No. 7. (US Department of Health and Human Services, Washington, DC, 2006; revised 2008). http://grants.nih.gov/grants/olaw/faqs.htm#proto_7.

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