



May 20, 2008

National Institutes of Health  
National Institute of  
Environmental Health Sciences  
P.O. Box 12233  
Research Triangle Park, N.C. 27709  
Website: [www.niehs.nih.gov](http://www.niehs.nih.gov)

Jessica Sandler  
Director, Regulatory Testing Division  
People for the Ethical Treatment of Animals  
501 Front Street  
Norfolk, Virginia 23510

Dear Ms. Sandler:

I am responding on behalf of Secretary Leavitt to your petition submitted to the U.S. Department of Health and Human Services to initiate rulemaking. In your petition, you request rulemaking concerning "animal testing by or for the National Toxicology Program ('NTP')," and ask that the following criteria be satisfied:

1. There must be a showing that no alternatives to the proposed tests involving animals are available or will be available within the reasonably foreseeable future.
2. There must be a showing that there is, or are, no existing studies, research or data on the subject of interest, or studies, research or data which are closely related to the subject of interest and can be extrapolated thereto (i.e. route-to-route extrapolation, QSAR Toolbox, *Medline*, *Scopus* and similar resources). Compounds and substances which are already known to be hazardous to human health or to the environment are presumptively unsuitable for testing on animals.
3. There must be a showing to a reasonable degree of scientific certainty that the adverse effects caused to the animals are significantly outweighed by the expected benefits to be gained from the research.
4. There must be a showing that there are no existing human data and that any proposed animal tests have relevance to human health effects, and that the results of such tests will be predictive of human outcomes.
5. There must be a sworn affidavit executed by the principal investigator certifying to compliance with the foregoing under penalty of perjury.

Because the criteria you request are redundant to existing federal mandates that already apply to research before the NTP, your petition for rulemaking is respectfully denied (5 U.S.C. § 555(e)). For example, the Public Health Service (PHS) Act, the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act and accompanying regulations already provide legal and policy bases for consideration of alternatives.

Ms. Jessica Sandler – Page Two

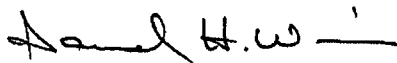
Prior to approval of study protocols that include the use of live vertebrate animals, Institutional Animal Care and Use Committees (IACUC) must conduct a review of those components related to the care and use of animals. Fulfillment of this IACUC responsibility, with appropriate documentation, is considered central to an institution's compliance with its Animal Welfare Assurance, the PHS Policy, and the Animal Welfare Act and accompanying regulations.

The Federal mandate to avoid or minimize discomfort, pain, and distress in experimental animals, consistent with sound scientific practices, is also relevant to the consideration of alternative methods that reduce, refine, or replace the use of animals. These issues are already incorporated into IACUC review, investigator training, research/testing protocols, and the ongoing monitoring of the institutional animal care and use program. IACUCs, acting as agents of institutions, implement and evaluate these aspects of the institutional animal care and use program to ensure compliance with the PHS Policy, which holds the institution responsible for compliance with statutory and policy requirements regarding the use of animals in PHS supported activities. These processes provide an ongoing basis for consideration of alternatives.

We appreciate your continued and shared interest in animal welfare. The NTP, through the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), is engaged in a concerted and coordinated federal effort to identify, validate, and promote regulatory acceptance of alternative test systems where appropriate. University-based researchers are also involved in this alternative methods development and validation through the National Institute of Environmental Health Sciences/National Institutes of Health extramural grants program.

A duplicate letter under separate cover is being sent to Susan L. Hall.

Sincerely,

A handwritten signature in black ink, appearing to read "Samuel H. Wilson", with a horizontal line extending to the right.

Samuel H. Wilson, M.D.  
Acting Director