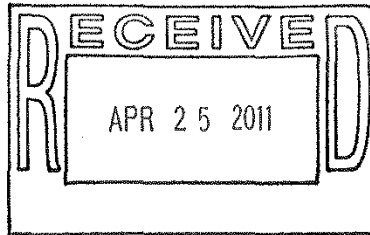




DEPARTMENT OF HEALTH & HUMAN SERVICES

April 22, 2011

Mr. Joseph Manupello
Research Associate
People for the Ethical Treatment of Animals
501 Front Street
Norfolk, Virginia 23510



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

Dear Mr. Manupello:

I am responding on behalf of Secretary Sebelius to your citizens petition submitted to the U.S. Department of Health and Human Services (HHS) to initiate rulemaking. In your petition, you request that "HHS and its institutes, the National Institutes of Health ("NIH"), the National Institute of Environmental Health Sciences ("NIEHS"), the National Center for Toxicological Research ("NCTR"), and the National Institute for Occupational Safety and Health ("NIOSH"), commence rulemaking concerning cessation of funding for, or animal testing by or for the National Toxicology Program ("NTP") and the NIH."

In addition to the requirements you cite, research conducted by NTP and NIH follows the Public Health Service (PHS) Act, 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 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.

Prior to the 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. IACUC review also provides an ongoing basis for consideration of alternatives.

HHS and its component institutes are committed to sound scientific practices and consideration of alternative methods that will reduce, refine, or replace the use of animals in research and testing. As the largest government program in toxicology, the NTP for more than 30 years has played a critical role in generating, interpreting, and communicating toxicological information. In addressing areas for research and testing, the NTP is guided by goals to provide information about potentially hazardous substances in our environment and communicate that knowledge to all stakeholders, to develop and validate improved testing methods, and to strengthen the science base in toxicology. Draft research concepts outlining NTP's approach of study are released for public comment and presented to the NTP Board of Scientific Counselors (BSC) in a public meeting where the BSC is asked for comment regarding to the study's validity, rationale, scientific merit, scope,

overall significance, and potential public health impact. The NTP carefully considers both public comments and BSC comments in finalizing the research concept and moving forward, including possible revisions to the plan of study.

In 2004, the NTP put forth a vision and roadmap for the 21st century that called for toxicology to evolve from a predominantly observational science to a predictive science⁶ and that established a high throughput screening initiative useful for (1) identifying mechanisms of action for further study, (2) prioritizing substances for further in-depth toxicological investigation, and (3) developing *in vitro* predictive models for *in vivo* biological responses. In carrying out its roadmap, the NTP has been actively involved in assessing current and new methods toward development of a toxicity testing strategy in line with the 2007 National Research Council's (NRC's) vision and goals for testing in the 21st century. In addition to activities within NIEHS, we have partnered with the U.S. Environmental Protection Agency, the NIH Chemical Genomics Center, and the U.S. Food and Drug Administration to merge federal agency resources, including scientific technology and knowledge, in a strategic and coordinated manner called Tox21. Elements of the NRC vision have been central for development of the Tox21 collaboration. Tox21 activities were highlighted at the BSC meeting on November 30 – December 1, 2010. The BSC's response to the overall initiative as well as activities being carried out at NIEHS was extremely favorable, noting the relevance of Tox21's goals to public health and the overall promise of the approach.⁷ A recent NTP workshop in January found participants generally supportive of using Tox21 approaches to identify chemicals that might impact biological processes important to the development of obesity or diabetes and thereby potentially lead to refinement of endpoints for future screening.⁸ On March 10, 2011, the Tox21 partners announced purchase of a new robotic system dedicated to screening chemicals for toxicity *in vitro* that adds to the innovative chemical screening technologies being used to better understand human susceptibility to toxicity and disease and improve how chemicals are tested in the United States.

We appreciate your continued and shared interest in animal welfare. HHS and NTP, through the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), are engaged in coordinated federal and international efforts toward the development, validation, use, and harmonization of alternative test methods for regulatory safety testing where appropriate.⁹ On March 8, 2011, NIEHS and NTP joined international counterparts in expanding the International Cooperation on Alternative Test Methods (ICATM),¹⁰ an agreement that promotes enhanced cooperation and coordination on the scientific validation of alternative test methods to reduce the number of animals required

⁶ NTP Vision and Roadmap for the 21st Century are available at <http://ntp.niehs.nih.gov/go/vision>

⁷ Minutes are available at

http://ntp.niehs.nih.gov/NTP/About_NTP/BSC/2010/NovDec/Minutes20101201.pdf

⁸ Information about the workshop is available at <http://cerhr.niehs.nih.gov/evals/diabetesobesity/>

⁹ Summary of test methods evaluated or under consideration by ICCVAM is available at <http://iccvam.niehs.nih.gov/methods/methodsSum.htm>

¹⁰ Information about the agreement is available at <http://iccvam.niehs.nih.gov/about/icatm.htm>

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for safety testing worldwide. South Korea newly joined this update to the April 2009 ICATM Memorandum of Cooperation, which was also signed by the representatives of the European Union, and the governments of Canada and Japan.

University-based researchers are also involved in alternative methods development and validation through the NIH extramural grants program. This program includes Small Business Innovative Research grants to stimulate technological innovation in the private sector.

The materials you provided and your recommendations have been carefully considered and reviewed, and your petition for rulemaking is respectfully denied (5 U.S.C § 555(e)).

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

Sincerely,

A handwritten signature in cursive script that reads "Linda S. Birnbaum".

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Director
National Institute of Environmental Health Sciences
& National Toxicology Program