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October 6, 2003

Michael J. Holland
Office of Science and Technology Policy
1650 Pennsylvania Avenue, NW
Washington, DC 20502
RE: NSTC Research Business Models Comments

Dear Dr Holland:

These comments are submitted in response to the Request for Information published in the *Federal Register* (Volume 68, Number 151, 8/6/03). We support the comments submitted on behalf of the Alternatives Research & Development Foundation, and also submit the following.

**B. Inconsistencies of policies and practices among Federal agencies**
**C. Inconsistencies of policies and practices among universities**

The U.S. Department of Agriculture (USDA) does not cover birds, mice, and rats (among other species) through law enforcement of the Animal Welfare Act, but these animals are covered under Public Health Service Policy. Therefore, if projects involving these animals are conducted and not funded by the federal government, the investigators may not have to abide by basic standards of humane care and use, including review of the research protocol by an Institutional Care and Use Committee (IACUC). This giant loophole not only leads to significant animal welfare concerns, but also puts the scientific rigor and standardization of such projects into question. It is important that animals commonly used in laboratories—such as birds, mice, and rats who represent over 95% of warm-blooded animals used— receive basic protections and that all researchers using these animals adhere to the same basic standards. The United States is one of the few countries to not provide this oversight to these commonly used animals and if researchers rely so heavily on these animals to improve public health, we should take their care and use seriously.

**E. Regulatory requirements**

We feel strongly that requirements stating that Primary Investigators conduct proper searches into reduction, refinement, and replacement of the use of animals in protocols for research, testing, and education remain intact and enforced. Scientists should not undermine ethical considerations when using animals as the public has significant concerns about animal welfare. It is the responsibility of IACUCs to ensure that investigators and Committee members are trained in searching existing databases and actually conduct accurate searches for alternatives.

We urge the Subcommittee on Research Business Models to consider investigating new regulatory requirements related to genetically-engineered animals—many of whom have special care needs due to genetic alteration. Other countries (e.g. Canada and Great

Britain) and organizations (e.g. Federation of European Laboratory Animal Science Associations) have produced documents that will support this initiative.

USDA's Animal Care Division oversight and expansion is also vital to improving animal welfare and ensuring 'humane' science, and we urge additional funding for the addition of USDA Inspectors.

**F. Research support**

We encourage additional activity through the Interagency Coordinating Committee for Validation of Alternative Methods (ICCVAM), including a provision for making grants available to scientists conducting research into alternatives that reduce, refine, or replace methods of using animals. This encourages innovative research that could benefit many in the scientific community.

Thank you for your consideration of our comments.

Sincerely,

Crystal Miller-Spiegel
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