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October 6, 2003

Michael J. Holland
Office of Science and Technology Policy
1650 Pennsylvania Avenue, NW
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via electronic mail to:
nstc_rbm@ostp.eop.gov

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). The Alternatives Research & Development Foundation (ARDF) welcomes this opportunity to present information on policies, procedures and plans relating to the business relationship between federal agencies and research performers.

The Alternatives Research & Development Foundation is a non-profit organization headquartered in Jenkintown, Pennsylvania, that funds research and development of scientifically sound alternative methods to the use of animals in biomedical research, product testing and education. ARDF also engages in public education and advocacy to promote greater understanding and broader acceptance of non-animal methods, and to accelerate the validation and adoption of alternatives.

Since we initiated our funding program more than ten years ago, we have distributed over one million dollars in grants to stimulate innovative scientific research. In an example of our efforts, one such grant resulted in an economical, practical alternative to the ascites method of monoclonal antibody production.

The story of how this method, along with other alternative methods of producing MAbs, are now increasing in use is a model of a successful intervention by a federal agency to fulfill its congressional mandate to encourage the use of alternatives by creating a simple policy that advances good science. At ARDF's urging, and in accordance with the 1993 NIH Reauthorization Act and a number of scientific workshops that established a consensus that MAb alternatives were feasible in small, medium, and large scale operations, the Office of Laboratory Animal Welfare of the National Institutes of Health took action in 1999. It incorporated new language into its guidance documents for grant applicants, directing that in vitro methods be considered the ***default*** method for producing MAbs, and therefore animal use required justification. NIH continued to support the creation and maintenance of centralized labs where skilled technicians improved the quality of the MAbs produced.

The US Department of Agriculture has the primary responsibility from Congress to place researchers and alternatives to uses of animals in painful procedures within its purview. The requirement under the regulations of the Animal Welfare Act is that researchers "consider" alternatives in these situations. In its efforts to clarify inspectors' expectaions, USDA issued Policy 12, "Consideration of Alternatives to Painful/Distressful Procedures". Modifications issued on June 21, 2000 made compliance more flexible, instructing that varied sources of information, such as consultations with alternatives experts, would be accepted with sufficient documentation as evidence of an alternatives search/consideration. **In ARDF's view, it is vital that Policy 12 continue to set a clear standard regarding alternatives.**

Meanwhile, advancing technology and greater understanding of critical related issues, such as simple use of essential keywords, has enhanced the sometimes-disparaged database search for alternatives. Much work has been done in this field, some of which was presented at the Fourth World Congress for Alternatives and Animal Use in the Life Sciences in 2002 in the U.S. In November, 2003, a workshop: "Retrieval Approaches for Alternative Methods to Animal Experiments" will be held in Berlin, bringing together experts in information resources and search strategies, including several from the U.S. A number of federal agencies and other public/private entities, including ARDF, are helping to make this information more widely available. Participants in the workshop will include federal agency representatives from NLM, VA, AWIC, as well as institutes located at academic institutions Johns Hopkins and U. of California - Davis.

Technology is responsible for tremendous advances in the alternatives field in general, and federal agencies can play an important role to stimulate their use, as well as perform the monitoring function that the public relies on for accountability.

Another role that federal agencies can perform in relation to the research industry, is that of ensuring fairness in the industry. ARDF is concerned about the huge accountability gap for laboratories that do not use any animals except mice, and which are therefore not even required to register with USDA, nor, of course, consider alternatives to painful procedures. Mice alone comprise upwards of 90% of all animals in laboratories. The inclusion of mice, rats and birds as regulated species under the AWA would create a level playing field for all facilities and all researchers and contribute to more uniformity and reliability of data generated by different labs by ensuring uniform standards. With the added complication of care for genetically modified animals, this concern needs urgent attention.

Researchers themselves favor protection of a wide range of species of "lab animals". A poll reported in Lab Animal magazine in June 1999, showed that animal researchers who sit on Institutional Animal Care and Use Committees endorse AWA regulation of specific animals as follows: Primates, 99.7%; Dogs, 98.6%; Cats, 98.3%; Rats/mice, 73.9%; Pigeons, 67.9%.

In summary, our experience is that use of alternatives and uniform, high standards of humane care of animals contribute to the long-term development of better science. The federal agencies play an important role in advancing that through regulation and policy, and ensuring public accountability. ARDF endorses strengthening that role where possible.

Thank you for your solicitation of comments.

Respectfully submitted,

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