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Comments of The Humane Society of the United States
In Response to the USDA *Federal Register* Announcement of August 6, 2003
Docket Number 03-19935
NSTC Research Business Model Comments
October 6, 2003

These comments are being submitted on behalf of The Humane Society of the United States (HSUS), the nation's largest animal protection organization, and our more than 7.5 million members and constituents. We would like to thank the National Science and Technology Council Subcommittee on Research Business Models for providing the opportunity to comment on means of improving the mechanisms related to federal funding of scientific research. These comments will focus exclusively on the care and use of animals in biomedical research, testing and education. The decisions made by the Subcommittee on the issues at hand are important to the welfare of research animals. Our primary aim is to ensure that efforts to change mechanisms related to federal funding do not in any way decrease animal welfare.

We have provided comments per specific area, as requested in the *Federal Register* notice. Please note that we have only provided comments on items A, B, E and G.

Section A. Accountability

Accountability is a major factor related to the use of animals in biomedical research as the public is concerned about animal suffering. Public support for animal research declines drastically when the animals are subjected to pain and distress. A 2001 opinion poll commissioned by The HSUS found that 75% of the American public disapprove, and most strongly disapprove, of experiments that subject animals to severe pain and distress. Sixty percent oppose experiments that cause even moderate pain and distress. Thirty-three percent of those surveyed oppose research and testing that involves little or no pain or distress to animals.

As a result of this public concern, it is important for the government to demonstrate a commitment to refining animal use so that the animals experience less suffering, as well as to reducing the number of animals used and replacing animal use altogether when possible. The government has stated the importance of these issues in the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.* According to principle III:

> *"The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered."*

Principles IV and V stress the importance of minimizing animal pain and distress:

> *"Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative…Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia…"*

Minimization of pain and distress is the central theme of the Animal Welfare Act and section 13 (a)(3)(B) requires that the "principal investigator considers alternatives to any procedure likely to produce pain and distress in an experimental animal."

The U.S. Department of Agriculture, the agency charged with enforcing the Animal Welfare Act, has a policy and regulations regarding consideration of alternatives to procedures that cause animal pain and/or distress. Policy #12 supports the Animal Welfare Act and Government Principle III by requiring researchers to "provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements." This policy was revised, and actually weakened, in June of 2000. The previous policy required a database search of publications, but the new policy allows other sources, such as conferences, expert consultants and other sources in lieu of or in addition to the database search. Therefore, due to the fact that a database search is only an option and not a requirement in order to fulfill Policy #12, there is no need to eliminate this language from the USDA policy. Although weakened, **Policy #12 is essential to replacement, reduction and refinement in animal research and should not be eliminated as a legal requirement**.

Additionally, there are at least three factors that could strengthen Policy #12:

1. Training: Literature searches that are properly conducted can lead to decreased animal suffering and, given the expense of conducting animal research, could decrease costs of research as well. However, too often alternatives searches are not properly conducted, and this prevents researchers from finding useful information. The Animal Welfare Information Center provides online tutorials and hands-on workshops regarding how to conduct alternatives searches properly; each researcher should be required to complete the tutorial or workshop before using animals in the laboratory.

2. Adoption of alternatives: The current Policy #12 requires that researchers *consider* alternatives and justify why available alternatives are not used, if they are not. The Institutional Animal Care and Use Committee and the USDA should closely examine the justification and strongly recommend *adoption* of alternatives when possible.

3. Enforcement: The USDA should increase enforcement to ensure that alternatives searches are being conducted properly and that justification for not adopting alternatives is valid.

Any effort to eliminate the alternatives search requirement, as suggested by some organizations, will decrease level of accountability which runs counter to the aims of the Subcommittee on Research Business Models. Efforts to strengthen the alternatives search requirement, however, will increase accountability. The public is concerned about animal suffering and expects responsible animal use.

Section B. Inconsistency of policies and practices among Federal agencies

There should be a mechanism in place in order to increase communication between the USDA and the National Institutes of Health funding and grants offices regarding Animal Welfare Act violators. The current funding system provides millions of federal dollars to some institutions, and these funds continue even if the institution is fined for Animal Welfare Act violations. Additionally, these funds could actually be used to pay for the violations. An improved system would involve funding consequences for those institutions that are fined for Animal Welfare Act violations; such a system would improve animal welfare as well as accountability.

If there are any additional efforts related to consistency of policies and practices among these agencies, we request that any changes are not implemented at the expense of animal welfare.

Section E. Regulatory requirements (is there are more efficient approach?)

Some of the items discussed in relation to alternatives searches (section A above) relate to efficiency. If searches are not properly conducted, for example, a researcher may get a list of thousands of papers that are irrelevant to his/her area. If s/he attempts to sort through all of these papers, this can waste a significant amount of time. If

researchers learn how to conduct searches properly through the Animal Welfare Information Center resources, or some equally useful means, time will not be wasted and animal suffering will be decreased.

Section G. Multidisciplinary/collaborative research

The National Primate Research Centers (NPRCs) are a network of nonhuman primate research laboratories that are funded by the National Institutes of Health's National Center for Research Resources and house more than 20,000 primates. These centers were previously known as Regional Primate Research Centers, but the name was changed to reflect that they form a national network. Unfortunately, there is currently no database or other system in place in order to network information between the centers. This lack of communication can result in duplication of efforts and, given the invasiveness of the research conducted at the centers (e.g. infectious disease and cancer) can cause unnecessary suffering of an unknown number of nonhuman primates. Duplication of effort can significantly waste federal dollars as well. The NPRCs should be required to share information and streamline efforts in order to decrease the number of animals used, the amount of animal suffering and waste of federal funding.

Thank you again for the opportunity to comment on these issues.

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