October 6, 2003

Kathie L. Olsen,
Associated Director
National Science and Technology Council Subcommittee on Research Business Models
Office of Science and Technology Policy

Dear Ms. Olsen:

As a member of the NIH Regulatory Burden Working Group (now consolidated into the Peer Review Oversight Group), I represent the Animal Welfare view on issues related to laboratory animal use and regulation of that use. I would like to make a specific comment about the Animal Welfare Act (AWA) regulatory requirement that investigators consider alternatives to procedures that may cause more than momentary or slight pain or distress to animals and to provide a written narrative of the methods used and sources consulted to determine the availability of alternatives.

During our working group discussions, it was apparent, and understandable, that many of the regulations regarding animal use caused additional work in order to be implemented properly. The question before us, however, concerned regulatory *burden*, which was defined as workload that could be eliminated or modified without diminishing the intended protection to animals. I have extensive experience in laboratory animal medicine, having been the Director of the Laboratory Animal Science Center at Boston University Medical Center and veterinarian in charge of program for 23 years. I believe that the issue of pain in animals in research, its relief, and the search for alternatives to eliminate pain are the most critical animal welfare issues in research. There should be no question regarding the priority for these issues.

I realize that there is no simple formula or single data base that can be searched to quickly and efficiently identify alternative approaches to painful research activities. This has led to frustration among some scientists who often are submitting their animal use protocols to the IACUC at the last minute. As a result, some scientists have resorted to going through the motions of making data base searches simply to fulfill the AWA requirement, knowing in advance that the effort will accomplish little or no meaningful results. This approach has furthered the opinion among some researchers that this regulation is a burden and should be eliminated, because it is not accomplishing any improvement in animal welfare.

What is missing in these cases, is an institutional commitment to the importance of minimizing and, if possible, eliminating pain in the millions of animals used in research. If that commitment were present, methods would be found to overcome the issues related to identifying alternatives to painful procedures. The

USDA/APHIS Animal Care staff have already provided alternative methods to accomplish a satisfactory search for alternatives. Policy #12 states that while data base searches are considered the most effective and efficient ways to locate alternative methods, most recent information in this area may also be obtained from conferences, colloquia, subject experts, and other sources. The Federation of American Societies for Experimental Biology has recommended that regulations requiring data base searches for alternatives be eliminated. I believe that this is a short sighted recommendation that is an embarrassment to scientists who personally should be committed to elimination of pain in their research subjects. In addition, the FASEB should be aware of the public's understandable sensitivity to this issue. Instead of recommending changes in regulations and policies, institutions should be focused on the importance of pain relief and should be developing methods to identify all possible approaches to accomplish this important goal. It is not the lack of ability to properly search for alternative methods to painful procedures that is the problem, after all, these are research institutions with many of the world's most capable scientists. The problem is institutional commitment to developing a culture that places a priority on pain relief in research animals.

Two months ago, I participated in an ICCVAM advisory committee meeting, where a representative from the European Union's similar committee (ECVAM) was discussing their ban on animal testing for ingredients of cosmetics. It was pointed out by members of my committee that it may not be possible for ECVAM to develop the alternatives to animal tests in just a few years. The response was that this certainly was a difficult task, and the timeline might have to be extended, but *they were going to try.* This was evidence of a culture of commitment to improving animal welfare by developing alternatives. When some of our United States scientists state that they want the requirement to find alternatives to painful procedures eliminated, they are sending the wrong message which carries with it the implication that our scientists do not place a priority on this issue. Instead of calling for a change in the regulations that already allow for alternative approaches, it is my view that they should be reinforcing the importance of this issue, and developing methods to effectively and efficiently find all possible alternatives to painful procedures.

Thank you for your solicitation of comments on these many important issues.

Respectfully,

Peter Theran, VMD
Vice President of Animal Sciences
Massachusetts Society for the Prevention of Cruelty to Animals
350 South Huntington Avenue
Boston, Massachusetts 02130
Phone: 617-571-8114