Animal Welfare Institute
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To: National Institutes of Health, regburd@od.nih.gov

From: Cathy Liss, Executive Director and Adam Roberts, Research Associate

Animal Welfare Institute

Re: Comments on the Report on Regulatory Burden, VI. Animal Care and Use

On behalf of the Animal Welfare Institute I am writing to register our strong opposition to the "Section VI. Animal Care and Use" of the Report on Regulatory Burden and to express outrage at those who seek to dismantle the current sound laws and regulations enforced by the U.S. Department of Agriculture

The Animal Welfare Institute seeks to reduce the sum total of pain and fear inflicted on animals by people. We are not an anti-vivisection organization. We seek humane treatment of animals in the laboratory and support the universally-accepted "3 R's" (replacement of experimental animals by alternatives, refinement to reduce pain and suffering when animals are still used, and reduction of numbers of animals used). We produce a quarterly newsletter and books such as Comfortable Quarters for Laboratory Animals and Environmental Enhancement for Caged Rhesus Macaques which we make available free of charge to research facilities.

The use of animals in research includes a weighty responsibility to ensure the best possible care and treatment for these animals whose lives will be sacrificed following experimentation. Animals who are treated well will produce more sound research results with a lower variance. ("The Benefits of Giving Experimental Animals the Best Possible Environment" by Michael Chance and William Russell, Comfortable Quarters for Laboratory Animals, pages 12-14) However, there is a segment of the research community who do not wish to be regulated or who would like to reduce the regulatory requirements imposed on them.

In 1995, following widespread public concern and extensive documentation of the need for legislation and of the failure of institutions to self-regulate, hearings in both the House of Representatives and the Senate, and careful consideration and negotiation, Congress adopted the Improved Standards for Laboratory Animals amendment to the Animal Welfare Act. Many researchers and the lobbyists who represented them fought against this law, as those before them fought against the Laboratory Animal Welfare Act of 1966 (later re-named the Animal Welfare Act). Having lost that battle, opponents fought against regulations for enforcement of the law until weakened regulations were finally adopted four years later. Now a new avenue is being pursued, to wipe out as much of the Animal Welfare Act as possible under the guise of "regulatory burden".

Following are my specific comments:

The Committee make-up and individuals interviewed should have included a wider spectrum of people including the non-affiliated member of the Institutional Animal Care and Use Committee (IACUC) and scientists who are known for their advocacy of animal well-being, at least one representative from the Animal Welfare Information Center at the National Agricultural Library and members of the humane community. Any future committees that may be established should have this broader constitution.

I recently participated in an extremely well-attended, national laboratory animal conference, the annual meeting of Public Responsibility in Medicine and Research. I was shocked to hear an administrator and researcher from a large institution announce from the podium that most researchers do not know what the "3 R's" are. That this should be said 10 years following implementation of a law that mandates research investigators to consider alternatives reveals the need for additional regulation or oversight, rather than weakening of the current system.

Unfortunately, at far too many institutions, the directors of the facilities and the chairs of the IACUCs do not place sufficient emphasis on alternatives and fail to encourage consideration of alternatives by the researchers at the institution. As a result, the literature search, conducted as a last step in the process, is seen as a mandatory hurdle to comply with the law and not as the valuable tool that it is. The investigators are merely going through the motions.

Perhaps what is needed is more specific direction about the literature search. For example, the search for alternatives should be conducted early in the development of a research protocol, at a time when the investigator is conducting other searches of the literature. In addition, the search needs to look at all three "R's", not just alternatives to the use of animals. Can the numbers of animals used be reduced? And particularly, what refinements can be used to improve the situation for the animals? Perhaps the refinement is as simple as provision of better post-surgical bedding.

It is appropriate that researchers consider alternatives to procedures which may cause more than momentary pain or distress to animals, even if pain relief is given. There are a number of reasons for this including the fact that a number of animals will experience different degrees of "discomfort" despite provision of pain relief and it is important to ensure that the best, most suitable method of pain relief is provided--and at the proper dose and intervals.

An OIG audit titled "Enforcement of the Animal Welfare Act", dated January 5, 1995, identified the failure of IACUCs to meet their current responsibilities under the law and the failure of researchers to provide a complete protocol for review by the IACUC. At 12 of 26 facilities, "the committees were not adequately fulfilling their responsibilities under the Act." Further, when committee members were questioned about the deficiencies, they "stated that they were not aware of the provisions of the Act." "The deficiencies disclosed by our review show the need for tighter controls over the activities of the committees." Protocol review should continue to be mandated at least once per year, and USDA's careful oversight of the IACUC is vital.

I have conducted tours of research facilities across the country. Despite the fact that my visits are announced, I have always seen some failure to comply with the minimum requirements of the Animal Welfare Act. Site visits are extremely important. There is great usefulness in the current system that mandates, at minimum, bi-annual inspections by the IACUC (permitting some self-regulation), but augmenting this with the UNANNOUNCED inspections by USDA veterinary

inspectors. Review of USDA inspection report forms provides powerful evidence of the utility and great need for their work.

Accreditation inspections of hospitals should not be compared to inspections of animal research facilities for two major reasons. At research facilities, those entitled to protection under the law are animals, unable to voice objections to conditions, and secondly, hospitals are frequented by the general public, people who are able to voice concerns without fear of reprisals.

Perhaps NIH can do away with their site visits since it is not an activity which they undertake with regularity. In those instances where a registered research facility is not in compliance with the law, perhaps it is a USDA inspector who should be sent in to conduct an unannounced inspection, rather than a team of individuals organized by NIH who make a scheduled visit.

I do not know why the Association for Accreditation of Laboratory Animal Care International (AAALAC) is mentioned in this report on regulatory burden at all. An institution's decision to request accreditation by AAALAC is voluntary, therefore, those institutions who do not wish to be burdened with the additional responsibilities or cost of accreditation can simply refrain from requesting accreditation. The majority of research facilities in the United States are not accredited.

In this age of computerization, it is easy to prepare a program so research facility personnel can enter data for use in generating two separate annual reports, one for USDA and another for NIH. Alternatively, the research institution is not prohibited from providing additional information beyond what is mandated by the agency, so the requirements of both USDA and NIH could be supplied in one document. These agencies do not have the legal authority to mandate this, so it must be left up to the research facility. I'm certain that the two agencies could agree on one submission deadline for the annual report.

The requirement in the Animal Welfare Act for no animal to be subject to more than one major operative procedure is sound. Exceptions are permitted, but must be approved by the Deputy Administrator, Animal Care, APHIS. There is no indication that the Deputy Administrator takes an excessive amount of time in responding to requests for exceptions. Such exceptions should rarely be necessary and submission of an already-completed protocol to the Deputy Administrator for approval cannot be viewed as overly burdensome.

It is appalling for the report to complain of USDA's rigid requirements for cage sizes. USDA's requirements are MINIMUM standards, and facilities should be providing at least the mandated amount of space. Animals should not have to sacrifice space in order to get companionship.

Regarding training of inspectors, why doesn't the report suggest the need for additional funds for training? Such training should not include "the philosophy underlying the use of animals in research" since this has nothing to do with enforcement of the Animal Welfare Act, and would not serve to enhance the quality of inspections conducted by USDA.

In the Section titled, "Complexity of regulations governing the transportation of animals and biological materials from non-human primates," the suggestion that the "rigid interpretation of these regulations, have the unintended consequence of impeding research, and can also be life-threatening" is both hyperbolic and anecdotal. The regulations governing import and export of CITES listed specimens, whether a live animal or the part or product from a live animal, are based on

an international Treaty, the tenets of which have been agreed to and implemented by the 145 Parties to CITES, including the United States.

The primary responsibility of the FWS is to ensure that trade in CITES-listed species is done in accordance with the Convention and that the precautionary principle is applied when examining each permit application for a species in trade. The FWS is not charged with facilitating "transportation of research materials." Furthermore, although "non-human primates" is referred to specifically in the background discussion, the recommendations under 7. contain no such specificity. Hence, if changed, the regulations will be unacceptably misleadingly, and vaguely weakened beyond any specific species reference.

Although the notification claims that there are three categories of species' population status and subsequent protection, these references have no correspondence to legal language in the Endangered Species Act or the CITES Treaty. The notice asserts: "The highest level of control is on those animals threatened with extinction, where a permit is required from both the importing and exporting country; those not threatened with extinction, but likely to be so without trade regulation, require an export certificate; and species for which any of the 100 signatory nations has designated a restriction requires an export permit, a re-export certificate, or a certificate of origin." Nowhere in the Treaty's description of Appendix I or Appendix II specimens are the phrases in recommendation 7.b. "immediately threatened with extinction" or "not presently threatened with extinction" found. Without strict adherence to the textual language of CITES, it is impossible to address proposed alterations to regulatory controls accurately. It is illogical and unacceptable to change regulatory responsibility for the Fish and Wildlife Service, while using language that does not have any regulatory reference in the domestic or international law which the Service is charged with enforcing.

Both recommendations (7. a. and b.) concerning reform of regulations on importation of threatened and endangered specimens reveal a fundamental lack of knowledge of, and confidence in, the CITES Treaty. Specimens on CITES Appendix I, by definition, "include all species threatened with extinction which are or may be affected by trade. Trade in specimens of these species must be subject to particularly strict regulation in order not to endanger further their survival and must only be authorized in exceptional circumstances." Hence, to weaken in any way the regulatory structure for Appendix I specimens would be to bring the United States government in violation of the Treaty it signed in Washington , DC in 1973. Appendix I species, by definition, require the greatest international controls to prevent further population decline.

Further, according to the Treaty, specimens on CITES Appendix II "shall include: all species which although not necessarily now threatened with extinction may become so unless trade in such species is subject to strict regulation in order to avoid utilization incompatible with their survival." Again, the regulation of trade in threatened wildlife is mandated by CITES and implemented by the United States - not the other way around. By requiring proper permits and certificates, the US Fish and Wildlife Service is meeting its international obligations under the CITES Treaty.

The CITES Treaty was signed specifically to protect "certain species of wild fauna and flora against over-exploitation through international trade." But these trade controls do not prohibit access to or importation of wild and captive-bred specimens; they merely provide a standard process governing such trade.

The text of the CITES Treaty specifically defines “specimen” as “any animal or plant, whether alive or dead” and, for species in Appendices I and II, “any readily recognizable part or derivative thereof.”

Appropriate CITES permit controls are fundamentally necessary, even in the event of importation or exportation of blood, tissue, and other bodily fluids or organs. Without such regulatory controls, threatened and endangered wild populations may meet increased pressure for samples of these specimens - which may result in increased mortality and significant adverse impacts to animal well-being in the collection process. This is precisely why the Treaty requires a non-detriment finding before any export of Appendix II specimens is authorized.

The scenario used by the working group to justify the complaint that the CITES permitting process is too cumbersome is fundamentally misapplied: “A workgroup member described an incident involving an individual bitten by a zoo animal (non-endangered) in Canada where a blood sample from the animal could not be immediately shipped to the U.S. for tests to ascertain the possibility of transmission of a deadly disease.” In this instance, the zoo animal is noted as being “(non-endangered)”. Assuming this is a reference to an Appendix II species, no import permit from the US is required - all that is required is an export permit from Canada. Any delays in transport of the blood sample in question is not representative of any problem with the process from the United States side of the equation.

Issuing blanket permits to research institutions is dangerous and unnecessary. No blanket permit should be given to a research institution for the importation of any species listed under the Endangered Species Act or the Appendices to CITES. In general, each species importation and/or exportation must be looked at individually to determine whether there is a justifiable reason for such importation and to see the impact of such import on the species’ wild populations.

It is absolutely unacceptable and a potential violation of the Treaty to propose eliminating “the extension of permit requirements for research materials to those animals not categorized as being immediately threatened with extinction.” Again, as stated above, Appendix II species (if that’s what we are referring to), which are not yet threatened with extinction, also require trade controls - but not importation permits. Therefore, any concern over alleged delays in importing CITES Appendix II species are concerns that cannot be addressed by the regulations of the Fish and Wildlife Service since the Fish and Wildlife Service does not issue Appendix II import permits. The delays come from the exporting government, not the US.