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June 7, 2005

Dr. Chester Gipson  
Deputy Administrator  
Animal Care Unit  
USDA - APHIS  
4700 River Road  
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Dear Dr. Gipson:

I am writing on behalf of The Humane Society of the United States (HSUS) and our 8.5 million members and constituents in order to urge the USDA to take action on its proposal entitled "Animal Welfare: Definitions for and Reporting of Pain and Distress" (*Federal Register*, July 10, 2000). Contrary to the pronouncements of some, there is evidence of a consensus among the research community regarding a particular definition of distress as well as the need for an improved pain and distress categorization system.

### **Definition of distress: consensus within the animal research community**

In March and November of 2003, The HSUS wrote to the USDA in order to request that the agency move forward on the pain and distress proposal, which encompasses two issues: defining the term *distress* and revising the current pain and distress categorization system. In July of 2003, we received a response to our March 2003 letter from Dr. Accord, which indicated that the agency would not be moving forward on the proposal "at this time" because "there is not a clear definition of distress and further research needs to be conducted to resolve this issue" (a copy of this letter is enclosed). However, our November 2003 letter to Dr. Accord (a copy of which is enclosed) indicated that 97% of the comments submitted by the research community supported one particular definition of distress, namely that included in the National Research Council publication "Recognition and alleviation of pain and distress in laboratory animals." Dr. Accord did not respond to this letter.

### **Pain and distress categorization system: consensus within the animal research community**

Since our correspondence with USDA on this issue in 2003, we have conducted an analysis that shows that nearly nine out of every ten comments submitted by the research community to USDA (88.7% of over 2,000 comments) were supportive of a revised and/or changed categorization system. This demonstrates that there is general consensus among the research community (100% consensus among all parties will never be reached) and that a revised categorization system should be proposed at this time. For this reason, we would like the USDA to reconsider the proposal.

The following categories reflect the majority of recommendations submitted by the research community regarding a revised categorization system:

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- Reflect actual rather than potential pain, regardless of whether or not anesthesia and/or analgesia are administered
- Include non-pharmacological efforts to relieve pain and distress
- Adopt completely new categories of pain and distress
- Adopt The HSUS system that was published as part of the *Federal Register* notice
- Adopt the Canadian Council for Animal Care (CCAC) system that was published as part of the *Federal Register* notice.

According to the *Federal Register* notice itself (enclosed), “[a] different categorization system could produce data that more accurately depicts the nature of animal pain or distress and provide a better tool to measure efforts made to minimize animal pain and distress at research facilities.” This statement, as well as the fact that the proposal was published, clearly indicates that the USDA recognizes the importance of improving the categorization system. The HSUS firmly supports this effort.

### **Proposed system**

As we have conveyed in the past, we urge the USDA to transform its current classification system into a graded scale of pain and distress that reflects levels of severity. In our submitted comments on the issue, we proposed a system that essentially would replace the current three categories with three new categories, namely, minor, moderate, and severe. For continuity between the current and proposed systems, we proposed that the minor category be subdivided according to whether or not pain and/or distress relief was provided. If this continuity were deemed to be unnecessary, then the new proposal boils down to a simple system of minor, moderate, or severe. Any “gray” areas between minor and moderate, and between moderate and severe, could be minimized through USDA guidance and exemplars.

A revised system that reflects levels of pain and distress would finally provide an accurate picture of what the research animals are experiencing, thus providing interested stakeholders with a more accurate picture of the cost of research to the animals. The revised system also would help identify those techniques that cause the most severe pain and distress, and thus allow interested stakeholders to focus much needed attention on how to alleviate these adverse effects. Moreover, the new system would allow international comparisons regarding animal use, given the prevalence of similarly graded severity scales overseas, including those from Canada, Finland, the Netherlands, Switzerland, and the United Kingdom. As a matter of fact, The British Home Office, the Canadian Council on Animal Care, and the New Zealand Ministry of Agriculture and Forestry each submitted comments to USDA in support of adoption of a true severity scale in the U.S. Identifying international trends in the severe category would inevitably lead to a focus on how procedures in that category could be refined in order to decrease, and perhaps eventually eliminate pain and distress on a worldwide basis. This would lead to a true focus on the Three Rs of replacement, reduction, and refinement, as USDA Policy #11 intends.

The current pain and distress classification has several shortcomings. The *Federal Register* notice published by USDA recognizes this and states as follows:

*“For example, the current system does not include a means to report:  
 An assessment of the relative intensity or duration of pain or distress either observed in the animal or anticipated to be experienced by the animal;  
 An assessment of the anticipated or observed efficacy of the pain- or distress-relieving agent provided to animals undergoing a painful or distressful procedure;*

*A distinction between procedures causing animal pain and procedures causing animal distress;*

*Animals that were prevented from experiencing pain or distress by the appropriate and effective use of pain- or distress-relieving methods or procedures (e.g., well-anesthetized animals that undergo terminal surgery);*

*Animals that did not experience pain or distress due to the appropriate and effective use of pain- or distress-relieving methods or procedures other than anesthetic, analgesic, or tranquilizing agents;*

*Animals that experience unrelieved pain or distress for a reason other than that the use of anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, experiments, surgery, or tests; or*

*Animals that experience pain or distress without having been used in a procedure (e.g., illness in animals that have been genetically altered to develop disease)”.*

There are additional problems with the current system that were not captured in the *Federal Register* notice; for example, there is no category for procedures causing pain and distress that are partially but not fully alleviated by the administration of drugs.

#### **Stakeholder group examines severity categorization**

The United Kingdom-based Boyd Group recently issued a discussion document regarding severity categorization (similar to pain and distress categorization—but the laws in the UK do not refer to “distress”) in animal research. This document is enclosed. The Boyd Group consists of a number of stakeholders including veterinary surgeons, animal care and welfare officers, animal protection representatives and researchers who have a license to conduct animal research. The following were points that all stakeholders agreed upon in regards to the use of a severity categorization system:

- The process of assigning severity categories and discussion between the researcher and the institution’s ethical committee (similar to IACUC’s in the US) can assist in thinking about levels of suffering and encourage refinement.
- The categories themselves help with implementing humane endpoints and identifying techniques, procedures and protocols that cause the most animal suffering
- Retrospective reporting would be more meaningful than prospective reporting.
- It is important to provide examples for each category in order to provide guidance to researchers
- The categories should encompass all potential adverse effects—psychological as well as physical
- The categories should reflect duration of the adverse effects.
- The categories should be conveyed through words and should not be numbered, as this improves the focus on refinement.

The stakeholders also agree that the term “moderate” is too often used; some suggested that the term “significant” may be more appropriate. The term “moderate” may be something to reconsider as part of the USDA proposal.

Overall, The Boyd Group report only further demonstrates the value of using a pain and distress categorization system.

**Conclusion**

In summary, we urge the USDA to promptly define distress and revise and simplify its categorization system so that it reflects the levels of pain and distress that animals experience in biomedical research, testing and education. It has been almost five years since the USDA published the pain and distress proposal and this issue should not be postponed any longer. Thank you for your time and consideration and we look forward to hearing your response on this matter

Sincerely,

Martin L. Stephens  
*Vice President, Animal Research Issues*

Cc: Ron DeHaven, Administrator, APHIS