

AAU Association of American Universities
APLU Association of Public and Land-grant Universities
COGR Council on Governmental Relations

Dr. Carol Clarke
Research Program Manager
Regulatory Analysis and Development, PPD
Docket No. APHIS-2014-0050
United States Department of Agriculture
APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

May 29, 2015

Re: Petition to Define Alternatives to Procedures that May Cause Pain or Distress and to Establish Standards
Regarding Consideration of these Alternatives

Dear Dr. Clarke:

On behalf of the leading U.S. research universities that our associations represent, we write to express our concerns regarding USDA's Federal Register Notice dated March 30, 2015, entitled "Petition to Define Alternatives to Procedures that May Cause Pain or Distress and to Establish Standards Regarding Consideration of these Alternatives." Our associations emphatically oppose the Petition to initiate rulemaking on the four issues included in the Petition. The proposed regulatory changes will not improve animal welfare and are unnecessary for the Agency's ability to carry out its authority under the Animal Welfare Act (AWA). We concur with our colleagues at the National Association for Biomedical Research (NABR) that the Petition for regulatory change relies on false premises to support its conclusion.

The Petition to define "alternatives" is unnecessary because the definition is already adequately provided in Policy #12 of the Animal Care Resource Guide. Policy #12, which has been in place since 1997, requires principal investigators to provide a written narrative to the IACUC to enable the committee to "assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods." If an identified alternative is not used, the investigator must justify why. This policy, which has been in place since 1997, functions well and there is no need to alter it.

The Petition to clarify the definition of "painful procedure" is also unnecessary because the current definition covers situations in which more than momentary or slight pain is relieved. It is well understood by both the regulated community and the Agency that alternatives must be considered even when the pain is relieved. The Agency has the authority to issue citations in rare instances where the requirement is not met.

The regulations provide research facilities, acting through the IACUC, with sufficient flexibility to determine that alternatives were adequately considered by the principal investigator.

The petition to include specific requirements for consideration of alternatives is based on a false premise that researchers have no regard for using alternatives to animals. The IACUCs and principal investigators have no purposeful intention of violating USDA regulations. Institutions and researchers are well aware of the consequences of non-compliance, both financial and reputational, and the rare instances of non-compliance should continue to be dealt with in accordance with current enforcement provisions of the regulations.

The petitioner argues that to optimize enforcement of the AWA, USDA's authority to regulate how "research will treat or affect an animal, the condition of an animal, and the circumstances under which an animal is maintained" should be explicitly set forth in USDA's regulations. USDA should amend 9 C.F.R. § 2.31(a) by adding, as a final sentence, the following: "APHIS is authorized to issue orders to correct deficiencies or deviations from the standards set forth in this section." We believe the regulations fully address deficiencies and deviations regarding animal welfare. Adding the petitioner's final sentence is unnecessary and duplicative to that which already exists.

Response to USDA Questions:

- 1) *Should APHIS establish regulatory standards for consideration of alternatives to procedures that may cause more than momentary or slight pain or distress to animals?*

We believe that the current regulations allowing research facilities flexibility in devising internal procedures is sufficient and allows the Agency to identify and impose the proper enforcement actions pertaining to minimal cases of non-compliance. We recommend that the standards for consideration of alternatives remain within the Animal Care Resources Guide.

- 2) *What constitutes an alternative to a procedure that may cause more than momentary or slight pain or distress? If we amend the AWA regulations to define the term alternative, what definition should we use?*

We recommend that the definition contained within the Animal Care Resources Guide remain unchanged. A revision to define alternatives is unnecessary as the broader research community is already documenting its basis for alternative methodologies in accordance with the AWA. Furthermore, specifying alternatives in one area may become obsolete or less effective in others as technology rapidly changes.

- 3) *What constitutes a thorough consideration of alternatives? Does this differ depending on the nature of the research conducted? If so, how?*

As indicated above, we believe that the current definition within the Animal Care Resources Guide is sufficient and provides agencies with the flexibility to modify the guidance related to alternatives as technology changes. Ongoing research can attempt to add to the already suggested alternatives, but this question is best left to the expertise of veterinarians, IACUC committees, and Principal Investigators.

- 4) *Who should make a determination regarding the thoroughness of a primary investigator's consideration of alternatives: The IACUC for a facility, APHIS, or both parties?*

We believe that the determination should be made by the IACUC, comprised largely of scientists, veterinarians, and administrators who have the expertise and knowledge of the work being performed.

- 5) *If the IACUC and APHIS should jointly make a determination, which responsibilities should fall to APHIS and which to the IACUC in terms of evaluating thoroughness?*

As stated in Question 4, we believe that only the IACUC be involved in making this determination. To require APHIS to participate in the determination would unnecessarily delay review and approval of animal protocols and interfere with the timely conduct of research. The Agency already has the necessary authority to intervene in those rare cases where an IACUC has failed to carry out its responsibilities in a thorough manner.

- 6) *What documentation should the primary investigator provide to demonstrate that he or she has done a thorough consideration of alternatives?*

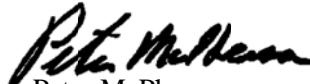
We believe that the current requirements to provide a written narrative of the sources consulted are adequate to satisfy a thorough consideration of alternatives. Research studies will vary and ongoing research will further define future alternatives. The flexibility to devise internal procedures along with the outcomes of research is necessary to further scientific progress.

In closing, we believe that there are many unfounded comments by the petitioner and that modifying the existing regulations will be counterproductive. We fail to see the point the petitioner aims to make when the research he clearly cites shows that US and Canadian didactic teaching methods, class and small-group clinical case discussions, standardized patient exercises, echocardiography, observed surgeries and other procedures, faculty-mentored hands-on training, and many other progressive educational methods *have all replaced the use of animals*. We request that the current regulations and guidance remain and that any breach of regulation be met with the appropriate enforcement and corrective action deemed necessary by USDA. Thank you for providing the opportunity to comment.

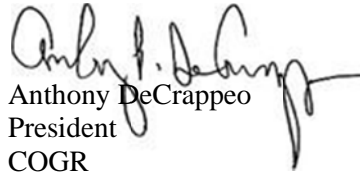
Sincerely,



Hunter R. Rawlings III
President
AAU



Peter McPherson
President
APLU



Anthony DeCrappeo
President
COGR