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August 3, 2015

Dr. Carol Clarke, DVM, DACLAM
Research Program Manager
Regulatory Analysis and Development, PPD
Docket No. APHIS-2014-0098
APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Re: *Petition to Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research* - 80 Federal Register 24840

Dear Dr. Clarke:

The Council on Governmental Relations (COGR) is an association of over 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. The Association of American Universities (AAU) is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. On behalf of member institutions, COGR and AAU appreciate the opportunity to respond to the United States Department of Agriculture (USDA) request for comments on the *Petition to Develop Specific Ethologically Appropriate Standards for Nonhuman Primates in Research*.

As indicated in the notice, the petition requests the Animal and Plant Health Inspection Service (APHIS) amend §3.81 of the Animal Welfare Act (AWA) regulations to require research facilities to construct and maintain an environment that is appropriate with respect to the patterns of behavior exhibited by nonhuman primates in their natural state (referred to as an “ethologically appropriate” environment) and to specify minimum standards that must be met for an environment to be considered ethologically appropriate. As indicated in the Federal Register notice, §3.81 of the AWA regulations requires research facilities to “develop, document, and follow an appropriate plan for environmental enhancement adequate to promote the psychological well-being of nonhuman primates” that is “in accordance with currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian for the facility.”

The petitioners agree that the intent of the regulations is to ensure that the environment provided to nonhuman primates housed at research facilities promotes their psychological well-being. However, it suggests that the regulations allow research facilities broad discretion that enables them to meet the requirements without meeting their intent. The petition states that by amending

the AWA regulations in the manner that the petitioners suggest the USDA would remove these ambiguities and facilitate regulatory compliance.

We wonder what data exists to support this assertion and suggest that research facilities are meeting or exceeding both the requirements and their intent. The research community has worked with the USDA to ensure environmental enrichment plans meet the psychological needs of nonhuman primates and continues to make enhancements to their housing and social environment on an ongoing basis consistent with currently accepted professional standards. We note that a 2014 [survey](#) conducted by the Board of Directors of the Association of Primate Veterinarians (APV) found that more than 84% of the nonhuman primates housed in research facilities are maintained in either social groups or are paired housed and less than 0.03% are housed singly without physical contact with other animals. The limited use of single housing is reviewed and approved by the IACUC and subject to review by the USDA-APHIS Veterinary Medical Office during their routine inspections. The percentage of animals being socially housed will continue to increase as the number of older animals that cannot be socially housed declines. We submit that the petition is not aimed at ensuring regulatory compliance as indicated, but rather, changing what are presently effective regulations.

In response to specific questions, question A requests comments on whether APHIS should amend §3.81 of the AWA regulations to require research facilities to construct and maintain an ethologically appropriate environment for nonhuman primates, and specify the minimum standards that must be met for an environment to be considered ethologically appropriate. As noted above, we believe the current standards are effective, both in practice and intent, and the housing and social environment of nonhuman primates are continually enhanced. APHIS should not amend §3.81 of the AWA regulations.

In response to question D, does an ethologically appropriate environment for nonhuman primates used in research differ from an ethologically appropriate environment for nonhuman primates that are sold or exhibited? We don't believe it differs or that research facilities should be independently targeted. The AWA requires that the standards be applicable to all of these environments. The research itself is a separate entity and is highly regulated. The current regulations are effective and it is unnecessary and costly for regulations to be revised and to target particular species or type of facility (i.e., a research facility, dealer or exhibitor).

In response to question E, who should make the determination regarding the ethological appropriateness of the environment for nonhuman primates at a particular research facility: The attending veterinarian for the facility, APHIS, or both parties?

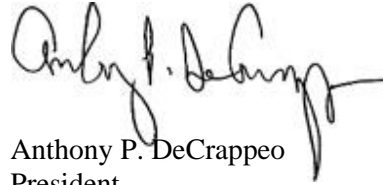
Under the current standards the attending veterinarian makes this determination, consistent with the intent of the AWA, and the IACUC reviews and approves all single housing. These standards are effective and should be maintained. Research facilities and attending veterinarians consult with APHIS as needed to ensure that each nonhuman primate is housed in a way that promotes their psychological well-being. Housing animals in a way that promotes their well-being is the goal of the researchers as well.

In conclusion, we believe there is no evidence to suggest that the regulations and standards should change. The proposed changes would make it difficult or impossible to conduct some or all nonhuman primate research and that is the intent. COGR and AAU strongly recommend that the USDA not initiate the rulemaking requested by the Petition. We also wish to note that acquiescence to petitions of this nature without significant scientific data serves only to further the agendas of anti-research groups while undermining the mission of biomedical research.

Sincerely,



Hunter R. Rawlings III
President
Association of American Universities



Anthony P. DeCrappeo
President
Council on Governmental Relations