

## **Animals in Research Point-Counterpoint**

- 1. Describe the goals of your organization. How can biomedical researchers and animal advocacy groups work together to form a partnership to address our mutual concerns about animal care and usage?**

### **AAA Believes...**

The American Association of Anatomists (AAA) is a nonprofit scientific organization dedicated to the advancement of the anatomical sciences. AAA's membership is comprised of researchers and educators who recognize the importance of animal models in studying disease states in both humans and animal species. AAA strongly supports the use of animals in biomedical research, understanding that data from animal research has played a significant role in advancing both public health and safety worldwide, while at the same time increasing our basic knowledge about nature.

At the same time, AAA acknowledges the significant role that animal rights groups play in ensuring the optimal care and handling of animals used in scientific research. Scientific organizations and animal rights groups should work together to facilitate the biomedical community's continuing effort to improve its care and use of research animals. We can also contribute to the ongoing education of scientific researchers *and* the general public.

To accomplish this, animal rights groups must meet us halfway and be open to the notion that animal research plays a critical role in the treatment and diagnosis of human disease, and that the present alternatives to animal testing can not provide the data needed to assess complex interactions occurring between human or animal organ systems. We can then work together to establish the most appropriate guidelines for the use of animals in biomedical research.

### **ARDF Believes...**

The Alternatives Research & Development Foundation (ARDF) was established to support the development, validation, dissemination and adoption of alternatives to traditional uses of animals in biomedical research, testing and education. We believe the issue is not the researchers nor the questions they are asking, but rather the tools chosen to answer those questions. From our perspective, alternatives represent more humane and scientifically appropriate methods. With sufficient motivation, imagination and resources, we foresee the day when it is possible to achieve biomedical progress while the use of animals becomes the rare alternative and non-animal approaches the norm.

Biomedical research and animal advocacy groups can best work together by abandoning the artificially created perceptions of opposing camps and promoting development of dialogue groups, in which all stakeholders are equally represented—free of political/constituent and media posturing. Such informal organizations need not be limited to advising the NIH and USDA, but (as with the Boyd Group in the UK) could create their own publications and resources.

Fundamental to the success of any such effort is acceptance by the biomedical research community that the use of animals is a privilege granted by society, not an inalienable right. As a consequence, full accountability is a reasonable public expectation. Further, the utilization of alternatives (3Rs of replacement, reduction, and refinement) is a basic operating principle of quality research, not a concession to animal rightists.

As a first step, all sides of the debate should work together to secure adequate, full funding for all USDA/AWA related responsibilities, as well as PHS funds to facilitate wider PHS and AAALAC accreditation for research facilities.

### **AAA Responds....**

AAA applauds these constructive suggestions for working together. We fully agree that the use of animals in biomedical research is a privilege granted by society for which we should be held accountable—not only for ethical reasons, but also because taxpayers' dollars are used to support our research. While the replacement of animals with *in vitro* systems is a desirable goal, we do not yet foresee a time when this goal will be reached.

### **ARDF Responds....**

- ARDF agrees that both sides of the animal research controversy should be able to work together to achieve their individual and common goals. The best approach to this may be to find areas of immediate agreement and respectfully examine areas of disagreement. Some possibilities are:
  - Realistic and effective systems to provide for humane care and use of all laboratory animal species.
  - Reexamine the concept of an “animal model”. What really constitutes a valid animal model? Do biologically objective criteria exist?
  - Promoting the development, validation and adoption of alternatives that either replace, reduce or refine (the 3 Rs) the use of laboratory animals.
  - Adopting the concept that if an alternative is reasonably and practically available, it should be used.

The concept of alternatives has grown dramatically since first formulated in the 1950s. Although all uses of laboratory animals cannot be replaced today, the sophistication and applicability of alternatives is far greater than generally realized. Replacement is only one of the 3 Rs. The “alternatives approach” to biomedical research, testing and education should be acceptable to both sides, while agreeing to disagree on some of the specifics. This attitude provides a common ground on which to build further cooperation. Alternatives are positive for animal welfare interests and represent good science when properly developed.

**2. Would inclusion of rats, mice, and birds affect the welfare of currently regulated species and the development of biomedical research as we know it in the U.S.?**

**AAA Believes...**

The federal government through grants from the National Institutes of Health (NIH) funds most biomedical research in academia. All NIH grantees must follow strict guidelines on the use of animals in research. These guidelines—PHS/ILAR—include rats, mice, and birds. In its present form, USDA staff has neither the necessary experience nor expertise to oversee the use of animals in biomedical research. Moreover, the USDA has acknowledged that the PHS/ILAR standards are stricter in sections than those of the Animal Welfare Act (AWA), which now excludes rats, mice, and birds from its coverage.

Under PHS/ILAR guidelines, most academic research institutions have well-established mechanisms for ensuring the highest level of care and safety for animals used in medical research. AAA believes that existing NIH guidelines are appropriate and sufficient in ensuring animal welfare. Adding another layer of regulation under USDA would not improve conditions. In fact, it could have the unintentional effect of hampering improvement, as laboratory staff must spend more time on regulatory paperwork—time that could otherwise be spent on animal welfare duties.

We believe that the best route is to continue to refine the existing PHS/ILAR regulations, incorporating new directives and guidelines appropriate for new applications of animals in research, such as transgenic models—one area in particular in which USDA lacks the expertise to develop appropriate regulations.

There will always be cases where individuals or institutions do not abide by regulations. The federal government should impose stronger penalties consistent with those proposed for clinical studies. Simply adding another regulatory layer via USDA is not the answer.

**ARDF Believes....**

Currently only 5% of laboratory animals are covered by legally mandated, minimal standards of care and use. Expanding this coverage to include all species commonly used in research, testing, and education could only benefit those animals, since all institutions would be required to provide the same level of care for all species, thus eliminating substandard facilities at which the welfare of research animals is actually jeopardized. Good animal care equals better-quality science. This is why both NIH and AAALAC have always included rats, mice, and birds in their animal care and use policies.

In the United States, one-third of currently registered research facilities are AAALAC accredited and already include rats, mice, and birds under rules stricter than those of the federal government. Furthermore, 60% of registered research facilities (representing all of the top universities and private companies) are compliant with NIH regulations, which also include rats, mice, and birds. All of these major biomedical research entities have conducted their scientific programs for decades with the inclusion of care and daily accountability standards for rats, mice, and birds.

AALAS, ACLAM, and SCAW are strongly pro-animal research organizations that conditionally support inclusion of rats, mice and birds. They would not endorse any action that would threaten biomedical research, testing, or education.

In Europe, such research powerhouses as England, France, Switzerland, and Germany have always included rats, mice, and birds in their standards for care and use, with England having done so for more than 115 years. These countries have no problem maintaining world class research programs while providing basic protections for these species.

Along with the conditional support of organizations such as AALAS and ACLAM, there is also a recent unambiguous, random survey conducted by professionals on the attitudes of IACUC members, chairpersons and animal researchers who specialize in using rats, mice, and birds. Fully two-thirds of the respondents supported the inclusion of these animals, with no significant differences between researchers and IACUC members. The authors of the survey observed that “it would be a distortion to present the debate as a conflict between animal researchers and animal protectionists.”

Many of the claims of dreadful consequences resulting from the ARDF/USDA settlement are identical to the those offered nearly 20 years ago in opposition to the 1985 amendments to the AWA. Senator Bob Dole recently noted that, “I am aware of efforts by opponents of animal welfare to prevent coverage of birds, mice, and rats as detrimental to research. This notion is preposterous. A similar strategy was employed by opponents of my 1985 amendments to the Act. I am happy to observe that none of their predictions about the dire consequences for research ever materialized.”

It is difficult to take claims of financial hardship seriously for institutions that have for decades maintained rats, mice, and birds at a level of care equivalent to or higher than typical AWA requirements. However, this has not stopped some organizations from touting extreme cost increases (\$80-\$300 million) derived from a highly biased, nonscientific survey on the implementation costs for currently nonexistent rats, mice, and birds regulations.

The only acknowledged economic considerations pertain to the ability of USDA/APHIS to fully enforce the new AWA regulations for rats, mice, and birds (whatever they might be), while not diminishing current enforcement practices. Since the rulemaking process resulting from the ARDF/USDA settlement agreement will take several years to complete, there is more than enough time to increase the latter’s enforcement budget to adequate levels.

#### **AAA Responds....**

ARDF notes above that “both NIH and AAALAC have always included rats, mice, and birds in their animal care and use policies” and that AAALAC accreditation standards are “stricter than those of the federal government.” What, then, is the rationale for USDA involvement in the regulation of animal use for biomedical research? Rather than fully fund USDA responsibilities under the Animal Welfare Act (AWA), as suggested earlier, perhaps we should be working together to bring all oversight of animal use for biomedical research under the auspices of the NIH, with sufficient funding to ensure full implementation. (See #3, below.)

#### **ARDF Responds....**

- ARDF agrees that the PHS Guide has several aspects that are superior to the AWA regulations (i.e., the former applies to all vertebrates). However, the PHS system is also characterized by multiple, serious program deficiencies that are covered by USDA efforts (see original answer to Question #3).
- Rather than adding another layer of bureaucratic regulations and paperwork, we see the inclusion of rats, mice and birds as only having a serious impact on facilities currently entirely out of the system. Institutions registered with NIH or with AAALAC accreditation already deal with these species and the associated recording requirements. The rulemaking process will recognize that fact and respond accordingly.
- The formal rulemaking process taps the expertise of the entire biomedical and animal advocacy communities to arrive at an appropriate final set of regulations.

- We agree that stronger penalties for violations of animal care and use regulations consistent with those proposed for clinical studies would be appropriate and welcome. The USDA, however, is the only agency with the statutory authority to exercise binding legal consequences. We have always maintained that violation of the law (USDA) provides far more effective motivation than simply disappointing one's colleagues (PHS/AAALAC). As noted by Senator Dole, the heart of the Animal Welfare Act is "real legal consequences for failure to perform." For animal advocacy groups this is one of the basic, foundation principles of animal protection that must be maintained.

**3. What is the most effective approach to provide appropriate care and usage of animals in research, testing, and education? Discuss the respective role(s) of Federal Government (NIH/ILAR), AAALAC, and IACUCs.**

**AAA Believes...**

At the institutional level, Institutional Animal Care and Use Committees (IACUCs) oversee enforcement of federal guidelines. IACUC makeup and practice varies from institution to institution according to available resources and local requirements. The PHS/ILAR guidelines provide an appropriate framework within which individual IACUCs function.

Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) provides a second tier of assurance that appropriate conditions for animals exist. While the demanding AAALAC accreditation process may not be practical for smaller institutions due to insufficient resources, where possible it is a positive step to ensure appropriate care and usage of research animals. AAA encourages AAALAC accreditation of biomedical research institutions.

Some view the planned AAALAC inspections as less effective than the surprise inspections performed by USDA under the Animal Welfare Act. In principal, there is no reason why surprise inspections could not be incorporated into the AAALAC accreditation process, given the necessary resources. Also, NIH should develop stricter penalties for abusers of the PHS/guidelines. It would be appropriate for AAALAC to communicate any infractions to NIH.

Medical research involves ever changing and new protocols and experimental procedures. As is the case for other Federal regulatory agencies, USDA is at its best in regulating existing established procedures, but has difficulty responding to modifications or new procedures. Local IACUCs are better able to analyze and evaluate the cutting edge research issues and interpret guidelines based on this new knowledge.

**ARDF Believes....**

We believe the current tripartite (i.e., PHS, AAALAC, AWA) system has many advantages and should be maintained. Each aspect represents different mandates and strengths, occupying unique niches with little realistic overlap. AAALAC maintains the highest standards of the industry, but has no effective enforcement or public accountability. A similar situation exists for the PHS guidelines, which do not apply to all registered and none of the unregistered facilities (estimated to be between 1200 and 2000). As noted by Senator Bob Dole, "... neither NIH's policy nor voluntary accreditation includes legal consequences for failure to perform. The Animal Welfare Act does. That is the heart of the law." Historically, serious problems at biomedical research institutions have been identified by technicians, janitors, support staff, students, animal advocates and, to a lesser extent, USDA inspectors—not NIH or AAALAC.

Public accountability is the only means to guarantee full provision of adequate standards of laboratory animal care. This involves information (who, what, when, and where), problem identification (failures to perform), consequences (legal versus simply disappointing one's colleagues and funders), and attitude (the distinction between privileges and rights). From our perspective, an increased emphasis on NIH, AAALAC, and IACUCs creates a reduced level of accountability. Logistics, cost, and time are all secondary issues, with the welfare of the animals being the primary concern.

USDA enforcement of the AWA provides the only comprehensive source of statistics (necessary to set priorities and track trends and compliance); legally mandated consideration of alternatives, pain, and distress; realistic public accountability; and information from real-time laboratory inspections rather than the pre-announced, sanitized tours characteristic of NIH and AAALAC.

From our experience, the majority of real-world burdens typically identified by researchers can be traced to local institutional policies, not AWA legal requirements. In such instances, IACUCs can play the lead role in conflict resolution and regulatory compliance. In the few instances where jurisdiction/requirements might overlap, the existing Memorandum of Understanding between the relevant federal regulatory agencies avoids serious problems.

**AAA Responds....**

USDA is not equipped to regulate biomedical research. As we suggested earlier, there is no reason why certain aspects of AWA enforcement (*e.g.*, surprise inspections, stricter penalties, statistical tracking, public accountability, improved reporting of infractions) could not be incorporated into PHS oversight.

**ARDF Responds....**

- ARDF agrees that universal AAALAC accreditation would provide a quantum increase in the quality of care and use of laboratory animals, especially if unannounced inspections are incorporated into the process. It is our understanding, however, that AAALAC has neither the desire nor the resources to effect such a massive increase in its program.
- Although welcome, such activity would only serve to duplicate either programs or authority already given by Congress to the USDA. We believe the most appropriate response is to enhance and expand the existing USDA inspection and enforcement activities. Reliance on AAALAC and NIH could not be effective unless all facilities currently using laboratory animals were involved including those not presently registered with the USDA.
- We do not believe that, as presently constituted and functioning, the PHS/USDA IACUC system is capable of consistently addressing the issues of concern to animal advocacy organizations (see original answer to question #4) and would not be acceptable as substitutes for the USDA.

#### **4. What are the strengths and weaknesses of the present IACUC approach for institutional regulation of animals in biomedical research?**

##### **AAA Believes....**

The key strength of the IACUC system is that it allows flexibility for academic institutions to ensure the best use of animals in research given each institution's unique circumstances. IACUC composition, governed by strict guidelines, generally provides the necessary expertise to subjectively evaluate the proposed research conditions, based on the regulations of the PHS/ILAR guidelines.

This flexibility is sometimes cited as a limitation of the IACUC system, particularly when an academic institution does not have the resources to form an appropriate committee. NIH should develop a uniform proposal format, with guidance on how to assess various factors. Enforcement is another limitation. While annual AAALAC inspections do provide some measure of corroboration of compliance, they do not provide a continual monitoring process. Continuing education and training of IACUC committee members, animal care staff, and researchers who use animals is essential.

##### **ARDF Believes....**

The current IACUC system is designed to create a level playing field for all research facilities regarding pre-experimentation screens for such critical factors as investigator competency, adequate veterinary care and supervision of research procedures, avoidance of duplication, and consideration of alternatives. IACUCs should represent a serious commitment to fulfilling the regulatory, animal welfare, and good science requirements placed on the use of laboratory animals. These goals are a major improvement over the earlier investigator-driven and controlled approach to seeking grant support and assuring regulatory compliance.

Although many IACUCs take their responsibilities seriously and are providing exemplary service, from the animal advocacy perspective, the IACUC system far too often is little more than a rubber-stamp for the status quo. Comprehensive surveys by OLAW, AAALAC, USDA, and Plous and Herzog (*Science*, 293:608-609) all identified significant deficiencies with multiple existing IACUCs, often directly affecting the lives of laboratory animals. Such reviews, however, also act as a guide to needed improvements.

Most IACUCs still fail to provide adequate accountability by restricting public participation and attendance; holding deliberations behind closed doors; creating confidential reports and decisions; conducting self-inspections; and inadequately guaranteeing investigator compliance and IACUC member competency. Realistically, members of IACUCs may be subject to peer pressure from colleagues, institutions, and corporate officials. Only a significant non-institutional presence on the committees and unrestricted public access to all IACUC documents and activities can overcome the perception of a closed, potentially biased system. In general, IACUCs need to be more transparent, especially considering that all of the protocols will be paid for by either consumer or tax dollars.

From the animal advocacy perspective, IACUCs need to pay closer attention to the documentation requirements of USDA Policy 11 and 12. These should not degenerate into generic boxes to be marked on a form, but rather be recognized as serious legally and ethically mandated requirements.

Because IACUC member understanding of complex research and regulatory issues varies widely, there is a pressing need to provide unambiguous documentation to aid the protocol review process (e.g., scales of invasiveness to identify and classify pain and distress, comprehensive examples of the 3Rs [reduction, refinement and replacement] to establish true consideration of

alternatives). Requests for clarification from non-scientists on confusing or contested points in a protocol is one of the strengths of the IACUC process; but a greater emphasis on inclusion of individuals with appropriate, but often overlooked, expertise (e.g., laboratory animal technicians) is essential. For example, in Sweden the IACUCs consist of one-third researchers, one-third animal advocates, and one-third technicians—a far more sensible representation than the U.S. emphasis on animal-users as preferred IACUC members.

If reviews of potential or real IACUC deficiencies are used as guides to enhance overall performance of the system, then the present IACUC approach could be optimized across the board for all institutions, projects and species.

#### **AAA Responds....**

Some form of IACUC standardization is certainly desirable. This issue offers an excellent opportunity for animal activist groups and biomedical researchers to work with AAALAC toward a common goal.

#### **ARDF Responds....**

- As outlined in our original answer to this question, the current PHS/USDA IACUC system has neither the history nor the uniformity of composition and activity to assume primary oversight for the care and use of laboratory animals. We agree that some institutions lack the resources to form appropriate committees and others (unregistered with USDA and NIH) have none at all.

If the IACUC system is to function as originally envisioned by the 1985 amendments to the Animal Welfare Act, then universal compliance with basic composition and performance standards is essential. We agree that initial and continuing education and training of IACUC members, animal care staff, students and researchers who use these animals is essential. Consideration of opening IACUC meetings to public attendance may be another means to provide increased confidence that the system is functioning as intended.

Improvements in the current IACUC system is another area where the biomedical and animal advocacy communities share a common interest and should be able to work together.

## **5. What is the most appropriate approach to recognizing and responding to pain and distress in biomedical research?**

### **AAA Believes....**

Good biomedical researchers recognize that pain and distress in experimental animals will bias their research results. Thus, it is in their own best interests to understand and minimize pain and distress.

At most research institutions, the presence of a trained veterinarian and the implementation of PHS/ILAR guidelines offer sufficient expertise and guidance to identify pain and suffering in research animals. In protocols routinely used for IACUC evaluation, a number of pain categories have been defined. The difficulty is that it is often not possible or realistic to predict the pain category that the animal will fit into prior to performance of the study; thus, researchers typically predict a higher level of pain than the animal is actually likely to experience. Pain categories need to be reviewed on a continual basis.

The issue of identifying distress in animals is controversial. In larger animals, distress is usually readily identified; in small animals, this can be a daunting task. There is much disagreement about what constitutes an appropriate measure. This issue is under investigation in research laboratories aiming to identify suitable biological endpoints for the development of pharmaceuticals for human use. Since pain and distress are controlled by the central nervous system, emerging technologies such as imaging offer insights into human and animal responses. The development of distress criteria could be an appropriate collaborative project of the scientific community and animal rights groups.

### **ARDF Believes....**

The most appropriate approach to recognizing and responding to pain and distress in biomedical research is for laboratory personnel and oversight bodies such as the USDA to begin to pay close attention to animal pain and distress—especially distress, which has received much less attention than has pain. Laboratory personnel should draw up lists of the signs of pain and distress in each species used in a given facility, consulting the literature and outside experts, if necessary.

Measures of the levels of pain and distress, which are influenced by the intensity and duration of adverse effects, should also be explored and assessed. Protocol-specific signs and levels of pain and distress should be addressed in protocol use forms and discussed during IACUC deliberations. Protocol-specific score sheets or similar mechanisms should be implemented to track the signs and levels of pain and distress in individual experiments, and used to identify the most humane endpoints as well as appropriate intervention points for supportive treatment.

Following an experimental insult, the animals should be observed frequently to assess and score any signs of pain and distress and their intensity. Supportive interventions should be administered promptly. A mechanism for summoning prompt veterinary attention should be in place 24 hours a day/7 days a week. Research institutions should hire personnel who are appropriately qualified to handle and treat animals in ways that minimize their pain and distress, and personnel should receive ongoing training.

The efforts of laboratory personnel to minimize pain and distress should be complemented by the actions of oversight agencies. The USDA should follow through on its proposal to provide a regulatory definition of “distress” and to modify its pain and distress categories (the existing three categories can be altered to reflect minor, moderate, and severe pain and distress, for example). The USDA should put the regulation of distress on equal footing with that of pain. NIH and AAALAC should play active roles in identifying and disseminating best practices that result in less pain and distress or better animal welfare, and conversely, in identifying practices that are no longer considered acceptable.

Organizations involved in funding, overseeing, or conducting animal research should make funds available for studies aimed at reducing pain and distress in laboratory animals, to answer the many unanswered questions in this arena.

#### **AAA Responds....**

AAA supports increased funding for studies related to pain and distress in laboratory animals. This is certainly an area in which the biomedical research and animal activist communities could work together. The other suggestions above are well worth considering—except that USDA should *not* be the agency to oversee the development and implementation of pain and distress guidelines.

#### **ARDF Responds....**

- ARDF agrees that recognition and elimination of pain and distress are hallmark characteristics of good, responsible science. This applies both for the quality of the research and the lives of the animals involved.
- Although the presence of a trained veterinarian is essential to dealing with issues of pain and distress, recent examples suggest this is no guarantee that technicians, students or investigators will not cause severe harm to animals either through impatience, insensitivity or ignorance. Although having trained personnel on the IACUC (i.e., laboratory animal veterinarian) may help identify and modify pain and distress issues before the project begins, the most critical stage for alleviating such potential sources of suffering is at the point of actual use of the animal.
- To assist IACUC members, technicians and end users of laboratory animals, a comprehensive system of pain categories with realistic examples and institution-wide education is needed. This effort should also include consideration of humane endpoints and the current approach of protocol-specific scoring sheets to assist in recognition of the onset of pain and distress responses.
- ARDF strongly agrees that pain categories and associated documentation should be reviewed on a regular basis and that development of pain and distress criteria would be an appropriate project for collaborative efforts by the scientific and animal advocacy communities.

## **6. What should be done to improve the mechanism(s) of animal care and usage regulation by the USDA and achieve appropriate enforcement of the AWA?**

### **AAA Believes....**

USDA does not have sufficient resources to appropriately enforce the Animal Welfare Act. Even with a modest budget increase, USDA's other activities would be compromised if rats, mice, and birds were added to the enforcement agenda—particularly given the significant increase in laboratory mice and rats anticipated with the use of transgenic strains. In its January 1999 *Federal Register* notice, USDA stated: "To conduct annual inspections of research facilities that use rats, mice, and birds, we would need to reduce by approximately one-third the number of inspections in other areas, such as breeders and dealers of dogs and cats, commercial carriers, large and small zoos, and circuses. We believe that such a reduction in inspection services would greatly compromise our efforts to ensure AWA compliance of all currently regulated facilities and adequate protection to all currently covered species." (*Federal Register*, January 28, 1999, Volume 64, Number 18, 4356-4367.)

Beyond the financial issue, however, AAA believes that USDA does not have the appropriate expertise to regulate animals used in biomedical research. The regulation of these laboratory animals should fall under PHS or DHHS guidelines.

### **ARDF Believes....**

The AWA regulations should eventually apply to all vertebrate species, as is now the case with PHS and AAALAC guidelines and most European countries. No institution using such animals in research, testing, or education should be exempt from these basic minimal legally enforceable standards.

To achieve the goal of an institution/species level playing field, USDA/APHIS must receive adequate funding to support a full enforcement program, as well as sufficient numbers of adequately trained inspectors. This is one win-win issue on which both the biomedical research and animal advocacy communities should be able to work together.

### **AAA Responds....**

While USDA should receive better funding for their existing programs, the regulation of animals used in biomedical research should fall under PHS/ILAR. This would require additional funding for NIH to establish animal regulatory programs—as the FDA regulates the human Institutional Review Boards (IRBs). Alternatively, NIH could contract out such regulatory oversight to organizations such as AAALAC.

### **ARDF Responds....**

- All sides of this issue agree that addition of rats, mice and birds should not be allowed to compromise USDA's existing activities under the Animal Welfare Act. U.S. animal advocacy organizations are committed to securing resources sufficient to allow the USDA to cover rats, mice and birds along with its other programs and would welcome the assistance and support of the biomedical research community. This is an obvious area where joint efforts should be possible.
- For a variety of reasons (including potential conflicts of interest), regulation of laboratory animals by the PHS has been proposed and rejected by Congress several times and would be vigorously opposed by the animal advocacy community. However, as has been proposed recently, merging the resources and programs of the NIH Office of Laboratory Animal Welfare into the USDA to establish a single agency with realistic enforcement powers is worth examining. Historically, great pains have been taken to harmonize laboratory care and use

requirements between the AWA and PHS Guide for Care and Use of Laboratory Animals. Further, those aspects of the PHS Guide that are superior to the existing AWA regulations might also be added to the latter as another aspect of consolidation of oversight for laboratory animal care and use.