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Institutional Animal Care and Use Committees: A Flawed Paradigm or Work in Progress?

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ethics, animal care, animal welfare, IACUC

ABSTRACT

In his challenging article, Steneck (1997) criticized the creation of the Institutional Animal Care and Use Committee (IACUC) system established by the 1985 amendments to the Animal Welfare Act. He saw the IACUC review and approval of biomedical and behavioral research with animals as an unnecessary "reassignment" of duties from existing animal care programs to IACUC committees. He argued that the committees are unable to do the work expected of them for basically three reasons: (a) the membership lacks the expertise in matters relevant to animal research and care, (b) there exists an inherent and disabling conflict of interest, and (c) the committee's operational base of authority is alien to academic culture and violates essential aspects of academic freedom. In addition, he found that the system is burdensome, requiring enormous expenditures of time and money that inappropriately diverts resources away from the business of scientific discovery. We dispute several aspects of Steneck's historical account and the coherence of his proposals. We believe his proposals, if followed, would be a step back into a failed past.

In his recent and challenging article, Steneck (1997) took to task the creation of the Institutional Animal Care and Use Committee (IACUC) system established by the 1985 amendments to the Animal Welfare Act. He saw the IACUC review and approval of biomedical and behavioral research with animals as an unnecessary "reassignment" (p. 178) of duties from existing animal care programs to IACUC committees. Further, Steneck attempted to support the claim that the IACUC system, as it stands, is thoroughly and perhaps hopelessly flawed. He argued that the committees are unable to do the work expected of them for basically three reasons: (a) the membership at large lacks the expertise in matters relevant to animal research and care, (b) there exists an inherent and disabling conflict of interest, and (c) the committee's operational base of authority is alien to academic culture and violates essential aspects of academic

freedom. He further argued that the system is burdensome, requiring enormous expenditures of member time and excessive funds that inappropriately divert resources away from the business of scientific discovery.

In its place Steneck (1997) advocated a system where the activities of program oversight, protocol review, conduct of research, and assurance of legal compliance are the responsibility of two committees. One committee (an animal care committee), composed of animal care and research professionals, would be responsible for the review, approval, and activities of actual animal care and use. The second committee, organized like an IACUC with its complement of public and nonscientist members, would be limited to setting animal care standards, providing oversight and assurance of the animal care committee's performance, and advising on ethical conflicts. Steneck's critique and proposals emerge from and are supported by a historical description of the development of animal research and care programs at the University of Michigan that he believes are representative of other large state research universities.

We dispute several aspects of Steneck's (1997) historical account, and also the coherence of his proposals. With regard to the historical account, the major impact of the 1985 amendments was that new responsibilities of mandated protocol review were established. The major thrust of this legislation was not a matter of "transferring" or "reassigning" responsibilities as Steneck (1997) argued. Protocol review had never been a requirement before 1985, so how could these responsibilities be "reassigned"? Furthermore, Steneck's general proposals run the risk of a retreat to a system when benign neglect and occasions of egregious mistreatment of animals existed at unacceptable levels. We critique Steneck's thesis by reviewing the historical precedents for his preferred system, followed by an analysis of the flaws he elaborated.

HISTORICAL DEVELOPMENT OF THE ANIMAL WELFARE ACT

As Steneck (1997) accurately described, the IACUC system evolved in a series of steps beginning with responsibility for the care and use of laboratory animals residing entirely with each individual investigator. On the whole, this paradigm failed because the individual investigator and untrained custodial staff lacked the knowledge to adequately treat and protect the variety of animals that came to be used. Following the expansion in animal research after World War II, there was a move toward professionalism, at least at some of the larger and wealthier universities and private laboratories. These institutions began to hire trained veterinarians to participate in animal care functions. Such professional participation, however, was left largely to the individual investigator's choice, and indeed Steneck chronicled the resistance to such professional involvement at a leading institution, the University of Michigan.

Expansion in animal research also led to increased public interest in the conditions to which research animals were exposed. That increased interest was fueled at times by disclosures of animal mistreatment. Steneck (1997) recounted one such incident at Wayne State University that he trivialized. He stated that there was a complaint about a "barking" dog and that two dogs were "reportedly" found left without proper care following "experimental operations" (p. 177). One dog was near death. More accurately, the dog was not merely barking, but was crying out in pain. According to the police officer's own report:

At about 9.30 P.M. on Thursday, July 9, 1964, while working Sect. 1-1 with Patrolman Bloomingfield, we received a radio run to the Memorial Hospital about a complaint. Upon arriving, the head nurse at the information desk stated a dog in the Wayne University Laboratory was moaning and crying for three hours. It was disturbing the patients at the hospital. We went to the laboratory, and the night watchman took us in the basement, where we found two dogs in steel cribs. One looked dead but the other was crying as if in great pain. Blood and foreign matter was pouring from the mouth. Some of the blood was

dry indicating the dog was left to suffer some time. The dog seemed paralyzed, and the tongue was gagging the dog to the point it could not get sufficient air. I asked the night watchman what doctor was in attendance of the dogs if they in a were post-operative state, and he merely said that no one watched them, and everyone had gone home. (Animal Welfare Institute, 1965, p. 4)

Following complaints made by the Animal Welfare Institute, corrective action was then taken by the Michigan State Health Commissioner. Patrolman John Mobley, the reporting officer, received the Animal Welfare Institute's Albert Schweitzer Medal for outstanding contributions to animal welfare.

An additional source of fuel for public scrutiny and mistrust centered around the part played by the National Society for Medical Research (NSMR). Whereas Steneck (1997) reported that NSMR "lobbied universities advocating for the use of animals in research" (p. 176), it is more accurate to state that NSMR lobbied for state legislation that would permit mandatory seizure of animals from humane shelters for use in research (see Stevens, 1978, pp. 51-52). It was this incursion into the animal protection work of humane societies that caused disenchantment among some scientists of the activities of NSMR (see Orleans, 1993, pp. 44-45). Leading this disaffection was Dr. Robert Gesell, professor and chair of the department of physiology at the University of Michigan who, with his daughter Christine Stevens, formed the Animal Welfare Institute in 1952. This organization became one of the most powerful organizations for legislative reforms that protect animals.

ETHICAL FOUNDATION OF THE ANIMAL WELFARE ACT

Although it is true that the word *ethics* does not appear in the Animal Welfare Act, the heart of the legislation and its amendments is to provide protection for sentient entities that cannot speak for or protect themselves. The 1985 amendments provide that prior to the initiation of a research project investigators submit a detailed description and justification of the proposed research. As it currently stands, Congress has mandated review of proposed research protocols by a broadly constructed committee (the IACUC), comprising not less than five persons, including at least a veterinarian, a practicing scientist experienced in animal research, a member whose primary concerns are in a nonscientific area, and an individual who is not affiliated with the institution in any way. Investigators are required to elaborate not only the purpose of the experiments but also the methods they plan to use to reduce the required number of animals and minimize the levels of pain and distress to which the animals will be exposed. In other words, the needless consumption of animal lives and exposure to unnecessary pain, distress, and suffering is seen as an unethical set of acts.

This direct enunciation establishes the premise that animal lives have value beyond that conferred by research participation. In addition, it establishes that the right to research inquiry is not absolute and must be justified beyond the population of scientist peers and colleagues. Instead, the researcher must stand before colleagues and the public and seek approval.

Lack of Expertise

In his criticism of the IACUC system, Steneck (1997) first argued that the makeup of the committee is such that it lacks the requisite skill to review and evaluate the research protocols before it. Steneck wondered where the committee members are supposed to learn about topics such as psychological well-being, appropriate care, and experimental design, which are required for adequate exercise of their responsibility. He argued for a system like the one that arose at the University of Michigan where proposals were presented to a committee of peers and animal care professionals who presumably do not

lack the training and experience necessary to make approval decisions. The standards used in this review would reflect state, federal, and institutional guidelines.

We agree that the current IACUC system has definable difficulties. Significant problems exist. Supporting this view is a report by the Office of the Inspector General of the U.S. Department of Agriculture (USDA; 1995) that found that IACUCs did not always meet the standards of the Animal Welfare Act. The Inspector General investigated 26 research facilities and reported that "at 12 of the 26 facilities, the [IACUCs] were not adequately fulfilling their responsibilities Committees did not always provide assurance that pain and discomfort of animals used in research activities would be minimized" (p. 24). In our view, USDA inspections of IACUC operations need to be more thorough and frequent, reduction in animal pain needs attention, and other improvements are called for.

Also, we agree with Steneck (1997) that the task for IACUC members can be daunting. Indeed, as he stated, to function effectively, committee members need to add substantial skills and knowledge to their repertoire. Our position is that members unwilling to learn should not be on the committee and that, as needed, committee membership should be expanded and consultation and review from additional university resources should be sought. Recall that the legislation provides for the minimum membership and does not limit the size of the committee. Steneck missed the point. The legislation intends that researchers present their proposals in language that can be understood by nonspecialists. It is in that way that the researchers increase the trust of the nonscientific and public community in their work.

Steneck's (1997) recommendation of a two-committee system (an animal care committee to do protocol review and an IACUC-type committee to set standards and provide oversight) runs the risk of taking us back to the pre-1985 days when protocol review, if it happened at all, was often little more than a rubber stamp of approval by institutional colleagues of the animal researcher. The failure of this system of collegial review was apparent in the disclosures of the appalling conditions of the animals that were uncovered in some of the celebrated cases of the early 1980s. It was evidence of the unacceptable conditions of the rhesus monkeys at Taub's laboratory in Silver Spring, Maryland, and of Gennarelli's head-injured baboons at the University of Pennsylvania that convinced Congress that the then-prevailing review system was hopelessly inadequate.

Furthermore, direct review solely by institutional colleagues is less likely to result in the application of the "three Rs" of reduction, refinement, and replacement. These alternative ways to conduct the investigation are attempts to reduce the ethical burden that falls on the animals. Pressure for application of the three Rs stems mainly from outside the biomedical community; therefore nonscientific and public members should be involved in the review process to ensure that this pressure is felt. Additionally, the animal care staff, whose jobs are typically dependent on animal researchers, may be less likely than a broader based committee to press reforms that may be resisted by researchers.

Conflict of Interest

Steneck (1997) was concerned that IACUCs, as currently constituted, are faced with a conflict of interest. He argued that IACUCs are an intrinsic part of part of the animal care program and yet are required to declare whether the institution is in compliance with the requirements of the Animal Welfare Act. Steneck asserted that IACUCs are, in fact, being asked to certify the adequacy of their own performance. We assume that the conflict with which Steneck is concerned is one where the IACUC might be more likely to affirm institutional compliance when it does not exist, because to declare the institution out of compliance would initiate a cascade of consequences that might result in the limitation of animal research activities at the institution. On this he was correct. However, what is not clear is how his dual system eliminates these conflicts. In his proposed organization, if the separate IACUC declares the operation of the animal care

committee out of compliance, the same cascade of effects follow and are thus not free of the conflict of interests. As it stands today, the USDA inspector reviews the operation of IACUC and the validity of its declarations. As long as the committees are formed substantially from within an institution, conflicts of interest cannot be completely avoided. On the other hand, such conflicts, when acknowledged and discussed, can be a source of motivation for careful and accurate operation.

Restrictions on Academic Freedom

Steneck (1997) reminded us that universities have a long established chain of command and responsibility that works to prevent any single individual or committee from exerting unchecked authority. The current IACUC system stands outside this scheme in that its decisions may not be overruled by other institutional officials. Steneck was concerned about the precedents such an arrangement sets and the potential restrictions on academic freedom that might arise.

We agree that the arrangement is unique, but then the responsibilities of the IACUC are unique. After all, the mandated mission of the IACUC is the enforcement of federal law. It is not a body of university-created policy. Therefore this is a quite different mission than other university committees. Being in charge of enforcing federal law requires different patterns of authority that render inappropriate the oversight and action of a university appeal system. Certainly Steneck (1997) would not give a faculty member accused of breaking a speeding law on campus the option of having the police officer's actions reviewed by the dean, provost, and president. Nonetheless there is nothing in the provisions of the Animal Welfare Act that prevents a committee member who is found to be working in bad faith from being removed from the committee as the membership appointments are the responsibility of the chief executive officer of the university. In this regard, it is essential that we recall how it came to be that a set of federal laws was created to deal with the animal research domain. These laws did not emerge in a vacuum, merely because a group of Washington legislators were wondering how they could create statutes that would restrict the academic freedom of researchers. These statutes emerged at the behest of the public following unfortunate evidence that the research community was not consistently doing an adequate job of policing itself. Steneck's own recounting of the history at the University of Michigan makes clear that their dual-committee structure gained a degree of needed influence when their actions were finally backed by federal authority (p. 178).

Diverted Resources

Finally, Steneck (1997) was deeply concerned that "animal welfare is being purchased at the expense of the welfare of animal research. Bigger cages must be purchased instead of new research equipment. Staff time for caring for animals has replaced staff time for conducting research" (p. 180). However, he presented not one iota of evidence to support the claim that animal welfare reforms have slowed the advances in biomedical research. Steneck seemed to believe that welfare improvements having to do with such things as cage size, social housing patterns, provisions for exercise, and facilitation of psychological well-being are not improvements at all. Rather they are simply changes and matters of taste, such as whether one chooses to use cosmetics. This position neglects the fact that before animals become laboratory animals they are first entities with an evolutionary history that shapes their physical and mental attributes and a repertoire of species-typical behavior that both helps to define the concept of normal and gives their lives meaning and purpose. There is a substantial body of literature to demonstrate that animals in poor health, that are poorly maintained, and the welfare of which has not been looked after produce research results that are often confounded and worthless (see Rollin & Kesel, 1990). In other words, to house animals in ways that neglect these crucial welfare considerations is both cruel and scientifically self-defeating.

Steneck (1997) seemed to believe that economic conditions are sufficient to protect animal welfare. He stated:

Economic incentives already exist for reducing the numbers of animals used in research and for replacing costly animals with less costly animals, which usually means replacing higher species with lower species. Animal welfare might be better protected by institutionalizing such cost incentives rather than relying on expensive committee time to achieve the same ends. (p. 181)

Certainly there is some validity to his point. However, would not these same economic conditions argue for cost-cutting activities like the employment of smaller and less educated animal care staffs, cheaper food and medicines, and so on? Because economic incentives like the kind enumerated by Steneck are not a new development and to our knowledge have not been effective in the past, why would they now gain the force necessary to promote reform in animal welfare?

CONCLUSIONS

Although we agree that the IACUC has serious failings like heavy workload, isolation of public members, uncertainty around the judgment of scientific merit, and insufficient information concerning the invasiveness of experimental procedures, we consider that the current system is an extensive improvement over pre-1985 days. There is no question in our minds that the treatment of many animals has been improved and the understanding between scientists and the public has been improved as a result of the 1985 legislation.

At the beginning of his article, Steneck (1997) acknowledged that we the public owe something to animals, something akin to the veneration and respect revealed in practices of people even 50,000 years ago. By the conclusion of his article we are left with the impression that, from his view, if we owe animals anything beyond the thoughts of veneration and respect it must not cost too much money, must not take much time, must not challenge the lines of authority typical of university administrations, and must not require a public ethical analysis. This position attempts to separate ethics from the practice of research, thereby failing to motivate the ethical self-examination required by a moral scientific life.

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