DEPARTMENTAL GRANT APPEALS BOARD

Department of Health and Human Services

SUBJECT: Institute for Behavioral Resources -- Dr. Edward Taub
Docket No. 83-116
Decision No. 538

DATE: May 31, 1984

DECISION

The principal investigator (PI) of a research grant awarded to the Institute for Behavioral Research (IBR) appealed the termination of the grant by the National Institutes of Health (NIH). The amount in dispute is $109,965.55, which represents the unexpended balance of the grant award. NIH decided that the grantee (IBR) failed to comply materially with the terms and conditions of the grant award. NIH based its decision on findings which it set forth in the letter of termination dated August 30, 1982. Appeal File, Tab 9. The Public Health Service Grant Appeals Board (PHS Board) heard an initial appeal by IBR and the PI under the procedures set out at 42 CFR Part 50, Subpart D, and affirmed the NIH decision on the grounds stated in the letter of termination. The PI then appealed that decision to this Board, on his behalf and that of IBR. 1/

The primary question in this appeal is whether there was a sufficient basis for the NIH conclusion that the grantee failed to comply materially with the terms and conditions of the grant award, specifically, the applicable principles for the care and use of laboratory animals. Although we conclude that the evidence does not fully support all of the NIH findings, we conclude, nevertheless, that NIH had sufficient basis to terminate the grant for cause because IBR did not correct some deficiencies in the physical facilities identified at the time the grant was suspended, failed to renegotiate its letter of assurance that it would comply

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1/ The Institute for Behavioral Research (IBR) and its parent institution, the Institutes for Behavior Resources, Inc., participated in the PHS Board proceedings but chose not to appeal the decision further. However, IBR requested that the PI be allowed to prosecute the appeal before this Board. IBR agreed to accept the Board's decision in the appeal and NIH agreed to the PI's prosecution of the appeal under these circumstances.

with applicable policies for the care and use of laboratory animals, and because an attending veterinarian did not supervise the animal care program by making regularly scheduled visits to the laboratory.

This decision is based on the written record and on an evidentiary hearing.

Summary of our Decision

The record here shows that NIH reacted immediately and, in context, fairly, to stop what NIH perceived to be a serious threat to IBR's laboratory animals. Our detailed analysis, conducted with the benefit of hindsight and a record that has become voluminous, indicates that some of NIH's bases for the termination are not substantially supported by the record. Nevertheless, the record shows that IBR did not comply with certain federal requirements for the care and use of animals and that this failure to comply was material. Specifically, IBR did not make certain improvements in the physical facilities which NIH reasonably required, although IBR was given ample time to make the corrections. IBR failed to show that it ever intended to comply with the requirements and, thus, could not renegotiate its letter of animal assurance. This noncompliance and the lack of a new animal assurance were material, and NIH, therefore, clearly had reasonable grounds for terminating the grant. Moreover, the record shows that IBR violated the NIH Guide for the Care and Use of Laboratory Animals and USDA requirements that a veterinarian supervise the animal care program and make regularly scheduled visits.

What we do not find persuasive are the arguments that the condition of the monkeys showed that there had been inadequate veterinary care. The record suggests that the animals' condition, pointed to by NIH as evidence of mistreatment, resulted from the research performed. The record shows that the animals' condition largely was unavoidable given the nature of the experiments. The Board is not dealing with an issue of propriety of the experimental research. Thus, our determination to uphold NIH's decision here does not deal with the merit or quality of the research performed, nor with the personal integrity of the PI. Rather, our decision is that the institutional grantee, IBR, failed to make capital improvements, failed to renegotiate its animal assurance, and failed to provide the required veterinary supervision and regularly scheduled visits, and that these failures constituted material noncompliance with requirements applicable to IBR's grant.

We also conclude that the procedures used by NIH and PHS in terminating the grant are not a basis for reversing the termination. IBR and the PI have had ample time and opportunity to examine the evidence, to discuss with NIH the

deficiencies identified by the Ad Hoc Committee, to rebut the NIH findings, and to correct deficiencies. Moreover, the PI has had a full opportunity, including an evidentiary hearing, to present his case before this Board.

The Research Grant and the Effects of Deafferentation

The research grant, entitled "Effects of Somatosensory Deafferentation," was awarded on April 4, 1980 for a project period of two years. The grant continued research which had been started several years earlier and which had been supported by NIH through several project periods. Appeal File, Tab 71. At the time the grant was initially suspended (October 1981), about six months of the project period remained.

The grant's purpose was to assess movement in primates (monkeys) following deafferentation of one or both forelimbs. Deafferentation consists of cutting the dorsal roots of the nerves transmitting sensation from the limbs to the central nervous system. Following deafferentation, the monkeys have no sensation in the deafferented limbs, although the muscles are not paralyzed, and the animals generally do not use the limbs (unless they receive behavioral retraining) because they have no sensation in them. As a result they treat the limbs as foreign objects. Hearing Transcript (Tr.), pp. 35-42. In addition, certain autonomic reflexes which control blood flow to the limbs are disturbed and, thus, the circulation in the limbs is no longer normal. Visible lesions appear on the limbs and the monkeys have a tendency to "self-mutilate," picking at the lesions and causing them to increase in size. In some cases, the monkeys lose some of their digits because of the circulatory problems. Some animals also suffer from broken bones or dislocated joints as a result of the altered blood flow and the lack of sensation. The evidence presented, however, showed that the appearance of lesions, the animals' tendencies for self-mutilation, and the other physiological symptoms are typically associated with deafferentation, and that the animals feel no pain despite the presence of these symptoms. Tr., pp. 35-40; 223-230. Persons ignorant about the peculiar effects of deafferentation might perceive that any deafferented animals have suffered from very poor care, but the record here indicates that, even with the best of care, poorly-healing injuries may occur in deafferented animals.

The monkeys involved in this research had been deafferented some four to five years prior to the time the grant was suspended. Tr., pp. 253-254. The issues in this appeal do not concern the initial surgery but center on the care of the animals and the state of the associated physical facilities

during the period of this grant award prior to suspension (1980-1981).

The research plan involved training the monkeys to use the deafferented limbs even though they no longer had sensation in them. The final step in the plan was to "sacrifice" (i.e., kill) the animals and perform anatomical studies on the nervous system. The purpose of this research was to develop models for helping humans who exhibit physiological symptoms similar to those of the deafferented monkeys. Such symptoms apparently may occur in humans who have strokes or spinal cord injury and in certain retarded children who develop self-mutilation syndromes similar to those seen in the monkeys. Tr., p. 38.

Both NIH and the scientific experts who testified on behalf of the PI at the hearing agreed that the studies were important and had valuable clinical implications. Furthermore, the record showed that NIH, when it awarded the grant, was aware of the nature of the experiments, what deafferentation entailed, and at least to some extent, the physiological results of the experiments. Appeal File, Tab 100; Tr., pp. 285-286. 2/

How the Dispute Arose

In May 1981 a person who had expressed an interest in a possible career in animal research began to work as a volunteer in the PI's laboratory. The volunteer had responsibility for watering, feeding, and cleaning two monkeys, and

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2/ The PI testified that he had been performing research in somatosensory physiology for about 25 years and that his first experiments were supported by NIH. Tr., pp. 298, 756-757. NIH had supported this particular project for approximately eleven years. One of the conditions associated with NIH research grants is that copies of publications reporting research results must be submitted to NIH with the required progress reports. PHS Grants Policy Statement, 1976, p. 42. NIH probably had been informed, through progress reports, of the effects of deafferenting animals. Moreover, NIH research grants are discretionary awards resulting from competitive applications which are subject to a peer review system. Thus, this research plan had been reviewed and approved by a committee of knowledgeable scientists. The record also shows that, over a period of years, NIH conducted several site visits in which the physical facilities were visited by people from NIH. Tr., p. 12.

the PI permitted the volunteer to participate in some of the behavioral experiments. Appeal File, Tab 72, p. 10. During part of August and September 1981 the PI was away from the laboratory for two weeks on vacation. The PI testified later that two animal caretakers, college students who had worked for him for some time, did not report to work on seven days during this period. Tr., p. 340. The PI also testified that this was unusual; during the preceding 14 months, these same persons were absent a total of one day, and they were not absent at all during the PI's vacation the preceding year. Tr., pp. 339-340. The animal room and the cages holding the monkeys were not cleaned thoroughly while the PI was on vacation in 1981 because the caretakers did not report for work. While the PI was on vacation, the volunteer brought five persons to visit the laboratory. The visits were made at night and the people subsequently recorded their observations in the form of affidavits. 3/ The PI testified that the animal room conditions were considerably worse than normal as a result of the caretakers' absence. The PI accepted full responsibility for the state of the laboratory, even though he had been unaware of the conditions at the time they occurred. Tr., p. 345. On September 11, 1981, the Montgomery County Police visited the laboratory with a search warrant and seized 17 monkeys and laboratory records.

NIH became aware of this incident through the media and initiated an investigation of the incident and allegations. Tr., p. 579. The Deputy Director for Extramural Research and Training (then titled Associate Director) asked the Director of the Office for Protection from Research Risks (OPRR) 4/ to take responsibility for the investigation. Letter of September 16, 1981, Appeal File, Tab 76. The OPRR Director formed an Ad Hoc Committee which included the Assistant Director of OPRR, three OPRR staff persons, the Program Director of the NIH Laboratory Animal Sciences Program, the Acting Deputy Director of the awarding component of NIH, an NIH attorney, and a veterinary consultant from outside NIH. Appeal File, Tab 72, pp. 4-6.

3/ The record indicates that, unknown to the PI, the volunteer was an officer in an anti-vivisectionist group. At least four of the five persons who visited the laboratory and prepared affidavits were also active in animal rights groups. PI Rebuttal to NIH Statement, Tab 2, p. 4; Reply Brief, p. 6.

4/ OPRR is the office responsible for the administration and implementation of the NIH policy requiring animal assurance statements. PHS GAM: 1-43-50A.

reviewed the progress and financial management of the grant in October 1981. Appeal File, Tab 91, A. The Deputy Director stated that NINCDS found that the PI had made progress toward the stated scientific goals and had carried out the experiments within the framework that NIH expected and for which the PI had responsibility. Furthermore, NINCDS found that neither the PI nor IBR had used grant funds inappropriately and that there were no material problems with the financial management of the grant. Tr., pp. 581-582.

On October 9, 1981 the Montgomery County Circuit Court ordered the monkeys placed in the custody of NIH where they were to be monitored by a court-appointed veterinarian. The monkeys have been at the NIH Animal Center in Poolesville, Maryland since that time, and have been cared for by NIH veterinarians. The monkeys were first examined by NIH veterinarians on or about October 15, 1981. Tr., p. 630.

The Executive Director of IBR and the PI discussed with NIH the renegotiation of IBR's animal assurance and the future status of the grant. They also cooperated with NIH in trying to find an alternative which would allow the PI to complete his experiments at another laboratory. However, the State refused to release the monkeys so that the experiments could be completed. On August 30, 1982 NIH notified IBR that the grant would be terminated for good cause. 6/ The termination was appealed to the PHS Board by IBR and the PI. The PHS Board upheld the termination. 7/ The PI then appealed to this Board under the circumstances described in footnote 1.

6/ In November 1981 the PI was tried under Maryland's Animal Anti-Cruelty statute for 17 counts of animal cruelty. The Maryland District Court convicted him of six counts after a non-jury trial. In July 1982 the Maryland Circuit Court, on appeal, provided a trial de novo and convicted him of only one count. In August 1983 the Maryland Court of Appeals reversed that conviction on the ground that the Maryland statute does not apply to federally-supported research.

7/ The PI argued that the PHS Board review was unfair. His reasons included: the composition of the panel was biased (three veterinarians and one neuroscientist); the PHS Board should not have used an abuse of discretion review standard; NIH failed to allow him time to review the police photographs prior to responding to the Ad Hoc Committee report; and the PHS Board failed to take into account evidence of political pressure on NIH to

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Applicable Law and Guidelines for Terminating Grant Awards

The regulatory standard for terminating grant awards for cause is found at 45 CFR 74.115(a). The regulation provides, in pertinent part:

> The granting agency may terminate any grant in whole, or in part, at any time before the date of expiration, whenever it determines that the grantee has materially failed to comply with the terms of the grant. . . . .

The PHS Grants Administration Manual (GAM), Chapter 1-500, addresses grant suspension and termination also. The GAM states that when a grantee has materially failed to comply with the terms and conditions of a grant, PHS may suspend the grant, terminate for cause, or take other legal and appropriate remedies.

7/ Cont.
terminate the grant. We conclude that none of these are a basis for overturning the termination. The PI had approximately one year in which to review all the evidence used by NIH, and the PHS Board allowed him to argue his case in person and to present rebuttal information. The PHS Board review is an "informal preliminary" process which allows PHS an "opportunity to review decisions of its officials and to settle disputes with grantees." 42 CFR 50.403. The PI has had a full opportunity to present his case before this Board, which is independent from the PHS program decisionmakers. The PI has submitted legal arguments, documents, and other written evidence, and has presented witnesses and argument at an evidentiary hearing.

Concerning the allegation of "political pressure," we note that the Board reviewed the stated bases for the termination and concluded that the termination was reasonable because the grantee failed to materially comply with certain terms and conditions of the grant award. Here the record suggests that NIH received many inquiries about the situation at IBR but there is no evidence that the inquiries improperly affected the decision-making process at NIH. Mere evidence of "political pressure" does not render an agency's decision arbitrary. Where the stated reasons for the decision are supported by the record, this Board will not consider the mental processes of the decisionmaker. Hercules Inc. v. EPA, 598 F.2d 91 (D.C. Cir. 1978).

General guidelines and procedures for suspension and termination are set out at PHS GAM: 1-500-50:

A. General Considerations

1. The decision to terminate a grant represents a serious judgment that must reflect a thorough analysis of all relevant factors. It initially must be determined that the grantee has failed to comply with one or more terms and conditions of the grant. Additionally, it must be determined that such noncompliance is of sufficient magnitude to warrant the termination of grant support. . . . the important distinction is the degree or magnitude of noncompliance.

* * *

PHS policies contain no other indication about what constitutes material noncompliance except a footnote to PHS GAM: 1-43-50E, which says that a violation of sections 19 or 20 of the Animal Welfare Act will be considered a material failure to comply. Section 19 refers to dealers and exhibiters and, thus, does not apply to IBR and the PI, but section 20 authorizes the Secretary of Agriculture to issue cease and desist orders where a research facility violates the Animal Welfare Act or implementing rules and regulations.

PHS GAM: 1-500-50 also provides:

D. Termination Action

1. Termination action will normally be taken after a suspension has been in effect for a reasonable length of time without correction of the deficiency. . . .

Applicable Law and Guidelines for the Care and Use of Laboratory Animals

The PHS GAM prescribes the policies and responsibilities for the care and use of animals in PHS-supported activities. See PHS GAM: 1-43. An institution must submit an acceptable assurance to the Office for Protection of Research Risks (OPRR) that it will comply with the principles set out at Exhibit X1-43-1 of the GAM, the NIH Guide for the Care and Use of Laboratory Animals (Guide), provisions of the Animal Welfare Act, and other applicable laws and regulations. PHS GAM: 1-43-20B, 1-43-40A. All of these principles are part of the terms and conditions of the grant award. The institution must also appoint a committee for oversight of

the animal care program, PHS GAM: 1-43-40A, and must have its facilities reviewed for conformance with the Guide, either by being accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) or by review, "at least annually," of the institution's facilities and procedures by the animal care committee. PHS GAM: 1-43-40B. Finally, the GAM provides that suspension or termination may occur where an institution fails in a material manner to comply with the terms of the policy. PHS GAM: 1-43-50E.

Below we point out specific requirements for animal care when we discuss the findings which formed the basis for termination.

The Stated Grounds for the Termination

NIH terminated the research grant because it found that IBR had failed to comply materially with the terms and conditions of the grant award, specifically, the applicable principles for the care and use of laboratory animals. The grounds cited by NIH were: IBR provided inadequate veterinary care (NIH included in this ground violations concerning the attending veterinarian and the amount of supervision and care he provided, as well as an allegation that the animals' condition showed evidence of inadequate veterinary care), the IBR Animal Care Committee lacked the necessary expertise to provide adequate oversight, the physical facilities for housing the animals did not meet federal requirements, and IBR did not maintain an adequate occupational health program for IBR staff. Finally, NIH and the PHS Board found that IBR had violated its animal assurance statement that it would comply with the applicable requirements and principles for the care and use of animals.

Discussion of the Stated Grounds for Termination

We conclude that the record supports the NIH findings about the need for improvements in the physical facilities, IBR's failure to renegotiate an animal assurance, and the attending veterinarian's failure to regularly monitor the animals and their veterinary care. We further conclude that these findings are a sufficient basis for terminating the grant for material failure to comply with the grant award terms.

We also conclude that the record shows that at the time the grant was suspended, the grantee lacked an occupational health program. Since unrebutted evidence shows that the grantee instituted an occupational health program prior to termination, however, we do not uphold that finding as a basis for termination. We also conclude that the NIH

findings about the condition of the monkeys as an indication of the adequacy of veterinary care and about the expertise of the Animal Care Committee are not substantially supported by the record.

The physical facilities for housing the monkeys.

NIH alleged that the physical facilities did not meet the requirements of the PHS Animal Welfare Policy (Appeal File, Tab 72, B) and the Guide. The Ad Hoc Committee Report listed several improvements in the laboratory facilities which the Committee believed were necessary for the laboratory to meet federal standards. The Committee recommended that IBR acquire adequate animal cages, use standard attached feed containers in the cages, place protective covers on the lights in the animal room, meet the requirements for an aseptic surgery, and develop an efficient ventilation system with separate circulation of the rooms used by humans and animals. 8/

The Ad Hoc Committee recommended that IBR acquire adequate animal cages because the cages did not have food containers, the galvanized coating was chipping off ("inviting" rust and general uncleanliness, Tab 72, p. 14) and there were mineral deposits as well as dirt, hair, rust, and chipped paint in the catch trays and supporting runners. Four cages had broken or bent wires in the floors and the Committee believed that the construction of the cages made adequate cleaning "seemingly impossible." Appeal File, Tab 72, p. 14. The Committee recommended that IBR buy movable cages because the colony room lacked a "comprehensive drainage system which might ameliorate those cleaning problems posed by the immobile structure of the cages." 9/ Tab 72, p. 14.

8/ The Committee also noted that the plasterboard walls were heavily painted, and that the walls would not be easy to disinfect and maintain. In addition, the Committee concluded that police photographs had indicated an "extensive vermin problem." p. 15. However, the NIH Report stated that it did not rely on the evidence shown in the police photographs, and the NIH presentation in this appeal did not emphasize either of these findings, so we do not address them further.

9/ NIH acknowledged that the Guide does not require floor drains; however, NIH stated that because the cages were not movable and there were no floor drains, cleaning and sanitizing the cages in the colony room was more difficult. Tr., pp. 419-420.

The Committee found that the animal room was ventilated by an exhaust fan which drew air from an adjacent hallway, and that the air was heated and cooled by a central unit located in the space occupied by humans. The Committee concluded that there was inadequate separation of the ventilation systems for humans and primates.

Although NIH pointed to many parts of the Guide as support for its position, we set out only a few here.

- The caging or housing system is one of the most important elements in the physical environment of laboratory animals. Inasmuch as the well-being of the animals and the control of experiments are influenced by the caging or housing system, it should be designed carefully. . . . The system should be designed to facilitate effective sanitary maintenance and servicing. For example, bends and crevices in animal cages that may be difficult to clean should be avoided, and feeding and watering devices should be easily accessible for filling, changing, or servicing. Throughout the system, keeping the cages . . . in good repair should be considered mandatory to prevent injury to the animals, to promote physical comfort, and to facilitate effective sanitary maintenance and servicing. Particular attention should be given to avoiding sharp edges and broken wires, to keeping cage floors in good conditions, and to refurbishing or replacing rusted equipment. pp. 3-4.

- The animal facility and human occupancy areas should be ventilated separately. The system should provide frequent changes of room air without drafts, preferably 10-15 changes per hour. p. 25.

The PI alleged that there was nothing materially wrong with his laboratory. 10/ Post-Hearing Memorandum, p. 9. He

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10/ The PI argued that terminating the grant on the basis of the laboratory conditions during the two-week period while the PI was on vacation (and at the close of which time the monkeys were seized) was not a sufficient basis for termination because the condition of the laboratory during that period was an aberration from the PI's record of many years of substantial compliance, and that the conditions existing during that two-week period could have been and were corrected. We note that although the NIH Ad Hoc Committee discussed the circumstances leading to the monkeys' seizure, NIH did not

offered the opinions of several persons that the laboratory facilities were adequate. 11/ Post-Hearing Memorandum, pp. 11-12. The PI argued the following in rebuttal to the NIH findings:

- The PI alleged that the four cages with broken wires were not used and had been set aside for repair. He also alleged that all the defects noted by the Committee had been accepted by the USDA inspector as minor problems which did not make the cages inadequate or unhealthy. Tr., pp. 283-285. The PI maintained that the cages were adequately cleaned and sanitized. Finally, the PI contended that the acquisition of new cages would cost about $20,000, an amount which IBR, a small grantee, did not have. The PI argued that the grantee was caught in a "catch-22" situation where it did not have funds to make the improvements, but could not get funds from NIH unless it made the improvements.

- The PI presented evidence that ventilation tests made in the colony room showed that the air exchange was acceptable. Appeal File, Tab 101. The PI acknowledged that there was some exchange of air between the human and primate areas, but argued that it was

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10/ Cont.
rely specifically on the temporary condition of the laboratory during the two-week period just prior to the police raid as a basis for suspension or termination. NIH Post-Hearing Memorandum, p. 15. In fact, NIH acknowledged that probably the laboratory conditions during that two-week period were an aberration. NIH emphasized that it was the conditions observed at the time the Ad Hoc Committee visited IBR which were of primary concern. Post-Hearing Memorandum, pp. 14-15.

11/ The PI presented as witnesses two scientific experts who have training and degrees in both neuroscience and veterinary science. Both men were knowledgeable about the type of research performed, the clinical implications, the physiological symptoms resulting from such experiments, the care and treatment of deafferented animals, and standard principles of veterinary care. These men did not know the PI personally prior to the suspension of his grant, although, as scientists, they were familiar with his work.

insignificant. 12/ Furthermore, the PI argued that changing the ventilation system would require spending $5,000, and that IBR could not afford that expense without aid from NIH.

Analysis.

In evaluating the evidence here, we find that, on the one hand, there is some support for the PI's position that the cages were adequate. The scientific experts and other professionals such as those from scientific societies that investigated this incident believed that the cages were adequate. The dissenting member of the PHS Board also believed, based on evidence presented before the PHS Board, that conditions in the laboratory were acceptable. The PI testified that he believed that the cages and physical facilities met federal standards because the laboratory met USDA inspections. Several NIH committees had made site visits to the laboratory in connection with the PI's grant applications, and while their purpose was not specifically to review compliance with laboratory animal care standards, all those committees, including one in 1979 which had a veterinarian as a member, found the physical facilities generally adequate. Appeal File, Tab 48; Post-Hearing Memorandum, p. 10, fn. 7.

On the other hand, NIH has twice recommended (in 1977 and 1981), after actually inspecting the laboratory, that IBR purchase new cages. In 1977 NIH made a site visit to the laboratory in response to a complaint made by a private citizen. The report of that visit, written by the NIH veterinarian who participated in the site visit, found the laboratory conditions generally adequate but stated that the cages should be upgraded "in the near future," because of difficulties in cleaning and maintaining the cages. Appeal

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12/ The PI argued that many of the NIH primate laboratories do not have adequate air exchange systems, if measured by the standard to which NIH held him. Memorandum Concerning Issues Relating To Animal Care, p. 20; Tr., pp. 467-471; Post-Hearing Memorandum, p. 19. We do not think that this necessarily excuses the IBR laboratory from meeting federal standards. Moreover, the PI did not develop this argument or present evidence supporting his allegations and showing that the NIH decision here was arbitrary.

File, Tab 103c, p. 2. 13/ Again in 1981, after inspecting the cages, the Ad Hoc Committee recommended that IBR purchase new cages.

Thus, we are faced with a difference of opinion about the adequacy of the cages. Some scientists and the USDA inspector believed that the cages were generally adequate. Two separate NIH committees recommended that new cages be purchased to meet federal standards, although NIH did not make the 1977 recommendation mandatory. Even though USDA did not find violations of the Animal Welfare Act and the implementing rules and regulations, the NIH Guide contains many specific details not found in the USDA regulations. NIH has the authority to decide about the adequacy of the facilities for animal research funded by NIH. PHS Principles for the Care and Use of Animals, Exhibit PHS: XI-43-1, require that post-experimental care of animals must minimize discomfort in accordance with acceptable veterinary practice. The condition of the animals' cages is crucial to the comfort and health of the animals. Moreover, the Guide indicates that the adequacy of the animal cages is material. Thus, we conclude NIH acted reasonably in requiring the grantee to replace cages which NIH considered inadequate.

We also think that there are valid reasons, such as odor, comfort, and prevention of diseases, for being concerned about the ventilation of the animal room. The requirement is for the protection of the monkeys as well as the humans. The PI admitted that the laboratory did not have separate air supplies and argued that he believed NIH "would not consider the ventilation system . . . to be a violation." Post-Hearing Memorandum, p. 20. However, the Guide does require separate ventilation systems and NIH could require the grantee to meet federal standards by renovating the ventilation system. Thus, we conclude that NIH acted

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13/ The PI argued that he never received the page of the report on which this recommendation was included. Tr., pp. 360-363. This contradicts a statement made by the PI during the hearing before the PHS Board that he had read the recommendation about new cages and discussed it with someone at NIH. Hearing Exhibit 1 (PHS), pp. 140-141. Regardless of whether the PI knew in 1977 that NIH recommended new cages, however, the primary point remains that the NIH recommendation in 1977, based on its view of the adequacy of the cages, and its recommendation in 1981 show a consistent belief by NIH that new cages were important.

reasonably in recommending that the ventilation system be changed to comply with the Guide.

The primary reason why IBR did not make the changes recommended by NIH was that IBR was a small grantee and considered $25,000 a large investment, particularly when the grant was near the end of the project period. Moreover, unrebutted testimony by the PI indicates that he could have completed the experiments in a short time (18 days). Post-Hearing Memorandum, p. 7. The PI argued that, in view of these circumstances, it was unfair of NIH to require the changes as a condition of reinstating the grant. However, institutions seeking federal funds must provide adequate facilities for performing the research. NIH has no obligation to fund capital improvements for a grantee receiving discretionary research funds. The grantee institution did not make the recommended improvements during a ten-month period. PHS policy provides that termination will "normally be taken" after a deficiency is not corrected within a "reasonable length of time." PHS GAM: 1-50-50D. NIH cooperated with IBR in trying to make alternative arrangements for completing the experiments, but NIH is responsible for insuring that grantees comply with the requirements for protecting laboratory animals. Thus, NIH had sufficient reason to terminate the grant for material failure to comply. 14/

Renegotiation of IBR's statement of assurance about the care and use of laboratory animals.

A grantee institution must file an acceptable assurance with OPRR in order to be eligible for federal funds. PHS GAM: 1-43-20B, 1-43-40A. The Ad Hoc Committee recommended that

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14/ We do not think that the materiality of some of the more minor findings made by the Ad Hoc Committee is supported by the record. For example, unrebutted testimony by scientists about the ability of the deafferented monkeys to use their limbs shows that it is not reasonable to use food containers where the animals are handicapped by being deafferented. Similarly, although the Deputy Director of OPRR testified that the Ad Hoc Committee estimated that the monkeys could reach the light bulbs, the record indicates that the USDA inspector actually made measurements and concluded that the monkeys could not reach the light bulbs. Finally, we think that requiring that the PI continue to maintain a room as an aseptic surgery when the laboratory had not performed surgery for over two years is impractical in such a small facility.

IBR's assurance be withdrawn until IBR complied with the Committee's recommendations and renegotiated the assurance. IBR immediately complied with all the recommendations except that it did not purchase new cages or alter the ventilation system. Appeal File, Tabs 65, 66 and 67. The record shows that IBR failed to comply with these two NIH recommendations. Nor did IBR assure NIH that it would comply at some future date. 15/ The PI argued that IBR did not violate its assurance because IBR had always been "committed" to complying, which was what the assurance promised. However, NIH believed that the federal requirements it alleged were violated were important and that IBR must demonstrate its commitment before renegotiating the assurance. Since a grantee must have an assurance to get federal funding, NIH was justified in terminating the grant when IBR failed to comply with NIH conditions for renegotiating the assurance.

The occupational health program for IBR staff.

We conclude that although NIH's finding about the IBR occupational health program was a supportable basis for the suspension, it could not serve as a basis for termination under PHS' procedures because the record shows that the grantee had corrected this aspect of its animal care program prior to termination.

Chapter III, E, p. 19 of the Guide provides that an occupational health program is mandatory for personnel working in laboratory animal facilities and for other personnel with substantial animal contact. Such a program includes physical examinations, immunization schedules, maintenance of records concerning wounds and illnesses, and regularly scheduled examinations for tuberculosis. The rationale for such a requirement is obvious.

The PI acknowledged that the laboratory did not have such an occupational health program at the time NIH suspended the

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15/ The PI contended that prior to termination NIH would not guarantee reinstatement of the grant even if IBR made the changes. However, the record shows that the IBR had additional concerns which influenced its decision not to make the changes. See p. 16 above. There is no indication in the record that NIH was arbitrary in not providing a guarantee of reinstatement. We know of no obligation on NIH to guarantee reinstatement of a grant where circumstances exist in addition to those which a grantee may correct (e.g., the pending criminal proceedings and the related animal custody question).

grant. Unrebutted evidence indicates that IBR instituted an occupational health program thereafter, even though the PI believed the laboratory did not need such a program because of the size and stability of the monkey colony and the good health of the persons working with the monkeys. Tr., pp. 355-357. Tab 66, Letter from IBR to NIH, October 8, 1984; Tab 67, Letter from IBR to NIH, November 2, 1981. Thus, at the time of termination, IBR had already instituted an occupational health program and the earlier NIH finding was no longer a basis for NIH action in terminating the grant.

The veterinary care provided at the IBR facility.

NIH found that IBR had provided inadequate veterinary care to the monkeys. We conclude that this finding is supported by the record in this appeal concerning the lack of regular veterinary attendance. We also conclude that the record does not support a finding that the attending veterinarian was not qualified for the position or a finding that the health of the monkeys was impaired because of the care they received.

NIH set forth several reasons for its finding that IBR provided inadequate veterinary care:

- The PI did not consult with the attending veterinarian other than at the annual meeting of the IBR Animal Care Committee and, in particular, the PI did not consult with the veterinarian when two monkeys died. The Ad Hoc Committee recommended that a veterinarian provide "regularly scheduled care with a frequency deemed appropriate by the OPRR and in strict compliance" with both the PHS Animal Welfare Policy and the Guide. Appeal File, Tab 72, p. 16. The veterinary consultant who had been a member of the Ad Hoc Committee testified that the Committee believed that veterinary participation in an animal care program on a regular basis is essential in order to monitor the general health of the animals. Tr., pp. 499-501.

- The attending veterinarian was not experienced in the care and treatment of laboratory primates. The Ad Hoc Committee, relying on the attending veterinarian's alleged statement, at the time of the site visit, that he was a pathologist and had had little experience with research animals, recommended that IBR appoint a veterinarian who had expertise with laboratory primates. Appeal File, Tab 72, p. 12.

° The health of the deafferented monkeys had been impaired because the monkeys had not received regular care by a qualified veterinarian. NIH concluded this on the basis of Drs. Ott and Robinson's report of their examination of the monkeys 6 days after the monkeys were taken from the IBR laboratory, and the opinion of NIH veterinarians that the condition of the monkeys improved at the NIH facility. 16/

The requirements for adequate veterinary care pointed to by NIH are found in the United States Department of Agriculture (USDA) regulations implementing the Animal Welfare Act, 9 CFR 3.84, and in the NIH Guide.

Section 3.84(a) of the USDA regulations provides:

> (a) Programs of disease control and prevention, euthanasia, and adequate veterinary care shall be established and maintained under the supervision and assistance of a doctor of veterinary medicine.

The NIH Guide provides, at Chapter II, A, p. 11:

> Adequate veterinary care should be provided by a veterinarian qualified by postdoctoral training . . . or pertinent experience. Such care includes: full-time or regularly scheduled attendance by a veterinarian with a

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16/ The PHS Board decision indicated that, although NIH had based its position about inadequate care partly on the condition of the monkeys, the PHS Board could not assess the monkeys' condition. Thus, the PHS Board decision based its conclusion that the monkeys had received inadequate veterinary care on the lack of a veterinary program under the supervision of a qualified veterinarian, rather than on the condition of the monkeys. PHS Board decision, p. 10. Moreover, the Associate Director for Extramural Research and Training stated that NIH would have made a finding of inadequate veterinary care even in the absence of the determinations about the monkeys' condition. Tr., p. 602; NIH Post-Hearing Memorandum, March 12, 1984, p. 10. Throughout the appeal before this Board, however, NIH continued to maintain that the monkeys had improved while in the NIH facility and that this improvement showed that the monkeys had previously received inadequate care. NIH Brief, December 14, 1983, pp. 11-14; Post-Hearing Memorandum, March 12, 1984, pp. 10-11; Tr., p. 429; Memorandum to PHS Board from Associate Director for Extramural Research, NIH, Tab 6.

> frequency appropriate to institutional needs; . . . frequent observations of all animals by a person qualified to verify the health of each animal; availability of veterinary medical service for animals found to be ill or injured; . . . establishment of procedures for disease containment and surveillance; consideration of humane aspects of animal experimentation, such as the proper use of anesthetics, analgesics, and tranquilizing drugs; . . . .

The Guide also provides that adequate veterinary care is an institutional responsibility; that animal care programs require professional direction in addition to that provided by the user of the animal; and that the programs should be directed by veterinarians who have special training or experience in laboratory animal medicine. Chapter III, B and C, pp. 17-18.

The PI argued that he had provided adequate veterinary care for these animals and that he had met federal requirements for an animal care program. The PI alleged that the attending veterinarian was qualified for that position. He testified that, in contrast to the attending veterinarian's statement to the NIH Ad Hoc Committee, the veterinarian had held himself out as qualified when first approached by the Chairman of the Animal Care Committee and the PI. Tr., p. 265. The PI contended that the requirements in the Guide are ambiguous about the need for veterinary supervision of the animal care program, and that the attending veterinarian, who was not an expert on deafferentation, had delegated many of his responsibilities to the PI, particularly those concerning the animals' daily care and problems arising from deafferentation. 17/

The PI also alleged that the monkeys were healthy and needed little veterinary care other than for problems arising from

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17/ The PI also alleged that in earlier years he had consulted veterinarians experienced with deafferented animals, but that NIH had told him that the attending veterinarian should be a "diplomate" (a form of professional certification signifying qualifications in addition to a degree in veterinary medicine). The PI then asked a person who was a diplomate to be attending veterinarian. The PI argued that it was unreasonable to find that a veterinarian with the accreditation required by NIH is unqualified. Since we conclude that the attending veterinarian was qualified, we do not consider this point further.

deafferentation. He contended that there was no showing that the monkeys had been harmed in any way by the amount of veterinary care provided and, further, that the evidence presented by NIH did not show that the monkeys had significantly improved since they were taken from the IBR laboratory. The PI also alleged that the two veterinarians who examined the monkeys after the police seized them and the NIH veterinarians who have subsequently cared for the animals were not qualified to judge the treatment and normality of the symptoms shown by the deafferented monkeys because they lacked experience and knowledge about deafferentation. The PI argued that since the problems the veterinarians pointed to were those resulting from deafferentation, and the veterinarians were not qualified to make judgments about these problems, the veterinarians' opinions could not form the basis for a conclusion that the monkeys had received inadequate care.

Analysis.

a) The requirements for supervision of the animal care program by a veterinarian.

Appendix V of the Guide, p. 68, provides that the housing, care, and feeding of all experimental animals must be supervised by a properly qualified veterinarian "or other scientist competent in such matters." The PI argued that this statement made the Guide ambiguous about whether a veterinarian must supervise the animal care program.

We quoted above, at page 20, the provisions at 9 CFR 3.84(a) and the requirement from Chapter II, A of the Guide. Both of these require that animal veterinary care and disease control programs be supervised by a veterinarian. The statement from the Appendix of the Guide allows supervision of the "housing, care, and feeding" by a non-veterinarian. The Guide distinguishes requirements for housing, sanitation, and husbandry (feeding and bedding) from requirements for veterinary care. The former are termed laboratory animal management and do not involve monitoring the animals for disease, illness, or injury. The NIH Office of General Counsel stated that laboratory animal management did not include veterinary care. Appeal File, Tab 52, p. 2.

We do not think that the Appendix makes section 3.84(a) or the text of the Guide ambiguous. The position of NIH here is that the overall health and disease prevention program for the animals would benefit from the regular supervision by a veterinarian. The Appendix does not contradict that position, and does not supersede the clear language of the text of the Guide or of the USDA regulation. We conclude

that federal law requires that a laboratory using research animals must have an attending veterinarian who supervises the animal care program. 18/

b) The degree of involvement by an attending veterinarian in an animal care program.

The Guide provides that there should be regularly scheduled attendance by a veterinarian with a "frequency appropriate to institutional needs" and that frequent observations should be made by a person "qualified to verify the health of each animal." p. 11. Moreover, the Guide requires the "availability of veterinary medical service for animals found to be ill or injured." p. 11. The Guide, however, acknowledges that part-time employment of veterinarians may provide adequate veterinary care for institutions where it is not feasible to have a large staff for animal care and the number of animals is small. Guide, p. 18. NIH did not point to any federal requirement which specifies how often a veterinarian should visit or be consulted. Moreover, the Introduction to the Guide specifically says that the Guide is written in general terms so that the recommendations may be applied in diverse scientific institutions, using professional judgment to interpret the recommendations. p. 1. Thus, reading the Guide as a whole, we find that the degree of necessary veterinary involvement is not a fixed standard but depends on the situation presented in a particular institution and that the application of the Guide is somewhat flexible.

18/ In a supplemental submission, dated April 23, 1984, the PI informed the Board of new policies and regulations on laboratory animal welfare that are being proposed by PHS. The PI noted that in these proposed policies, PHS has dropped the language "or other scientist competent in such matters," and that the role of veterinarian has been emphasized by several other additions and changes in the policies. The PI argued that these changes mean that the previous language was indeed ambiguous and that PHS is now seeking to make it less ambiguous. We have already concluded that the language in the Appendix does not contradict or make ambiguous the requirement that a veterinarian supervise the animal veterinary care program, even if someone else supervises the animal husbandry. The new proposed policies are consistent with the position already taken by NIH. We see no reason to consider further policies which were not in effect at the time of the action being reviewed and which are not even in effect yet.

The PI testified that the monkey colony was well-settled, with no new animals entering the colony, that the colony was small, and that problems associated with the postsurgical stage of deafferentation no longer existed during the relevant project period. NIH did not contradict any of these assertions, nor did NIH point to any particular health problems or incidents (other than the two deaths we discuss below) which might indicate a need for more frequent visits by a veterinarian. Moreover, the grantee was a small institution with limited funds. Thus, generally, the evidence presented showed that the institutional need for and the feasibility of frequent consultations with a veterinarian was not great. 19/

On the other hand, the record does not indicate that the attending veterinarian or any other veterinarian provided regularly scheduled supervision or care during the project period. The PI argued that the care he provided was enough to meet federal requirements, in conjunction with the attending veterinarian's attendance at the annual meeting of the Animal Care Committee, and the inspections made by the USDA veterinarian. However, as we conclude above, the USDA regulations and the NIH Guide specifically require regularly scheduled visits and supervision by a veterinarian. The USDA veterinarian did not examine the monkeys thoroughly on a regular basis and provide care for them. His role was solely to ascertain whether the laboratory was complying with USDA regulations. Although the record indicates that he was interested in the research and offered useful suggestions to the PI about the animals' care, nevertheless, his inspections were not intended to substitute for the supervision and care of a veterinarian, as required by the Guide. Testimony indicated that the PI was well qualified to treat problems associated with deafferentation and NIH did not rebut this testimony. Moreover, after many years of working with primates, the PI probably had acquired considerable general knowledge about the animals and their care. The record also shows that, although the NIH veterinarians criticized the PI's treatment of certain problems, they adopted some of the PI's techniques, after consulting with the PI on several occasions while the monkeys were in their custody, and that

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19/ The record shows that the PI used veterinarians on a regular basis between 1971 and 1977. Appeal File, Tab 58; Tr., p. 311. The PI maintained that he consulted veterinarians less frequently after 1977 because by that time the care and treatment of the monkeys centered primarily around husbandry and the care of problems associated with deafferentation.

their own early treatment, based on standard veterinary practice, did not prove entirely satisfactory. Appeal File, Tabs 49 and 87. Nevertheless, the PI was not a veterinarian and he acknowledged that he was not competent to act generally as a veterinarian. Tr., p. 310.

NIH alleged that the PI should have called a veterinarian in connection with the deaths of two monkeys in 1980. One animal died within 48 hours of the first signs of illness, allegedly from a torsion (twisting) of the intestine. The PI admitted that it would have been wiser to have called a veterinarian when the first signs of illness developed, but he testified that the circumstances at the time of the animal's illness did not seem to warrant calling a veterinarian on an emergency basis.

The second monkey had had his hindlimbs deafferented and, as a result, was suffering from a degenerative condition affecting the spinal cord. The animal developed a urinary tract infection, common among animals with spinal cord degeneration. Tr., p. 302. NIH argued that the urinary infection could have been cured and that veterinary intervention would have prevented the animal's death. However, the PI testified that the animal would have continued to deteriorate even if the urinary tract infection were treated, and for that reason he decided to sacrifice the animal by euthanasia. Tr., pp. 300-305. NIH did not argue either that the PI's decision to sacrifice the animal or that the diagnosis of the animal's overall condition was wrong, and there is no evidence here that this death would have been prevented by veterinary intervention. 20/

Nevertheless, we think the PI, as a precautionary measure, should have consulted a veterinarian about the condition of both monkeys. Although we do not think that these deaths by themselves mean that generally the monkeys were receiving inadequate care, we do think they support the finding concerning lack of supervision by an attending veterinarian. Thus, the care provided by the PI and his associates did not

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20/ NIH also suggested that these two deaths represented a significantly high mortality rate for 1980. However, the PI pointed out that he had had an extremely low mortality rate in the laboratory for eleven years, and argued persuasively that it is unfair to rely on a mortality rate for one year out of eleven as a basis for deciding about the adequacy of veterinary care in the IBR laboratory. Post-Hearing Memorandum, p. 16. We do not find that the mortality rate for 1980 is significant.

fulfill the federal requirement concerning veterinary care. We do not think it is necessary for us to determine what amount of supervision would have been adequate to meet federal requirements here because there is no evidence at all of veterinary participation in supervising or actually caring for the animals.

c) The attending veterinarian's qualification for the position.

NIH also alleged that the person appointed as attending veterinarian was not qualified for the position. We do not agree.

The Ad Hoc Committee Report contained an alleged statement by the attending veterinarian that he was not in fact qualified to act in that capacity, but was really only a consulting veterinarian. The Committee therefore recommended that a person qualified to act as attending veterinarian be appointed. Contrary to this, however, a member of the Ad Hoc Committee who was a veterinarian testified that he knew the attending veterinarian personally and was familiar with his credentials and experience. The witness admitted that the attending veterinarian is very qualified generally as a veterinarian, and that even though the man's more recent experience was as a pathologist, he had had experience in the past with live research animals. The witness testified that he did not believe that the attending veterinarian was unqualified for that position. Tr., pp. 526-532.

The PI introduced evidence about the attending veterinarian's credentials and alleged that the veterinarian had held himself out as qualified and familiar with the Guide. Tr., pp. 62-64. Moreover, the PI pointed out that the man had signed several forms as attending veterinarian. The PI pointed out that he had initially briefed the attending veterinarian in detail about surgical procedures, the care of the animals, the medication provided, and all other significant aspects of the animal care program, and that the attending veterinarian had made several recommendations about the laboratory at that time. Appeal File, Tab 57.

Thus, the only evidence that the attending veterinarian was not qualified was his statement to the Ad Hoc Committee after the monkeys were seized. His statement is contradicted by his actions. He clearly held himself out as attending veterinarian. Although he characterized himself as "consulting veterinarian" to the Ad Hoc Committee, Appeal File, Tab 72, p. 12, he had accepted the position of attending veterinarian and carried out at least some of those duties. His credentials were excellent and a member of the Ad Hoc

Committee who knew him personally testified that he was qualified. Thus, we conclude that the attending veterinarian was qualified for the position. Although he carried out his duties minimally there is no evidence to show that he was not qualified to provide standard veterinary care as an attending veterinarian. 21/

In summary, then, we find that the attending veterinarian was qualified and that he fulfilled at least some of his duties. However, there is no indication in the record that the attending veterinarian (or any other veterinarian) examined the monkeys or otherwise provided supervision and veterinary care to the animals. Thus, we conclude that at the time of the suspension of the grant, the grantee had violated the requirement for regular supervision by an attending veterinarian. The monkeys had been removed from IBR by court order, and, at the time of termination, NIH had no reason to believe that the grantee would be able to institute regularly scheduled veterinary care for the monkeys. We find that the grantee violated the requirement for veterinary supervision and regularly scheduled visits.

d) The monkeys' condition.

The record does not substantially support the NIH allegation that the monkeys' condition improved markedly while at the NIH facility and that this indicated that they had received inadequate veterinary care while at IBR.

We first discuss the reports of the examinations made by Drs. Ott and Robinson.

Drs. Ott and Robinson examined the monkeys 6 days after they were taken from the IBR laboratory. The reports showed the monkeys to be in normal condition except for the lesions and other symptoms related to the deafferented limbs. Appeal File, Tab 72, H. The scientific experts testified that the condition of those limbs as described in the reports was consistent with typical deafferented limbs.

The PI questioned the impartiality of Drs. Ott and Robinson and their ability to judge the condition of the deafferented limbs and the appropriateness of treatment provided for

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21/ Although his denial was not uttered three times before the cock crowed, it does bring to mind the story of the effect intimidating circumstances may have on one's description of events. The Bible, Revised Standard Version, Matthew Chapter 26, verse 69.

symptoms shown by the monkeys in those limbs. Although we make no conclusions here about the impartiality of Drs. Ott and Robinson, we note that anti-vivisectionists brought them from other parts of the country to perform the examinations and no explanation has ever been provided about why the monkeys could not have been examined by locally available veterinarians. Moreover, a local veterinarian who examined the monkeys prior to their seizure by the police believed that their condition was good, and that there was no reason to call the police. Appeal File, Tab 93. The PI pointed out that Drs. Ott and Robinson had never heard of deafferentation at the time they examined the monkeys and, therefore, had no way of knowing whether the problems they saw were typical of the condition.

Although the scientific experts never saw the monkeys while they were at the IBR laboratory, they testified that on the basis of the reports made by Drs. Ott and Robinson, the pictures taken of the animals at the time they were seized and their observations of the animals in visits to the NIH facility, they believed that the monkeys were in generally good health at the time they were taken from the IBR laboratory and that they had been treated appropriately both in terms of standard veterinary care and for the specific problems associated with deafferentation. Tr., pp. 45-47; 58-59; 136.

The testimony shows that Drs. Ott and Robinson examined the monkeys as though they were normal monkeys and made their conclusions on that basis. Tr., p. 76. To the uninformed, the condition of a deafferented monkey may be alarming. Weighing their conclusions against those of persons who are experts on deafferentation, we think that Drs. Ott and Robinson's reports do not show dispositively that the monkeys were in poor condition at the time they were seized or that they were suffering because of inadequate veterinary care.

The NIH veterinarians cited two aspects of the monkeys' condition as evidence that the monkeys improved after they were moved to NIH. These were a decrease in the size of lesions occurring in the monkeys and a gain in the monkeys' weight. Moreover, the veterinarians criticized the PI's treatment of broken bones in deafferented limbs, saying that the bones should have been pinned. Although the NIH veterinarian who testified acknowledged that the monkeys' lesions seem to develop spontaneously and that the presence of lesions is not in itself evidence of inadequate care, he stated that none of the monkeys have had their lesions develop to the size shown by two monkeys upon arrival at the NIH facility in 1981, and that the NIH veterinarians believed this was significant. Tr., pp. 676, 741-754.

The PI did not specifically address the significance of the decreased size of the lesions exhibited by the monkeys while at NIH, but argued that there was no evidence showing that the monkeys' condition had changed radically since their arrival at NIH. He testified that seven of the nine deafferented monkeys had not had lesions at all for one and one-half years prior to being taken from the IBR laboratory, yet four of these animals developed lesions during their stay at NIH. Post-Hearing Memorandum, pp. 3-4.

The evidence presented in this appeal is inconclusive about the significance of the size and number of lesions developed by the monkeys. The lesions appear to be spontaneous in nature and, to some extent, the size of a lesion depends on the extent of self-mutilation a monkey engages in. The scientific experts testified that when monkeys are not taken from their cages regularly for behavioral experiments they seem to self-mutilate less. Tr., p. 61. However, the parties did not present any data specifically collected under controlled circumstances which might show the relationship of treatment to the size of the lesions, and thus we can draw no definite conclusions.

Nor do we think that the information presented about weight gain supports a conclusion that the monkeys' condition improved substantially during their two years at NIH. NIH submitted a chart which showed that the seven normal monkeys gained an average of 1.2 kg over the two-year period and that the nine deafferented monkeys gained an average of .3 kg. These figures included some monkeys who lost weight and some who gained only slightly. Hearing Exhibit 4 (PHS). The PI submitted a chart, based on NIH records, showing the deafferented monkeys' weight at varying times throughout the two-year period. Appeal File, Tab 89. The chart shows that the monkeys' weight fluctuated over the period, with the monkeys showing weight gain at times and weight loss at other times. The PI also argued that the monkeys were just reaching puberty when they were transferred to the NIH facility and that that factor alone could account for the weight gain. Finally, the PI argued that the weight gains shown by NIH were not statistically significant. NIH argued that any weight gain shows that the monkeys were healthier at the NIH facility. Tr., pp. 724-727, 742. We think this is too simplistic; the record does not support a finding that the weight gain is significant or that it shows an improvement in the animals' condition.

Finally, the NIH veterinarian who testified at the hearing alleged that the PI's treatment of the monkeys' broken bones was evidence of inadequate veterinary care. Tr., pp. 678-679. His only reason for this conclusion was that

standard veterinary care would be to pin broken bones and the PI did not pin the monkeys' bones. However, the PI presented testimony by the scientific experts which indicated that, after about the first year of deafferentation, the disturbed blood flow causes bones in the deafferented limbs to "rarify." As a result, the bones fracture easily and joints dissolve. The PI and the experts testified that pinning these bones causes a number of problems and it is better to simply allow the bones to heal on their own, even though healing would take longer and the bones would not be joined perfectly. 22/ On the basis of the testimony presented by both parties, we cannot conclude that the PI provided inadequate veterinary care if he did not pin broken limbs in animals who had been deafferented for some time.

In evaluating all the testimony and evidence, we have weighed the relative expertise of the witnesses and other persons making conclusions about the monkeys' condition. The Assistant Director of OPRR acknowledged that no one on the Ad Hoc Committee was an expert on deafferentation. Tr., p. 445. The consulting veterinarian, who was a member of the Ad Hoc Committee and who testified on behalf of NIH, and the NIH veterinarian who testified were obviously competent veterinarians. However, both of them admitted that they knew very little about deafferentation. The outside consultant wryly admitted that he had learned more about the subject during the hearing before this Board than he would ever have wanted to know. Tr., pp. 535, 541-542. The NIH veterinarian asserted that he had some familiarity with deafferentation, because five other deafferented animals had been housed at the NIH facility. Tr., p. 628. However, when questioned by the PI, he admitted that he knew nothing about the history of those monkeys, what had been done to them, or for what purpose they were being studied. Tr., pp. 682-686. We think that his experience in treating those monkeys was of limited relevance here because the PI testified, without contradiction, that those monkeys had been selected for study primarily because they did not self-mutilate and had not lost digits. Moreover, the NIH veterinarian did not appear to be well-acquainted with some of the conditions associated with deafferentation. Instead he read from a medical dictionary about conditions discussed knowledgably by the scientific experts. Tr., pp. 643, 691, 693-95, 700-701.

22/ NIH tried to show the inconsistency of the PI's argument by pointing out that in 1977 the PI had treated a monkey's broken limb by pinning. The PI testified, however, that that particular fracture had occurred in the first year of deafferentation, before the bones had rarified.

In summary, NIH did not present any definitive evidence which showed that the monkeys' general condition was poor while at IBR or that it clearly improved while at NIH. The evidence at best shows a difference of opinion among veterinarians and scientists about the significance of certain methods of veterinary care and the type of treatment which should be provided for symptoms peculiar to deafferentation. In weighing these opinions, we have accorded more weight to those who have considerable experience and knowledge about deafferentation, and have taken into account the fact that no problems with the monkeys' general health have been pointed out. 23/ Moreover, none of the NIH witnesses could point to

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23/ The PI pointed out that the USDA inspector, a qualified veterinarian, had visited the IBR laboratory over 15 times between 1977 and 1981, in unannounced inspections, and had never found any material problems. The PI argued that this showed that he was complying with the federal Animal Welfare Act and its regulations. NIH attempted to discredit this evidence by suggesting that USDA altered its method of inspection for compliance with the Animal Welfare Act as a result of this situation. However, no evidence was presented showing that the inspector was incompetent, that he falsified his reports, or that there were in fact material failures to comply with the Act or the regulations. Thus, we believe that the fact that USDA never made a finding of material noncompliance with regard to IBR has some weight, although it is not determinative of violations of the Guide. The PI also presented information that a number of scientific societies had investigated the circumstances of the termination and that these societies had concluded that the PI had not committed any egregious wrongs. Post-Hearing Memorandum, pp. 11-13. NIH also attempted to discredit these conclusions at the hearing by suggesting that the members of these societies were biased in favor of animal research. Tr., pp. 156-158. However, since the issue here is not about the appropriateness of animal research, and since NIH itself funds animal research, any bias in favor of animal research is irrelevant for purposes of this appeal. Testimony indicated that the investigation made by the Society for Neuroscience was made by a committee concerned with the ethics of animal research for precisely the same reasons that NIH is concerned with the application of the Animal Welfare Act and the Guide. Tr., p. 148. The societies in question are composed of persons who are experts in physiology, psychology, pharmacology, and other sciences related to the issues presented here, Tr., p. 153, and, thus, their scientific opinions also have some weight.

any specific type of care by either the NIH veterinarians or the PI which would account for a change in the monkeys' condition. Tr., pp. 653-654. Thus, it is difficult to evaluate how the intervention of veterinarians made a difference. NIH argued that a clear showing of harm was not a prerequisite to a finding of inadequate veterinary care. Brief, March 12, 1984, p. 10. However, we think it is relevant insofar as NIH's finding implied mistreatment of the animals.

Both parties put on the record evidence concerning the NIH veterinarians' decision to amputate a forelimb of one deafferented monkey within a short time after the monkeys were transferred to the NIH facility. The PI argued that the NIH veterinarians' testimony that they amputated the limb, with the permission of the PI, because they believed the animal suffered from osteomyelitis, or an infection of the bone marrow, led to his criminal conviction with regard to that animal. The PI testified that blood tests and a pathology report showed that there was no osteomyelitis, and NIH did not dispute this. The NIH veterinarians and the PI disagree, however, about the amputation of deafferented limbs as appropriate veterinary treatment. Both parties implied that the circumstances surrounding this amputation showed that the other party had provided the monkey inadequate veterinary care. The scientific experts and the PI argued that the monkey's limb would not have deteriorated and would have eventually improved if the NIH veterinarians had not bandaged the monkey's limb, causing circulatory problems. The evidence in this record is inconclusive, however, about whether the monkey's limb should have been amputated. Appeal File, Tab 92. The evidence shows that there was no osteomyelitis and, thus, we cannot conclude on this basis that the monkey received inadequate veterinary care while at IBR.

In summary, the record does not support a conclusion that the monkeys actually were harmed by the lack of regular veterinary supervision, or that the condition of the monkeys showed inadequate veterinary care.

The expertise of the Animal Care Committee

NIH set out several reasons for its finding that the IBR Animal Care Committee lacked expertise. The Ad Hoc Committee found that the IBR Animal Care Committee had not considered the use of analgesics during the past two years, and that the Animal Care Committee members were unfamiliar with the Guide's requirements and with their review role. The Ad Hoc Committee also stated that the PI and the Chairman of the Animal Care Committee "were not aware that NIH had been notified that one member . . . had left the Animal Care

Committee and that no one had been appointed as a replacement." Appeal File, Tab 72, p. 16. NIH pointed out that minutes of the Animal Care Committee's annual meetings in 1979 and 1980 showed that one member of the Committee had not attended and that, at the annual meeting held in 1980, there had not been a quorum. In addition, NIH noted that IBR had developed no written guidelines to serve as aids in complying with the Guide.

Federal requirements for an animal care committee are minimal. The regulations implementing the Animal Welfare Act refer to an animal care committee, at 9 CFR 3.84(c)(2), and say:

> (2) It shall be incumbent upon each research facility through its animal care committee and/or attending veterinarian to provide guidelines and consultation to research personnel with respect to the type and amount of tranquilizers, anesthetics, or analgesics recommended as being appropriate . . . .

The NIH Guide refers to an animal care committee only in general terms and the PHS GAM: 1-43-40, provides that an institution's animal assurance must indicate that the institution has appointed and will maintain a committee for oversight of the animal care program. The composition of the committee is set forth only in the example of an acceptable assurance (PHS X1-43-2). That example provides that the committee will have at least five members with appropriate education and experience to perform their duties. The example also says that if the conduct of a specific project is to be reviewed, the quorum will not include any member having an active role in the project. A requirement for a quorum is not otherwise mentioned. The example also states that changes in membership will be reported annually to the OPRR. IBR's letter of assurance contained language similar to the example. Appeal File, Tab 7.

The PI contended that the members of the Animal Care Committee had the necessary expertise to provide adequate oversight as required by the Guide. In support of this position, the PI presented testimony by a member of the Animal Care Committee. That witness, who had not been listed as present in the minutes of the annual meetings for two years, testified that he remembered attending at least one such meeting and that he had visited the laboratory on many occasions to participate in experiments and consult with the PI about the research, including the use of analgesics. Tr., pp. 199-200.

The witness testified about his expertise as well as that of the other members and alleged that the members of the Committee, particularly he and the PI, had considered the use of analgesics in great detail. The witness was a psychopharmacologist with excellent credentials, experience with deafferentation, and extensive knowledge about drugs. His testimony displayed considerable knowledge about the PI's experiments and research goals, the scientific aspects of deafferentation, and the effects of analgesics on the monkeys. He testified that he and the PI had extensive discussions about the use of analgesics at the time the surgery was performed and that they decided not to use them because they would depress the cardiovascular and respiratory systems of the animals postsurgically and could possibly lead to the deaths of the animals. He also testified that the animals would probably suffer for a very short period of time from the pain associated with postsurgery, and thereafter would have no pain whatsoever because of the deafferentation. Tr., pp. 201, 211-213. The witness and the PI indicated that the surgery and the discussions about analgesics had been in the earlier years of study, prior to the appointment of the current attending veterinarian, and that, thereafter, there was no need for discussion of analgesics because no further surgery was undertaken. Tr., pp. 286-288.

The PI also testified that the Chairman of the Animal Care Committee had reported the loss of one of the Committee's members to NIH and that both the Chairman and the PI were aware that they needed another member and that NIH had been notified. Tr., pp. 328-329, 476-477. The PI testified that they had planned to appoint a new member in the fall of 1981 in anticipation of the Committee's annual meeting.

Analysis.

IBR's failure to have five members on the Committee for a period of time and the lack of a quorum at some of the annual meetings, in context, do not appear to amount to material noncompliance in the absence of notice and opportunity to correct the problems before termination actions as set out in the PHS GAM: 1-500-50D. Moreover, the NIH criticism about reporting the loss of a Committee member is not clear and appears unfounded. There is no indication that IBR intended to circumvent any NIH requirements, and in view of the fact that there were no specific requirements about the composition of animal care committees except those set out in an example assurance, we do not see the materiality of these

points to the question of the Animal Care Committee's substantive role and the expertise of its members. 24/

The credentials of the members of the Committee are excellent and the members appear to be very qualified in the area of research being conducted. The Chairman and PI in particular have had years of experience in this area. Tr., pp. 204-206. The record does not reflect how familiar these persons were with the Guide, although there was testimony that all the members were generally familiar with the Guide. There is no affirmative evidence that any of the members were generally unqualified for their duties and the Ad Hoc Committee's report did not provide any details about the alleged lack of familiarity with the Guide. 25/ Nor did the report indicate that the members failed to perform oversight duties. Moreover, there is no requirement for written guidelines implementing the Guide, and in an institution as small as this one where the PI has had a great deal of experience caring for the animals, we do not think that the absence of these is crucial.

The Guide provides that the choice and use of drugs is a matter for the professional judgment of the attending veterinarian, p. 13, and 9 CFR 3.84(c) provides for the same discretion. Moreover, we conclude that there was no need to consider the use of analgesics during the relevant time period since no surgery was being performed and since there

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24/ We note that the new proposed regulations for laboratory animal care expand the information and requirements for an Animal Research Committee (presently Animal Care Committee). PI Submission of April 23, 1984, p. 5.

25/ The PI pointed out that a recent NIH report of site visits checking the general level of compliance with animal welfare policies indicates that the animal care committees were generally not as active as they should be, and that not all issues were discussed by committees as a whole. Supplemental Submission, April 23, 1984, NIH Guide, Special Edition, pp. 6-7. Moreover, the report indicates that many investigators, although familiar with the Guide, did not have precise knowledge of all of its contents. These comments substantiate our conclusion that the required level of knowledge on the part of the committee members about the Guide and their oversight role was not precisely defined by NIH and that there is no evidence that this committee violated specific guidelines.

is no substantial evidence that the animals otherwise suffered from pain for which analgesics might be ameliorative. The record shows that at the time surgery was performed, the PI and at least one member of the Committee, who was well qualified to make such a decision, evaluated their use and rejected it. This is clearly within the discretion provided by the Guide.

Thus, we conclude that there is no substantial evidence showing that the Committee lacked the necessary expertise, or that the general oversight functions of the Committee were not fulfilled. Moreover, there is no basis for finding that the Committee should have considered the use of analgesics during this project period.

Conclusion

We conclude that the termination of the NIH research grant awarded to IBR should be upheld because IBR failed to materially comply with the terms and conditions of the award when it failed to purchase new animal cages, alter the ventilation system, renegotiate its animal assurance, and provide regular supervision and veterinary care by a veterinarian.

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