February 5, 2024

Brent C. Morse, D.V.M. Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

Via e-mail: MorseB@mail.nih.gov

Dear Dr. Morse:

I'm writing on behalf of People for the Ethical Treatment of Animals— PETA entities have more than 9 million members and supporters globally to request that your office investigate possible noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and the *Guide for the Care and Use of Laboratory Animals* (the Guide) related to the treatment of animals at Legacy Health (Animal Welfare Assurance ID D16-00148).

According to a December 6, 2023, U.S. Department of Agriculture (USDA) inspection report for Legacy Health, a rhesus macaque sustained full-thickness burns that staff didn't notice or treat for six days. On September 12, 2023, the monkey underwent a scheduled procedure. Prior to the start of the procedure, she was hypothermic, even with heat support during anesthesia preparation. During the procedure, heat support brought her body temperature up a couple of degrees, but she never maintained a normal temperature. During recovery, staff placed the monkey on a heating pad, wrapped her in a large towel, and then put her under a heat lamp. When the animal was moved to her cage, a technician placed a heat lamp outside of it. On September 18, the macaque was sedated for another procedure and staff saw that she had third-degree burns on the back of her upper legs.

Staff determined that the monkey had likely sustained the burns during recovery from anesthesia while she was hypothermic. The inspection report states, "Poor tissue perfusion of the extremities due to hypothermia increases the risk of thermal burns from heat lamps. The animal care technician does not recall exactly how close the heat lamp was to the animal, but believes it was closer than the recommended 20 inches," and the technician didn't check the heat again after placing the lamp. Between the time when the monkey sustained the burns and the burns were discovered six days later, staff didn't report any health concerns about her.

The issues raised in the USDA's complaint for Legacy Health—failure of veterinary staff to provide appropriate care during and after a procedure and failure of the Institutional Animal Care and Use Committee (IACUC) and the attending veterinarian (AV) to ensure and monitor the administration of

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appropriate veterinary care—also indicate noncompliance with PHS Policy and the Guide. These issues include the following:

1. Failure of veterinary staff to provide appropriate care during and after a procedure

The Guide states, "Successful surgical outcomes require appropriate attention to presurgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal well-being, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care" (p. 115). Additionally, care after surgery should include "behavioral signs of postoperative pain [and] monitoring for postsurgical infections" (p. 120). Furthermore, "[s]urgical outcomes should be continually and thoroughly assessed to ensure that appropriate procedures are followed and timely corrective changes are instituted" (p. 115) and "[a]ll animals should be observed for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs. As a rule, such observation should occur at least daily, but more frequent observations may be required, such as during postoperative recovery" (p. 112).

The Guide also provides that the "investigator and veterinarian share responsibility for ensuring that postsurgical care is appropriate" (p. 116). Furthermore, "[t]o be effective in providing clinical care, the veterinarian should be familiar with the species and various uses of animals in the institutional research, teaching, testing, or production programs and have access to medical and experimental treatment records" (p. 114).

At Legacy Health, the veterinary staff didn't take the necessary steps to have a successful procedure outcome or provide appropriate post-procedure care, as they proceeded with the procedure even though the monkey was already hypothermic during preparation and wasn't able to maintain a normal body temperature with heat support. They also placed the monkey under a heat lamp, even though the hypothermia made her more susceptible to burns, placed the heat lamp closer to her than the recommended distance, didn't check the heat after placing the lamp, and took six days to notice that the animal had severe burns and to provide treatment.

This timeline and the thickness of the burns—which damaged all layers of the monkey's skin—indicate repeated failures to monitor and care for the monkey appropriately.

2. Failure of the IACUC and AV to ensure and monitor the administration of appropriate veterinary care

The Guide instructs that an institution's animal care and use program must include adequate policies, procedures, and practices "to achieve the humane care and use of animals in the laboratory and throughout the institution" (p. 6). Additionally, the institution must maintain an environment in which the IACUC can "function successfully to carry out its responsibilities" and the institution is responsible for ensuring that "IACUC members are provided with training opportunities to understand their work and role" (pp. 6 and 17). Furthermore, the IACUC is responsible for "assessment and oversight" of the institution and should have "sufficient authority and resources (e.g., staff, training, computers, and related equipment) to fulfill this responsibility" (pp. 14–15).

The IACUC, along with the AV, is "responsible for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures" (p. 116). The Guide also

maintains that the AV "is responsible for the health and well-being of all laboratory animals used at the institution. The institution must provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care" (p. 14).

In addition to establishing this responsibility of the IACUC and the AV, the Guide addresses the importance of the proper training for staff involved in animal care and procedures. It states, "Personnel caring for animals should be appropriately trained ... and the institution should provide for formal and/or on-the-job training to facilitate effective implementation of the Program and the humane care and use of animals. Staff should receive training and/or have the experience to complete the tasks for which they are responsible" (p. 16). Furthermore, "[t]he institution should provide appropriate education and training to members of research teams—including principal investigators, study directors, research technicians, postdoctoral fellows, students, and visiting scientists—to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used" (pp. 16–17).

The IACUC also has the responsibility—under federal law, regulations, and policies—to continually monitor the use and care of animals (p. 33). Post-approval monitoring includes "observation of animals by animal care, veterinary, and IACUC staff and members" (p. 33).

The failure of the IACUC and AV at Legacy Health to ensure that veterinary staff provided appropriate veterinary care—which caused a hypothermic monkey to undergo a procedure, sustain severe burns, and not receive treatment for six days—illustrates that the institution didn't maintain an environment in which the IACUC could successfully fulfill its responsibilities and that the IACUC and AV failed in their oversight of animal care.

We urge you to investigate the concerns summarized in this letter and to take swift and decisive action against Legacy Health. Thank you for your time and consideration.

Sincerely,

and je

Amanda Schemkes, J.D., M.S. Laboratory Oversight Specialist Laboratory Investigations Department PETA