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January 3, 2020

Patricia A. Brown, VMD, MS, DACLAM
Director
Office of Laboratory Animal Welfare
National Institutes of Health
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Via e-mail: brownp@od.nih.gov

Dear Dr. Brown,

I'm writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters to request that the Office of Laboratory Animal Welfare (OLAW) withdraw its approval for the Public Health Service (PHS) Animal Welfare Assurance granted to Lovelace Respiratory Research Institute (LRRI; PHS Assurance A3083-01).

Federal reports document a pattern of carelessness and disregard for basic safety conditions for the animals confined in LRRI's laboratories. U.S. Department of Agriculture (USDA) inspections and self-reports indicate that animals have been under the "supervision" of untrained and oblivious staff whose actions and omissions have resulted in profound animal suffering and numerous animal deaths. The frequency and severity of these incidents cause us to believe that LRRI is not interested in or capable of following the provisions afforded by the "Guide for the Care and Use of Laboratory Animals" ("the *Guide*"), the federal Animal Welfare Act (AWA), or the "PHS Policy on Humane Care and Use of Laboratory Animals" ("PHS Policy").

Documents obtained by PETA, for the period from 2014 to 2019, reveal a litany of egregious violations of PHS Policy and the AWA:

1. On November 19, 2019, a US Department of Agriculture (USDA) inspection revealed the following:

    a. A 2.5-year-old male cynomolgus macaque monkey died unexpectedly during a face-mask inhalation procedure. A veterinary technician examined the monkey, but was unable to

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resuscitate him. A full necropsy was not conducted in violation of the study protocol.

b. Another 2.5-year-old male cynomolgus macaque monkey was found dead in the cage where he was held with five other male monkeys. Records for the monkey failed to note that the monkeys who were caged together were not compatible. According to the necropsy report, the monkey "was found to have marked dehydration, little to no visceral fat, and an overall thin body condition." The USDA report suggests that the monkey may not have been allowed access to food or water.

c. The 2.5-year-old macaque who died during the face-mask inhalation procedure had not been properly monitored. Also, the arm restraints on the chairs where the animals were held were too large for some of the animals—allowing them to become entangled in the equipment. In addition, the monitoring equipment was not functioning correctly, making it difficult to monitor the animal's condition. Near the end of the procedure, the technician found the animal to be non-responsive, but a veterinarian was not notified to try to resuscitate him.

2. On August 14, 2019, a USDA inspection found that an experimenter administered a dose of a test compound to 12 monkeys without first securing the approval of the IACUC.

3. On June 19, 2018, a USDA inspection revealed that an experimenter deviated from the protocol that had been approved by the IACUC for a study in which six primates were killed.

4. On December 5, 2017, a USDA inspection found that two beagles suffered from hair loss on their forelimbs and had reddened, inflamed skin—but their condition was not observed by LRRI workers and was not treated by veterinary staff.

5. On April 11, 2019, a USDA inspection revealed the following:

   a. A 9-year-old male beagle had a mass, the size of a grape, on his right forelimb, and the skin in the area was reddened, inflamed and contained at least two visibly erosive areas with a small amount of blood-tinged discharge. The mass was painful to the touch. The beagle received no veterinary care for this mass.
   b. In two cages holding monkeys, there were plastic barrels in disrepair—with roughened, ragged edges.

6. On October 12, 2016, a USDA inspection revealed that a primate was found dead in his/her cage. The primate had not been eating the biscuits provided, indicating loss of appetite. The protocol had indicated that when an animal exhibited loss of appetite, the study director and clinical veterinarian should be contacted. However, the clinical veterinarian was not consulted, likely resulting in "prolonged pain and suffering."

7. On July 19, 2016, a USDA inspection found the following:

a. A Sinclair pig was subjected to two cerebrospinal fluid collections during a training sessions—although these procedures were not included in the IACUC-approved protocol. According to the USDA report, such deviations from an approved protocol "could result in unanticipated pain and distress, and put the animal's welfare at risk."
b. LRRI's IACUC failed to conduct appropriate reviews of procedures carried out on primates for a particular protocol in which the monkeys were dosed with drugs in different combinations and at different doses.
c. Six guinea pigs died during transportation for study-related activities. The guinea pigs were held in an enclosure for approximately 45-60 minutes before being transported. Three contributing factors were identified: the density of guinea pigs in the enclosure, the length of time the animals were held in the cage, and the fact that the filter top on the cage was wet, possibly contributing to decreased air exchange in the cage.

8. On June 17, 2015, a USDA inspection revealed the following:

    a. A dog died when a technician connected him/her to a device used to measure pulmonary function via endotracheal tube and failed to notice that the device "was still attached to house air," which led to the dog experiencing respiratory arrest.
    b. In three separate occasions, two rhesus macaques and a cynomolgus monkey escaped from the confinement areas. The report noted: "Accidental opening of [primate] enclosures poses a risk of injury to the animals and personnel should the animals escape or become caught in the process of opening the enclosure."

9. On March 3, 2015, a USDA inspection revealed the following:

    a. Monkeys used in protocol 14-002 did not receive supportive care:
        i. Three monkeys in cohort C did not receive acetaminophen when they reached a temperature threshold above 103°F.
        ii. Fifty-seven monkeys in cohort C did not receive IV fluids.
        iii. Three monkeys who had liquid stools did not received anti-diarrheal medication.
    b. Two rhesus macaques escaped when technicians failed to safely handle them.
    c. Another rhesus macaque suffered a fracture of his/her lower left canine tooth while being moved to a chair apparatus.
    d. A beagle was locked outside overnight and exposed to the elements when security personnel failed to check that all animals were in the indoor confinement areas.
    e. A large male rhesus macaque escaped from the confinement area.
    f. In two occasions, a rhesus macaque had one of his/her right fingers stuck in the food receptacle.

10. Reports submitted by LRRI to your office between February 21 and November 20, 2014, included the following incidents:

a. Three mice died due to careless handling. In one incident, a mouse suffered "inadvertent cervical dislocation." In another incident, two mice died when a technician dropped the cage where the animals were confined.
b. Two dogs were locked outside and left without water for more than 18 hours.
c. A guinea pig was euthanized after he/she broke a leg. The cause of the broken leg was undetermined, but it was noticed after the animal was removed from a confinement area that was filling up with water due to a pipe leak.
d. Seven mice who suffered lipopolysaccharide-induced injuries (LPS) died when they were given an experimental drug one day after the LPS. It was later established that the timeframe to give them this drug was too short.
e. Multiple mice quarantined in inhalation exposure chambers with wire bottoms suffered injuries to their feet when untrained staff manipulated the pans underneath the cages.
f. Mice became sick, died or had to be euthanized when they were given a higher dose of bleomycin than the dose established in the protocol.
g. Four mice died when they were restrained with a device that allowed them to turn, which led to respiratory impairment.
h. A mouse was left without water for 14 hours when an experimenter failed to appropriately place a water bottle.
i. A primate was anesthetized by a veterinary technician who had not been trained in this procedure.
j. Five primates were exposed to 36 consecutive hours of room lighting.
k. A cynomolgus monkey was euthanized after suffering a fracture in his/her leg when he/she became trapped between the cage panels.
l. A rhesus monkey died after "the chain holding the perch wrapped around" his/her neck and "became entangled in the collar."
m. Two mice were left without water for 18 hours when no one noticed that the water bottle was out of their reach.
n. Two primates were left without food for 16 hours when no one noticed that the feeders' lids were blocking the access of the animals to the food.
o. Six African Green monkeys were left without water overnight when a technician failed to connect the water supply.
p. Twenty-three monkeys "were not fed for approximately one day" when a technician failed to notice the date on the directive sign.
q. A mouse was "left in a biosafety cabinet without food and water" for 18 hours.

Additionally, in 2011, LRRI was cited and fined $21,750 by the USDA for six serious violations of the AWA—including failure to provide adequate veterinary care to animals, failure to ensure that experimenters conducted searches for alternatives to the use of animals in painful procedures, and failure to ensure that personnel were adequately qualified. These violations included the strangulation death of a monkey who became caught on an experimental jacket and the escape of an infant monkey.

OLAW's mandate includes monitoring facilities privileged to receive federal grants for compliance with the PHS Policy "to ensure the humane care and use of animals …

thereby contributing to the quality of PHS-supported activities." Violations at LRRI have resulted in acute suffering and death for animals and have squandered taxpayer dollars.

In 2018 and 2019 financial years, LRRI received more than $11 million in public funding from the National Institutes of Health (NIH); and has received additional money through contracts with federal agencies. The privilege of securing public funds comes with the responsibility of adhering to federal regulations and guidelines.

As you know, the "NIH Grants Policy Statement" (NIHGPS)—which outlines the rules governing activity in federally funded research projects—clearly specifies that the PHS Policy "requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all recipient organizations receiving PHS support for research or related activities using live vertebrate animals." Conditions of maintaining this approval include compliance "with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals," and each institution must confirm that it "has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals*."

The NIHGPS also states that "OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances." And Section IV.A of the PHS Policy gives NIH the discretion to "condition, restrict, or withdraw approval" for animal experimentation to take place at any facility receiving NIH funding.

Although the USDA has filed report after report on Lovelace's failures—and even fined the institution—these efforts have failed to bring the company into compliance and have left monkeys, dogs, and other animals at the mercy of a laboratory that, frankly, doesn't seem to care. We urge you to protect animals and ensure proper stewardship of public funds by withdrawing approval of LRRI's PHS Animal Welfare Assurance, as OLAW has the authority and obligation to do.

Thank you for your time and consideration. I look forward to hearing from you regarding your next steps. I can be contacted at MagnoliaM@peta.org.

Sincerely,

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