

August 31, 2020

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Via e-mail: [Betty.J.Goldentyer@usda.gov](mailto:Betty.J.Goldentyer@usda.gov)

Dear Dr. Goldentyer,

I hope this correspondence finds you well. I am writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters to respectfully request that the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) investigate disturbing allegations regarding the mistreatment of animals at the University of Alabama at Birmingham (UAB; USDA Certificate No. 64-R-0004) in Birmingham, Alabama.

The allegations pertain to the use of baboons and pigs in UAB's Xenotransplant Program, which is directed by David K.C. Cooper; and they were communicated to PETA by an inside source at UAB. The insider informed PETA that David Cooper's laboratory obtains organs from genetically modified pigs bred at Blacksburg, Va.-based company Revivacor, Inc. (also known as Lung LLC; USDA Certificate No. 52-R-0113) and transplants these organs into baboons. We believe the alleged treatment of animals, if true, constitutes violations of the Animal Welfare Act (AWA) and the Animal Welfare Regulations (AWRs), including:

1. Failure to maintain a program of adequate veterinary care [9 C.F.R. §2.33(b)];
2. Failure to ensure that personnel conducting procedures are qualified to perform their duties [9 C.F.R. §2.32(a)];
3. Failure to promote the psychological well-being of nonhuman primates [9 C.F.R. §3.81]; and
4. Failure to provide sufficient food to animals [9 C.F.R. §3.129].

In addition, we believe UAB's Institutional Animal Care and Use Committee (IACUC) failed to carry out its legally mandated responsibilities, including failing to review proposed use of animals sufficiently to ensure that:

1. "Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals" [9 C.F.R. §2.31(d)(1)(i)];
2. Animals who "would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure" [9 C.F.R. §2.31(d)(1)(v)];
3. "Medical care for animals will be available and provided as necessary by a qualified veterinarian" [9 C.F.R. §2.31(d)(1)(vii)]; and

4. “Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices” [9 C.F.R. §2.31(d)(1)(ix)].

## **I. Failure to maintain a program of adequate veterinary care**

Section 2.33(b) of the AWRs states: “Each research facility shall establish and maintain programs of adequate veterinary care.” In particular, Section 2.33(b)(2) mandates that the veterinary care program shall include the “use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.” Section 2.33(b)(4) and (5) mandate that the program shall include “[g]uidance to principal investigators and other personnel involved in the care and use of animals regarding ... euthanasia” and “[a]dequate ... post-procedural care in accordance with established veterinary medical and nursing procedures.”

### Laja (B5916):

However, the UAB insider’s account of a female baboon named Laja (B5916) indicates that the Cooper laboratory failed to use appropriate methods to ensure that this baboon received adequate or appropriate veterinary care; and failed to limit Laja’s suffering through the implementation of humane endpoints. The insider informed PETA that in January 2019, a kidney that had been taken from a genetically modified pig was transplanted into Laja’s body. With such experimental transplant surgeries, the U.S. Food and Drug Administration’s guidance<sup>1</sup> recommends that tissue samples from recipient animals be collected at six months after transplant. Five months after the transplant, on June 11, 2019, a 33-second video of Laja<sup>2</sup> was recorded to show to the grantors that the transplant had been “successful.” This video shows that Laja had become very thin and had lost a considerable amount of hair from her body. She engages in stereotypic behavior, performing back flips while holding onto the bars at the top of her cage. A July 23, 2019, e-mail sent by Hayato Iwase to other members of the Cooper laboratory reported that the experimenters had performed a kidney biopsy on Laja that morning. The email reads, “>6 months survive.”<sup>3</sup>

In August 2019, Laja began to develop a lesion on her right thigh. The lesion was similar to a pressure ulcer with a mounded, bubbly appearance. It grew quite large, to more than an inch in diameter. The Cooper laboratory’s Takayuki Yomomoto repeatedly pulled the scar tissue off the lesion. Pockets of fluid—perhaps lymphatic fluid—collected under Laja’s skin, along the incision for the transplant surgery; and the area had become ulcerated. The experimenters filled a syringe with Woolite laundry detergent and applied the detergent on the suture closing the transplant incision and over the area of the lesion. The insider believes this action may have been taken to hide the poor condition of Laja’s skin, or perhaps to help keep the area clean. However, it seems that the Woolite would have caused additional pain and irritation.

The insider reports that Laja appeared to be in terrible pain. She suffered with excess fluid (edema) in her face and thighs. Her condition also produced ascites, and there was fluid buildup

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<sup>1</sup> US Food and Drug Administration. (2019). Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans. 2003.

<sup>2</sup> The video is here: <https://www.youtube.com/watch?v=IHtqMcnJbsM&feature=youtu.be>

<sup>3</sup> This e-mail is attached.

in her abdominal area. In September 2019, Laja’s condition deteriorated to the extent that she had to be euthanized. According to the insider, there would have been no endpoint to the experiment had she not rejected the xenograft.

Failure to comply with veterinary standards of practice:

The UAB insider reports multiple incidents in which the Cooper laboratory failed to conduct itself in accordance with established veterinary standards of practice, including the following:

1. The individuals in the Cooper laboratory used expired medications or medications that were not included in the protocol. In September 2019, both of these violations were reported to David Cannon, Director of UAB’s Institutional Animal Care and Use Committee (IACUC). However, according to the insider, the IACUC declined to take action against the laboratory. Even though David Cannon observed the expired medications in the laboratory, he said that since he didn’t directly see members of the laboratory use these medications, he would not take action.
2. The insider observed lapses in recordkeeping, wherein employees failed to record notations related to post-operative observations of baboons and veterinary concerns. For example, employees did not document lesions observed on the baboons. In some cases, records were falsified, with earlier dates records on veterinary care records to suggest that treatments had been administered to animals earlier than had actually been done.
3. The insider reported that in the Cooper laboratory, the same intravenous (IV) tubing would be used to give baboons fluids and proteins. The tubing was rarely labeled and sometimes, the experimenters would use the same tubing for different animals, changing the catheter but not the tube or the IV bags.
4. Individuals in the Cooper laboratory left bottles of ketamine—a controlled substance—in unsecured desk drawers and in an unlocked procedure room. The insider shared photographs of bottles of ketamine in the unsecured desk drawer of Abhijit Jagdale, a visiting scientist in the Cooper laboratory.<sup>4</sup>
5. Laboratory workers left syringes and needles with exposed needles in the open, where other workers could get hurt.<sup>5</sup>
6. The insider reports that Abhijit Jagdale would not change out of his animal facility apparel when he returned from the animal rooms and entered the office.
7. The insider shared a photograph of used personal protective equipment that was discarded in an open waste paper basket in a hallway.<sup>6</sup>

Failure to ensure that veterinary staff have sufficient and appropriate authority to ensure that adequate veterinary care is provided to the animals:

The insider reports that Darvi Michell B. Sergio, DVM, Senior Clinical Laboratory Animal Veterinarian with UAB’s Animal Resources Program would not stand up to the people in the Cooper laboratory when things were done incorrectly and “animals were harmed as a result.” The director of the Animal Resources Program—a woman named Lisa [surname not known] was also aware of the lapses in animal care, but also failed to speak up for the animals.

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<sup>4</sup> These photographs are attached.

<sup>5</sup> This photograph is attached.

<sup>6</sup> This photograph is attached.

## **II. Failure to ensure that personnel conducting procedures are qualified to perform their duties**

Section 2.32(a) of the AWRs states: “It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties.” Moreover, Section 2.32(c)(1) states that “[t]raining and instruction of personnel must include guidance” in “[p]roper handling and care for the various species of animals used by the facility”; and “[p]roper pre-procedural and post-procedural care of animals.”

However, the UAB insider reports that baboons in the Cooper laboratory suffered from excessive bruising, which he believes stemmed from blood being drawn from the animals too frequently, and blood draws being conducted inappropriately. The experimenters would often draw blood repeatedly from the same vein or would inexpertly search for veins, causing more injury to the veins than necessary.

The application of Woolite laundry detergent on Laja’s incision and lesion, described in the earlier section, also demonstrates that members of the Cooper laboratory who were directly involved in “treatment” of animals in the laboratory were not qualified to perform those duties; and moreover, were not corrected by UAB’s veterinary or animal care staff.

## **III. Failure to promote the psychological well-being of nonhuman primates**

Section 3.81 of the AWRs requires that “research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates,” including “specific provisions to address the social needs of nonhuman primates known to exist in social groups in nature.”

However, the extensive hair loss and stereotypic movements displayed by the baboon named Laja suggest that UAB failed to promote the psychological well-being of primates in the Cooper laboratory.

## **IV. Failure to provide sufficient food to animals**

Section 3.129 of the AWRs stipulates that animals must be given food “of sufficient quantity and nutritive value to maintain ... good health”; and that “[a]nimals shall be fed at least once a day.”

However, the UAB insider shared emails that were exchanged between members of the Cooper laboratory and David Ayares, the CEO of Revivicor—the Virginia-based facility from which the Cooper laboratory acquires genetically-modified pigs. In an e-mail dated March 20, 2020, Ayares raised concerns that a pig who had been scheduled be used in a transplant surgery on March 23, 2020 was “growing slowly,” but they would “hit a point of no return” if the surgery was delayed past May 4, 2020. In a subsequent email dated March 23, 2020, Ayares informed David Cooper that Revivicor had “the pig on a reduced ration.” According to the insider, the experimenters at Revivicor and at UAB would “ration the food [given to the pigs to limit their

growth] but sometimes Dr. Cooper would want to starve them to make sure they didn't grow too big before the transplant.”

## V. Failures on the part of UAB's IACUC

Section 2.31(d) of the AWRs stipulates that the IACUC's “review of activities involving animals ... shall determine that the proposed activities” meet certain requirements, including that “[p]rocedures involving animals will avoid or minimize discomfort, distress, and pain to the animals”; that animals who “would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure”; that “[m]edical care for animals will be available and provided as necessary by a qualified veterinarian”; and that “[a]ctivities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices.”

However, according to the UAB insider, the Cooper laboratory's interest in gathering data took precedence over the welfare of baboons who were subjected to transplants. This was codified in the protocols that had been approved by UAB's IACUC that did not ensure compliance with the AWRs noted above. The insider shared the following examples:

1. A blind baboon named Laura Lynn who was prone to suffering with seizures. She would run in circles in her cage and would often hit her face on the cage walls.
2. According to a July 23, 2019, e-mail sent by Hayato Iwase to other members of the Cooper laboratory, a baboon identified only as B15816 was euthanized on July 22, 2019 “because he got weaker and [became] inactive.” The email also states: “At necropsy, the pig kidney graft had slightly patchy spots and ureter was distended.” Such distension suggests that B15816 may have been in pain before he was euthanized. The same e-mail also states that a baboon identified only as B517 was “a little quiet,” suggesting possible pain and discomfort.<sup>7</sup>
3. According to a March 19, 2020, e-mail from Hayato Iwase to other members of the Cooper laboratory, a baboon identified only as B37355 was described as follows: “B37355 is eating well, passing urine and stool. Edema on thigh looks similar or a little bit less. We can see the edema around the middle incision ... no ascites.”<sup>8</sup>
4. According to a May 19, 2020, e-mail from Hayato Iwase to other members of the Cooper laboratory, a baboon identified only as B37369 had been subjected to a kidney transplant seven days previous. This baboon was reported to be “quiet,” passing “less urine,” and with a distended abdomen. An ultrasound indicated a distended stomach. The experimenters “aspirated the gastric contents (about 400 ml) with stomach tubes” and the abdomen became flat and soft. Iwase also reported: “The baboon looks dehydrated, and we gave metoclopramide and increased the dose of fluid.” However, according to the insider, the Cooper laboratory was using metoclopramide well before the drug was included on its protocol.<sup>9</sup>

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<sup>7</sup> This e-mail is attached.

<sup>8</sup> This e-mail is attached.

<sup>9</sup> This e-mail is attached.

5. The insider also reported that in April 2020, a baboon was subjected to an orthotopic heart transplant from a pig. The baboon was then placed in an oxygen chamber. A photograph of this baboon in the oxygen chamber shows the baboon's miserable condition; and that the intravenous tube was leaking.<sup>10</sup> According to the insider, in spite of the baboon's pain and distress, he was not euthanized but died one or two days after the surgery.

### **Conclusion**

We urge you to investigate the concerns summarized in this letter and, if the claims are substantiated, to take swift and decisive action that includes citing UAB and Revivacor for violations of the AWA; and assessing civil penalties against the facilities.

I look forward to hearing from you regarding this matter and am available to assist you in your investigation. I can be contacted at (757) 803-6447 or [AlkaC@peta.org](mailto:AlkaC@peta.org). Thank you.

Sincerely,



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<sup>10</sup> This photograph is attached.