

PhysiciansCommittee

for Responsible Medicine

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February 10, 2022

Robert Gibbens, DVM
Director, Animal Welfare Operations
USDA/APHIS/Animal Care
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Submitted by email: robert.m.gibbens@aphis.usda.gov

Re: Violations of the Animal Welfare Act at University of California, Davis (93-R-0433) and Neuralink (93-R-0586)

Dear Dr. Gibbens:

The Physicians Committee for Responsible Medicine (Physicians Committee) requests that the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA) investigate apparent egregious violations of the Animal Welfare Act related to the treatment of monkeys used in invasive brain experiments. These experiments were carried out pursuant to contractual agreements¹ between the University of California, Davis (UC Davis), and Neuralink, a private company founded by Elon Musk based in California. Both parties to these agreements are registered under the Animal Welfare Act as research facilities. Because these agreements allowed personnel from both Neuralink and UC Davis to have access to taxpayer-supported facilities and animals at the university, and because the animals were, at different points in time, both the property of UC Davis and the property of Neuralink, the Physicians Committee believes there is an overlapping of responsibility for the apparent violations outlined in this complaint. As a result, we are asking that *both* facilities be investigated, and, if violations are confirmed by your agency, that both registrants be cited.

Overview

Pursuant to California's state open records law, the Physicians Committee obtained animal use protocols and amendments, health records, surgical logs, necropsy reports, and other documents related to the use of monkeys in invasive brain experiments funded by Neuralink. These documents form the primary evidentiary basis for this complaint and the facts described herein.

In producing these documents, UC Davis refused to provide the actual animal identification numbers that it assigned to the monkeys used in the experiments, thereby making it impossible

¹ Exhibit A. University Services Agreements, Amendments, and related contracts between Neuralink and the Regents of the University of California (Bates stamp range UCD 0001-0029).

for the Physicians Committee or enforcement authorities to cross-reference the same animals in Animal Welfare Act inspection reports and Certificates of Veterinary Inspection. UC Davis instead produced a legend that correlated page ranges with specific animals.² This complaint uses these masked animal identification numbers. UC Davis also withheld the names and other identifiers for individuals involved in the incidents described below. These redactions and withholdings of identifiers of animals and individuals hampered the Physicians Committee's ability to fully track and identify violations of law. As a result, it is possible that the experiments resulted in more violations than those presented below.

The records reviewed by the Physicians Committee indicate that many, if not all, of the monkeys experienced extreme suffering as a result of inadequate animal care and the highly invasive experimental head implants during the experiments, which were performed in pursuit of developing what Neuralink and Elon Musk have publicly described as a "brain-machine interface." These highly invasive implants and their associated hardware, which are inserted in the brain after drilling holes in the animals' skulls, have produced recurring infections in the animals, significantly compromising their health, as well as the integrity of the research. Additionally, the records make clear that significant deviations occurred from the protocol approved by UC Davis's Institutional Animal Care and Use Committee (IACUC).³ The Physicians Committee believes that the detailed facts outlined below make clear that the research facilities in question violated the following Animal Welfare Act regulations:

- 9 C.F.R. § 2.31(d)(1)(i): Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.
- 9 C.F.R. § 2.31(e)(2): Proposed activities must contain a rationale for involving animals, and for the appropriateness of the species and number of animals to be used.
- 9 C.F.R. § 2.31(c)(7): The IACUC will review and approve, require modifications in, or withhold approval of proposed significant change regarding the care and use of animals in ongoing activities.
- 9 C.F.R. § 2.31(e)(4): Discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic and anesthetic.
- 9 C.F.R. § 2.31(d)(1)(ii): The IACUC shall ensure that the Principal Investigator (PI) has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources.
- 9 C.F.R. § 2.33 (b)(3): Daily observations of all animals shall take place to assess their well-being and there shall be a mechanism of direct and frequent communication to the facility's attending veterinarian.
- 9 C.F.R. § 2.33(b)(4): The attending veterinarian shall provide guidance to personnel involved in the care and use of animals regarding anesthesia.
- 9 C.F.R. § 2.32(a): It shall be the responsibility of the research facility to ensure that all personnel involved in animal care, treatment, and use are qualified to perform their duties.

² Exhibit B. October 8, 2021 email from Michael R. Goldstein, Principal Counsel for the University of California.

³ Exhibit C. UC Davis Animal Use Protocol #21222 and approved amendments, "Development of a Large-Scale Brain-Machine Interface in Rhesus Macaques."

- 9 C.F.R. § 3.81(a): It shall be the responsibility of the research facility to develop, document, and follow an appropriate plan for environmental enhancement adequate to promote the psychological well-being of nonhuman primates.

Experimental Procedures

At least 23 rhesus macaque monkeys were used at UC Davis in a Neuralink-funded project titled “Development of a Large-Scale Brain-Machine Interface in Rhesus Macaques.” According to the protocol, some monkeys used in this experiment underwent “multiple major survival surgical procedures” in which as many as 10 craniotomies were performed and electrodes implanted into the animals’ brains. The monkeys also underwent “head fixation” using either a head-post implant or what the UC Davis deems “pillows” to keep the animal’s head immobile during periods of “prolonged restraint.” During recording sessions, monkeys assigned to survival procedures were also restrained to a chair for up to five hours per day. Experimenters state in their protocol that the monkeys “may be chair restrained multiple times in a single day” and that “[c]hair restraint may be performed every day, including weekends.” Some monkeys assigned to the protocol also underwent terminal (fatal) procedures, including a “device explant.”

Protocol Deviation

According to documents reviewed by the Physicians Committee, experimenters involved in this protocol unambiguously deviated from the approved protocol. Their deviation is outlined in detail in a narrative titled “Adverse Effect Amendment: Inadvertent Use of Drugs” submitted to the UC Davis IACUC.⁴ The “lead surgeon” who was performing craniotomies and electrode implantation on a monkey on August 19, 2019, “had concerns about the void in between the two implants and applied Bioglue to fill the dead space.” Later, a necropsy revealed that the monkey had Bioglue on the surface of his brain. There was no mention of Bioglue being applied in the surgical record for this procedure, indicating poor and possibly noncompliant recordkeeping by lab personnel.⁵ Bioglue was never an approved substance for use in surgery in the approved protocol. Based on the date of the surgical procedure and other details about the condition of this animals, other records received by UC Davis indicate that this monkey was “Animal 8.”⁶

Troublingly, it appears *this same protocol deviation* occurred earlier but *was never reported* to the UC Davis IACUC. According to a necropsy report dated September 13, 2018 for “Animal 21”⁷ (an animal who suffered significant and deadly adverse effects from her electrode implantation—described in more detail below), pathologists observed that “Bioglue is covering and compressing a large area of the left cerebrum” and that an “acute neuronal necrosis” occurred in “the areas of bioglue.” The negligence of UC Davis and Neuralink personnel to adhere to their approved protocol directly led to the extreme suffering and death of this animal nearly a year prior to “Animal 8,” and yet the incident was apparently never reported to the

⁴ Exhibit D. “Adverse Effect Amendment: Inadvertent Use of Drugs.” Written by Principal Investigator John Morrison, dated August 29, 2019.

⁵ Exhibit E. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. The records for this surgery are located on page with the Bates stamp range UCD 0166-0167.

⁶ Exhibit E. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 8” are located on pages with the Bates stamp range UCD 0162-0172.

⁷ Exhibit F. Final Necropsy Report, Report ID 65860, “Animal 21.”

IACUC. This inexcusable unreported earlier violation set the stage for the future deviation of the same nature involving “Animal 8.”

Animal Care Negligence

Documents reviewed by the Physicians Committee reveal a troubling pattern of monkeys suffering from chronic systemic infections resulting from their crude surgeries, indications that monkeys with implanted hardware were isolated from one another (despite a lack of an IACUC-approved deviation from social housing), and evidence that monkeys are suffering from extreme psychological distress. While records for all 23 monkeys reflect this pattern of extreme suffering and staff negligence, below is a brief summary of some of the most concerning evidence of suffering found in the UC Davis records for eight of the monkeys:

- **“Animal 4”**⁸ was an 11-year-old macaque monkey who was killed in the Neuralink/UC Davis experiments in July 2018. Prior to being used in this fatal procedure, this monkey’s records indicate that he or she was on anti-depressants and had chronic diarrhea and poor appetite. A note on the monkey’s care logs indicate that in December 2017, staff was under the impression that the monkey was going to be used in a project with a “terminal endpoint” in “~1 month,” however, the monkey lived an additional seven months at UC Davis. During these months, UC Davis staff frequently observed that this monkey was “lethargic” and “depressed,” with repeated observations of liquid stool, poor appetite, “hunching,” and “bloody diarrhea.” These observations continued consistently until the animal was used in a deadly procedure on July 20, 2018.
- **“Animal 5”**⁹ was a macaque monkey who was shipped from UC Davis to Neuralink’s facility on October 1, 2020. Prior to this shipment, the monkey frequently changed cages at UC Davis, a known stressor for monkeys in laboratories. On September 6, 2019, UC Davis staff noted that this monkey had “patchy alopecia [hair loss] on arms [and] legs.” On December 3, 2019, the monkey had “significant weight loss” which staff thought “could be related to recent relocations.” Staff requested a behavioral assessment, but it isn’t clear if this occurred. On January 21, 2020, staff “inadvertently” administered an anticonvulsant to this monkey.
- **“Animal 6”**¹⁰ was a 6-year-old macaque monkey who was killed on January 16, 2019, as part of the “experimental design.” On October 10, 2018, he or she underwent a highly invasive surgical procedure in which staff drilled holes in their skull and implanted electrodes in their brain. The implants “were placed using an investigational robot” and were then “attached to skull using titanium implant screws.” Beginning in December 2018, the area around the monkey’s head implant became infected, and lab staff had to frequently clean the implant, including by flushing with “copious amounts” of antibiotics. Staff noted that the skin was eroding near the “pillbox where the prongs were cut & the

⁸ Exhibit D. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 4” are located on pages with the Bates stamp range UCD 0124-0132.

⁹ Exhibit D. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 5” are located on pages with the Bates stamp range UCD 0133-0139.

¹⁰ Exhibit D. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 6” are located on pages with the Bates stamp range UCD 0140-0156.

edges were sharp.” At times, staff observed “serious discharge” from the infected area surrounding the implant. On January 14, 2019, staff noted that the implant was “showing through skin edges” and that it was bloody, due in part to the animal “picking” at it. Two days later, staff euthanized “Animal 6.”

- **“Animal 10”**¹¹ was an 8-year-old macaque monkey who was shipped to Neuralink’s facility on October 1, 2020. Prior to this shipment, records for “Animal 10” indicate that this monkey experienced repeated unspecified “traumas” to their body, causing lesions, erythema (reddened skin), as well as blood and “tissue” found in the bottom of his or her cage. The monkey was also reported to have “significant hair loss” and to be exhibiting self-mutilating behavior.
- **“Animal 11”**¹² was approximately 11 years old when he or she was killed in a terminal procedure at UC Davis on March 15, 2019. Prior to this procedure, the monkey had a cranial implant surgically placed inside his or her brain on December 3, 2018. Following this procedure, the implant became chronically infected. The monkey began to have a depressed appetite. In October 2018, UC Davis staff noted that the monkey was “missing multiple digits [on] both hands, [right] foot,” possibly from self-mutilation or some other unspecified trauma. On December 18, 2018, staff decided to “prophylactically or conservatively start [antibiotic treatment]” for the monkey after observing that “the skin was eroded” surrounding the implant. In the following two months, there are frequent observations of the monkey having a bloody, infected head wound from the device experimenters attached to his or her skull. The monkey was prescribed several types of antibiotics during this time period. In January 2019, staff observed that the monkey had a “bloody head...dried blood around base at cranial implant.”
- **“Animal 12”**¹³ was approximately 7 years old when he or she underwent a craniotomy and electrode insertion procedure on July 17, 2018. Following this procedure, the monkey began to experience seizures, and staff prescribed an anticonvulsant. Over the next several days, “Animal 12” had severe clinical adverse effects following the implantation, had poor stool quality, was not eating, and had an eye infection. The records for this animal abruptly end on July 30, 2018.
- **“Animal 15”**¹⁴ was a female macaque who was approximately 7 years old when she underwent a craniotomy and recording device implantation on December 17, 2018. Almost immediately after the animal recovered from the surgery, she began pulling and picking at her head implant. Lab staff noted that the area became infected and bloody. The monkey was observed “grooming & holding hands w/roommate through the cage” on December 19. The same day, she was observed laying down and possibly “head

¹¹ Exhibit E. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 10” are located on pages with the Bates stamp range UCD 0180-0201.

¹² Exhibit E. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 11” are located on pages with the Bates stamp range UCD 0202-0244.

¹³ Exhibit E. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 12” are located on pages with the Bates stamp range UCD 0245-0264.

¹⁴ Exhibit E. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 15” are located on pages with the Bates stamp range UCD 0329-0364.

pressing.” The animal was observed on December 21 to be “shivering & scratching.” On December 28, the animal was observed to have a “stress response to some personnel coming into the room or close to her” and was prescribed anti-anxiety medication. For the next three months, the animal was intermittently given antibiotics as well as probiotics to try to address recurring infections, poor appetite, and liquid stool. The animal was ultimately euthanized on March 21, 2019. A necropsy report indicates that they found internal bleeding, “remnant electrode threads,” and a cerebral cortex that was “focally tattered.”

- “**Animal 21**”¹⁵ was a 7-year-old female macaque who underwent an “electrode insertion survivability” procedure where “[e]lectrode implants were placed [in the monkey’s brain] using investigational robotics” on September 10, 2018. The next two days, the monkey was observed repeatedly vomiting, gasping, “retching” and had “very little interaction with environment/observers.” On September 11, animal care staff wrote that the animal had “weakness, esp in hind limb due to fatigue” and that they “suspect neuro signs.” On September 13, the animal was observed to be pale, with yellow discharge from the implant, and there was vomit in the cage. Staff wrote that the monkey “appeared to collapse from exhaustion/fatigue.” The animal was euthanized, and a necropsy was performed, which found multiple adverse conditions, including brain hemorrhage, “Bioglue” covering the brain, and “acute esophageal ulcers...likely due to vomiting.”

Conclusion

The documents reviewed by the Physicians Committee reveal a systematic disregard for Animal Welfare Act regulations by UC Davis and Neuralink personnel. The carelessness by these facilities resulted in the suffering and death of several monkeys. We believe that this situation warrants a serious investigation by USDA. If our allegations are corroborated, we ask that USDA cite UC Davis and Neuralink for each noncompliance with federal regulations, and seek an assessment of the maximum civil penalty available per violation, pursuant to 7 U.S.C. § 2149(b).

The Physicians Committee appreciates your agency’s dedication to enforcing the Animal Welfare Act and looks forward to hearing the results of any investigation. Should you have any additional questions, we can be reached at 202-527-7388 or jbeckham@pcrm.org.

Sincerely,

A handwritten signature in black ink that reads "JEREMY BECKHAM". The signature is stylized, with the first letters of each name being larger and more prominent.

Jeremy Beckham, MPA, MPH, Research Advocacy Coordinator

A handwritten signature in blue ink that reads "Deborah Dubow Press". The signature is written in a cursive, flowing style.

Deborah Dubow Press, Esq., Associate General Counsel

¹⁵ Exhibit E. Veterinary, procedure, and health records for monkeys assigned to Neuralink protocols. Records for “Animal 8” are located on pages with the Bates stamp range UCD 0618-0645.