November 30, 2004

Elizabeth Goldentyer, D.V.M. Regional Director Animal Care—Eastern Region U.S. Department of Agriculture 920 Main Campus Dr., Ste. 200, Unit 3040 Raleigh, NC 27606

Dear Dr. Goldentyer:

I am writing to ask that the USDA reopen its investigation into Columbia University and formally charge the university for its failure to humanely treat dogs, baboons, rabbits, and macaques used in experiments conducted by Mehmet Oz, E. Sander Connolly, Raymond Stark, Michel Ferin, Peter Danilo, Jeffrey Ascherman, and Jie Wang. To those familiar with this most recent case of Columbia's cruelty to animals, it is clear that the university has somehow curried favor with the USDA, with the result that it has escaped with a paltry \$2,000 stipulation for violations of the minimal standards of the federal Animal Welfare Act (AWA) that would have shut another laboratory down. Multiple recent charges filed against the University of California, San Francisco (UCSF), indicate significant differences between the way that the USDA handled UCSF and the way that it has handled Columbia—and we believe that there is more to this than meets the eye.

The USDA stipulation arising from PETA's September 25, 2003, complaint enumerates serious violations of the AWA, pointing to systematic failures by Columbia that were not appropriately redressed by the fine:

- An entire litter of whelped puppies was killed by injections into their hearts without prior sedation. This is excruciatingly painful, not to mention internationally condemned by veterinary experts—the screams of these puppies could be heard through closed doors. All of these puppies, lying in a plastic garbage bag, were killed in the presence of their littermates.
- The "dog exercise plan does not provide evidence that [the] plan is approved by the attending veterinarian." Anyone who knows the AWA and how it is enforced knows that this means that the dogs do not receive exercise.
- The "primate enhancement plan provides no evidence that [the] plan is directed by the attending veterinarian." Anyone who knows the AWA and how it is enforced knows that this means that the primates receive no enrichment. This fact is evident from our videotape of the primate cages.



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- The Institutional Animal Care and Use Committee (IACUC) approved protocols that failed to provide a reason for the number of animals requested by the experimenters.
- The IACUC approved protocols that failed to describe how pain would be identified and how it would be alleviated by drug administration.
- The IACUC approved protocols that had no plan for postoperative care and analgesia.
- The IACUC approved protocols that "indicated the improper administration of an injectable euthanasia agent."
- Other violations noted on the stipulation include rusty baboon cages, primate enclosures without the perches specified in the "enrichment program," and dangerous sharp edges on metal feeders that posed injury threats to the primates.

Of all the above violations, the most disturbing involve the IACUC's miserable failure in its duties to oversee the most fundamental elements of properly devised protocols for animal experiments. It is shocking that the members of the Columbia IACUC—who are supposedly trained by the university—have been reviewing and approving protocols for years that result in cruelty to animals and that they would have continued to do so had it not been for Dr. Catherine Dell'Orto's complaint.

In the matter of Dr. Dell'Orto's complaints, the USDA has improperly accepted the findings and corrective actions of Columbia's internal committee without filing formal charges against the university for serious AWA violations. As you know, the researchers who are mentioned in the opening paragraph of this letter were all found to have failed to provide proper veterinary treatment, painkillers, and euthanasia to the animals in their highly invasive and painful protocols. It is astounding that the USDA not only accepted the findings of Columbia's internal investigative committee as reported to the NIH Office of Laboratory Animal Welfare (OLAW), but that it did not formally charge the university based on the findings. These findings revealed horrendous suffering and longstanding violations of the most important standards of the AWA. It is even more astonishing that the findings of the internal committee should have been accepted by the USDA at face value, given that they cleared Michel Ferin and Raymond Stark of animal mistreatment despite Dr. Dell'Orto's personal knowledge of the macaques and baboons used in their experiments. Furthermore, four people on the internal committee were also members of the IACUC, presenting a clear conflict of interest. They should not have been allowed to participate in the review process.

The USDA should require that Columbia University suspend all further use of animals by Dr. Mehmet Oz. Dr. Oz, featured on the Discovery Health Channel, *The Oprah Winfrey Show*, and other national network programs, is responsible for the extreme suffering endured by dogs used in his heart experiments. Columbia's IACUC appears to have approved these highly invasive and stressful experiments without demanding a humane endpoint for the animals. It does not appear that anyone from the IACUC actually bothered to inspect the dogs used in Oz's experiments despite the invasiveness of the experiments and the strong potential for suffering.

When Dr. Dell'Orto complained to the head veterinarian, Sulli Popilskis, about the condition of one of these dogs and requested that the animal be euthanized, Popilskis replied, "You still don't understand do you? It's all political." Dr. Dell'Orto understood this to mean that Oz could do whatever he wanted without being questioned because of his celebrity status.

Oz Dog 6269

The USDA should charge Columbia with multiple violations of the AWA concerning dog 6269. Documents arising from the Columbia internal committee's investigation into shoddy animal care state the following about Dog 6269:

Researchers performed a sternotomy and radiofrequency ablation on July 17, 2002. The clinical records show that on July 19, 2002, the animal developed paralysis, but was given appropriate veterinary care. On July 22, the records indicate that the animal was lethargic, vomiting, paralyzed and in renal failure which was confirmed by blood work. The animal was euthanized on July 24 at 11:30 a.m. but the records don't show why the animal was kept alive until July 24.

From two days after her surgery until the day she was finally put out of her misery, dog 6269 was vomiting and unable to stand up. She had bloody urine and black tarry stool. How the internal committee could possibly make the determination that she received "appropriate veterinary care" is a mystery. Columbia is not exempt from abiding by humane endpoints.

Oz Dog 6406

The USDA should charge Columbia with multiple violations of the AWA concerning dog 6406. Documents arising from the Columbia internal committee's investigation into shoddy animal care state the following about dog 6406:

Researchers performed a sternotomy and radiofrequency ablation on July 11, 2004. The records show that on July 13, the animal was in chronic distress (paralyzed in the hind quarters) and that it [sic] showed some improvement over time. The animal was euthanized on August 9, 2002. There is no documentation of adequate bladder care. The records did not confirm a rationale for keeping the animal alive in a paralyzed condition for a prolonged period of time.

The above description minimalizes the almost unbelievable suffering that this dog endured for 29 days. From the second day after surgery, she could not move her hind legs. From 14 days after surgery until the end of her miserable life at Columbia 15 days later, she suffered from urine scalds on her hindquarters. Although the internal committee does not try to make the ridiculous claim that dog 6406 received appropriate veterinary care, it is still astounding that both the USDA and the NIH looked at this dog's records and decided that the university's internal investigation was itself sufficient in addressing the matter.

A university is obliged to perform such an investigation if it gets federal funding—as does Columbia. This is not something for which the USDA should reward Columbia—the USDA should use the findings of the internal committee to appropriately charge the university.

Oz Dog 6313

The USDA should charge Columbia with multiple violations of the AWA concerning dog 6313. Amazingly, the Columbia internal committee's investigation into shoddy animal care determined that this animal received appropriate veterinary care. This is a tragically inaccurate finding. Documents from the investigation state the following about dog 6313:

This study is designed to assess the efficacy of epicardial radiofrequency ablation in the treatment of patients in chronic atrial fibrillation. Researchers performed a sternotomy and radiofrequency ablation on August 7, 2002. The records show that the animal had labored breathing for 12 days and that it [sic] experienced significant weight loss in the course of the experiment. The conditions that were observed were secondary to the protocol and were treated. The animal was used by [Mehmet Oz] in a terminal procedure on September 4, 2002.

The following is a recap of dog 6313's records, spanning 29 days:

- Day 1: Surgery—sternotomy and RF Ablation for Protocol AAAA 024-200 1
- Day 2: "Chest tube was leaking;" 430 mL and 300 mL of bloody fluid suctioned out from the chest tube site
- Day 3: "Leaking blood from either incision or chest tube? Bruising present at incision site;" face and muzzle still swollen
- Day 4: Dog 6313 eats a small amount of food; "bruising still present, swollen all over body;" 300 cc of bloody fluid removed from chest tube
- Day 5: "Right front leg and left hind leg still swollen slightly;" jugular catheter pulled
- Day 6: Dog 6313 did not eat last night or this morning; 285 cc and 255 cc of bloody fluid aspirated later in the evening
- Day 7: Did not eat; 235 mL of bloody fluid aspirated
- Day 8: "Still not eating, incision clean, dry, and intact but leaking"
- Day 9: Ate a bit of chicken
- Day 10: Did not eat in the morning; ate a small amount in evening
- Day 11: Temperature—103° F
- Day 12: Ate a small amount
- Day 13: Ate half of food offered
- Day 14: Ate small amount of food; "Picky eater!"
- Day 15: Ate very little; discharge from incision
- Day 16: Red discharge from incision

Day 17: Dog 6313 was found to be breathing heavily; Catherine Dell'Orto, the veterinarian who blew the whistle on Columbia, ordered that the dog receive x-rays and antibiotics

Day 18: Did not eat

Day 19: "Second day animal is not eating"

Day 20: "Right ventral severe crackles; try chest tap this evening if no improvement—removed jacket to help breathing"

Day 21: "Shivering, lungs sound conjested [sic] ... seems cold, not eating"

Day 22: "Breathing still labored, condition remains the same ... no stool ... chewing at her catheter, e-collar intact, lethargic"

Day 23: "Weak, not eating or drinking, losing weight, breathing labored"

Day 24: "Not eating or drinking, slightly dehydrated, labored breathing"

Day 25: "No stool; K-9 vomited pepsid tablet—appears nauseous"

Day 26: "Right foot starting to swell; cut leg wraps on both sides top and bottom. Offered baby food (ham flavored); ate right from jar."

Day 27: "Labored breathing, right front leg swollen; applied new catheter; rewrapped animal's front right leg. Did not eat any of its food."

Day 28: "Not eating, labored breathing, no stool."

Day 29: "Does not want to come out of cage, right hind leg swollen; catheter out; chewed through [tube], not eating, breathing very labored, no stool, tried to feed—will not eat anything; p.m. [Mehmet Oz] took for last experiment"

Again, Columbia failed to abide by humane endpoints. Dog 6313 was obviously in no condition to be kept alive but not only was she forced to endure a month of cruelty, she was used in a final experiment whose data can only be considered unusable because of her condition. It was dog 6313 who was the subject of Sulli Popilskis' comment to Dr. Dell'Orto that euthanasia would not take place for "political" reasons. The internal committee's conclusion that this dog's suffering was all "secondary to the protocol" must not be allowed to stand.

The USDA should require that Columbia University suspend all further use of animals by Dr. E. Sander Connolly and charge the university for numerous violations of the AWA in regard to his experiments on baboons. As you know, in these NIH-funded stroke experiments, Connolly cut out the left eyes of the baboons and cut off blood flow to their brains by using the empty eye socket to access a major artery with a clamping device. The descriptions below, quoted from the internal committee's report, are of animals found to have received inadequate veterinary care but they do not do justice to the horrible suffering experienced by these animals:

Baboon B739

"Surgery was performed on October 16, 2001. The clinical records show that the animal lost a significant amount of blood (quantity not specified) and also contain long gaps between observational notes. On October 17, the last entry, at 2:00 p.m., indicates that the animal was down. The animal was found dead on October 18, 2001."

Baboon B754

"Surgery was performed on October 9, 2001. The animal was not doing well clinically and had a respiratory rate of 100, but was not intubated. On October 11, a note in the record indicates that the animal was not moving in the cage. The clinical record had no indication that a veterinarian was contacted. The animal was found dead on October 12, 2001."

Baboon B777

"Surgery was performed on September 18, 2001. The records show that the animal did well on September 19, but that on September 20 the animal lacked physical alertness [and] was unable to sit upright or to eat. On September 21, the records indicate that the animal was awake and motionless but unable to eat, and could only drink water if squeezed into its mouth. It had vomited in the morning. The animal died while in its [sic] cage on September 21, 2001, at 1:30 p.m."

Baboon B819

"Surgery was performed on April 18, 2002. The records include only one note on April 19. The records for April 20 show that the animal had poor motor skills and head tilt, was unable to self-feed and, during the evening, was propped in the back of the cage. The animal was found dead on April 21, 2002."

Baboon B781

"Surgery was performed on July 23, 2002. The animal did well on July 24, but there was then a gap in the notes until the evening of July 25. At that time, the records indicate that the animal was quiet, clumped over and could not right itself [sic]. The animal was intubated, placed on IV fluids, and underwent MRI, but was then extubated and kept alive. The principal investigator was notified. On July 26, the records indicate that the animal was weak and unresponsive. According to the principal investigator's records, the animal was euthanized on July 26."

Baboon B179 (We believe that this animal's number reads incorrectly as <u>B13179</u> on the committee's document. The "B" on the original postsurgical records appears to be a "13" because of the writer's sloppiness. If we are correct, it is disturbing that the committee did not even realize that it had an incorrect animal number in its report.)

"Surgery was performed on July 24, 2001. The clinical records show that on July 26, the animal had impaired ambulation and was unable to self-feed. On July 27, 2001, the animal was still unresponsive, was intubated, taken for MRI, and then euthanized."

For the mistreatment and abuses of the six baboons mentioned above, Columbia University should be cited and <u>severely</u> fined for violations of the AWA. It is inconceivable that the USDA should be complacent about the horrific suffering of the primates and the fact that the most fundamental tenets of the AWA were ignored.

The committee's finding that baboon B816 received adequate veterinary care is ridiculous. The committee states that surgery was performed on January 15, 2002. The postoperative recovery records are dated January 17, 2002, and according to the committee's report, there is only one entry for this animal (dated January 18), which reads, "QAR, NSF, cheek pouches look full of saliva. Monkey slumped against back wall of retracted cage. Tried to straighten him up and offered tang. Drinking O.K. No movement seen in right side leg or arm. Left side has considerable strength and grip." The baboon was found dead the following morning at 7:30 a.m. The internal committee claims a surgery date that is not reflected in the records we have and it accepts that there are no entries on the records until two days after surgery. There is no indication that this animal was ever seen by a veterinarian.

The internal committee also claims that baboon B778 received adequate veterinary care: "The clinical records show that on September 9, the animal had a swollen arm, but that it [sic] was eating, drinking, and had a good attitude." The report downplays the serious nature of this baboon's condition and injury. The records for September 6 state, "Unable to raise right arm, still swollen considerably. Oozing from wound between thumb and index finger. Arm cold." And on September 7: "Right arm still swollen, red patches with some oozing on distal portion of forearm, head still swollen." On September 8: "Right arm still swollen, red patch has begun to slough." The baboon did not receive veterinary care for this condition until September 9. The records for that date describe the oozing injury as follows: "Injured right hand P3-P4 dorsal aspect skin split, edematous hand and pressure necrosis." By that evening he was "picking at fingers." On September 11, he was "picking at loose stitch in left eye" before Connolly euthanized him and opened his skull.

The USDA should examine the records for these baboons and insist on seeing all of the Spetzer scores, which should have been assessed for each animal according to the protocol. These scores do not appear in any of the records.

The USDA should file charges against Columbia University for Jeffrey Ascherman's failure to ensure humane treatment for rabbit 1R161. The internal committee found that, after surgery to create a cranial injury was performed on September 4, 2002, the rabbit had several seizures but was never seen by a veterinarian despite the belief that the animal had been blinded by the experiment. No lab work was done to determine the origin of the seizures, and when the veterinarian Sulli Popilskis was notified—after the rabbit endured a 2-hour-long seizure—he simply told the technician to contact Ascherman. The rabbit was not put out of his misery until September 12.

The USDA should file charges against Columbia for <u>its</u> failure to ensure humane treatment of dogs used in his chronic heart failure experiments:

Wang Dog 6423

The internal committee found that this dog, who underwent surgery on June 19, 2002, developed a fever. Muscle was cut out of the dog eight weeks after the surgery while he still had a high white blood count and a temperature:

"On August 20, 2002, the animal had an open leg incision, was vomiting, lethargic, and had a high temperature. The last entry indicates that the animal was found dead that same evening."

Wang Dog 6496

This dog, used in the same protocol as dog 6423, had a similar miserable existence after surgery on August 5, 2002.

"The records show that the animal developed a fever, had a high white blood count and worm infection. It ran a fever for a number of days but it was not put on antibiotics during the first six days of fever. It [sic] became lethargic and did not eat and was then put on antibiotics for three days. The dog was found dead on September 7, 2002."

Columbia's failure to provide basic veterinary care for this dog should prove to the USDA that the university thumbs its nose at regulations and believes that it can get away with murder.

The USDA should file charges against Columbia for its failure to provide veterinary care to six German shepherd puppies used by Peter Danilo, chair of the IACUC. It is not difficult to provide veterinary care to six puppies infected with scabies, yet Columbia failed in this small mercy and let the puppies scratch and bite themselves until their hair fell out. Columbia most likely thought that there was no sense in providing care for them since the puppies were soon going to be killed in Danilo's experiment. The USDA cannot allow Columbia to get away with this shabby treatment of animals. One can only imagine what a poor example Peter Danilo, as the head of the IACUC, set for the entire committee.

The USDA should prohibit Raymond Stark from using baboons in multiple survival surgeries. It is evident that the IACUC did not know how to properly execute its functions. No decent IACUC would approve five survival surgeries as Columbia's did for Raymond Stark's nicotine protocol. If the USDA would review baboon 6533's records and consider her history of multiple surgeries, it might disagree with the findings of the internal committee that she had received adequate veterinary care. Is it possible that the USDA has already reviewed those records and has concurred with the committee's findings? We hope not.

The USDA should prohibit Michel Ferin from inducing stress in monkeys by his cruel and barbaric surgical attachment of metal pipes to their skulls. This is yet another example of gross failures by the IACUC. Any decent IACUC would seek a less invasive way of inducing stress in these animals. We ask that the USDA review all records for Ferin's monkeys in this protocol to determine if they have received and are receiving proper postsurgical care and pain relief. We also ask that the agency review the IACUC's deliberation records on this experiment to see if there is any hint as to how they could have allowed this project to go forward as described.

The USDA should reopen the Columbia University case and vigorously pursue administrative or criminal action against the university as it should have done when Dr. Dell'Orto first contacted the agency in late 2002. John LoPinto, the USDA inspector for Columbia, did not respond to Catherine Dell'Orto's request for action in 2002. It was only when PETA filed its September 2003 complaint that the USDA made any effort to contact Dr. Dell'Orto. We believe that Mr. LoPinto failed in his duties to thoroughly inspect the laboratories at Columbia.

Columbia's failure to abide by the minimal standards of the AWA is also the USDA's failure. It is totally unacceptable for a prestigious university to utterly ignore common decency toward animals and the federal law that is supposed to protect them from cruelty and neglect.

Please let us know if your office will reopen an investigation and do what it should have done in 2002 and 2003. We look forward to hearing from you and thank you for your time.

Sincerely,

Mary Beth Sweetland, Senior Vice President Director, Research & Investigations Department

cc: Phyllis K. Fong, Inspector General, Office of the Inspector General, USDA Catherine Dell'Orto, D.V.M.