



PETA

PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS

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March 3, 2004

Daniella Gallo, Assistant District Attorney
New York County District Attorney's Office
1 Hogan Place, Trial Bureau 50
New York, NY 10013

Dear Ms. Gallo:

Re: Request for Investigation and Prosecutorial Action Concerning Cruelty to Animals at Columbia University Health Sciences' College of Physicians and Surgeons

I. Introduction

Dr. Catherine Dell'Orto, D.V.M., and People for the Ethical Treatment of Animals (PETA), write to request that you investigate individuals at Columbia University Health Sciences' College of Physicians and Surgeons for egregious violations of the state cruelty-to-animals statute, N.Y. Agric. & Mkts. Law § 353,¹ in relation to a scientific experiment on baboons that was not "properly conducted" as required by law. We respectfully request that you thoroughly investigate this matter and prosecute all culpable individuals to the fullest extent of the law.

Dr. Catherine Dell'Orto, the co-complainant, is a veterinarian in good standing with the state of New York, who worked as a postdoctoral fellow at the Institute of Comparative Medicine (ICM) from July 2001 through February 2003. During that time, Dr. Dell'Orto witnessed multiple baboons involved in the scientific experiment at issue who were subjected to torture and unjustifiable injury, maiming, and mutilation within the meaning of § 353. As you are aware, §

The statute provides as follows:

Any person who overdrives, overloads, tortures or cruelly beats or unjustifiably injures, maims, mutilates or kills any animal, whether wild or tame, and whether belonging to himself or to another ... or causes, procures or permits any animal to be overdriven, overloaded, tortured, cruelly beaten, or unjustifiably injured, maimed, mutilated or killed ... or who willfully sets on foot, instigates, engages in, or in any way furthers any act of cruelty to any animal, or any act tending to produce such cruelty, is guilty of a misdemeanor.

The statute further provides the following:

Nothing contained herein shall be construed to prohibit or interfere with any **properly conducted** scientific tests, experiments or investigations, involving the use of living animals, performed or conducted in laboratories or institutions, which are approved for these purposes by the state commissioner of health.

N.Y. Agric. & Mkts. Law § 353 (emphasis added).

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353 authorizes cruelty charges against perpetrators of cruelty who are engaged in “scientific tests, experiments or investigations involving the use of living animals” when such scientific tests, experiments, or investigations are not “properly conducted.”² *Id.* For the reasons set forth herein, that is clearly the case here.

In this particular experiment, the eyes of living and sometimes conscious baboons were cut out, and arteries to their brains were clamped to induce strokes. Test drugs were administered and effects measured over a period of days, while the animals languished without the required monitoring, analgesics, anesthetics, or euthanasia. As described in more detail *infra*, both the scientific basis for this experiment’s protocol and the manner of its implementation were significantly flawed, causing torture, unjustifiable injury, maiming, mutilation, and death within the meaning of the Agriculture & Markets law.

The respondents are as follows:

1. **Gerald D. Fischback**, M.D., is the executive vice president for Health and Biomedical Sciences and dean of the Faculty of Medicine, Health Sciences, at Columbia University. Dr. Fischback is responsible for all experiments that involve the use of living animals within Health Sciences, pursuant to regulations of the New York State Department of Health. *See* N.Y. Comp. Codes R. & Regs. Tit. 10, § 55-1.4(a).

2. **Dennis Kohn**, D.V.M., director of the Comparative Medicine Department, is, on information and belief, the individual designated to be in charge of animal care at Columbia University’s Institute of Comparative Medicine, pursuant to N.Y. Comp. Codes R. & Regs. Tit. 10, § 55-1.4(a).

3. **E. Sander Connolly**, M.D., is the “principal investigator” of the experiment that is the subject of this request for an investigation and prosecution, and he had overall authority for its design and implementation.

4. **Sulli Popilskis**, chief of Columbia University’s Experimental Surgery Section, drafted part of the experimental protocol for this experiment and had the most direct oversight responsibility for the treatment and care of its baboons.

5. The following Columbia University **Institutional Animal Care and Use Committee (IACUC) Members** approved the methodology and subsequent implementation of the flawed protocol³:

² Thus, although the New York Assembly chose to exempt conduct associated with carefully planned and vigilantly monitored scientific experiments from prosecution under the cruelty statute, it also recognized the need to limit the exemption in order to prohibit cruel behavior by individuals and institutions for whom compliance with approved research protocols constitutes an “inconvenience” and who therefore fail to protect animals against the unjustifiable pain and suffering that § 353 was designed to prevent.

³ Pursuant to the federal Animal Welfare Act, 7 U.S.C. §2131, each research facility that uses live animals must establish an Institutional Animal Care and Use Committee (IACUC) which, by law, “shall represent

- Ms. Rose Marie Holman, Director
- Richard Ethan Abbott
- Dr. Peter Danilo, Chair
- Dr. Yelena Akelina
- Dr. Mohammed Athar
- Mr. Richard Ehrenreich
- Dr. Alan Herron
- Dr. Dennis Kohn
- Dr. Jan Koniarek
- Dr. Vernice Jackson-Lewis
- Dr. Neil MacLusky
- Dr. Sulli Popilskis
- Mr. Paul Rubock
- Dr. Hal Skopicki
- Dr. Michel Ferin
- Mr. Peter Guastella
- Dr. David Pinsky
- Dr. Raymond Stark

society's concerns regarding the welfare of animal subjects used at such facility." 7 U.S.C. § 2143(b)(1). Pursuant to federal rules, the IACUC is responsible for the following:

- approving or rejecting proposed experiments
- ensuring that procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals
- ensuring that the experiment's principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals
- ensuring that the activities do not unnecessarily duplicate previous experiments
- ensuring that procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics, or anesthetics
- ensuring that animals who would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized, when appropriate, following the procedure
- ensuring that medical care for animals will be available and provided as necessary by a qualified veterinarian
- ensuring that personnel conducting procedures on the species being studied are appropriately qualified and trained in those procedures
- ensuring that activities that involve surgery include appropriate provision for post-operative care of the animals in accordance with established veterinary medical and nursing practices
- suspending a previously approved activity if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator

See 9 C.F.R § 2.31(d).

Moreover, N.Y. Comp. Codes R. & Regs. Tit. 10, § 55-1.4(b) requires the IACUC to "review the **propriety** of the procedures used and the **scientific justification** for the use of animals in experiments" (emphases added).

This committee must further ensure that "[p]ain and discomfort [are minimized] by proper use of tranquilizers, analgesics and anesthetics." Id., § 55-1.5(c).

II. Legal Allegations

Between July 2001 and September 2002, respondents, collectively, tortured or unjustifiably injured, maimed, and/or mutilated baboons and/or caused, furthered, or permitted said baboons to be tortured or unjustifiably injured, maimed, or mutilated by designing, and subjecting said baboons to, an experimental protocol that failed to minimize pain and discomfort through proper use and dosage of analgesics and anesthetics during and after a highly invasive experimental procedure.

Between July 2001 and September 2002, respondents tortured or unjustifiably injured, maimed, and/or mutilated baboons and/or caused, furthered, or permitted said baboons to be tortured or unjustifiably injured, maimed, or mutilated by failing to follow the experimental protocol's requirements for provision of post-operative veterinary care and monitoring.

Between July 2001 and September 2002, respondents tortured or unjustifiably injured, maimed, and/or mutilated baboons and/or caused, furthered, or permitted said baboons to be tortured or unjustifiably injured, maimed, or mutilated by designing and implementing a highly invasive, painful experiment that caused prolonged suffering and death and that, contrary to rules prescribed by the state commissioner of health, lacked any reasonable "scientific justification" in that:

- a) any positive benefit of the neuroprotective agents could virtually never be replicated in a clinical human population because of extreme and unavoidable differences in the clinical setting;
- b) the experiment represents a mere extension of 25 years worth of failed animal experiments on at least 30 different putative neuroprotective agents; and
- c) both the experimental protocol and the failure to follow it precluded meaningful results.

The individual members of the IACUC furthered acts of cruelty to baboons by failing to adequately review the propriety of the procedures used in the experiment, as well as the scientific justification for the use of the baboons, as required by administrative rules, thereby allowing the animals to be subjected to torture, unjustifiable injury, maiming, mutilation, and death within the meaning of § 353.

The acts of cruelty perpetrated by, or under the authority of, respondents are evidenced by statements of a veterinarian who directly observed the cruelty; by statements within the four corners of the written experimental protocol; by animal-care records; and by independent, internationally renowned neurology and veterinary medicine experts' reviews.

III. Discussion

A. Background

Simply put, this request for an investigation and prosecutorial action stems from an experiment in which baboons' eyes are cut out while the baboon is secured to a stereotactic head-holder—a device that keeps the animals' heads from moving. Strokes are then induced in the baboons by manually clamping arteries to their brains, an experimental drug is administered, and its effects are measured. This is a highly invasive procedure, and even in the best of circumstances—i.e., when a proper experimental protocol is followed—the effects of the stroke would disfigure and severely cripple the baboons. As explained below, the protocol was not proper, and in any event, it was not followed.

Baboons were subjected to this experiment on July 26, 2001; September 19, 2001; October 10, 2001; October 18, 2001; January 17, 2002; April 18, 2002; July 24, 2002; and September 4, 2002.

There are two independent bases for imposing criminal liability on those who conceived, approved, and carried out the experiments:

1. Even assuming, *arguendo*, that the experiment in question was legitimate, it was not “properly conducted” because (a) the written experimental protocol that governed the experiment was so recklessly drafted, with respect to its inadequate prescriptions for anesthesia, that it was reasonably calculated to cause torture (see § III(B)(1) *infra*) and (b) in any event, the protocol was grossly violated, and the proximate result was that the baboons suffered unjustified injuries, torture, and ignominious deaths (see § III(B)(2) *infra*).

2. The experiment in question was *not*, in fact, legitimate. Neither state nor federal law or policy permits wasteful experiments that torture animals,⁴ and therefore, those who design, approve, and implement such experiments fit cleanly within the parameters of § 353's prohibition against cruelty to animals. An experiment cannot be considered “properly conducted” when, as here, it cannot be justified to begin with. This painful experiment was designed, approved, and implemented *despite* the perpetrators' real or constructive knowledge that it had virtually no chance of obtaining results that would be useful or meaningful to humans in any fashion. The experiment was merely a pretext for obtaining federal money issued at taxpayers' expense. See § III(C), *infra*. The

⁴ See note 2, *supra*. Further, New York Department of Health Rules limit licensure of laboratories using live animals to those engaged in “properly performed or conducted scientific tests, experiments, or investigations.” N.Y. Comp. Codes R. & Regs. Tit. 10, § 55-1.1(a). And significantly, these rules explicitly *disallow* licensure of labs that use live animals “unless evidence is presented that the general research or teaching program of the institution or laboratory **will contribute to the understanding of the problems of human or animal health.**” Id., § 55-1.1(b) (emphasis added).

mantra of “research” cannot be used as a thin veil for cruelty merely because it occurs at a prestigious university where one least expects to find cruelty.⁵

B. The Experimental Protocol

1. The Incompetently Drafted Surgical Protocol Ensured That the Underlying Experiment Would Torture the Baboons, Constitute a “Cruel Beating,” and an “Unjustifiable Injury, Maiming, or Mutilation” Within the Meaning of § 353.

This experiment—Protocol 2860, “Treatment for Progressive Microvascular Failure in Non-Human Primate Stroke”—used young adult male baboons in an extremely invasive procedure that requires the removal of one eye in each baboon and the subsequent inducement of strokes, with an endpoint of death days later. Electrodes were inserted into the central tendon of the wrist to record motor-evoked responses. Then, the anterior cerebral arteries and the left internal carotid artery were temporarily obstructed with clips that restricted blood flow through the arteries. The clips were left in place for 60 to 90 minutes, after which the orbital cavity was sealed and the eyelids trimmed and sewn shut. The severely debilitated baboons, who lose the use of one side of their bodies and are predictably unable to self-care and perform basic functions, are then isolated in individual cages and used to test the efficacy of experimental pharmaceutical treatments.

Dr. Nicholas Dodman, a board-certified anesthesiologist and former professor of veterinary anesthesiology, reviewed the part of the protocol regarding administration of anesthetics and found that “[a]nesthetic protocol was designed by a human anesthesiologist who did not take into account the difference in potencies of anesthetics between humans and non-human primates.” Affidavit, para 4, attached. Dr. Dodman concluded that the baboons were likely conscious during surgery and that “the analgesia was inadequate to prevent the perception of pain during extirpation of the eyeball and some other aspects of the surgery.” *Id.*, para 15. Dr. Dodman further remarked on the respondents’ “lack of understanding of animal anesthesia” apparent from the protocol. *Id.*, para 16.

Dr. Dell’Orto’s affidavit also addresses the insufficiency of the anesthesia and reports that Dr. Popilskis, the head veterinarian, commanded the veterinary technician to

⁵ It bears mention that this prestigious university has previously had its approval to conduct all vivisection involving warm-blooded vertebrates other than rodents *withdrawn* by the National Institutes of Health pending correction of “serious deficiencies” discovered in an on-site evaluation, including the following:

- inadequate veterinary care program with insufficient number of qualified professionals
- major survival surgery routinely conducted under non-aseptic conditions
- “entirely inadequate” area to house dogs who were being quarantined or undergoing “condition screening”
- humans subjected to health hazards from sheep used in research

Dr. Dell’Orto concludes her affidavit by remarking on this laboratory’s “culture of callousness,” further dispelling any myth that animal use at an Ivy League school is more above-board than elsewhere.

actually *decrease* the level of anesthetics provided during the experiments on at least three baboons. Dell'Orto Affidavit, para 13. These horrific acts were actually done in accordance to the protocol. Dr. Dell'Orto shared Dr. Dodman's belief that the baboons were conscious while their healthy eyes were cut out and had the perception of pain throughout the procedure. A highly invasive experiment such as this, which so badly misconstrued such a basic element as anesthesia administration during removal of a healthy eye, constitutes one of the clearest examples of a "scientific" experiment that is not "properly conducted" within the meaning of § 353.

2. The Protocol for Post-Surgical Care Was Profoundly Violated, Causing Torture, Unjustifiable Injury, and Death to Numerous Baboons

The post-surgical protocol for this experiment, described in relevant part in the attached affidavit of Dr. Dell'Orto, requires that the baboons shall:

- a) remain intubated, sedated, and monitored for at least 18 hours by members of the neurosurgical team;
- b) after the initial 18 hours, be monitored in the intensive care unit with a minimum of three visits per day by a member of the neurosurgical team to assess the animals' levels of function and distress;
- c) remain intubated, if scoring low on a neurological-functioning test, either until they can "self-care," i.e., eat, drink, maintain body posture, and interact, or until euthanasia at 72 hours;
- d) be observed by a neurosurgical team member at all times until extubated or euthanized;
- e) be "maintained" for 10 days if they are self-ventilatory, aware, not in a state of distress, and able to sit up and eat; and
- f) be euthanized at any point at which they are identified as being in distress, as dictated by staff of the Emergency Surgery Section.

This protocol was all but ignored, as evidenced by the lack of veterinary treatment and other cruel mistreatment of the baboons confirmed by records and observations. While strict adherence to protocol would not have prevented the animals' suffering and eventual death, it would have significantly truncated their agony by allowing administration of required post-operative care, including analgesics, and by affording them the relief of euthanasia when they were clearly in a state of significant distress.

Contrary to the approved protocol, respondents utterly failed to provide the baboons with required monitoring, intubation, analgesics, or timely euthanasia. The annotated records for the affected animals, reproduced at paragraph 18 of Dr. Dell'Orto's attached affidavit, detail a veritable laundry list of serious post-operative medical

complications and respondents' wholesale failure to monitor, treat, acknowledge, or even recognize them or to euthanize baboons who were obviously suffering and unable to sit up, eat, ambulate, or communicate. The records reveal that animals who were unable to even sit upright in their cages or swallow were nonetheless left to languish in their pain until they died in their cages or were killed up to seven days after the protocol required such action. Dr. Carol J. Van Petten, M.D., of the Department of Neurology at the Southern California Permanente Medical Group concludes, after a review of the animal-care records, that "the inadequacy of animal supervision and care ... exhibited by the experimental team ... is an alarming example of failure to maintain minimal humane standards." Affidavit, para 12.

The comprehensive surgical decimation of an animal, devoid of the post-operative care required by a written experimental protocol, constitutes torture and unjustifiable injury and death within the meaning of § 353.

C. The Experiment Had No Legitimate Scientific Justification and Thus Constitutes Cruelty, Irrespective of Any Deviation From the Protocol

As indicated in § III(A), *supra*, federal Animal Welfare Act regulations (9 C.F.R. § 2.31(d)) and the administrative rules of New York's Department of Health prohibit meaningless, pointless, or futile experiments, and the IACUC—which is charged with "represent[ing] society's concerns regarding the welfare of animal subjects"⁶—must vigilantly ensure that meaningless, pointless, or futile experiments are not approved. As noted *supra*, the IACUC is obligated to review an experiment's "propriety" and "scientific justification." N.Y. Comp. Codes, R. & Regs. Tit. 10, § 55-1.4(b). It is thus both federal and state law and policy to avoid wasteful, as well as abusive, experiments. When an experiment is meaningless, pointless, or futile, and therefore should not be approved in the first place, it would be illogical to maintain that the experiment could be "properly conducted."

Reputed neurologists Drs. Hoffman and Van Petten both highlight a significant difference between clinical conditions in stroke experiments on animals and human clinical practice: Any positive results in the animal tests require near-immediate administration of the neuroprotective agent following the onset of stroke, yet the tiniest minority of human patients presents to an operating room within this necessary time frame. Dr. Hoffman explains, "[I]n clinical neurological practice, such immediate administration is obviously impossible due to the inevitable delays in patients presenting to emergency departments and the time necessary for evaluating them." Affidavit, para 9. Dr. Van Petten concludes, "[A]ny otherwise effective neuroprotective agent will be of use only in a tiny minority of patients." Affidavit, para 9. Because neuroprotective agents can only rarely be administered to humans within the required timeframe, Dr. Hoffman writes, "[T]hey would be essentially useless for treatment of humans." Affidavit, para 10.

Dr. Robert Hoffman, upon thorough review of this experiment's protocol, tagged it as the latest in a long string of "dismal failure[s]." Affidavit, para 16. Dr. Hoffman

⁶ 7 U.S.C. § 2143(b)(1).

explains why this experiment was calculated to fail from the outset, just like the approximately 30 previous reported animal experiments involving strokes. Citing a wide body of scientific references, Dr. Hoffman verifies that “from an ethical point of view, the use of the animals for this research is indefensible, since its clinical promise is practically nil.” Affidavit, para 14. But Dr. Hoffman addresses more than just ethics: He also notes that from a strictly medical standpoint, the underlying study is merely a smaller piece of two full decades of failed research on neuroprotective agents, representing a “blind alley” from which funding should be redirected. *Id.* Dr. Carol Van Petten, an experienced clinical neurologist with significant experience treating stroke patients, independently notes that not a single one of at least 30 “putative” neuroprotective agents studied in the last 25 years, such as the one used in the Columbia University experiment, has proven to be of any benefit to human patients. Affidavit, para 8.

Furthermore, as Dr. Hoffman explains, stroke research on baboons is futile because baboons’ nervous systems differ enough from our own that the strokes induced in them are qualitatively different from ours and implicate different impairments and cortical functions, some of which cannot be tested. Affidavit, para 11.

The argument against this experiment’s scientific justification is bolstered by the work of Columbia University’s own Department of Neurology, College of Physicians & Surgeons. In an article titled “Lifestyle factors and stroke risk: exercise, alcohol, diet, obesity, smoking, drug use, and stress,” published in Curr. Atheroscler. Rep. 2000 Mar; 2(2): 160-6 (synopsis attached), Columbia University researchers stressed the correlation between controllable lifestyle factors, including exercise, alcohol, diet, obesity, smoking, drug use, and stress, and risk of stroke. Columbia University’s Department of Neurology encourages health professionals to continue to further identify such lifestyle factors and thus help improve the ability to *prevent* stroke in the first instance. This finding and recommendation is in direct accord with a wave of scientific literature addressing human strokes; hence, redirecting the flow of money away from futile research and toward prevention is the first major step toward addressing the problems associated with this condition. See also “Diet, nutrition and the prevention of chronic diseases,” World Health Organ Tech Rep Ser. 2003; 916: i-viii, 1-149; “Sports, exercise and health. On the way into a new century,” Orthopade, 2000 Nov.; 29(11): 930-5. Dr. Van Petten writes that “prevention of stroke is still the most effective way to address [strokes], and requires emphasis over animal experimentation because no cure either exists or can be reasonably anticipated as a result of animal research.” Affidavit, para 9.

The IACUC oversees some of the most important safeguards afforded to sentient animals used in laboratory experiments, including the obligation to ensure the propriety of procedures used and scientific justification for the use of the animals. When these safeguards are disregarded, animals suffer horrendously **and for absolutely no reason**, just as the baboons at Columbia University have suffered, in clear violation of the state cruelty-to-animals statute, N.Y. Agric. & Mkts. Law § 353.

IV. Conclusion

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