ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK
COMMITTEE ON LEGAL ISSUES PERTAINING TO ANIMALS

S. 1916 (Sen. Richard Burr – R-NC)
H. 3295 (Rep. Jim McCrery – R- LA4th)

THIS LEGISLATION IS APPROVED WITH RECOMMENDATIONS

This proposed federal legislation, the Chimpanzee National Sanctuary System (Amendment to the CHIMP Act), would amend the Public Health Service Act to modify the existing sanctuary system for surplus chimpanzees retired from research so as to terminate the current authority to recall such surplus chimpanzees for biomedical research under certain circumstances. However, the proposed bill does not prohibit the recall of chimpanzees for either non-invasive behavioral research or for specified medical research involving the chimpanzee colony, and we recommend that the legislation be expanded to ban the recall of chimpanzees for all purposes.[1]

Under existing law, chimpanzees can be recalled from the federally funded sanctuary to be re-used in research under limited criteria. 42 U.S.C. Sec. 287a-3a (Chimpanzee Health Improvement, Maintenance, and Protection Act (CHIMP Act). The CHIMP Act provides in subdivision (d)(3)(A) as follows:

> "(i) The chimpanzee may be used for noninvasive behavioral studies or medical studies based on information collected during the course of normal veterinary care that is provided for the benefit of the chimpanzee, provided that any such study involves minimal physical and mental harm, pain, distress, and disturbance to the chimpanzee and the social group in which the chimpanzee lives."

Existing law also permits recall of the chimpanzee from the federally funded sanctuary for invasive biomedical research if the Secretary of the USDA certifies that standards set forth in

subdivision (d)(3)(A)(ii) are satisfied. These concern the alleged needs of the research community for that particular chimpanzee in light of that chimpanzee's medical history, and the

[1] On August 1, 2007, S. 1916 was referred to the Committee on Health, Education, Labor and Pensions, where it is pending as of this date. In the House, H. 3295, on the same date, was referred to the Committee on Energy and Commerce and then on the same date, to the Subcommittee on Health, where it is currently pending.

alleged unavailability of other chimpanzees or research methods, etc. The proposed bill would completely eliminate (ii) and B (a further subdivision necessary to effectuate (ii)). Thus, the designated surplus chimpanzees, while not completely legally retired under the proposed amendments, would be effectively shielded from additional biomedical research. Therefore, this proposed bill would properly protect the retired chimpanzees from virtually all repeated invasive biomedical research involving physical pain and stress.

Generally, primate experimentation presents two troubling issues. First, no reasonable person would dispute that any sentient being, regardless of its intelligence, has a right not to be subjected to cruelty. However, the acknowledged high intelligence, relatively large size, and social nature of primates when compared to fruit flies, lizards, or even mice – other common subjects of scientific research – as well as their genetic similarity to humans, renders confinement of primates in a laboratory setting for the alleged greater good of scientific advancement ethically problematic.

The problems of enforcement of the required humane conditions in laboratories are illustrated in *Taub v. State*, 296 Md. 439, 463 A. 2d 819 (1983), where the Maryland Court of Appeals ruled that state animal cruelty laws are preempted by the Animal Welfare Act, if research laboratories have Federal grant money. Accordingly, the Court reversed the state animal cruelty conviction of Dr. Edward Taub for failing to provide adequate veterinary care for monkeys in his research laboratory that was operated with a grant from the National Institute of Health.[2]

Factually, this case is similar to one brought by Otero County District Attorney Scott Key in New Mexico in September 2004. In a press release to the Alamogordo Daily News, on Sept. 11, 2004, DA Key stated: "The USDA has given the NIH permission to police themselves. They are so non-thorough, it's not even funny. No one is looking out for the chimps." The DA's investigation had been triggered by contact with whistleblowers and the organization *In Defense of Animals* that had reported the deaths of two chimpanzees and the serious illness of another as a result of inhumane conditions in the research laboratory. Unfortunately, the New Mexico Court of Appeals, in an unreported case available on the Internet (*State of New Mexico* v. *Dr. Donald Rick Lee, DVM and Charles River Laboratories, Inc*., June 14, 2007), found that state animal cruelty laws – even in the face of gross negligence and willful neglect of laboratory monkeys - could not be invoked against animal research laboratories and veterinarians operating therein pursuant to Federal funding.[3] The Court in the *State of New Mexico* case (at pp. 4-5), describes the undisputed facts that lead to the deaths of two of the chimpanzees, Ashley and Rex, and the near death of a third, Topsy.

[2] Dr. Taub had been arrested based on information provided by a former employee of his laboratory that the conditions were unsanitary, the monkeys were inadequately fed and they did not receive proper veterinary care. Nevertheless, based on Federal preemption, the Court remanded to the Circuit Court of Montgomery County with instructions to dismiss.

[3] The Court conceded that the sick monkeys, two of whom had died, had been abandoned to the care of night security guards. The Court, however, opined that while " a physician can be criminally charged for treatment outside the accepted standard of care, the concept does not yet apply to the treatment of animals in New Mexico. It is patently clear that we treat animals differently than humans." (p.11) Accordingly, the Court, an intermediate appellate court, affirmed the District Court's pretrial order dismissing the state animal cruelty charges against Charles River Laboratories and Dr. Lee. The case is currently on appeal to the highest appellate court of that state, the New Mexico Supreme Court.

> "On September 16, 2002, Ashley was attacked from all sides in her cage by her eleven cage mates, evidently during the Lab's regular business hours, and suffered a wound to her perineal sexskin. Following the attack, Ashley was moved to a treatment area where she bled continuously throughout the day. In the afternoon, during a five-minute period of observation, she was observed standing on her head and shaking in a continuous and violent manner. Around 3:30 p.m., the animal care workers who were monitoring Ashley, apparently recognizing the need for heightened care, informed the night security guard that he should check on Ashley once an hour instead of the standard once every two hours. The trained care workers then left for the day. When the security guard, who was new to the job and had no animal training care of any kind, expressed concern about the large pools of blood forming on the floor around Ashley, he was told by Dr. Lee, the facility director, and others not to worry. The security guard discovered Ashley dead within hours after the animal care staff had left the facility.
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> Rex had been ill for several months and on December 30, 2002, failed to regain consciousness after being anesthetized for a physical examination the previous day. He was vomiting repeatedly, and an animal care worker stayed in Rex's cage for much of the day, removing vomit from his mouth with the aid of a suction-pump machine. Although Rex had never recovered from sedation, the animal care workers left at the end of the day, again telling the security guard to check on Rex hourly instead of every other hour. Rex was later found dead by the night security guard with vomit in his mouth and trachea.
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> On June 26, 2003,Topsy suffered a wound in her sexskin, and bled steadily during the day whenever she would pick at her wound. At the end of regular business hours, she was prescribed Diazepam, and was left in her own cage instead of a sick room where her continued bleeding might have been noticed. The following morning, she was discovered in a pool of fresh blood, and had to undergo an emergency blood transfusion. After having about half of her blood volume replaced, Topsy survived, but her medical records indicate that she was in weakened state for days following the incident."

The Court further noted that the defendant Charles River Laboratories operated the Alamogordo Primate Facility (APF), where Ashley and Rex died and Topsy nearly died, as a housing facility for about 250 chimpanzees that had been effectively retired from invasive biomedical testing research at the Coulston Foundation of Alamogordo and other national research sites:

> " In 2002, the {Charles River} Lab won a ten-year, $42.8 million government contract to maintain and care for the chimpanzees at APF. Many of the chimpanzees had been the subject of various medical testing and had been exposed to diseases and conditions like AIDS and hepatitis." *Ibid.*

Enforcement of violations of the Animal Welfare Act is not the subject of this position paper and therefore will not be analyzed herein but suffice it is to say that, even when the fines are levied, they are insignificant and provide no deterrent – they represent nothing more than a

cost of doing business.[4] Moreover, while Federal law requires research facilities to create Institutional Animal Care and Use Committees ("IACUCs") to oversee the facility's compliance with the Animal Welfare Act, the USDA's Office of the Inspector General, in a 2005 audit report, noted repeated failures of the IACUCs to detect, report, or correct serious problems in research programs. The audit report concluded, among its many critical findings, that (1) the number of research facilities cited for violations of the Animal Welfare Act steadily increased during the period examined, (2) "some IACUCs did not ensure that unnecessary or repetitive experiments would not be performed on laboratory animals" and (3) facility inspections revealed that IACUCs do not effectively monitor the "search for alternative research, veterinary care, review of painful procedures, and the researchers' use of animals".[5] Federal regulations are designed not only to protect animals from cruel research, but also to protect animals from research that is unnecessarily duplicative of previous experiments, causes more than minimal discomfort, distress or pain or can be avoided through the use of alternative methods of testing.[6]

The United States is grossly out-of-step with many other developed countries in its failure to legislate prohibitions on primate research. In 1997, Great Britain banned all biomedical research on great apes: chimpanzees, gorillas, bonobos, and orangutans.[7] New Zealand banned the use of "nonhuman hominids" in research, testing, or teaching in an amendment to its Animal Welfare Act in 1999, unless such research or testing was in the best interest of the nonhuman hominid. A "nonhuman hominid" under the New Zealand statute was a chimpanzee, gorilla, bonobo, or orangutan. In the Netherlands, Article 10E of the Dutch Animal Testing Law enacted in 2002 prohibited any testing after that date on chimpanzees, gorillas, bonobos, or orangutans. In 2003, Sweden banned invasive biomedical research on great apes but not behavioral studies. This ban was enacted in the form of a binding regulation originally passed

[4] On October 2, 2007, the Associated Press reported that in Atlanta, Georgia, USDA inspectors fined the Yerkes National Primate Center at Emory University $15,000 after a macaque monkey died from emphysema related to incorrectly assembled anesthesia equipment. The Department's inspectors had twice previously found substandard conditions in that laboratory, which in 2006 had received approximately $40 million in federal funding for its animal research. On April 30, 2007, the Associated Press reported that Covance Laboratories, a New Jersey based federally funded primate research laboratory, was fined $8,270 by the USDA for numerous violations which included physical abuse, inadequate veterinary care, and inadequate pain treatment.

Under current policy of the Animal and Plant Health Inspection Service (APHIS), which has the responsibility to inspect all facilities covered under the AWA and follow up on complaints of abuse and non-compliance, the Animal Care unit offers a 75% discount on stipulated fines (which, in any event, are not mandatory but agreed to by the violator) as an incentive for violators to settle out of court to avoid attorney and court costs. In addition to the discount, APHIS offered other concessions to violators, lowering the actual amount paid to a fraction of the original assessment. U.S.D.A., Office of Inspector General, Audit Report, "APHIS Animal Care Program Inspection and Enforcement Activities", Report No. 33002-3-SF, September 2005, p. ii.

[5] *Ibid at* p. iii and 19.

[6] 9CFR, Chapter 1, Subchapter A, Part 2, Subpart C, Section 2.31(d)(1) which provides, in relevant part, as follows: "the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals;(ii) The principal investigator 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, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available; (iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;…"

[7] When Great Britain's Home Secretary announced in 1997 that no more licenses would be issued for biomedical research on great apes, he issued the following statement: "(T)his is a matter of morality. The cognitive and behavioral characteristics and qualities of these animals mean it is unethical to treat them as expendable for research."

by the Swedish Board of Agriculture. In December 2005, Austria amended its animal protection laws to ban research on chimpanzees, gorillas and orangutans. While Japan has not yet banned chimpanzee research, there is a moratorium in effect in that country.[8] This enlightened, international trend, in fact, extends beyond primates. As recently as November 20, 2007, it was reported that the European Union has banned animal testing for the cosmetics industry, effective March 2009.[9]

While this humane bill as drafted would accomplish the important and justified objective of terminating the authority to recall surplus chimpanzees from sanctuaries for biomedical research, we recommend, for the same reasons as stated above, that the legislation be expanded to eliminate recall for "behavioral experiments", so that there would be no right to recall the animals from retirement. Currently, the CHIMP Act permits such recall for noninvasive behavioral studies. Sanctuary should mean permanent sanctuary, without loopholes.

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[8] While this memorandum does not purport to analyze whether the use chimpanzees for scientific experimentation is necessary or serves a worthwhile scientific goal that cannot be met by alternative testing methods, we note there is significant disagreement as to the need for subjecting chimpanzees to such testing. See, e.g., *Laboratory Primate Newsletter,* Volume 23 (June 2004); Complaint, *Tufford v. Merck & Co., Inc.,* Case #619 of Vioxx Litigation (filed July 11, 2005); Statement of Albert Sabin, M.D., before U.S. Congress House of Representatives, Committee on Veterans' Affairs, Subcommittee on Hospitals and Health Care, April 26, 1984, Serial No. 98-48, quoted by former animal researcher C. Ray Greek, M.D., in "Sacred Cows and Golden Geese: The Human Cost of Experiments on Animals", C. Ray Greek, M.D. and Jane S. Greek, D.V.M., Continuum International Press, 2000 (Dr. Sabin, creator of one of the most effective polio vaccines, testified that experiments with polio vaccines on monkeys had retarded, not hastened, the development of the vaccine. He referred to the "erroneous conception of the human disease based on misleading experimental models of the disease in animals").

We note that alternative methods of testing drugs include: *in vitro* testing using human cells and tissues (conducted in cultures), computer models to analyze structure-activity relationships and potential toxicity, computer simulation programs, and recombinant DNA and stem cell technologies. *Tufford v. Merck & Co., Inc., supra;* C. Ray Greek, M. D. and Jane S. Greek, D. V. M., "Sacred Cows and Golden Geese: the Human Cost of Experiments on Animals", International Continuum Press, 2000.

In the specific area of toxicological tests, Congress has already mandated this result in the passing of the ICCVAM Authorization Act of 2000. Pursuant to that Act, the Interagency Coordinating Committee on the Validation of Alternative Methods ("ICCVAM") was formed with a stated purpose, among other things, to "reduce, refine, or replace the use of animals in testing, where feasible." 114 Stat. 2722, Public Law 106-545, Sec. 3(b)(5). The Act's purpose is "To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness." Under that Act, the term "alternative test method" means a test method that (A) includes any new or revised test method; and (B) (i) reduces the number of animals required; (ii) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or (iii) replaces animals with non-animal systems or one animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate". Public Law 106-545, Section 2(1).

See also 9 CFR, Chapter 1, Subchapter A, Part 2, Subpart C, Section 2.31(d)(1), *supra at* Ftne. 6.

[9] Carvajal, D., 'A New Science, at First Blush: Cosmetics Makes Turn To Artificial Skin To Replace Animal Testing', *New York Times*, 20 November 2007, C1. Similarly, *The Jerusalem Post* reported that the Knesset in Israel passed a law on May 21, 2007, effective immediately, outlawing all animal testing for cosmetic and cleaning products.