



IN DEFENSE OF ANIMALS Cover Page Plus Five Pages of Testimony

Prepared Testimony Regarding the National Institutes of Health and The Coulston Foundation

Submitted to

**The Subcommittee on Labor, Health and Human Services,
Education and Related Agencies, House
Committee on Appropriations**

on March 20, 2000 by

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Eric Kleiman is a public witness scheduled for oral testimony before the Subcommittee on March 21, 2000 at 2:00 p.m. in Room 2358 of the Rayburn House Office Building.

Eric Kleiman has been Research Director for In Defense of Animals, an international animal protection group, since December 1994.

In Defense of Animals has not received any federal funds during the current fiscal year, or the previous two fiscal years.

**This Testimony will be publicly available March 21, 2000
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In Defense of Animals (IDA) appreciates the privilege of testifying before the Subcommittee. IDA is an international animal protection organization that has investigated The Coulston Foundation (TCF), the world's largest chimpanzee colony, as well as the National Institutes of Health's (NIH) failure to provide federally mandated oversight of NIH-funded laboratories. During the past five years, IDA has provided evidence regarding TCF's negligence and violations of federal law to the U.S. Department of Agriculture and the Food and Drug Administration. These agencies have used this evidence to take extraordinary, repeated legal actions against TCF.

This testimony will document TCF's record of unparalleled animal welfare negligence as well as its violations of data integrity and human safety regulations. We will focus on the NIH's continued mishandling of TCF's violations of federal law even as the chimpanzees continue to die due to negligence. In closing, we will suggest solutions to the escalating crisis at this federally supported laboratory.

TCF's Record of Negligence: Federal Regulatory Agencies' Findings and Private Industry Actions

USDA – TCF is the only facility in history to have had three sets of formal USDA charges (7/95, 3/98, 2/99) filed against it for multiple violations of the Animal Welfare Act (AWA) relating to primate deaths caused by negligence. The USDA has documented repeated, facility-wide failures to provide adequate veterinary care, staffing and monitoring. The USDA has also documented inadequate research oversight and numerous physical plant and sanitary violations. These violations have been associated with the deaths of at least 14 chimpanzees.

- Terrance, Muffin and Holly died from the well-known side effects of a drug that was later tested in children.
- Donna, a former Air Force chimpanzee, died on November 9, 1999 due to carrying a large, dead fetus inside her womb for up to two months. TCF veterinarians removed one liter of pus from her abdomen during a belated C-section and reported seeing the skull of her decomposed fetus through the ruptured wall of her necrotic uterus.
- Another chimpanzee died during a drug study after losing 29 per cent of his body weight in just 2-4 weeks (three other chimpanzees lost similar life-threatening amounts of weight). Responding to the FDA's citation of these violations, TCF actually told the agency that the lab had "anticipated" this fatal weight loss.

On 8/24/99, TCF signed an unprecedented settlement decree with the USDA that mandated the facility divest 300 chimpanzees by 2002; provide adequate veterinary care and staffing; and restrict breeding. However, at least seven chimpanzees have died since TCF signed the decree, prompting USDA's seventh official investigation in as many years. Three months ago, the USDA cited TCF for failing to provide adequate veterinary care, the fourth such citation in less than two years, and found that TCF had only 2.4 clinical veterinarians to care for 650 chimpanzees and 300 monkeys. *Last month TCF was cited for illegally denying two USDA inspectors access to its laboratory.*

FDA – In August 1999, FDA investigators documented more than 270 violations of Good Laboratory Practice (GLP) regulations at TCF on just three studies reviewed. According to the FDA, GLP regulations exist to ensure data integrity and human safety. The FDA confirmed many of the USDA's findings, and identified new violations of animal welfare laws. On 12/22/99, the FDA issued a rare Warning Letter, finding the conditions at TCF to be "serious violations" with "wide spread consequences" for data integrity and human safety, and ordering TCF to halt all new GLP studies until the violations are corrected.

IDA believes these GLP violations have significant human safety implications and call into question the validity of every study ever conducted at TCF, including those funded by the NIH. For example, one of the three studies in which the FDA found multiple GLP violations apparently involved a drug, TXU-PAP, that was tested in children with cancer after the chimpanzees Terrance, Muffin and Holly had died at TCF on tests of this same drug. Fatih Uckun, who is NIH funded, helped sponsor these tests of TXU-PAP at TCF. Last December Uckun published an article about TXU-PAP's toxicity, claiming it had minimal side effects. Disturbingly, the article failed to mention that three of seven chimpanzees at TCF had died on tests of this drug.

AAALAC – In a February 1998 site visit to TCF, the Association for Assessment and Accreditation of Laboratory Animal Care International found fundamental problems related to deficient veterinary care, staffing, training and experience; deficient research oversight; and numerous physical plant violations. AAALAC is a universally recognized body of experts that evaluates animal research laboratories for compliance with the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals and the AWA, and accredits those facilities that meet its criteria. Its February 1998 findings mirrored those of the USDA and prompted AAALAC to reject TCF's application for accreditation. As documented by the USDA and the FDA, these deficiencies have continued to worsen since AAALAC's inspection two years ago. These findings directly contradict the NIH's, and demonstrate that TCF has been in continual violation of both the AWA and PHS Policy since at least February 1998.

AAALAC's importance to the NIH's regulatory framework cannot be overstated. AAALAC uses as its main accreditation criterion the *NIH Guide for the Care and Use of Laboratory Animals* – the very same *Guide* that the NIH is supposed to use to enforce PHS Policy. Gaining AAALAC accreditation is specifically mentioned in PHS Policy as one of two methods for a facility to assure PHS Policy compliance – required for receipt of PHS funds. If a facility is in violation of the *Guide*, it is in violation of PHS Policy, and cannot receive PHS funds. In 1994, the NIH site visitors told TCF it should achieve AAALAC accreditation in 3-5 years. *The actions of AAALAC, the USDA and the FDA demonstrate that TCF has been in chronic violation of the AWA and PHS Policy since at least 1998.* Despite these findings, the NIH has illegally funded TCF with millions in taxpayer funds since that time.

Private Industry Actions – Private drug companies have ended associations with TCF in light of the facility's record. Chiron Corp., the world's second-largest biotech company, severed ties with TCF because of animal welfare concerns. Last year, Pfizer did not proceed with a proposed study after being informed of TCF's record. Other companies have followed suit. According to documents obtained by IDA under the Freedom of Information Act (FOIA), TCF officials told the NIH last April that the lab had been steadily losing private contracts for more than a year. Notes from a 3/16/99 NIH meeting indicate that TCF CEO Fred Coulston had told the USDA that "no major company wants to work with us" because of the USDA charges. The comments of TCF officials demonstrate that TCF's regulatory problems have driven away industry funding.

The USDA. The FDA. AAALAC. Private industry. Practically every recognized inspection, regulatory, accrediting or funding body has found fundamental problems with TCF's compliance with federal law and scientific standards, with one conspicuous exception: The NIH, which has continued its taxpayer-funded support of TCF.

The NIH's Record: Deficient Oversight, Public Misrepresentation, and Unlawful Financial Support of TCF

Overview of NIH Actions – The NIH has essentially ignored the findings of the USDA, the FDA and AAALAC. The agency has misled Congress – including Speaker Hastert – as well as the public regarding TCF. It has told this Subcommittee that on-site visits by NIH veterinarians had shown chimpanzees in good health. But the agency did not report NIH audit/site visit findings of serious financial and veterinary staffing problems, or that other regulatory agencies have documented serious animal welfare, data integrity and human safety violations. And the NIH has violated the FOIA by withholding hundreds of pages of TCF-related information after IDA filed a FOIA request. Only *after* IDA filed a federal lawsuit did the NIH not only uncensor nearly 70 pages of information, but also *then locate approximately 1,000 additional pages responsive to IDA's request.*

Despite public pronouncements, internal documents obtained under FOIA indicate that the NIH Office of Director (OD) staff found the TCF situation "*VERY explosive.*" An April 1999 OD email stated, "*This one has the potential to be a nasty oversight issue, particularly with the endowment funds apparently having been spent for other purposes. This could be another NIH management problem if they think that we have not been diligent in our oversight of contracts.*" Internally, the NIH was so concerned about TCF that then-NIH Director Harold Varmus specifically "tasked" the deputy director of the National Center for Research Resources (NCRR) to deal with the situation. To the public and Congress, however, the NIH continues to whitewash the rapidly deteriorating situation at TCF. The NIH also continues to fund TCF through existing contracts and subcontracts, *as well as an additional \$1.1 million in publicly funded "supplemental awards" intended to avert bankruptcy at this private laboratory.*

NIH Mandates under Federal Law – Several legal mandates govern the NIH's oversight responsibilities with regard to animal facilities. One is the 1985 Health Research Extension Act (HREA), which mandates that the Director of the NIH "shall suspend or revoke" PHS funds to any facility that, after being given a "reasonable opportunity to take corrective action," has failed to correct identified violations of animal welfare laws. Another is the Animal Welfare Act, which states that if animal care is not in compliance with standards under the Act, despite an opportunity for correction, then the federal funding agency "shall suspend or revoke Federal support of the project." NIH is also governed by a Memorandum of Understanding between the FDA, the USDA and the NIH that requires the agencies to share information to help ensure compliance with animal welfare laws.

TCF has been given *far more* than a "reasonable opportunity" to correct its transgressions. The NIH Director has a legal mandate to "suspend or revoke" PHS funding to this chronically noncompliant facility.

Responsibility for ensuring that PHS grantees comply with federal animal welfare laws rests with the Office for Protection from Research Risks (OPRR). This office has failed in its oversight responsibilities. According to OPRR documents obtained thus far by IDA, *every single charge contained in the USDA's March 1998 and February 1999 formal complaints against TCF either totally contradicts, or is not even investigated by, the OPRR.* Yet, OPRR's Division of Animal Welfare Director, Nelson Garnett, publicly stated in April 1998 that his office's findings were

“very consistent” with the USDA’s, and that TCF had fixed its problems and was in compliance with PHS Policy. Garnett’s statements are incredible in light of the fact that they were made less than *two months* after AAALAC had found fundamental, facility-wide deficiencies using the *very same NIH Guide* that OPRR is supposed to use when assessing a grantee’s compliance with PHS Policy. OPRR also claimed in a 3/16/99 meeting that it had no punitive mechanisms available in the TCF matter, *despite the “suspend or revoke” mandates in the HREA and the AWA.*

The NIH’s funneling of millions of taxpayer dollars to TCF since at least February 1998 is illegal. *The NIH has not only continued existing funding, but has actually approved new funding over the past two years.* The NIH has abandoned its federally mandated oversight and financial stewardship responsibilities.

NIH Internal Findings vs. Public Pronouncements – Internal documents reveal that the NIH has funneled millions of taxpayer dollars to TCF despite being aware of the lab’s financial, managerial and animal care problems. An April 1999 NIH site visit/audit found that TCF had \$800,000 in unpaid bills; \$2.6 million in outstanding loans; had been bringing in, *at most*, only one-third of the cash flow needed to keep it solvent; and was on the verge of bankruptcy. CEO Fred Coulston, who had sunk \$6.8 million of his own money into TCF, could no longer personally pay the \$200,000 monthly payroll. Auditors found it unlikely that TCF “could operate much more than two or three months longer.” The NIH describes TCF’s financial situation as “very precarious,” “severe,” “grim,” and “dire,” with remaining staff being paid paycheck to paycheck. TCF vice-president Ali Javadian expressed concern that if TCF filed bankruptcy, no sponsor would deal with them. He had earlier told NIH-funded researcher Patricia Fultz that he was concerned about TCF’s ability to care for its chimpanzees.

The NIH also found animal care deficiencies in its site visit report: “Veterinary care is problematic,” it said; the three full-time veterinarians were “very junior with no formal training in primate medicine, and may be inadequate for the job at hand.” Since 1994, 16 veterinarians with over 60 years of combined clinical chimpanzee experience have left TCF. Two of the three veterinarians cited in the April 1999 site visit have since left; their replacements apparently have even less chimpanzee experience.

NIH auditors also concluded that *TCF management had “expended” millions of taxpayer dollars in endowment funds meant for the long-term care of specific chimpanzees.* NIH emails worried about the “very explosive” situation, and the “nasty” oversight issues it raised. NIH documents indicate that CEO Fred Coulston had repeatedly misled NIH, “made many contradictory statements,” did “not appear to have faced the reality of his dire financial situation,” and specifically blamed In Defense of Animals for the lab’s funding losses. NIH also stated that then-TCF president Ron Couch was “evasive,” unfamiliar with the facilities, had told the funding agency that the \$800,000 in unpaid bills was none of its business, and last April misrepresented TCF’s financial situation to the Centers for Disease Control and Prevention. TCF management had earlier told the NCRR it was also none of the agency’s business how TCF uses millions of dollars in taxpayer-funded chimpanzee endowments. The NIH auditors had also found multiple irregularities with previous TCF contracts.

The USDA and the FDA have echoed the NIH’s internal concerns about TCF’s management. *In fact, TCF officials were apparently so uncooperative during the course of an official USDA investigation that agency lawyers were forced to draw up a subpoena in order to obtain necessary information.* Despite these documented management problems, the NIH continues to fund TCF – and even props it up with at least \$1.1 million in taxpayer money.

In its public pronouncements, the NIH has downplayed these fundamental problems. Last year, the NIH told Speaker Hastert that the April 1999 NIH site visit found that “In general, the facilities were acceptable at all sites.... All of the animals appeared to be in good physical condition...and were receiving good care by an attentive animal care staff.” This statement misrepresents the findings of the NIH site visitors recounted above; it ignores the formal USDA charges that were filed just two months prior; and it contradicts the scathing findings of the AAALAC site visit team. The statement also carefully omits reference to TCF’s veterinary staffing, which this same NIH site visit described as “problematic” and lacking both experience and training. The NIH knew that TCF’s veterinary staffing and care were deficient and at the heart of the laboratory’s animal care problems.

In a February 1999 written response to an inquiry from Rep. Carolyn Maloney (D-NY), the NIH stated that in 1994, NIH site visitors had recommended that TCF achieve AAALAC accreditation in 3-5 years, but then told Rep. Maloney that “Subsequent site visits have indicated continuing progress has been made toward that goal.” *The NIH told this to a member of Congress after AAALAC had already rejected TCF’s accreditation application.* Internal emails show that AAALAC’s rejection of TCF was common knowledge at the NIH.

The NIH testified before this Subcommittee last month that NIH veterinarians had visited TCF and found the health of the chimpanzees to be good. The record as described above speaks for itself regarding this statement to the Subcommittee. The NIH also testified that it was willing to take the 300 chimpanzees that TCF must divest under

the USDA settlement, but claimed that an unnamed legal hurdle prevented such action. However, the USDA settlement is a legally binding decree in which TCF is mandated to divest 300 chimpanzees to “acceptable” facilities. The NIH should explain the legal hurdle.

NIH Financial Support – Concerns about major changes in TCF’s animal care program, and the number and credentials of its veterinarians, prompted the OPRR on February 22, 1999 to place a restriction on TCF’s eligibility to receive federal funds. The “restriction” required TCF to hire seven “fully qualified” veterinarians, and that PHS-funded activities be conducted only by veterinarians trained and experienced in the care of the species being used. More than one year later, TCF’s veterinary staffing situation is worse than when OPRR issued its restriction. TCF’s failure to comply with this restriction should disqualify the lab from receipt of federal funds. The NIH, however, has failed to enforce its own restriction and has actually *increased* its support to TCF. In fact, the NIH has granted \$1.1 million in “supplemental awards” to TCF despite the laboratory’s failure to comply with the OPRR restriction.

1. “Regular” NIH/FDA Funding – IDA estimates that since 1993, TCF has received over \$30 million in PHS funds, including over \$10 million to breed chimpanzees for both the NCRR and the FDA.

2. “Supplemental Awards” – Since 6/11/99, the NIH has paid at least \$1.1 million in “supplemental awards” to this private laboratory despite its management problems, chronic noncompliance with federal law and apparent misuse of millions in taxpayer funds. A 6/16/99 letter from the NCRR clearly indicates that the NIH has given these awards to “prop up” TCF because of its dire financial condition; others mention its financial instability. Emails talk of “possible options and next steps to mitigate the financial situation” at TCF and express concern about “where the short-term money might come from.” These supplemental awards, *clearly intended to avert TCF bankruptcy*, are in addition to the estimated \$1 million the lab currently receives annually for NIH contracts. At least \$400,000 of these awards has come from the NIH OD’s budget. Whether or not these supplemental awards have been peer-reviewed or if they are even legal is unclear. According to NIH documents, the NCRR encouraged TCF, a private lab, to use these “supplemental awards” to pay off debts to subsidize its general operations, instead of using these taxpayer funds for specific NCRR contract purposes and costs.

The NIH may claim that it has continued to support TCF because of its concern about the chimpanzees’ welfare. However, in a March 16, 1999 meeting, NIH officials stated that they had “great concern about long-term situation/animals at serious risk” at TCF. A year has passed since this statement of professed concern, nine months have passed since the NIH began taxpayer-funded subsidies to prevent TCF’s bankruptcy, yet conditions at the laboratory have actually worsened:

- At least seven chimpanzees have died;
- The USDA is again officially investigating the facility for the death of Donna and possibly others;
- The FDA has issued a severe Warning Letter after finding hundreds of GLP violations;
- The USDA has cited the facility (for the fourth time in less than two years) for inadequate veterinary care related to the deaths of four chimpanzees, and documented only 2.4 clinical staff veterinarians;
- TCF has illegally refused access to USDA inspectors, and repeatedly violated the terms of its August 1999 settlement decree with the USDA;
- TCF president David Renquist, who had been brought in specifically to “clean up” TCF’s regulatory mess, resigned on March 2 after less than six months on the job. TCF has now had four presidents in 16 months.

3. New Subcontracts – Two new subcontracts – one approved in August 1998 for NIDDK-funded prostate research (Mitchell Steiner, P.I.), the other in May 1999 for NIAID-funded hepatitis C research (Christopher Walker, P.I.) – sailed through NIH’s peer review process despite TCF’s animal care problems and legal violations. The March 1998 second set of USDA charges was not mentioned *even once* during the entire peer review process of the Steiner subcontract. Walker’s grant was approved by a special NIDDK panel *just two months* after the USDA had filed its *third* set of formal charges and the OPRR had placed its restriction on the facility. Peer reviewers are required to consider animal welfare compliance as part of the grant awards process. To do so, they and principal investigators rely on OPRR oversight to assure compliance. As demonstrated above, the OPRR has failed entirely to meet its oversight responsibilities, corrupting the peer review process and enabling the NIH to continue to subsidize a laboratory that has been in chronic noncompliance with federal law for at least two years.

Suggested Solutions

Stop NIH Subsidies of TCF – The record documented by AAALAC, the USDA and the FDA shows that continued NIH funding of TCF cannot be legally justified. Only Congress has the power to prevent the NIH from continuing to fund this chronically noncompliant laboratory.

Investigate NIH's Oversight Failures – IDA has only been able to scratch the surface of this scandal that reaches the highest levels at the NIH. Only Congress has the power and authority to step in and demand accountability from the NIH for the taxpayer dollars it expends. We urge Congress to pursue the problems set forth in this testimony through an investigation, oversight hearing and/or a General Accounting Office investigation. IDA also urges Congress to examine the wisdom of continuing to fund the OPRR's Division of Animal Welfare, which has failed consistently to uphold its legally mandated responsibilities.

Develop a Plan for the Retirement of Chimpanzees in Research – TCF is symptomatic of a larger problem: what to do with the hundreds of “surplus” chimpanzees currently being warehoused in U.S. laboratories. The situation at TCF is an example of what happens when government has no vision for dealing with this issue, and when the NIH is allowed to sweep wrongdoing under the rug. It is time for our elected representatives to clean up the mess the NIH has enabled at TCF, and to prevent any more debacles like the TCF situation from occurring.

Since 1986, NIH has spent an estimated \$70 million to breed chimpanzees. The scientific community now widely recognizes that a surplus of chimpanzees in research exists. There is general agreement about the need to retire these animals. It is widely accepted that society and the scientific community have a special moral and ethical obligation to chimpanzees because of their close similarity to humans. But funding and vision are lacking to accomplish this goal. Federal funding for chimpanzee retirement makes sense because (1) it is less expensive than maintaining chimpanzees in laboratories, and (2) it would free up resources currently being spent on warehousing these animals. Permanent, private sanctuaries would also provide a permanent solution to this problem.

The broad consensus on this issue was reflected in the 1997 National Academy of Sciences (NAS) report on chimpanzees in research, which was commissioned by the NIH. The report talked about a “moral responsibility for the long-term care of chimpanzees” used in research. It stated that “Sanctuaries offer an opportunity for substantially reducing costs of long-term” care of chimpanzees no longer used in research, and that “This committee enthusiastically supports the principle of retiring chimpanzees not needed for research or breeding to a low-cost, high-quality life.” It also discussed retiring hundreds of chimpanzees and recommended a yearly budget of \$7.3 million to support 1,000 chimpanzees. To date, the NIH has ignored the panel's recommendation by stating publicly that it has no plans to fund chimpanzee retirement. Instead, the NIH plans a yearly budget of \$4.2 million to support approximately 600 chimpanzees and has presented no plan regarding the other 1,000 chimpanzees in federally funded laboratories.

Short-Term Solution – Currently, TCF is under federal order to divest 300 chimpanzees. At least 400 TCF chimpanzees are not on any current or anticipated protocol. TCF currently leases chimpanzee housing facilities on Holloman Air Force Base that were built with \$10.5 million in taxpayer funds. One logical solution is for Congress to appropriate funds to take over this facility and retire the mandated 300 animals there until sanctuary space can be built to accommodate them. The buildings, chimpanzees, personnel and the USDA decree are all in place. An emergency appropriation of \$5 million would be sufficient to support 300 chimpanzees on Holloman for three years. The 300 chimpanzees should be legally transferred from TCF to a nongovernment entity for permanent retirement. Due to its record in this matter, the NIH's involvement should be limited to funding; the agency has demonstrated a total lack of oversight, and cannot manage a chimpanzee colony. To ensure the welfare of the chimpanzees, animal protection organizations should be given a meaningful role in helping shape a solution to this problem.

Long-Term Solutions:

(1) Passage of the Chimpanzee Health Improvement, Maintenance and Protection Act (H.R. 3514) to create a network of federally supported private sanctuaries to retire permanently chimpanzees formerly used in research is a critical component of any solution to the escalating chimpanzee problem. The PHS has spent hundreds of millions of taxpayer dollars to breed and infect chimpanzees. Overbreeding and mismanagement by the NIH are primarily responsible for creating this crisis. Federal funding for chimpanzee retirement – perhaps a combination of congressional appropriation and money from the NIH's budget – would represent a tiny fraction of the federal funds used to breed and experiment on chimpanzees over the past few decades. Former NAS official Thomas Wolfle was correct when he said that the NIH is “morally responsible” for caring for the chimpanzees it paid to breed and infect. It is time to live up to our moral obligations, first by permanently retiring the Coulston chimpanzees to a private entity, and then by passing the CHIMP Act to provide long-term care and permanent, private retirement to the hundreds of chimpanzees who remain warehoused in labs.

(2) End breeding and phase out research on chimpanzees. We join with leading scientists such as the world-renowned Jane Goodall who advocate a phase-out of biomedical research on chimpanzees – humankind's closest genetic cousins and an endangered species – for scientific, financial and moral reasons.