BEFORE THE NATIONAL INSTITUTES OF HEALTH

In re: Southwest National Primate Research Center
   Alamogordo Primate Facility

Docket No. __

PETITION FOR ADMINISTRATIVE ACTION

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Date:

March 3, 2011

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1. **Action Requested**

This petition requests that the director of the National Institutes of Health ("NIH") exercise his authority to return 14 chimpanzees from the Southwest National Primate Research Center ("SNPRC") in San Antonio, Texas, to the Alamogordo Primate Facility ("APF") at Holloman Air Force Base in Alamogordo, N.M. The host institution for SNPRC is the Texas Biomedical Research Institute ("Texas Biomed"), formerly the Southwest Foundation for Biomedical Research. Until the middle of last year, these chimpanzees lived for nearly a decade at APF, where they were part of a large colony of chimpanzees free from invasive experiments. In June and July of 2010, NIH transferred these chimpanzees from APF to SNPRC, where they are now at risk of being subjected to invasive experiments. As set forth below, the director’s decision to transfer these 14 chimpanzees was arbitrary and capricious, in violation of the federal Administrative Procedure Act.¹

2. **The 14 Chimpanzees Recently Moved to SNPRC Are Part of the APF Group and Should Be Returned to Alamogordo**

Between the 1950s and the early 1970s, the U.S. Air Force maintained a colony of chimpanzees at Holloman Air Force Base. The Air Force used the chimpanzees in military flight experiments, space flight experiments, and decompression experiments until the early 1970s.² In 1972, the Coulston Foundation leased the chimpanzees for toxicology testing, preclinical drug testing, and infectious diseases experiments.³ Over the years, researchers exposed the chimpanzees to a variety of diseases, including hepatitis C and the human immunodeficiency virus ("HIV").⁴ NIH stopped funding the Coulston Foundation in 2000, after which ownership of 288 chimpanzees was transferred to the National Center for Research Resources ("NCRR"), a component of NIH.⁵ NIH then awarded Charles River Laboratories ("CRL") a $42.8 million, 10-year contract to operate the Holloman Air Force Base installation, now known as the Alamogordo Primate Facility, through 2011.⁶

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In 2010, NIH announced its intent to transfer to SNPRC all of the 200 chimpanzees then living at APF. In June 2010, CRL transported six male chimpanzees ranging in age from 17 to 28 to SNPRC. CRL transported eight additional chimpanzees—four females (ages 19 to 29) and four males (ages 25 to 28)—the following month. All 14 chimpanzees are infected with the hepatitis C virus.

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NIH’s plan to move the remaining 186 chimpanzees to SNPRC by 2011 generated intense public opposition, including a letter from U.S. Sens. Jeff Bingaman, D-N.M., Tom Udall, D-N.M., and Tom Harkin, D-Iowa; a petition and news conference by then New Mexico Gov. Bill Richardson; and letters from tens of thousands of citizens nationwide. On Dec. 31, 2010, NIH informed Gov. Richardson that NIH would not transfer the 186 chimpanzees until the Institute of Medicine (IOM) first completes a newly scheduled review of policies related to the use of chimpanzees in experiments, a process expected to take up to two years. NIH issued the following formal statement several days later:

The National Institutes of Health has determined that the chimpanzees currently located at the Alamogordo Primate Facility on the Holloman Air Force Base in Alamogordo, New Mexico, will remain there pending an Institute of Medicine (IOM) in-depth analysis to reassess the scientific need for the continued use of chimpanzees to accelerate biomedical discoveries. During this time, the Alamogordo chimpanzees will not be used in invasive research … The thoughtful analysis and rigorous review

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anticipated from the IOM report will be a valuable means to address this issue.\(^9\)

NIH’s reversal of position is a clear indication that its decision to transfer the first 14 chimpanzees to SNPRC last year was arbitrary and capricious, in violation of the Administrative Procedure Act (“APA”), a federal law that governs the conduct of administrative agencies. The APA provides for judicial review, and if necessary reversal, of agency decisions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”\(^10\) NIH’s recent conduct fails to meet this basic standard.

Inherent in NIH’s call for a reassessment of major research policies is NIH’s recognition that there may be no scientific need for the continued use of chimpanzees in experiments. As set forth below, continued use of chimpanzees is counter to the goals of advancing human health research. Therefore, NIH’s transfer of the first 14 chimpanzees was an abuse of discretion.

No new scientific development triggered NIH’s need for a reassessment of its research policies. The use of chimpanzees in experiments has steadily declined because chimpanzees are poor models to use in human health research and extremely expensive to support in the laboratory. As such, the rigorous reassessment that NIH called for in December was also necessary a few months earlier, when NIH transferred the first 14 chimpanzees to SNPRC. In fact, a June 24, 2010, letter from Barbara Alving, M.D., director of NCRR, clearly shows that NIH viewed the remaining 200 APF chimpanzees as a single population.\(^11\) In the letter, Dr. Alving stated that “[t]he projected timeline is that 14-15 animals will be moved this summer to existing facilities at Southwest and that the remaining animals will be moved around January 2011.”\(^12\) NIH’s transfer of chimpanzees prior to conducting this reassessment was arbitrary and capricious.

NIH’s formal statement explicitly says that NIH will not use the 186 chimpanzees at APF in invasive experiments while the reassessment is underway. Conspicuously absent from the statement is a similar pronouncement regarding the 14 chimpanzees that NIH transferred to SNPRC just prior to scheduling this reassessment. The reassessment and the IOM report will apply equally to all NIH-sponsored chimpanzee experiments. Likewise, NIH must apply the same standards to all of the chimpanzees under its control by moving the transferred 14 chimpanzees out of SNPRC, where they can be subjected to invasive experiments. NIH’s inconsistent application of its own research standards is arbitrary and capricious.

Given the expected two-year duration of the scheduled reassessment and the likelihood that the reassessment will significantly change NIH’s research priorities, the only remedy

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\(^11\) Unpublished letter from Barbara Alving, M.D., director of the National Center for Research Resources, to Senator Tom Udall, June 24; 2010.

\(^12\) Ibid.
to NIH’s arbitrary and capricious actions is to return the 14 chimpanzees now at SNPRC to APF, thereby restoring the APF chimpanzee colony to its status prior to NIH’s conduct.

3. SNPRC’s Research of Fatal Diseases Poses Great Risk to the APF Chimpanzees

SNPRC is the only national primate experiment facility with access to a biosafety level 4 (“BSL-4”) rated installation, which means animals at the facility are at risk of exposure to highly contagious diseases for which no known treatment exists, such as Ebola, Marburg, and Dengue fever. Statements by SNPRC scientists support the idea that the APF chimpanzees are in jeopardy of use in these types of experiments.

On Sept. 24, 2010, the San Antonio Express-News reported that John VandeBerg, SNPRC’s director, “said the chimps would help in studies of hepatitis B and C, AIDS and the Ebola virus.” The article went on to quote Dr. VandeBerg as saying, “These chimpanzees are needed in research.” This reflects statements made by two Texas Biomed researchers in a 2004 paper entitled Demand for Nonhuman Primate Resources in the Age of Biodefense. In that paper, Jean Patterson, Ph.D., and Ricardo Carrion Jr., Ph.D., chair and staff scientist, respectively, in the Department of Virology and Immunology at Texas Biomed, stated that “[n]onhuman primates are the preferred animal model for the study of human filovirus infection.” Filoviruses include Ebola and Marburg and cause hemorrhagic fever often characterized by severe joint and muscle pain, bloody emesis, and diarrhea.

Despite the severity of these diseases, according to a September 2008 Government Accountability Office (“GAO”) report, the Texas Biomed BSL-4 lab “demonstrated a significant lack” of security controls, such as “perimeter barriers, roving armed guard patrols, and magnetometers in use at lab entrances.” While Texas Biomed touts the “safe environment” provided by its BSL-4 installation, the GAO report raises serious concerns about whether the facility can properly contain deadly diseases.

4. SNPRC Has a History of Animal Abuse

The risk to the 14 APF chimpanzees who were moved to San Antonio in 2010 is further amplified by SNPRC’s years-long pattern of animal cruelty and neglect. Since July

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15 Ibid.
2006, SNPRC has been cited for at least 30 violations of the federal Animal Welfare Act (“AWA”), the law that sets minimum standards of care for animals in laboratories. This track record is proof that NIH’s plan is not only scientifically and financially misguided but also poses serious risks to the health of the 14 chimpanzees.

On Aug. 28, 2006, SNPRC staff was 10 minutes into a necropsy of a male baboon before discovering that he was still alive. This incident highlights the widespread lack of proper animal care at a facility that currently houses more than 3,000 nonhuman primates. Not only did staff fail to identify whether the baboon was dead before beginning the necropsy, but the committee charged with overseeing all aspects of animal care at SNPRC—the Institutional Animal Care and Use Committee (“IACUC”)—failed to report the incident to facility administrators. In addition, according to a U.S. Department of Agriculture (“USDA”) inspector, “there was no further investigation into the incident by the IACUC.”

Further bringing into question the IACUC’s ability to maintain minimum standards of oversight at SNPRC is its attitude when examining research protocols and requiring that they adhere to the AWA. On July 13, 2006, a USDA inspector discovered that a researcher planned to perform multiple cesarean sections on the same animal without any justification given to the USDA—the minimum standard required by the AWA when performing multiple survival surgeries on the same animal. The inspector ordered that this be corrected within one month, but when she returned more than four months later she discovered that no such justification had been sent. The USDA did not receive a written letter until February 2007—seven months after the original violation was cited. Meanwhile, the SNPRC IACUC allowed the protocol to continue.

More recently, in February 2010, a USDA inspector cited SNPRC for inadequate housing that allowed a young rhesus macaque to escape his enclosure at night when temperatures were below freezing. The following morning, the animal was found “moribund” and was euthanized likely due to the results of hypothermia. The USDA’s most recent

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21 Ibid.
22 Ibid.
26 Ibid.
28 Ibid.
inspection of SNPRC on May 13, 2010, revealed that multiple baboons had recently escaped their enclosures while being moved, injuring employees.29

The SNPRC track record of hazardous animal husbandry standards, inability to meet even the most basic requirements of the AWA, and its IACUC’s lack of oversight make it a dangerous place to house APF chimpanzees. Because SNPRC cannot properly care for the animals it currently houses, it was irresponsible of NIH to give the facility 14 more great apes, and the animals should be returned to APF.

5. Chimpanzees Are Not Appropriate Models for Human Disease Research

Chimpanzees have been used as human disease models for decades, and current uses focus primarily on the development of vaccines and treatments for a variety of infectious diseases. SNPRC has promoted and planned the use of nonhuman primates (including chimpanzees) for the study of vaccines and treatments for HIV/AIDS; hepatitis C; malaria; filoviruses such as Ebola and Marburg; flaviviruses such as Dengue; arenaviruses such as Lassa; hantaviruses; and bacterial diseases such as anthrax, tularemia, and plague.30 The chimpanzees transferred from APF to SNPRC in 2010 are at risk for inclusion in these experiments. The use of chimpanzees for such experiments has been widely criticized, and one goal of the pending IOM report is to determine if the use of chimpanzees for these purposes should be ended.

Although chimpanzees are humans’ closest genetic relatives, there are nonetheless tens of millions of genetic code differences between our species, as well as important evolutionary differences in human and chimpanzee transcriptomes,31 including significant differences within individual shared genes, as well as differences in the arrangement of genes and in gene expression and protein function.32 These and other genetic differences can in turn produce immutable differences in the acquisition, mechanisms, natural history, prevention, and treatments of many human diseases “modeled” in chimpanzees and other nonhuman primates.33 These diseases include but are not limited to those listed below as examples. Chimpanzee-based experiments on these and other human diseases have failed to significantly advance human health.

32 De et al., “The Impact of Genomic Neighborhood.”
Chimpanzees are very expensive animals to use for experiments, which leads to small sample sizes, further confounding data. Their use in experiments also raises profound ethical concerns, as chimpanzees in laboratories often suffer from serious psychological disorders and experience high morbidity and mortality rates due to their confinement and use in experiments.\(^{34}\)

### 5.1. Hepatitis C

Decades of hepatitis C experiments using chimpanzees have been disappointing.\(^{35}\) Prominent among the disappointments is the failure to produce a vaccine against hepatitis C, largely because the virus behaves very differently in chimpanzees than in humans.\(^{36}\) Chimpanzees are rarely affected by chronic hepatitis or complications associated with the disease—including liver cirrhosis and hepatocellular carcinoma—which commonly occur in humans infected with hepatitis C.\(^{37}\) Unlike the majority of human patients, chimpanzees spontaneously clear acute hepatitis C, leaving few of them available for vaccine studies.\(^{38}\) Vertical transmission of hepatitis C is observed in humans but has not been reported in chimpanzees, an important distinction that confounds data regarding acquisition and transmission of the virus in both species.\(^{39}\)

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5.2. HIV/AIDS

Infection of chimpanzees with HIV and other related immunodeficiency viruses has also resulted in a poor model for human disease research. More than a quarter century of HIV vaccine experiments using chimpanzees and other nonhuman primates have failed to produce a vaccine. Of the more than 85 preventive and therapeutic HIV vaccines demonstrating benefits in nonhuman primates, all have failed in a staggering 200 human trials.

Further, HIV vaccine experiments involving chimpanzees have provided misleading information that has placed humans at increased risk for harm. For example, in 2007, a safety review panel suspended a Merck vaccine candidate because the vaccine failed to protect subjects or lower viral loads in those infected and even increased the risk of HIV infection in human patients after testing safe and effective on chimpanzees. An urgent NIH-sponsored summit following the Merck vaccine debacle produced numerous comments from HIV vaccine experts and patient organizations confirming the inability of nonhuman primate experiments to even begin to solve the vaccine problem.

5.3. Cancer

The claim that chimpanzees are essential for cancer research is not supported by the medical literature. Cancers are common in humans but rare in chimpanzees, and malignancies that occur in chimpanzees differ significantly from the types of malignancies that affect humans. Although human cancer-associated genes are also present in chimpanzees, they are not expressed and thus neither induce malignant transformation nor predict cancer risk. There are vast differences between humans and

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42 Bailey, “An Assessment of the Role of Chimpanzees in AIDS Vaccine Research.”

43 Ibid.


45 National Institute of Allergy and Infectious Diseases, “Summit on HIV vaccine research.”


chimpanzees in cancer susceptibility and in the progression of cancer, including cell growth, cell death, and metastasis. These important differences make chimpanzees unsuitable for the study of human cancers and therapies, and no better than the discredited mouse xenograft model. An extensive review of chimpanzee cancer research papers found that half were never cited in subsequent papers, 35 percent were cited only in nonclinical reports, and the 15 percent cited in clinical reports contributed little or nothing to advances in human cancer treatment. Detailed analyses found that chimpanzee studies contributed little, if anything, to the progress in human clinical practice. The assertion that chimpanzees are necessary for research on cancer biomarkers is also untrue because these biomarkers can be studied ethically in human patients. Thus, for scientific and other reasons, the use of chimpanzees for cancer research today is minimal.

5.4. Malaria

Species differences also confound malaria research. Pathological strains of malaria differ for humans (primarily *Plasmodium falciparum*) and chimpanzees (primarily *Plasmodium reichenowi*), malaria susceptibility and genomic signature are divergent for the two species, and exposure to *P. falciparum* produces only brief and clinically irrelevant infection in chimpanzees. In 2008, the National Institute of Allergy and Infectious Diseases acknowledged that the host-parasite relationship observed in animal experiments does not replicate what occurs in humans, making chimpanzees poor

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49 Bailey, “An examination of chimpanzee use in human cancer research.”
subjects for malaria research. There is no malaria vaccine despite decades of research using chimpanzees.

6. Conclusion

Given the arbitrary and capricious actions taken by NIH related to the transfer of 14 chimpanzees from APF and the scientific arguments influencing the forthcoming IOM report, the only remedy is to return the 14 chimpanzees now at SNPRC to APF, thereby restoring the APF chimpanzee colony to its status prior to NIH’s conduct.

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