



U.S. National Institutes of Health Squanders Opportunity to Strengthen Protections for Nonhuman Primates in Laboratories

Alka Chandna, Ph.D.¹; Ingrid Taylor, DVM¹
¹People for the Ethical Treatment of Animals, Norfolk, VA, USA

Overview

In December 2015, following PETA's successful campaign to end NIH's decades-long cruel maternal deprivation experiments on infant monkeys, the U.S. Congress asked NIH to "conduct a review of its ethical policies and processes" regarding the use of nonhuman primates in experiments "to ensure ... appropriate justification."

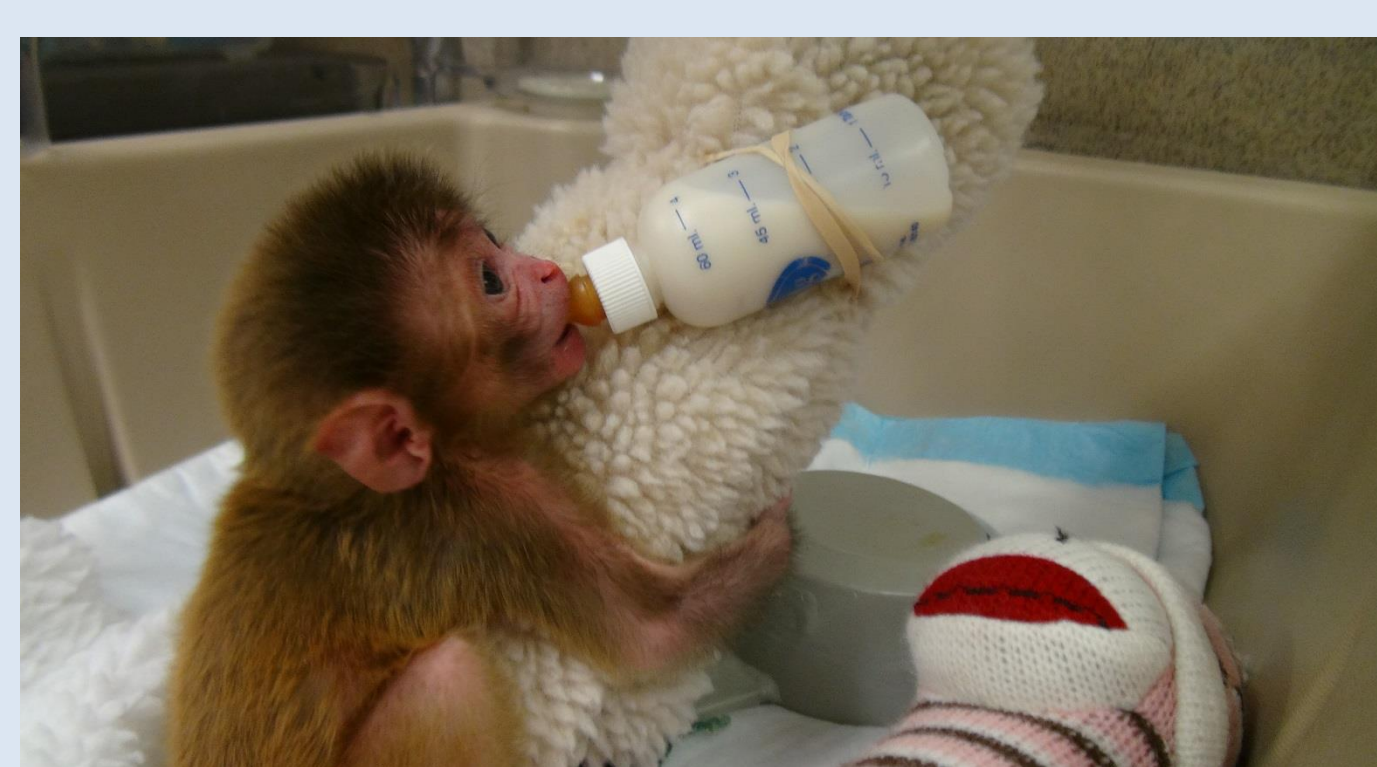
In September 2016, NIH's one-day primate workshop—convened in response to Congressional mandate—served as an infomercial for unfettered use of primates in experiments. Of the 47 individuals invited by NIH, only three were bioethicists—none of whom were given speaking slots. There were no representatives from the animal welfare community, as Congress had required; no experts on non-animal methods of research; and no one to address how our evolving understanding of the astonishing abilities and complexity of nonhuman primates should inform what we think is acceptable and unacceptable behavior by experimenters.

The NIH failed to take seriously the Congressional directive to conduct a legitimate examination of the scientific and ethical concerns surrounding experiments on primates. Because NIH did not live up to its responsibility to Congress and to the taxpayers that fund its research, taxpayer dollars will continue to be wasted and primates will continue to suffer in invasive and irrelevant experiments.

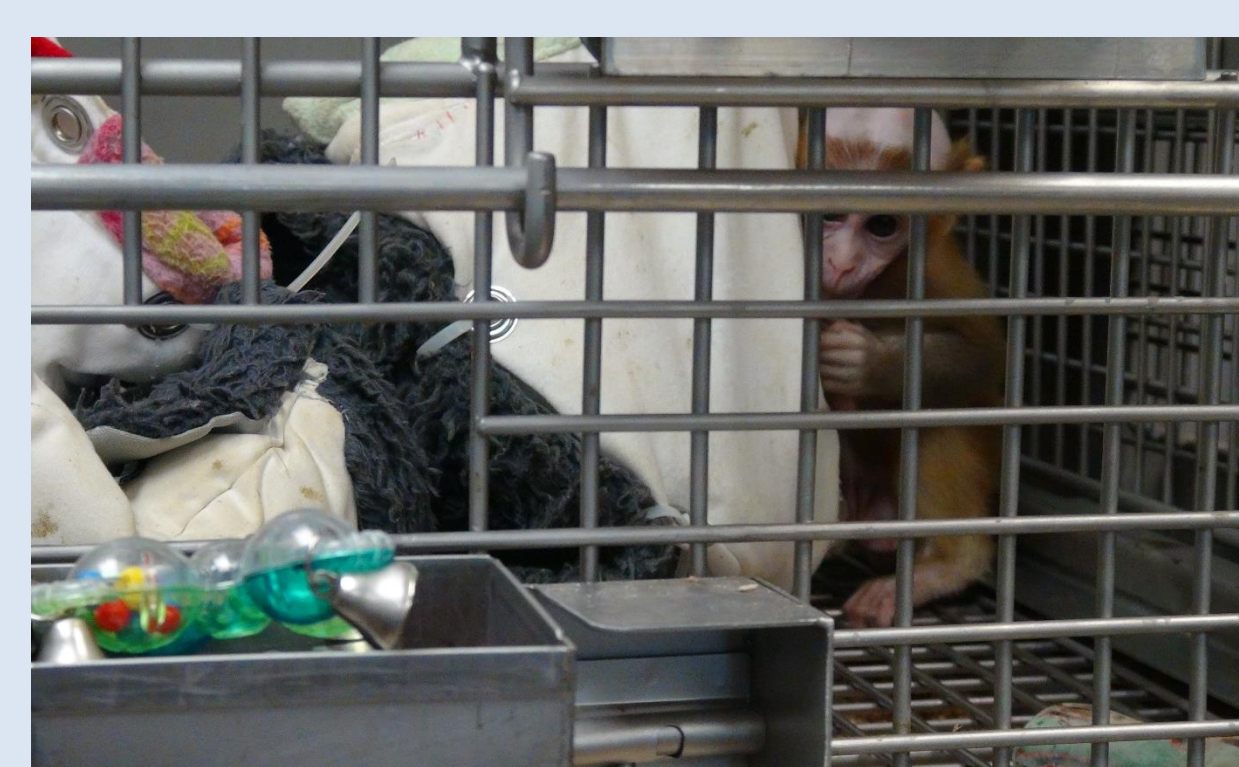
Background



In 2014, PETA launched a campaign to end a series of maternal deprivation experiments that had been carried out at NIH for more than 30 years.



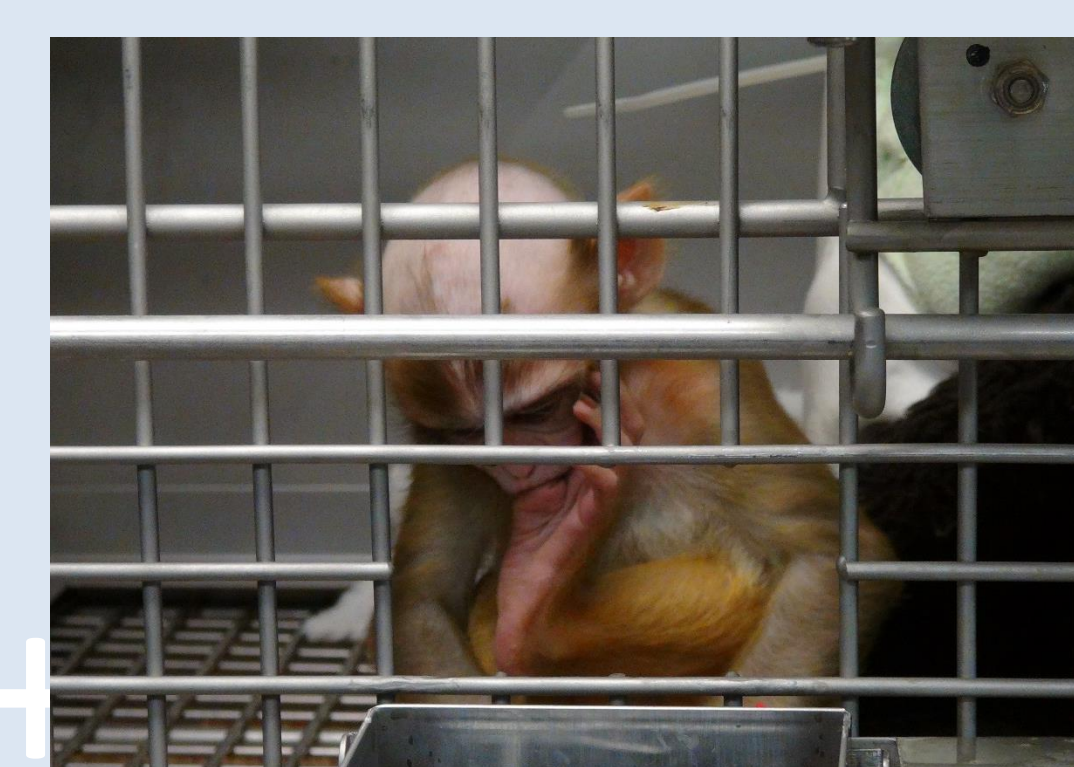
Monkeys—bred to be genetically predisposed to being more fearful, anxious and depressed than normal monkeys—were permanently removed from their mothers at birth.



They were caged alone for 22 to 24 hours daily.



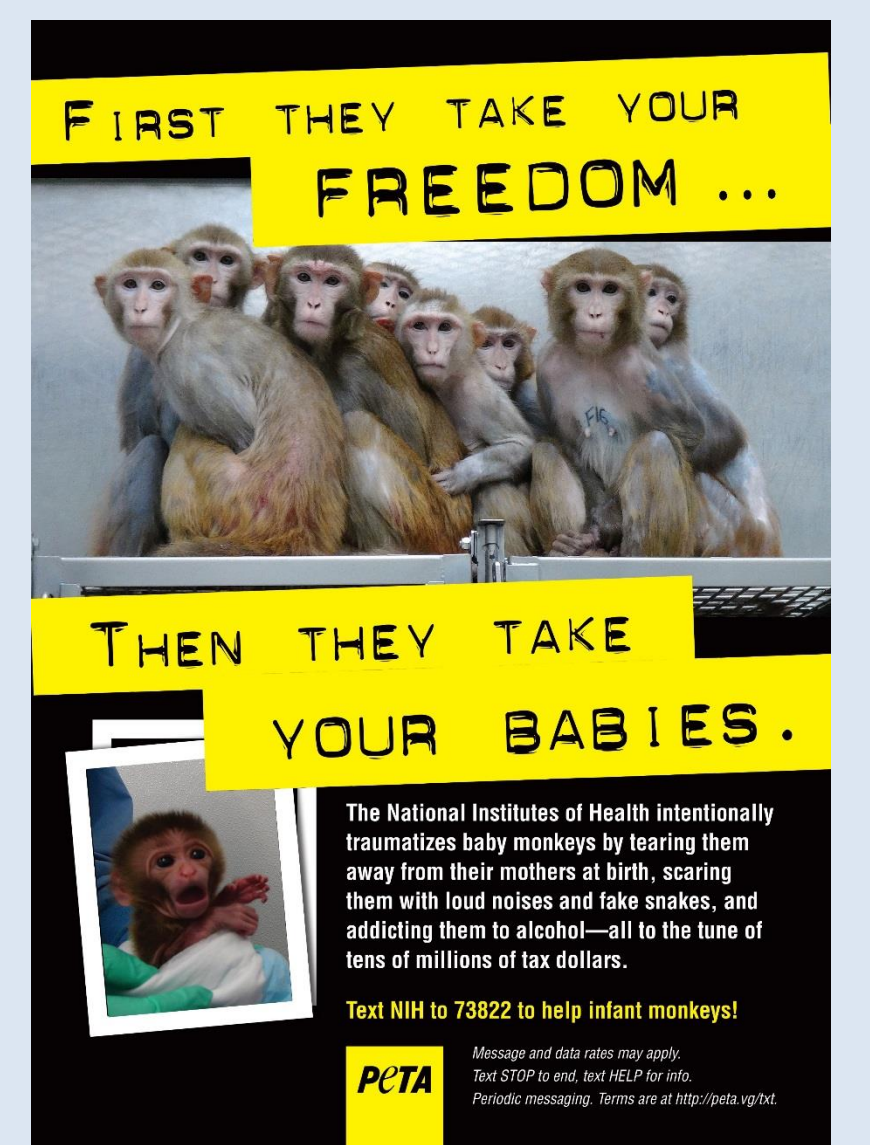
The infants were used in psychopathology experiments where they were subjected to loud noises, mechanical snakes, and the presence of threatening humans.



Although categorized as "Column C," suggesting no pain or distress, the monkeys suffered from severe and persistent cognitive, social, and physiological deficits.



A comprehensive review of these experiments conducted by a former NIH neuroscientist in consultation with independent medical doctors, mental health professionals, veterinarians, and primatologists, including Drs. Jane Goodall, John Gluck, and Barbara J. King, concluded that the experiments caused substantial long-term suffering to animals but had never led to treatments for human mental illness—even as superior non-animal research methods were readily available.



In 2015, NIH permanently ended the experiments.

Congressional Mandate

Chimpanzees in Research

In 2011 and 2013, reviews undertaken by the Institute of Medicine and the NIH on the scientific necessity of using chimpanzees in biomedical research revealed that:

- Ongoing research on chimpanzees is "largely unnecessary";
- The existing oversight system had failed; and
- Laboratory conditions could not address the psychological needs of chimpanzees.



The Call from Congress

Alarmed by the apparent failure of the oversight system in the case of chimpanzees and infant monkeys:

- Members of Congress instructed NIH to review the policies and processes governing primate experiments.
- This initiative was brought by Representatives Eliot Engel, Dina Titus, Lucille Roybal-Allard, and Sam Farr



Why an Ethics Review of Primate Experimentation?

- Research fails to translate to humans
- Evolving understanding of the complex psychological needs of primates
- Changing societal views of primate experimentation
- Availability of alternatives



References

Chan AWS, Jiang J, Chen Y, Li C, Prucha MS, Hu Y, ... Bachevalier J. (2015). Progressive Cognitive Deficit, Motor Impairment and Striatal Pathology in a Transgenic Huntington Disease Monkey Model from Infancy to Adulthood. *PLoS ONE*, 10(5).
 Clinical Trials.gov <https://clinicaltrials.gov/ct2/show/study/NCT02519336>
 Jackson K, Dayton R, Fisher-Perkins J, Didier P, Baker K, Weimer M, ... Klein R. (2015). Initial gene vector dosing for studying symptomatology of amyotrophic lateral sclerosis in non-human primates. *Journal of Medical Primatology*, 44(2), 66-75.
 Lane E, Dunnett S. (2008). Animal models of Parkinson's disease and L-dopa induced dyskinesia: How close are we to the clinic? *Psychopharmacology*, 199(3), 303-312.
 Lopresti-Goodman S, Shriver A. (2017). Missing from the NIH primate research ethics review: the ethics. *The Hastings Center*. <http://www.thehastingscenter.org/missing-nih-primate-research-ethics-review-ethics/>
 Mason, G. J. (1991). Stereotypes: a critical review. *Animal Behaviour*, 41(6), 1015-1037.
 Okun M. (2012). Deep-brain stimulation for Parkinson's disease. *The New England Journal of Medicine*, 367(16), 1529-38.
 Ozolin P, Silverman R. (2014). Treatment of amyotrophic lateral sclerosis: Lessons learned from many failures. *ACS Medicinal Chemistry Letters*, 5(11), 1179-81.
 Pochet R, Nicas C, & Mitrecic D. (2015). Translation of the focus toward excellence in translational science: Comment on "TDP-43 Repression of Nonconserved Cryptic Exons is Compromised in ALS-FTD". *Croatian Medical Journal*, 56(5), 493-495.
 Potashkin JA, Blume SR, and Runkle, NK. (2011) Limitation of animal models of Parkinson's Disease. *Parkinson's Disease*.
 PR Newswire. Potential Treatment for Huntington's Disease. Found Effective. Safe in Mice, Monkeys. Enters Clinical Testing. PR Newswire. Feb 26, 2016.
 Traub R, Mitsumoto H, & Rowland L. (2011). Research Advances in Amyotrophic Lateral Sclerosis, 2009 to 2010. *Current Neurology and Neuroscience Reports*, 11(1), 67-77.
 Williams R. (2010). Slowing the decline: The search is on for disease-modifying treatments for Parkinson's disease, but, as Ruth Williams discovers, developing a compound is only part of the problem. *Nature*, 466(7310), 513.

NIH Primate Workshop

On September 7, 2016, NIH hosted a workshop, the title of which—"Ensuring the Continued Responsible Oversight of Research with Non-Human Primates"—suggested a foregone conclusion.

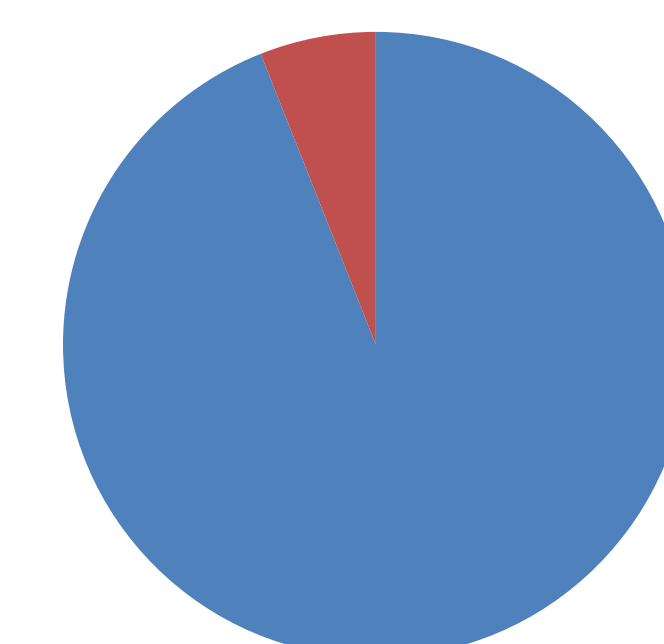
"We are confident that the oversight framework that we have in place for nonhuman primates in research is robust and has provided sufficient protections for the animals ..." — Carrie Wolinetz, Associate Director, NIH, in her opening statement.

The only "ethics" talk at the workshop was given by Ernest Prentice, a non-ethicist who took issue with the term, "harm-benefit relationship," noting that "harm" means "hurt, injure, damage, impair, inflict wound." Said Prentice: "I don't think this appropriately characterizes research involving animals ... I prefer the term 'cost-benefit analysis.'"

"The NIH does not have a glorious history of handling the ethical and policy issues pertaining to research involving animals." — Tom Beauchamp, one of the only three bioethicists who were invited to the workshop, none of whom was given a speaking slot.

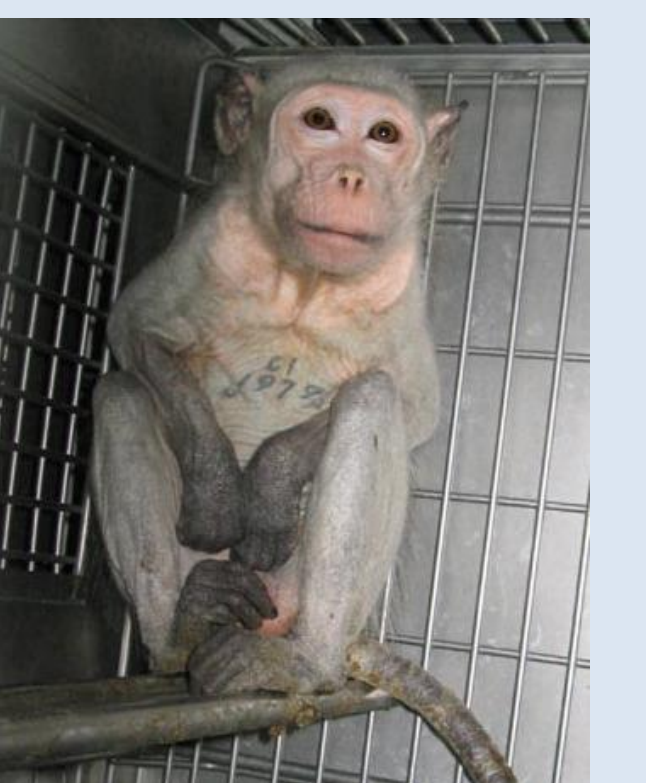
Representation of Different Interests on Workshop Committee

- Animal Experimenters
- Bioethicists
- Representatives from Animal Welfare Community
- Primatologists to discuss evolving understanding of primates
- Experts on non-animal research methods



Implications for Primate Use: The Failure of Neurobiology Experiments

More than 105,000 primates are currently held in U.S. laboratories, where they are used in toxicology and drug testing in which gavage tubes are forced into primates' nostrils and throats to administer toxic substances; infectious disease studies in which primates are infected with pathogens like Ebola and Marburg; neurobiology studies in which experimenters drill holes into primates' skulls and screw metal restraint devices into their heads; and so on. The social and psychological needs of primates are not met in the laboratory environment.



Experimental Model	Occurs Naturally in Primates?	NIH Workshop Claims	Failure of the Model
Alzheimer's Disease	No	"Nonhuman primates are the best model for higher order functions of the nervous system, especially if we are seeking relevance to human experience and disease."	<ul style="list-style-type: none"> • No new discoveries in ten years • Clinical failure rate of new drugs is 99.6% • The use of young animals in experiments and differences in lifespans fails to capture the progressive nature of this and other diseases
Amyotrophic Lateral Sclerosis (ALS)	No	"We don't do experiments in monkeys to do experiments in monkeys. We do experiments in monkeys only when that is the only system or the absolute best system to address a critically important scientific question, particularly those relevant to human health."	<ul style="list-style-type: none"> • No new therapeutics developed in last 20 years of research • Drugs effective in animal models have shown no positive effect in humans
Parkinson's Disease	No	"Through mapping out the circuits of the basal ganglia (using NHPs), treatments for Parkinson's disease (deep brain stimulation) were developed."	<ul style="list-style-type: none"> • Only patients with a narrow range of symptoms benefit from deep brain stimulation • Gait, balance, and speech impairments can worsen • Many adverse effects, including death, in humans • Creating lesions and administering toxins to induce disease creates stress and inflammation that confound experiments
Huntington's Disease	No	"Animal models are critical to our understanding of the human nervous system."	<ul style="list-style-type: none"> • Transgenic model developed in rhesus monkeys over past decade • Only one drug currently in clinical trials • High levels of suffering for the monkeys