July 26, 2021

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, DC 20201

Via e-mail: <u>Secretary@HHS.gov;</u> <u>Xavier.Becerra@HHS.gov</u>

Dear Secretary Becerra:

I am writing on behalf of People for the Ethical Treatment of Animals and our more than 6.5 million members and supporters to respectfully request your intervention in addressing chronic and systemic problems at the National Institutes of Health (NIH). The issues that I've detailed below impact not only animal welfare, but also public trust and the ability of the U.S. to maintain its position as a world leader in biomedical research. After reading the outlined concerns, I hope you will agree that it's time for a change in leadership at NIH.

Animal welfare abuses rampant in NIH's intramural laboratories

Federal documents, obtained by PETA via a Freedom of Information Act request and recently released to the public, reveal that NIH Director Francis Collins is not ensuring compliance with animal protection guidelines even within the agency's own laboratories. No fewer than 34 cases of serious animal welfare violations have been documented in NIH's Maryland laboratories for the 16-month period from March 2020 to June 2021. A sampling of the incidents—all of which are violations of federal animal welfare guidelines or regulations—is provided below. These incidents—stemming from incompetence, negligence, and frankly, a culture of callous disregard for the beings used and the guidelines resulted in unimaginable pain and misery for vulnerable animals. The incidents also represent contempt for laws that govern the treatment of animals in laboratories and reflect the expectations of the American public—the majority of whom disapprove of animal experimentation regarding minimal welfare standards.

Animal deaths caused by equipment malfunction and employee negligence:

• Flames erupted from the body of a mouse after experimenters used electrocautery during surgery on the mouse, but failed to notice that alcohol fumes had built up during the surgery, igniting the mouse's body.



PETA

Washington

1536 16th St. N.W. Washington, DC 20036 202-483-PETA

Los Angeles

2154 W. Sunset Blvd. Los Angeles, CA 90026 323-644-PETA

Norfolk

501 Front St. Norfolk, VA 23510 757-622-PETA

Info@peta.org PETA.org

Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands
- PETA Foundation (U.K.)

- Five zebrafish died when a malfunction in the heating system resulted in a 10 degree temperature drop in the animals' tank—and no one noticed.
- A three-day-old guinea pig died after they fell through an opening in the cage.
- Two hamsters died of suffocation when they were placed in transmission caging and tried to insert their heads into the ports, but could not extricate themselves.
- A mouse was found dead, entrapped between the side of the food hopper and the steel bars containing the food. The carcass was partially hanging down into the cage from the hopper.
- A marmoset died after becoming entangled in an "enrichment" device chain.
- A 6-year-old female marmoset was being prepared for an MRI, but died while under anesthesia after experimenters failed to notice that the tubing to the oxygen source had become disconnected.

Out of cage incidents:

• In three separate incidents, monkeys escaped from their cages, and in the ensuing struggle, employees were bitten on their thighs, hands, and fingers.

Failure to ensure animals had access to food or water:

- In ten separate incidents, experimenters failed to ensure that mice had access to food or water—resulting in animals dying of starvation or thirst.
 - In one incident, three recently weaned mice were found dead in a cage; the water bottle was empty and the bedding was soaked. It was determined that the water bottle had been leaking, but the wet cage was missed on more than one health check by two different animal technicians. The neonatal mice died from a combination of hypothermia and dehydration.
 - In another incident, a mouse who had been left without water was observed to be "hunched, lethargic, and with an ocular concern."
- Four monkeys were deprived of water after the water line to the cage in which they were held had become disconnected. This malfunction went unnoticed for three days. When the water line was reconnected, the monkeys immediately began drinking. The monkeys also had to receive subcutaneous fluids as part of their recovery.

Animals harmed and welfare jeopardized when experimenters deviated from approved protocols:

- An unapproved drug was injected into seven mice; one mouse became ill and had to be euthanized.
- Experimenters killed an unspecified number of mice using a method that had not been approved.
- An experimenter subjected a rhesus macaque to two survival surgeries, although only one surgery had been approved. Specifically, the protocol allowed for an injection into the inner ear of only one ear; however, the experimenter performed the same surgery on the opposite ear one week later.
- An 18-year-old rhesus macaque, who had been anesthetized for a tooth extraction, suffered an extensive burn—two inches by three inches and half an inch deep—to his abdomen when an experimenter placed a gel pack intended for heating support

directly on the monkey's abdomen, rather than wrapping the pack first, as required. Two days later, a lesion developed on the monkey's abdomen.

- After a mouse was observed to be emaciated and lethargic and have a hunched posture, the veterinarian instructed the experimenter to euthanize the mouse. However, five days later, the mouse had not been euthanized and was found with a large abdominal mass and emaciation. The mouse was finally euthanized at that point.
- Five mice died after they were given a chemical that was not in the approved protocol.

Failure to administer appropriate post-operative pain relief to animals:

- 75 mice were subjected to embryo transfer surgery, but were not given postoperative analgesia.
- 15 rhesus macaques were given an expired analgesic following their use in unspecified procedures.
- 142 mice were given an expired analgesic following a surgery.

Incompetence and neglect jeopardize welfare of animals:

- After two incompatible male rhesus macaques were caged together, one of the macaques sustained several serious injuries to his left arm, left leg, and back. He required "extensive surgical and medical treatment." According to the report: "This injury resulted in prolonged treatment, stress, and immune responses which will impact the long-term HIV study."
- In two separate incidents, vivarium staff noticed that used cages with several neonatal mice had been sent to the cage washer to be cleaned. The mice were discovered before the cages were run through the cage washer, and they were euthanized.

The issues described here are not an aberration. An earlier set of reports obtained by PETA document 41 similarly egregious violations of federal animal welfare guidelines for the period from January 2018 to February 2020. Those reports paint a similar picture of rampant neglect and incompetence. A female owl monkey lost 20% of her bodyweight and was severely anemic, but she wasn't provided with veterinary care and died in her cage. Dogs were used in a septic shock study that was suspended after experimenters deviated from the approved protocol, including by using sutures that caused infection. Lights were left on around the clock for almost five months in rooms where primates were held.

NIH is the agency responsible for ensuring that laboratories across the country are in compliance with federal animal welfare guidelines, but the agency has failed to comply with these minimal standards in its own laboratories.

Compromised science

Compromised animal welfare compromises the science being carried out in NIH's animal laboratories. The quality and validity of experiments is undermined not only by the difficulty of translating data from other animal species to ours, but also because problems

with husbandry and welfare further confound the data. A 2015 investigation concluded that between 50% and 89% of all preclinical research, a large part of which involves animal testing, could not be reproduced. At the most conservative U.S. estimate, this results in approximately \$28 billion per year spent on experimentation that is misleading. NIH Director Francis Collins and Principal Deputy Director Lawrence Tabak have admitted, "Preclinical research, especially work that uses

animal models, seems to be the area that is currently most susceptible to reproducibility issues." And yet, nearly half of the NIH's grants budget is squandered on this failed enterprise.

Stuck in a failed paradigm

NIH has reported that it spends 47% of its annual budget on animal studies. This amounts to \$19.5 billion in 2020 alone. However, studies show that more than 90% of the most promising discoveries from basic research, most of which involves animals, fail to lead to treatments in humans. NIH itself has acknowledged the failure of experiments on animals to produce human-relevant results. In its strategic plan for 2016-2020, the agency stated that "animal models often fail to provide good ways to mimic disease or predict how drugs will work in humans, resulting in much wasted time and money while patients wait for therapies." The agency has also admitted that 95% of drugs that appear safe and effective in animals, fail in human clinical trials. However, the agency has failed to take meaningful action to redirect the ample public resources with which it has been entrusted toward human-relevant, non-animal research methodologies that would actually help people. In short, the agency is failing the American public whose tax dollars bankroll its operations.

The need for a forward-thinking individual at the helm

Francis Collins has served as the director of NIH since August 2009. Even as scientific evidence has mounted on the failure of animal experiments to produce cures and treatments for animals and also on the sentience of animals, the agency has failed to heed this evidence and has continued to waste public funds on cruel and failed experiments. NIH's own animal laboratories serve as a poster child for abusive, deadly, and useless experiments—and this has been going on for years under Collins' watch. For the sake of animal welfare, sound science, public trust, and the U.S.' position as a global leader in biomedical research, we ask that you please consider replacing Collins with a more competent, forward-thinking director.

We would appreciate the opportunity to meet with you to discuss our concerns at further length. Thank you for your time and consideration.

Sincerely,

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Alka Chandna, Ph.D. Vice President Laboratory Investigations Cases <u>AlkaC@peta.org</u> | (757) 803-6447