



December 11, 2023

Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration

Via e-mail: robert.califf@fda.hhs.gov; commissioner@fda.hhs.gov

Dear Dr. Califf:

I'm writing on behalf of People for the Ethical Treatment of Animals—PETA entities have more than 9 million members and supporters globally—to request that in light of chronic and egregious violations of animal welfare guidelines in the U.S. Food and Drug Administration's (FDA) laboratories, you take personal responsibility for redirecting the agency's endeavors away from animal experimentation and toward non-animal, human-relevant research methods.

PETA obtained documents from the National Institutes of Health's Office of Laboratory Animal Welfare (OLAW) that detail numerous violations of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) across three FDA laboratories:

1. **National Center for Toxicological Research** (Jefferson, Arkansas)
 - Seven zebrafish died or required euthanasia following a mechanical malfunction of the aquatic system that resulted in diminished water quality. (Final OLAW letter dated July 7, 2023)
 - Seven zebrafish died following a failure of the primary water pump and a resulting acute change in water quality. (Final OLAW letter dated June 26, 2023)
 - A rat unexpectedly died and three others unexpectedly became severely ill after being given an experimental test agent that led to severe pathological changes. (Final OLAW letter dated November 23, 2022)
 - A rat was placed in the wrong cage and sustained a 3- to 4-cm laceration that exposed the muscle on their right shoulder during a fight with another rat in the cage. (Final OLAW letter dated October 18, 2022)
 - An experimenter didn't consider alternatives for a column E experiment—i.e., one in which animals experience pain but don't receive pain relief. (Final OLAW letter dated September 14, 2022)
 - An unapproved change occurred in the light cycle of an animal room housing mice during the first 48 hours after the animals were dosed with a compound. (Final OLAW letter dated September 14, 2022)
 - Three mice were found dead three days after arriving at the facility. A veterinarian checked them 24 hours after arrival, but it's unclear whether they were checked after that, before being found dead on the third day. (Final OLAW letter dated August 11, 2022)

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- Thirteen mice were transferred from one protocol to another, even though the experimenter had only been approved to transfer eight mice. Several mouse pups fell victim to cannibalism as a result of the overcrowding that stemmed from this error. (Final OLAW letter dated July 19, 2022)
- Eight rat pups who had been exposed to a test agent weren't euthanized at the time specified in the approved protocol, and the data couldn't be used. (Final OLAW letter dated March 8, 2021)
- Two primates fought, and one sustained an injured, bleeding finger. (Final OLAW letter dated March 4, 2021)
- Four mice didn't receive necessary treatment prescribed by a veterinarian for three full days. (Final OLAW letter dated December 29, 2020)

2. **White Oak Consolidated Animal Program** (Silver Spring, Maryland)

- Two frogs died and one required euthanasia after ingesting plastic aquarium plants used for "enrichment." (Final OLAW letter dated February 8, 2021)
- A hamster died due to lack of air caused by improper placement of a cage on a ventilated rack. (Final OLAW letter dated February 8, 2021)
- Two primates escaped from their cage after the door lock failed. The escaped primates got into fights, and three primates sustained injuries requiring veterinary care. (Final OLAW letter dated December 1, 2020)
- Two rabbits sustained scratches and one of them sustained a laceration requiring stitches when they moved the divider between their cages and fought. (Final OLAW letter dated December 1, 2020)
- A hamster was found dead in a specialized biocontainment cage, and another hamster in the cage was inactive, likely due to the improper placement or function of the exhaust filter on the cage lid. (Final OLAW letter dated July 16, 2020)
- A hamster died while under anesthesia after having difficulty breathing and bleeding from the nose. The anesthesia system had been set up incorrectly. (Final OLAW letter dated June 26, 2020)
- Two rhesus macaques escaped from their cage and fought with other stressed monkeys. A total of five animals sustained bite wounds to their hands, feet, or tongues—requiring wound cleaning, closure of wounds, surgical amputation of fractured digits, antibiotics, and pain medication. The cage lock hadn't been properly secured. (Final OLAW letter dated January 6, 2020)
- Mice were found to be hunched and scruffy. Staff were supposed to evaluate the mice to ensure that they didn't go beyond humane endpoints but failed to do so. Seven mice died, and five were in critical condition. (Final OLAW letter dated July 22, 2019)
- One rat died and another was moribund due to lack of food. The animals had been weaned by an experimenter and given a small amount of food, which was to be topped off by an animal caretaker—but this wasn't done. (Final OLAW letter dated February 11, 2019)

3. **Center for Veterinary Medicine** (Laurel, Maryland)

Three dogs in a study experienced acute episodes of lameness due to a compromised fence wire on which they had caught their paws when they jumped or climbed in reaction to staff entering the room. (Final OLAW letter dated March 4, 2022)

Across these incidents, the incompetence, neglect, and lack of adherence to even minimal animal welfare standards demonstrated by FDA staff has led to the unnecessary suffering and pain of dogs, fish, rabbits, mice, hamsters, rats, and primates. Additionally, the FDA itself stated the following:

[P]remarket animal-based assessments are time and resource intensive and may not always fully predict or detect potential concerns of FDA-regulated products for proposed uses in humans and animals. Alternative methods have the potential to provide both more timely and more predictive information to help accelerate product development, prevent products with increased toxicological risk from reaching the market, assess efficacy, provide insight into disease processes, and enhance emergency preparedness for the benefit of U.S. patients, consumers, and animals.¹

Yet—even though the FDA recognizes the severe limitations of animal experiments and the benefits of alternatives—only \$5 million was allocated for “Reducing Animal Testing Through Alternative Methods” in the FDA’s operating plan for FY 2023, which had a total program budget of over \$6.7 billion, with \$77 million allocated to the National Center for Toxicological Research and almost \$56 million allocated to the White Oak Complex.²

We ask that you address the treatment of animals in FDA laboratories and revise how the agency spends taxpayer dollars on experiments by implementing PETA scientists’ [Research Modernization Deal](#)—a strategy for replacing animal experiments with modern, human-relevant, animal-free research methods. This strategy will support the FDA in accelerating its own professed interest in adopting alternative methods.

Thank you for your attention to this important matter. You can contact me at AmandaSc@peta.org.

Sincerely,



Amanda Schemkes, J.D., M.S.
Laboratory Oversight Specialist
Laboratory Investigations Department
PETA

cc: Xavier Becerra, U.S. Secretary of Health and Human Services
(xavier.becerra@hhs.gov; secretary@HHS.gov)

¹FDA, “About Alternative Methods.” Accessed November 17, 2023. <https://www.fda.gov/science-research/advancing-alternative-methods-fda/about-alternative-methods>.

²FDA, “Operating Plan for FY 2023.” Accessed November 17, 2023. <https://www.fda.gov/media/165046/download?attachment>.