

Report on Research Compliance Volume 19, Number 9. August 25, 2022 PETA Publicizes Reports to OLAW, USDA Inspections, Targets NIH Intramural Program

By Theresa Defino

Nina F. Schor, M.D., had been in her job as acting deputy director of NIH's intramural research program (IRP) for 15 days when she received an email from Alka Chandna, congratulating her and noting "this new position brings with it an extensive set of responsibilities." But Chandna had more on her mind than wishing Schor well.

"While you serve in this role, I hope you'll take the opportunity to address ongoing systemic and egregious violations of animal welfare guidelines in NIH's intramural laboratories," Chandna, vice president for laboratory investigations cases for People for the Ethical Treatment of Animals (PETA), wrote in the Aug. 15 email. She included more than a dozen case reports of incidents at IRP labs that Chandna told RRC PETA obtained through Freedom of Information Act (FOIA) requests.

NIH has not been the only recipient of recent correspondence from PETA. On Aug. 10, Jeffrey R. Balser, M.D., president and CEO of Vanderbilt University Medical Center, received a letter from Andréa Kuchy, a PETA research associate. [2] Kuchy asked that Balser "take personal responsibility for addressing the chronic and egregious animal welfare violations that characterize the treatment of vulnerable animals" that Vanderbilt and its medical center are studying. Vanderbilt did not respond to repeated requests for comment from *RRC*.

On Aug. 17, PETA announced on its website that it had "filed a complaint with NIH, calling on it to turn off the money spigot" to Duke University. [3] According to a July 22 inspection report by U.S. Department of Agriculture (USDA) officials, three pigs were not observed during a weekend—they had water but no food—and two of four puppies "may have" died after a "researcher did not follow the university—wide communication policy when attempting to contact" the on–call veterinarian. The report states that "both items were corrected prior to inspection."

A day later, PETA issued a statement regarding the death of three bank voles, a type of rodent, that were left without food or water for several days at Dartmouth University. [4] The worker responsible was fired and retraining was conducted, according to the USDA report, which PETA also posted online.

The flurry of recent activity is part of PETA's strategy to hold NIH and funded institutions' feet to the fire when there are documented violations of either NIH guidelines for animals used in research or of the Animal Welfare Act (AWA), which a USDA division enforces.

Depending on the type of animals used in research, institutions (and NIH's own investigators) follow the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, a set of standards the NIH Office of Laboratory Animal Welfare (OLAW) enforces. [5]

The policy requires that institutions provide a "written Assurance acceptable to the PHS, setting forth compliance with the Policy" before any activities involving animals can be "conducted or supported by" PHS. They also must follow the *Guide for the Care and Use of Laboratory Animals*.

Institutional animal care and use committees (IACUCs), through their institutional officers, are also required to "promptly" submit to OLAW "noncompliance reports and actions taken." Specifically, they must report "any serious or continuing noncompliance," "any serious deviation from the provisions of the Guide; or any suspension of an activity by the IACUC."

"OLAW evaluates and reviews noncompliance reports and the actions taken. OLAW may ask for clarification or other information to assess the case; or recommend certain actions to enhance compliance and prevent recurrence," the website states. "After OLAW has completed its evaluation of the situation, a report of the findings and acceptance of the corrective actions is e-mailed to the Institutional Official and copied to the IACUC office/contact and any complainants in the case."

Animal Care, a unit within USDA's Animal and Plant Health Inspection Service (APHIS), enforces the AWA mostly through inspections.

"APHIS may take action in addition to inspections to promote compliance, including issuing a Letter of Information or an Official Warning Letter. A Letter of Information is an informal warning letter documenting that AWA noncompliance was found and advising an individual and/or business that more stringent action may be taken if they remain noncompliant. An Official Warning Letter is an official warning of an alleged violation of the AWA. It provides notice to an individual and/or business that the Agency may seek a civil or criminal penalty if noncompliance is found in the future," its website explains. [6]

Moreover, APHIS' Investigative and Enforcement Services (IES) staff "investigate alleged violations when licensees or registrants have not taken corrective measures to come into compliance with the AWA, individuals and/or businesses are conducting regulated activity without a license or without being registered with USDA, or the noncompliance presents (or presented) a direct risk to the health and well-being of the animals involved. IES investigations may lead to the issuance of a regulatory compliance or enforcement action."

PETA Focuses on FOIA, Inspections

Chandna told *RRC* that "for a selection of institutions of particular interest...we routinely file FOIA requests for correspondence between the institution and OLAW," she said. These include "the largest institutional recipients of NIH funding [and] some of the larger private institutions—because this is one way we can get something of a glimpse into what's happening in those laboratories."

PETA "does daily monitor[ing of] USDA inspection reports, and if we feel that the violations would be of interest to the public, we will issue a statement," Chandna said. "In certain circumstances, we contact the institution—for example, if a violation involved mistreatment of animals used in teaching, we might contact the institution to suggest that they switch to non-animal methods."

The animal rights organization may contact the federal agency that wasn't involved—"for example, in response to a USDA violation, we might contact NIH's OLAW if it appears that the AWA violation also violates PHS Policy and the *Guide*," meaning both agencies have jurisdiction, Chandna said.

Not the First Letter to NIH

The headline PETA used to describe the letter to Schor states, "Animals Starved to Death, Experimenters Gone Rogue in NIH Labs; Heads Must Roll, PETA Says." [7]

Chandna noted this was PETA's third such letter. Three others—in February 2020, December 2021 and earlier this year in March—were sent to Michael Gottesman, who was the deputy director for intramural research for 29

years. (Gottesman returned last month to Center for Cancer Research to be chief of the Laboratory of Cell Biology.)

Those letters sought a "thorough audit of the policies and processes employed in NIH's experimental use of animals" and for NIH to institute "a zero-tolerance policy for experimenters who fail to comply with approved protocols and directives from veterinary staff—as well as a zero-tolerance policy for animal husbandry staff who fail to provide animals with basic necessities such as food, water, and safe shelter," requests Chandna repeated in the new letter.

Chandna said PETA had received "case reports" that intramural researchers had submitted to OLAW from Jan. 5, 2018, to Nov. 23, 2021. According to PETA, these "document no fewer than 120 violations of federal animal welfare guidelines." These reports, which Chandna did not provide, show "excruciating pain and unrelenting misery for the animals imprisoned" in NIH labs.

"Animals died of starvation and thirst after workers failed to provide them with food or water. Experimenters used animals in invasive surgeries that caused pain but failed to provide them with pain relief as stipulated in the protocol—sometimes, failing to provide any pain relief. Some experimenters went rogue and carried out procedures that had not been approved by the Animal Care and Use Committee (ACUC). Other experimenters failed to comply with the humane endpoints specified in the ACUC-approved protocol, meaning that animals experienced pain and distress beyond what was permitted," the letter states.

Chandna added that other reports filed from Jan. 4 to May 19 showed "no fewer than 17 animal welfare violations in NIH's laboratories." Her letter summarized the incidents. Taken together, the reports show "feeble assurances of strengthened training, updated [standard operating procedures], enhanced ACUC oversight, discussions with staff, and experimenters' apologies specified in the case reports have been entirely insufficient to address the wholesale failures in NIH's laboratories," Chandna wrote.

She concluded the letter by asking to meet with Schor.

Intramural 'Pattern of Neglect' Alleged

RRC contacted NIH for a response to Chandna's letter. A spokesperson did not respond to a question about whether officials would meet with Chandna. The spokesperson noted that the incidents cited were all self-reported and that OLAW had deemed the IRP "in compliance" with the governing policies.

"In each case, OLAW reviewed the information presented within the context of the entire institutional program, considered the seriousness of the noncompliance and evaluated the corrective actions taken and the proposed plans to prevent recurrence," the spokesperson said. "Based on OLAW's ongoing review of the NIH IRP and their efforts to meet the requirements of their Animal Welfare Assurance agreement with OLAW, they are in compliance with the PHS Policy."

Chanda noted that IRP's self-reports to OLAW are required by law and that it "shouldn't be congratulating itself" for them. Chandna also said NIH's response to her was that she should contact OLAW.

"The point being made in our letter was that NIH's failures to comply with minimal standards of care have been going on for years," Chandna told *RRC*. "Instead, we see that animals in NIH's laboratories continue to die of starvation or thirst because employees fail to notice that they had no food or water; that principal investigators continue to deviate from the protocols that were approved by the Animal Care and Use Committee, causing harm to animals; that experimenters continue to ignore the mandated humane endpoints, resulting in extended misery for animals; that laboratory workers continue to use expired analgesia, botch euthanasia, withhold veterinary care, and so on."

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She maintained that a review of these incidents shows the same corrective actions and violations. "Our question is, who at NIH is stepping back and taking in the pattern of neglect, incompetence, and disregard that appears to be woven into the fabric of NIH's treatment of animals in its laboratories—and what, if anything, is being done about that?" Chandna asked.

PETA: Vanderbilt Has 'Culture of Disregard'

PETA's letter to Balser had a link to 19 reports related to incidents of noncompliance Vanderbilt reported to OLAW from January 2019 to August 2021.

Kuchy wrote that the reports were obtained through the FOIA, and cited other findings by USDA that resulted in fines.

"Employees' negligence resulted in suffering and death for numerous animals," Kuchy wrote. "Among other serious documented issues, the school's experimenters failed to provide nearly 300 mice with adequate pain relief before they were used in painful and invasive procedures. On eight occasions, mice and their pups died from starvation or dehydration because laboratory personnel didn't give them access to food or water. Four mice confined to a cage were found to be dying or already dead from suffocation because lab personnel didn't secure the positive pressure cage into the biocontainment unit rack, effectively cutting off all oxygen."

Kuchy said that Vanderbilt's "culture of disregard for basic animal welfare must not be allowed to stand."

Like RRC, Chandna said PETA also has not heard from Vanderbilt.

Push for 'Modernization'

As it did in its letter to Vanderbilt, PETA is advocating for investigators to adopt its Research Modernization Deal, which Chandna said "provides a roadmap and strategy for shifting away from failing experiments on animals." [8]

A "sensible step-by-step approach," Chandna said the plan calls for institutions and researchers to:

- "Immediately eliminate animal use in fields of research for which animals have been shown to be bad 'models' for humans and have impeded.
- "Rebalance the public funding of medical research so that the majority goes to sophisticated human-relevant, animal-free research methods.
- "Conduct scientific reviews of the efficacy of animal use to identify additional areas in which such use has failed to advance human health, or in which non-animal methods are now available, and can therefore be ended quickly.
- "Implement a cost-benefit analysis system for research involving animals that includes an ethical perspective and consideration of lifelong harm inflicted on animals, such as is used in the [United Kingdom].
- "Work with other world leaders to harmonize and promote international acceptance of high-tech nonanimal testing strategies in regulatory toxicity testing."

Contact Chandna at alkac@peta.org.

- 1 Alka Chandna, letter from PETA to Nina Schor, August 15, 2022, https://bit.ly/3AwW02t.
- 2 Andréa Kuchy, letter from PETA to Jeffrey R. Balser, August 10, 2022, https://bit.ly/3T5MmLl.
- **3** People for the Ethical Treatment of Animals, "PETA Files NIH Complaint Against Duke University After Recent Violations," news release, August 17, 2022, https://bit.ly/3K6TIue.
- <u>4</u> People for the Ethical Treatment of Animals, "Dartmouth Voles Forgotten in Cage Sent to Wash Room Starve to Death: PETA Statement," news release, August 18, 2022, https://bit.ly/3AArq84.
- **5** National Institutes of Health, Office of Laboratory Animal Welfare, "Reporting Noncompliance," https://bit.ly/3dydBOr.
- <u>6</u> U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "Animal Welfare Act," https://bit.ly/3wjNKAu.
- **7** People for the Ethical Treatment of Animals, "Animals Starved to Death, Experimenters Gone Rogue in NIH Labs; Heads Must Roll, PETA Says," news release, August 15, 2022, https://bit.ly/3CgWNpt.
- <u>8</u> People for the Ethical Treatment of Animals, *The Research Modernization Deal*, <u>https://bit.ly/3cfyw8F</u>.