

October 5, 2021

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

Dear Mr. Secretary:

Thank you for your service to our country. PETA and PETA entities around the globe have more than nine million members and supporters. I am writing on behalf of PETA U.S. to urge you to take the necessary steps to end public funding for the Washington National Primate Research Center (WaNPRC) at the University of Washington (UW), one of the seven remaining national primate research centers funded by the National Institutes of Health (NIH).

We are appealing to you, as NIH has largely turned a blind eye to the ongoing systemic failures at WaNPRC that compromise scientific integrity and threaten public health. Beginning in October 2019, I attempted multiple times to meet with officials at NIH, including Deputy Director for Extramural Research Michael Lauer, to share what we had uncovered; NIH officials refused. I later learned that NIH knew of many, though not all, of the deficiencies we outline in the attached report. I also tried, along with leading primate scientist and former WaNPRC researcher Dr. Lisa Jones-Engel, to meet with UW president Ana Mari Cauce; she, too, declined. At that point, we turned to investigative reporters. The *Arizona Republic* published an exposé today that reveals much of the malfeasance we uncovered.

PETA's careful review of thousands of pages of documents has uncovered multiple serious issues at WaNPRC and its Arizona breeding facility, including:

- failure to maintain biosecurity
- violations of state health and veterinary regulations
- environmental racism
- toxic waste exposures
- apparent financial mismanagement
- an appalling and unexplained death rate among monkeys
- multiple violations of animal protection laws

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Please see the attached report for further information. I would be happy to provide documentation for all these issues in the form of UW and NIH's own records, emails, letters, reports, and charts—all of which point to a stunning disregard for scientific integrity, public health, the responsible use of taxpayer funds, and the animals used. WaNPRC, like Harvard's New England National Primate Research Center, should have closed down years ago. As it has not, we urge you to act and immediately pull the funding.

May I hear from you on this urgent issue? Thank you.

Respectfully,

Kathy Guillermo

Senior Vice President

Laboratory Investigations Dept.

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## Threats to Scientific Integrity, Public Health, and Primate Welfare at The Washington National Primate Research Center University of Washington

and

The Washington National Primate Research Center Breeding Facility Located on Tribal Lands of the Salt River Pima-Maricopa Indian Community

### October 2021 PETA

# Washington National Primate Research Center (WaNPRC) Facilities Are Rife With Spontaneous, Unintended Infectious Agents

Documents uncovered by PETA reveal that WaNPRC has failed to maintain the biosecurity of its pig-tailed macaque colonies. Multiple infectious agents, including *Trypanosoma cruzi* (Chagas disease), *Coccidioides* (valley fever), *Campylobacter*, *Shigella*, *Salmonella*, *Cryptosporidium*, *Vibrio cholerae* (cholera), West Nile virus, MTBC (tuberculosis), MRSA, and multiple enzootic primate viruses are known to affect the monkeys housed in WaNPRC's breeding and research colonies. WaNPRC has sold or transferred monkeys to facilities in New York, Pennsylvania, Georgia, Maryland, Louisiana, New Mexico, and Texas. The presence of these pathogens threatens public health and safety, fails the scientific community that purchases monkeys from this facility, and wastes tens of millions of taxpayer dollars. Further, the act of transporting monkeys infected with these pathogens violates state laws.

Records show that NIH has been aware of WaNPRC's biosecurity failures and its use and sale of macaques with compromised immune systems for a decade. NIH apparently took no action.

#### WaNPRC Violated State Regulations Designed to Protect Public Health

In May 2021, the Washington State Department of Agriculture (WSDA), acting on a complaint from PETA, found that WaNPRC violated state laws and committed multiple offenses against society and the public, including:

- Offense #1, Failure to comply with importation and testing requirements for wild and exotic animals (Animal Health Violation WAC 16-54-180);
- Offense #2, Failure to comply with reporting requirements for diseases on the World Organization for Animal Health's (OIE) notifiable disease list (Animal Health Violation WAC 16-70-010);
- Offense #3, Failure to report diseases in animals, resulting in unlawful importation (Animal Health Violation RCW 16.36.080).

The WSDA investigation focused only on the presence of coccidioidomycosis (valley fever) infections in macaques being imported into and maintained in WaNPRC's Seattle facilities. However, records from the investigation show that WaNPRC veterinarians and interim director

Sally Thompson-Iritani failed to disclose the presence of infectious agents in monkeys as required by law. WaNPRC pathology records, animal clinical records, internal communications, grant applications, and published research papers reveal that in both the Arizona breeding colony and the Seattle research colony, monkeys are not only infected with coccidioidomycosis, but are infected with multiple zoonotic diseases (transmissible from animals to humans). All of these zoonotic diseases are included in the Washington State Department of Health list of notifiable conditions and/or the World Organization for Animal Health notifiable disease list. Records show that WaNPRC leadership, when questioned by WSDA state officials, claimed that it was not aware of the regulations or the consequences of moving monkeys infected with pathogens across state lines. The implications of this are stunning. WaNPRC is a 60-year-old, federally funded primate center charged with developing vaccines and treatments for human disease. It is housed at a public university that receives more than \$1 billion a year in public research funds. Yet its administration and veterinary staff claim that they were not aware of state laws on importing monkeys infected with pathogens.

Records that PETA obtained show that these violations, which potentially threaten public health and safety, involved multiple notifiable conditions and were not confined to Washington State. PETA will be filing complaints in multiple states.

### WaNPRC Compromised Its Research and Exploited a Vulnerable Human Population

Literature and records obtained by PETA show that WaNPRC scientists were and are aware that the presence of unintended infectious agents confounds research data, but they continue to use these macaques in experimental studies. Publications authored by WaNPRC researchers and/or involving the use of WaNPRC pig-tailed macaques have shown that monkeys exposed to and/or infected with MRSA, coccidioidomycosis, trypanosomiasis, West Nile virus, tuberculosis, and/or other bloodborne pathogens are compromised biomedical models.

Impact of Cannabis on Inflammation and Viral Persistence in Treated HIV/SIV is a recent example of an NIH-funded project, using both human and monkey subjects, that was likely compromised by the use of pig-tailed macaques from the WaNPRC Arizona breeding colony. In 2015, Nikki Klatt, a core scientist at WaNPRC, and other investigators across the country were awarded a multimillion-dollar, multiyear grant that relied on pig-tailed macaques experimentally infected with simian immunodeficiency virus (SIV) and given antiretroviral therapy (ART). The primates were then administered cannabinoids to assess whether they would have a therapeutic impact. This project also enrolled HIV-infected humans, who, like the monkeys, were subjected to blood draws and colorectal biopsies. Yet a 2013 UW case report and a 2017 internal WaNPRC report highlighted the prevalence and potential research-confounding effects of coccidioidomycosis in the colonies, and a recent WaNPRC peer-reviewed publication stated that monkeys with possible infection with or exposure to coccidioidomycosis should not be used for SIV studies. Klatt pursued this study even though reports from her own institution, which was supplying the monkeys, indicated that it would result in potentially confounded data and futile monkey suffering and death. On top of this, the questionable study involved the exposure of an already vulnerable human population to highly invasive procedures.

### WaNPRC's Pig-Tailed Macaque Breeding Colony Is Housed on a Toxic Waste Site

In 2012, the UW Board of Regents signed a 19-year lease with the Salt River Pima-Maricopa Indian Community (SRPMIC) allowing WaNPRC to create and house the nation's largest pigtailed macaque breeding colony on the site of a defunct chimpanzee research facility. UW, with the permission of NIH, allocated at least \$50,000 for the services of the Washington State assistant attorney general in the lease negotiations process. Until this point, WaNPRC housed the primates at several other private and university facilities. The macaques from the relocated colonies were to be purpose-bred, healthy, and available to WaNPRC scientists in Seattle and sold to other facilities, primarily as models for HIV research.

Records show that UW (and possibly NIH) either failed in its due diligence or chose to ignore a profoundly disturbing issue: The land on which the breeding colony was to be created was designated a toxic waste site by the state of Arizona in 1996.

The public records PETA found were easily obtained and revealed that in 1966, Nammo Talley Inc., a supplier of ammunition, missile products, and demilitarization services, began manufacturing weapons, aerospace equipment, and propellant at a facility on SRPMIC land. In 1996, it was disclosed that Nammo Talley's historic operations had resulted in contamination of the soil and groundwater with lead, perchlorate, volatile organic compounds (VOCs), and 1,4-dioxane at the Nammo Talley site and neighboring properties. The WaNPRC breeding colony is less than 500 meters from the epicenter of this toxic site.

In 2014, it was determined that the wells supplying the main water sources for the WaNPRC breeding facility were contaminated with perchlorate at levels that exceeded U.S. Environmental Protection Agency acceptable concentrations. By 2015, the Arizona Department of Environmental Quality (ADEQ) informed UW that the wells used to supply water to the WaNPRC breeding facility were contaminated and that a filtration system was necessary. Insiders informed PETA that, to date, no filtration system has been installed.

Recent documents prepared by Geosyntec Consultants, Inc. on behalf of Nammo Tally and obtained by PETA from ADEQ indicate that groundwater monitoring, including observations of concentrations of VOCs and perchlorate, showed that the toxic plumes resulting from the Nammo Talley soil and water contamination and Nammo Talley's subsequent remediation actions were moving closer to WaNPRC.

In short, NIH has spent tens of millions of taxpayer dollars housing the nation's largest breeding colony of pig-tailed macaques on a toxic waste site.

#### Monkey Health, and Thus WaNPRC Research, May Be Compromised by These Toxins

The thousands of pig-tailed macaques born and maintained at this contaminated facility would have toxic exposures across their lifespans, altering their immune and metabolic systems in unpredictable and heterogeneous ways. This would render them unreliable biomedical models.

Perchlorate exposures impact hormones in pregnant females, and this in turn has implications for their developing fetuses and infants, especially regarding brain development. *Infant mortality rates at this breeding site have exceeded 25 percent*. Perchlorate exposures can interfere with the normal functioning of the thyroid gland. Hormones produced by the thyroid play an important role in the regulation of metabolic processes throughout the body. Chronic exposure to lead can damage the nervous, circulatory, and reproductive systems, as well as the kidneys and liver. Lead is known to affect hematologic function and, as such, is a potential confounder of research on diseases, such as HIV, that impact this system.

There is no indication in the documents we have received that WaNPRC/UW leadership or NIH have disclosed to scientists who obtained animals from the Arizona breeding colony that the pigtailed macaques used in their research originated from a facility adjacent to a toxic waste site or that data collected from studies using them may be compromised.

# WaNPRC's Breeding Colony in Arizona Operates Without State Oversight and Engages in Environmental Racism

The decision to place the pig-tailed macaque breeding colony on SRPMIC tribal land has enabled WaNPRC and NIH to skirt all oversight by the Arizona Departments of Agriculture and Health, as well as the Arizona Game and Fish Department. It appears that officials and residents of Arizona and the tribal community are unaware that zoonotic pathogens such as *Trypanosoma cruzi*, *Vibrio cholerae*, *Campylobacter*, *Shigella*, *Salmonella*, *Yersinia*, *Cryptosporidium*, and flaviviruses, which are circulating in the blood, feces, and urine of these macaques, have been brought into their state.

WaNPRC and NIH are essentially engaging in environmental racism by leasing land in the SRPMIC and populating it with pig-tailed macaques who are carrying infectious agents that have the potential to endanger public health.

#### WaNPRC's Fiscal Mismanagement and Leadership Issues

WaNPRC is one of seven remaining national primate research centers (NPRCs) funded by NIH. Each NPRC is reviewed annually by the National Scientific Advisory Board (NSAB), a panel comprised of at least six scientists from other institutions. In 2018, the report prepared by the NSAB and delivered to NIH concluded that "[f]rom all appearances, the financial issues facing the WaNPRC are formidable/critical, and some may border on insurmountable." In response to this disturbing review, NIH took the unprecedented step of restricting funds to WaNPRC. The

<sup>&</sup>lt;sup>1</sup> The April 4, 2018, NSAB report states: "**Financial challenges.** From all appearances, the financial issues facing the WaNPRC are formidable/critical, and some may border on insurmountable. Unfavorable lease arrangements, considerable 'legacy' deficits that must be serviced, diminished levels of funding for the P51 base grant (not just 'flat' budgets, but additional cumulative annual cuts to funding as well), consternation related to the establishment of per diem rates, and inadequate support from UW (including an unfunded mandate for salary increases) are all major factors that contribute to the financial issues confronting the WaNPRC."

2019 and 2020 NSAB reports reveal that these issues have not been resolved and emphasize that WaNPRC has struggled for more than a decade with "legacy debts."<sup>2,3</sup>

The reports fail to detail the source of the fiscal issues. But whistleblowers informed PETA that they involve misuse of federal funds. We are told that in early 2018, under the leadership of former WaNPRC director Dave Anderson, money was redirected from the primate center's primary NIH grant (referred to as the "P51 grant") to support UW's Health Sciences Administration Center for Shared Services (CSS), which Anderson also oversaw. The CSS was established to provide support services (i.e., administrative, purchasing, shipping, IT, billing, and travel services) to several units within Health Sciences Administration, including the primate center. The expectation was that the consolidation of these administrative, fiscal, and IT services within CSS would lead to cost savings across the diverse units. However, numerous whistleblowers reported that the shifting of WaNPRC services to CSS led to what they called a "failure and financial suck" on WaNPRC. Wildly inflated prices were reportedly charged for services that had previously been done in house.

In brief, the whistleblowers allege that federal money for the primate center was appropriated to pay for services in units that were completely separate. This apparent fiscal mismanagement—and frankly, what appears to be a misuse of public funds—led to shortages at the primate center. One consequence was that some UW employees at the center lost their jobs. The center remains understaffed—particularly in the area of animal husbandry and care.

In 2020, a dramatic restructuring of CSS was undertaken in response to internal complaints that the shift of administrative and fiscal services from WaNPRC's control to CSS had resulted in WaNPRC's paying much more for services. There was also concern that CSS had used WaNPRC's P51 financial resources from NIH to prop up other units at UW. Support services for the primate center are no longer provided by CSS, and Dave Anderson was removed as the principal investigator of WaNPRC's core P51 grant. As of early 2021, Dave Anderson was no longer employed by UW.

WaNPRC did not have a permanent director during all of 2020 or most of 2021. On September 2, UW announced the <u>appointment</u> of Michele Basso as director. This is surely one of the most outlandish choices relating to WaNPRC that UW has ever made.

<sup>&</sup>lt;sup>2</sup> The March 22, 2019, NSAB report states: "**Legacy debt.** Although the NSAB unanimously agrees that forgiving the Primate Center's legacy debt would go a long way toward allowing the Primate Center to return to financial viability, we were told in no uncertain terms by the P51 PI that this was simply not going to happen. Therefore, even though this seems like a fairly straightforward way to improve the Primate Center's financial circumstances, we have little additional to say about it. We do however, strongly encourage UW to consider postponing the repayment of the debt until after the next competitive renewal of the P51 has been submitted (due Jan. 25, 2021). Although this only delays the inevitable, it would demonstrate important institutional support from UW, and that UW is willing to work with the Primate Center to address the situation."

<sup>&</sup>lt;sup>3</sup> The February 2020 NSAB report states: "Executive Summary. The finances of the Center remain precarious. The structural deficit created by a) flat funding from ORIP, b) legacy debt, and c) operating deficits (mostly driven by the costs of the Western facility) create a major challenge to the long-term integrity of the Center. Items b and c of course reflect poor decision making by previous Center leaders, but the consequences are critical now. A plan to restructure the Center's debt and to help the Center manage its deficit without being forced to make further painful cuts would be extremely welcome."

Basso is one of the few primate experimenters ever to be suspended from using animals over welfare violations. When she was at the University of Wisconsin, she created a firestorm over her unwillingness to abide by regulations or adhere to experimental protocols. As the university's chancellor wrote in a <a href="memo">memo</a> sent to all faculty on March 19, 2010: "Dr. Michele Basso has been cited by university animal care committees for a range of problems over a five-and-a-half-year period. Despite repeated efforts and an unambiguous warning by the School of Medicine and Public Health's ACUC [Animal Care and Use Committee], problems recurred."

Basso's "problems" in the Wisconsin laboratory, wrote the attending veterinarian, were that she "has had significant difficulties with the cranial explant model—many more than other investigators using the same model in the same animal care unit with the same veterinary staff, including failure to follow explicit instructions and reluctance to permit necropsies on animals that died. ... There have been multiple instances of proven or suspected brain abscesses, and multiple events involving screws penetrating the dura, leading to either hemorrhage or abscess. Animals have been left unattended for hours in compromised conditions. ... Medical records are often incomplete or inaccessible. ... Recently it was discovered that [Basso] has been inserting unsterilized materials into brain tissue."

Wisconsin officials eventually let her back into an animal laboratory—but only under enhanced supervision. Basso left Wisconsin for the University of California, Los Angeles, where her controversial treatment of animals has apparently continued, according to documents from the IACUC. In early 2020, the UCLA IACUC meeting minutes indicate that adverse events continue to occur in Basso's laboratory and that she has continued her track record of disregarding veterinary advice and basic animal care recommendations.

Given WaNPRC's troubled history with violations and chronic veterinary understaffing, Basso is the last person who should be allowed to take the helm.

#### **WaNPRC Has Violated Animal Welfare Laws Multiple Times**

The primate center has a long, sordid history of violating the federal Animal Welfare Act (AWA) and Public Health Service research guidelines. Monkeys have died of starvation, dehydration, veterinary error, strangulation, choking on their own vomit, and more. We are particularly concerned that since Sally Thompson-Iritani was appointed acting associate director in 2017, and then interim director (a position she currently holds until mid-October, when Basso is slated to take over as director), WaNPRC facilities in Seattle and Arizona have been cited 16 times by the U.S. Department of Agriculture (USDA) for violations of the AWA. These violations include:

- failure to ensure that all the monkeys confined in the WaNPRC facilities have access to food and water
- failure to ensure that the confinement areas are safe
- failure to follow the approved protocols
- failure to perform assigned responsibilities

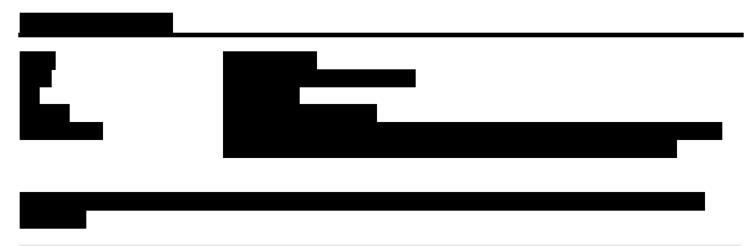
In May 2021, the USDA rejected UW's appeal to vacate recent citations for critical violations of the AWA. The USDA citations involved WaNPRC's failure to notice or report internally that a pig-tailed macaque was missing from her cage for 12 to 48 hours, without access to food or water. When the monkey was finally found, she was suffering from dehydration. The USDA also upheld citations for another incident at the primate center in which a macaque broke two locks on a set of cages and escaped along with his cagemate, sustaining injuries to their hands and fingers and injuring other caged monkeys in the room.

Despite the severity of the violations, UW attorneys sent a 54-page appeal to the USDA, arguing that the university should not be cited, in part because it had taken "corrective action" after the incidents occurred. In response, the agency's director of animal welfare operations, Dr. Robert Gibbens, noted that the three critical violations had occurred over a span of just nine months, writing to UW that such a record was "not indicative of a facility that is demonstrating success at preventing critical animal welfare issues."

These violations, in addition to the health issues we have uncovered, severely impact the wellbeing of the animals. In one recent eight-month period, between 2019 and 2020, WaNPRC and its breeding facility in Arizona had to treat a staggering 332 traumatic injuries (such as broken limbs and teeth), more than 200 cases of gastrointestinal problems, 149 cases of significant weight loss, 19 cases of rectal prolapse, and a dozen implant abnormalities.

#### Conclusion

There is overwhelming evidence that conditions and practices at WaNPRC may threaten human health, compromise research, and devastate the macaque populations in the colonies. The primate center faces financial and management issues—WaNPRC has fired, laid off, let go, or lost eight directors and associate directors over the past eight years and its newest hire is notorious for flagrant violations. Additionally, research at WaNPRC has failed to yield marketable vaccines and treatments. NIH would better serve American taxpayers by ending its funding for WaNPRC. The more than \$15 million a year that NIH spends to support WaNPRC's infrastructure, and the tens of millions of dollars that NIH annually allocates to support research using this flawed experimental model, could be directed toward more promising human-relevant research.



From: Kathy Guillermo

Sent: Friday, January 7, 2022 8:24 AM

To: Brown, Patricia [OLAW] (NIH/OD) [E] <br/>
srownp@od.nih.gov>

Cc: Anderson, James (NIH/OD) [E] <james.anderson2@nih.gov>; Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Grieder, Franziska (NIH/OD) [E] <griederf@mail.nih.gov>; Dr. Lisa Jones-Engel <LisaJE@peta.org>; Kearse, Deborah (NIH/OD) [E] <deborah.kearse@nih.gov>; Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Tabak, Lawrence (NIH/OD) [E]

<lawrence.tabak@nih.gov>; Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>

Subject: RE: Response to concerns

January 7, 2022

Dear Dr. Brown,

I don't believe I've ever before received a response from a federal agency informing me: "Further inquiries on these issues will not be reviewed." That this is your response to evidence of multiple violations and concerns over reportable diseases with the potential to endanger the public is particularly surprising.

Our expectation, when we contacted Secretary Becerra with concerns about the biosecurity at the Washington National Primate Research Center (WaNPRC) at the University of Washington (UW) was that the NIH would proceed with a comprehensive investigation. But it appears from your letter, as well as the letter that you supplied to WaNPRC on December 1, 2021, that your department has made no serious effort to pursue an independent and thorough investigation.

Some of the issues we raised were ignored, including the research compromised by the use of sick animals; the high death rate and toxic waste exposure at NIH-funded WaNPRC breeding facility in Arizona; the possible danger to the populations living near the breeding facility who may be exposed to pathogens such as *Trypanosoma cruzi, Vibrio cholerae, Campylobacter, Shigella, Salmonella, Yersinia, Cryptosporidium*, and flaviviruses, which are circulating in the blood, feces, and urine of the macaques brought into their state; the apparent financial mismanagement at WaNPRC; and the multiple, ongoing animal welfare violations.

If OLAW had thoroughly delved into the disease issues, you would have seen that WaNPRC routinely ships animals with clinical evidence of infectious diseases. As just one example, see attached **WaNPRC ships monkeys with clinical disease.pdf**, in which the UW staff discuss the fact that several of the monkeys were ill with valley fever, a reportable disease in Washington state and/or diarrheal disease of unknown origin. Yet for this shipment of monkeys, WaNPRC staff completed a United States International and Interstate Certificate of Health Examination for Small Animals, U.S. Department of Agriculture Animal and Plant Health Inspection

Service Form 7001, on July 18, 2019, certifying that these monkeys "appear[ed] to be free of any infectious or contagious diseases and to the best of [her] knowledge, exposure thereto, which would endanger the animal or other animals or would endanger public health"; see attached **AZ-WaNPRC USDA Health Cert with diseased animals.pdf** 

WaNPRC's certification that the monkeys were free of infectious disease—despite the emails between WaNPRC veterinarians acknowledging that several of the monkeys were being treated for valley fever and chronic diarrhea—appears to violate the Lacey Act's false-labeling provision, which makes it "unlawful for any person to make or submit any false record, account, or label for, or any false identification of, any . . . wildlife . . . which has been, or is intended to be . . . transported in interstate or foreign commerce." 16 U.S.C. § 3372(d)(2).

The evidence we have amassed and offered to provide—and which you did not seek—reveals that this NIH-funded facility has apparently violated state and federal laws, violated the integrity of science, and threatened public health with their movement of diseased animals. Whose interests do you represent—the American public's or the university employees' who have falsified forms?

As NIH is providing hundreds of millions of taxpayer dollars to UW, you may be interested to know that in late December 2021, the King County Superior Court held the primate center liable for its policy of intentionally destroying public records, after the former interim director and the current associate director for research admitted to it under oath.

Sincerely,

Kathy Guillermo Senior Vice President Laboratory Investigations 757-943-7443 KathyG@peta.org

From: Brown, Patricia [OLAW] (NIH/OD) [E] < brownp@od.nih.gov>

Sent: Wednesday, January 5, 2022 11:59 AM To: Kathy Guillermo < KathyG@peta.org >

Cc: Anderson, James (NIH/OD) [E] < <u>james.anderson2@nih.gov</u>>; Bulls, Michelle G. (NIH/OD) [E] < <u>michelle.bulls@nih.gov</u>>; Grieder, Franziska (NIH/OD) [E] < <u>griederf@mail.nih.gov</u>>; Dr. Lisa Jones-Engel < <u>LisaJE@peta.org</u>>; Kearse, Deborah (NIH/OD) [E] < <u>deborah.kearse@nih.gov</u>>; Lauer, Michael (NIH/OD) [E] < <u>michael.lauer@nih.gov</u>>; Morse, Brent (NIH/OD) [E] < <u>morseb@mail.nih.gov</u>>; Tabak, Lawrence (NIH/OD) [E]

<lawrence.tabak@nih.gov>; Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>

Subject: Response to concerns

Dear Ms. Guillermo,

Enclosed please find the response to your organization's concerns with the biosecurity of macaque colonies at the Washington National Primate Research Center at the University of Washington.

Sincerely,

Patricia Brown, VMD, MS, DACLAM (she/her) Director, Office of Laboratory Animal Welfare, Office of Extramural Research, Office of the Director, NIH 6700B Rockledge Drive Bethesda, MD 20892-6910 301-496-7163 brownp@mail.nih.gov

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Office of Laboratory Animal Welfare 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, Maryland 20892

January 5, 2022

Kathy Guillermo Senior Vice President Laboratory Investigations Department People for the Ethical Treatment of Animals 501 Front Street Norfolk, Virginia 23510

Dear Ms. Guillermo:

Thank you for your October 5, 2021 letter to Secretary Becerra and a December 1, 2021 letter from your colleague, Dr. Jones-Engel, to Ms. Deborah Kearse, Director, Division of Program Integrity, Office of Management Assessment, concerning biosecurity of macaque colonies at the Washington National Primate Research Center (WaNPRC) at the University of Washington (UW). As the Director of the Office of Laboratory Animal Welfare (OLAW), I am providing the following response. As you know, OLAW is the unit within the US Department of Health and Human Services responsible for investigating noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy).

As required by the PHS Policy, the Division of Compliance Oversight has investigated the concerns identified in your report and in the article in the Arizona Republic that you shared. The investigation reviewed WaNPRC's biosecurity measures used to identify and prevent the spread of infectious pathogens. The investigation also reviewed the institution's current practices for assessing the health status of nonhuman primates (NHPs) prior to their transfer to other animal facilities.

The investigation found the following:

WaNPRC conducts routine screening for infectious pathogens and performs additional screening as warranted based on clinical signs. Semiannual health assessments of NHPs include screening for tuberculosis, serologic testing for enzootic primate viruses (i.e., Simian retrovirus, Simian T-cell leukemia virus, Simian immunodeficiency virus and herpes B virus); *Trypanosoma cruzi*; and *Coccidioides* if in Arizona or shipped from Arizona. Animals seropositive for *Coccidioides* receive treatment. In addition, if animals exhibit clinical signs of possible infectious disease, they are tested for *Campylobacter*, *Shigella*, *Salmonella*, *Cryptosporidium* and *Vibrio* by multiplex PCR or culture and treated.

<sup>1</sup> O'Dell, Rob. Sickness and death at Mesa-area monkey farm threaten primate center viability. *Arizona Republic*, <a href="https://www.peta.org/wp-content/uploads/2021/10/2021-10-04-Sickness-and-death-at-Mesa-area-monkey-farm-threaten-primate-center-viability.pdf">https://www.peta.org/wp-content/uploads/2021/10/2021-10-04-Sickness-and-death-at-Mesa-area-monkey-farm-threaten-primate-center-viability.pdf</a>.

Regarding transportation, physical examinations are performed on animals to be transferred or transported from Arizona to other animal facilities. Animals with clinical evidence of infectious disease are not shipped, and all animals are screened for tuberculosis within 30 days of shipment.

Regarding compliance with state and local regulations pertaining to animal transfer or transport, the institution did receive a Notice of Correction in 2021. The notice pertained to errors made in interstate transport of NHPs. In response, a corrective action plan was implemented to the satisfaction of the State Veterinarian and included the following:

- 1. Development of a Standard Operating Procedure (SOP) for animal shipments, including those from Arizona to Seattle. Records and logistics personnel and veterinarians receive this SOP as part of their training requirement with an update annually.
- 2. Registration with Global Vet Link to prepare Certificates of Veterinary Inspection for future shipments. The institution has signed up with the office of the State Veterinarian to receive regulatory updates and will use group e-mails to ensure that they continue to receive the information particularly critical for staff turnover. The institution has implemented a procedure for annual check-ins with the State Veterinarian to confirm compliance with regulations.
- 3. All animals that have positive titers for Valley Fever that were shipped from Arizona to Seattle have been identified and their status reported to the <u>Washington State</u> <u>Department of Agriculture Animal Disease Reporting Portal</u>. The institution will report any future cases as described in their SOP.
- 4. Regular communication occurs with the Washington State Veterinarian to ensure that all reportable pathogens that animals are exposed to are properly reported and documented according to regulations and recommendations.

Based on OLAW's assessment of the institution's current biosecurity measures, health screening procedures, compliance with the state and local regulations, and interactions with the office of the State Veterinarian, there is no evidence of animal welfare concerns or noncompliance with the PHS Policy.

OLAW's review is conducted within the context of the entire institutional program and considers the seriousness of the noncompliance and the corrective actions taken by the institution. Based on OLAW's continuing review of the WaNPRC and the University of Washington and their efforts to meet the requirements of their Assurance agreement and to improve their program, the institution is compliant with the PHS Policy.

The goal in the system of compliance oversight afforded by the PHS Policy and endorsed by the NIH Grants Policy Statement is to enable improvement in the institution's animal care and use program. Public Law 99-158 requires that an institution 1) be notified that conditions of animal care, treatment, or use do not meet applicable guidelines; and 2) be provided a reasonable opportunity to take corrective actions. Only if appropriate corrective actions are not taken by an institution would OLAW consider restricting or withdrawing approval of the institution's Assurance. Because the concerns were appropriately addressed by the institution, no further action will be taken by OLAW or NIH. Further inquiries on these issues will not be reviewed.

Thank you for your concern regarding the care and use of animals in PHS-supported research.

Sincerely,

Patricia A. Brown, V.M.D., DACLAM Director, Office of Laboratory Animal Welfare

cc:

Dr. Anderson

Secretary Becerra

Ms. Bulls

Dr. Grieder

Dr. Jones-Engel

Ms. Kearse

Dr. Lauer

Dr. Morse

Dr. Tabak

Dr. Tubbs