April 11, 2022

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

Rochelle P. Walensky, M.D., M.P.H. Director of the Centers for Disease Control and Prevention 1600 Clifton Rd. N.E. Atlanta, GA 30333

Re: Active Public Health Threat Posed by Large Populations of Monkeys Infected with *Trypanosoma cruzi*

Dear Mr. Secretary and Dr. Walensky:

Thank you for your service to our nation. We are writing to alert you to evidence PETA has amassed revealing that populations of primates maintained at research, breeding, importation, and commercial facilities in the U.S. are epidemiologically significant reservoirs for the parasite that causes Chagas disease and likely place both public health and scientific integrity in jeopardy. Immediate action is needed.

Chagas disease is a vector-borne infection caused by the multihost, blood-borne parasite *Trypanosoma cruzi* (*T. cruzi*). The World Health Organization lists Chagas disease as a neglected tropical disease for which there is no vaccine. Detection and treatment following initial infection remains very low, as less than 1% of infected persons in the U.S. receive anti-parasitic treatment.¹ If not treated immediately, chronic Chagas disease can cause lifelong disability, including serious organ damage, primarily to the cardiovascular and gastrointestinal systems.

Chagas-infected, immune-compromised individuals (e.g., those suffering from HIV/AIDS or undergoing chemotherapy) are particularly vulnerable to severe heart and central nervous system disease. There is increasing concern that individuals with Chagas disease are at an increased risk of severe COVID-19 manifestations because of the latter's potential impact on the heart.²

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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¹Melissa S. Nolan and Natasha S. Hochberg, "<u>Chagas Disease in HIV-Infected Patients: It's Time</u> to Consider the Diagnosis," *American Journal of Tropical Medicine and Hygiene* 105, no. 3 (September 2021): 545–46.

²Ezequiel José Zaidel, et al., "<u>COVID-19: Implications for People With Chagas Disease</u>," *Global Heart* 15, no. 1 (2020): 69.

Specifically, Chagas disease, the "silent killer,"³ is a growing health concern in the Southern regions of the U.S., where media reports have detailed an increased risk of Chagas disease.^{4,5,6,7,8}

Documents uncovered by PETA reveal that several of the seven federally funded national primate research centers (NPRC)—which collectively have received hundreds of millions of taxpayer dollars in funding from the National Institutes of Health—as well as multiple private commercial primate facilities have failed to maintain the biosecurity of the monkeys who are used or sold for experimentation. They have failed to prevent the introduction and spread of a vector-borne parasitic zoonosis into their colonies and its subsequent spread to other mammals. Even more alarmingly, they appear to have failed to report to state health authorities or address the public health threat that their tens of thousands of monkeys pose.

This is a dangerous situation for residents of states where these facilities are located. Chagas disease must be treated promptly in order to prevent irreversible negative health effects, but symptoms typically don't appear until the disease has progressed to a dangerous stage. At that point, it is often too late.

Secretary Becerra, we ask that you take the necessary steps to end public funding for the NPRCs, and Director Walensky, we ask that you act immediately to close the commercial primate facilities in Texas, Louisiana, Georgia, Florida, and South Carolina, as the monkeys in these facilities serve as a reservoir for *T. cruzi* infections. CDC researchers acknowledged more than a decade ago that primates who are maintained in outdoor facilities and used in biomedical research may be at particular risk for acquiring *T. cruzi* infection.⁹

Please see the attached report, "Evidence on the Role of Large Nonhuman Primate Research Colonies in the Growing Threat of Chagas Disease in the Southern United States," for additional information. We would be happy to meet with you to discuss this important matter further.

Sincerely,

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AP21.

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³Rachel Nuwer, "<u>Bugs That Transmit 'Silent Killer' Are Biting More in the U.S.</u>," scientificamerican.com, April 9, 2012. ⁴NBC DFW, "<u>Texas Kissing Bug Spike Could Increase Risk of Chagas Disease</u>," July 17, 2020.

⁵Deb Belt, "Kissing Bug, Nocturnal Disease Carrier, Confirmed in Georgia," Patch.com, April 25, 2019.

⁶Caresse Jackman, "<u>Kissing Bug' Disease Detected in Louisiana: What You Need to Know</u>," www.ltv.com, April 29, 2019.

⁷Deb Belt, "Kissing Bug, Blood-Sucking Disease Carrier, Confirmed in Florida," Patch.com, April 25, 2019.

⁸Mackenzie Concepcion, "<u>Kissing Bugs' in Arizona: What You Need to Know</u>," 12News.com, May 1, 2019.

⁹Caryn Bern, et al., "*Trypanosoma cruzi* and Chagas' Disease in the United States," *Clinical Microbiology Reviews* 24, no. 4 (October 2011): 666.

Evidence on the Role of Large Nonhuman Primate Research Colonies in the Growing Threat of Chagas Disease in the Southern United States

The geographic range of triatomine bugs (commonly called kissing bugs), which feed on several species of mammals, including humans and other primates, has changed dramatically in recent decades, expanding northward from South and Central America to include all of the Southern and Western United States.¹⁰ The most recent estimates, which are more than a decade old, from the Centers for Disease Control and Prevention (CDC) suggest that at least 300,000 Americans are infected with Chagas disease; however, a lack of surveillance and health-professional awareness has likely led to many more cases of this "silent killer" going unreported.¹¹ If initial active infection with *T. cruzi* is not treated, chronic and debilitating disease can occur. Individuals chronically infected with the *T. cruzi* parasite are reservoirs for vector-borne transmission and can transmit the parasite through blood and/or organ donations as well as congenitally.¹² Research has shown that understanding the dynamics of transmission cycles and characterizing parasite genotypes in a region is critical for identifying the risk for human infections with Chagas disease.¹³

Texas

Formerly known as the Southwest Foundation for Biomedical Research, the Texas Biomedical Research Institute's Southwest National Primate Research Center (SNPRC) in San Antonio, Texas, has reported a long history of *T. cruzi* infections in the primates at the facility. In 1984, the sudden death of a baboon in an outdoor cage at SNPRC revealed that Chagas disease was established in that monkey colony.¹⁴ In 2001, researchers acknowledged that the parasite *T. cruzi* and Chagas disease had **become endemic in captive-reared baboons at SNPRC**,¹⁵ and subsequent publications described significant disease, mortality,¹⁶ and stillbirths¹⁷ among the infected monkeys. Rather than addressing the public health threat of endemic *T. cruzi* in their thousands of primates, researchers at SNPRC have touted their Chagas-diseased monkeys as excellent models for research in both reproduction and infection with *T. cruzi*, seemingly ignoring the confounding variables that these endemic and often undiagnosed infections would introduce into experimental design.¹⁸ SNPRC typically maintains more than 2,800 monkeys in its colony.

¹⁵E.R. Argañaraz, et al., "<u>Blood-Sucking Lice May Disseminate *Trypanosoma cruzi* Infection in Baboons," *Revista do Instituto de Medicina Tropical de São Paulo* 43, no. 5 (October 2001): 271–6.</u>

¹⁰Paula Stigler Granados and Rodney E. Rohde, "<u>Chagas Disease in the U.S.: What We Do and Don't Know</u>," asm.org, April 13, 2021.

¹¹Veterinary Medicine & Biomedical Sciences, Texas A&M University, <u>Kissing Bugs & Chagas Disease in the</u> <u>United States: A Community Science Program</u>, accessed February 17, 2002.

¹²Caryn Bern, et al., "Trypanosoma cruzi and Chagas' Disease in the Unites States," 655-81.

¹³Alheli Flores-Ferrer, et al., "*Trypanosoma cruzi* Transmission Dynamics in a Synanthropic and Domesticated Host Community," *PLoS Neglected Tropical Diseases* 13, no. 12 (December 2019).

¹⁴C.A. Gleiser, R.G. Yager, J.J. Ghidoni, "*Trypanosoma cruzi* Infection in a Colony-Born Baboon," *Journal of the American Veterinary Medical Association* 189, no. 9 (1986): 1225–26.

¹⁶Jeff T. Williams, et al., "<u>Natural Chagas Disease in Four Baboons</u>," *Journal of Medical Primatology* 38, no. 2 (April 2009): 107–13.

¹⁷Jessica L. Grieves, et al., "*Trypanosoma cruzi* in Non-Human Primates With a History of Stillbirths: A <u>Retrospective Study (*Papio hamadryas* spp.) and Case Report (*Macaca fascicularis*)," Journal of Medical *Primatology* 37, no. 6 (December 2008): 318–28.</u>

¹⁸Ibid.

These primates are bred, used for experimentation, and shipped to other facilities and laboratories around the country.

A 2020 publication from the Michale E. Keeling Center for Comparative Medicine and Research (KCCMR) in Bastrop, Texas, which maintains more than 2,500 primates,¹⁹ found the following: "The percentage of *T. cruzi*–seropositive animals ranged from 6.7% to 9.7% in adult animals and 0% to 0.44% in juveniles or weanling animals, depending on the year. An overall 3.9% seroprevalence of *T. cruzi* infection was found in the total population."²⁰ A 2018 study described KCCMR as "a nidus of transmission" and concluded, "Our findings illustrate a robust transmission cycle of *T. cruzi* involving NHPs, multiple local wildlife species, and triatomine vectors on the campus of a nonhuman primate facility in central Texas."²¹ These authors appropriately point out that the health of humans and nonhuman primates is being impacted by the "spillover from the robust sylvatic transmission in the surrounding environment."²²

It is noteworthy that despite the many cases of *T. cruzi*, the documented role that primates in laboratory facilities in Texas play in the maintenance and diversity of *T. cruzi*, and the Texas Department of State Health Services' (DSHS) prior requirement that Chagas disease in nonhuman animals be reported to DSHS officials between 2013 and 2015, there is no indication that any primate biomedical facility in Texas has reported *T. cruzi* cases in their monkey colonies.²³ The failure to abide by state regulations for notifiable conditions reporting can have significant consequences. When Dr. Jones-Engel spoke with a DSHS epidemiologist official recently, that person was surprised to learn that Texas had multiple outdoor primate facilities and that *T. cruzi* was endemic in those facilities. Had this information been communicated to DSHS authorities, it is likely that steps would have been taken regarding the collection of surveillance data from these facilities.

Furthermore, a review of the distribution and prevalence of *T. cruzi* vectors reveals that commercial primate facilities Envigo and Inotiv in Alice, Texas (which consistently house more than 10,000 monkeys), in addition to SNPRC in Bexar County and KCCMR in Bastrop County, are all in areas reporting high densities of kissing bugs.²⁴

Louisiana

Louisiana is home to the Tulane National Primate Research Center (TNPRC) and the New Iberia Research Center at the University of Louisiana–Lafayette. Together, these two facilities maintain more than 16,000 monkeys, with the majority housed in outdoor enclosures. **Recent publications have implicated these large, outdoor-housed colonies of primates in the**

¹⁹University of Texas, <u>Annual Report to the U.S. Department of Agriculture's Animal and Plant Health Inspection</u> <u>Service</u>, 2020.

²⁰April L. Kendricks, et al., "<u>Reproductive Outcomes in Rhesus Macaques (*Macaca mulatta*) With Naturally-Acquired *Trypanosoma cruzi* Infection," *Comparative Medicine* 70, no. 2 (April 2020): 152–59.</u>

²¹Carolyn L. Hodo, et al., <u>*Trypanosoma cruzi*</u> Transmission Among Captive Nonhuman Primates, Wildlife, and <u>Vectors</u>," *Ecohealth* 15, no. 2 (2018): 426–36.

²²Ibid, 427.

²³ <u>Texas Department of State Health Services Report of Zoonotic Diseases in Animals, October 8, 2015</u>.

²⁴Agriculture & Life Sciences, Texas A&M University, Kissing Bugs & Chagas Disease in the United States: A Community Science Program, <u>Interactive Map</u>.

maintenance, transmission, and genotype diversity of *T. cruzi* **in Louisiana.** The authors of a 2019 study conducted at TNPRC stated the following:

Importantly, the sequence haplotypes of TcI, TcIV and TcVI we observed in nonhuman primates were closely related, but not identical, to haplotypes previously detected in rodents from southern Louisiana. Since most of these animals were born and raised in Louisiana (except the baboons, [who] came from Ohio and Washington), it is most likely that infection occurred locally. These results suggest on the one hand that there may be some degree of spatial structuration of *T. cruzi* strains in the region and on the other hand that these nonhuman primates and rodents may be involved in a common parasite transmission cycle.

The authors concluded, "The observation of multiple *T. cruzi* sequence haplotypes in each nonhuman primate indicates possible multiclonal infections. These data suggest the participation of these nonhuman primates in local parasite transmission cycles and highlight the value of these naturally infected animals for the study of human Chagas disease."²⁵ In other words, **monkeys housed at these facilities are contributing to the spread of Chagas disease among humans and other animals**.

Georgia, Florida, and South Carolina

Large numbers of monkeys are housed in outdoor enclosures in Georgia at the Yerkes National Primate Research Center. In Florida, as many as 11,000 monkeys are maintained in commercial outdoor facilities by Mannheimer Foundation Inc., PreLabs, Primate Products Inc., Bioculture Group, and Worldwide Primates Inc. In South Carolina, Alpha Genesis maintains nearly 6,000 monkeys at its commercial facility. None of these facilities have published any data on the presence of *T. cruzi* in the monkeys they buy, sell, and/or experiment on, but other unintended zoonotic pathogens of significant concern for public health have been detected in these large colonies.^{26,27} Given the known distribution of the kissing bug vectors, we must assume that *T. cruzi* has infected some of these monkeys, effectively establishing a reservoir for ongoing transmission to other mammals, including humans.

The consequences that this presents for public health are clear. There are also consequences for scientific integrity and animal welfare. In 2002, researchers at the German Primate Center in Göttingen, Germany, reported that a monkey purchased from a commercial primate center in South Carolina experienced an unintended reactivation of his Chagas disease after being experimentally infected with simian immunodeficiency virus (SIV). The monkey had arrived in Germany in 1996 and was presumed to be healthy and free of unintended infections. However, it

²⁵Claudia Herrera, et al., "<u>Trypanosoma cruzi Diversity in Naturally Infected Nonhuman Primates in Louisiana</u> <u>Assessed by Deep Sequencing of the Mini-Exon Gene</u>," *Transactions of the Royal Society of Tropical Medicine and Hygiene* 113, no. 5 (May 2019): 281–6.

²⁶K. Kolappaswamy, et al., "<u>Outbreak of Pathogenic *Escherichia coli* in an Outdoor-Housed Non-Human Primate Colony</u>," *Journal of Medical Primatology* 43, no. 2 (April 2014): 122–4.

²⁷Xinjun Zhang, et al., "<u>Ancestry, *Plasmodium cynomolgi* Prevalence and Rhesus Macaque Admixture in</u> <u>Cynomolgus Macaques (*Macaca fascicularis*) Bred for Export in Chinese Breeding Farms," *Journal of Medical Primatology* 46, no. 2 (April 2017): 31–41.</u>

was determined that this animal had not been screened for possible *T. cruzi* infection prior to international shipment. The researchers concluded the following:

Because there are no routine tests for *T. cruzi*, it is possible for a chronically infected animal to be given a false health certificate and be imported from an area where *T. cruzi* is endemic into a *T. cruzi*–free region. Because there are no cures available for chronically infected animals, such naturally occurring infections in imported animals still present a risk to humans. Even in regions without vectorial insects there are potential sources of accidental transmission to animal handlers and uninfected laboratory animals. A bite from an animal infected with *T. cruzi* or contamination with a wound containing epimastigote blood forms during the acute phase of infection could result in a human becoming infected. This work shows that occult infection with *T. cruzi* can reactivate and lead to histologic or even symptomatic changes associated with Chagas' disease and could distort the results of otherwise well-designed studies. This should always be a consideration when working with monkeys from colonies derived from *T. cruzi*–endemic areas.²⁸ [*Emphases added*.]

In 2014, researchers at the Oregon National Primate Research Center reported that two monkeys who had been purchased in the late 1990s from a commercial breeding facility in Alice, Texas, succumbed to undetected Chagas disease after a decade of being used as biomedical research subjects. The first monkey died following cardiac complications related to Chagas disease. The second monkey's chronic Chagas disease reactivated after they were experimentally infected with SIV. The researchers concluded the following:

In summary, **Chagas disease is endemic in [nonhuman primates] housed in the southern United States**. Given the long period of clinical latency in both cases between the time of import and the onset of signs, **Chagas disease may be more prevalent in rhesus macaques than has been recognized**, and current information on prevalence is needed. Infection should be considered in animals originating from this region, even if many years have elapsed since acquisition. The **disease can have long-term health consequences, particularly for NHP entering longitudinal or immunosuppressive protocols**, and screening may be warranted.²⁹ [*Emphases added*.]

Federal Agencies Have Not Acted, Despite Evidence

Internal documents obtained by PETA through public records requests, in addition to publicly available data, show that both the National Institutes of Health (NIH) and the CDC have been aware for more than a decade that *T. cruzi* is present in colonies of monkeys who are sold, transported within the U.S., and used in research. In October 2021, following the explosive investigative report by *The Arizona Republic* detailing the failure of the Washington National Primate Research Center to maintain the biosecurity of its pig-tailed macaque colonies in

²⁸E. Kunz, et al., "<u>Reactivation of a *Trypanosoma cruzi* Infection in a Rhesus Monkey (*Macaca mulatta*)
 <u>Experimentally Infected With SIV</u>," *Veterinary Pathology* 39, no. 6 (November 2002): 721–5.
 ²⁹Mary F, Dickerson, et al., "<u>Chagas Disease in 2 Geriatric Rhesus Macaques (*Macaca mulatta*) Housed in the Pacific Northwest," *Comparative Medicine* 64, no. 4 (August 2014): 323–8.
</u></u>

Arizona and Washington,³⁰ PETA offered to provide HHS, NIH,³¹ and the CDC with additional documents confirming the presence of Chagas disease—among other pathogens—in this colony. However, none of these agencies have taken any apparent steps to address the public health, scientific, and animal welfare consequences of this zoonotic pathogen. It is remarkable that taxpayer funding is being used by NIH and the CDC to purchase monkeys from commercial primate suppliers³² and national primate research centers³³ where Chagas disease circulates in the colonies.

HHS and the CDC have the authority—and the obligation—to prevent further spread of Chagas disease and other infectious pathogens. For the sake of residents in Southern states and for the animals housed in the colonies, the agencies must begin the process of dismantling the financial infrastructure that supports these primate laboratories and suppliers so that the population of monkeys, when not added to through continued breeding or international importation, will decrease.

³⁰PETA, "<u>Exposé: Diseased Monkeys Bred Near Toxic Waste Were Sold to U.S. Labs</u>," PETA.org, October 5, 2021.

³¹<u>Kathy Guillermo to Secretary Xavier Becerra</u>, PETA.org, October 5, 2021.

³²WorldWide Primates Inc contract to NIH, arlo.riseforanimals.org, July 10, 2020

³³<u>CDC contract to purchase monkeys from the Washington National Primate Research Center</u>, sam.gov, February 9, 2021.