

December 18, 2022

Daniel Jernigan, MD, MPH
Acting Director
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Via e-mail: dbj0@cdc.gov

Re: Primate Importation Brings Tier 1 Select Agents into the U.S.

Dear Dr. Jernigan:

I am writing on behalf of PETA's millions of supporters to urge the CDC to end the importation of nonhuman primates for the protection of U.S. residents against deadly disease and bioterrorism agents, for the integrity of science, and for the welfare of the animals and their ecosystems.

On July 27, 2022, the CDC issued a news release alerting the public to the presence of *Burkholderia pseudomallie*, a Tier 1 Select Agent, classified by the CDC as a bioterrorism agent, detected in the soils and water sources in the Mississippi Delta. That same day, the CDC released records to PETA showing that a number of serious, reportable zoonotic pathogens entered the U.S. during 2019-2021 in monkeys destined for facilities around the country. Among these records was a report of primate infected with *Burkholderia pseudomallie* who had been imported in 2021.

It is PETA's understanding that the CDC has the authority to regulate the importation of primates who may be harboring infectious agents that are zoonotic and may pose a threat to public health. The wildlife trade, particularly trade in the two primate species who are used in experimentation—the long-tailed macaque (*Macaca fascicularis*) and rhesus macaque (*Macaca mulatta*) — is recognized as a driver of spillover risk and disease spread. Macaques caught up in the wildlife supply chain and destined for laboratories are like lighter fluid, catalysts poised to ignite the next pandemic.

The <u>recent investigation by U.S. Fish and Wildlife</u> agents into the illegal and hazardous practice of capturing wild long-tailed macaques and subsequent mixing of these monkeys with captive-bred animals at the monkey farms in Cambodia in order to "launder" these animals for export to the U.S. likely means that all of the long-tailed macaques moving through the primate experimentation

¹ Johnson CK, Hitchens PL, Pandit PS, et al. Global shifts in mammalian population trends reveal key predictors of virus spillover risk. *Proc Biol Sci.* 2020;287(1924):20192736. doi:10.1098/rspb.2019.2736.; Borsky S, Hennighausen H, Leiter A, et al., CITES and the Zoonotic Disease Content in International Wildlife Trade. *Environ Res Econ.* 2020; 76:1001–1017. https://doi.org/10.1007/s10640-020-00456-7.; Campbell, S, Timoshyna A, Sant G, et al., Options for managing and tracing wild animal trade chains to reduce zoonotic disease risk. 2022. *TRAFFIC*, Cambridge UK.

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pipeline have been exposed to infectious agents that present a threat to public health.

Summary

According to the documents that you released to PETA, primates arriving in the U.S. between 2019-2021 were also infected with *Yersinia pseudotuberculosis*, *Yersinia enterocolitica*, *Shigella*, *Campylobacter*, tuberculosis, simian retrovirus, and *Macacine herpesvirus* 1, as well as undetermined pathogens that caused hemorrhagic gastroenteritis (bloody diarrhea), and erosive colitis with serositis (diarrhea so profound that the lining of the gut is shed). The documents also show that it was reported to the CDC that monkeys imported into the U.S. and undergoing quarantine have exhibited "... [i]llness that may be of public health concern such as clinical signs consistent with filovirus [Ebola-like viruses] infection...". It is clear from your documents that these monkeys were then released from quarantine and sent to unidentified facilities in the U.S.

It appears that the CDC made no public announcement about the presence of these dangerous zoonotic pathogens, which had the potential to spillover and spread throughout the U.S. Indeed, the very same day that the CDC released the documents to PETA, it also released a media statement stating that melioidosis had been found in the Mississippi Delta region—and the CDC stated they did not know its origin or where else it might be found in the U.S.—despite the CDC's own evidence that one way melioidosis had entered the U.S. was in shipments of monkeys.

Further, a recent publication confirmed that contrary to the CDC's assertion that the 31-day mandated quarantine for newly imported primates is adequate to prevent the introduction or spread of zoonotic diseases, pathogens including *Yersinia*, *Shigella*, *Campylobacter*, *Salmonella*, and *Mycobacterium* are increasingly being identified in imported macaques who have cleared CDC-required quarantine and have been shipped to research facilities across the U.S. ² The presence of these pathogens not only threatens human and monkey health, they also introduces variability and unreliability, further confounding experimental data from these animals. In 38 states, *Yersinia enterocolitica* and/or *Yersinia pseudotuberculosis* infections are diseases that must be reported to state health agencies. Shigellosis and Campylobacteriosis are nationally notifiable infectious diseases that must be reported to your agency. All of these pathogens are considered foodborne diseases, can be carried by monkeys subclinically and represent a threat to human and other animal health.

On July 6, 2022, PETA wrote to you citing the potential public health risks, conflict of interest, lack of transparency and deficiencies in the CDC-required quarantine in which the monkey importers are expected to monitor, screen, and report incidents of disease in newly imported primates. We asked that you suspend all importation of monkeys into the U.S. for laboratory use. On that date we did not have the information about the prevalence and diversity of the zoonotic pathogens being brought into the U.S by monkey importers and you did not mention those issues in your response to PETA on July 15, 2022. In your December 12, 2022, letter to PETA, you assert that the CDC is responsible for carrying out federal regulations that "are in place to protect the United States from communicable disease that can spread from NHPs [nonhuman primates] to humans."

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² Johnson AL, Keesler RI, Lewis AD, Reader JR, Laing ST. Common and Not-So-Common Pathologic Findings of the Gastrointestinal Tract of Rhesus and Cynomolgus Macaques. Toxicol Pathol. 2022 Jul;50(5):638-659. doi: 10.1177/01926233221084634. Epub 2022 Apr 1. PMID: 35363082; PMCID: PMC9308647. See Table 1.

Now, with clear documentation of the overwhelming risks that the monkey importation industry represents and with the knowledge that this industry has pushed two species of macaques, both of which are keystone species in their native habitats, to the brink of extinction, we are asking the CDC, in its capacity as the federal agency charged with surveillance and epidemiological risk assessment of imported animals that you immediately end primate importation.

Highlights from CDC documents detail morbidity and mortality among primates in CDC-approved quarantine facilities

On July 27, 2022, in response to a FOIA request submitted by PETA six months earlier for "...one copy of all public records dated from January 1, 2018,...[r]elated to nonhuman primates who died while in CDC-approved quarantine facilities," your agency provided 79 pages of documents containing three presentations given by CDC Veterinary Medical Officers in the Quarantine and Border Services Branch of the National Center for Emerging Zoonoses and Infectious Diseases in the Division of Global Migration and Quarantine to the Animal Transportation Association, which included international and domestic shippers, brokers, carrier representatives, and to the American Association of Primate Veterinarians. In their 2018 presentation to the Animal Transportation Association the CDC noted that they were observing "trends in transportation that are causing CDC concerns (e.g., infractions noted during offloading of NHPs at the port of entry)."

The data covered by the CDC during these presentations was for primate importations from 2017-2021. During this period, CDC officials presented the following information to stakeholders in the primate importation industry:

- In fiscal year 2019, which covers the period prior to the start of a global COVID pandemic, the CDC oversaw the largest number of imported primates this century---33,818 primates (pg. 63)
- In FY2021, **during** the COVID pandemic, the CDC reported the second highest annual importation of primates this century--- 31,844 (pg.63)
- Between FY 2019 and 2021 a total of 92,390 NHPs, transported via 407 air-shipments were imported into the US. The average number of primates per shipment increased from 209 to 245. (pgs. 64-65)
- 87,967 (95%) of the primates imported during this three-year period were long-tailed macaques. The next largest group of monkeys imported during this period were African green monkeys.(pg. 67)
- Between FY 2019 and FY 2021, the CDC reported that they were informed that monkeys imported into the U.S. and undergoing quarantine have exhibited "... [i]llness that may be of public health concern such as clinical signs consistent with filovirus [Ebola-like viruses] infection, confirmed *Shigella* and *Campylobacter* infection and malaria." Monkeys who "recovered during the quarantine period" were released from quarantine.(pg. 72)
- The number of primates who were either dead on arrival (DOA) or died during the 31-day mandatory CDC quarantine increased by 77% from FY 2019 to FY 2021. (pg. 72)
- The CDC reported that the leading cause of death in FY 2020 (including DOAs and death during quarantine) were gastrointestinal diseases including *Yersinia* pseudotuberculosis, Shigella and Campylobacter, as well as gastritis, enteritis, colitis. In FY 2021, in addition to the pathogens reported in FY 2020, new pathogens and diseases were detected in the monkeys, and animals died of hemorrhagic gastroenteritis (bloody diarrhea), erosive colitis with serositis (diarrhea so profound that the lining of the gut is shed), and *Yersinia enterocolitica*. (pg. 73)

- In FY 2021 there was an 8-fold increase from the previous year in the number of monkeys being euthanized during quarantine for suspected tuberculosis infection. (pg.74) In FY 2020 and FY 2021, eight shipments required extended tuberculosis quarantine (pg.75).
- During FY 2020 and FY 2021, the number of monkeys dying during quarantine due to "undetermined/indeterminate" cause more than doubled (pg. 73).
- During FY 2020 and FY 2021, 17 monkeys were found to be infected with either Simian retrovirus (SRV) or Herpes B virus (*Macacine herpesvirus 1*) and euthanized during quarantine (pg. 74). These zoonotic viruses are naturally found in wild populations of macaques; however, the presence of these infections are inconsistent with specific-pathogen free macaques and/or macaques that are purpose bred.
- During quarantine in FY 2021, one monkey was diagnosed with melioidosis, a disease caused by *Burkholderia pseudomallei*, and deemed by the CDC to be bioterrorism agent (pg. 74.)

Dangerous Pathogens and Public Health Risk

The CDC is aware that that the importation of primates represents a significant public health risk, as these imported animals have been shown to harbor dangerous and even deadly pathogens.³ *Burkholderia pseudomallei*, is classified as <u>Tier 1 Select Agent</u> capable of posing a severe threat to human and nonhuman animal health. The bacterium is prevalent in the soil throughout Asia, including the countries where hundreds of thousands of primates have been trapped, farmed, and exported to the U.S.

In 1969, outbreaks of *Burkholderia pseudomallei* (called *Pseudomonas pseudomallei* at that time)—in macaques imported months or years earlier from India, Thailand, and Indonesia—were detected in laboratories at the National Institutes of Health in Washington, DC, the Washington National Primate Research Center in Seattle, WA, and the Aeromedical Research laboratory at Holloman Air Force Base, NM.⁴ In 1973 a rhesus macaque was imported into the U.S. by a commercial vendor and subsequently transferred to the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland.⁵ The monkey began showing signs of illness in 1979 and was subsequently euthanized in 1983. *Pseudomonas pseudomallei* (aka *Burkholderia pseudomallei*) was cultured and identified from cerebrospinal fluid. In 2004, *Burkholderia pseudomallei* was cultured from the bladder, kidney, and liver abscesses in a long-tailed macaque imported from Indonesia into a colony at Wake Forest University in Salem, NC.⁶ The animal had remained asymptomatic and was considered healthy throughout the prior year.

³ General Q&A - Updates to Regulations for Importation of Nonhuman Primates | Laws & Regulations | Importation | CDC "What is the risk to human health from NHPs? NHPs may carry infectious diseases that are dangerous and sometimes fatal to humans. These infections include those caused by Shigella, Salmonella, Ebola virus, herpes B virus, Mycobacterium tuberculosis complex (bacteria that cause tuberculosis, or TB), yellow fever virus, and many others. People working in temporary or long-term NHP holding facilities or involved in transporting NHPs (e.g., cargo handlers and inspectors) are especially at risk for infection."

⁴ Kaufmann AF, Alexander AD, Allen AM, Cronin RJ, Dillingham LA, Douglas JD, Moore TD. Melioidosis in Imported Non-Human Primates. J Wildl Dis 1 October 1970; 6 (4): 211–219. doi: https://doi.org/10.7589/0090-3558-6.4.211

⁵ Fritz PE, Miller JG, Slayter M, Smith TJ. Naturally occurring melioidosis in a colonized rhesus monkey (Macaca mulatta). Lab Anim, 1986:20, 281-285.

⁶ Conference 03 - 2013 Case: 01 20130925 (askjpc.org)

In 2012, fatal *Burkholderia pseudomallei* was detected in a long-tailed macaque from an Indonesian colony.⁷ That same year, a pig-tailed macaque imported from Indonesia completed quarantine at a CDC-registered import facility and was subsequently sent to a CDC laboratory.⁸ Within a week of arrival at the CDC, the animal began showing signs of illness, which progressed over five months to include neurologic symptoms.⁹ *Burkholderia pseudomallei* was eventually confirmed in abscesses, lung, and liver tissues.⁸ In December 2012, *B. pseudomallei* was added to the National Select Agent Registry.

In 2013, CDC officials further revised primate importation regulations, ostensibly to increase surveillance in response to public health threats associated with primate importation; however, no mention of screening for *Burkholderia pseudomallei* was made. In 2014, the year *after* the CDC revised primate importation regulations, and CDC officials acknowledged that a primate harboring a Tier 1 Select Agent somehow slipped through CDC-required quarantine, there was a 33% increase in the number of primates imported into the U.S. (pg. 9). It should be noted that the lesions that accompany melioidosis are nonspecific and cannot be distinguished clinically or by gross or histopathology from those of other bacterial infections, and that host risk factors (including immunosuppression) play a significant role in clinical presentation and severity of disease. In

Review of the primary literature confirms that **your agency has been aware of the presence of** *Burkholderia pseudomallei* in imported monkeys for more than five decades and that animals have arrived with pre-existent foci of infection which became active weeks or years later. However, during a 2014-2015 CDC investigation into the origin of *Burkholderia pseudomallei* amidst an outbreak of disease among outdoor housed monkeys at the Tulane National Primate Research Center (TNPRC) in Covington, LAm your <u>agency did not deem it plausible</u> that the natural source of *Burkholderia pseudomallei* could have been imported macaques. During the outbreak, TNPRC's 5000+ monkeys included wild-caught and captive reared monkeys imported from Asia and/or transferred from the Washington National Primate Research Center (WaNPRC), a facility that had previously imported macaques infected with *Burkholderia pseudomallei*.¹²

On October 21, 2022, PETA submitted a FOIA request to the Louisiana Department of Wildlife & Fisheries (LDWF) requesting all public records from the LDWF pertaining to the investigation by the CDC, USDA, and APHIS into the presence of *Burkholderia pseudomallei* at Tulane National Primate Research Center (TNPRC) during 2014-2015. Despite ample documentation--including in the CDC's own facility in 2013--- that primates imported and maintained in research facilities have been a source

⁷ Prabandari S. Arifin E. Rosmanah L, Kartika D, Narani A, Iskandriati D, Pamungkas J. Fatal Burkholderia (Pseudomonas) pseudomallei septicaemia in a cynomolgus monkey (Macaca fascicularis) at the facility of Primate Research Center, Bogor Agricultural University. In Proceedings of the Kyoto Univ and IPB International Symposium: Diversity and Conservation of Asian Primates, Bogor, Indonesia, 20–21 August 2012

⁸ Johnson CH, Skinner BL, Dietz SM, Blaney D, Engel RM, Lathrop GW, Hoffmaster AR, Gee JE, Elrod MG, Powell N, Walke H. Natural infection of *Burkholderia pseudomallei* in an imported pigtail macaque (Macaca nemestrina) and management of the exposed colony. Comp Med. 2013;63(6):528-35. PMID: 24326230; PMCID: PMC3866985.

⁹ Ritter JM, Sanchez S, Jones TL, Zaki SR, Drew CP. Neurologic melioidosis in an imported pigtail macaque (Macaca nemestrina). Vet Pathol. 2013 Nov;50(6):1139-44. doi: 10.1177/0300985813485249. Epub 2013 Apr 10. PMID: 23576240.

¹⁰ Federal Register :: Control of Communicable Disease; Foreign-Requirements for Importers of Nonhuman Primates (NHP)

¹¹ Currie BJ. Melioidosis: Evolving Concepts in Epidemiology, Pathogenesis, and Treatment. Semin Respir Crit Care Med 2015;36:111–125.

¹² Has JC, Robinette RL, Davis A. Survival and Reproduction in the First Two Years Following a Large-Scale Primate Colony Move and Social Reorganization. Amer J Prim. 2000; 50:131–138.

of *Burkholderia pseudomallei* outbreaks, there is no mention in the documents that the monkeys maintained in TNPRC were a possible original and/or sole source of the outbreak.

A study published the following year, conducted to assess the predicted global distribution of *Burkholderia pseudomallei* modeled the likelihood that the bacterium would spread to a geographic area based on documented human and nonhuman animal cases, the suitability of the environment, and whether the bacteria had ever been released into the environment. The authors concluded that "... [i]t would be possible for *Burkholderia pseudomallei* to become established in Louisiana if the bacterium were to be released widely." The study also predicted that the environment in the contiguous area covering southern parts of Florida, Louisiana, and Texas was highly suitable for *Burkholderia pseudomallei*. Tens of thousands of primates have been imported into primate facilities in these states.

In 2016, serosurveys conducted in response to the fatal melioidosis in a macaque at an Indonesian research center, which was established in collaboration with the WaNPRC, confirmed that up to 76% of macaques in the Indonesian colonies used for domestic experiments and for export were seropositive *Burkholderia pseudomallei*. ¹⁴ The bacteria was also detected in free-ranging primates on Tinjil island, a population that is regularly harvested for use in research. ¹⁵

Conclusion

The commercial importation of primates is a secretive, dangerous, unethical, and financially lucrative enterprise for several major companies. However, it is U.S. citizens and endangered primates who may be paying the price for this industry's practices. The CDC has overseen the importation of nearly 100,000 monkeys during the COVID pandemic, and the agency's own documents make it painfully clear that many of these monkeys have arrived and then been moved throughout the U.S. with pathogens that can cause illness, and even death among humans. Primates in their natural habitats do not represent a significant infectious threat to humans. But no primate can withstand the immune system-destroying stress of capture, horrific conditions, and exposure to pathogens while in captivity and transit. The monkeys caught up in the wildlife trade for experimentation are exposed to pathogens along every point of the trip. Monkeys ensnared in this trade have transmitted pathogens to humans and in some cases those humans have died. It is perhaps just a matter of time before a recognized or novel deadly agent sparks a new pandemic.

As the CDC is the U.S. agency mandated to protect public health, we ask that you immediately end all primate importations. The scientific community has known for decades that the monkey model fails to provide meaningful treatments and vaccines for humans. This, coupled with the devastation wreaked on wild macaque populations and the zoonotic disease threat that imported and/or domestic colonies of primates pose to humans, make it clear that the time has come to end this threat to human and monkey welfare.

¹³ Limmathurotsakul D, Golding N, Dance DA, Messina JP, Pigott DM, Moyes CL, Rolim DB, Bertherat E, Day NP, Peacock SJ, Hay SI. Predicted global distribution of Burkholderia pseudomallei and burden of melioidosis. Nat Microbiol. 2016 Jan 11;1:15008. doi: 10.1038/nmicrobiol.2015.8. PMID: 27571754.

¹⁴ Testamenti VA, Noviana R, Iskandriati D, et al. Humoral Immune Responses to Burkholderia pseudomallei Antigens in Captive and Wild Macaques in the Western Part of Java, Indonesia. Veterinary Sciences. 2020; 7(4):153. https://doi.org/10.3390/vetsci7040153

¹⁵ Testamenti VA, Iskandriati D, Wahyudi AT, Pamungkas J. Detection of Antibody to Burkholderia pseudomallei in Captive and Wild Macaques in West Java and Bali, Indonesia. Microbiology Indonesia. 2018 12(1), 4. https://doi.org/10.5454/mi.12.1.4

Respectfully,

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