July 6, 2022

Christopher Braden, M.D. Acting Director National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention

Via e-mail: <u>crb5@cdc.gov</u>

# **Re: Public Health Threat Posed by Thousands of Monkeys Imported Into and Transported Throughout the U.S. Every Month**

Dear Dr. Braden:

Thank you for your service to our nation. I'm a former primate scientist with nearly 40 years of experience working in the primate biomedical community and in primate-habitat countries. My research focused on the transmission of infectious diseases between populations of humans and other primates and the consequences of this for human health and primate conservation. I now serve as PETA's senior scientific advisor. PETA U.S. is the largest animal rights organization in the world, and PETA entities have more than 9 million members and supporters globally. I'm writing today on behalf of PETA U.S., because as acting director of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) of the Centers for Disease Control and Prevention (CDC), you have oversight of the Division of Global Migration and Quarantine (DGMQ), which is the division of the CDC responsible for ensuring that imported animals do not jeopardize health, safety, or security in the U.S.

The CDC controls the flow of primates into the U.S., and as gatekeepers, you have the life-changing ability to mitigate primate-borne disease introduction and transmission. The tens of thousands of primates who are now annually captured in their natural homes or intensively bred in factory farming operations for exportation to laboratories are typically stressed, immunocompromised, injured, and diseased. We urge the CDC to acknowledge the public health risks that wild-caught and farmed monkeys present and immediately end all importation of monkeys destined for biomedical research.

On multiple occasions over the past three decades, primates imported into the U.S. as part of the biomedical trade have arrived with infectious agents capable of causing a global pandemic.<sup>1,2,3</sup> In 1975, you acted "to protect U.S. residents

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<sup>&</sup>lt;sup>1</sup>Roberts, JA, Andrews, K. Nonhuman primate quarantine: its evolution and practice. *ILAR Journal*. 2008;49(2):145–156. doi:10.1093/ilar.49.2.145

<sup>&</sup>lt;sup>2</sup>Jahrling PB, Geisbert TW, Dalgard DW, et al. Preliminary report: isolation of Ebola virus from monkeys imported to USA. *The Lancet*. 1990;335(8688):502–505. doi:10.1016/0140-6736(90)90737-P

<sup>&</sup>lt;sup>3</sup>CDC. Epidemiologic notes and reports update: Ebola-related filovirus infection in nonhuman primates and interim guidelines for handling nonhuman primates during transit and quarantine. *MMWR*. 1990;39(2):22–24, 29, and 30. Accessed June 22, 2022. https://www.cdc.gov/mmwr/preview/mmwrhtml/00001538 htm

from severe infections that can spread from monkeys to humans" by banning the importation of primates as "pets."<sup>4</sup> The risk of disease transmission posed by the importation of thousands of monkeys to U.S. laboratories every month is clear and present.

### Public Health Risks Associated With the Importation of Primates

The federal regulations on the importation of primates<sup>5</sup> lead even the casual reader to the understanding that the overall risk of importing a monkey with a significant known or unknown infectious disease is high. The <u>CDC website</u> is explicit about the infectious threat that imported primates pose to human health:

NHPs [nonhuman primates] 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 of infection. [*Emphasis added*.]

## Trade in Two Primate Species Linked to Greatest Zoonotic Risk

Just prior to the global SARS-CoV-2 pandemic, in an effort to assess the risk of spillover events associated with particular species, scientists assessed the presence of zoonotic viruses in mammals and concluded that only a fraction of mammalian species harbor zoonotic viruses,<sup>6</sup> and among that select group, rodents, bats, and primates accounted for three-fourths of the zoonotic viruses that have been described to date. The authors concluded that primates and bats are the species most likely to be involved in spillover events.<sup>7</sup>

Researchers interested in the inherent zoonotic disease risks associated with the international animal trade used the Convention on International Trade in Endangered Species of Wild Fauna and Flora database coupled with the recent analyses by Christine K. Johnson *et al.* and determined that trade in two primate species—*Macaca fascicularis* (long-tailed macaque) and *Macaca mulatta* (rhesus macaque)—carried the greatest potential for zoonotic disease.<sup>8</sup> A 2022

<sup>&</sup>lt;sup>4</sup>CDC. Bringing a nonhuman primate into the United States. Accessed June 22, 2022. https://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/monkeys.html

<sup>&</sup>lt;sup>5</sup>CDC. Foreign requirements for importers of nonhuman primates. *Federal Register*. 42 CFR § 71.53. Accessed June

<sup>22, 2022. &</sup>lt;u>https://www.federalregister.gov/documents/2013/02/15/2013-03064/control-of-communicable-disease-foreign-requirements-for-importers-of-nonhuman-primates-nhp</u>

<sup>&</sup>lt;sup>6</sup>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. p. 4. <u>doi:10.1098/rspb.2019.2736</u> ("Among 5,335 wild terrestrial mammal species, we found that only 11.4% of mammalian species (n = 609) have been identified with one or more of the zoonotic viruses investigated here and, of these, most species (58.1%, n = 354) have been reported with only one zoonotic virus each.")

<sup>&</sup>lt;sup>7</sup>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. pp. 7–8. <u>doi:10.1098/rspb.2019.2736</u> ("[S]pecies in the *primate* and bat orders were significantly more likely to harbour zoonotic viruses compared to all other orders, after adjusting for domestication, species abundance, criteria for listing and the number of PubMed publications at the species level" [*emphasis added*].)

<sup>&</sup>lt;sup>8</sup>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. doi:10.1007/s10640-020-00456-7 ("[E]ither macaca fascicularis or macaca mulatta show the highest average volume of potential zoonotic disease traded.")

publication acknowledged that recent importations of these species have been associated with "increased exposure to naturally occurring pathogens," all of which are zoonotic.<sup>9</sup>

This issue is of particular concern because in the last decade alone, more than a quarter of a million long-tailed macaques and rhesus macaques have been brought into the U.S.<sup>10</sup> by commercial primate importers—including Charles River Laboratories, Laboratory Corporation of America, Envigo, Covance, Orient BioResource Center (OBRC), Shin Nippon Biomedical Laboratories (SBNL), and Bioculture Group—all of which have been registered and permitted by the CDC. Most of these imports originate in commercial facilities in Southeast Asia, China, and Mauritius. In the past decade—and especially during the COVID-19 pandemic—scientists in habitat countries have noted a rise in the capture of primates in their natural homes for biomedical research, and countries have begun reinstating quotas for such captures in response to increasing demand and financial opportunity.<sup>11</sup> Breeding centers exporting captive-bred primates may launder wild-caught animals as captive-bred and regularly capture primates in nature for upkeep. The International Society of Primatologists recently issued a policy statement recommending ending the use of wild-caught primates for use in biomedical research.<sup>12</sup>

# Conflict of Interest, Lack of Transparency in Quarantine System, and Monkeys on the Move

The CDC-registered/permitted importers arrange for macaques to be transported throughout the U.S. to CDC-approved quarantine facilities at undisclosed locations. The commercial importer is then solely responsible for husbandry, health screening, illness detection, and reporting during the mandated 31-day quarantine period. A recent publication confirmed the failure of international and domestic quarantines to identify even highly studied infections, such as tuberculosis, in monkeys consistently used in biomedical research.<sup>13</sup> There are numerous examples of imported primates clearing the required 31-day quarantine and subsequently developing dangerous zoonotic diseases, including infections listed by the <u>CDC as Tier 1 select agents</u>, such as *Burkholderia pseudomallei*.<sup>14,15</sup> Before and after the required and obviously flawed quarantine period, monkeys crisscross the country in trucks from the importers to laboratories. PETA has documented dozens of occasions when veterinary inspections were not

<sup>12</sup> IPS | Harvesting of wild primates for use in biomedical research

<sup>&</sup>lt;sup>9</sup>Johnson AL, Keesler RI, Lewis AD, et al. Common and not-so-common pathologic findings of the gastrointestinal tract of rhesus and cynomolgus macaques. *Toxicol Pathol*. Preprint posted online April 1, 2022;1926233221084634. doi:10.1177/01926233221084634

<sup>&</sup>lt;sup>10</sup>Galland G. Nonhuman primate importation during the SARS-CoV-2 pandemic. Gale Galland CDC importation - Google Search

<sup>&</sup>lt;sup>11</sup>Reuter KE, Andriantsaralaza S, Hansen MF, et al. Impact of the COVID-19 pandemic on primate research and conservation. *Animals*. 2022;12(9):1214. <u>doi:10.3390/ani12091214</u>

<sup>(</sup>internationalprimatologicalsociety.org)

<sup>&</sup>lt;sup>13</sup>Yee JL, Prongay K, Van Rompay KKA, et al. Tuberculosis detection in nonhuman primates is enhanced by use of testing algorithms that include an interferon- $\gamma$  release assay. *Amer J Vet Res.* 2022;83(1):15–22. Abstract.

doi:10.2460/ajvr.21.08.0124 ("The detection and management of MTBC infection in captive nonhuman primate populations is an ongoing challenge, especially with animal imports and transfers. Despite standardized practices of initial quarantine with regular intradermal tuberculin skin testing, spontaneous outbreaks continue to be reported.") <sup>14</sup>Johnson CH, Skinner BL, Dietz SM, et al. Natural infection of *Burkholderia pseudomallei* in an imported pigtail macaque (*Macaca nemestrina*) and management of the exposed colony. *Comp Med.* 2013;63(6):528–535. Accessed June 22, 2022. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3866985/</u>

<sup>&</sup>lt;sup>15</sup>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. doi:10.3390/vetsci7040153

conducted within the required 10 days before shipment, and the veterinarians doing the inspections were often from small-animal practices and lacked experience working with primates.<sup>16</sup>

It appears that at every point in the pipeline—from forest to laboratory—the companies that have the most to gain financially have been granted the authority to determine what level of infectious threat will be tolerated. The potential conflict of interest cannot be ignored, particularly given that several of these importers are currently under governmental investigation.

# Quarantine System Deficiencies: Known Knowns, Unknown Knowns, and Unknown Unknowns

Recent U.S. Securities and Exchange Commission (SEC) filings reveal that Inotiv, Laboratory Corporation of America, Envigo, Covance, and OBRC have been subpoenaed by the U.S. Attorney's Office for the Southern District of Florida (USAO) for documents related to their primate procurement and importation activities.<sup>17</sup> And Charles River, one of the largest primate importers in the U.S.—with foreign acquisition and breeding facilities in Mauritius and Southeast Asia—began divulging in its March 2020 SEC filings that the animals it imports may carry zoonotic infectious agents that could cause disease in exposed humans. These importers also noted that contamination of animals at their suppliers' facilities was possible and that the presence of contaminated animals could complicate and lengthen CDC-required quarantine, thereby affecting their revenue.<sup>18</sup>

Government investigations, subpoenas, and acknowledgment that the act of animal importation carries with it a risk sufficient enough to warrant an SEC disclosure are deeply alarming and

<sup>&</sup>lt;sup>16</sup>PETA. USDA transportation complaint. April 18, 2022. Accessed June 22, 2022. <u>2022-04-18-usda-transport-complaint-compled.pdf (peta.org)</u>

<sup>&</sup>lt;sup>17</sup>On June 15, 2021, Envigo Global Services Inc. (EGSI), a subsidiary of the company acquired in the Envigo acquisition, received a grand jury subpoena requested by the USAO for the production of documents related to the NHPs from foreign suppliers for the period January 1, 2018, through June 1, 2021. The subpoena relates to a previous grand jury subpoena requested by the USAO and received by EGSI's predecessor entity, Covance Research Products, in April 2019. Envigo acquired EGSI from Covance Inc., a subsidiary of Laboratory Corporation of America Holdings, in June 2019. On January 27, 2022, EGSI acquired OBRC, which owns and operates a primate-quarantine and holding facility located near Alice, Texas. In 2019, OBRC received grand jury subpoenas requested by the USAO requiring the production of documents and information related to its importation of NHPs into the U.S. On June 16, 2021, OBRC received a grand jury subpoena requested by the USAO requiring the production of documents related to the procurement of NHPs from foreign suppliers for the period January 1, 2018, through June 1, 2021. The OBRC purchase agreement provides for indemnification of EGSI and its officers, directors, and affiliates by the seller, Orient Bio Inc., for liabilities resulting from actions, inactions, errors, or omissions of Orient Bio Inc. or OBRC related to any period prior to the closing date. Laboratory Corporation of America Holdings April 2022 SEC Form 10-Q and Inotiv, Inc. April 2022 Quarterly Report SEC Form 10-Q <sup>18</sup>Charles River made the following statement in its declaration to the SEC in March 2020: "In some cases, we may produce or import animals carrying infectious agents capable of causing disease in humans; and in the case of such a contamination or undiagnosed infection, there could be a possible risk of human exposure and infection and liability for damages to infected persons. We are also subject to similar contamination risks with respect to our large research models. While some of these models are owned by us and maintained at our facilities, others are reserved for us and maintained at sites operated by the original provider. Accordingly, risk of contamination may be outside of our control, and we depend on the practices and protocols of third parties to ensure a contamination-free environment. A contamination may require extended CDC quarantine with subsequent reduced sales as a result of lost client orders, as well as the potential for complete inventory loss and disinfection of the affected quarantine rooms." crl-20200328 (sec.gov)

raise obvious questions about the likelihood and **public health consequences** of macaques being imported into the U.S. and carrying any of the following three categories of infectious disease: CDC-regulated disease, known nonregulated disease, and unknown nonregulated disease.

### Failures in Danville, Pennsylvania

In late January, newly imported monkeys—delivered to John F. Kennedy International Airport in New York via Kenya Airways from Mauritius and destined for a mandatory CDC quarantine facility—spilled out onto a Danville, Pennsylvania, highway hours after being unloaded. The crates were not labeled as containing primates, and for the first 20 to 30 minutes, no instructions were given not to approach the crates or move about the site. While attempting to offer assistance to the human and nonhuman primate victims, one passerby received multiple exposures to monkey saliva, feces, and urine. Three long-tailed macaques escaped and were eventually shot and killed.

The DGMQ was on site during the accident and informed about the exposures. Standard of care and best practices that apply to laboratory personnel who have been exposed to macaques are clear, and it is also clear that many of these protocols were not followed after this unsuspecting citizen was exposed.<sup>19</sup> Within days, PETA filed a complaint with the USDA, noting—among other concerns—that the mishandling of the macaques and on-site failure to follow the federally mandated infection-prevention procedures had led to multiple exposures among first responders and others. The accident demonstrated that companies involved in the mass importation of primates are not taking the public health threat seriously.

## Conclusion

The commercial importation of thousands of monkeys each month into the U.S. and their transport throughout the country are inviting pathogen spillover from these often diseased and stressed animals. This industry is a secretive, dangerous, unethical, and financially lucrative enterprise for several major companies. However, it is U.S. citizens who may be paying the price. 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 research on monkeys fails to lead to meaningful treatments and vaccines for humans. This failure—coupled with the devastation wreaked on wild macaque populations and the zoonotic disease threat that imported and domestic colonies of primates pose to humans—makes it clear that the time has come to end this threat to human and monkey welfare. I would be happy to provide you with any additional information you might need. Thank you for your time and attention to this important matter. I look forward to your response.

Sincerely,

AN1.

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<sup>&</sup>lt;sup>19</sup>Barkati S, Taher HB, Beauchamp E, et al. Decision tool for herpes B virus antiviral prophylaxis after macaquerelated injuries in research laboratory workers. *Emerg Infect Dis*. 2019;25(9):e190045. <u>doi:10.3201/eid2509.190045</u>