

Fact-Checking Safer Human Medicine’s “Facts”

SHM Claim: Without primates, medical research comes to a halt.

Fact: The National Institutes of Health’s own data show that the results of animal tests generally are not applicable to humans, with more than 90% of drugs found to be safe and effective in animals going on to fail in human trials. Many alternative tests which are based on human biology are now available and are in high demand—even major primate suppliers are realizing this. In early 2023, James Foster, the CEO of Charles River Laboratories (CRL), stated that the primate shortage has endedⁱ. In a recent earnings call, Foster reported that CRL had a 25% reduction in primates used in 2023, noting that one strategy of the company is “reducing animal usage.” CRL has now introduced virtual control groups for toxicology studies as an alternative to using primatesⁱⁱ. Similarly, another major primate supplier, Inotiv, stated that they had a 37% decrease in nonhuman primate sales from the previous year, and specifically had a 60% decrease in monkey sales from Q4 2022 to Q4 2023.ⁱⁱⁱ

SHM Claim: The health and welfare of animals under our care is top priority.

Fact: The capture of long-tailed macaques for laboratory experimentation has contributed to dramatic population level declines in their natural homes in Asia. This species of monkey was recently elevated to Endangered on the IUCN Red List^{iv}. Monkeys shipped to facilities like the one Safer Human Medicine (SHM) is attempting to establish in Bainbridge were torn away from their homes in nature or else were confined on squalid breeding farms in Asia or Africa. When these monkeys are shipped to the U.S., they’re separated from their families, locked inside small wooden crates, and crammed into dark, terrifying airplane cargo holds for as long as 30 hours.

The leaders of SHM are former executives from Envigo, Charles River, and Covance, companies that profit from animal misery and are in charge of facilities that have faced federal citations for repeated violations of the most basic federal animal welfare regulations. While SHM’s Chief Operating Officer, Jim Harkness, was the COO at Envigo, he was in charge of animal research models when the company’s beagle-breeding facility in Virginia was raided by the U.S. Department of Justice (DOJ), which found and seized hundreds of dogs in acute distress^v. At Charles River, 32 monkeys were baked alive when no one noticed a thermostat malfunction and at an Envigo facility, a monkey recently died when a squeeze cage panel was dislodged and crushed the animal.^{vi,vii} Charles River had five shipments of monkeys imported from Cambodia refused clearance by U.S. Fish and Wildlife agents because the company could not prove that these monkeys were not illegally captured from the wild. These 1,269 monkeys continue to languish in cages here in the U.S. and Charles River has refused to send these monkeys to sanctuary, even though they know that the monkeys can never be sold or used in experimentation.^{viii}

The photographs provided by SHM appear to be AI-generated and do not depict reality. Inotiv’s Alice, Texas facility houses 8,000 macaques in the same space that SHM plans to house 30,000^{ix}. The Global Federation of Animal Sanctuaries recommends a minimum of 5,500 square feet per outdoor enclosure for 4-8 macaques, meaning that SHM would need approximately 473 acres just for primate housing in order to meet minimum care standards.^x

According to SHM documents, at full capacity, the company plans to have one attending (lead) veterinarian and six veterinarians—roughly one veterinarian per 4,300 monkeys.

SHM Claim: Primates provide the most reliable model to demonstrate how a drug will impact our biological systems.

Fact: Even chimpanzees, our closest living relative, do not respond to serious human pathogens the same way that we do. It is futile to study infections in animals that do not contract them in any similar way. The U.S. government redirected \$10 million of AIDS research funding away from chimpanzee studies after

concluding they are a ‘deficient model’, and 80 AIDS vaccines have failed in human trials following success in primates.^{xi}

The major experimental use of monkeys is for safety testing of medicines. Yet primates’ track record at predicting drugs’ dangerous side effects is abysmal. Many drugs that were safe for monkeys have gone on to injure or kill people. Six young men nearly died at Northwick Park Hospital in 2006 when they were given a new drug because it had been ‘proven safe’ in monkeys at high doses^{xii}. The arthritis drug Vioxx, withdrawn in 2004, killed up to 140,000 people—the biggest drug disaster in history—after being ‘proved safe’ in monkeys^{xiii}. Hormone replacement therapy, given to millions of women on the basis of research in monkeys, has been found to increase rather than decrease the risk of heart disease and stroke, as well as breast and ovarian cancer. HRT (labelled ‘the new thalidomide’ by the German Commission on the Safety of Medicines) caused 20,000 cases of breast cancer in Britain in one decade plus 1,300 cases of ovarian cancer since 1991.^{xiv}

The second major use of primates is for brain research, yet the most dramatic differences between humans and other primates are in the brain. Human brains can now be studied non-invasively using remarkable high-tech scanners^{xv}. These enable the conscious brain to be observed while engaged in a variety of cognitive tasks of which monkeys are not even capable. Everything we know about neurological diseases such as Alzheimer’s and Parkinson’s has come from studying patients, their families and their tissues. Hundreds of drugs for stroke have been developed and tested in primates and other animals, yet all of them have failed and even harmed patients in trials.^{xvi}

SHM Claim: Science has not yet advanced to the point where we have reliable alternatives.

Fact: The Non-Animal Alternative Testing Market has increased dramatically in recent years. In 2022, the market size was valued at \$1.7 billion and was estimated to reach over \$4.5 billion by the end of 2023^{xvii}. These technologies, which are based on human biology, are proving to be more effective than animal tests. In a recent study, human Liver-Chips correctly identified 87% of drugs that caused severe liver toxicity and deaths in human patients despite passing animal tests.^{xviii}

SHM Claim: Each drug’s safety testing in primates is required by law.

Fact: In December 2022, President Biden signed the FDA Modernization Act 2.0 into law. This bill removes a Depression-era regulation that mandated animal testing for every new drug development protocol. The legislation allows the use of alternatives to animal testing to assess drug safety and effectiveness.^{xix} Even before the bill passed, primates were never specifically required for drug safety testing.

SHM Claim: Non-human primates share more than 98% of DNA with humans.

Fact: This statistic relates only to chimpanzees. SHM will be using macaques who have not shared an ancestor with humans for more than 24 million years. Shared DNA between humans and macaques is less than 93%.^{xx}

SHM Claim: The primates housed in the SHM facility will not pose a disease threat to local citizens.

Fact: The Centers for Disease Control and Prevention (CDC) has warned that imported monkeys pose a significant risk to public health. Bacteria and viruses that the monkeys are exposed to in Asia and Mauritius can be spread to humans and other animals here. Monkeys involved in the wildlife trade for experimentation are known to carry and transmit a slew of nasty pathogens and diseases, including herpes B virus, tuberculosis, Ebola-like viruses, simian hemorrhagic fever virus, shigellosis, salmonellosis, Campylobacter, malaria, dengue, and leprosy.

Bacteria shed by these monkeys can enter the soil, including a bacteria so deadly, it has been classified as a bioterrorism agent: *Burkholderia pseudomallei*. This bacteria causes an infectious disease called Melioidosis, which has a mortality rate approaching 50 percent. The bacterium is shed in bodily fluids and can survive in contaminated soil or water for years. It was detected in the CDC's monkey colony in 2013, in an outdoor colony in Louisiana in 2015, and in Inotiv/Envigo's primate quarantine facility in Texas in 2021. The incubation period for Melioidosis in primates is not definitively known but can be prolonged; one report described a rhesus macaque that developed melioidosis 10 years after importation into the U.S.^{xxi}

The monkeys coming into this facility originate from countries where malaria is commonplace. As Georgia has numerous mosquitoes, threat of zoonotic malaria transmission looms large, given that the proposed facility would house monkeys who could be naturally infected with malaria parasites from Asia and that the presence of standing water would create ideal breeding grounds for mosquitoes, who could feed on the monkeys' blood and then transmit malaria parasites to humans. **Although the CDC is aware of this risk, importers are able to choose whether or not they want to screen imported animals.**^{xxii}

In December 2023, the CDC revealed that from 2021 to 2023, there was a shocking increase in imported shipments of monkeys with tuberculosis (TB), which is transmissible to humans. In January 2023, a shipment of macaques from Southeast Asia contained the largest percentage of monkeys infected with TB in the history of primate importation into the U.S.^{xxiii} In June 2023, imported monkeys at a lab in Michigan tested positive for TB—despite having undergone a 31-day CDC-mandated quarantine at a facility in Florida—and at least two workers were infected.^{xxiv} The CDC quarantine failed to detect these infections, which is not surprising given that the test for TB in monkeys is notoriously unreliable.^{xxv}

SHM Claim: Primates do not escape from these facilities.

Fact: In 2021, a pickup truck on its way to a quarantine facility hauling a trailer with 100 long-tailed macaques collided with another vehicle in Pennsylvania. Several monkeys escaped and some of the people who stopped to survey the scene of the accident had direct contact with the newly imported monkeys. At least one individual required preventive treatment after being exposed to macaque bodily fluids.^{xxvi}

Primates have escaped from even the most “prestigious” monkey laboratories. In 2018, four baboons who had broken out of Texas Biomedical Research Institute were seen by passersby on a highway before they were recaptured.^{xxvii} Primates have also escaped from MD Anderson Cancer Center, Tulane University, Oregon Health & Science University, Emory University, and Wake Forest University.

SHM Claim: Nothing discharged from the SHM facility will create an environmental hazard or risk.

Fact: The waste generated by this facility would contaminate the soil and water. Monkey urine, feces, saliva, blood, and other bodily fluids, along with any infectious agents present in them, could be introduced into the environment during routine husbandry and enclosure cleanings. SHM estimates that when the site reaches full capacity in its ninth year, it will use more than 555,000 gallons of municipal water per day. The proposed monkey facility would generate an enormous amount of biological waste and an estimated 444,000 gallons of wastewater per day by its ninth year.

Inotiv/Envigo, where SHM's CEO hails from, is currently under investigation for violating the Clean Water Act, the Texas State Water Control Law and local water pre-treatment requirements for their Alice, Texas facility—which holds about one-third the number of monkeys as the proposed Bainbridge facility.

SHM Claim: In 50 years, there is only one documented instance when non-human primates shipped to the U.S. carried Ebola virus.

Fact: Multiple Ebola-like virus outbreaks have occurred in primate laboratories in the U.S. In 1989, Reston Ebola Virus (RESTV) was introduced into quarantine facilities in Virginia and Pennsylvania by monkeys imported from the Philippines. In 1989-1990, RESTV was introduced into primate quarantine facilities in Texas by monkeys imported from the Philippines. In 1996 in Alice, Texas, an outbreak occurred at the Texas Primate Center.^{xxviii} Ebola is a filovirus, and the CDC reported that between 2019 and 2022 multiple monkeys were imported with clinical signs consistent with filovirus infection.

ⁱ Reuters. "Charles River Beats Quarterly Estimates on Firm Demand for Drug Discovery Services." Reuters, 9 Aug. 2023, <https://www.reuters.com/business/healthcare-pharmaceuticals/charles-river-beats-quarterly-estimates-firm-demand-drug-discovery-services-2023-08-09>.

ⁱⁱ Q3 2023 Charles River Laboratories International, Inc. Earnings Conference Call. 8 Nov. 2023, <https://ir.criver.com/events/event-details/q3-2023-charles-river-laboratories-international-inc-earnings-conference-call>.

ⁱⁱⁱ Inotiv Reports Fourth Quarter and Full Year Financial Results for Fiscal 2023 and Provides Business Update, 11 Dec. 2023, <https://ir.inotivco.com/news/news-details/2023/Inotiv-Reports-Fourth-Quarter-and-Full-Year-Financial-Results-for-Fiscal-2023-and-Provides-Business-Update/default.aspx>

^{iv} Weston, Phoebe. "\$20,000 monkeys: inside the booming illicit trade for lab animals." The Guardian. 7 Dec. 2023, <https://www.theguardian.com/environment/2023/dec/07/how-the-demand-for-lab-monkeys-is-driving-trade-in-endangered-macaques-aoe>

^v U.S. Department of Justice. "Justice Department Secures the Surrender of Over 4,000 Beagles from Virginia Breeder of Dogs for Research." 18 July 2022. <https://www.justice.gov/opa/pr/justice-department-secures-surrender-over-4000-beagles-virginia-breeder-dogs-research>

^{vi} Sonner, Scott. "32 Research Monkeys Die in Accident at Nevada Lab." Journal Star, 8 Aug. 2008, <https://www.pjstar.com/story/news/2008/08/08/32-research-monkeys-die-in/42401334007/>

^{vii} USDA Inspection Report, Envigo Global Services Inc (Envigo, 74-B-0332). 8 Jun 2021.

^{viii} Reuters. "Charles River gets DoJ subpoena on Cambodian supply of lab monkeys." Reuters, 22 Feb. 2023, <https://www.reuters.com/world/us/charles-river-gets-doj-subpoena-cambodian-supply-lab-monkeys-2023-02-22/>

^{ix} Inotiv Now Hiring Veterinarians. Jan 2024. inotivco.com/careers

^x Global Federation of Animal Sanctuaries. "Standards for Old World Primate Sanctuaries." Dec. 2019, <https://sanctuaryfederation.org/wp-content/uploads/2020/02/OldWorldMonkeyStandards-2019.pdf>

^{xi} Safer Medicines – Primates in Medical Research. <https://safermedicines.org/primates/>

^{xii} Dowsing, T, and M J Kendall. "The Northwick Park tragedy--protecting healthy volunteers in future first-in-man trials." *Journal of clinical pharmacy and therapeutics* vol. 32,3 (2007): 203-7. doi:10.1111/j.1365-2710.2007.00808.x

^{xiii} Prakash, Snigdha, and Vikki Valentine. "Timeline: The Rise and Fall of Vioxx." NPR, 10 Nov. 2007, <https://www.npr.org/2007/11/10/5470430/timeline-the-rise-and-fall-of-vioxx>.

^{xiv} Beral, Valerie, and Million Women Study Collaborators. "Breast cancer and hormone-replacement therapy in the Million Women Study." *Lancet* (London, England) vol. 362,9382 (2003): 419-27. doi:10.1016/s0140-6736(03)14065-2.

^{xv} Kim, Beomsue et al. "A brief review of non-invasive brain imaging technologies and the near-infrared optical bioimaging." *Applied microscopy* vol. 51,1 9. 25 Jun. 2021, doi:10.1186/s42649-021-00058-7

^{xvi} Narayan, Sunil K et al. "Preclinical animal studies in ischemic stroke: Challenges and some solutions." *Animal models and experimental medicine* vol. 4,2 104-115. 23 Apr. 2021, doi:10.1002/ame2.12166

^{xvii} Global Market Insights. "Non-animal Alternative Testing Market - By Product (Organs-on-chip, Tissue Line), Method (Ex vivo, Computer Modelling), Technology (Cell Culture, High Throughput), Application (Infectious, Immunological), End-use (Biotech Companies, CRO)- Global Forecast to 2032." May 2023.

^{xviii} Ewart L, Apostolou A, Briggs SA, Carman CV, Chaff JT, Heng AR, et al. Performance assessment and economic analysis of a human Liver-Chip for predictive toxicology. *Communications Medicine*. (2022) 2:154. doi: 10.1038/s43856-022-00209-1

^{xix} FDA Modernization Act 2.0.

^{xx} Ebeling, Martin et al. "Genome-based analysis of the nonhuman primate *Macaca fascicularis* as a model for drug safety assessment." *Genome research* vol. 21,10 (2011): 1746-56. doi:10.1101/gr.123117.111.

^{xxi} Taetzsch, Sara J et al. "Meloidosis in *Cynomolgus* Macaques (*Macaca Fascicularis*) Imported to the United States from Cambodia." *Comparative medicine* vol. 72,6 (2022): 394-402. doi:10.30802/AALAS-CM-22-000024.

^{xxii} 42 CFR 71.53

^{xxiii} Swisher, Samantha. *Mycobacterium orygis* Outbreak in Imported Macaques. December 2023 ZOHU Call, Centers for Disease Control and Prevention. 6 Dec 2023.

^{xxiv} Hicks, Justin. M Live. "Infected monkeys at Michigan research lab threaten health and science." 21 Jun. 2023.

<https://www.mlive.com/public-interest/2023/06/infected-monkeys-at-michigan-research-lab-threaten-health-and-science.html>

^{xxv} Yee, JoAnn L et al. "Tuberculosis detection in nonhuman primates is enhanced by use of testing algorithms that include an interferon- γ release assay." *American journal of veterinary research* vol. 83,1 15-22. 10 Nov. 2021, doi:10.2460/ajvr.21.08.0124

^{xxvi} Levensen, Michael. The New York Times. “Monkeys Escape After Truck Crashes on Pennsylvania Highway.” 21 Jan. 2022. <https://www.nytimes.com/2022/01/21/us/monkeys-truck-crash-pennsylvania.html>

^{xxvii} Schmidt, Sarah. The Washington Post. “Ingenious baboons escape Texas biomedical lab for brief taste of freedom.” 17 Apr. 2018. <https://www.washingtonpost.com/news/morning-mix/wp/2018/04/17/ingenious-baboons-escape-texas-biomedical-lab-for-brief-taste-of-freedom/>

^{xxviii} Roberts, Jeffrey A, and Kirk Andrews. “Nonhuman primate quarantine: its evolution and practice.” *ILAR journal* vol. 49,2 (2008): 145-56. doi:10.1093/ilar.49.2.145