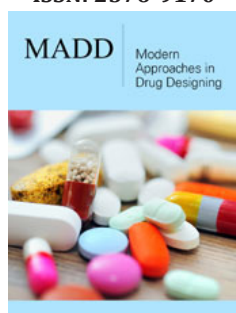


Addressing the Monkey Wrench in America's Bioscientific Enterprise

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Opinion

It takes 10 to 15 years and \$2.6 billion for a medical discovery to go through the drug research and development pipeline [1,2]. The process involves rodent and non-rodent laboratory animals as well as complementary *in vitro* and *in silico* methods, followed by human clinical trials [3]. Nonhuman primates are the most predictive species for drug safety and efficacy testing [4,5] and long-tailed macaque monkeys are the most widely used nonhuman primate for drug and vaccine testing [6]. These animals are essential for the advancement of CRISPR-based cancer immunotherapy treatments [7-9], immunology science [10], regenerative medicine [11] and genetic disease research [12]. A big monkey wrench (pun intended) in America's biomedical research enterprise is the shortage of nonhuman primates and specifically long-tailed macaque monkeys for research and testing. The shortage became evident in early 2020. That year, demand from the biomedical research sector increased. At that time China stopped exporting these primates to the U.S. for public health reasons [13]. The shortage became exacerbated in late 2022 when the federal government restricted the importation of all long-tailed macaques of Cambodian origin as well as any blood serum and tissue samples originating from Cambodian long-tailed macaques [14].

The government implemented these restrictions following an internal investigation alleging Cambodian breeders and the government of Cambodia sold wild-caught long-tailed macaques with doctored permits to American biomedical research facilities. Good science and animal welfare go hand in hand. Drug and vaccine developers and pharmaceutical sponsors rely on nonhuman primates bred in a controlled, specific-pathogen free environment to maintain the scientific integrity of data. They do not seek wild-caught animals for use in drug and vaccine development that fail to meet scientific controls. They are concerned about wild-caught monkeys making it into the U.S. research sector. However, they are also eager for a solution to the continuing research nonhuman primate shortage. Pharmaceutical and biotechnology executives have said on the record that it takes three months longer and costs 15 times more today than in 2020 to obtain nonhuman primates for research [13]. Some predict this increased cost will be passed on to the consumer which could foreshadow a decline in Americans' quality of life [4].

As many as 14,750 drugs and vaccines in preclinical development [15-17] could be in jeopardy if no measures are implemented to remedy the shortage of nonhuman primates in research. The long-tailed macaque shortage and overall nonhuman primate shortage in research may also drive companies to move their pre-clinical research to countries where nonhuman primates are more readily available for research [18]. This would jeopardize America's leadership in scientific innovation. In order to address the current monkey wrench in America's R&D sector, policymakers and regulators should support the regulated importation of long-tailed macaques and other types of monkeys used in research from humane breeding facilities in Southeast Asia and Mauritius. They should also increase the U.S. investment in domestic nonhuman primate breeding facilities, potentially in partnership with private

companies. Addressing the research nonhuman primate shortage is crucial for the continued success of the biomedical research sector and for the development of new drugs and new vaccines.

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