PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Ministry of Fisheries, Animal Husbandry and Dairying

14 July 2020

Via e-mail jspf-dadf@nic.in

Subject: For Dr Chaudhary, from PETA India: Request to replace the use of monkeys at the NIV with superior, non-animal methods

Dear Dr Chaudhary,

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) India and our more than 2 million members and supporters to draw your attention to the Maharashtra government's recent decision to grant permission for the capture of rhesus monkeys for use by the National Institute of Virology (NIV) in the testing of a vaccine for the novel coronavirus (SARS-CoV-2). **We respectfully ask that you overrule this decision; instruct the NIV and the Maharashtra government to adopt superior, human-relevant, animal-free research methods instead of capturing monkeys; and urge the NIV to invest in non-animal approaches, which are more effective, ethical, and economical.**

Regulations Require the Use of Available Non-Animal Research Methods
Section 17(2)(d) of The Prevention of Cruelty to Animals (PCA) Act, 1960, states that "experiments on animals [must be] avoided wherever it is possible to do so".[1]

Accelerated Development of Reliable Therapeutics
The current pandemic demands new and improved standards for the development of therapies, including by testing the safety and efficacy of new therapeutics without experimenting on animals. In response to the pandemic, regulatory agencies around the world have shown that regulations requiring extensive animal testing before human clinical trials create unnecessary barriers to introducing life-saving drugs.

The report of the first Global Regulatory Workshop on COVID-19 Vaccine Development of the International Coalition of Medicines Regulatory Authorities states, "The rapid spread of SARS-CoV-2 requires accelerated development timelines for SARS-CoV-2 vaccine candidates to enter expeditiously into Phase 1 clinical trials." It advises researchers developing vaccines to draw on their experience of vaccine platforms and suggests that toxicology data and clinical data from other vaccines from the same platform can be used to support first-in-human (FIH) clinical trials. It also states that

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[1]The Prevention of Cruelty to Animals Act, 1960. http://cpcsea.nic.in/WriteReadData/userfiles/file/No_59.pdf.

developers do not need to demonstrate vaccine efficacy in "animal challenge models" before proceeding to FIH clinical trials.[2]

The Central Drugs Standard Control Organisation, the regulatory body responsible for approving drugs in India, has also reduced unnecessary requirements for animal toxicity tests in the development of therapies for COVID-19.[3]

Animal Testing Hinders the Development of Therapeutics

Experimenting on animals is not only unethical but also unjustifiable from a scientific perspective. The primary purpose of medical research is to promote human health, yet every year, crores of rupees and hundreds of thousands of animals' lives are wasted on experiments and policies that fail to produce results that address pressing human health issues. In the past decade, particularly, the limitations of animal experiments, including their inability to predict human responses reliably in clinical trials, have become glaringly evident.[4]

For example, the use of non-human primates in biomedical research aimed at finding cures for HIV and hepatitis C in humans has not yielded results.[5] More than 95% of all new drugs that are shown to be safe and effective in animal tests fail in human trials because they don't work or are dangerous,[6] exemplifying the need for more human-relevant approaches. A well-known example of a drug that appeared successful in animal experiments but did not translate into benefits for humans is TGN1412, which actually caused severe inflammatory reactions in humans during clinical trials.[7]

Risk of Zoonosis

In addition to recognising the consistent failure of animal tests to produce results that reliably translate to humans, it is important to note that the

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[2]International Coalition of Medicines Regulatory Authorities. Global regulatory workshop on COVID-19 vaccine development: Summary report. 2020. http://www.icmra.info/drupal/sites/default/files/2020-03/First%20regulatory%20COVID-19%20workshop%20-%20meeting%20report_March%202020.pdf.

[3]Central Drugs Standards Control Organisation order listing the regulatory pathways regulatory pathway for research and development for drugs and vaccines. 19 March 2020. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTc2OQ.

[4]Perel P, Roberts I, Sena E, *et al*. Comparison of treatment effects between animal experiments and clinical trials: Systematic review. *BMJ*. 2007;334(7586):197. doi: 10.1136/bmj.39048.407928.BE.

[5]Institute of Medicine (US) and National Research Council (US) Committee on the Use of Chimpanzees in Biomedical and Behavioral Research, Altevogt BM, Pankevich DE, Shelton-Davenport MK, Kahn JP, eds. *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*. Washington (DC): National Academies Press (US); 2011.

[6]National Center for Advancing Translational Sciences (NCATS). About the NCATS. https://ncats.nih.gov/about. Updated 9 November 2018. Accessed 3 July 2020.

[7]Attarwala H. TGN1412: From discovery to disaster. *J Young Pharm*. 2010;2(3):332-336. doi: 10.4103/0975-1483.66810.

majority of pandemics are zoonotic.[8,9] Health and disease surveillance agencies in India and globally have recognised that monkeys, like humans, are natural hosts and sources of several zoonotic diseases. India's National Centre for Disease Control has listed monkeys among the important reservoirs of rabies in India.[10] They have also been associated with the spread of other zoonotic diseases, such as Kyasanur Forest Disease,[11,12] tuberculosis,[13] hepatitis A, and possibly malaria,[14] among other risks.[15] These primates often carry and transmit disease without showing any visible symptoms of the infection.

According to the US Centers for Disease Control and Prevention, fewer than 20% of humans infected with COVID-19 are symptomatic. If the same applies to monkeys – or, indeed, if that percentage is even lower – colonies could be infected with undetected diseases. Given that there is still uncertainty regarding the factors that affect the transmission of COVID-19 and that there are differences in the severity of symptoms in humans and in animals, the risk of zoonosis and reverse zoonosis (transmission from humans to animals) is very high. Those in direct contact with monkeys, such as NIV experimenters, laboratory technicians, and other employees, as well as those in indirect contact with them, such as the family members of NIV staff, are vulnerable to contracting COVID-19 and other serious zoonotic diseases from monkeys, and *vice versa*.

Non-Animal Testing Approaches Are More Effective

Since the initial reporting of coronavirus infections, scientists have observed that animals are not affected by COVID-19 in the same way that humans are.

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[8]Devaux CA, Mediannikov O, Medkour H, Raoult D. Infectious disease risk across the growing human-non human primate interface: A review of the evidence. *Front Public Health*. 2019;7:305. doi: 10.3389/fpubh.2019.00305.

[9]Dhiman RC, Tiwari A. Emergence of zoonotic diseases in India: A systematic review. *Med Rep Case Stud*. 2018;3(3):163. doi: 10.4172/2572-5130.1000163.

[10]National Centre for Disease Control. National Rabies Control Programme. https://ncdc.gov.in/index1.php?lang=1&level=1&sublinkid=146&lid=150.

[11]Sayyed N. Maharashtra takes measures against spread of Kyasanur forest disease. *Hindustan Times*. 24 January 2019. https://www.hindustantimes.com/pune-news/maharashtra-takes-measures-against-spread-of-kyasanur-forest-disease/story-niFej2v3yFqR7K1ShIIrEL.html.

[12]Yadav PD, Sahay RR, Mourya DT. Detection of Kyasanur forest disease in newer areas of Sindhudurg district of Maharashtra State. *Indian J Med Res*. 2018;148:453-455.

[13]Sahani NS. Uttarakhand monkeys may have TB, could be threat to humans: Experts. *Hindustan Times*. 13 January 2016. https://www.hindustantimes.com/india/uttarakhand-monkeys-may-have-tb-could-be-threat-to-humans-experts/story-dHXMVIqNUsUmpzvMeRQ38J.html#:~:text=A%20senior%20forest%20official%20has,to%20humans%20in%20the%20state.&text=Monkeys%20in%20Uttarakhand%20might%20be,forest%20(CF)%20Western%20Circle.

[14]Dixit J, Zachariah A, P K S, Chandramohan B, Shanmuganatham V, Karanth KP. Reinvestigating the status of malaria parasite (*Plasmodium* sp.) in Indian non-human primates. *PLoS Negl Trop Dis*. 2018;12(12):e0006801.

[15]National Research Council (US) Committee on Occupational Health and Safety in the Care and Use of Nonhuman Primates. Occupational Health and Safety in the Care and Use of Nonhuman Primates. Washington (DC): National Academies Press (US); 2003. https://www.ncbi.nlm.nih.gov/books/NBK43452/.

Even when animals are genetically engineered to make them susceptible to the coronavirus, they show only mild symptoms of COVID-19 – their response to infection differs from that experienced by humans.

The permission granted to the NIV to test potential vaccines on animals is an apparent violation of national and international guidelines and is unethical and unjustifiable scientifically, since research shows that reliance on data from tests on animals delays the development of effective therapeutics. Dedicating resources to animal experiments represents a missed opportunity to make use of existing modern, humane, human-specific tools and techniques that could help develop safe, effective, life-saving therapeutics. These include three-dimensional reconstructed human respiratory tissue models,[16] such as those from Epithelix[17] and MatTek Life Sciences,[18] which can be used to study COVID-19 infection and screen for potential treatments.

In India, a Bangalore-based company, Eyestem Research Pvt Ltd (EPRL), was selected to be part of the Centre for Cellular and Molecular Platforms (C-CAMP) COVID-19 Innovation Deployment Accelerator[19] (C-CIDA) and announced[20] that its anti-COVID screening platform using iPSC-derived lung progenitors would be available immediately, providing the research community with a unique resource for determining the efficacy of vaccines and other drugs using the closest human host cell line. Recognising the importance of testing drugs *in vitro*, the Council of Scientific and Industrial Research Centre for Cellular & Molecular Biology has collaborated with ERPL.[21]

Progressive scientists in India and around the globe are investing their time and efforts in modern techniques and technology, such as the use of human organoids,[22] organs-on-chips,[23] super-computers,[24] and other non-animal

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[16]Barosova H, Maione AG, Septiadi D, *et al*. Use of EpiAlveolar lung model to predict fibrotic potential of multiwalled carbon nanotubes. *ACS Nano*. 2020;14(4):3941-3956.
[17]Epithelix. *In vitro* 3D human airway epithelia. https://www.epithelix.com/news/448?filter=evts .
[18]MatTek Life Sciences. COVID-19 message. 23 March 2020. https://www.mattek.com/covid-19-message/.
[19]Urs A. C-CIDA shortlists 6 innovations to fight Covid-19. *The Hindu Business Line*. 27 April 2020. https://www.thehindubusinessline.com/news/science/c-cida-shortlists-6-innovations-to-fight-covid-19/article31441841.ece#.
[20]Eyestem Research Pvt Ltd. CSIR-Centre for Cellular and Molecular Biology (CCMB), Hyderabad & Eyestem Research Private Limited, Bangalore announce a unique public-private collaboration in the fight against Covid-19. May 2020. https://www.eyestem.com/updates/.
[21]*Ibid*.
[22]Cookson C. Coronavirus could infect human brain and replicate, US study shows. *Financial Times*. 15 June 2020. https://share.getcloudapp.com/bLuje6NX.
[23]Healthcare-In-Europe.com. "Organ-on-a-chip" model to find out how COVID-19 invades our bodies. 9 April 2020. https://healthcare-in-europe.com/en/news/organ-on-a-chip-model-to-find-out-how-covid-19-invades-our-bodies.html#.
[24]Kadioglu O, Saeed M, Greten HJ, Efferth T. Identification of novel compounds against three targets of SARS CoV-2 coronavirus by combined virtual screening and supervised machine learning. 21 March 2020. doi:10.2471/BLT.20.255943.

methods in order to understand the virus and its behaviour in humans and find effective and reliable treatments quickly. Scientists at Gauhati University are using advanced computer simulation[25] methods to determine which parts of the virus are best suited to triggering an immune response in humans – and this could aid the design of safe and effective vaccines.

Based on the scientific evidence presented here and the provisions of the PCA Act, 1960, we request that you overrule the permission granted to NIV to experiment on monkeys, prohibit the capture of monkeys and other animals for experiments, and advocate the use of non-animal methods and techniques to accelerate the development of vaccines and treatments for COVID-19.

I'd be happy to arrange a teleconference to discuss this important issue. I can be contacted on +91 8800897382 or at DiptiK@petaindia.org. I look forward to hearing from you.

Kind regards,

Dipti M Kapoor, PhD
Science Policy Adviser

[25] Baruah V, Bose S. Immunoinformatics-aided identification of T cell and B cell epitopes in the surface glycoprotein of 2019-nCoV. *J Med Virol*. 2020;92(5):495-500. doi:10.1002/jmv.25698.