



September 25, 2017

Dr. Jane Goodall, DBE
Founder, the Jane Goodall Institute &
UN Messenger of Peace
1595 Spring Hill, Suite 550
Vienna, VA 22182

Dear Dr. Goodall:

I appreciate your letter to me conveying concerns regarding the use of monkeys in research, including a specific research study conducted by the Food and Drug Administration (FDA) to investigate the relationship between nicotine dosing and addiction. I take very seriously FDA's obligations to ensure responsible and humane animal testing methods and to make sure that the Agency continually complies with the rules and guidance governing the use of animals for research.

After learning of concerns related to the study you referenced, I directed the Agency to place a hold on the research study earlier this month. Accordingly, at this time, all experimentation involving the monkeys in the study you referenced has been halted. I asked for a medical team of primate experts to conduct a site visit to evaluate the safety and well-being of the monkeys and to understand whether there are additional precautions needed. I also appointed an independent FDA review team, led by senior career experts and with the guidance of primate veterinarians, to assess the science and integrity of the animal research process for this study. I also asked this team to evaluate whether the re-initiation of the study you referenced is necessary to fulfill FDA's public health responsibilities, or if the study should be halted indefinitely.

Although the study is currently on hold, I want to assure you that should FDA terminate the study, I will direct the Agency to identify an alternative home that can provide the monkeys with appropriate long-term care. Moreover, I want to share that as Commissioner of the Food and Drug Administration, I am committed to doing all that I can to reduce the reliance on animal-based studies and to best ensure the appropriate care of animals in our possession.

In recent years, we have seen an evolution of in vitro assays and computer models that can, in certain circumstances, replicate and replace the need for animal-based and human studies, while still providing access to critical, reliable data. Although we are hopeful that in vitro assays and computer models can ultimately help to replace the need for animal testing, currently there are still some areas for which non-animal testing is not yet a scientifically valid and available option. In these instances, I am committed to ensuring responsible and humane animal testing methods when animal testing is needed as part of scientific studies that are conducted to help fulfill

FDA's public health responsibilities.

Thank you again for your letter on this important topic.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott Gottlieb MD". The signature is fluid and cursive, with the letters "S", "G", and "M" being particularly prominent.

Scott Gottlieb, M.D.
Commissioner of Food and Drugs