Congress of the United States Washington, DC 20515

March 21, 2019

The Honorable Scott Gottlieb Commissioner, U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Gottlieb,

As a follow-up to our letter to you dated October 26, 2018 we are writing to express concern and request additional information about serially noncompliant primate research at the FDA's National Center for Toxicological Research (NCTR) in Jefferson, Arkansas.

According to documents released recently through the Freedom of Information Act, on August 3, 2018, a 5-year-old rhesus monkey died at NCTR after being strangled in a restraint chair while left unsupervised during an experiment.

Such a preventable animal death suggests a persistent lack of proper oversight, animal care and training at NCTR. These are similar to the problems you identified at this facility when you rightfully shut down its primate nicotine testing lab and retired the monkeys to sanctuary after another four monkey deaths between 2015-17.

On January 26, 2018, following revelations about the earlier monkey deaths at NCTR, you released a statement expressing concern about, "a generalized lack of adequate oversight that could lead to similar issues for other protocols and procedures, as well as several repeated reported deficiencies that occurred under the third-party animal welfare contractor used during the study." You further expressed that, "FDA's animal program may need to be strengthened in some important areas."

We are confident that you share our concern that seven months after FDA pledged to address these serious problems, with a review of all agency animal research programs and the creation of an Animal Welfare Council, the abuses continued and caused the preventable death of yet another primate.

We request that all primate research at NCTR be suspended until this pattern of negligence and abuse can be thoroughly investigated and corrected.

Additionally, please provide our offices with the following information:

- 1. The title and description of the project on which the Aug. 2018 monkey death occurred.
- 2. Was this project funded by taxpayers? If so, how much funding has it received to date, and since when?
- 3. What USDA pain category is this project assigned to? What is done to the primates at the end of the study?
- 4. Why did it take three days for the NCTR IACUC to be notified about the primate death?
- 5. Have any other unanticipated primate deaths occurred on this protocol or others since January 2018?
- 6. Did this research involve any of the same staff who were involved in earlier primate deaths, either in a research, support or oversight capacity?
- 7. What new policies and procedures have been implemented since the FDA's January 2018 commitment to improve animal care and reduce and place primate testing?

Thank you for your consideration.

Sincerely,

Matt Gaetz

Member of Congress

Brendan Boyle

Member of Congress