October 17, 2017

Scott Gottlieb, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

On behalf of the American Brain Coalition (ABC), I am writing to reiterate our support for the appropriate and ethical use of animals in research to help understand and treat the up to 50 million Americans afflicted with a neurological or psychiatric condition.

ABC seeks to advance the understanding of the brain and to reduce the burden of disabling brain disorders and we maintain that the use of animals in research is essential for accomplishing this goal. In general, the brain cannot be adequately examined directly during life, except for rare instances during neurosurgical procedures. In order to overcome these limitations, animal models have been employed by scientists to glean information about the brain and the rest of the nervous system. In particular, we have a great deal to learn about the underlying mechanisms of addiction, a condition that afflicts many Americans and has wreaked havoc on our local communities.

The ABC recently learned that you directed Food and Drug Administration (FDA) officials to halt research being conducted at the National Center for Toxicological Research in Arkansas following a letter that Dr. Jane Goodall sent regarding a study on the behavioral and biological effects of nicotine in squirrel monkeys. In your response to this letter, you note that “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.”1 We commend you for articulating that this is only the case in certain circumstances and urge you to practice caution when placing barriers on research that seek information on how drug use can impact the brain. The National Institute for Drug Abuse (NIDA) reports, that tobacco use kills approximately 440,000 Americans each year, with one in every five U.S. deaths the result of smoking.2 While research on nicotine is certainly geared towards curbing the use of tobacco products, the knowledge gained can also be applied to facilitate our general understanding of addiction and thus, will have broader implications. In most cases, the use of in vitro assays and computer models cannot recapitulate the complexity of drug use/addiction and do not allow researchers to gather much needed information about the role of neural function, genes, and the environment. Therefore, we also applaud you for recognizing that “currently there are still some areas for which non-animal testing is not yet a scientifically valid and available option.”

ABC strongly supports the laws, regulations, and institutional policies that ensure the humane treatment and safety of animals utilized in scientifically meritorious research projects. We hope that the FDA finds that researchers at the National Center for Toxicological Research have adhered to these policies and as a result, will let this important research continue. ABC has grave concerns that Dr. Goodall’s letter may have falsely described the study and the care of the animals as part of this study. Further, the letter fails to

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1 https://www.fda.gov/downloads/TobaccoProducts/AboutCTP/UCM577248.pdf
2 https://www.drugabuse.gov/publications/research-reports/tobacco/letter-director
address why a non-human primate model is considered appropriate in this particular context. Worse, Dr. Goodall paints an overly broad and quite distorted picture of the legal use of animals in research. ABC hopes that the FDA will take the necessary steps to reject false representations of the use of animals in neuroscience research and confirms its support of life-saving research and the advancement of scientific knowledge.

We are eager to learn of FDA’s decision on this issue. In the interim, if you have any questions or if ABC can be helpful, please contact Katie Sale, ABC’s Executive Director at (763) 557-2913 or at ksale@americanbraincoalition.org.

Sincerely,

Janet Hieshetter
Chair, American Brain Coalition