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Via email: <u>gary.gibbons@nih.gov</u>, <u>laura.moen@nih.gov</u>,

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Dear Directors Gibbons, Moen, Lauer and Bulls,

Good afternoon. I am writing on behalf of People for the Ethical Treatment of Animals and our more than 6.5 million members and supporters worldwide to share serious ethical concerns about a series of experiments conducted on nonhuman primates and funded in part by the National Heart Lung and Blood Institute (NHLBI). The experiments in question were described in a recently published article titled "Chronic unpredictable mild stress produces depressive-like behavior, hypercortisolemia, and metabolic dysfunction in adolescent cynomolgus monkeys." The publication, attached here for your reference, lists funding from grant R01HL087103 to author Carol A. Shively, at Wake Forest University, as a source of support.

These experiments subjected cynomolgus macaques to:

- inescapable foot shocks
- food and water deprivation
- space restriction
- flashing strobe lights
- shrill noises
- cold water shocks
- social isolation

These atrocities—which are, I'm sure you realize, identical to those that have been used to torture humans—were carried out in an attempt to induce symptoms of depression in the monkeys for the purpose of creating an experimental

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"model." Please note that the monkeys in these experiments endured these chronic and unpredictable stressors for up to 12 hours at a time for 55 consecutive days.

It is inconceivable that the NHLBI, or the National Institutes of Health (NIH), would approve or financially support subjecting nonhuman primates to these sorts of procedures for any purpose, let alone for such a flawed and unnecessary series of studies. Attempting to model the complex and interacting genetic, environmental, epigenetic, age, and endocrinological factors associated with human depression by tormenting captive adolescent male monkeys is ludicrous, and does not meet the scientific or ethical standards of your institute, or of the NIH.

Additionally, these NHLBI-funded experiments were conducted at Chongqing Medical University in China, yet Chongqing Medical University is absent from NIH's list of <u>Institutions with a PHS</u> Approved Animal Welfare Assurance.

The <u>Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals</u> (PHS Policy) states explicitly:

No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with this Policy.

Moreover, Section 4.1.1.1 of the <u>NIH Grants Policy Statement</u> to which Shively, as a recipient of an NIH grant, is expected to adhere is also clear:

No costs for activities with live vertebrate animals may be charged to NIH grants in the absence of a valid Assurance on file with OLAW [NIH's Office of Laboratory Animal Welfare].

Additionally, Section 4.1.1.4 of the NIH Grants Policy Statement advises:

When the recipient is a domestic institution and performance sites are foreign (i.e., domestic grant with a foreign component), PHS Policy requirements are applicable. Accordingly, the recipient remains responsible for animal activities conducted at the foreign site and must provide verification of IACUC approval (i.e., certification that the activities as conducted at the foreign performance site are acceptable to the recipient). The recipient IACUC may accept, as its own, the approval of a foreign organization's IACUC; however, the recipient IACUC remains responsible for the review. Additionally, the foreign site must obtain an Animal Welfare Assurance for Foreign Institutions as described [earlier].

Thus, the use of NIH grant money to help fund the Chongqing monkey experiments appears to be a clear violation of both PHS Policy and the NIH Grants Policy Statement.

It appears that Wake Forest University's Institutional Animal Care and Use Committee (IACUC) did not review the experiments conducted on monkeys at Chongqing Medical University, as no such review is mentioned in the published paper. It is deeply concerning that Dr. Shively, who has received \$5,968,906 of US taxpayer money for this project, used some of these funds to support cruel procedures, apparently without any U.S. oversight.

I hope you will investigate this matter immediately, and take the necessary steps to ensure that NIH funds are not used to support studies of this inherently cruel nature. I also ask that you consider directing Dr. Shively to reimburse the NHLBI any disallowed costs utilized to support procedures that did not follow PHS Policy or NIHGPS guidelines or were not approved by the appropriate oversight committees. Further, Dr. Shively's research program should be reviewed for other breaches of NIH policies.

I look forward to your reply.

Sincerely,

Katherine V. Roe, Ph.D. Senior Research Associate

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