April 5, 2017

Thomas E. Price, M.D. Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Via e-mail: Secretary@HHS.gov

Dear Secretary Price:

I hope this letter, respectfully submitted on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 5 million members and supporters, finds you well. As you work with the U.S. Congress in deliberations over the 2018 Department of Health and Human Services budget, we recognize that you are faced with the difficult challenge of prioritizing certain critical programs while also identifying "programs that are duplicative or have limited or unproven impact on public health and well-being" and can therefore be eliminated to improve efficiency. We applaud this effort and wish to share information that may be useful to you.

As you know, the use of animals to understand human disease has long been the dominant paradigm in biomedical research; approximately 40 percent of NIH's budget – at least \$12 billion – goes to animal studies. However, there is growing concern about the lack of applicability of animal research to humans.

Systematic reviews published in peer-reviewed journals document limitations in translating results from animal studies to humans for numerous disease areas. As noted in a 2014 *BMJ* article: "[I]f research conducted animals continues to be unable to reasonably predict what can be expected in humans, the public's continuing endorsement and funding of preclinical animal research seems misplaced."¹ Equally troubling, the U.S. Food and Drug Administration reports a 92 percent failure rate of clinical trials for new pharmaceutical drugs following preclinical success in animals.²

A 2015 analysis concluded that the prevalence of irreproducible preclinical research was between 50 and 89 percent, which, at the most conservative U.S. estimate, results in approximately \$28 billion *per year* spent on research that is misleading.³ NIH Director Francis Collins and Principal Deputy Director Lawrence Tabak have admitted that, "Preclinical research, especially work that

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Pound, P., & Bracken, M. B. (2014). Is animal research sufficiently evidence based to be a cornerstone of biomedical research? *BMJ*, *348*, g3387. http://doi.org/10.1136/bmj.g3387
Food and Drug Administration. (2004). Innovation or stagnation: challenge and opportunity on the critical path to new medical products. *Washington, DC: Food and Drug Administration*.
Freedman LP, IM Cockburn and TS Simcoe. The Economics of Reproducibility in Preclinical Research. PLOS Biol 13.6 (2015): e1002165.

uses animal models, seems to be the area that is currently most susceptible to reproducibility issues."4

PETA's team of scientists, with expertise in a wide variety of scientific areas, has prepared a report, which I have attached with this communication. The report offers a robust blueprint on how limitations in animal use to model human disease can be translated into actions aimed at eliminating inefficiencies from NIH's budget. We have highlighted a number of strategic priorities regarding areas of both regulatory and non-regulatory research where opportunities lie for the immediate and forthcoming replacement of animal use. In addition to ensuring greater fiscal responsibility, the strategy outlined in the report also promises to be popular with the public as a 2014 Pew Research report indicates that a majority of Americans now oppose taxpayer-funded animal experiments.

We would be happy to meet with you to discuss these suggestions in greater detail. I can be reached at 757-943-7443 or KathyG@peta.org.

Thank you for your time and consideration.

Sincerely,

Kathy Jallones

Kathy Guillermo Senior Vice President

⁴ Collins FS and LA Tabak. NIH plans to enhance reproducibility. Nature 505.7485 (2014): 612-613.