March 2, 2017

The Honorable Gene L. Dodaro
Comptroller General of the United States
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

My colleagues and I read with concern the letters from 3 Senators and 13 Representatives asking the GAO to investigate intramural animal research at 5 federal agencies.1,2 I am writing to give you the perspective of the American Physiological Society (APS) on these audit requests. To summarize our view, these letters contain misleading statements and fail to validate the authors’ criticisms about agency oversight of research programs.

The APS was founded in 1887 to promote scientific exchange and the dissemination of physiological research. Now, 130 years later, our membership consists of nearly 11,000 research scientists who study the biological processes that sustain life. Some physiologists study human health, while others focus on animal health, and still others seek to understand biological traits that enable animals to adapt to their environment. Many of the questions we seek to answer through our research can be found by studying isolated cells, tissues or organs, or by creating computer models. However, in some cases, we can only answer these questions by studying biological processes in living animals. Physiologists recognize that animal welfare is an essential component of sound science, and we are committed to the humane treatment of animals. We also know that a majority of innovations used today to diagnose and treat disease were first developed or tested in animals. Moreover, most of these treatments serve both human and animal patients.

The White Coat Waste Project is not a credible source of information

The two Congressional letters sent to you in December 2016 rely heavily on a report3 by the White Coat Waste Project (WCWP) to justify concerns about accountability and transparency in biomedical research conducted at NIH, DVA, DOD, CDA, and FDA. Given that the stated purpose of WCWP is to end federally-funded animal research, this report is not an objective source of information. Consequently, the issues WCWP raises

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1 Letter to Gene L. Dodaro from Representative Ken Calvert et al., December 8, 2016.
concerning agency transparency are simply a pretext to obtain additional information it can distort in its efforts to undermine public support for animal research.

The supposedly “controversial experimentation on dogs” mentioned in the December 21 Senate letter are perceived as such only when seen through the lens of WCWP’s lurid language and misleading statements. Nor is it surprising that WCWP would label animal research as wasteful given that its stated purpose is to “cut government spending that hurts animals.”1 In reality, WCWP’s goal is to eliminate all government spending on animal research, despite the fact that strict oversight ensures the welfare of these animals, and the research itself remains essential to the search for cures.

**Allegations against USMARC were not substantiated**

Both letters contain inaccurate statements presented as justification for their audit requests. The December 8 House letter asserts there were “animal mistreatment and oversight failures” at USDA’s Meat Animal Research Center (USMARC), an agricultural production research facility. This apparently refers to a 2015 *New York Times* article,2 which claimed that significant lapses in animal welfare oversight at USMARC caused animal suffering and high levels of mortality. However, after that article was published, USDA’s Office of the Inspector General (OIG) investigated 33 allegations from the article. Its investigators “did not note evidence indicating a systemic problem with animal welfare at USMARC.”3 (Emphasis added.) Re-hashing discredited statements does not advance accountability, improve animal welfare, or justify expansive information requests. It is also a matter of concern that after the *New York Times* article was published, USMARC employees “received multiple threats of physical harm from multiple sources” according to USDA official Chavonda Jacobs-Young.4

**GAO studies cited do not validate assertions of a systemic problem**

The December 8 House letter suggests that the conclusions of 4 previous GAO studies provide evidence that intramural animal research oversight is lacking at NIH, DVA, DOD, CDA, and FDA. The 4 studies in question were done over the course of nearly 20 years and addressed various topics: DOD’s biomedical research database (1998)5; the effectiveness of DOD

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4 Ibid, p. 48. Jacobs-Young is the Agricultural Research Service Administrator, which is the division of USDA responsible for USMARC. This comment was part of the ARS response to the OIG investigation and was published in its report.
internal controls on animal use (1999); USDA oversight of sales of random-source dogs and cats for research (2010); and the potential for cost savings by consolidating NIH’s arrangements for the care of chimpanzees no longer needed in biomedical research (2016). The two earliest studies—dating from the late 1990s—found issues with internal research oversight at DOD, but the more recent reports address topics unrelated to research oversight. Thus, the content of these reports does not validate the assertion that GAO studies have found evidence of a systemic problem with agency oversight of research involving animals.

**Michael Bracken did not single out animal research as wasteful or inefficient**

The December 21 Senate letter further argues that “transparency about federal spending on animal research is especially critical given some evidence suggesting that such research is often wasteful and inefficient.” Everyone agrees that government agencies must provide appropriate stewardship of public resources, but we take issue with the assertion that animal research represents a particularly problematic case. This statement in the letter refers to an NIH newsletter article about a talk given by Michael B. Bracken, who has a long-standing interest in topics related to the reproducibility of research findings. In the newsletter article, Bracken criticized biomedical research for waste and inefficiency due to flaws in study design and data analysis. While he did raise some issues specific to animal research, his talk addressed problems that affect all areas of research, such as designing studies to minimize sources of experimental bias and ensuring that sample sizes are large enough to produce statistically valid data. Moreover, the reason Bracken was invited to speak at NIH was that the agency is working to address these issues across its entire research portfolio.

**The WCWP report made deliberately misleading statements**

The Congressional letters also point to the WCWP report to justify their broad audit and disclosure requests. For this report, WCWP collected information on intramural studies involving 1,183 dogs in FY 2015: 695 at NIH; 295 at CDC; 104 at VA Medical Centers; 89 at DOD; and 8 at FDA. The report claimed that “with very few exceptions, the agencies receiving tax money to conduct these studies fail to disclose what they are doing.” In fact, 60% of these dogs were part of studies conducted by NIH, which WCWP acknowledged “maintains a database

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6 GAO. DOD animal Research: Controls on Animal Use are Generally Effective but Improvements are Needed. GAO-99-156 (Washington, DC, 1999)
7 GAO. Animal Welfare: USDA’s Oversight of Dealers of Random Source Dogs and Cats Would Benefit from Additional Management Information and Analysis. GAO-10-945 (Washington, DC, 2010). Since FY 2016 Congress has prohibited USDA from using funds to license Class B dealers who sell dogs or cats for research.
8 GAO. NIH Chimpanzee Management Program: Consolidation Should Achieve Cost Savings, but a Clear Implementation Plan is Needed. GAO-16-945.
10 Rigor and Reproducibility index page for NIH resources. URL: https://grants.nih.gov/reproducibility/index.htm.
11 White Coat Waste Project, p. 4.
(the NIH Intramural Database) providing taxpayers [with] access to information about current research projects being conducted by the agency.” Thus, “very few exceptions” refers to the number of agencies providing the information since the NIH database provides information about 60% of the dogs in question. This deliberately misleading statement is characteristic of the unreliability of WCWP’s assertions.

The WCWP report further asserts that animal studies “rarely translate to improvements in human health.” To the contrary, looking back, research with dogs played a critical role in the discovery of insulin as a treatment for type diabetes, organ transplantation, and treatments for heart disease including open heart surgery and pacemakers. As noted in the attached fact sheet, research with dogs continues to figure prominently in the development of treatments for many diseases that affect both humans and animals.

The letters do not justify sweeping audits of agency oversight

As GAO reviews the Congressional letters, we encourage you to consider whether the proposed approaches to accountability are reasonable. The December 8 letter asked GAO to “identify and assess systems used by each agency for informing Congress and the public about the purpose, status, outcomes, and cost of all recent and ongoing animal research and testing projects” [emphases added]. The purpose and status of projects should be readily identifiable. We lack the familiarity with agency accounting systems to say how feasible it will be to determine project costs. What we do know is that the outcomes of individual research projects will be very difficult to assess. Because science is an incremental process, there is rarely a one-to-one relationship between projects and major outcomes. Rather, hypotheses are tested, refined, and re-tested in experiments that provide incremental outcomes that progressively, over a period of years, lead to major breakthroughs. Thus, this proposal is not a reasonable way to provide accountability. More importantly, the sweeping audit requests in the letters are not justified nor would they be a productive use of GAO resources.

We would be happy to discuss this further with you. Thank you in advance for taking our concerns into account.

Sincerely,

Jane F. Reckelhoff, Ph.D.
President

12 Idem.
13 Ibid., p. 3.
Enclosure:


CCs:

The Hon. Jeanne Shaheen
The Hon. Elizabeth Warren
The Hon. Cory Booker
The Hon. Ken Calvert
The Hon. Dina Titus
The Hon. Donald Beyer, Jr.
The Hon. Ryan Costello
The Hon. Raul Grijalva
The Hon. Tom Marino
The Hon. Betty McCollum
The Hon. Erik Paulsen
The Hon. Lucille Roybal-Allard
The Hon. Edward Royce
The Hon. Mike Simpson
The Hon. Niki Tsongas
The Hon. Mimi Walters
Animal Research Saves Lives
Facts on Studies with Dogs

The Federation of American Societies for Experimental Biology (FASEB) affirms the essential contribution of animal research aimed at improving the health of both humans and animals. Dogs remain critical in understanding the fundamental processes of life and in developing treatments for injury and disease.

**Canine Research Helps People**

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**Canine Research Helps Dogs**

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<td>Obesity</td>
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Dogs and humans have 82% genome similarity and share many of the same diseases.

Less than 0.5% of animals used in research are dogs.

Dogs were essential in developing 22 of the 25 most prescribed drugs in the U.S. in 2014.

**Canine Research is Closely Regulated**

- Studies include dogs only when necessary.
- Researchers and animal care staff are trained to work with dogs.
- Dogs are provided with food, veterinary care, interaction with other dogs and/or caregivers, and get regular exercise.
- An ethical review committee must approve all studies that involve dogs.

- The federal Animal Welfare Act regulates the care and use of dogs in research.
- All institutions where dogs are studied are subject to unannounced USDA inspections.
- Only dogs specifically bred for research are allowed in NIH-funded studies.

2. [http://www.nabr.org/biomedical-research/laboratory-animals/animal-research-behind-top-drugs/](http://www.nabr.org/biomedical-research/laboratory-animals/animal-research-behind-top-drugs/)

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