



The American Physiological Society

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The Charlie Dent, Chairman
House Appropriations Subcommittee on Military Construction,
Veterans Affairs and Related Agencies
HVC-227
Washington, DC 20515

Dear Mr. Chairman:

I am writing on behalf of the American Physiological Society to urge the House to remove House Amendment 226 to H.R. 3219. This will enable the Department of Veterans Affairs (VA) to continue supporting research that can save veterans' lives and improve their quality of life.

House Amendment 226 would prohibit the VA from funding necessary medical research involving dogs. This would halt studies that are urgently and critically needed to develop treatments for conditions such as heart disease and diabetes, as well as a life-threatening breathing problem—the inability to clear the lungs by coughing—that afflicts paralyzed veterans. Amendment 226 is a disproportionate response to problems at the Hunter Holmes McGuire VA Medical Center (HHMVAMC) in 2015-2016 that were promptly identified and addressed through the animal welfare oversight mechanisms already in place. Since then the Department has taken further steps to enhance research oversight at the Richmond VA Medical Center.

A group known as the White Coat Waste Project (WCWP) raised concerns about VA research with dogs in a complaint submitted to the VA Inspector General earlier this year.¹ According to its website, the goal of the WCWP is to “cut government spending that hurts animals.”² The APS has observed numerous instances—including this one—where WCWP presents information about animal research out of context or otherwise distorts it in an effort to achieve that objective.

The WCWP complaint noted three animal welfare problems at Hunter Holmes McGuire in Richmond. These were problems that the facility had already reported and corrected. WCWP based its complaint on the VA's own reports of what transpired—reports that had been released through FOIA. The VA's Office of Research Oversight (ORO) then investigated the WCWP's allegations. ORO concurred with the WCWP's characterization of what happened in only one instance, namely that a Principal Investigator (PI) had acted negligently by over-sedating a dog during surgery and

¹ Justin Goodman, WCWP. March 21, 2017 letter to VA Inspector General Michael J. Missal.

² <http://whitecoatwaste.org/>. Accessed February 10, 2017.

failing to monitor its condition afterwards.³ This problem was discovered the next day, at which point the dog was treated and recovered fully. ORO deemed WCWP's characterizations of two other incidents as only "partially substantiated." It also said the Richmond VA's Institutional Animal Care and Use Committee (IACUC) had responded appropriately to all three incidents.⁴

In addition to promptly reporting what happened, the IACUC took a series of increasingly stringent remedial steps to prevent future problems. These included temporarily halting surgeries; requiring a veterinarian to attend future surgeries; instructing the PI to ask researchers who had done similar surgeries about potential complications; telling the PI to update the research protocol to list potential complications; and insisting that a second surgeon be present. The PI was also required to undergo additional training in animal welfare requirements, counseled about his responsibilities for animals in the study, and called in to meet with the IACUC chair. Ultimately, the committee decided to replace the PI with a more experienced surgeon. Significantly, ORO found no systemic problems related to the actual care of animals. We therefore believe that these incidents should not be allowed to define a program that has done so much to support the health and quality of life of our nation's veterans, nor should veterans have to suffer because of issues that were addressed and resolved.

ORO dismissed WCWP's other allegations regarding record-keeping and reporting. WCWP had accused the Richmond VA of failing to report its FY 2016 research with dogs to the USDA as required by the AWA, but the document the WCWP submitted purporting to show this was inaccurate.⁵ According to ORO, the document provided in the WCWP complaint "does not reflect what USDA has on file as being submitted by HHMVAMC for FY16."⁶

ORO also dismissed WCWP's charge that the Richmond VA failed to provide information about its research to RePORTER (<https://projectreporter.nih.gov/reporter.cfm>).⁷ RePORTER is a government website that provides information about federally-funded research. Since only one of the six studies in question was federally funded, it was the only one listed on RePORTER. The other five studies were not eligible for inclusion because they were privately funded.

Despite much progress in the development of alternative methods, animal research remains critical to medical progress. As VA Chief Veterinary Officer Dr. Michael Fallon told a Richmond television station, "We don't know enough about the human body" to rely exclusively on non-animal alternatives in efforts to discover new ways to treat disease and test whether these treatments are safe and effective. Dr. Fallon also underscored the fact that "research is absolutely a part of modern health care, and you cannot separate the two."

Dogs are estimated to comprise less than 0.05% of all animals in VA research. Nevertheless, this research has been critical to the development of new therapies for heart disease, diabetes, digestive

³ Office of Research Oversight, "For-Cause Review: Canine Research Studies and Associated Facility Oversight." May 30, 2017, p. iii.

⁴ Idem.

⁵ WCWP letter, p. 2 and Appendix B.

⁶ ORO report, p. 13.

⁷ Ibid, p. 15.

disorders, and many other health problems. Importantly, treatments that were originally developed for human patients are now used to treat to pets with similar conditions. One recent innovation developed by a VA researcher is the Medtronic MiniMed 670G, a portable device that works like an artificial pancreas. This is a significant breakthrough for people with Type I diabetes because the device automatically monitors blood sugar levels and injects the exact amount of insulin needed to maintain stable blood sugar. The MiniMed 670G received FDA approval in 2016 after decades of work including research and testing with dogs. Research with dogs was also critical for the development of the cardiac pacemaker, which has proven to be a life-saving technology for millions of people throughout the world.

We still have much to learn about how to prevent and treat diabetes and heart disease, and dogs are an essential part of this. These types of research cannot be performed on species such as rats and mice because of their small size. Dogs are also physiologically more similar to humans than species such as rodents in terms of their cardiovascular system and how diabetes affects them. Dogs, therefore, provide a better research model for these diseases. Unfortunately, this is the kind of life-saving and life-changing research that would be eliminated if House Amendment 226 were to become law.

Decisions about which animal species to study depend upon what research question is being asked. Rats, mice, and fish—the most common experimental animals in biomedical research—are frequently utilized to answer questions about basic biological processes. However, when the purpose of the research is to assess whether a new treatment is likely to be effective and safe for patients, researchers need to study animals more physiologically similar to humans, such as dogs and non-human primates. Under the Animal Welfare Act (AWA)—the federal law governing research with all large animals—before a study can be approved, the researcher must show why the species and number of animals proposed in the study are appropriate. The researcher's answers to these questions are submitted to the institutional animal care and use committee (IACUC) for approval. This animal welfare oversight panel has the final say on all research plans involving animals.

The AWA also requires research institutions to submit an annual report with the number of regulated animals they used for research, testing, teaching, or breeding and whether they experienced pain or distress. Animals are classified according to the highest level of pain they *might* experience, no matter how briefly. Animals used for breeding or observation are assigned to Category B. Animals that undergo simple procedures such as blood draws or injections—similar to what pets experience during a veterinary check-up—are listed as Category C. Animals that undergo more significant procedures such as surgery are listed in Category D *even though they are given drugs and supportive care to protect them from experiencing significant pain or distress*. Most of the VA's critical research with dogs falls within Category D, meaning that potential pain is controlled by putting the animals under anesthesia, giving them analgesics, and providing post-operative nursing care—*the same pain-management procedures commonly used in human and veterinary medicine*. Animals that undergo significant procedures where pain or distress cannot be fully relieved despite the use of drugs and supportive care are assigned to Category E. Animals in studies where pain-relieving drugs would interfere with the research itself are also assigned to Category E. IACUCs are required to scrutinize Category E proposals carefully before approving them. Researchers must provide scientific

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justification for any Category E research. The researcher must also define humane endpoints, meaning that if animals show signs of pain and distress beyond a certain level, there must be a plan in place to euthanize them before the conclusion of the study. *Amendment 226 would prohibit not only Category E studies but also Category D studies that use appropriate drugs for pain relief.*

Dr. Fallon of the VA has said that research with dogs is “essential to developing crucial medical advancements.” For this reason, halting life-saving research—as House amendment 226 would do—is the wrong response. Problem-solving—as the VA is doing—is the right answer. As Fallon explained in his television interview, the benefits of research are not immediately apparent: “We can’t really tell which project is going to provide that clinical breakthrough,” Fallon said, “but if we don’t do the projects, then we know we are not going to have a clinical breakthrough.”

As explained above, VA researchers study dogs only after serious consideration of other options and only when dogs represent the best research model of the disease being studied. I therefore urge you to delete House Amendment 226 from the final version of the VA’s FY 2018 appropriation so the agency can continue to fund this vital research.

Sincerely,



Dennis Brown, PhD
President

The American Physiological Society (APS) was founded in 1887 to advance physiological research. Our membership consists of nearly 11,000 research scientists who study biological processes that sustain life. Our U.S. members work in academia, industry, and government where they seek to understand human and animal diseases as well as biological traits that enable animals and humans to adapt to their environment. Physiologists combine different research techniques depending upon the scientific questions they seek to answer. Answers to some questions may be found by studying genes, proteins, or isolated cells, tissues or organs. Other answers may be found through computer modeling of biological processes. However, due to the complexity of biological processes, in many cases it is also necessary to study living animals. Physiologists recognize that animal welfare is an essential component of sound science, and we are committed to the humane treatment of animals.