

Representing Over 130,000 Researchers

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March 22, 2021

The Honorable Denis McDonough Secretary of Veterans Affairs 810 Vermont Ave, NW Washington, D.C. 20420

Dear Secretary McDonough,

As the largest coalition of biomedical researchers in the United States, representing 29 member societies and over 130,000 individual scientists, the Federation of American Societies for Experimental Biology (FASEB) seeks to advance public health and welfare by promoting progress and education in biological and biomedical sciences. To fulfill this mission, FASEB strongly advocates for federal support of pre-clinical research with animals. For decades, the Department of Veterans Affairs (VA) has conducted such research, leading to numerous health advances, including the development of the cardiac pacemaker and more recently a cough stimulator, which assists veterans with spinal cord injuries to breathe without a ventilator and cough effectively. Biomedical breakthroughs such as these, which both required studies in canines, have dramatically improved Veterans' quality of life.

We are writing to urge the VA to continue and further strengthen its support for animal research, recognizing that some of the research that is needed is currently best done in large animal translational models. While non-animal alternative methods are rapidly evolving and are valuable for some areas of research, the consensus among scientists remains that such techniques provide limited information and cannot be used alone to replace animal studies. *In-vitro* methods such as computer simulations, cell culture, and organs on a chip supplement and expand our understanding of how well-defined systems respond but cannot supplant information gleaned from animal studies or tell us how to define these biological systems in the first place.

The primary challenge to the use of alternative models is their ineffectiveness in providing insight into complex biological and disease mechanisms. For example, investigating and developing treatments for spinal cord injury (SCI)—a debilitating condition <u>affecting</u> over 27,000 veterans under the VA's care—depend on the study and testing of systems that mimic the anatomical and physiological characteristics of human SCIs. Observations have shown that rodent models differ in important ways from what occurs in humans, and currently available knowledge is not yet sufficient to create non-animal systems. In contrast, the canine spinal cord is anatomically and physiologically more similar to the human spinal cord than rodents. Furthermore, canines also suffer from SCIs, accounting for approximately two percent of traumatic injury cases presented to veterinarians. Therefore, large animal translational models such as canines offer an authentic paradigm for researchers to examine and treat this and several other conditions, including traumatic brain injuries and lung cancer, ultimately benefitting Veterans as well as our beloved animal companions.

The specifics of certain research questions necessitate other distinct animal models. The ongoing COVID-19 pandemic has clearly demonstrated this, as researchers depended on hamsters, ferrets, and nonhuman primates,

among other species to create a vaccine because wild-type mice are unable to contract the virus. By contrast, toxicological studies have made dramatic improvements towards utilization, where feasible, of non-animal techniques, most recently skin sensitization testing for active ingredients. However, no two scientific disciplines are the same, and cannot be expected to abide by the same timeline in developing alternative models. Individual research questions possess unique characteristics that require specific tools and resources that may or may not be currently available. Recently, the National Academies Committee on the Assessment of the Care and Use of Dogs in Biomedical Research Funded by or Conducted at the U.S Department of Veterans Affairs further underscored this principle after carefully examining whether dogs continue to be necessary for biomedical research related to the VA's mission. Their findings, published in the report, "Necessity, Use, and Care of Laboratory Dogs at the U.S. Department of Veterans Affairs" concluded that canine research is scientifically necessary for the foreseeable future, particularly for cardiovascular and spinal cord injury studies.

FASEB recognizes that VA researchers are committed to the established ethical, legal, and scientific standards that strictly regulate animal research, including the three R's—reduction, replacement, and refinements of the use of animals in research. For instance, VA policy requires that this work—and all other VA research with animals—meets standards of care that exceeds United States Department of Agriculture and National Institutes of Health policies, requiring VA animal research to be conducted only in AAALAC International-accredited facilities, a voluntary accrediting organization that promotes internationally accepted standards of humane, responsible animal care and use. More importantly, as with all federally supported studies with animals, VA research proposals undergo a rigorous evaluation process before receiving federal funds, including review by the Institutional Animal Care and Use Committee (IACUC), a committee that includes a community representative and is responsible for reviewing all animal procedures and protocols. The IACUC and veterinary staff routinely monitor animals throughout the lifespan of studies to ensure both regulatory compliance and optimal animal welfare.

Advances in Veteran care in critical areas such as spinal cord injuries, traumatic brain injuries, and neurodegenerative disorders such as Parkinson's Disease are dependent on research with large animal translational models. Therefore, in keeping with the Biden Administration's commitment to science-based policies, FASEB urges the VA to sustain support for this research. We also encourage the agency to utilize and share the many FASEB animal research factsheets, including biomedical and pharmaceutical breakthroughs of the decade and the role of large animal translational research in improving human and animal health when communicating the VA's use of animal models to support Veterans' health. Please do not hesitate to contact us should you have any questions regarding this important topic.

Sincerely,

Louis B. Justement, PhD FASEB President

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