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BEFORE THE
SUBCOMMITTEE ON NATIONAL SECURITY
HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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Good morning, Chairman DeSantis, Ranking Member Lynch, and Members of the Subcommittee. Thank you for the opportunity to speak about Veterans with posttraumatic stress disorder (PTSD) and service dogs. VA is in the midst of an ongoing study that pairs Veterans with PTSD with service dogs. I am accompanied today by Dr. Patricia Dorn, Director, Rehabilitation Research and Development Service, and Dr. Chris Crowe, Senior Mental Health Consultant and Liaison to the DoD Defense Centers of Excellence for Psychological Health and TBI.

Section 1077 of the 2010 National Defense Authorization Act directed VA to undertake a 3-year study to assess the benefits, feasibility, and advisability of using service dogs for the treatment or rehabilitation of Veterans with physical or mental injuries or disabilities, including PTSD. VA designed the study to focus completely on Veterans with PTSD because: the benefits of utilizing service dogs and guide dogs for physical disabilities were well established; PTSD is a high priority health issue in Veterans, and the benefits of service dogs in assisting people with mental health diagnoses have not been established in scientific literature. As mandated by Section 1077, the study assesses the impact of service dogs on Veterans' quality of life, their usage of prescription drugs and healthcare resources, and their employment status.

The study has been conducted in two phases. The first phase started in July 2011 and was a pilot study based primarily at the Tampa VA Medical Center (VAMC). Service dogs for the study were purchased from three organizations through contracts. Veteran enrollment in the pilot study had to be suspended in January 2012 after two

different service dogs bit the children of Veterans in the study. In response to these bite incidents, VA study team members maintained responsibility for interactions with Veterans after pairing, reduced involvement of the service dog vendor post-pairing, and increased the frequency of interactions between Veterans and the study team to identify and solve potential dog behavior problems as soon as possible. Veteran enrollment resumed in July 2012, but less than a month later, Veteran enrollment was again suspended due to the discovery of serious problems with the health and training of dogs provided by the remaining dog organization under contract. 26 Veterans already participating had the opportunity to finish the study, but no new Veterans could be enrolled because no additional dogs were available. Of the 26 Veterans enrolled in this phase, twelve completed the study, and four are expected to finish by February 2017.

VA recognized that major changes to the dog procurement contracts, study design, and study management were needed. Visits were conducted with a variety of dog training groups to seek advice and get suggestions on how to prevent the serious problems encountered in the pilot study. These groups included well-established and respected service dog organizations, military working dog training organizations, and Department of Defense and civilian Federal dog training units.

The original study design was reviewed again by mental health professionals, all of whom have a research interest in diagnosing or treating PTSD in Veterans and have academic appointments at affiliate universities. Collectively, they have published over 100 articles on PTSD, trauma recovery, or stress in scientific journals. Dr. Thad Abrams leads the Iowa City study team. He is a psychiatrist with the Iowa City VAMC Mental Health Service Line and has extensive experience treating Veterans with PTSD. Dr. Bekh Bradley-Davino was the initial lead for the Atlanta study team until he assumed greater responsibilities as the Director of the Mental Health Service Line at the Atlanta VAMC. Previously, he was the Director of the Atlanta VAMC Trauma Recovery program. Dr. Kelly Skelton now leads the Atlanta study team. She is the Acting Deputy Director of the Mental Health Service Line in Atlanta and the Medical Director of the Atlanta VAMC Trauma Recovery program. Until her recent retirement from VA, Dr. Kathy Magruder was a Research Health Specialist in the Research Service Line at the

Charleston, South Carolina VAMC. She has extensive experience as a clinical researcher, has published extensively on PTSD and other mental health conditions in Veterans, and is an Associate Editor of the Journal of Traumatic Stress. Dr. Dan Storzbach leads the Portland, Oregon study team. He is a Research Psychologist and the Lead Neuropsychologist for the VA Portland Health Care System Neuropsychology Clinic.

As a result of consultation with dog training experts and the mental health research team, as well as thorough analysis of other lessons learned, key changes were made in the study design:

- VA hired its own dog trainers to provide support to Veterans after they received a study dog, thus eliminating bias in the study. This required developing an entirely new position within VA.
- VA developed its own contract health, behavior, and training standards for dogs, instead of relying on the varying standards in use by individual organizations. These standards are based upon portions of DoD working dog contract health standards, and utilize the Assistance Dog International Public Access Test and the American Kennel Club Basic and Advanced Canine Good Citizen tests.
- VA dog trainers tested candidate dogs against the VA contract standards before accepting dogs into the study and paying for them.
- VA study staff are responsible for interacting with Veterans after they receive a dog to ensure that any problems with the dog or Veteran-dog pairing are quickly identified and corrected.
- Veterans with children less than 10 years of age in the household would not be eligible for the study until the safety record of at least 20dogs from each organization could be evaluated. Note: no vendor has reached the 20 dog delivery mark yet; the evaluations are still in progress. .
- Instead of purchasing dogs only from organizations located close to a VA study site, a full and open contract competition was held to seek out the best possible dog producers. The new dog “vendors” chosen were Canine Companions for

Independence (Santa Rosa, California and other sites), the Armed Forces Foundation and partner K2 Solutions (Pinehurst, North Carolina), and the Auburn Technology and Research Foundation with partner iK9, incorporated (Auburn, Alabama).

- Instead of only one VA study site, three sites are opened to increase the enrollment rate and enroll Veterans from different parts of the country. Atlanta, Georgia; Iowa City, Iowa; and Portland, Oregon were chosen as the study sites for the revised ("Phase 2") study.

We also standardized the service dog required tasks so that dogs from different vendors would have similar training, reducing experimental variability. The service dog tasks chosen, based upon Veteran feedback in the Tampa pilot study and input from VA PTSD clinicians, were "block," "behind," "lights," "sweep," and "bring" (retrieve).

The study was also strengthened by adding a second experimental group of Veterans who received emotional support dogs instead of service dogs. The basic obedience and health standards are the same for both types of dogs in the study, and both dog types provide love, affection, and an emotional bond with people, and have legal rights to housing and the cabins of commercial aircraft. However, service dogs are given much wider public access rights than emotional support dogs through the Americans with Disabilities Act, and only service dogs are trained in specific tasks that assist with a disability. By comparing and contrasting the results of the two groups, we expect to be able to better determine what features of each dog type are responsible for any benefits observed in the Veterans. Each Veteran enrolled in the study has a 50/50 chance of receiving a service dog or an emotional support dog.

A description of all the test instruments used in the study and instructions for Veterans interested in volunteering for the study are found on the http://www.clinicaltrials.gov website (study number NCT02039843). The instruments are administered about quarterly over 21 months to assess measures of self-care, interpersonal interactions and participation in society, the severity of PTSD symptoms, sleep-related problems, suicidal ideation, severity of mood disorders and substance

abuse, anger directed at others, inpatient and outpatient visits, medication usage, and measures of employment and work productivity. Veteran enrollment in the revised Phase 2 study began in December of 2014. Early planning suggested that the three study sites would collectively be able to enroll about 12 Veterans a month; however, the study experienced severe delays due to human resources problems in hiring VA dog trainers, and the complexity of the study required additional staffing at each of the three study sites. These problems led to a much lower monthly enrollment rate. As of the first week in April 2016, 107 of 220 Veterans have been enrolled in the study, and all three study teams will finally be fully staffed to achieve an enrollment rate of 12-15 Veterans per month, which would allow all 220 Veterans to be enrolled by the end of this year or early 2017. Veterans remain in the study for about 21 months so data collection will end about 21 months after the last Veteran is enrolled, which would be late 2018. The data will then be analyzed, and the results will be published in a peer-reviewed scientific journal.

While VA does not purchase service dogs for Veterans, VA does provide benefits to eligible Veterans with a recognized service dog, which include free high quality veterinary wellness and medical/surgical insurance, certain hardware costs, and certain Veteran travel costs associated with training with the service dog. This benefit extends to service dogs prescribed for a disabled Veteran to manage a diagnosed visual, hearing, or substantial mobility impairment, in order to enable the Veteran to live independently. 38 C.F.R. § 17.148 (77 Fed. Reg. 54,381, Sept. 5, 2012). .

Currently, VA does not provide benefits for PTSD or mental health dogs because they are not known to be effective in overcoming specific functional limitations; this study is incredibly important in building the evidence base. VA continues to monitor other scientific literature for quality evidence to inform future policies and remains strongly committed to completing the current PTSD and service dog study at an estimated cost of at least $12 million.

Existing Effective Treatment of PTSD

VA is strongly committed to the delivery of the best care for Veterans with PTSD. Advances in research have led to a range of effective treatments for PTSD that reduce symptoms and increase functioning and well-being. The VA/Department of Defense Clinical Practice Guideline recommends trauma-focused cognitive behavioral therapy [such as Prolonged Exposure (PE), and Cognitive Processing Therapy (CPT)], Eye Movement Desensitization and Reprocessing, stress inoculation, selective serotonin reuptake inhibitors, and venlafaxine, a serotonin norepinephrine reuptake inhibitor, as primary treatments for PTSD. PE and CPT are among the most widely studied types of trauma-focused cognitive behavioral therapy. Evidence demonstrating their effectiveness is particularly strong. VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, requires that all VA medical centers provide access to either PE or CPT. VA has supported this requirement by training upwards of 7,000 therapists in these treatments as part of a broader initiative to disseminate evidence-based psychotherapy for mental disorders. Uptake of PE and CPT across the VA health care system was rapid; by 2009, 96 percent of VA facilities were providing PE or CPT and 72 percent were providing both. VA also offers a range of treatment options to treat PTSD and associated symptoms and is using telehealth technologies to increase the availability of treatment for PTSD. VA remains open to new and innovative treatments for PTSD and supports research on these treatments as part of its portfolio on PTSD and related conditions.

Mr. Chairman, I appreciate the opportunity to appear before you today. We are prepared to answer any questions you or other Members of the Committee may have.

CURRICULUM VITAE

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3. E-mail Address: michael.fallon@va.gov

4. Citizenship: USA

5. Current Titles and Affiliations:

   a. Federal administrative appointments:

      Chief Veterinary Medical Officer, Office of Research and Development, Central Office, Department of Veterans Affairs, Washington, DC (1997-present)

      Attending Veterinarian, Veterinary Medical Unit, Atlanta VA Medical Center, Decatur, GA (1989-present)

   b. Academic appointments:

      Associate Professor, Dept of Pathology and Laboratory Medicine, Emory University School of Medicine (1996-present)

6. Previous Academic and Professional Appointments:

   1990-1996: Assistant Professor, Department of Pathology and Laboratory Medicine, Emory University School of Medicine.

   1989: Instructor, Department of Comparative Medicine, University of Alabama at Birmingham, Birmingham, Alabama.

7. Previous Administrative and/or Clinical Appointments:

8. Licensures/Boards:

   1984-present. License to practice veterinary medicine, Indiana.
   1977-81. ALAT, LAT, and LATG certifications, AALAS
   2012-present. USDA-accredited veterinarian.

9. Specialty Boards:

   2007-present. Certified Professional IACUC Administrator (CPIA)
   1991. Diplomate, American College of Laboratory Animal Medicine (ACLAM)

10. Education:

Undergraduate studies- University of Maryland, College Park, Maryland, 1977-1980.

DVM- Purdue University, School of Veterinary Medicine, Lafayette, Indiana, 1984.

Ph.D.- Department of Pathology, University of Alabama at Birmingham, Comparative Pathology Graduate Program, Birmingham, Alabama, 1989. Dissertation: “Effects of MHV Infection on Salmonella Resistance in Mice.” (laboratory animal fellowship completed concurrently)

11. Postgraduate Training:

NIH-sponsored Postdoctoral Fellowship in Laboratory Animal Medicine- University of Alabama at Birmingham, Department of Comparative Medicine, Schools of Medicine and Dentistry, Birmingham, Alabama, 1985-1988.

12. Military or Government Service:

1976-1980. US Army, military occupational specialty 91T, Veterinary Specialist (Technician), separated with Honorable Discharge as Specialist 5 (E-5).

1980. Army Commendation Medal.

1978. Walter Reed Army Institute Soldier of the Month, and Walter Reed Army Medical Center Soldier of the Month.

1976. Honor graduate, Veterinary Specialist MOS Course (Association of the U.S. Army recognition).

13. Committee Memberships:

a. National and International:

Member, VA Animals in Healthcare Working Group, VHA, VA, 2012-present
Designated Agency Representative, OPM Veterinary Talent Management and Advisory Committee, 2011-present
Member, VA Office of Research and Development RAMS Software Steering Committee (2011-present)
Member, Certified Professional IACUC Administrator Committee (2011-2014)
Chair of the Workforce Planning Action Team, Veterinary Talent Management and Advisory Committee for the Federal Veterinary Workforce, OPM (2010-2015)
Member, Certification Review Board, AALAS (1994-1996)
Member, National Advisory Research Resources Council, NIH (1997-1998)
Chair and Vice-Chair, Education Committee, AALAS (1995-1999)
Member, U.S. Federal Interagency Research Animal Committee, (2005-2012)
Member, ACLAM Government and Regulatory Affairs Committee (2007-2009)
Member, ACLAM Role Delineation Task Force (2008)
Member, Federal Interagency Animal Models Committee, (2005-2008)
Member, ACLAM Examination Validation Committee (2009)
Chair, ACLAM Distance Education Task Force (2009-2010)
President, Vice President and Newsletter Editor, Association of Veterans Affairs Veterinary Medical Officers (1994-1997)
AALAS Animal Technician Certification Board, District IV representative (1993-1995)

Section Chief, Veterinary Medicine, AMSUS Annual Conference (2005-2006)
Member, CDC committee on updating ABSL guidelines for the 7th edition of Biosafety in Microbiology and Biomedical Laboratories (released 2007)
Member, ACLAM Auto-Tutorial Committee (1997-1999)

b. Regional and State:

President, Southeastern Branch of the AALAS (1999)
Member of Board of Directors, Southeastern Branch, AALAS (1995-1997)
Treasurer, Southeastern Branch, AALAS (1993-1995)

c. Institutional

Chair, Atlanta VAMC Subcommittee on Research Safety (2012-2014)
Chair, Atlanta VAMC Institutional Biosafety Committee (2013-present)
Voting Member, Atlanta VAMC Research and Development Committee (2012-2014)
Voting Member, Atlanta VAMC IACUC (1989-present)
Voting member, Emory University IACUC (1989-1997)
Member, Yerkes Laboratory Animal Resident Training Review Committee (2009)

14. Consultantships:

1993. Design review consultant for Army Corps of Engineers review of Walter Reed Army Institute of Research animal facility constructed at Forest Glen, Maryland.

15. Editorships and Editorial Boards:

2014-2015. Associate Editor, Journal of Rehabilitation Research and Development, VHA.

16. Manuscript reviewer:

Lab Animal, Nature Publishing Company
Contemporary Topics, American Association for Laboratory Animal Science
Journal of Rehabilitation Research and Development

17. Honors and Awards:

1981. Recipient, Summer Fellowship in Laboratory Animal Medicine at University of Texas Health Science Center at Dallas, Texas.

1984. American Veterinary Medical Association Auxiliary Senior Student Award, presented for advancing the prestige of the Purdue School of Veterinary Medicine.

2006. Joseph Garvey Award, AALAS, for meritorious contribution or outstanding accomplishments in administration, education, or support programs relating to the care, quality, or humane treatment of animals used in biomedical research.

2015. VA DUSH Commendation for commitment to excellence and support of colleagues.

18. Society Memberships:

American Veterinary Medical Association (1984-present)
American Association for Laboratory Animal Science (1989-present)

19. Organization of National or International Conferences:

a. Administrative positions:

Veterinary Session organizer, American Military Surgeons of the United States, 2008-2010.

b. Sessions as chair:

PRIMR meetings, VA IACUC training session chair, 2005-present.
Chair, Using the Semi-Annual IACUC Review as an Improvement Tool, National AALAS, 2008

20. Invitations to National or International Conferences:

2005. Invited Participant, International workshop "Retrieval approaches for information on alternative methods to animal experiments", hosted German Federal ZEBET organization (Centre for Documentation and Evaluation of Alternative Methods to Animal Experiments), Federal Institute for Risk Assessment.

21. Bibliography:

a. Published and accepted research articles (clinical, basic science, other) in refereed journals:

1. Fallon MT. Navigating Jointly Sponsored Research and Peer Review of Hazardous Agent Use in Animals: IACUC-IACUC and IACUC-IBC Overlaps. Biosafety Anthology IX, J Richmond, ed., American Biological Safety Association, 2006.

2. Talkington DF, Shott S, Fallon MT, Schwartz SB, Thacker WL. Analysis of eight commercial enzyme immunoassay tests for detection of antibodies to *Mycoplasma pneumoniae* in human serum. Clin Diagn Lab Immunol 2004; 11:862-7.

3. Duffee N, Fallon MT. ResearchTraining.org and AALASLearningLibrary.org: Online learning management systems for technicians, researchers, and IACUCs. Alternatives to Laboratory Animals 2004; 32 (Supplement 1): 539–543.

4. Grune B, Fallon MT, Howard C, Hudson V, Kulpa-Eddy JA, Larson J, Leary S, Roi A, van der Valk J, Wood M, Dorendahl A, Kohler-Hahn D, Box R, Spielmann H. Report and recommendations of the international workshop "Retrieval approaches for information on alternative methods to animal experiments. ALTEX 2004; 21:115-27.

5. Mak P, Pohl J, Dubin A, Reed MS, Bowers SE, Fallon MT, Shafer WM. The increased bactericidal activity of a fatty acid-modified synthetic antimicrobial peptide of human cathepsin G correlates with its enhanced capacity to interact with model membranes. Int J Antimicrob Agents. 2003; 21:13-9.

6. Fallon MT, Shafer W, Jacob E. Use of cefazolin microspheres to treat localized methicillin-resistant *Staphylococcus aureus* infections in rats. Journal of Surgical Research, 1999; 86(1):97-102.

7. Duffee N, Fallon MT. The New Frontier: Investigator Training. Lab Animal, 1998; 27(8): 32-38

8. Schleicher RL, Hunter SB, Zhang M, Zheng M, Tan W, Bandea CI, Fallon MT, Bostwick DG, Varma VA. Neurofilament heavy chain-like messenger RNA and protein are present in benign prostate and down-regulated in prostatic carcinoma. Cancer Research, 1997; 57(16):3532-6.

9. Jacob E, Cierny G, Zorn K, McNeill JF, Fallon MT. Delayed local treatment of rabbit tibial fractures with biodegradable cefazolin microspheres. Clinical Orthopaedics and Related Research, 1996; Mar (336):278-85.

10. Schleicher RL, Fallon MT, Austin GA, Zheng M, Zhang M, Dillehay D, Collins DC. N-nitroso-N-methylurea induction of prostate cancer in rats: intravenous versus intraprostatic administration. The Prostate, 1996; 28:32-43.

11. Mead JR, Ilksoy N, You X, Belenkaya Y, Arrowood MJ, Fallon MT, Schinazi RF. Evaluation of maduramycin and alborixin in a SCID mouse model of chronic cryptosporidiosis. Antimicrobial Agents and Chemotherapy, 1995; 39(4):854-8.

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13. Jacob E, Cierny G, Fallon MT, McNeill JF, Sideras G. Evaluation of cefazolin sodium microspheres for the prevention of infection in experimental open rabbit tibial fractures stabilized with internal fixation. Journal of Orthopaedic Research 1993; 11:404-411 .

14. Fallon MT, Benjamin WH Jr., Schoeb TR, Briles DE. Mouse hepatitis virus strain UAB infection enhances resistance to *Salmonella typhimurium* in mice by inducing suppression of bacterial growth. Infection and Immunity 1991; 59:852-856.

15. Fallon MT, Schoeb TR, Benjamin WH Jr, Lindsey JR, Briles DE. Modulation of resistance to *Salmonella typhimurium* infection in mice by mouse hepatitis virus (MHV). Microbial Pathogenesis 1989; 6:81-91

16. Talkington DF, Fallon MT, Watson HL, Thorp RB, Cassell GH. *Mycoplasma pulmonis* V 1 surface protein variation: Occurrence in vivo and association with lung lesions. Microbial Pathogenesis 7:429-436, 1989.

17. Watson HL, McDaniel LS, Blalock DK, Fallon MT, Cassell GH. Heterogeneity among strains and a high rate of variation within strains of a major surface antigen of *Mycoplasma pulmonis*. Infection and Immunity 1988; 56:1358-63.

18. Fallon MT, Reinhard MK, Davis TK, Gray BH, Lindsey JR. Inapparent *Streptococcus pneumoniae* type 35 infections in commercial mice and rats. Laboratory Animal Science

1988; 38:129-32.

19. Fallon MT, Reinhard MK, DaRif CA, Schoeb TR. Diagnostic exercise: Eye lesions in a rabbit. Laboratory Animal Science 1989; 38:612 613.

b. Book chapters:

1. Shafer WM, Katzif S, Bowers S, Fallon MT, Hubalek M, Reed MS, Pohl JT. 2002. Tailoring an antibacterial peptide of human lysosomal cathepsin G to enhance its broad-spectrum action against antibiotic-resistant bacterial pathogens. Current Pharmaceutical Design 8:99-110, 2002.

2. Fallon MT. Rats and Mice. In Handbook of Rodent and Rabbit Medicine. Laber-Laird, M Swindle, P.A. Flecknell, eds. Pergamon Press, Oxford England, 1996.

3. Cassell GH, Davis JK, Simecka JW, Lindsey JR, Cox NR, Ross S, Fallon MT. Mycoplasmal Infections: Disease Pathogenesis, Implications for Biomedical Research, and Control. In Viral and Mycoplasmal Infections of Laboratory Rodents; PN Bhatt, RO Jacoby, H Morse, AE New, eds. Academic Press 1986; pp 87-130.