

April 1, 2020

The Honorable Richard Shelby
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

The Honorable Richard C. Durbin
Ranking Member
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Chairman Shelby and Ranking Member Durbin,

On behalf of the thousands of veterans and their interests represented by our organizations, we would like to offer our support for your efforts in securing the necessary resources to support the continued work by the treatment-focused Gulf War Illness Research Program (GWIRP), part of the Congressionally Directed Medical Research Program (CDMRP) funded within the Department of Defense (DoD). We thank you for your strong past support for the GWIRP, including providing the program \$22 million in Fiscal Year (FY) 2020.

Successive federally funded, peer-reviewed studies have concluded that Gulf War Illness (GWI) affects as many as one-third of the veterans of the 1990-91 Gulf War.¹ By congressional design, the GWIRP is a unique, treatment-focused research funding program narrowly focused on the vision of improving the health and lives of these veterans with GWI. Reports by the National Academy of Sciences (NAS) and federal research committees have shown that GWI, a debilitating physical condition likely caused by toxic exposures, typically includes, "some combination of widespread pain, headache, persistent problems with memory and thinking, fatigue, breathing problems, stomach and intestinal symptoms, and skin abnormalities."^{1, 2}

GWIRP-funded treatment target identification and treatment development have shown significant advances – including through the two Gulf War Illness Consortia (GWIC) at Boston University and Nova Southeastern University; the Boston Biorepository, Recruitment, and Integrative Network (BBRAIN); and the recently-funded Gulf War Illness Clinical Trials and Interventions Consortium (GWICTIC). The GWIRP's broad goals are to fund preclinical research to inform treatment targeting, fund high-risk/high-reward potential-treatment pilot studies, and then speed those that show success into larger clinical studies than can provide the statistical significance to translate successful treatments into the clinic for GWI patients. As the steady stream of peer-reviewed published study results continue to show, the GWIRP's strategy is clearly working, with key recent GWIRP-funded results including:

- The first direct evidence of neuroinflammation in veterans with GWI,³ a treatable target.
- Significantly different gut microbiome patterns in GWI, including greater plasma levels of an inflammatory cytokine and associated with significantly more reported GW chemical weapons exposure and GWI symptoms.⁴

¹ Research Advisory Committee on Gulf War Veterans' Illnesses, U.S. Department of Veterans Affairs, "*Gulf War Illness and the Health of Gulf War Veterans: Research Update and Recommendations, 2009-2013*," 2014.

² National Academy of Sciences, Institute of Medicine, "*Gulf War and Health, Volume 8: Update of Health Effects of Serving in the Gulf War*," 2010.

³ Zeynab A, Albrecht DS, Bergan C, Akeju O, Clauw DJ, Conby L, Edwards RR, Kim M, Lee YC, Protsenko E, Napadow V, Sullivan K, Loggia ML. (February 2020). **In-vivo imaging of neuroinflammation in veterans with Gulf War illness.** *Brain, Behavior, and Immunity.* <https://doi.org/10.1016/j.bbi.2020.01.020>

⁴ Janulewicz, Patricia A.; Seth, Ratanesh K.; Carlson, Jeffrey M.; Ajama, Joy; Quinn, Emily; Heeren, Timothy; Klimas, Nancy; Lasley, Steven M.; Horner, Ronnie D.; Sullivan, Kimberly; Chatterjee, Saurabh. (2019). "**The Gut-Microbiome in Gulf War Veterans: A Preliminary**

- A 25 percent reduction in key GWI symptoms by treating GWI with KPAX002, a proprietary combination designed to support mitochondrial function.⁵

A research publication from VA's Millennium Cohort Study Team early this year concluded that, "Gulf War veterans' increased risk of CMI/GWI persisted across the study period, highlighting the continued importance of screening and improving treatment options among this population."⁶ And, an October 2019 publication by VA WRIISC researchers concluded that, "[e]stablishment of a standard case definition, prioritized GWI research funding for the characterization of the pathophysiology of the condition, and rapid replication and adaptation of early phase, single site clinical trials could substantially advance research progress and treatment discovery for this condition."⁷ These findings and recommendations strongly support the GWIRP's active funding strategy, which is narrowly focused by congressional design on GWI's pathobiology, definition and diagnosis, and a clear treatment development "pipeline." It is a testament to the GWIRP's progress that its GWIRP-funded pilot studies are now advancing to these larger-scale clinical trials ready.

The NAS has called for the federal government "to speed the development of effective treatments, cures, and, it is hoped, preventions."⁸ Bearing in mind that the GWIRP is the only federal program exclusively focused on developing treatments for this debilitating condition, we respectfully request your support in providing adequate FY2021 funding for the GWIRP to continue its vital and effective work and to support its progress into larger-scale clinical trials – a well-justified, added cost indicative of its steady progress. It is critical to the program's success and accountability that it remains as a stand-alone program within the CDMRP and not be combined as a topic area within broader, less-targeted research programs.

Thank you for your consideration of this request. We appreciate your support.

Sincerely,

Association of the United States Navy
Blinded Veterans Association
Burn Pits 360
Cease Fire Campaign
DAV (Disabled American Veterans)
Fleet Reserve Association
High Ground Veterans Advocacy
Jewish War Veterans of the USA
Military Order of the Purple Heart
National Veterans Legal Services Program
National Vietnam & Gulf War Veterans Coalition
Non Commissioned Officers Association
ROA

Sergeant Sullivan Circle
Swords to Plowshares
The Quinism Foundation
TREA: The Enlisted Association
United Soldiers and Sailors of America- USASOA
Veteran Warriors
Veterans and Military Families for Progress
Veterans of Foreign Wars
Veterans for Common Sense
Vets First
Vietnam Veterans of America
Wounded Warrior Project

Report." *Int. J. Environ. Res. Public Health* 16, no. 19:3751. <http://doi.org/10.3390/ijerph16193751>. See also: "[GWIRP-funded project expands exciting gut biome finding for Gulf War Illness](#)"

⁵ Holodniy M, Kaiser JD. (November 2019). **Treatment for Gulf War Illness (GWI) with KPAX002** (methylphenidate hydrochloride + GWI nutrient formula) in subjects meeting the Kansas case definition: A prospective, open-label trial. *J. of Psych. Rsch.*, 118: 14-20.

<https://doi.org/10.1016/j.jpsychires.2019.08.003>. See also: "[A Prospective Open-Label Clinical Trial of Methylphenidate plus a GWI-Specific Nutrient Formula in Patients with Gulf War Illness and Concentration Disturbances](#)".

⁶ Porter B, Long K, Rull RP, Dursa EK, for the Millennium Cohort Study Team. (2020). "Prevalence of Chronic Multisymptom Illness/Gulf War Illness Over Time Among Millennium Cohort Participants, 2001 to 2016." *J. of Occup. & Environ. Med.* 62(1):4-10, January 2020. <http://DOI.org/10.1097/JOM.0000000000001716>

⁷ Chester JE, Rowneki M, Van Doren W, Helmer DA. (2019) "Progression of intervention-focused research for Gulf War illness." *Mil Med Res.* 2019 Oct 18;6(1):31. <http://doi.org/10.1186/s40779-019-0221-x>.

⁸ NAS 2010