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FDA-Approved Marijuana/PTSD research in 76 US Veterans Appeal to VA Sec. David Shulkin for Cooperation from Phoenix VA

By Dr. Sue Sisley, Site-PI of Marijuana/PTSD Study Sponsored by MAPS

Dr. Shulkin, thank you for all the exemplary leadership you've been providing to the VA system! I'm writing to appeal for your help regarding an FDA-approved randomized, blinded, controlled trial that is being conducted in Phoenix, Arizona. This study is examining both safety and efficacy of 4 different varieties of NIDA cannabis in 76 military veterans with treatment-resistant PTSD. The study is being funded by a \$2.15 million grant from the Colorado Department of Public Health and Environment (CDPHE) to a non-profit research and educational organization, MAPS.

As a result of an aggressive recruitment effort over the past year, we have enrolled 20 of the 76 participants necessary to complete the study. We are currently not receiving inquiries or new enrollments at a rate that will allow us to complete the study within the timeline allowed for by our grant.

Despite our best efforts to work with the Phoenix VA hospital and share information about the study, they have been unwilling to assist by providing information to their patients and medical staff about a federally legal clinical trial happening right in their backyard that is of crucial importance to the veteran community.

Currently, the Phoenix VA Hospital Director is citing regulations that she cannot support research that does not utilize VA personnel. We would like to see if you can help us move forward in cooperation with the VA in a way that respects VA policies and the importance of this research for veterans.

We are requesting your help with the following:

- 1) contact the Phoenix VA Hospital Director Rima Ann Nelson and ask her to allow us to distribute the IRB-approved physician referral letter to her medical staff (all depts) and other support staff including social workers etc.



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2) include information about the PTSD/cannabis study in any kind of electronic communications that are shared with VA staff and patients (such as a monthly newsletter, etc.)

3) enable us to post FDA/IRB approved flyers around the Phoenix VA hospital in appropriate designated areas.... particularly focusing on rooms that host PTSD support groups, VA library etc.

4) allow us to present a medical Grand Rounds lecture to the Phoenix VA medical staff inviting physicians and nurses etc. from all specialties to attend. Ideally this would be presented by Sue Sisley, MD, the Site principal investigator or Marcel Bonn-Miller PhD, the Coordinating principal investigator or both.

We were invited to present this Grand Rounds lecture 4 years ago and were met with tremendous enthusiasm from the (standing room only) Phoenix VA audience. However, we did not have all of the federal government approvals in place at that time to request patient referrals. We were told by department chairman Carlos Carrera MD that we would be allowed to return to the Phoenix VA hospital when the study had completed all the required approvals and was finally implemented. That has not happened.

We are asking for your assistance in ordering the VA in Phoenix to allow us to return to share vital information about how veterans suffering with treatment-resistant PTSD may be able to volunteer for this research.

If we cannot recruit enough veterans, we will need to change the inclusion criteria to allow subjects with PTSD from any cause to enroll in the study. This is a change that we do not want to make if at all possible.

Sue Sisley, MD
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P.S.I just learned that I will again be speaking at the American Legion national convention mainstage. I hope to see you in Reno to discuss this further.