Combating PTSD

Through Stellate Ganglion Block Treatment R&D

THEENDEAVOURGROUP

March 12, 2019

Ms. Cassandra Martin

Defense Health Agency
Office of Small Business Programs
7700 Arlington Boulevard
Falls Church VA

Dear Ms. Martin,

Thank you for taking the time to speak with us regarding new and advanced procedures that are now available for treating Post Traumatic Stress Disorder (PTSD) and depression. Following our dialog, I would like to attach a white-paper which addresses the product, efficacy, evidenced based research and trial data regarding use cases, and success rates. Allow us to quickly recap our PTSD Capability in order to provide you with a summary for reference.

1) What This Is: Patented PTSD Injection with symptom relief at 85%+ efficacy (Within 60-min).

2) Efficacy:
PTSD Treatment Results

- 85% + PTSD patients experienced relief from symptoms within 60-min lasting months to years.
- Re-treatment is rarely needed (2.5 per patient). Positive effects have been observed for up to 10 years.

Peer Review:

- Walter Reed Hospital, Ft. Bragg, Tripler Army Medical Center
- San Diego Naval Medical Center, and Long beach VA

3) What Problem Does This Solve?
PTSD & Soldier / Veteran Suicide

- Current success rates in treating PTSD are only 20 – 30% after 4-years of standard treatment.
- This Patented PTSD Injection raises the success rate to 85%+ and within a far reduced time-frame.

Economic

- Current expenditures are in the Billions for combined treatment and disability payments due to limited success rate. Our increased efficacy will reduce costs accordingly.
- Soldiers & Veterans may return to work and form stable families once PTSD symptoms are resolved.

4) How To Access:
Current procedures and patented 'injections' are billed through standard TRICARE and/or MEDICARE billing codes, with some slight modifications. The Endeavour Group, a SDVOSB, will serve as the contractor to introduce this procedure to your agency if you find this to be of value. Should there be sufficient interest, I'll defer to you both for the best contracting solution.

Thank you again for speaking with us, and we look forward to hearing from you and to delivering this solution of all our soldiers and veterans.

Sincerely,

Eugene Lipov, MD

Attachment: Combating PTSD

THEENDEAVOURGROUP

Combating PTSD

OBJECTIVE
Provide a breakthrough treatment to soldiers and veterans with “treatment-resistant” Post Traumatic Stress Disorder (PTSD) through R&D. This method to be researched utilizes the injection of a fast acting solution, which we have observed to provide relief (within 1-hour) at an efficacy rate of over 85%.

CURRENT PROBLEM and SOLIDER / VETERAN SUICIDE
Current treatments of PTSD rely upon the 'Gold Standard', which includes a combination of pharmaceuticals in conjunction with psychodynamic therapies. However, the results have been minimal: after 4-years of treatment (with only a 20 – 30% recovery) veterans continue to commit suicide each day.

CURRENT CHALLANGES

- Current treatments have not achieved even marginal success rates (<30% cured), and costs for treatment, follow-up care, and medications are estimated at $2 Billion*
- The Defense Department is understaffed to meet the demand to treat all PTSD patients, with a limited number of trained Medical Doctors and/or qualified medical personnel available.
- An unacceptable number of military members and veterans, many with PTSD, are committing suicide every day.
- *The CBO estimates the cost of disability payments for post-combat stress induced disability claims to be $355 billion - $534 billion over the next 50-years.

PROJECTED SAVINGS
The majority of this cost is a result of treatments, which persist for many years and do not produce effective results (75%+ are still symptomatic after 4-years). This new and patented procedure, offering increased efficacy, reduced treatment duration, reduced disability payments, and an 85%+ success rate, will produce a significant degree of cost savings for the DoD, VA, and the American tax-payer.

A NEW TREATMENT METHOD
The rapid and long-lasting benefits of the Stellate Ganglion Block injection for PTSD were discovered in 2005. The results of the treatment typically occur within 30-60 min, and the effects have been observed to last for years without relapse and rare need for re-treatment. Thus far, Dr. Lipov has personally treated an estimated 550 patients, while 200 of those were veterans, and 30 have been soldiers. This new treatment has been successfully used in the Walter Reed Hospital, Ft. Bragg, Tripler Army Medical Center, San Diego Naval Medical Center, and the Long beach VA with a 70 to 75% success rate through using the original 2005 method. Dr. Lipov’s private practice success rate is over 85% due to a modified proprietary technique and injection protocol. Dr. Frank Ochberg (Harvard Psychiatrist), previously of the National Institutes for Mental Health, and Dr. McClean, MD at Tripler Army Medical Center will both corroborate efficacy of this procedure.

THE PROCEDURE:

Stage 1: Telemedicine (Screening) - Electronic PTSD and Psychometric assessment for a selected group of veterans with treatment-resistant PTSD (defined as 4 years of conventional treatment without recovery).

Stage 2: Rapid Treatment - Patients will receive an injection, administered by a licensed MD.

Stage 3: Monitoring & Follow-up - The PTSD and Psychometric assessment will be re-administered electronically 90-days after completion of treatment.

MECHANISM OF ACTION
The mechanism of action is believed to be related to the injection's capacity to down-regulate arousal of the bottom-right amygdala, a region of the brain that is over-active in PTSD cases. Through administering the very well tolerated and low risk injection, this nerve pathway's excitatory response is suppressed, and the amygdala's over-arousal is rapidly mitigated.

RISK PROFILE (LOW)
The potential risks have been well researched, and after 45,000 people have been treated for other conditions with this injection protocol, 99.952% of individuals did not experience side-effects. Thus far, there has been a very low incidence of seizure, air in the lungs, or allergic reaction in 0.024%, .02%, and .004% of the population, respectively. Meanwhile, the more commonly used second generation antipsychotics double the risk of cardiac death and are nearly 15x more side-effect prone.

CHAMPIONS WITHIN GOVERNMENT

- Dr. Alkiere (Long Beach VA)
- Dr. McLean (Tripler Hospital)
- Dr. Bazinski (Ft. Bragg)
- Dr. Frank Ochberg (Previously National Institutes of Mental Health)

CONGRESSIONAL TESTIMONY & NEWS
Dr. Lipov's work appears in his congressional testimony (2010), where he explains why he believes this method should be explored. This method has also been featured on a growing number of news publications such as the Wall Street Journal, Military Times, ABC, Fox News, and others, resulting in growing interest in researching this intervention.

PENTAGON FUNDED R&D
The Department of Defense has funded a $2Million FDA Phase IIa trial, and treatments have been provided to patients at Ft. Bragg, the Long Beach Veterans Administration, Womack Army Medical Center, Tripler Army Hospital, the Naval Hospital in San Diego, CA, as well as the Army's Landstuhl military hospital in Germany.

FDA STATUS
The Federal Government's regulations currently permit an MD to provide treatment through Research & Development (Studies). The compound and injection protocol have been well studied since 1925 – Only the indication has changed. Letters from DHS support this position.

WHY BEGIN NOW?
The process of discovery began in 2005, and the method required additional research, validation, and peer-review, which has recently matured. Publications through Johns Hopkins University researchers (2016), the recent VA Position Paper (2017), and recent Pentagon funded research at Tripler Army Medical Center (2018) have ensured that this method has been rigorously investigated.
Therefore, we are now prepared to submit this proposal to you in order to request funding for a larger scale Clinical Trial R&D program, which we would like to expand upon annual review.

United States Senate

WASHINGTON, DC 20510

November 15, 2007

Ms. Pamela Fisher
Contracting/ Grant Officer
Department of the Army
US Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, MD 21702 - 6014

Dear Ms. Fisher:

We are writing to request that the Department of the Army consider the application, "Proposal to Conduct a Two-Part Study on Stellate Ganglion Block and Pulsed Radio Frequency to Relieve Post Traumatic Stress Disorder in Military Personnel," submitted by Dr. Eugene Lipov and supported by Northwest Community Hospital in Illinois. This application proposes research into potential new treatment methods for Post-Traumatic Stress Disorder (PTSD).

As you know, there is a growing body of evidence to suggest that PTSD is affecting a growing number of our heroic service members returning from Iraq and Afghanistan. We have both worked in the Senate to strengthen the quality of mental health care provided by the US Armed Forces and the Veterans Administration (VA), and we continue to support important new investments in the screening and treatment of PTSD and Traumatic Brain Injuries (TBIs). We believe that PTSD and other forms of combat stress, anxiety and depression will require ongoing support and counseling for those with such diagnoses as well as their loved ones. At the same time we believe it is important to consider any new approaches that may hold potential for helping our service members get the care they need.

While we leave the evaluation of the merits of this particular proposal to the judgment of the selection committee, we appreciate your ongoing commitment to improving mental health care for our service members.

Sincerely,

Barack Obama
United States Senator

Richard Durbin
United States Senator

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

REPY TO
ATTENTION OF

September 15, 2010

Eugene Lipov, M.D.
Advanced Pain Center, S.C.
2260 West Higgins Road
Hoffman Estates, Illinois 60169-2431

Dear Dr. Lipov:

I am writing as a follow-up to the phone conference held on September 14, 2010, regarding your proposed research study, "Placebo-Controlled Study of Stellate Ganglion Block to Relieve Posttraumatic Stress Disorder in Military Personnel". This study has the potential to significantly impact in the treatment of PTSD in military servicemembers.

The Military Operational Medicine Research Program (MOMRP) is interested in supporting this study contingent upon availability of funding and collaboration with others organizations to assist in the recruitment of military subjects for your initial study.

If you have any further questions please contact me at 301.619.7304 or at Carl.Castro@us.army.mil.

Sincerely,

Colonel Carl A. Castro
Director, MOMRP

U.S. House of Representatives
COMMITTEE ON VETERANS' AFFAIRS
ONE HUNDRED ELEVENTH CONGRESS
335 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
http://veterans.house.gov

November 23, 2010

Honorable John McHugh
Secretary of the Army
1400 Defense Pentagon
Washington, DC 20301

Dear Mr. Secretary:

On July 21, 2010, the House Committee on Veterans' Affairs held a roundtable discussion on "Innovative Treatments for PTSD and TBI". We brought together scientists whose research is paving the way for new PTSD and TBI treatment methods, companies that are pioneering innovations in this area, and practitioners who are leading the way to make innovative treatment tools available to our veterans with PTSD and TBI.

Among the participants was Eugene Lipov, M.D., DABA, FABA, who is a lead proponent and developer of a novel procedure for treating PTSD. Dr. Lipov is an anesthesiologist based in Chicago with a specialty in pain management. He has adapted an often used pain injection to treat PTSD. Results are said to be immediate, lasting and readily available. His early findings have been replicated in a small study conducted at Walter Reed by LTC Sean Mulvaney. Dr. Mulvaney's study, following the subjects for a year post treatment, has been published.

Dr. Lipov has submitted applications for DOD funding in 2007 (PT074412) and 2009 (PT090071.) One 2007 reviewer stated that "(t)his proposal is offering a treatment…that in minutes may relieve the individual's symptoms related to PTSD. This is a treatment that is minimally invasive and offers immediate results; it could change the mental health system in a major way." Nevertheless, both proposals were rejected. Most recently, Dr. Lipov has submitted a third proposal to DOD which has been accepted and is in line for funding pending the FY 2011 appropriations provided for DOD.

Given the potential of Dr. Lipov's "blockage" procedure, I encourage that funding be expedited and made available as soon as possible. In doing so, we can test the procedure on a larger sample of servicemembers and veterans to provide more conclusive evidence on the efficacy of this approach.

Thank you for your attention to this matter and I look forward to working with you to help our returning servicemembers and veterans who are suffering from PTSD and TBI.

Sincerely,

BOB FILNER
Chairman

CW/kp