

VIP Manifesto for Change Addendum

By Micaela Bensko, Founder Veterans In Pain VIP

Subject: The legitimizing of Chronic Pain as a systemic autoimmune disease of the CNS with the propensity to become terminal, allows Veterans suffering intractable pain levels the compassion and common sense allocation of humane therapeutic resources available through Regenerative medical solutions, provided within VIP's framework, and funded by the system created to serve those who have sacrificed their quality of life in service to our country.

Our Veterans In Pain VIP Manifesto for Change summarizes the reasons why our Veterans are suffering more now than ever before, and our ultimate long term goal of mandating a comprehensive multidisciplinary Chronic Pain program throughout the VA system and ultimately into a brick and mortar VIP Facility.

However, in order to move forward, it's essential to keep the process of incorporating accessible Regenerative Medicine solutions into the VA patient flow, as simple as possible. We understand all too well that shifting an entire division within the VA system into a cohesive multidisciplinary program for Chronic Pain, comprised of multiple specialties within which specialists often new to the system will need to be procured, is a daunting

task to many. So to begin this shift, our focus is narrowed to a 5-Step process.

- 1. Amendment to the Right to Try Act establishing Chronic Pain as a Systemic Autoimmune Disease of the CNS
- 2. Establish the VIP Voucher Program with Government Funds Allocated to States for Mental Health Services and Suicide Prevention
- 3. Utilize VIP and its Physician Network as the VA's CCN for Regenerative Solutions Ensuring Compliance, Quality of Care, and Cost-Effective Therapeutic Healing for Veterans Suffering from Chronic Pain
- 4. Inclusion of IV Stem Cell Procedures for Systemic Inflammatory Chronic Pain Diseases through the Right to Try Act
- 5. Create Access to and Cost Coverage for PRP and BMAC Joint and Spine Specific Protocols for Veterans through VIP-Trained VA Practitioners, or VIP's CCN of Regenerative Specialists within FDA Compliance Guidelines

The first step to establishing awareness of Chronic Pain as a systemic autoimmune disease of the Central Nervous System with a propensity to become terminal, is through an Amendment to the Right to Try Act. This will validate the terminal disease aspect of Chronic Pain through suicide and organ degeneration, while providing

access to non FDA Approved systemic and joint/spine specific Regenerative medical solutions for Veterans who have otherwise lost hope.

Chronic Pain is a leading cause of suicide amongst Veterans, and can also be the underlying factor for physiological death through diseases such as Complex Regional Pain Syndrome (CRPS). CRPS is a Chronic Pain disease which can be caused by an injury or a surgery. This results in a cellular breakdown of pain inhibitors, and brain-pain signaling goes haywire. This results in pain levels on the McGill Pain Scale of 1-10, as a medically designated 1000. This condition over time can spread to vital organs resulting in death, and has been termed by pain specialists as a "Suicide Disease". This is just one example when patients, such as myself, are told there is no hope, only prescription medication, which does not even begin to touch the surface of pain relief, and within 10-15 years expire either due to organ degeneration or suicide.

Another Chronic Pain disease is Arachnoiditis. This is when the body reacts to the injection as an invasion, and the immune system begins to attack the nerves within the dura by coating them in plaque. This plaque buildup over time causes a burning sensation throughout the patient's core, and spinal cord, accompanied by devastating contractions, and can be caused by just one puncture to the dura of the spinal cord. A mother has one epidural and within two weeks she is paralyzed, but with pain levels akin to CRPS and is also coined a "suicide disease". Our Veterans are afflicted continuously by injections to the spinal cord for back pain as one of very few option's currently available to them other than prescriptive opioids. None of which are therapeutic. And with every steroid injection, the quality of the tissue and bone in the region is degraded by 10% with each treatment, resulting in only temporary relief, and long term damage. Not to mention each injection has the potential to cause Arachnoiditis. The number of Veterans who have come to VIP have ultimately been diagnosed with CRPS or Arachnoiditis after their Intake, is truly overwhelming. To not have awareness of such maladies and their connection to soft tissue inflammatory disease by VA physicians, is a neglect resulting in deaths which could otherwise be prevented.

This is where our Initiative becomes personal. I am sharing the following as it is not just my story, but a similar story to hundreds of Veterans who have shared their journeys with us.

After an accident, enduring over 20 spine surgeries and procedures and years in a wheelchair, I was diagnosed with Arachnoiditis complicated by CRPS of the spinal cord. After 6 years in bed 80-90% of the time, with labor-type contractions in my spine every 10-15 minutes any time I would place pressure on my tailbone, and even being married to my soul mate with 4 amazing children, I had completely lost hope, and could no longer see how I could possibly physically endure another 40 years on this planet.

Just before the unthinkable, I was told about stem cells and a an intravenous procedure utilizing adipose-derived mesenchymal stem cells from my own body, minimally manipulated to concentrate, and

reintroduced through an IV. Within one day after the procedure, the crippling spinal contractions were completely gone. That was 2017. It is now 2023 and they have not returned since. I learned how to walk again over the period of a year, and live a life I never dreamed could be possible. This is why I founded Veterans In Pain, and why we are fighting so hard for the plight of Veterans in pain to be heard.

Too many Veterans have lost the same hope I was so fortunate to find. Too many are dismissed or seen as problem patients only because wellmeaning VA physicians don't know of such solutions or that they even exist. Or that Regenerative solutions are often more conservative than any additional measures they could provide. That when a Veteran has no other options, they are simply left to die of these Chronic Pain diseases, when those suffering from a more understood disease such as Cancer, are allowed access to possible pain relief or life-saving protocols, which may not be FDA Approved, just because it is accepted as a potentially terminal illness when Chronic Pain is not. Yet it is a disease with the potential to become terminal.

Next is to establish the VIP Voucher Program by utilizing Government funds allocated to states for Mental Health Services and Suicide Prevention. These government-funded vouchers will be available to Veterans applying to VIP for proven Regenerative medical solutions within FDA Compliance Guidelines and accessible through the Veterans In Pain VIP Physician Network. Essentially, VIP would become the Community Care Partner for Regenerative solutions, for the VA system.

So, the question is, how to create access to such solutions safely and effectively, at the same time reducing the bottom line of government spending, while increasing the quality of life of our country's Heroes, through healing.

The most important aspect of providing Regenerative solutions, is safety. After 5 years, and having conducted Intakes for over 450 Veterans, facilitating over \$4,000,000 in value of services for Veterans in need, VIP not only knows which protocols work, but also how to facilitate such solutions responsibly and within FDA Compliance Guidelines. Our organization is endorsed by, and comprised of, the most renown and respected experts and practitioners in the field, today, with access to supportive numerical data, as well as corporate partnerships through which to provide training for VA Center physicians on how to conduct these procedures, properly, and to do so within FDA Compliance Guidelines.

Stating that the VA provides the Regenerative protocol of PRP, and providing access to these procedures, are in conflict. Currently, TriCare does cover the cost of Platelet Rich Plasma (PRP) for Veterans under narrowly defined parameters. Unfortunately, the majority of Primary Care Practitioners (PCP) within the VA, and administrators who conduct approvals, are not aware such conservative measures exist, nonetheless how to perform them, or where to responsibly refer Veterans to obtain them. Therefore, these requests for coverage of PRP protocols through the VA's Community Care Network (CCN) through which our Veterans are supposed to have access, are more often than not, denied.

Now let's look at joint and spine specific procedures we hope to include in this Voucher program.

Platelet Rich Plasma (PRP) is Regenerative in nature but is not comprised of Stem Cells. This is often a misnomer in the field of Regenerative Medicine, that all protocols are stem cell related. PRP involves the traditional draw of one's blood which is then placed through a centrifuge to extract a golden yellow 'Buffy Coat' comprised of Hyaluronic Acid, growth factors and proteins which, when injected into the area of concern, inciting an inflammatory response instructing the damaged tissue to regenerate.

Bone Marrow Aspirate Concentrate (BMAC) is most often used when addressing spine, as well as joints. This procedure occurs in an operating room for sterility purposes, with live X-ray video fluoroscopic guidance. Bone marrow is extracted through a needle most often from the iliac crest of the hip, and the bone marrow derived stem cells are reintroduced via injection into the damaged tissue where the cells instruct the damaged tissue to regenerate.

Both of these, although not FDA Approved, are available within FDA Compliance Guidelines, and have the potential for providing therapeutic

healing, eradicating the need for any future surgeries or expensive and extensive treatments.

We have seen throughout our years of Veteran Intakes, those who are told there is nothing anyone can do and surgery or a joint replacement is the only answer. Only to come to us for help, receive a Regenerative procedure such as PRP or BMAC, and the majority now live a functional and meaningful life.

What is this cost-savings? An average knee replacement can cost a hospital upwards of \$65,000. However, a BMAC procedure, with therapeutic results, can be conducted for approximately \$4,500. Not only is this a massive cost savings for the VA system, but our Veterans are granted the healing they so greatly deserve. PRP begins at \$2,500. Our intent is to create a flat rate one-sheet of pricing specifically for the Voucher system for each available procedure so this does not fluctuate.

The argument again often resorts back to, but aren't these procedures unproven? The answer is these procedures are proven, with supportive data available through our partners at Data Biologics, and available upon request.

In summary, the legitimizing of Chronic Pain as a system and potentially fatal disease, allows Veterans suffering intractable pain levels the compassion and common sense allocation of humane therapeutic resources, provided within a structured framework, and funded by the system created to serve those who have sacrificed their quality of life in service to our country.

It is our greatest hope that the authors of the Right to Try Act consider our plea on behalf of our Veteran pain population to incorporate the inclusion of Chronic Pain, and access to systemic, joint-specific and spine related Regenerative protocols proven effective for service-borne and degenerative based diseases.

Micaela Bensko Founder, Veterans In Pain VIP 310-990-8389 | <u>MBensko@VeteransInPain.org</u>