

## Memorandum

To: House Health Care Committee
From: Dr. Sam Russo, Legislative Chair, Vermont Association of Naturopathic Physicians (VANP)
Date: April 21, 2021
Re: S.22 – Stem Cell Products

I am writing on behalf of the Vermont Association of Naturopathic Physicians (VANP) regarding S.22 – stem cell products. We are specifically concerned about the impact of S.22 on health care providers who perform platelet rich plasma (PRP) injections.

We supported the initial draft of S.22; however, an amendment in the Senate to the definition of a stem cell product as "intracellular or extracellular components or vesicles" could be construed to include platelet rich plasma (PRP). Our understanding is that PRP will not be regulated by the FDA, because the FDA considers it to be a blood product that is not subject to regulation per the 2020 guidance for Human Cells, Tissues, and Cellular and Tissue-Based Products. The FDA does regulate the equipment utilized in the preparation of PRP.

Therefore, capturing PRP in the definition of unapproved stem cell products, for purposes of S.22, is misinformed, as it is just not subject to FDA approval. As the use of PRP moves into mainstream medicine, S.22 would require providers who practice using PRP to forever continue to have a notice in their office that casts a dubious light on legitimate practices:

PRP is utilized for chronic non-healing diabetic, pressure, and/or venous wounds and is actually covered by third party payers, including Medicare, for this purpose. As a primary care provider at the Community Health Centers of Burlington. I have been administering PRP for knee osteoarthritis for 15 years based on a substantial amount of evidence supporting this application. PRP is also offered at the University of Vermont Medical Center in their orthopedics department.

If it is not the intention of the legislature to include PRP, then we request the following amendment to the S.22:

## CHAPTER 87. STEM CELL PRODUCTS § 4501. DEFINITIONS As used in this chapter:

(2)(B) For purposes of this chapter, "stem cell and stem cell-related products" does not include the use of whole blood or blood products for routine transfusions or use of

hematopoietic stem cells for reconstitution of bone marrow after treatment of bloodrelated cancers or diseases such as leukemias or lymphomas <u>or platelet rich plasma</u>.

Thank you.

Sam Russo ND, LAc, RMSK Legislative Committee Chair, Vermont Association of Naturopathic Physicians