From: Dr. Jonathan Fenton
Subject: S.22 Testimony

Dear Committee:

I am happy with the new bill as written.

Peter Marks, MD, PhD, the director of the Center for Biologics Evaluation (CBER) at the FDA clarified what is allowed by the FDA in a lecture given at the (virtual) meeting of The American Academy/Association of Orthopedic Medicine 12/6/2020, stating categorically that the use of bone marrow concentrate (BMC) for orthopedic applications (bones, tendons, joints, ligaments) and for critical limb ischemia are FDA approved as autologous, minimally manipulated, and meeting criteria for same day surgical exemption.

Those practitioners using BMC (orthopedics, physiatry, interventional pain, sports medicine, veterinarian, podiatric, vascular surgery) for these applications would not have to meet the posting requirements of this bill.

Those claiming stem cells when using fat, amniotic or umbilical cord tissues would be subject to this bill. In fact cord and umbilical tissues are presently not allowed for the above applications, even if no cellular claims are made!

The use of amniotic or cord tissues is not allowed without a specific IND research application.

The use of fat is not allowed as a stem cell product, only as a "spacer," or structural tissue, and only if minimally manipulated.

PRP is not considered a biologic product or a source of stem cells so is not regulated as such by the FDA.

The FDA codified this in updated guidelines last month confirming what is and isn't allowed.

https://www.fda.gov/media/109176/download

https://www.fda.gov/media/89920/download

Thank you for allowing me to help clarify the FDA rules.

I can provide the recorded lecture and Q&A he gave clarifying these positions, if requested.

I can also have the AAOM contact Dr. Marks if the committee needs direct confirmation from him.