

Dear Committee members:

I am writing to counter erroneous and inflammatory testimony and undo regulatory influence from Dr. Weiss regarding what are clearly FDA approved uses of bone marrow concentrate (BMC) in clinical medical practice. Dr. Weiss is not a clinician, only representing research interests and biotech firm interests. The last-minute change in S.22 of the definition of stem cells is unscientific and not in keeping with FDA rules. It truly is a travesty of language and would not hold up in court, but it would be easier to change it before it becomes law. I would have to post a notice that is untrue, since BMA IS FDA approved.

As I testified to the Senate committee (many supporting documents uploaded) the FDA has clearly and unequivocally stated the bone marrow can be used in office and surgical based procedures based on minimal manipulation and same day surgery exemption. This is not a loophole but purposeful.

Present uses of BMC (at UVMMC) include as an adjunct to spine fusion, for use in AVN drilling of hips and knees, and for re-vascularization in peripheral vascular disease. I use it only for orthopedic applications, and can provide plenty of high level evidence for their clinical use, as well as FDA clearance.

The language of S.22 before that final last minute change was FDA compliant and legally correct.

Please let me know how I can help to make that change happen. I have plenty of supporting documentation, lecture from the head of the CBER division at FDA Peter Marks, MD, PhD, and can make direct contact to Dr. Marks for the committee to “get it from the horse’s mouth!”

I have worked with state and federal authorities (nursing board, attorney general, US attorney, FDA enforcement) to get these fraudulent stem cell clinics close and have succeeded. The only clinics open in VT now are fully board certified specialist and subspecialist ethically run. This law, as written, actually creates a loophole for the fraudulent use of allogenic products, which are now (starting May 1) subject to aggressive enforcement by FDA to prevent their use.

I doubt the law would be used to force UVMC or other hospitals to post that they are doing “non-FDA approved procedures,” so this law also singles out independent practices like mine.

I have been practicing in Vermont since 1992 with never any actions or investigations against me, maintaining the highest professional and academic standards, and continuing to teach ethical approaches to Orthobiologic interventional orthopedics as the Treasurer of the American Academy of Orthopedic Medicine.

I look forward to your reply.

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