



Interventional
Orthopedics
Foundation

January 5, 2016

SAMPLE LETTER FOR
PLACENTAL TISSUE-DERIVED PRODUCT COMPANY

We are the Interventional Orthopedics Foundation ("IOF"), a not-for-profit (501)(C)(3) organization. An important function of the IOF is to provide pertinent information to our physician community through research efforts targeted at investigating and vetting current cell therapies. Our exploration and examination of new orthobiologics on behalf of the regenerative interventional orthopedics community is of paramount importance.

Recently, many clinics have popped up offering amniotic "stem cell therapy". Our organization is interested in this phenomenon because many of these products are registered within the FDA 361 category as devitalized tissue or as a non-living tissue graft. Despite this, we have received physician complaints that sales representatives for these companies are telling physicians that these products contain live stem cells. As part of an initiative to help clarify these issues, we tested several amniotic tissue products in our research lab. Our in vitro data showed no significant living cell populations within any of the amniotic products tested, despite many physicians who claim that they are offering amniotic stem cell therapy and some even touting the viable stem cell content within these preparations.

Our goal is to clear up a common misconception that many physicians have regarding these products as containing live stem cells and to ensure that accurate information and documentation is readily available and shared on our website.

Therefore, the IOF is asking you to provide a public statement that will be shared with physicians on our website about whether or not your product, which you are marketing contains living and metabolically active stem cells when used as directed by a physician's office.

As an example see the statement below by a company offering an amniotic tissue product known as "PX50".

Our PX50® product was created specifically not to be a stem cell product as it does not contain live cells. ".....we have already done extensive independent assays similar to the ones you are proposing and have documented how well our proprietary HydraTek® process preserves the natural GF's, collagens, etc found in unprocessed placentas.

The IOF will list the status of your public statement regarding this topic on our website and distribute it amongst our physician community, see <https://interventionalorthopedics.org/research/>. We will also be promoting this program heavily on social media and with the press. We look forward to having your statement on this issue.

Sincerely,

Nancy Ho
Executive Director