

Therapeutic Use of Stem Cells and Regenerative Medicine

Regenerative medicine is defined as the use of biological therapies including platelet rich-plasma, pluripotent stem cells, and multipotent stem cells to effect therapeutic benefit in disease states. While regenerative medicine holds promise of improvements in the treatment of a variety of diseases, many of which lack adequately effective treatments, questions remain. The AVMA supports the continued scientific development of these modalities while at the same time encouraging its members to employ caution with respect to their use.

While data continue to accumulate suggesting therapeutic benefit from regenerative medicine, published peer-reviewed studies definitively documenting benefit are still lacking for many diseases. Nor has a scientific consensus for stem cell type, stem cell origin, dosage, transfer media, or method of administration been developed for each disease being treated. Despite these scientific insufficiencies, the adoption of regenerative medicine in the veterinary profession has grown rapidly. Unfortunately, some therapies being propounded and the processes and equipment being sold have outpaced the science which supports them. Veterinarians have few guidelines and limited resources for differentiating valid and effective therapies from ones which have insufficient data supporting the processes and/or therapies. Therefore, it is incumbent upon veterinarians engaged in regenerative therapies to be well versed in the emerging science of the field in order to successfully select the specific therapeutic protocols, processes, equipment, and vendors most likely to result in clinical benefit for their patients.

Use of regenerative medicine by veterinarians should include the following considerations:

1. Regenerative therapies should be used in compliance with FDA Guidance for Industry #218 (GFI #218). Veterinarians engaged in the use of regenerative therapies should be well familiar with the contents of this document in order to best assess the many therapeutic systems, products, and procedures available and ensure compliance with the regulations for their use. Careful attention should be given to the definitions in GFI #218 of autologous Type I, autologous Type II, minimal manipulation, and homologous versus non-homologous use, as these largely encompass the current enforcement priorities of the FDA with regard to regenerative therapies.
2. Regenerative therapy protocols should be formulated from evidence-based medicine. Veterinarians should refrain from recommending regenerative medicine protocols for which documented benefit has not been shown by clinical trials.
3. Regenerative therapies should utilize systems, equipment, and processes which have been adequately validated to produce therapeutic cell numbers, documented cell types, adequate cell viability, and sterility. The use of systems without such validation poses unnecessary risk to the patient, compromises treatment successes, impedes collection of therapeutic data, and exposes the attending veterinarian to potential liability.

4. Collection, preparation, processing, activation, and administration of stem cells should be performed under a strict aseptic technique following validated protocols and employment of adequate quality control measures.
5. Laboratories selected to process, characterize, culture, tissue expand, or bank stem cells in order to provide any stem cell or regenerative services should be experienced, equipped, and staffed with personnel proficient in the handling and processing of stem cells using validated protocols with quality control measures and should comply with all laws and regulations governing the use of cell-based products.
6. Veterinarians who engage in processing of cells in the hospital will be considered by the FDA to be a manufacturer with all the attendant manufacturer requirements including, but not limited to, maintaining current Good Manufacturing Practices. Therefore, systems should be in place to ensure adequate operator training and validated lab procedures which allow assessment of cell type, viability, quantity, morphology, and sterility when appropriate. Additionally, as a manufacturer, the veterinarians must be aware that they, and not the medical device equipment vendor, assume liability for any and all adverse events associated with cell products and therapies.
7. Only autologous Type II (minimally manipulated autologous products for homologous use in non-food animals) stem cells and regenerative therapies should be utilized in clinical cases unless and until FDA approval has been achieved for other categories of stem cells.
8. Veterinarians engaged in the use of regenerative medicine and vendors of cell products, equipment, laboratory services, and processes should refrain from making claims in client communication, advertising, or websites that are not fully supported by peer-reviewed, published data.
9. Practitioners engaged in the use of regenerative therapies should be fully apprised of the potential for liability not fully covered by their professional liability insurance.