

SOCIAL MEDIA STUDY | BENCHMARKING | DERMATOLOGY



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# Trends

magazine

A microscopic view of a petri dish containing a culture of cells. A pipette is positioned above the dish, with its tip pointing towards the cells. The background is a soft, out-of-focus blue and white gradient.

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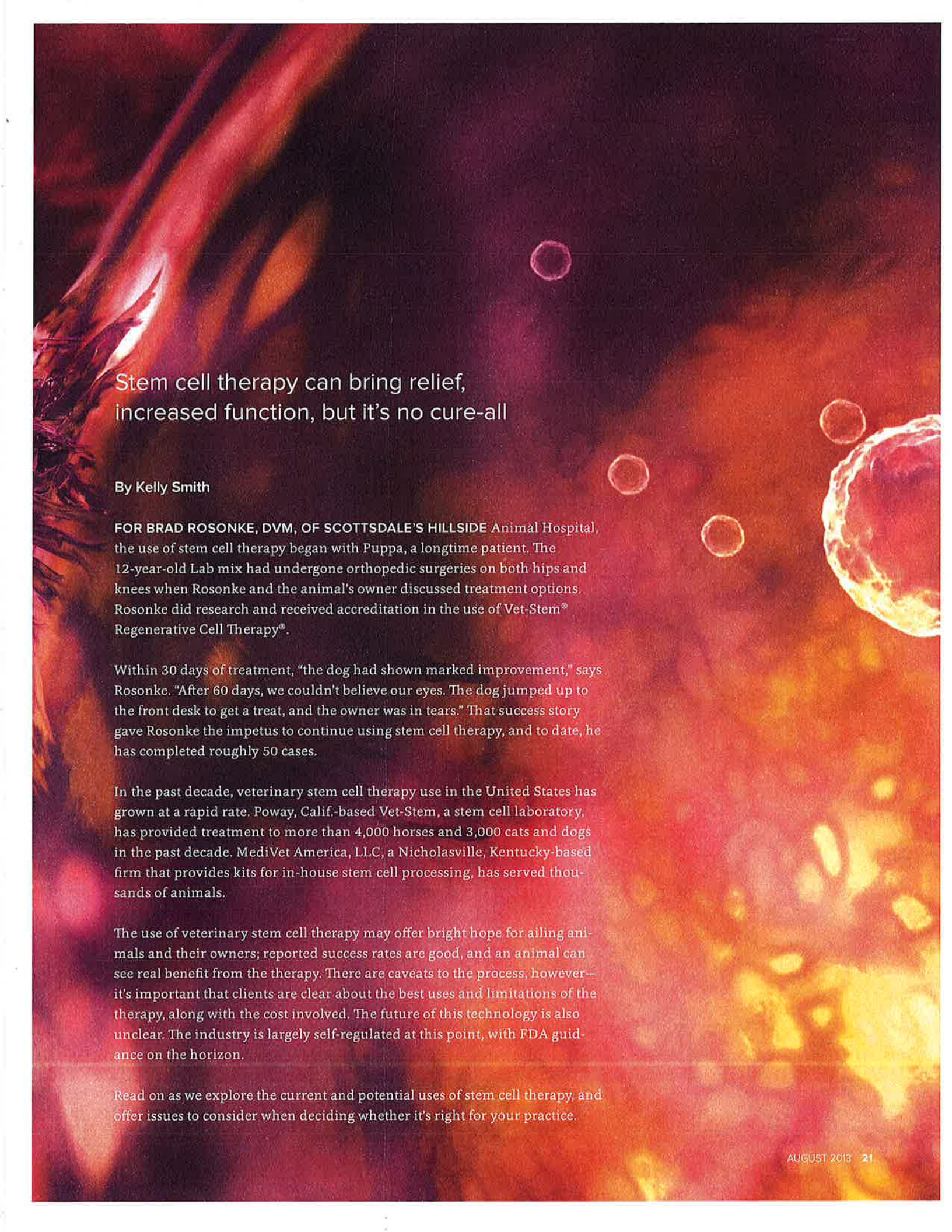
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**Silver  
Bullet  
or  
Flash  
in the Pan?**





## Stem cell therapy can bring relief, increased function, but it's no cure-all

By Kelly Smith

FOR BRAD ROSONKE, DVM, OF SCOTTSDALE'S HILLSIDE Animal Hospital, the use of stem cell therapy began with Puppa, a longtime patient. The 12-year-old Lab mix had undergone orthopedic surgeries on both hips and knees when Rosonke and the animal's owner discussed treatment options. Rosonke did research and received accreditation in the use of Vet-Stem® Regenerative Cell Therapy®.

Within 30 days of treatment, "the dog had shown marked improvement," says Rosonke. "After 60 days, we couldn't believe our eyes. The dog jumped up to the front desk to get a treat, and the owner was in tears." That success story gave Rosonke the impetus to continue using stem cell therapy, and to date, he has completed roughly 50 cases.

In the past decade, veterinary stem cell therapy use in the United States has grown at a rapid rate. Poway, Calif.-based Vet-Stem, a stem cell laboratory, has provided treatment to more than 4,000 horses and 3,000 cats and dogs in the past decade. MediVet America, LLC, a Nicholasville, Kentucky-based firm that provides kits for in-house stem cell processing, has served thousands of animals.

The use of veterinary stem cell therapy may offer bright hope for ailing animals and their owners; reported success rates are good, and an animal can see real benefit from the therapy. There are caveats to the process, however—it's important that clients are clear about the best uses and limitations of the therapy, along with the cost involved. The future of this technology is also unclear. The industry is largely self-regulated at this point, with FDA guidance on the horizon.

Read on as we explore the current and potential uses of stem cell therapy, and offer issues to consider when deciding whether it's right for your practice.



### The stem cell therapy process

For many clients, the words “stem cell” have a negative connotation, partly because of controversial human embryonic stem cell issues. Stem cell use in the veterinary field is markedly different. Veterinary use involves cultivating the animal’s own adult cells (typically adipose cells, though bone marrow cells are also an option), treating those cells, either at an off-site laboratory or by means of an in-house kit, and then injecting them back into the body.

The therapy has been used to care for a variety of injuries and conditions, primarily in equine, feline and canine patients. The conditions that are typically treated include osteoarthritis and orthopedic soft tissue injuries, meniscal injuries and fractures, and equine tendon and ligament injuries.

Bob Harman is co-founder and CEO of Vet-Stem, Inc., one of the major veterinary stem cell laboratories in the country. Vet-Stem is the exclusive global license holder for more than 50 issued patents covering the use of adipose stem cells.

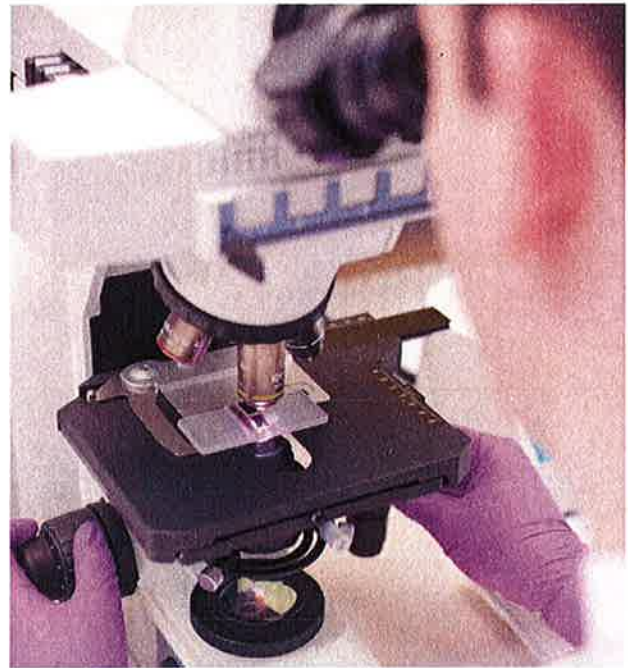
“These cells can halt progression of disease, and repair and regenerate tissues,” Harman says. “Two-thirds of the dogs we have treated have had chronic ongoing degenerative joint disease. This therapy turns off the chronic inflammation so cells can then go about repairing tissues.”

Harman notes that Vet-Stem has treated dogs that were so bad off their owners were considering euthanasia, but afterward these dogs had a normal quality of life.

His firm has also been working on compassionate-use treatment of chronic kidney failure in cats and is participating in a double-blind study on the topic.

MediVet’s typical patient has osteoarthritis, soft tissue injuries or fractures. MediVet also treats other cases under compassionate use, including feline gingivitis, end-stage renal disease, liver and kidney failure, inflammatory bowel disease and pulmonary fibrosis.

Rosonke explains the procedure on a typical canine as it takes place in his practice: During a short surgery, he removes approximately 60 cc of adipose tissue from the anesthetized animal. He closes the incision and sends



Stem cell research for both human and veterinary use has the potential to treat diseases ranging from those of the liver, kidney and heart to neurologic and immune disorders.

the animal home to rest. The tissue is sent by overnight mail to the Vet-Stem facility for processing. The following day, he receives a package of between 6 and 12 sterile syringes, depending on the animal and the condition being treated.

The animal comes back for a 30- to 40-minute outpatient procedure—he sedates it, prepares the joint and administers the injections. The animal can go home that day, with instructions to ice and “swim” the joint. After a 10-day quiet recovery period, the animal can begin simple movements.

“It’s important for veterinarians to understand how simple it is,” says Rosonke. “It’s as simple as any joint injection.” Harman echoes that sentiment, stating that the tissue-removal procedure is roughly equivalent in difficulty to that of a neuter or spay surgery.

Gregory Carastro, LVT, is the hospital administrator at referral hospital Veterinary Medical Center of Long Island (VMCLI). His practice uses the services of MediVet, which provides kits that allow VMCLI staff to process the cells in-house rather than sending them out for cultivation.

The extraction and injection process are much the same as described above, with the exception that his practice treats the cells in-house.

"We prepare the mixture, using a kit supplied by us through MediVet," he says. "We use a centrifugation process, add platelet-rich plasma and then the cells go through an LED light process. Cells are then re-injected back into the patient within 4 hours after removal."

There is often enough adipose tissue to create more stem cells than are needed for the initial treatment. Both off-site and in-house providers have the ability to provide cold storage of stem cells for future use, or to culture cells in the future. In either case, the initial surgery to remove adipose cells is typically the only such procedure that is required.

Depending on the type and severity of the condition and the age of the animal, follow-up injections may be required, ranging from 6 months to 2 years in the future. Animals with any signs of cancer are disqualified from receiving the therapy, due to uncertainties about the effect of stem cells on the malignancy. The price to clients generally ranges from \$2,000 to \$3,500 for the initial round of therapy.

### **The future of stem cell therapy**

There is ongoing research into further uses for stem cell therapy, both in the types of conditions that are treated and the animals that receive therapy. Vet-Stem has done work with exotic animals, including a project with the Navy marine mammal program, working with dolphins, sea lions and pilot whales.

"We've worked with rare hoof stock, zoo animals and some big cats, including Florida panthers and mountain lions, with an animal rescue association," Harman says. "All mammals appear to have this sort of stem cell, for this biologic purpose and use."

Stem cell research for both human and veterinary use has the potential to treat diseases ranging from those of the liver, kidney and heart to neurologic and immune disorders.

MediVet spokesman Mike Hutchinson, DVM, is the owner of Animal General of Cranberry veterinary clinic, near Pittsburgh, Pa. He speaks both nationally and internationally on stem cell topics.

"I get to go around the world speaking on this topic and treating animals. I've treated camels, horses, even a bird," he relates. "The universities are doing studies on stem cells, and we will be hearing more in the coming years."

Hutchinson believes that stem cell treatments for compatible diseases between animals and humans will be at the forefront of research.

"Degenerative myelopathy is similar to Lou Gehrig's disease in humans, for instance," he says. "That's where the first breakthroughs will come."

### **Benefits of stem cell therapy**

Carastro says stem cell therapy "has applications for being used succinctly with other treatments. It's a great adjunct to therapy to help the healing process."

He goes on to say, "There may be applications for dermatology, arthritis, neurology, back cases that may be recovering from paralysis and collapsed disks that are removed. We can use this therapy to help recovery."

Rosonke cautions that stem cell therapy may not be correct for every dog, but says 95% of his clients who used stem cell therapy said they would do it again.

"The pets do seem to do better," he acknowledges. "We get good client acceptance and feedback from the proce-

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"With every year, there are more and more diseases and conditions that have benefitted from regenerative stem cell therapy."

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—LANCE HIRSH, DVM

dure. It's also helped to build my practice, both through the procedure itself and through referrals. For us, it's one more option to offer our clients."

## Checklist for Stem Cell Therapy

*Vet-Stem published the following discussion guidelines for pet owners and veterinarians who are considering the use of stem cell therapy.*

### The following conditions are the best candidates for stem cell therapy:

- Leg joint osteoarthritis due to hip dysplasia, elbow dysplasia, other congenital malformation, normal wear and tear of any leg joint, etc., but X-rays or arthroscopy are suggested to confirm diagnosis
- Partial tears (25% or less) of tendons or ligaments
- Polyarthrititis (arthritis in many joints with immune system involvement)
- OCD, cartilage damage (suggest treating bony fragments with arthroscopy and cells together)
- Fractures

### General health considerations:

The pet should be in general good health as indicated by recent physical exam. Current diagnostic workup indicating good health may include chest X-ray, CBC, chemistry profile, urinalysis, thyroid test and/or tick titers.

### The following conditions disqualify a pet for stem cell therapy:

- Cancer or tumor of undetermined type
- Active systemic infection
- Conditions that might reduce the success of stem cell therapy, in addition to the ones listed above:
- Neurologic disorders, such as degenerative myelopathy, intervertebral disc disease
- Spinal cord arthritis, spinal cord injuries, lumbosacral disease, nerve damage, paralysis
- Poorly controlled diabetes
- Any organ disease (heart, liver, kidney, etc.)

### Aftercare:

- Review need for pain medications
- Review recuperation from surgery, possible seroma formation at collection site and follow-up examinations
- Review restricted exercise after stem cell therapy and rehabilitation plan

Lance Hirsh, DVM, founder of The Veterinary Center of Buckhead, a full-service veterinary medical facility near Atlanta, Ga., is also positive. "All of our clients have been happy with the outcome," he says.

"We also have a program where we harvest stem cells at an early age, during a spay or neuter, for example, and then bank them for later use. With every year, there are more and more diseases and conditions that have benefitted from regenerative stem cell therapy. This is truly a fantastic tool that we have to help our patients who, in many cases, had no more treatment options available until now."

Hutchinson notes that the main objectives of stem cell therapy are to reduce pain, scar tissue and inflammation, and to induce regeneration. "We've found that the major effect comes from the paracrine effect. When I inject stem cells into the joint of an animal, they elicit a response in the body that might bring stem cells in the neighborhood. Paracrine modulates the immune system, and we're seeing dramatic effects."

### Considerations for choosing stem cell therapy

Communication with clients is paramount when considering stem cell therapy. It's important that they understand the cost of the procedure and what to expect in terms of recovery and anticipated results.

Harman says, "Soft tissue can regenerate, but you have to be careful when using the word 'cured.' The only significant risk [economically] is that the therapy doesn't work," he continues. "It's important for veterinarians and clients to know there is an 80% success rate in improvement of quality of life."

For Rosonke, having the correct diagnosis is imperative. "If you think it's arthritis and it's a cruciate rupture, it [stem cell therapy] will not fix it," he notes. In his experience, other conditions in dogs that don't respond to stem cells include neurological disease and degenerative myelopathy.

Cancer is another issue in stem cell treatments; at present, veterinarians and labs will refuse to provide stem cell therapy to an animal with cancer. "If an animal has cancer, there's no way to know if you are helping or hurting," Rosonke says.



For him, sending out the adipose tissue for processing is the preferred method. "I would not feel comfortable injecting stem cells that were done in-house into either a joint or an IV."

Hutchinson echoes his colleagues when he says, "This is not a panacea. You have to have very good case selection, practice good ethics and set realistic expectations with the client. Will an animal see an improvement in movement? Yes, that's likely. Will they be like a puppy again? That's not realistic."

Finances, or perceived high cost by clients, is the number-one drawback for Carastro. "Clients have to understand that this is another advanced process and that most of these procedures are done in a specialty referral facility," he says.

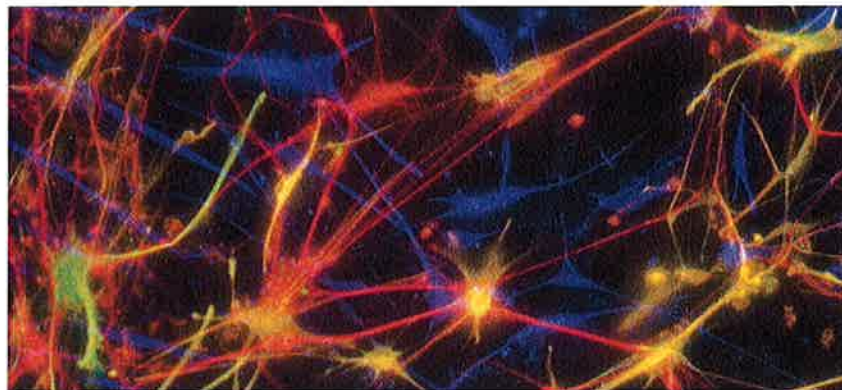
At this time, the veterinary stem cell industry is not under regulation by the U.S. Food and Drug Administration, primarily because the cells are transferred from an animal back to itself; the treatment is categorized as a transplant rather than a drug treatment.

The FDA's Center for Veterinary Medicine is the regulatory body for drugs that are given to animals. They are in the process of creating a set of guidelines for veterinary stem cell use; according to the FDA website, those guidelines are scheduled to be published in late 2013. The guidelines may bring about changes in how the process is administered.

### **Is it right for your practice?**

"We typically have treated dogs with osteoarthritis, but we have also treated a cat with inflammatory bowel disease. We treat an average of six to eight patients per year but recently have seen a jump in interest," says Hirsh.

His practice has been using stem cell therapy for 5 years and uses Vet-Stem for the stem cell cultivation. "They use careful, documented sterile techniques in their processing, and therefore we have had no incidences of infections post-op. Actually, we have had no complications in any of the patients we have treated."



The FDA is creating a set of guidelines for veterinary stem cell use, which are scheduled to be published in late 2013.

Hirsh also notes, "Virtually all of our cases have exhibited marked improvement in their symptoms."

Carastro believes that using stem cell therapy may be cost-prohibitive for a general practice. "You won't be doing enough to see benefit to the practice," he relates. "If you are only doing one every 6 months, it's not cost-effective. At our referral practice, we see these cases frequently."

For a practice that is considering offering stem cell therapy, either by referral or through its own specialty practice, he recommends that veterinarians "look at success stories; we've seen owners who were considering euthanasia, and now the animals are doing incredibly well."

Also, many animals treated with stem cell therapy have concurrent diseases, notes Carastro. Stem cells have helped things other than what the animal was referred for. "The body's own healing potential is incredible," he says. "Stem cell treatments amplify that."

There are differing opinions in the veterinary community about the benefit of using an off-site laboratory for stem cell preparation versus doing the procedure in-house. AAHA does not endorse one procedure over another and advises veterinarians to research each preparation method if choosing to provide stem cell therapy to their clientele. ※



Kelly Smith is an award-winning writer and lifelong pet owner. She lives with her family in Littleton, Colo.