

Why the FDA Won't Approve Your Regenerative Medicine Practice

March 1, 2020

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The Food and Drug Administration does have Congressional authority to investigate and regulate a wide variety of medical products and services. It's crucial for doctors, researchers, medical device companies, and other health providers to speak with an experienced FDA approval lawyer before working with any type of regenerative medicine.

If the FDA has authority to regulate a practice's regenerative medicine products or treatments, and the health business fails to follow their requirements, the business could be subject to warning letters, seizure of the products, injunctions against further work, fines and even criminal penalties.

Stem Cell products and therapies

Stem cells use the patient's own cells to help repair tissues, blood, muscles, bones, and other parts of the body. Cells are usually taken from the hip or a person's bone marrow. The cells are injected into the damaged part of the part with the aim of regenerating that part of the body. One concern is that the cells may mutate which could cause tumors.

The Food and Drug Administration does regulate stem cell therapies but it doesn't regulate the practice of medicine. States regulate the practice of medicine. For this reason, physicians often, usually without success, try to argue that their stem cell treatments are just the practice of medicine. The FDA recommends that consumers check that the stem cell therapies being offered by their physicians are FDA approved or are part of a clinical study that has been given the green light by the Food and Drug Administration. Patients need to check for FDA approval even when their own stem cells are being used – which is often the case as there are safety concerns and dangers involved.

PHYSICIAN STEM CELL THERAPIES LEGALLY AMBIGUOUS, WHILE REGENERATIVE CLINICS PROSPER

Recent press calls into question widespread "regenerative" and anti-aging medicine, and physician practices that use stem cell therapies.

Stem cell products are treated like biological drugs. This means they are regulated through the FDA's Center for Biologics Evaluation and Research (CBER).

The National Institutes of Health states that, in 1997, the FDA began a

"risk-based, tiered approach to regulating cellular and tissue-based products. As a result, human cells, with the exception of

those deemed minimally manipulated and used for autologous treatments, would be subject to FDA premarket approval as biologics.”

To date, the FDA has been slow to place products in the “minimally manipulated category.”

“Regulating stem cell therapies is a challenge. The FDA has sent warning letters to several clinics that claim to offer treatments, prevention, or even cures using stem cell therapies that are not approved. For example, the FDA took action against Regenerative Sciences, LLC, which manufactured a product called Regenexx™, which consisted of autologous mesenchymal stem cells that were manipulated outside of the body and injected back into patients with orthopedic injuries.”

In addition to regulation by the FDA, state medical boards:

- Can regulate experimental stem cell therapies
- Do regulate the practice of medicine

States are helping to fund regenerative medicine research because it has the potential to help make so many people’s lives better. Along with this research, states, such as California, are also creating laws and regulates to monitor regenerative medicine products and therapies.

CALIFORNIA STEM CELL REGULATIONS GUIDE THE EMERGING STEM CELL RESEARCH EFFORT AND INDUSTRY

California stem cell laws boost the stem cell industry by funding stem cell research, but the product side of industry is largely in the hands of the FDA.

As we’ve pointed out, the bottom line for physicians practicing **regenerative and anti-aging medicine** is that:

- FDA maintains that a **stem cell product cannot get to market unless it is either approved by FDA or studied under a clinical investigation that has been submitted and allowed to proceed by FDA.**
- FDA has approved relatively few stem cell products.
- Stem cell products must comply with the HCT/P regulations, which among other things, require registration and listing.
- Culturing stem cells constitutes more than “minimal manipulation” (i.e., **FDA approval as a biologic drug** is required).

PRP products and therapies

Platelet rich plasma (PRP) is a regenerative medical procedure that uses your own blood. PRP uses a solution of platelet cells, proteins, and other growth factors. The platelets are rich with substances which help rebuild tissue and help the body heal. An advantage of PRP is that because it uses your own blood – there aren’t any foreign or synthetic chemicals that can cause damage. Additionally, because a patient’s own blood is used, there’s minimal chance of an allergic reaction.

In a PRP procedure, the platelets are injected in the part of the body that isn’t working correctly. Basically, the medical staff draws your blood and then prepares it. The staff uses a centrifuge to separate the platelets from your red blood cells. The platelets are then injected. Normally, patients need several procedures. When PRP works, the repair to the damaged tissue or body part is usually long-term. Patients normally see quick results. PRP is used for many different types of health problems such as sports injuries.

Dangers include nerve damage, infections, and bleeding.

The FDA regulates two parts of the PRP process

FDA Approval of the PRP device

The first part of the FDA approval process is the device used to separate the platelets from the red cells. Generally, medical devices can be approved in several different ways. These include:

- **Premarket Approval.**

- Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
- PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device.

- **510 (k) clearance.**

- Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification – also called PMN or 510(k).
- This allows the FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories.
- Thus, “new” devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified.
- Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

Generally, FDA approval of the PRP device is sought through the 501(k) clearance process because it is generally cheaper and quicker. Essentially, a 501 (k) clearance is given because the device is substantially similar to a device that has already been approved. This type of clearance only authorizes the device itself – not the treatments based on using the device.

FDA approval of the platelet injections

Generally, physicians can use the PRP device for its indicated usage. If the doctor uses the device for a use that isn't indicated, that's considered an off-label use. An off-label use requires that the doctor be well informed about the device and that its use be based on sound medical evidence and scientific principles. The doctor must keep records on the use of the device.

Doctors should review with experienced regenerative medicine lawyers when they are practicing medicine (which is generally regulated by state medical boards) and when the use of the device may be regulated by the FDA – for example, when there is a non-indicated use.

Gene therapy

The US Food and Drug Administration (FDA) in November 2017, as reported in a [BioNews release](#), indicated that the FDA is

working to fast-track gene therapies, another form of regenerative medicine.

The US National Institutes of Health states that:

“Gene therapy is an experimental technique that uses genes to treat or prevent disease. In the future, this technique may allow doctors to treat a disorder by inserting a gene into a patient’s cells instead of using drugs or surgery. Researchers are testing several approaches to gene therapy, including:

- *Replacing a mutated gene that causes disease with a healthy copy of the gene.*
- *Inactivating, or “knocking out,” a mutated gene that is functioning improperly.*
- *Introducing a new gene into the body to help fight a disease.*

Although gene therapy is a promising treatment option for a number of diseases (including inherited disorders, some types of cancer, and certain viral infections), the technique remains risky and is still under study to make sure that it will be safe and effective. Gene therapy is currently being tested only for diseases that have no other cures.”

As of 2017, the FDA had only approved two gene therapy treatments for leukemia and lymphoma.

FDA fast-track guidelines

The new FDA faster-track guidelines generally apply to regenerative medicine advancements such as stem-cell therapies, PRP, and gene therapy. Treatments will be labeled high-risk will require a high degree of pre-market regulations or low-risk which requires less regulation.

Therapy developers and researchers need to review these new guidelines (mentioned at the start of the first article) with experienced regenerative medicine lawyers. The new guidelines have support from developers who want to get their products to market faster but raise concerns that the rush to market could be very dangerous. Clinical trials will still be an essential part of any FDA approval process.

Stem cell therapy, platelet rich protein therapy, and gene therapy are just three types of regenerative medicine. The FDA has strict regulations and new guidelines for how to bring regenerative medicine products and treatments to market. There are other federal laws and state laws that regulate regenerative medicine. Doctors who use regenerative medicine must also comply with state medical practice laws.

The consequences for failing to follow FDA rules are severe. Health companies, researches, and practitioners may be enjoined from using unapproved treatments. The produces may be seized. Criminal prosecutions may be initiated by the FDA. To understand which laws apply to your regenerative medicine practice, you need the help of an experienced stem cell and regenerative medicine lawyer. We serve a broad range of medical practices including hospitals, doctors, biotechnology and life science providers, and many other types of medical companies and individuals. For skilled healthcare law advise, call [Cohen Healthcare Law Group PC](#) today at 310-844-3173 or use our [online contact form](#) to schedule an appointment.

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