Categories (**highlight category**):

Biologics	(*biology of bone, inflammatory signals, science of arthritis)*
Company News	(*corporate mergers, fund raises, executive hires or fires, plant openings or closings, sales news)*
Extremities	*(products or procedures for elbows, shoulders, hands and wrists, foot and ankles, product awards)*
Large Joints	*(products or procedures for hips or knees, product awards)*
Legal & Regulatory	(*FDA news, lawsuits)*
People in the News	*(surgeon or doctor news, retiring, hiring, awards, deaths, milestones for ortho community)*
Reimbursement	(*Medicare or other payer news)*
Spine	(*products or procedures for back pain, spine surgery, product awards)*
Sports Medicine	(*products or procedures to treat sports related injuries, product awards)*
Trauma	(*products or procedures for fracture and soft tissue repair resulting from a traumatic injury)*

Key Words: R3, R3 Stem Cell LLC, stem cells, HCT/Ps, allografts, Food and Drug Administration, FDA, biologics license, investigational new drug, IND

Caption: The R3 Stem Cell Company Logo) ; Source:
https://r3stemcell.com/

Title: FDA Questions R3 Stem Cell LLC For Distributing 'Stem Cell' Treatments

In its latest not-quite-enforcement action against sellers of human cell and tissue products (HCT/Ps) without biologics licenses or investigational new drug status, the Food and Drug Administration (FDA) announced May 30 that it had sent an "untitled letter" to an Arizona company called R3 Stem Cell LLC and its chief executive, David Greene, MD, MBA.

(https://www.fda.gov/media/126709/download)

The letter to R3 doesn't threaten or mention any enforcement action the agency could take; it asks the company to respond.

The company's website, with disclaimers, describes its products as treatments for a vast variety of orthopedic conditions, including Achilles tendinitis and tears, rotator cuff tears, fractures, arthritis of the hand, wrist, hip, and knee, and stenosis of the spine, at prices of $1,000 to $8,000 per injection.

One of Dr. Greene's blog entries, "Adipose Tissue-Derived Stem Cells for Osteoarthritis," says, "Adipose tissue-derived stem cells (ASC) ... can potentially be used in the treatment of osteoarthritis (OA), and, "Now, through ASC-induced cartilage regeneration, we have a shot at curing OA."

(https://r3stemcell.com/adipose-tissue-derived-stem-cells-for-osteoarthritis/)

However, the FDA, in its letter, seemed less concerned about the orthopedic treatment claims than with the company's claims of treatments for dementia, Parkinson's disease, amyotrophic lateral sclerosis (ALS), diabetes, kidney failure, and Lyme disease.

R3's website also claims or implies that its products can treat aging, autism, diabetes, and headaches.

One affiliated clinic in California had this come-on at its website home page: "Indications: Repair and regenerate damaged tendons, ligaments & cartilage from arthritis or sports injuries. Hair restoration & PRP facelifts too!"

We didn't check to see whether the clinic was claiming all that could be accomplished with just one treatment.

The FDA letter says that R3 Stem Cell offers its therapies at affiliates "throughout the United States." An FDA spokeswoman said, "The FDA has notified each of R3 Stem Cell, LLC's more than 50 affiliate centers or clinics of this action."

A search using R3's "Find a Clinic" application at its website found more than two dozen affiliates, more than half in California, in a search of about a dozen states. None of the clinics which popped up in the search described itself as an orthopedic practice.

The FDA letter doesn't order the company to take any particular action, but says, "Based on a review of your website, it appears that R3 Stem Cell, LLC does not qualify for any exception in 21 CFR 1271.15 and the stem cell therapies offered by R3 Stem Cell, LLC are intended for nonhomologous uses and would be regulated as drugs as defined in section 201(g) of the FD&C Act [21 U.S.C. 321(g)] and biological products as defined in section 351(I) of the PHS Act [42 U.S.C. 262(I)]. In order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]."

It adds: "We note that your products are intended to treat a variety of serious or life-threatening diseases or conditions. Such unapproved uses raise potential significant safety concerns. Additionally, because the products are administered by various higher risk routes of administration, including IV, their use, if contaminated could cause a range of adverse events."

The letter is FDA's latest announced action under its 36-month period of "enforcement discretion" which ends in November 2020, under which it does a lot more coaching and counseling of companies to come into compliance than drastic enforcement actions. It's the 46th such letter the agency has sent, an FDA press release says.

We emailed Dr. Greene asking for his comments on the FDA letter.— *WVD*