



Regenexx Responses to Kaiser Health News Questions  
KHN Reporter: Liz Szabo  
Date: May 19<sup>th</sup>, 2019

**1. Reporter: How many clinics does Regenexx run?**

**Regenexx:** First, we believe it's important to note that 2/3rds of what the Regenexx Medical network uses to help patients avoid surgery is platelet rich plasma, which is also offered to Kaiser patients, see <https://mydoctor.kaiserpermanente.org/ncal/providers/waisarsala>, so in full disclosure KHN should note this in any piece on orthobiologics. In addition, the Kaiser health system continues to perform partial meniscectomies, see <https://hpp.kaiserpermanente.org/health-wellness/health-encyclopedia/he.meniscectomy-for-a-meniscus-tear.uh2055>. So KHN needs to note that its own clinic system does not practice evidence based orthopedic care as this procedure has been shown to be no better than placebo in at least 3 large RCTs, see <https://regenexx.com/blog/should-i-have-meniscus-surgery/>. Meaning that the Kaiser system is not following what you have espoused in your own pieces on orthobiologics.

We have 53 affiliated clinics in the US and 7 outside the US.

**2. Reporter: How many corporate clients does Regenexx have? Can you send me a list?**

**Regenexx:** By the beginning of June 2019, we will have 117 employers offering Regenexx to their workers. In addition, we have 20 health care interventionalists (third-party entities) and 3 health sharing ministries.

**3. Reporter: Many stem cell clinics are happy to let patients pay cash for their services. Why are you pursuing insurance coverage?**

**Regenexx:** The goal of the Regenexx Corporate program is to replace more invasive surgical orthopedics with less invasive interventional orthopedics. This means the precise injection of orthobiologics using x-ray and ultrasound guided imaging to specific damaged areas of the musculoskeletal system. This reduces orthopedic spend for the self-insureds with whom we contract.

**4. Reporter: If Regenexx procedures really save so much money, why do Medicare and every commercial payer refuse to pay for them? Wouldn't Medicare want to save 80% on orthopedic costs, too?**

**Regenexx:** Every new technology goes through a predictable adoption curve with regards to insurance coverage. Self-insureds are often the first to cover various procedures or programs that

Medicare and Commercial payers later adopt. This is because they can be more agile, proactive, and cost-savings-centered than larger programs. Medicare and health plans need more data and time in order to make a coverage decision. While Regenexx has invested in significant research and has been a leading publisher of research in orthobiologics, it will take time and more research for coverage to occur. Coverage for these plans is often also political. For example, insurers have enough level 1 data to drop routine coverage for partial meniscectomy (one of the most common elective orthopedic surgeries), but all continue to cover it (including Kaiser).

**5. Reporter: How much does Regenexx charge for a typical stem cell procedure?**

**Regenexx:** A common misconception is we are “stem-cell” treatment company. Since 2005, we have performed about 90,000 procedures, of which 20,000 have been stem cell and 70,000 have been platelet-rich plasma (PRP). Hence, it’s critical to note that most of what we offer is PRP. If needed, we offer bone marrow concentrate, what has been described as a same-day stem cell procedure. Costs for Regenexx procedures depend on the type and severity of the condition being treated. In general, Regenexx procedures range from \$1500 - \$9000 with blood-based products like PRP being on the lower side of cost and stem cell products on the higher end.

**6. Reporter: Do corporate clients get a discount off this rate? Is the discount related to volume?**

**Regenexx:** No, there are no incentive discounts for corporate clients.

**7. Reporter: Meredith Corporation employees appear in several Regenexx marketing videos. Has Regenexx paid Meredith Corporation or its employees for these endorsements, either in cash, in-kind services or other ways? Has Regenexx or any of its employees invested in Meredith? Other than an insurance contract, what financial ties exist between the two companies?**

**Regenexx:** There is no financial relationship between Meredith and Regenexx other than the provision of services to members on their health plan.

**8. Reporter: Have any Meredith employees, past or present, invested in Regenexx? If so, what are their names and how much have they invested?**

**Regenexx:** No.

**9. Reporter: Independent scientists have questioned the efficacy of stem cells. A 2016 review in the Journal of Bone and Joint Surgery concluded that “the value and effective use of cell therapy in orthopaedics remain unclear.” The following year, a review in the British Journal of Sports Medicine concluded, “We do not recommend stem cell therapy” for knee arthritis. A recent randomized controlled trial by Shapiro et al. found that bone marrow aspirate worked no better than placebo. Given the uncertainty about whether stem cells work, is it unethical to charge high prices for them?**

**Regenexx:** First, we use mostly PRP, however, we understand that writing about PRP use doesn’t drive reader clicks in the same way as writing about “stem cells”. However, we don’t use “stem cells” in the corporate program, but bone marrow concentrate.

Second, a 2016 or 2017 review (performed most likely in 2015 and 2016 due to submission-publication lag) in the field of orthobiologics is already ancient, as many new studies are published

each year. So, using these references in your article would not be scientifically fair or even appropriate.

Third, you have referenced a very small (n=25) single blinded (meaning the patients knew which therapy they had received) RCT that used bone marrow concentrate to treat knee OA that was authored by Shane Shapiro of the Mayo Clinic. You should read Dr. Shapiro's recent press release on orthobiologics here: <https://www.newswise.com/articles/expert-alert-mayo-clinic-orthopedist-shares-perspective-on-regenerative-medicine>. That RCT had serious issues which Regenexx's Dr. Centeno discussed here: <https://regenexx.com/blog/new-bmc-study-adds-confusion/>. The biggest issue was the fact that the cell dose was very low and bilateral knees were treated. However, we have since published a larger RCT than Dr. Shapiro's using bone marrow concentrate that is published here: <https://translational-medicine.biomedcentral.com/track/pdf/10.1186/s12967-018-1736-8>. Our trial was a cross-over design against physical therapy, a common control group for orthopedic studies in knee OA.

**10. Reporter: Is it accurate to state that Regenexx prevents 70 percent of orthopedic surgeries, if the value of stem cells in orthopedics hasn't been established?**

**Regenexx:** Your question mixes multiple concepts and erroneously conflates them to one. The first concept is whether an orthobiologic procedure can prevent an orthopedic surgery. For these self-funded companies on this program that's a cost issue. Meaning, do they save money when patients who would otherwise need surgery choose PRP or bone marrow concentrate instead. The second assertion is, as discussed, that we use primarily "stem cell therapy." We use primarily platelet-rich plasma and sometimes bone marrow concentrate. The third concept is whether there is enough research on PRP or bone marrow concentrate to justify physician use. These therapies are being used at Mayo, Emory, Stanford, and at many other academic institutions. So physicians, who would be more qualified than a bench scientist to make that determination, obviously believe the evidence is good enough to begin offering these therapies. Your article would not be fair and balanced if you did not get quotes from these academic physicians who use these therapies but instead focused on bench scientists who are not qualified to answer a clinical question. The fourth concept is whether there is enough research on these therapies for commercial carriers to add them, the answer is that there is not yet enough research as described above.

**11. Reporter: On your site, you say that Regenexx can reduce costs by 80 percent. Do you have any data to show how the number of knee replacement surgeries have changed at Meredith before and after it began using Regenexx, for example? Do you have any data to show that any of the Meredith employees who've used Regenexx were definitely candidates for joint surgery? How many patients who used Regenexx went on to later have surgery – something that would increase costs, not decrease them?**

**Regenexx:** Here, you are asking about one procedure these health plans pay for (Total Knee Arthroplasty) and conflating that to an 80 percent cost savings for the company on all surgeries. We offer many different interventional orthopedics procedures that would cover shoulder, hip, ankle, wrist, spine, etc. The 80% you discuss is based on the cost savings estimated in our early pilot studies for procedures on which we could intervene. This was a rough estimate based on the immediate cost savings of substituting interventional orthopedic procedures such as a knee PRP or bone marrow concentrate injection for knee surgery, or shoulder rotator cuff repair, or lumbar fusion. We are now creating conservative outcomes-based cost models for our employer clients. Until we have large datasets of tens of thousands of claims processed, we won't be able to apply an

actuarial model. Meaning, for even a large employer, the numbers of specific surgical procedures per year is small.

- 12. Reporter: Your cost savings calculations appear to be based simply on the difference in prices between Regenxx and knee surgery (\$8000 for Regenxx compared to \$50K for knee surgery). Do you have any other data to bolster this claim, such as actual outcomes from patients?**

**Regenxx:** Please see above answer. Please see the above referenced randomized controlled trial.

- 13. Reporter: Regenxx touts the benefits of its stem cells. Is it possible that the accompanying physical therapy – or the placebo effect -- should actually get the credit?**

**Regenxx:** We continue to research orthobiologics. In our recently published randomized control trial (RCT) on Knee OA, we compare to physical therapy. There was a clear superiority over PT. We have other RCTs we are conducting right now that benchmark against physical therapy and are designed to rule out what you assert.

- 14. Reporter: Some Regenxx patients undergo general anesthesia during bone marrow aspiration. Are the risks of general anesthesia worth the benefit, if the efficacy of stem cells hasn't been fully established?**

**Regenxx:** First, the term “general anesthesia” usually means using IV medications, intubation, and inhaled medical gases to render a patient unconscious for a surgical procedure. This is NEVER used for a bone marrow aspiration. You may be confusing general anesthesia with MAC anesthesia, which is usually the use of IV medication to make the patient sleepy or comfortable during a procedure (i.e. twilight sedation). It's rare for our patients to use MAC anesthesia for a bone marrow aspiration. The vast majority only have the local site numbed with lidocaine.