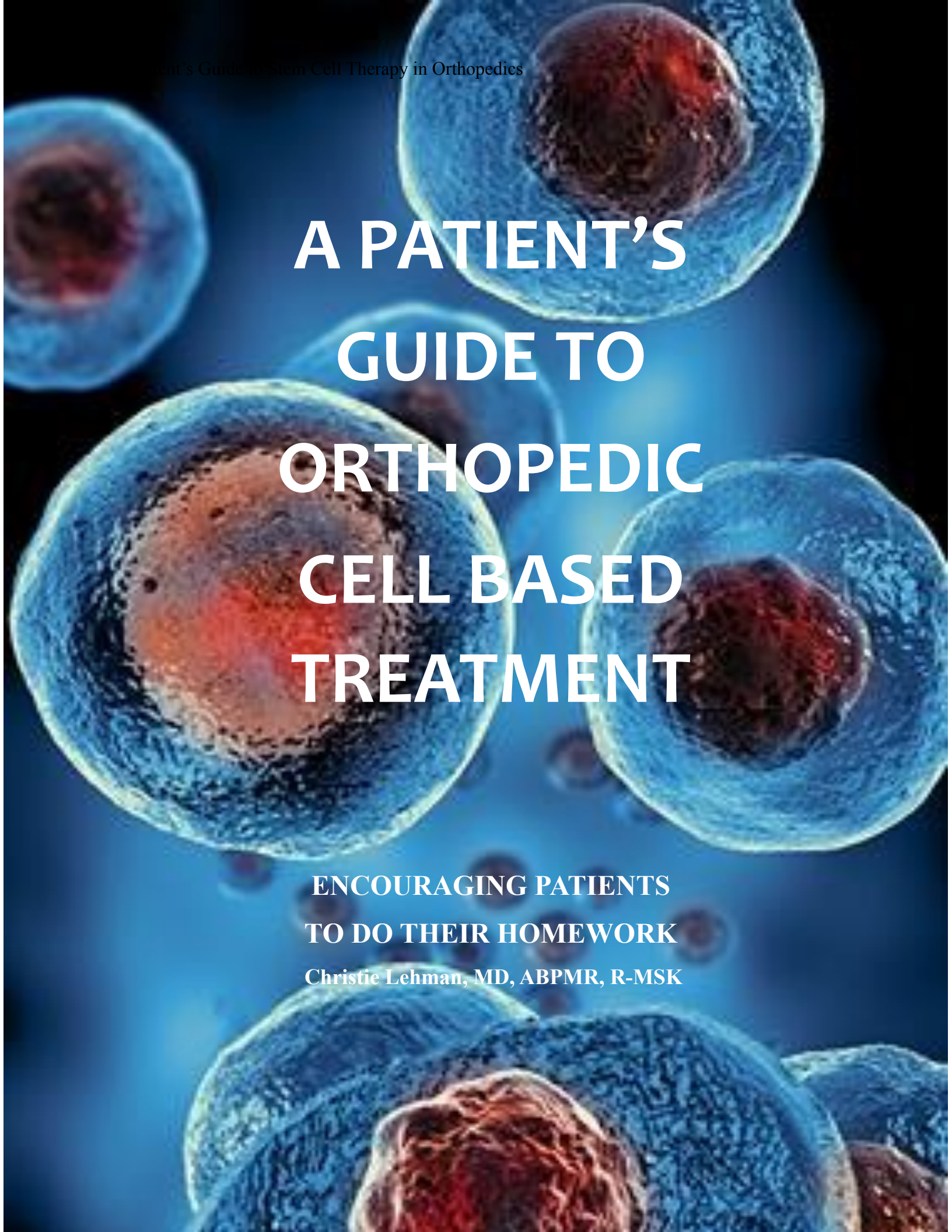

A PATIENT'S GUIDE TO ORTHOPEDIC CELL BASED TREATMENT

ENCOURAGING PATIENTS TO DO THEIR HOMEWORK

Christie Lehman, MD, ABPMR, R-MSK

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April, 2020

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Introduction

I commend you for downloading this eBook. You are demonstrating a sincere interest in becoming educated in this complex, new area of medicine. The purpose of this book, as stated in the subtitle, is to encourage people interested in Stem Cell treatments for orthopedics to become adequately informed before committing to a procedure.

This eBook will demonstrate that there are Good Actors and Bad Actors out there providing cell-based therapies. It is important for physicians and patients to understand the key differences between cell-based treatment options and those providing them. Lastly, there are many links to sites that can help you stay informed.

Chapter One: The Wild West

Everyone is excited about the promise that stem cell research offers for the treatment of many untreatable medical conditions. However, most stem cell therapies are only in the early investigational stage. Significant advances have been made in the fields cell biology, genetics, immunology and tissue engineering. Yet, complete understanding of the safety and efficacy of stem cell therapies in orthopedics will take many more years.

In the meantime, several clinics have already begun to offer many different types of cell-based therapies. The level of physician training at these clinics and the types of treatments offered vary widely across the country. It is important for physicians and their patients to understand the key differences between different treatment options.

Healthcare providers that offer cell-based therapies are obligated to comply with state and federal regulations. The U.S. Food and Drug Administration (FDA) regulates the use of stem cells as Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps) under Title 21 Part 1271.

https://www.fda.gov/media/70689/download

Unfortunately, an increasing number of "stem cell" clinics choose to mislead patients and sell illegal birth tissue derived and donor tissue products instead of providing FDA compliant cell-based therapy. A recent study by Frow, et. al. identified 238 "stem cell" clinics in six Southwestern states (California, Arizona, Colorado, Nevada, New Mexico and Utah) offering a wide range of cell-based therapies.

https://www.cell.com/stem-cell-reports/pdfExtended/S2213-6711(19)30253-X

Nearly 20% of the clinics used amniotic tissue, which does not contain live stem cells.

https://interventionalorthobiologics.org/wp-content/uploads/2019/02/Consensus-Statement-on-Aggressive-Marketing-of-Birth-Tissues-as-Stem-Cell-Therpeies-Final-Published-Feb-18-2019-v2-1.pdf

Sixty-six percent of the clinics processed adipose tissue with a method that is not compliant with FDA guidelines. The FDA has filed an injunction against two of these clinics.

https://www.fda.gov/news-events/press-announcements/fda-seekspermanent-injunctions-against-two-stem-cell-clinics

Twenty five percent of the clinics were operated by a company that has been put on notice by the FDA for marketing unapproved stem cell products.

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

https://finance.yahoo.com/news/r3-stem-cell-international-now-040000452.html

https://www.fda.gov/news-events/press-announcements/fda-puts-company-notice-marketing-unapproved-stem-cell-products-treating-serious-conditions

https://www.phoenixnewtimes.com/news/deadly-arizona-doc-hawks-bogus-stem-cell-treatment-11288787

Of the 238 clinics studied, 28% were operated by healthcare providers who did not have a medical license (chiropractors and naturopathic doctors). And 30% claimed to treat four or more conditions from different medical specialties, suggesting that these physicians treat medical conditions for which they have insufficient training.

In a recent study published in the Journal of the American Medical Association (JAMA), Fu et. al. identified more than 700 "stem cell" clinics in the United States. More than 80% of the clinics treated non-orthopedic conditions without appropriate specialty training.

https://jamanetwork.com/journals/jama/article-abstract/2736545

The Federal Trade Commission (FTC) has begun to crack down on the most egregious offenders and issued warning letters to fraudulent "stem cell" clinics. They maintain that these products require scientific evaluation under FDA approved clinical trials before being marketed to patients. Without scientific evidence, unsubstantiated product claims constitute fraud.

https://www.ftc.gov/news-events/press-releases/2018/10/ftc-stops-deceptivehealth-claims-stem-cell-therapy-clinic

The FTC has returned more than $500,000 to consumers who bought deceptively marketed amniotic "stem cell" therapy. However, much more effort will be required to fully enforce FDA and FTC regulations.

https://www.ftc.gov/news-events/press-releases/2019/04/ftc-returns-almost-515000-consumers-who-bought-deceptively

In April 2018, The Federation of State Medical Boards (FSMB) adopted policy to address the growing concern about clinics that are undermining progress in the field of stem cell research. Specifically, they reviewed actions by physicians who engage in deceptive or false advertising.

http://www.fsmb.org/siteassets/advocacy/policies/fsmb-stem-cell-workgroup-report.pdf

In July 2019, the House of Representative Committee on Energy and Commerce drafted a letter to acting FDA commissioner, Dr. Norman Sharpless emphasizing their concern over the limited FDA enforcement. They requested a rapid response to several of their concerns.

https://energycommerce.house.gov/newsroom/press-releases/bipartisan-ec-leaders-raise-concerns-with-fda-over-proliferation-of

Summary of the fraudulent actions in many "Wild West" clinics -

- Using products that don't contain stem cells (ex. Donor birth tissue)

- Processing fat cells in a way not compliant with FDA guidelines
- Deceptive and false advertising. Making unsupported false claims.
- Non-physician providers performing procedures not having medical licenses
- Physician providers treating medical conditions for which they have insufficient training

Chapter Two: Are Stem Cell Therapies from Birth Tissues Safe?

In January 2019, the Center for Disease Control and Prevention (CDC) identified more than a dozen patients who were treated for bacterial infections after receiving umbilical cord blood injections that were manufactured by Genetech and distributed by Liveyon.

https://www.cdc.gov/hai/outbreaks/stem-cell-products.html

There is some evidence that stem cells obtained from donor tissue (allogeneic) may induce changes in a patient's immune system. Whether or not these changes impact patient health has yet to been determined. Until proper scientific studies confirm the safety of umbilical cord blood, amniotic tissue, exosomes and other donor tissues, it's best to avoid these risks.

https://regenexx.com/blog/stem-cell-treatment-side-effects-iv-umbilical-cordrisks/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741939/pdf/13287_2017_Article_742.pdf https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4320647/pdf/nihms642541.pdf

Chapter Three: Are There Any Safe and Effective Cell-Based Therapies Available That Comply with FDA Guidelines?

Patients have obtained significant medical benefits from responsible physicians who offer FDA compliant cell-based therapy. But how do you know if your doctor is practicing in compliance with the law? There simply aren't enough state and federal regulators to conduct investigations on every clinic, which leaves patients vulnerable to fraud and potential harm.

Several scientific studies on the safety and efficacy of cell-based therapies exist. Physicians who use cells obtained from the patient's own tissues (autologous) require advanced training in Regenerative Medicine to minimize the risks and maximize benefits. Common sources of autologous cell-based treatments include bone marrow aspirate concentrate (BMAC) and minimally processed adipose tissue (fat).

These tissues are known to contain live stem cells, however it is difficult to accurately determine the number of cells at the time of treatment. Therefore, it is misleading to refer to these therapies as a "stem cell" therapy even though they may contain live stem cells. Multi-cellular tissue graft therapy may be a more appropriate term.

Bone marrow and adipose tissue (fat) contain several different types of cells. Although significant advances have been made in the field of stem cell research, scientists do not yet completely understand the role of each of these cells in tissue healing. Bone marrow and adipose tissues have been used as a cell source in Regenerative Medicine therapies for more than 20 years. The safety and efficacy for specific orthopedic medical conditions is well established.

Below is a short list of clinical trials that use bone marrow or adipose tissue for the treatment of orthopedic conditions.

Bone marrow aspirate concentrate (BMAC) clinical studies:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6293635/pdf/12967_2018_Article_1736.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5478493/pdf/WJO-8-491.pdf

https://www.ncbi.nlm.nih.gov/pubmed/27566242

https://www.ncbi.nlm.nih.gov/pubmed/29166682

https://www.ncbi.nlm.nih.gov/pubmed/30871903

Minimally processed adipose tissue (MFAT) clinical studies:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6563172/pdf/CroatMedJ_60_0227.pdf

https://www.ncbi.nlm.nih.gov/pubmed/30517209

https://www.ncbi.nlm.nih.gov/pubmed/30705531

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5626678/pdf/40634_2017_Article_108.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5977739/pdf/12891_2018_Article_2105.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6503401/pdf/ACTA-90-75.pdf

In summary, there are two FDA compliant cell-based forms of therapy with studies to support safety and demonstrate patient outcomes. These cells are obtained from the patient's own tissues – bone marrow or adipose tissue.

Additionally, platelet rich plasma, or PRP, can be used to treat orthopedic conditions and is considered FDA compliant. This is considered a blood product without the presence of stem cells.

Chapter Four: Questions to Ask Your Physician When Considering Stem Cell Based Therapies

We recommend that patients do their research before consenting to an investigational medical procedure that may not have sufficient scientific evidence to support its use. We recommend that you ask your physician performing the procedure these questions to determine if a treatment is right for you.

1) What medical training have you completed?

Fraudulent "stem cell" clinics are typically operated by healthcare providers who do not have adequate medical training. Ask your doctor if they are board certified in the medical specialty that treats your condition.

For example, patients with arthritis or tendon injuries require a doctor who has training in the diagnosis and treatment of orthopedic conditions. These physicians are typically board certified in Physical Medicine and Rehabilitation (PM&R, physiatrists), Orthopedic Surgery or Sports Medicine.

Chiropractors, physician assistants, Naturopathic doctors, and nurse practitioners do not have the training required to inject patients with cell-based therapy. Their training is typically less that of a licensed medical physician. In most states, they are not allowed to perform any kind of injection, including stem cell or exosome injections.

Your doctor should also have advanced training in musculoskeletal ultrasound and/or x-ray (fluoroscopic) guided injections necessary to offer comfortable, effective and safe treatment.

Finally, your physician should have the necessary training to manage any complications.

2) What Regenerative Medicine training have you completed?

Medical schools and residency programs do not offer Regenerative Medicine training. Ask your doctor how they received their Regenerative Medicine education and skills. Well trained physicians have completed a Regenerative Medicine fellowship or are board certified in Regenerative Medicine. They may train other physicians in fellowship programs or at national medical conferences.

3) What "stem cell" tissue source do you use?

Common illegal "stem cell" products include amniotic fluid, amniotic membrane, umbilical cord blood, Wharton's Jelly or exosomes. Despite the misinformation spread by some tissue manufacturers or "stem cell" clinics, the FDA maintains that the current evidence for safety and efficacy of these products does not exist and amniotic or umbilical cord blood derived "stem cell therapies" are not FDA approved.

FDA approved clinical trials must be conducted prior to marketing these products. There is insufficient scientific evidence to support their unproven marketing claims and until these studies are conducted it is illegal to sell them.

https://www.fda.gov/vaccines-blood-biologics/development-approvalprocess-cber

In addition, recent evidence suggests that amniotic fluid and umbilical cord blood products do not contain any living stem cells at all.

https://regenexx.com/blog/new-data-on-amniotic-and-cord-stem-cell-products- this-is-a-scam/

https://journals.sagepub.com/doi/abs/10.1177/0363546519829034

https://www.oarsijournal.com/article/S1063-4584(19)30724-1/abstract

4) Which cell-based therapies are allowed by the FDA?

At this time, only platelet rich plasma, bone marrow derived cells and adipose tissue derived cells (that are not processed with enzymes) are allowed and considered compliant with the FDA.

The above mentioned are all derived from the patient being treated and are not donated. The FDA does not regulate (not considered drugs) the use of a patient's blood and cells when used the same day and not manipulated.

All other donor cell-based therapies (umbilical cord blood, amniotic fluid, amniotic tissue, Wharton's jelly, placenta and exosomes) are considered to be illegal drugs.

5) Do you track clinical outcomes in a patient registry?

Responsible physicians track their patient's outcomes in a registry and conduct follow-up care after treatment. There are several HIPAA compliant patient data registries, so there is no excuse to not use one.

6) Do you publish your outcomes or present data at national medical conferences?

Responsible Regenerative Medicine physicians, either on their own or as an affiliate of a larger group of clinics, collect and publish outcome data and conduct clinical research to advance the field of Regenerative Medicine. There are several examples of IRB approved and FDA approved clinical trials. https://clinicaltrials.gov

7) How do I know if a product in a vial really contains live stem cells?

Except for certain diseases of the blood; there are NO FDA approved stem cell donor products. That means that, at this time, stem cell therapy does not come in a bottle. It is a myth. Some clinics will claim that their product in a vial is FDA registered, but just because a product is FDA registered, does not mean it contains living stem cells. And FDA registered is not the same thing as FDA approved. FDA registration only means

that the manufacturer filed a form stating that their product in a vial does not contain live stem cells and is not subject to the FDA drug approval process.

To learn if a product does not contain live stem cells, visit:

https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/Index.cfm?

Enter the registered product name (Establishment name).

If the box "HCT/P described in 21 CFR1271.10" is checked, it means the manufacturer has claimed that their product does NOT contain any live stem cells.

8) How do you justify the cost of your treatment?

Physicians should not overcharge patients for cell-based treatments. A bottle of amniotic fluid or umbilical cord blood typically costs less than $800. So why do these clinics charge $5,000 or more for a 5 minute injection?

This becomes even more unreasonable when you consider that the evidence for the safety and efficacy of these products does not exist. In addition, many healthcare providers who use donor tissues are not adequately trained to diagnose or manage your condition, do not have advanced ultrasound or xray guided injection training and may make unproven claims about the treatment safety and efficacy.

Why would anyone consider paying for substandard care?

On the other hand, well trained physicians who harvest bone marrow or adipose tissues for their regenerative medicine treatments can assure patient comfort, safety and efficacy. If they can support these claims with peer-reviewed published data or an IRB approved patient registry, then the cost of treatment may be warranted.

https://centenoschultz.com/how-to-choose-the-right-stem-cell-clinic-whowhat-where-when-and-how/

9) I was told that my fetal tissue injection could be covered by insurance. Is this correct?

No. These cellular therapies are not covered by insurance for the treatment of orthopedic conditions. Amniotic tissues or fluid may be covered for non-healing diabetic wounds or specific eye conditions, but are NOT covered for problems like knee arthritis. That provider is using "fishy billing" that could wind up causing them serious problems.

https://regenexx.com/blog/inovoflo/

10) Are there safety concerns for umbilical cord blood and exosomes?

The FDA and CDC issued public safety notices for products that have caused patients to become ill after using umbilical cord blood or exosome products.

https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/publicsafety-notification-exosome-products

https://www.cdc.gov/hai/outbreaks/stem-cell-products.html

https://www.medicalmalpracticelawyers.com/drug-claims-2/fda-warns-companiesthat-process-and-distribute-unapproved-products-derived-from-umbilical-cord-blood/

https://www.medicalmalpracticelawyers.com/health-care-facts-and-statistics/fdaissues-public-safety-notification-on-exosome-products/

Chapter Five: More Frequently Asked Questions

WHAT IS A STEM CELL?

Stem cells are unique in that they have the ability to self renew and differentiate into other cell types (e.g. bone, cartilage, muscle). In the body, stem cells have many additional properties that are essential to healing including decreasing inflammation, promoting blood vessel formation and tissue regeneration.

WHERE ARE STEM CELLS FOUND?

Stem cells are found everywhere in the body, but they are most easily harvested from the bone marrow or adipose tissues. These cells may be stem cells (e.g. adipose stem cells or hematopoietic stem cells) or stem cell precursors (e.g. pericytes and adventitial progenitors).

WHAT ARE STEM CELLS USED FOR?

Stem cells can be used to treat chronic injuries that need assistance to heal. The use of cell-based therapy for several orthopedic conditions such as joint arthritis, tendon tears, non-healing fractures or disc degeneration has been described in the published medical literature.

WHAT ARE ALLOGENEIC STEM CELL THERAPIES?

Cells or cell products that are obtained from another person. Common examples of donor tissues are amniotic tissue, umbilical cord blood, placenta and exosomes.

ARE ALLOGENEIC (DONOR) STEM CELL THERAPIES SAFE?

There is limited data on the safety of stem cells obtained from donor tissue. The manufacturers claim that birth tissue derived cells are immunoprivileged and will not induce an immune reaction. There is evidence, however that these products can induce a subclinical immune reaction.

An additional challenge is that healthcare providers who offer allogeneic stem cell therapies (chiropractors, naturopathic doctors, nurses) may not have the training to identify a severe adverse event or complication, delaying appropriate medical care.

ARE MANUFACTURED STEM CELL THERAPIES FDA APPROVED?

No, except the use of certain types of stem cells for certain types of blood disorders, there are no stem cell therapies yet available for orthopedic or many other medical conditions.

The FDA will only approve a drug or biologic product after multiple clinical trials have been performed that demonstrate safety and efficacy. The FDA will give approval for a Biological License Application (BLA) that permits the manufacturer of the product to market to patients.

Marketing products as having the ability to treat, cure, alleviate the symptoms of, or prevent developing diseases and disorders is simply not permitted by law without FDA approval.

DOES THE FDA ALLOW THE USE OF STEM CELLS THAT ARE NOT FDA APPROVED?

No. Not unless the patient is being treated as part of an FDA approved clinical trial. An IRB approved clinical trial is not necessarily an FDA approved clinical trial.

At this time, umbilical cord blood is considered, by the FDA, to be a drug. It is not allowed to be marketed to patients without FDA approval.

https://www.fda.gov/media/70736/download

DO UMBILICAL CORD BLOOD PRODUCTS, REGISTERED WITH THE FDA AS A SECTION 361 PRODUCT CONTAIN LIVE STEM CELLS?

No. Testing at independent labs confirms the absence of stem cells in these products.

https://www.newyorker.com/news/news-desk/the-birth-tissue-profiteers

https://www.youtube.com/watch?v=xwZVCgWxYOg

DO AMNIOTIC FLUID PRODUCTS, REGISTERED WITH THE FDA AS A SECTION 361 PRODUCT CONTAIN LIVE STEM CELLS?

No.

IS THERE A DIFFERENCE BETWEEN FDA REGISTERED PRODUCT AND AN FDA APPROVED PRODUCT?

Yes. A product is not FDA approved until it undergoes rigorous evaluation with multiple clinical trials. Phase I clinical trials evaluate the safety of the product, while Phase II and III studies look at the efficacy with placebo controlled, randomized clinical trials.

FDA registered products do not undergo this level of evaluation. The manufacturer simply completes a short form stating that their product satisfies the exceptions to the FDA approval process.

HOW DO I KNOW IF A PRODUCT IS REGISTERED AS A SECTION 361 AND DOES NOT CONTAIN LIVE STEM CELLS?

The FDA maintains an updated list of all Section 361 registered products.

https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/Index.cfm?

Type in the registered product name (establishment name). If the box "HCT/P described in 21 CFR1271.10" is checked, it means the company has claimed that this product does NOT contain live stem cells.

ARE UMBILICAL CORD BLOOD STEM CELLS SAFE TO INJECT INTRAVENOUSLY?

There is evidence that they may not be safe and may induce serious immune reactions.

ARE PHYSICIANS ALLOWED TO MAKE CLAIMS ABOUT STEM CELL SAFETY AND EFFICACY THAT ARE NOT SUPPORTED BY THE PUBLISHED MEDICAL LITERATURE?

No. Physicians are required to offer medical opinions that are based on scientific evidence and clinical experience. Making false claims is a betrayal of patient's trust and constitutes fraud, which should be reported to the Federal Trade Commission.

https://www.ftc.gov/faq/consumer-protection/submit-consumer-complaint-ftc

HOW DO STEM CELL THERAPIES AND DRUGS OBTAIN FDA APPROVAL? https://www.fda.gov/media/82381/download

ARE THERE ANY FDA APPROVED STEM CELL THERAPIES?

Yes, but only for blood related diseases. There are no FDA approved stem cell therapies for orthopedic conditions, autoimmune conditions, neurodegenerative conditions, anti-aging benefits and many other medical conditions.

https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-celltherapies

WHERE CAN I LEARN MORE ABOUT ONGOING STEM CELL RESEARCH TRIALS?

https://clinicaltrials.gov

WHERE CAN I LEARN MORE ABOUT STEM CELL RESEARCH THAT HAS BEEN PUBLISHED IN PEER REVIEWED MEDICAL JOURNALS?

https://www.ncbi.nlm.nih.gov/pubmed/

ARE PHYSICIANS ALLOWED TO SELL PRODUCTS THAT ARE NOT FDA APPROVED AND DON'T HAVE AN APPROVED BIOLOGICAL LICENSE APPLICATION (BLA)?

No, that is the use of an illegal biologic drug. This illegal activity is regulated by the Food and Drug Administration (FDA) and state medical boards. Report the illegal use of biologic drug to the FDA:

https://www.fda.gov/consumers/consumer-updates/how-report-product-problemsand-complaints-fda

WHAT ARE EXOSOMES?

Exosomes are extracellular vesicles that facilitate cell to cell communication. They may contain proteins, lipids, mRNA, miRNA and DNA. In the lab, they are manufactured from cultured stem cells. There is evidence that they may have a therapeutic benefit, however the evidence for safety and efficacy is extremely limited.

ARE EXOSOMES FDA APPROVED?

No. Manufacturers market their exosome products as a Section 361 biologic, even though they often do not satisfy the requirements. Perhaps in the future, a company will file an Investigational New Drug (IND) application and conduct clinical studies.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

Enter "1271.10" in search box.

ARE EXOSOME PROVEN TO BE SAFE?

No, there are no published studies of safety in humans.

CAN EXOSOMES BE INJECTED INTRAVENOUSLY?

No, there is no safety data on the IV use of exosomes.

ARE EXOSOMES PROVEN TO BE EFFECTIVE FOR TREATMENT?

No, there are no published studies of efficacy in humans.

DOES THE FDA ALLOW THE USE OF EXOSOMES?

No. Not unless the patient is being treated in an FDA approved clinical trial. If the patient is in a clinical trial the treatment should be offered at no cost to the patient.

WHAT IS INFORMED CONSENT?

Physicians are required to inform their patients about the risks and benefits of all treatment options. An understandable description of the treatment should be provided in writing for any patient who will receive an investigational treatment regardless of whether or not they are in a clinical trial. The form should be signed by the patient and the physician before initiating treatment. The patient should retain a copy for their records.

WHERE DO I FILE A COMPLAINT ABOUT A MANUFACTURER OR HEALTHCARE PROVIDER WHO IS NOT IN COMPLIANCE WITH THE LAW?

REPORT MANUFACTURERS TO THE FOOD AND DRUG ADMINISTRATION (FDA)

https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

REPORT MEDICAL DOCTORS TO THE STATE MEDICAL BOARD

Contact the medical board in your state.

http://www.docinfo.org/report-a-doctor/

http://www.fsmb.org/contact-a-state-medical-board/

In North Carolina: https://www.ncmedboard.org/contact

REPORT CHIROPRACTORS TO THE BOARD OF CHIROPRACTIC EXAMINERS

Contact the Board of Chiropractic Examiners in your state.

In North Carolina: https://ncchiroboard.com/contact-us/

REPORT NATUROPATHIC DOCTORS TO THE MEDICAL BOARD

In North Carolina: http://ncanp.com/contact-us/

REPORT A CLINIC TO THE FEDERAL TRADE COMMISSION

https://www.ftc.gov/faq/consumer-protection/submit-consumer-complaint-ftc

Or mail to: Federal Trade Commission / CRC 600 Pennsylvania Avenue NW Washington, DC 20580

REPORT AN ADVERSE EVENT FROM A STEM CELL TREATMENT TO THE FDA

https://www.fda.gov/drugs/fda-adverse-event-reporting-system-faers/fda-adverseevent-reporting-system-faers-electronic-submissions

https://www.fda.gov/media/85598/download

THE BEST WAY TO PROTECT YOURSELF IS TO STAY INFORMED

New information is available all the time. Stay up to date with these websites:

https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-celltherapies

https://www.fda.gov/media/124138/download

https://www.closerlookatstemcells.org/stem-cells-medicine/nine-things-to-knowabout-stem-cell-treatments/

https://regenexx.com/blog/avoid-the-stem-cell-scam-a-patient-speaks-out/

https://ipscell.com/patients-guide-to-stem-cell-treatments/

https://www.closerlookatstemcells.org/learn-about-stem-cells/stem-cell-basics/

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https://sdomg.com