

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

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STATE OF IOWA ex rel.  
BRENNA BIRD,  
ATTORNEY GENERAL OF IOWA

Plaintiff,

v.

BIOLOGICS HEALTH, LLC.,

SUMMIT PARTNERS GROUP, LLC, D/B/A  
SUMMIT HEALTH CENTERS,

RYLEE JOHN MEEK and

SCOTT DAVID THOMAS

Defendants.

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**EQUITY No. EQCE \_\_\_\_\_**

**PETITION IN EQUITY**

COMES NOW the State of Iowa ex rel. Attorney General Brenna Bird, by and through Assistant Iowa Attorney General J. Andrew Cederdahl, and states as follows in this enforcement proceeding against the above-named Defendants under the Iowa Consumer Fraud Act, Iowa Code section 714.16, the Door-to-Door Sales Act, Iowa Code chapter 555A, and the Older Iowans Law, Iowa Code section 714.16A:

**I. INTRODUCTION**

Defendants Biologics Health, LLC, Summit Partners Group, LLC, Rylee Meek, and Scott Thomas advertised and sold stem cell therapy to Iowans, falsely and deceptively claiming that their services could provide relief from pain and other symptoms caused by common medical conditions. The Defendants targeted older Iowans with direct mailers claiming that stem cell therapy could provide a “Life Without Pain!” and repair damage in the body linked to health problems such as back or joint pain. They repeated these claims in live dinner seminars held all

over the state. Their sales representatives then traveled to the homes of consumers for a “pre-screening” and to finalize the sale of stem cell therapy for, on average, over \$9,000 per person. Finally, Defendants contracted for a nurse practitioner to perform stem cell injections and IVs in consumers’ homes.

According to the U.S. Food and Drug Administration (FDA), stem cells are “[s]ometimes called the body’s ‘master cells.’”<sup>1</sup> They are the cells that “develop into blood, brain, bones, and all of the body’s organs” and “have the potential to repair, restore, replace, and regenerate cells, and could *possibly* be used to treat many medical conditions and diseases” (emphasis in original).<sup>2</sup> Researchers “hope stem cells will one day be effective in the treatment of many medical conditions and diseases.”<sup>3</sup>

However, stem cell therapy has not yet been proven safe and effective for most medical conditions.<sup>4</sup> According to FDA officials, “[p]ublished data derived primarily from small, uncontrolled trials plus a few well-controlled, randomized trials have not reliably demonstrated the effectiveness of stem-cell treatments even in some of the most systematically studied conditions...”<sup>5</sup> At this time, the only stem cell-based products approved by the FDA are for treatment of certain disorders that affect the body system involved in the production of blood.<sup>6</sup>

Stem cell therapy’s potential has created a significant opening for the proliferation of false, deceptive, and misleading advertising claims. In a September 2019 consumer update, the FDA warned consumers: “Stem cells have been called everything from cure-alls to miracle treatments”

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<sup>1</sup> *FDA Warns About Stem Cell Therapies*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies> (last visited Jan. 10, 2023).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> Peter W. Marks et al., *Clarifying Stem-Cell Therapy’s Benefits and Risks*, 376 *NEW ENG. J. MED.* 1007, 1008 (2017).

<sup>6</sup> *See FDA Warns About Stem Cell Therapies*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies> (last visited Jan. 10, 2023).

and implored them: “don’t believe the hype. Some unscrupulous providers offer stem cell products that are both unapproved and unproven.”<sup>7</sup> Former FDA Commissioner Scott Gottlieb stated in 2019 that, “some actors are leveraging the widespread belief in the eventual promise of [stem cell] products, flouting the statutes and [FDA] regulations, and deceiving patients by illegally... selling purported therapies, and falsely promoting their benefits.”<sup>8</sup> More recently in a June 3, 2021 posting titled, “Important Patient and Consumer Information About Regenerative Medicine Therapies,” the FDA discussed its regulation of regenerative<sup>9</sup> medicine, including stem cells derived from umbilical cord blood. The agency stated, “if you are being charged for [regenerative medicine] products or offered these products outside of a clinical trial, you are likely being deceived and offered a product illegally.”<sup>10</sup>

Defendants Meek, Thomas, and their companies misled and deceived Iowa consumers by promoting stem cell therapy as safe and effective to treat pain and symptoms caused by numerous medical conditions and, in so doing, violated Iowa’s Consumer Fraud Act, Iowa Code Section 714.16 (“CFA”). The CFA prohibits the use of false or misleading claims to advertise products and services. Also, the CFA mandates that those who make performance claims for a product or service must have a reasonable basis for their claims at the time they make them. The Defendants lacked the required substantiation to support their claims about stem cell therapy and engaged in

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<sup>7</sup>*Id.*

<sup>8</sup> *Statement by FDA Commissioner Scott Gottlieb and Biologics Center Director Peter Marks*, U.S. FOOD & DRUG ADMIN. (Apr. 3, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-biologics-center-director-peter-marks-md-phd-fdas>. (last visited Jan. 10, 2023).

<sup>9</sup> The term regenerative medicine “refers to cell therapies, gene therapies, and medical treatment intended to repair or replace damaged, diseased, or dysfunctional cells, tissues and organs.” *See FDA’s Framework for Regulating Regenerative Medicine Will Improve Oversight*, PEW CHARITABLE TR. (Oct. 17, 2019), <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/10/17/fdas-framework-for-regulating-regenerative-medicine-will-improve-oversight> (last visited Jan. 10, 2023). “Regenerative medicine” is generally understood to include treatment with stem cells.

<sup>10</sup> *Important Patient and Consumer Information About Regenerative Medicine Therapies*, U.S. FOOD & DRUG ADMIN. (JULY 9, 2021), <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies>. (last visited Jan. 10, 2023).

false, misleading, and deceptive conduct and unfair practices in the sale and advertisement of stem cell therapy in Iowa. The Defendants further failed to abide by the requirements of the Door-to-Door Sales Act, Iowa Code Chapter 555A (“DTDSA”), while selling the unproven and dangerous injections to consumers with high-pressure sales pitches inside their kitchens and living rooms. These activities and tactics had an outsized negative impact on older Iowans.

This lawsuit seeks a permanent injunction against Defendants to stop them from swindling additional Iowa victims; an order directing them to reimburse money victims paid for stem cell therapy and imposing enhanced civil penalties for their false, misleading, and deceptive conduct and unfair practices; and other relief as authorized by law.

## **II. PARTIES AND VENUE**

1. Brenna Bird is the Attorney General of the State of Iowa and is expressly authorized to enforce the CFA under Iowa Code section 714.16(7).
2. Defendant Rylee John Meek is a resident of Prior Lake, Minnesota. Meek is a co-owner (with business partner Defendant Scott Thomas), principal, member, and manager of Defendants Biologics Health, LLC and Summit Partners Group, LLC. With Thomas, Meek capitalized both Biologics Health, LLC and Summit Partners Group, LLC. Upon information and belief, Meek personally conducted sales seminars marketing stem cell therapy for both companies at Iowa venues on at least 8 occasions from June through December 2019 and participated in making sales to 7 consumers in Iowa. Upon information and belief, Meek exercises a degree of control over, and involvement in, the activities of the corporate defendants sufficient to make him responsible under the CFA for the violations alleged herein.

3. Defendant Scott David Thomas is a resident of Thonotosassa, Florida. Thomas is a co-owner (with business partner Meek), principal, member, and manager of Defendants Biologics Health, LLC and Summit Partners Group, LLC. With Meek, Thomas capitalized both Biologics Health, LLC and Summit Partners Group, LLC. Thomas has served as Biologics' "Chief Education Officer." Upon information and belief, Thomas personally conducted at least one sales seminar in Fort Dodge, Iowa in December 2019 and participated in making a sale to at least one Iowa consumer. Upon information and belief, Thomas exercises a degree of control over, and involvement in, the activities of the corporate defendants sufficient to make him responsible under the CFA for the violations alleged herein.
4. Defendant Summit Partners Group, LLC (hereinafter "Summit") is a Minnesota limited liability company that is now inactive. Summit did business in Iowa under the name "Summit Health Centers." Summit's principal place of business was 7127 Shady Oak Road, Eden Prairie, Minnesota 55344. Summit has also listed its registered office address as 202 North Cedar Avenue, #1, Owatonna, Minnesota 55060, and its principal executive office address as 1121 Atwood Court, Shakopee, Minnesota 55379.
5. Defendant Biologics Health, LLC is a Florida limited liability company organized in 2019 by Defendants Meek and Thomas. Its principal place of business was formerly 320 West Kennedy Boulevard #700, Tampa, Florida 33606, and is now 7901 4th Street North, Suite 300, St. Petersburg, Florida 33702.
6. Venue is proper in Polk County pursuant to Iowa Code section 714.16(10) because the Defendants have directed advertising for their services into Polk County and sold their merchandise to residents of Polk County.

**III. KEY LEGAL PROVISIONS**

7. The CFA at Iowa Code section 714.16 (2)(a) provides, in pertinent part:

*The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice.*

*It is deceptive advertising within the meaning of this section for a person to represent in connection with the lease, sale, or advertisement of any merchandise that the advertised merchandise has certain performance characteristics, accessories, uses, or benefits or that certain services are performed on behalf of clients or customers of that person if, at the time of the representation, no reasonable basis for the claim existed. The burden is on the person making the representation to demonstrate that a reasonable basis for the claim existed.*

8. The CFA at Iowa Code section 714.16 (1) provides the following definitions (among others):

*(a) The term “advertisement” includes the attempt by publication, dissemination, solicitation, or circulation to induce directly or indirectly any person to enter into any obligation or acquire any title or interest in any merchandise.*

*(f) “Deception” means an act or practice which has the tendency or capacity to mislead a substantial number of consumers as to a material fact or facts.*

*(i) The term “merchandise” includes any objects, wares, goods, commodities, intangibles, securities, bonds, debentures, stocks, real estate or services.*

*(j) The term “person” includes any natural person or the person’s legal representative, partnership, corporation (domestic or foreign), company, trust, business equity or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof.*

*(n) “Unfair practice” means an act or practice which causes substantial, unavoidable injury to consumers that is not outweighed by any consumer or competitive benefits which the practice produces.*

9. In further describing what the attorney general must allege and prove under the CFA, Iowa Code section 714.16 (7) provides, in pertinent part:

*Except in an action for the concealment, suppression, or omission of a material fact with intent that others rely upon it, it is not necessary in an action for reimbursement or an injunction, to allege or prove reliance, damages, intent to deceive, or that the person who engaged in an unlawful act had knowledge of the falsity of the claim or ignorance of the truth.*

10. In describing remedies under the CFA, Iowa Code section 714.16(7) provides, in pertinent part, as follows:

*If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys...which have been acquired by means of a practice declared to be unlawful by this section . . . .*

*In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section; provided, however, a course of conduct shall not be considered to be separate and different violations merely because the conduct is repeated to more than one person . . . .*

11. The DTDSA at Iowa Code section 555A.4 provides that those sellers who engage in door-to-door sales, as defined by subsection 555A.1(3)(a), have enumerated “duties” and “shall”:

- a. *Furnish two copies of the notice of cancellation to the buyer, and complete both copies by entering the name of the seller, the address of the seller's place of business, the date of the transaction, and the date, not earlier than the third business day following the date of the transaction, by which the buyer may give notice of cancellation;*
- b. *Inform each buyer orally, at the time the buyer signs the contract or purchases the goods or services, of the buyer's right to cancel;*
- c. *Not misrepresent in any manner the buyer's right to cancel;*

- d. *Not negotiate, transfer, sell, or assign any note or other evidence of indebtedness to a finance company or other third party prior to midnight of the seventh business day following the day the contract was signed or the goods or services were purchased.*

12. Section Iowa Code 555A.2 of the DTDSA provides:

*Every seller shall furnish the buyer with a fully completed receipt or copy of any contract pertaining to a door-to-door sale at the time of its execution, which is in the same language as that principally used in the oral sales presentation and which shows the date of the transaction and contains the name and address of the seller, and in immediate proximity to the space reserved in the contract for the signature of the buyer or on the front page of the receipt if a contract is not used and in boldface type of a minimum size of ten points, a statement in substantially the following form:*

*You, the buyer, may cancel this transaction at any time prior to midnight of the third business day after the date of this transaction. See the attached notice of cancellation form for an explanation of this right.*

13. Section Iowa Code 555A.5 of the DTDSA further provides that:

*. . . [T]he failure to provide a copy of the contract to the buyer as required by this chapter shall void any contract, note, instrument, or other evidence of indebtedness executed or entered into in connection with the contract and shall constitute a complete defense in any action based on the contract, note, instrument or other evidence of indebtedness brought by the seller, the seller's successors or assigns . . .*

14. Iowa Code section 555A.6 of the DTDSA provides:

*A violation of [chapter 555A, the DTDSA,] is a violation of section 714.16, subsection 2, paragraph 'a.'*

15. Subsections 714.16A(1)(a) & (3) of the Older Iowans Law provide, respectively:

*If a person violates section 714.16, and the violation is committed against an older person, in an action by the attorney general, in addition to any other civil penalty, the court may impose an additional civil penalty not to exceed five thousand dollars for each such violation.*

*As used in this section, 'older person' means a person who is sixty-five years or age or older.*

16. Subsection 714.16A (2) provides that, in determining whether to impose a civil penalty under the Older Iowans Law, and the amount of any such penalty, the court shall consider the following:

- a. *Whether the defendant's conduct was in willful disregard of the rights of the older person;*
- b. *Whether the defendant knew or should have known that the defendant's conduct was directed to an older person;*
- c. *Whether the older person was substantially more vulnerable to the defendant's conduct because of age, poor health, infirmity, impaired understanding, restricted mobility, or disability, than other persons;*
- d. *Any other factors the court deems appropriate.*

#### **IV. FACTUAL BACKGROUND**

##### **A. Defendants' Business**

17. Beginning in approximately June 2019, the Defendants opened a business under the name "Summit Health Centers" selling stem cell therapy to Iowa consumers using a combination of dinner seminars and door-to-door sales, as described below in Section C.

18. In December 2019, Defendants Meek and Thomas established Biologics Health, LLC, and changed from using the name "Summit Health Centers" to using the name "Biologics Health."

19. Accordingly, while at the time the Defendants began doing business in Iowa they were operating via Defendant Summit as "Summit Health Centers," they eventually began operating via Defendant Biologics as "Biologics Health" as a successor corporation.

20. The Defendants' claims, advertising and sales operations in Iowa relating to stem cell therapy were the same but for the names the Defendants used to conduct business, and their

business continued unabated in Iowa after the change from “Summit Health Centers” to “Biologics Health.”<sup>11</sup>

21. During the time they operated in Iowa, the Defendants sold stem cell therapy to over 250 Iowa consumers.
22. Iowa consumers paid at least \$1.5 million to the Defendants for therapies.
23. Neither Defendant Meek nor Defendant Thomas are healthcare providers. They are self-described, “internationally recognized sales trainers” and creators and principals of “Social-Dynamic Selling.”
24. “Social-Dynamic Selling” is a company that sells a “value-based approach to lead generation” that “combines a free dinner with an informative seminar...”
25. Upon information and belief, Defendants Meek and Thomas employed the “Social-Dynamic Selling” system to sell stem cell therapy in Iowa.<sup>12</sup>
26. The Defendants sold umbilical cord-derived stem cell products from four different manufacturers to Iowa consumers:
  - a. From February 2019 through September 2019, the Defendants used Liveyon Pure, Liveyon PurePro, and Liveyon Restore, all of which are manufactured by California-based Liveyon.
  - b. From June 2019 through October 2019, the Defendants used Bio 10 and Bio 30, which are manufactured by a Texas-based stem cell company called Biogenix.

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<sup>11</sup> All references to “Biologics” hereinafter refer to the Defendants’ operations advertising and selling stem cell therapy in Iowa, regardless of whether they were using the “Summit Health Centers” or “Biologics Health” moniker at the particular time.

<sup>12</sup> Meek’s history in sales dates back over a decade. Beginning in at least 2011, Meek owned Innovative Energy Solutions, LLC (“IES”). In 2011, Meek and IES entered into an Assurance of Voluntary Compliance settlement agreement with the North Dakota Attorney General to resolve allegations that they sold insulation and energy conservation products without a Transient Merchant license and violated N.D.C.C. § 51-15-02 by falsely representing to consumers that they were licensed and in compliance with or authorized by law to provide such services. Meek subsequently renamed IES three times, eventually calling it “Summit Partners Group” in 2018. Summit’s Operating Agreement from November 2018 states that it was established as an “an insurance business to market, broker and sell insurance products,” along with conducting other legal business.

- c. From October 2019 through February 2020, the Defendants used CB 0100, CB 0200, CB 0300, CB 0400, and CB 030 mil, made by Invitrx.
- d. From February 2020 through at least May 2020, the Defendants used products called Protex and Coretex made by Regenerative, a manufacturer in Pensacola, Florida.

**B. Consumer Complaints**

- 27. The Defendants' marketing and sale of stem cell therapy resulted in complaints in Iowa and nearby states.
- 28. In January 2020, the Consumer Protection Division ("CPD") of the Iowa Attorney General's Office received a complaint against Biologics (then-Summit) from an older Iowa consumer who paid \$5,845 for stem cell treatment to treat "severe hip osteoarthritis." His wife paid \$2,650 for her own treatment. However, the consumer reported that his hip pain had not improved after waiting for results over 5 months after his treatment.
- 29. The CPD received a second complaint in December 2020 from another older Iowa consumer who paid Biologics (then-Summit) \$16,580 to help her sciatic nerve and arthritis pain with stem cell therapy. The complainant alleged that she had "experienced no improvement whatsoever" over a year after the stem cell therapy treatment.
- 30. The second complainant further indicated that she reported the fact she had not experienced any improvement of her sciatic nerve pain and arthritis to the Defendants, but their phone number became inoperative.
- 31. The Defendants never refunded the second complainant's money or otherwise addressed her complaint.
- 32. The Defendants' business also attracted attention from the Better Business Bureau ("BBB") of Minnesota and North Dakota which, on October 16, 2019, asked Summit to

substantiate numerous claims and testimonials on its website that stem cell therapy is effective and safe, among other things.

33. According to the BBB, Summit, “did not provide information supporting any of the claims made on the website and indirectly in the testimonials” and the BBB had an “alert” for Summit on its website.<sup>13</sup>

### **C. Defendants’ Advertising and Sale of Stem Cell Therapy in Iowa**

34. To market stem cell therapy to Iowa consumers, Biologics followed a three-step strategy: 1) advertising through mailers and its website; 2) holding dinner seminars; and 3) closing the sale while at the consumer’s home.
35. Once a consumer bought the therapy, the Defendants sent a nurse practitioner to his or her home to perform the stem cell therapy injection or intravenous administration.

#### **1. Step One: Advertising by Direct Mail and Internet**

36. On the Defendants’ website ([www.summithealthcenters.com](http://www.summithealthcenters.com)) under the banner, “Conditions This May Help,” they stated, expressly or by implication, that stem cell therapy could reduce or alleviate pain associated with knee, hip, shoulder, back and spine, elbow, hand and wrist, and ankle and foot ailments.
37. Excerpts from the website appear on the next two pages as Exhibit A:

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<sup>13</sup> Business Profile of Summit Partners Group, BETTER BUSINESS BUREAU, <https://www.bbb.org/us/mn/eden-prairie/profile/sales-presentation/summit-partners-group-0704-96341696>. (last visited Jan. 10, 2023).

Excerpts From Defendants' Website ([www.summithealthcenters.com](http://www.summithealthcenters.com)) (Ex. A)

CALL US NOW +1 800-582-0670 Contact Us

 **SUMMIT**  
HEALTH CENTERS

HOME ABOUT ▾ OUR APPROACH ▾ CONDITIONS IT MAY HELP ▾ NEWS & RESEARCH RESOURCES ▾

# Conditions This May Help



➔ **Knee**

Regenerative cell therapy has helped thousands of people avoid knee surgery. Get the facts. Get the truth. Discover how Summit Health Centers Helps people just like you with their knee pains.

**ACL Tears**

**Knee Osteoarthritis**

**Meniscus Injuries**

[Learn more.](#)



➔ **Hip**

Hip pains from injury or the degenerative process does not mean that your only options are dangerous painkillers or surgery.

Regenerative medicine is changing the game when it comes to hip pain relief. Summit Health Centers has a team that stands ready to answer your question.

**Hip Labrum Tears**

**Hip Osteoarthritis**

**Hip Tendon Tears**

[Learn more.](#)



➔ **Shoulder**

Shoulder pain that radiates can be debilitating. It may limit your driving or even just getting a drink of water. We understand. Whether it's just a function of aging or an old injury, stem cells have been changing the quality of life for the better for people just like you. Will you be the next person raising your hand saying Summit Health Centers has reduced your pain and increased your quality of life?

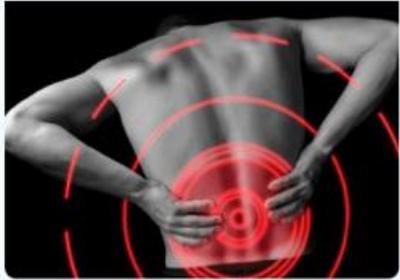
**Rotator Cuff Tear**

**Shoulder Labrum Tear**

**Shoulder Osteoarthritis**

[Learn more.](#)

(Ex. A continues onto the next page)



#### Back & Spine

Back pain affects every single thing you do. Walking, sleeping, and breathing may all be painful events due to back injuries or disc issues. You'll want the experienced professionals at Summit Health Centers to help you get away from dangerous over-the-counter pain pills or prescription meds. You owe it to yourself to discover how stem cells may help you too.

- [Bulging Disc](#)
- [Failed Back Surgery](#)
- [Herniated Disc](#)
- [Neck Pain](#)
- [Torn Disc](#)
- [Learn more](#)



#### Elbow

Elbow pain that is from an injury or from tendonitis. Golfer's elbow or tennis elbow, all types of elbow pain has responded well to stem cell therapy. Imagine if you could reach for an object without hesitating because you're not sure if the pain will strike again. Doesn't it just make sense to see how regenerative medicine may reduce your pain and 'put you back into the game of life again?'

- [Tennis & Golf Elbow](#)
- [Learn more](#)



#### Hand & Wrist

We live in a 'screen society' where people rely on cell phones and computers daily. Painful hands and wrists effectively reduces your options in life. Driving or even just using a handrail are challenging events. Don't allow pain to hold you a prisoner of what you can and can't do. Discover if regenerative medicine may help you grasp ahold of the quality of life that you deserve.

- [Carpal Tunnel Syndrome](#)
- [TFCC Tear](#)
- [Thumb Osteoarthritis](#)
- [Learn more](#)

38. The Defendants did not have a reasonable basis to claim that stem cell therapy is safe or effective treatment for the conditions identified in Exhibit A.

39. Beginning in June 2019, Biologics sent direct mail solicitations inviting Iowans to attend purportedly educational seminars at local restaurants.

40. The Defendants' mailer made numerous claims, directly and through implication, that stem cell therapy could provide pain relief, including the following:

- “Discover A Life Free of Pain Without Costly and Painful Surgery”
- “Imagine Life Without Pain! Yes It's Possible!”
- “Patients are seeing real, long term pain relief.”
- “Why Stem Cells Can Heal So Many Things - Discover the truth behind the amazing healing power of stem cells and if they make sense for you.”
- “Stem cells offer a Non-Invasive solution that can heal the body naturally to deliver long-term relief from pain.”

41. The mailers stated, directly and through implication, that stem cell therapy would treat or “improve” numerous common health problems.

42. For example, the mailers read:

- a. “If you suffer from any of the below ailments this is a must attend event: Knee Pain, Low Back Pain, Shoulder Pain, Joint Pain, Neck Pain, Tennis Elbow.”
- b. “Stem cell therapy has been shown to improve a variety of conditions and injuries including arthritis, osteoporosis, joint pain, sports injuries, and more.”

43. The Defendants did not have a reasonable basis to claim that stem cell therapy is safe or effective treatment for the conditions identified in Exhibit B

44. Below is a sample of a direct mailer that Defendants sent to Iowa consumers:

**Sample Version of Defendants’ Direct Mailer (Ex. B) Continues on Next Two Pages**

Sample Version of Defendants' Direct Mailer (Ex. B)

Join us for a Complimentary Dinner immediately following:  
**Discover A Life Free of Pain  
 Without Costly and Painful Surgery**

During this Free Dinner event, Industry Experts will discuss the latest techniques and advancements in Regenerative Medicine using Stem Cell Therapy. Please call (800) 816-3890 and give your RSVP code 397451.

**Imagine Life Without Pain! Yes It's Possible!**  
**Stem Cell Therapy Isn't The Future...IT'S TODAY!**

Regenerative Medicine uses stem cells to regenerate and repair tissues in your body that are damaged due to age, disease and defects. Stem cells have the power to go to these damaged areas and generate new cells, rebuilding and repairing the area.

**What You're Going To Learn:**

- Patients are seeing real, long term pain relief - Get real stories from real people and how Stem Cell therapy changed their life.
- Why Stem Cells Can Help So Many Things - Discover the truth behind the amazing healing power of stem cells and if they make sense for you.
- There are 5 Types of Stem Cells You Can Get - Learn which ones are the best and WHY.

(There are no embryonic stem cells involved in this... please understand that we as doctors and responsible human beings understand that there are lines over which no person should go, especially doctors)

**Find Out If Regenerative Medicine Is Right For You!**

If you suffer from any of the below ailments this is a must attend event:  
 Knee Pain, Low Back Pain, Shoulder Pain, Joint Pain, Neck Pain, Tennis Elbow

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|   |  |  |  |
|---|--|--|--|
| <p><i>Dinner</i></p> <p>MONDAY OR MONDAY</p> <p>OCTOBER 21ST</p> <p>4:00 PM</p> | <p><i>Dinner</i></p> <p>MONDAY OR TUESDAY</p> <p>OCTOBER 21ST</p> <p>6:30 PM</p> | <p><i>Dinner</i></p> <p>TUESDAY</p> <p>OCTOBER 22ND</p> <p>6:30 PM</p> |  <p>MONTAGE<br/>       222 MAIN STREET<br/>       CEDAR FALLS, IA 50613</p> |
|---|--|--|--|

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Menu: Montage Sirloin or Chicken

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**Reserve Your Seats (800) 816-3890**

Your Personal RSVP Code is 397451  
 or register online at [seminar.rsvpyes.com/397451](http://seminar.rsvpyes.com/397451)



© 2017 Summit Regenerative  
 387-011 - Contact Us

Sample Version of Defendants' Direct Mailer (Ex. B)



## **2. Step Two: Dinner Seminars**

45. The second step in Biologics' marketing strategy was to conduct group sales seminars at Iowa restaurants, where they offered a free meal and made a sales presentation, including a PowerPoint slideshow, touting the purported benefits of stem cell therapy.
46. Seminars were a key part of the Defendants' sales plan and were usually scheduled twice on those dates they were held – one earlier and one later in the same day.
47. Iowa consumers across the state attended the Defendants' sales seminars in response to the Defendants' direct mailers.
48. The Defendants held over 200 seminars across Iowa between June 2019 and February 2020 at restaurants including, for example, the Waterfront Seafood Market in Ankeny, Prime N Wine in Mason City, Houlihan's in Dubuque, CRAVE in Sioux City, and The Hawkeye Restaurant in Keokuk.
49. While the Defendants billed these events as a chance to hear from "Industry Experts" they were, in fact, extended sales pitches by unlicensed sales representatives with no healthcare training.
50. Defendants Meek and Thomas could not have provided healthcare training to Biologics' salespeople because, upon information and belief, they do not have sufficient medical training or expertise.
51. The Defendants never provided any other formal training to their salespeople, who learned how to present the slideshows by "riding along" with another sales representative for several weeks before conducting seminars independently.

52. Upon information and belief, Defendant Meek personally presented sales seminars on at least nine dates between February 2019 and December 2020 at Iowa locations including Atlantic, Muscatine, and Charles City.
53. Upon information and belief, Defendant Thomas personally presented at least one seminar in Fort Dodge in December 2020.
54. All seminar presenters used PowerPoint slides that contained misleading and deceptive information.
55. The PowerPoint slides were, upon information and belief, prepared by Defendant Thomas.
56. The slideshow identified numerous additional specific health conditions that Defendants claimed, directly or through implication, that their stem cell therapy could treat:

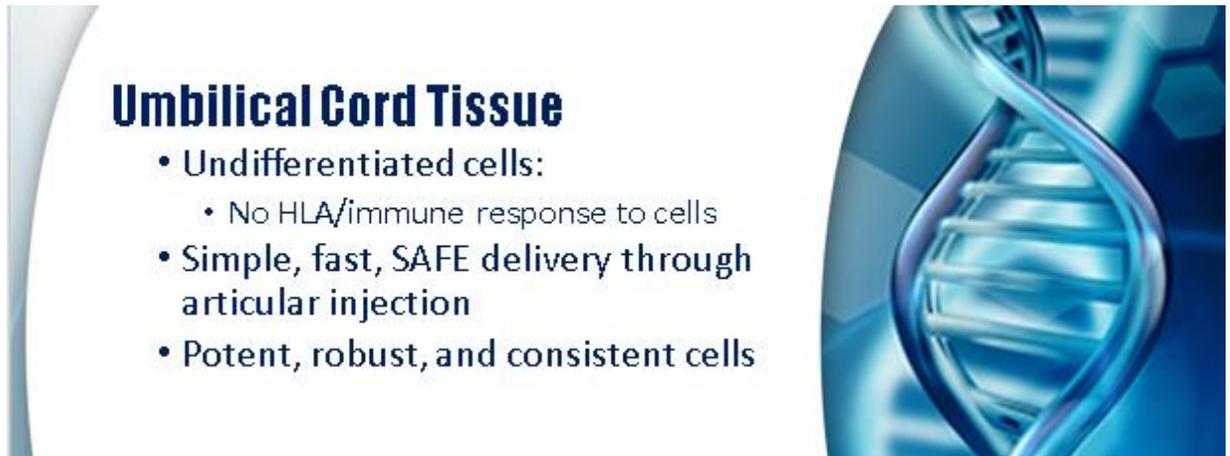
**Excerpt 1 from Defendants' Slideshow (Ex. C)**



57. The Defendants did not have a reasonable basis to claim that stem cell therapy is a safe or effective treatment for the conditions identified in Exhibit C.

58. Another slide emphasized that umbilical cord-derived stem cell therapy is “[s]imple, fast, SAFE” and provides, “[p]otent, robust, and consistent cells,” as shown below:

**Excerpt 2 from Defendants’ Slideshow (Ex. D)**



59. Yet another slide misleadingly claimed that stem cell therapy would replace “surgery, rehab, pills, time, pain, opportunities lost...” and the cost was, therefore, “very low”, as shown below:

**Excerpt 3 from Defendants’ Slideshow (Ex. E)**



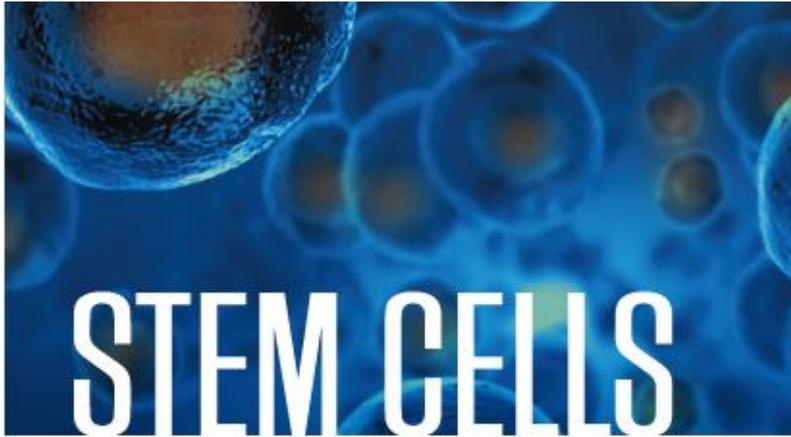
60. At the conclusion of each seminar, the presenter encouraged attendees to sign up for a personal appointment with a sales representative.

**3. Step Three: Sale at Each Consumer's Home**

61. In the third step of their marketing strategy, Biologics sales representatives met with individual Iowans, usually at the consumer's home, to discuss the therapy as it related to each consumer's specific health concerns, enter into sales contracts, and receive payments.
62. Typically, the consumer's seminar presenter made the home visit where the sales were finalized.
63. Upon information and belief, Defendant Meek made in-person sales to consumers in Iowa locations including Algona, Floyd, Des Moines, and Davenport.
64. Upon information and belief, Defendant Thomas made an in-person sale to a consumer in Altoona.
65. In connection with their door-to-door sales, the Defendants' representatives gave consumers written materials that reiterated, directly or through implication, their claims that stem cells can treat or "improve" health conditions.
66. For example, the materials stated that, "[r]esearch has indicated that stem cells can benefit a wide variety of health complications and may assist individuals in leading stronger, healthier lives," as shown on the next two pages in Ex. F:

**Defendants' Consumer Handout (Ex. F) Continues on Next Two Pages**

Defendants' Consumer Handout (Ex. F)



# STEM CELLS

...The Future of Medicine, Personal Health & Longevity.

Stem cells are specialized cells that are able to receive signals from the other cells in your body. Stem cells then seek out inflammation and degeneration and go to that location to begin repairing tissue.

Stem cells have been shown to help repair muscle, bone, cartilage and tendons. Research has indicated that stem cells can benefit a wide variety of health complications and may assist in individuals living stronger, healthier lives.



Research continues to show an increasing number of potential benefits from the anti-inflammatory, immunomodulatory and regenerative actions of stem cells.

#### HOW DOES STEM CELL THERAPY WORK AND WHAT DO THEY DO?

Stem cells are our body's natural internal repair system. In short, stem cells seek out damage in the body and work to regenerate damaged tissue.

#### WHERE DO STEM CELLS COME FROM?

These human umbilical cord stem cells are collected from hospitals across the US. The mother signs a consent form, donating the umbilical cord blood to the hospital after the live birth of a healthy baby. Only cord blood cells from healthy mothers and babies are accepted.

#### ARE THERE ANY NEGATIVE SIDE EFFECTS OR CONTRAINDICATIONS?

In a very small percentage of patients, we occasionally see a minor reaction of flu-like symptoms. This does not last more than 24-48 hours maximum. This actually demonstrates the cells' anti-inflammatory and immune-privilege potential.

#### WHO IS A GOOD CANDIDATE FOR STEM CELL THERAPY?

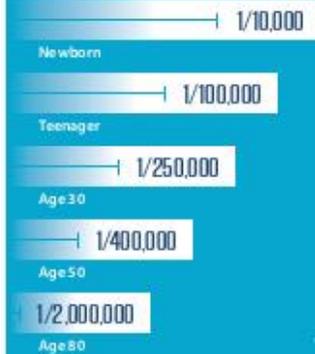
If you are looking for a more natural solution towards regenerating the body, we recommend you consult with one of our Regenerative Medicine Experts to discuss your specific issues.

This information is not FDA approved and is solely provided for educational purposes and is not intended to diagnose.

[www.SummitHealthCenters.com](http://www.SummitHealthCenters.com)



Stem cells rapidly decline with age.  
Longer repair and recover times.  
More prone to aging and disease.



67. As shown in Exhibit F, the handout contained testimonials praising stem cell injections and implying they are effective to treat numerous conditions, including osteoarthritis; back pain; multiple sclerosis, fibromyalgia, degenerative joint and disc disease, scoliosis, a torn rotator cuff, and knee problems:

### Defendants' Consumer Handout (Ex. F) Continued

#### What people are saying about Stem Cell Therapy

*"The Osteoarthritis set in fast; as well as the pain from the severely torn meniscus in both knees and the extreme bone on bone. I had no cartilage left, I could feel the bones grinding and clicking. So, I had my stem cell injections.... the next morning, I woke up and took a deep breath, swung me feet over the bed side and touched the floor. Holy crap! No PAIN... No Hobbling... No Tears...No Fear! I welcome the journey to recovery and getting back to being able to do things I lost to the injury."*

—Vicki R.

*"I had severe injuries to my ankle, bulging discs in my back, and arthritis. I would play a game each morning, guessing my pain level.... My back-pain specialist wanted me to do injections, but I didn't want medication. I never knew about stem cells.... Eight days after my appointment, I was driving to work and realized I didn't play my game. I didn't have to, it was so great."*

-- Crystal R.

*"I had Multiple sclerosis (MS), fibromyalgia, degenerative joint and disc disease, and scoliosis.... My husband couldn't put his arm around me because of the pain.... I was on opioids and used a walker and couldn't get out of bed most days.... I'm now off them and don't need the walker. My husband can put his arm around me again and I don't have the popping in my back."*

--Grace

*"I tore my rotator cuff while at work... They told me I needed surgery. I'm 26 years old... I had no interest in letting them cut into my body. I looked for alternatives and found stem cells... And after only one injection, and 30 days later, 80-90% of my range of motion in my shoulder has returned and I have minimal to no pain... AND no recovery time from surgery."*

-- Ethan M.

*"For years, I could not bend my leg up over my knee, so that I could put my socks on. I had to stand up and bend over. What a pain. .... I signed up, came in here, got my injection. Three days later I'm sitting on the bed thinking, I'm going to try this. I just want to see if there's anything going on. You're not going to believe this, I was just shocked. I took my little right leg here, and I picked it up. I put it over my knee, and I hadn't done it for 10 years. .... I've had no pain whatsoever. None. Will I recommend this to others? You better believe it."*

-- Margaret P.

*"I wasn't able to do much of my moving towards my right, with my knee problem. Since I've got the shot, the three weeks, I've been bouncing around, walking all over the place, and almost running, riding bike, things that I wasn't able to do. I've been talking to a lot of people, they've been asking me, "Where did you get it?" I've referred them to the doctor. I gave them the office number, and their address. A few of them have gone, have probably taken the procedure, and they're doing great."*

-- Roy B.

*"My problem is in my right knee and I was feeling a lot of burning sensation and since I've taken stem cell system, it has diminishing quite a bit. My knee's feeling great, I'm back to dancing, where I couldn't before and it's working for me."*

-- John R.

68. The U.S. Federal Trade Commission (FTC) issued guidance on use of testimonials and endorsements. *See* 16 C.F.R § 255.
69. Under the FTC’s regulations, where a consumer endorsement “will be interpreted as representing that the product or service is effective for the purpose depicted in the advertisement” or “will likely be interpreted as representing that the endorser’s experience is representative of what consumers will generally achieve with the advertised product or service in actual, albeit variable, conditions of service,” the advertiser should have “adequate substantiation, including, when appropriate, competent and reliable scientific evidence.” 16 CFR § 255.2(a), (b).
70. According to the FTC, “[c]onsumer endorsements themselves are not competent and reliable scientific evidence.” *Id.* at 255.2(a).
71. The testimonials in Exhibit F would be interpreted as representing that stem cell therapy is effective to treat, heal, cure or mitigate osteoarthritis, back pain, multiple sclerosis, fibromyalgia, degenerative joint and disc disease, scoliosis, a torn rotator cuff, and knee problems.
72. The testimonials in Exhibit F would be interpreted as representing that the experience described in the endorsements is representative of what consumers could generally achieve by using stem cell therapy to address their own medical conditions.
73. The Defendants did not have a reasonable basis to claim that stem cell therapy is a safe or effective treatment for any of the conditions identified in the testimonials in Exhibit F.
74. While at each consumer’s home, the sales representative would typically use various sales techniques – including reducing the price of the therapy by several hundred dollars - in order to persuade the consumer to make the purchase.

75. The therapy was expensive. Iowa consumers each paid between \$3,200 to \$20,000 for stem cell therapy.
76. Consumers could either pay outright or, in the event they could not afford the cost, Biologics helped consumers obtain financing through Green Sky, a third-party company that offers consumer loans through a digital application that consumers could complete at home.
77. Those consumers who financed some or all of their stem cell purchase through Green Sky incurred significant additional expense in the form of finance costs and other charges.
78. As just one example, an Iowa consumer who financed a \$17,500 Green Sky loan to pay Defendants for stem cell therapy did so at an annual percentage rate of 26.99%. The finance charge was \$16,245.38, nearly equal to the principal. The result was that the total amount that consumer would pay over the life of the loan could be as much as \$33,754.38.
79. Upon information and belief, approximately 96 Iowa consumers took out Green Sky loans to finance their purchases from Biologics.
80. After the sale was completed, the consumer was given an appointment with an Iowa-based nurse practitioner employed by Definitive Wellness LLC, a third-party contractor based in Ohio and engaged by Defendants (hereinafter “Nurse Practitioner.”)
81. The Defendants selected the stem cell suppliers and placed orders for the stem cell products that were used with Iowa consumers.
82. The products the Defendants selected were first shipped directly to the Nurse Practitioner’s personal Iowa residence in a dry ice-filled cooler.

83. The Nurse Practitioner then drove to the consumer's home, where she administered the stem cell therapy, typically through injection or intravenously in the case of "general wellness" therapies.
84. None of the injections performed on Iowa consumers were assisted by imaging equipment in placement of the needle by the Nurse Practitioner.
85. The Nurse Practitioner never diagnosed or assessed any consumer's medical condition or the appropriateness of stem cell therapy before administering the stem cell products.
86. The Nurse Practitioner did not exercise any independent judgment in diagnosing medical problems, determining dosing levels, or evaluating the appropriateness of the treatments with any individual Iowa consumer.
87. Instead, the Nurse Practitioner strictly followed directions provided to her by Definitive Wellness, which were based on the in-home sales made by the Defendants to consumers.
88. Although the Defendants contracted with an Arizona-based Chief Medical Officer ("CMO") beginning in November 2019, the Nurse Practitioner did not know the CMO or communicate with him on any topic, including treatment of Iowa consumers.
89. The Nurse Practitioner facilitated and reinforced Defendants' misrepresentations about stem cell therapy, as discussed in greater detail in Section D, below.

**D. Additional False, Deceptive, Misleading, Unfair and Unsubstantiated Claims  
Defendants Made About Stem Cell Therapy**

**1. The Defendants Presented Stem Cell Therapy as a Panacea**

90. The Defendants boldly proclaimed that stem cells "seek out" inflammation, degeneration and damage throughout the body and migrate to those areas to fix them.
91. For example, Defendants' handout (*see* Ex. F) claimed:

- a. “[s]tem cells then seek out inflammation and degeneration and go to that location to begin repairing tissue;” and
- b. “HOW DOES STEM CELL THERAPY WORK AND WHAT DO THEY [*sic*] DO?”

Stem cells are our body’s natural repair system. In short, stem cells seek out damage in the body and work to regenerate damaged tissue.”

92. In a pre-litigation subpoena,<sup>14</sup> the Attorney General requested the Defendants to provide the legally required substantiation for the specific statements identified in Paragraph 91 and shown in Exhibit F under oath.

93. The Defendants cited five articles and one book in support of the statements elaborated in Paragraph 91.

94. However, the sources the Defendants cited under oath do not constitute the legally required substantiation necessary under the CFA at Iowa Code section 714.16(2)(a).

95. Four of the articles the Defendants provided are insufficient to substantiate their claims because:

- a. The articles are summaries or overviews of scientific research into stem cells that review research into how different types of stem cells function at a cellular, molecular or similar level.
- b. One article discussed only bone marrow-derived stem cells, while Defendants sold umbilical cord-derived stem cell products, which are different from bone-marrow-derived stem cells in meaningful ways.
- c. The articles do not document or describe clinical trials or other scientific studies that examine the safety or efficacy of stem cell therapy to treat any specific health or medical conditions in humans.
- d. The studies do not address the use of stem cells to cure, treat, or mitigate the numerous conditions that Defendants purport to treat.

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<sup>14</sup> The CFA authorizes CPD to issue investigative subpoenas under subsections (3) and (4) of the Act.

96. The only article involving treatment of a human the Defendants provided is a case study of a single person with psoriatic arthritis (a condition Defendants did not purport to treat) written by employees of Invitrx, a stem cell product manufacturer from which Defendants purchased stem cell products.
97. The Invitrx article does not constitute a reasonable basis for Biologics' claims about umbilical cord-derived stem cells because it describes the experience of a single person with a condition that Defendants do not even purport to treat.
98. Finally, Defendants generally cited a book titled, "Stem Cell Therapy: A Rising Tide" by Neil H. Riordan.
99. Riordan's book, comprised of anecdotes of individual patients and his work in stem cell therapy, does not substantiate Defendants' claims that their stem cell therapy could provide relief from pain and other symptoms to Iowans.
100. The Defendants' claims that stem cells would "seek out" inflammation, degeneration or other damages and "repair" or "regenerate" that tissue lacked legally required substantiation.
101. Despite its lack of substantiation, Biologics' claim that stem cells would seek out damage or inflammation in the body were repeated and confirmed by the Nurse Practitioner.
102. Significant numbers of Iowa consumers received "general wellness" IVs (as opposed to targeted injections), based on the unfounded idea that stem cells would "seek out" and correct their medical problems.
103. Iowa consumers believed the unfounded idea Biologics fostered that stem cells would "seek out" medical problems.

104. One Iowa consumer was concerned that stem cells injected into her body would travel to heal her mouth instead of her back because she had one tooth pulled immediately prior to Biologics' therapy. She purchased therapy from Biologics to address her back pain.

105. Other Iowa consumers hoped that the stem cell therapy would relieve various other ailments for which stem cell therapy is unproven, such as scarring, chronic obstructive pulmonary disease, Parkinson's Disease and diabetes.

106. Instead of correcting these misimpressions, the Nurse Practitioner allowed Iowa consumers to continue believing that stem cell therapy Biologics sold them could help with these indications.

107. Whenever consumers expressed concern or doubt the therapy they received would work after failing to experience relief, the Nurse Practitioner would simply instruct them that healing could take longer and that they should drink more water.

**2. Defendants Made Blanket Claims that Stem Cells Can Repair Damaged Tissue**

108. The Defendants claimed that stem cells could regenerate tissue and repair damage caused by the aging process and illness in all areas of the body.

109. Specifically, the Defendants claimed that "Regenerative Medicine uses stem cells to regenerate and repair tissues in your body that are damaged due to age, disease, and defects. Stem cells have the power to go to these damaged areas and generate new cells, rebuilding and repairing the area." *See* Ex. F.

110. In a pre-litigation subpoena, the Attorney General requested the Defendants to provide substantiation for the statement in Paragraph 109.

111. The Defendants cited two of the five articles described above in Section D(1) to support their claims. One of the articles is a 2015 "Review Article" summarizing the state of

research on use of mesenchymal stem cells derived from Wharton's Jelly (a substance found within the umbilical cord). The second article discussed the use of stem cells in wound healing, and summarized studies involving work in laboratory setting and with animals.

112. The articles are not sufficient to substantiate the Defendants' claims because:
- a. They do not document or describe clinical trials or other scientific studies that examine the safety or efficacy of stem cell therapy to treat any specific health medical conditions in humans.
  - b. The studies do not address the use of stem cells to cure, treat, or mitigate the numerous conditions that Defendants purport to treat.
113. Defendants also cited the "Rising Tide" book. Again, that book does not substantiate Defendants' claims that their stem cell therapy could provide relief from pain and other symptoms to Iowans.
114. Neither source provided by Defendants evidenced a reasonable basis for their claims that stem cells can uniformly, "regenerate and repair tissues in your body that are damaged due to age, disease and defects" or "generate new cells."

### **3. Defendants Sold Doses of Stem Cells to Elderly Iowans Without a Reasonable Basis**

115. Defendants sold Iowa consumers various "doses" of stem cells.
116. Some Iowa consumers purportedly received 5 million cells, while others received 30 or 60 million cells, sometimes broken up into separate injections and other times delivered all at once.
117. Each consumer determined the "dose" of stem cells she or he received by choosing from a range of differently-priced options sold by Defendants.<sup>15</sup>

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<sup>15</sup> Upon information and belief, the specific doses offered were developed by Definitive Wellness, LLC, the third-party company with whom Defendants contracted for nurse practitioner services.

118. The Nurse Practitioner introduced whatever “dose” the consumer decided to purchase after meeting with a Biologics’ salesperson.
119. Upon information and belief, there are no uniform or objective dosing criteria for umbilical cord-derived stem cells for the conditions Biologics purported to treat that have been proven or otherwise established in the field of regenerative medicine.
120. It is not necessarily true that “more is always better” in terms of the efficacy of stem cells, let alone that the stem cells sold to Iowans would be safe or effective for the specific ailment for which consumers sought treatment.
121. Defendants did not have a reasonable basis to claim any particular dose of stem cell therapy was safe or effective to treat any specific medical or health condition.
122. Effectively, the Defendants ran scattershot, for-profit experimentations on older Iowa consumers who sought their assistance with medical problems.

#### **4. The Defendants Misrepresented the Risks of Stem Cell Therapy**

123. In their slideshow, the Defendants described their stem cell therapy as, “Simple, fast, SAFE ...” *See* Ex. D.
124. In their handout, Defendants claimed that the worst potential side effect of stem cell therapy could be “minor reaction of flulike symptoms” which was seen, “in a very small percentage of patients.” *See* Ex. F.
125. However, stem cell therapy poses greater risks than what Defendants described in both theory and practice.
126. The FDA warned consumers that “unproven stem cell therapies can be particularly unsafe,” citing “severe adverse events” that have occurred.<sup>16</sup>

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<sup>16</sup> *FDA Warns About Stem Cell Therapies*, U.S. FOOD & DRUG ADMIN, *supra* note 1.

127. Such events have included one patient becoming blinded after injection of stem cells into the eye, and another suffering from a spinal tumor after a spinal cord injection.<sup>17</sup>
128. The FDA has stated, “[o]ther potential safety concerns for unproven treatments include . . . administration site reactions, the ability of cells to move from placement sites and change into inappropriate cell types or multiply, the failure of cells to work as expected, and the growth of tumors.”<sup>18</sup>
129. In December 2018, the FDA reported that 12 patients who received Genetech umbilical cord stem cell products from Liveyon (one manufacturer whose stem cells Defendants sold to Iowans) became ill due to blood and other infections caused by bacteria, including *E. coli*, found in the stem cell products.<sup>19</sup>
130. The Defendants’ own stem cell therapy products were not as safe as they claimed or implied.
131. Defendants sold stem cell products that were likely tainted with cytomegalovirus (“CMV”) to at least two Iowa consumers.
132. CMV is a common virus that can cause serious health problems in people who are immunocompromised or in babies,<sup>20</sup> so it is important that anyone receiving potentially CMV-positive cells be screened to prevent health complications.
133. Neither the Defendants nor Definitive Wellness screened Iowa consumers to determine if they were immunocompromised prior to receiving the stem cell therapy.

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Denise Grady, *12 People Hospitalized With Infections From Stem Cell Shots*, N.Y. Times, (Dec. 20, 2018) <https://www.nytimes.com/2018/12/20/health/stem-cell-shots-bacteria-fda.html> (last visited Jan. 10, 2023).

<sup>20</sup> Cytomegalovirus (CMV) and Congenital CMV Infection, U.S. Centers for Disease Control, <https://www.cdc.gov/cmV/overview.html> (last visited Jan. 10, 2023).

134. In October 2019, Definitive Wellness staff operating in another state became aware that one batch of stem cells they were introducing inside consumers was labeled as “positive” for CMV on its product analysis certificate.<sup>21</sup>
135. In the same month, the Nurse Practitioner gave injections to two Iowans with stem cells that reflected CMV-positive product analysis certificates.
136. At the time, the Nurse Practitioner did not realize she had used stem cell products identified as positive for CMV.
137. Upon becoming aware of the potentially CMV-positive injections, neither Definitive Wellness nor the Defendants informed the two Iowa consumers that they had received a stem cell product that was labeled as positive for CMV.<sup>22</sup>
138. Definitive Wellness ultimately replaced the product with another product that did not have CMV-positive labels and continued administering stem cell therapy to Iowa consumers on behalf of the Defendants.
139. Furthermore, one of the typical directions Definitive Wellness provided consumers who received therapy was to drink more water, which was implicitly- if not explicitly- tied with the alleged efficacy of the treatment in aiding the cells to alleviate problems.
140. In emails exchanged with Definitive Wellness management, the Nurse Practitioner requested that some patient history be collected from all consumers prior to treatment in order to screen for chronic kidney disease based on her concern that people experiencing

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<sup>21</sup> A product analysis certificate is a document that accompanies each batch of stem cell product and communicates the results of testing done on the product.

<sup>22</sup> Upon learning of these events, CPD staff, after consulting with staff from the Iowa Department of Health and Human Services, notified the two affected consumers in July 2021 that they had received a stem cell product that could be CMV-positive.

chronic kidney disease may need to limit their water intake and they may risk harm by drinking too much water.

141. Upon information and belief, the Nurse Practitioner's recommendation was never adopted by the Defendants or Definitive Wellness, potentially exposing Iowa consumers suffering from chronic kidney disease while receiving stem cell therapy to injury.

142. The Defendants' claim that the stem cell therapy they sold Iowans was safe was a deceptive, misleading, and unfair practice, and lacked legally required substantiation.

**5. The Defendants' Disclaimers Were Inadequate to Mitigate Their Deceptive, Misleading, and Unsubstantiated Claims and Do Not Nullify Their Affirmative Legal Obligations to Possess Reasonable Bases for Them When Made**

143. Some of Defendants' promotional and enrollment materials contained disclaimers or warnings stating that stem cell therapy was "not guaranteed and the results will vary" and described it as offering, "the possibility...[to] provide some therapeutic benefit."

144. The Defendants at times made limiting statements that their stem cell therapy services were not intended to provide a medical diagnosis or guarantee results. For example, one slide in Defendants' presentation said, "NOTE- we DO NOT diagnose or treat any disease."

145. One disclaimer on the "Informed Consent for Stem Cell Therapy" admitted, the "FDA recently re-confirmed that there is only one registered stem cell product," and "while there is enormous promise in stem cell therapies, . . . these are not at the point where they would meet the scientific standard" and "[s]tem cell therapies have enormous promise, but the science in its use is still in the developmental stage. Professional judgment and expertise are needed in using stem cells for any therapeutic use."

146. These disclaimers, warnings, and limiting statements (or any other such disclaimer, warning, or statement associated with Defendants' products or promotional activities) were not sufficient to overcome the net impression the Defendants created that stem cell therapy was effective to treat pain and other symptoms from numerous medical conditions.

147. Regardless of the Defendants' inadequate disclaimers, warnings and limiting statements, the Defendants had affirmative legal obligations to have a reasonable basis for each of their claims at the time they made them.

**E. The Defendants Violated Iowa's Door-to-Door Sales Act**

148. Though the Defendants were selling an expensive, invasive, unproven, and dangerous treatment to older Iowa consumers suffering from chronic and painful medical conditions in a high-pressure door-to-door context, they nonetheless failed to honor consumers' most important Door-to-Door Sales Act rights.

149. Selling stem cell therapy outside a typical clinical office setting was central to the Defendants' business model.

150. The Defendants' self-described "mission" was to "offer patients non-surgical and non-opiate options to improve their pain, mobility and quality of life all in the convenience of a *home setting*..." (emphasis added).

151. Despite their volume of sales in Iowa, Defendants never had a business or clinic location in the state, though in 2019-20 they used a "virtual office" mailbox in Des Moines as an Iowa address to give consumers the impression of a legitimate presence in the State.

152. Iowa consumers typically paid for stem cell therapy by making a payment directly to a Biologics representative during the sale inside their home, and never at Biologics'

principal place of business in Tampa and St. Petersburg, Florida; at Summit Health Centers' principal place of business in Eden Prairie, Minnesota (or other Minnesota locations); or Defendants' virtual office mailbox location in Des Moines.

153. Iowa consumers' agreements to purchase stem cell therapy from the Defendants therefore occurred outside of Defendants' "place of business" or their "main or permanent branch office of local address . . ." The transactions constitute "door-to-door sales" under Iowa Code § 555A.1(3) and are governed by the requirements of Iowa Code Chapter 555A.
154. The Biologics sales contracts did not contain a statement notifying each consumer that she or he had the right to cancel the transaction any time prior to midnight of the third business day after the date of the transaction, in violation of Iowa Code § 555A.2.
155. The Biologics sales contracts did not include a Notice of Cancellation, in violation of Iowa Code § 555A.3.
156. Biologics failed to furnish two completed copies of a Notice of Cancellation to Iowa buyers, in violation of Iowa Code section 555A.4(1).
157. Upon information and belief, Biologics did not orally apprise Iowa consumers of their right to cancel in violation of Iowa Code section 555A.4(3).
158. In a pre-litigation subpoena, the Attorney General asked Defendants to provide, "exemplar copies of all written material [their] door-to-door salespersons gave to or otherwise exchanged with Iowa consumers on or after January 1, 2017 . . . [including,] exemplars of all documents [they] allege[] comported with the requirements of Iowa Code section 555A."
159. The Defendants did not provide documents proving their compliance with Iowa Code section 555A because the Defendants did not comply with the DTDSA.

160. To the extent the Defendants refused to provide refunds to Iowa consumers who were never afforded rights to cancel transactions or took other similar steps in contravention of Iowa consumers' rights, they misrepresented buyers' rights to cancel in violation of Iowa Code section 555A.4(4).

**F. The Defendants' Negative Impact on Older Iowans Justifies Enhanced Civil Penalties**

161. The Defendants targeted older consumers in their advertising by promoting the idea that stem cell therapy could mitigate slower rates of healing or recovery that older people experience because they have fewer stem cells than they did at a younger age.

162. Biologics' mailers stated, "[s]tem cells rapidly decline with age" and included graphics showing that the relative amount of stem cells in the body shrinks with age (Ex. F).

163. Biologics' website contained numerous similar claims, such as:

Remember how quickly you would heal when you were younger and had an injury like a sprained ankle or cut? That's because your body would recruit your plentiful stem cells to come and reduce the swelling and repair the damage. As you've gotten older and sustained an injury, you may have noticed it takes significantly longer to heal. That's because we get older our bodies produce drastically less stem cells.

164. Approximately 69% of the Iowa consumers who bought stem cell therapy from Defendants were age 65 or older at the time of the purchase.

165. The Nurse Practitioner who administered the treatments the Defendants sold confirmed that most of her clients were older Iowans.

166. The Defendants' conduct was in willful disregard of the rights of older Iowans.

167. The Defendants knew, or should have known, their conduct was directed at older Iowans.

168. Older consumers were typically more vulnerable to Defendants' marketing and sales strategy and messaging due to their advanced age and poor health conditions.

169. All the Defendants' violations of the CFA and DTDSA that the Court finds have targeted or otherwise negatively impacted older Iowans should be accompanied by civil penalties enhanced by up to \$5,000 or other such lesser sum as the Court deems appropriate.

**MISCELLANEOUS ALLEGATIONS**

170. Neither all nor any part of the application for injunctive relief herein has been previously presented to and refused by any court or justice. Iowa R. Civ. P. 1.1504.

171. In an action by the State, no security shall be required of the State. Iowa R. Civ. P. 1.207.

**COUNT 1**

**CONSUMER FRAUD ACT VIOLATIONS**

**(Iowa Code Section 714.16)**

172. The introduction and Paragraphs 1- 171 are incorporated herein.

173. The Defendants' acts and practices violate the prohibitions of Iowa Code section 714.16(2)(a) against misleading, deceptive, and unfair acts and practices, and otherwise violate that subsection of the CFA.

174. Although it is not necessary to establish reliance, damages or intent to deceive to obtain injunctive relief or reimbursements under the CFA, establishing these factors (particularly intent) is nevertheless relevant inter alia to the Court's determination of the appropriate scope of injunctive relief and the appropriate amount of civil penalties. Those acts and practices of Defendants in violation of subsection (2)(a) of the CFA alleged in this Court would in fact induce reliance on the part of consumer victims, would in fact cause damage to consumers, and/or were in fact intentional.

**COUNT II**

**IOWA DOOR-TO-DOOR SALES ACT VIOLATIONS  
(Iowa Code Chapter 555A)**

175. Paragraphs 1 - 174 are incorporated herein by reference.

176. Defendants violated the provisions of Iowa Code Chapter 555A by selling stem cell therapy products and services valued at more than \$25.00 to consumers for personal and family purposes, at a place other than the Defendants' place of business and:

- a. violated Iowa Code § 555A.2 by failing to furnish a form containing a statement notifying the consumer that she or he may cancel the transaction any time prior to midnight of the third business day after the date of the transaction;
- b. violated Iowa Code § 555A.3 by failing to furnish a form that contained a "Notice of Cancellation" that also contains the required statutory notice;
- c. violated Iowa Code § 555A.4(1) by failing to furnish two copies of the "Notice of Cancellation" to consumers and completing both copies by entering the name of the seller, the address of the seller's place of business, the date of the transaction, and the date by which the consumer may give notice of cancellation; and
- d. violated Iowa Code § 555A.4(3) by failing to orally apprise Iowa consumers of their rights to cancel.

177. Pursuant to Iowa Code § 555A.5, Defendants' failure to provide a copy of the contract to a consumer as required by Chapter 555A shall void any contract, note, instrument or other evidence of indebtedness executed or entered into in connection with the contract.

**COUNT III**

**OLDER IOWANS ACT VIOLATIONS**

178. The introduction and Paragraphs 1-177 are incorporated herein by reference.

179. The Defendants' violations of the CFA and DTDSA were committed against older Iowans within the meaning of Iowa Code section 714.16A and give rise to the penalties set forth in that provision.

**PRAYER**

Plaintiff prays the Court grant the following relief:

- A. Pursuant to Iowa Code section 714.16(7), and upon further request by Plaintiff separately addressed to the Court, enter a preliminary injunction restraining Defendants, and each of them, and (as applicable), each such Defendant's directors, officers, principals, partners, employees, agents, servants, representatives, subsidiaries, affiliates, successors, assigns, merged or acquired predecessors, parents or controlling entities, and all other persons, corporations, and other entities acting in concert or participating with Defendants who have actual or constructive notice of the Court's injunction, from engaging in any of the deceptive, misleading, and unfair practices alleged in this Petition or otherwise violating the Consumer Fraud Act or the Door to Door Sales Act.
- B. Pursuant to Iowa Code section 714.16(7), after trial on the merits, enter a permanent injunction, expanding their provisions as necessary by including, *inter alia*, such "fencing in" provisions as are reasonably necessary to ensure that Defendants and other enjoined persons and entities do not return to the unlawful practices alleged herein, or commit comparable violations of the law.
- C. Pursuant to Iowa Code section 714.16(7), enter judgment against all Defendants for amounts necessary to restore to Iowans all money acquired by means of acts or practices that violate the Consumer Fraud Act or, if the cost of administering reimbursement outweighs the benefit to consumer or consumers entitled to reimbursement cannot be

located through reasonable efforts, for such funds as are necessary to ensure complete disgorgement of all ill-gotten gain traceable to the unlawful practices alleged herein.

- D. Pursuant to Iowa Code section 555A.6 void all sales contracts and finance agreements for consumers whom the Court deems to be entitled to such a remedy as a result of Defendants' unlawful acts or practices pursuant to Iowa Code section 555A.5 and/or Iowa Code section 714.16(7).
- E. Pursuant to Iowa Code section 714.16(7), enter judgment against each Defendant for up to \$40,000.00 for each separate violation of the Consumer Fraud Act and/or the Door-to-Door Sales Act.
- F. Pursuant to Iowa Code section 714.16A, the Older Iowans Law, enter judgment against each Defendant for a civil penalty of up to \$5,000.00, to be added to each civil penalty imposed under the Consumer Fraud Act and Door-to-Door Sales Act.
- G. Award Plaintiff interest as permitted by law.
- H. Pursuant to Iowa Code section 714.16(11), enter judgment against all Defendants for attorney fees and state's costs.
- I. Retain jurisdiction as necessary to ensure full compliance with the pertinent provisions of the Consumer Fraud Act, Door-to-Door Sales Act, and the Older Iowans Law, and with the Court's orders.
- J. Assess court costs against Defendants.
- K. Grant such additional relief as the Court deems just and equitable.

Respectfully submitted,

BRENNA BIRD

Attorney General of Iowa

By: /s/ J. Andrew Cederdahl

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