THE IOWA DISTRICT COURT FOR POLK COUNTY

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 MEEK, and SCOTT THOMAS, Defendants.	CASE NO. EQCE089356 **FINDINGS OF FACT, CONCLUSIONS OF LAW, JUDGMENT, AND ORDER**

This case was tried in equity.[1] Trial in this matter was held March 17-21, 24-25, 2025. The court permitted the parties to file proposed findings of fact and conclusions of law after receiving the certified trial transcript.[2] The court also allowed the parties' to respond to the other's submissions.[3] The parties received the transcript on August 19, 2025.[4] The court granted an extension allowing proposed

[1] Iowa Code section 714.16(7) ("A civil action pursuant to this section shall be by equitable proceedings."); *See also State ex rel. Att'y Gen. of Iowa v. Autor*, 991 N.W.2d 159 (Iowa 2023) (discussing "equitable proceedings" in CFA actions brought by the Iowa Attorney General).
[2] D0265, Order Regarding Proposed Findings and Conclusions.
[3] D0265, Order Regarding Proposed Findings and Conclusions.
[4] D0270, Order Regarding Certified Trial Transcripts.

findings and conclusions to be filed September 26, 2025 and responses by October 10, 2025.[5]

The plaintiff, State of Iowa *ex rel.* Attorney General Brenna Bird, was represented by Assistant Iowa Attorneys General J. Andrew Cederdahl, Laura Mommsen, and Noah Goerlitz (until Mr. Goerlitz's withdrawal). Defendants were represented by Nathan Russell.

Having (i) considered the pleadings, (ii) heard the testimony, (iii) reviewed exhibits, (iv) reviewed the parties' pre- and post-trial briefings and proposed findings of fact and conclusions of law, (v) reviewed the parties' responses to each of the proposed findings and conclusions, and (vi) been otherwise fully advised, the court makes the following findings of fact, conclusions of law, judgment and order.

I. PROCEDURAL BACKGROUND

The State filed a petition in equity on September 13, 2023,[6] where the State alleged the defendants engaged in unlawful conduct in violation of the Iowa Consumer Fraud Act ("CFA"), the Iowa Door-to-Door Sales Act, ("DDSA"), and Older Iowans Act ("OIA").[7] The State requested the court award remedies under the CFA, DDSA, and OIA related to the defendants' conduct including permanent

[5] D0403, Order Granting Plaintiff's Unopposed Extension Motion.
[6] D0001, Petition.
[7] D0001, Petition.

injunctive relief, consumer reimbursement, voiding of all contracts between the defendants and consumers, civil penalties, and an award of the State's attorney fees, court costs, and costs of its investigation of the defendants.[8]

The defendants answered on October 11, 2023.[9] The defendants asserted five affirmative defenses: (1) laches, estoppel, waiver; (2) failure to state a claim/lack of personal and subject matter jurisdiction; (3) they had a reasonable basis for their claims; (4) informed consent; and (5) the corporate veil protects the individual defendants Thomas and Meek from personal liability. On March 11, 2024, the defendants amended their answer[10] and pled two additional affirmative defenses: (6) "That Plaintiff's assurance of voluntary compliance ["AVC"] with Definitive Wellness, LLC, Angela Jayes and Tim Jayes (collectively, "Definitive Wellness") includes Defendants herein."; and (7) "That there was a joint venture and/or partnership and/or principal-agent or other relationship between Definitive Wellness and Defendants."[11] On August 21, 2024, the defendants filed a motion for summary judgment related to affirmative defenses (6) and (7), and the court denied that motion on December 27, 2024.[12] On February 26, 2025, the Iowa

[8] D0001, Petition Prayer, ¶¶A-K.
[9] D0009, First Answer and Affirmative Defenses.
[10] D0024, Amended Answer and Affirmative Defenses.
[11] D0024, Amended Answer and Affirmative Defenses.
[12] D0048, Order Denying Summary Judgment.

Supreme Court denied the defendants' application for interlocutory appeal of the order denying summary judgment.[13]

II. FINDINGS OF FACT

This case involves the defendants' advertisement and sale of stem cell therapies. The defendants Rylee John Meek and Scott David Thomas operated a regenerative medicine business through the defendant companies that advertised and sold stem cell therapies to Iowa consumers.[14] The delivery of the therapies was primarily by injection into the body and occurred in the homes of Iowa consumers and other non-clinical settings.[15] They also sold general wellness IVs.

The defendants advertised numerous health conditions they claimed stem cell therapy could help. The conditions included:

> Neck pain, joint pain/injury, shoulder pain, tennis elbow, tendonitis, back pain, low back pain, knee pain, ACL/MCL tears, degenerative arthritis, plantar fasciitis, degenerative joint disease, arthritis joint pain or injury, degenerative cartilage/ligaments, neuropathy, osteoarthritis of the knee, ligament strains and bursitis,[16] meniscus injuries, hip labrum tears, hip tendon tears, rotator cuff tears, shoulder labrum tears, and others;[17] rheumatoid arthritis, autoimmune disease, celiac

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[13] D0055, Denial of Defendants' Interlocutory Appeal Application.
[14] *See* D0001, Petition; D0024, Amended Answer and Affirmative Defenses.
[15] D0142, Trial Ex. 11at 176. ("Mission Statement – The mission for our company is 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).
[16] D0024, Amended Answer ¶56; D0145, Trial Ex. 23 at 992; D0146, Trial Ex. 24 at 1003.
[17] D0024, Amended Answer ¶37, Ex. A ("Conditions This May Help," screenshots of Defendants' website, www.summithealthcenters.com).

> disease, lupus, Parkinson's disease, Graves' disease, Inflammatory bowel disease, Crohn's disease, ulcerative colitis, multiple sclerosis, psoriasis, bronchial asthma, cardiovascular disease, COPD, diabetes (type 1 and type 2), erectile dysfunction, fibromyalgia, hair loss, heart disease, kidney disease, liver disease, Lyme disease, reflex sympathetic dystrophy, spinal cord injuries, "sports-related inflammation," "surgery-related tissue damage," and traumatic brain injury.[18]

A. Background: Scott Thomas and Rylee Meek

Meek and Thomas are not licensed healthcare providers nor were they formally educated or trained in medicine.[19] They never sold products that would be injected inside consumers' bodies prior to starting their stem cell business.[20] They are not regenerative medicine industry experts as advertised in their mail solicitations.[21] Instead, Meek's and Thomas' experience lies primarily in marketing and sales. Thomas and Meek used that experience to co-found a sales/marketing strategy known as the social dynamic sales system, which they used to advertise and sell stem cell therapies to Iowa consumers.[22] Their marketing strategy utilized direct mail to invite consumers to dinner seminars where the stem cell therapies were presented and sold to them.[23] The defendants admit Meek invented this

[18] D0168, Trial Ex. 33, 1049-1058.
[19] D0024, Amended Answer ¶23.
[20] Trial Tr. Vol. 3, 76:25-77:1-3.
[21] Trial Tr. Vol. 3, 68:9-11; D0144, Trial Ex. 22 at 990.
[22] Trial Tr. Vol. 3, 70:25-71:1-3; 75:7-10.
[23] Trial Tr. Vol. 3, 71:4-18.

concept by combining aspects of other established sales systems.[24] Though Meek was the creator of the system, Thomas assisted Meek in operating it.[25]

The defendants' system was an effective concept they used with Iowa consumers. The defendants also used this system in Ohio to sell stem cell therapies prior to implementing it with Iowa consumers.[26] They discovered their system was more effective than cold, non-targeted, internet advertising.[27]

The court finds Meek and Thomas employed the defendants' salespersons to implement this system with Iowa consumers in advertising and selling stem cell therapies. The court also finds Meek and Thomas personally operated the important facets of the system to advertise and sell the therapies to Iowans.

The defendants also included neuro-linguistic programming in their program.[28] They learned they "could get humans to respond in different ways by changing what they see. From a headline to a graphic to the way you lay things out…"[29] They wrote that stressing a single word in the same written sentence could

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[24] Trial Tr. Vol. 3, 71:19-72:7.
[25] Trial Tr. Vol. 3, 72:8-10.
[26] Trial Tr. Vol. 3, 72:13-25; 73-74; 75:1-6.
[27] Trial Tr. Vol. 3, 72:13-25; 73-74; 75:1-6.
[28] D0218, Trial Ex. 61.
[29] D0218, Trial Ex. 61 at 3312. Trial Tr. Vol. 3, 153:12-18; D0218, Trial Ex. 61 at 3320 (The defendants wrote they further believed: "Many scientific studies have shown that the words you use are not nearly as important as how you use them. Your tone can literally set the tone for your conversation with the prospect and help you lead them in the direction you want; i.e. closing the deal.").

be received in dramatically different ways depending on one's in-person tone.[30] They also admitted in their book, and Thomas testified at trial, they believe consumers buy products largely based on emotions that advertisers attach to speak to the subconscious to "visualize what the final product or service is going to look like."[31] The emotions the defendants capitalized on were the suffering, pain, desperation and hope stemming Iowa consumers experienced resulting from their health problems.

B. Defendants' Founding and Operation of the Summit and Biologics Companies

In approximately November 2017, Meek, Thomas, and others met in Ohio to plan the start of the regenerative medicine venture.[32] Meek and Thomas would begin advertising and selling "stem cell" therapies in multiple states after each state was "greenlit" for business, which nurse practitioners from Definitive Wellness, LLC would implement.[33]

Beginning in June 2019, Meek and Thomas began doing business in Iowa[34] through "Summit Health Centers" using the defendant, Summit Partners Group,

[30] Trial Tr. Vol. 3, 153:19-25; 154:1-4, 13-15; D0218, Trial Ex. 61 at 3320.
[31] Trial Tr. Vol. 3, 154:24-25; 155:1-16; D0218, Trial Ex. 61 at 3334.
[32] Trial Tr. Vol. 2, 19:2-21.
[33] Trial Tr. Vol. 3, 192:1-7.
[34] D0024, Amended Answer ¶34; Trial Tr. Vol. 3, 77:8-19.

LLC.[35] Meek and Thomas operated those businesses and were the sole owners.[36] In December 2019, Meek and Thomas changed the name of their stem cell therapy business to "Biologics Health" and began using the defendant, Biologics Health, LLC to conduct business.[37] "Biologics Health" operated in Iowa until about April 2020.[38]

At trial, Thomas claimed or implied the only reason the defendants stopped doing business in Iowa in April 2020 was because the State requested it.[39] This testimony contradicted his deposition testimony where he testified the defendants ceased business because their model using in-person restaurant seminars no longer worked during the covid-19 pandemic.[40]

C. Nurse Angela Jayes and Definitive Wellness, LLC

Nurse Angela Jayes, formerly Angela Schertz, is an Ohio resident who founded Definitive Wellness, LLC ("DW").[41] DW contracted with the defendants to provide nurse practitioners to administer stem cell therapies to Iowans that the defendants identified had purchased the stem cell therapies from them.[42]

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[35] D0001, Petition ¶¶ 18-20; D0024, Amended Answer ¶17.
[36] Trial Tr. Vol. 3, 80:8-83:13.
[37] D0024, Amended Answer ¶¶18-20.
[38] Trial Tr. Vol. 3, 78:7-79:7; D0142, Trial Ex. 11 at 262-63.
[39] Trial Tr. Vol. 4, 8:23-9:11; 14:11-15:8.
[40] Trial Tr. Vol. 4, 14:11-15:8.
[41] Trial Tri. Vol. 2, 6:19-21:18-22:17.
[42] Trial Tri. Vol. 2, 22:18-22.

DW was a separate business from Summit and Biologics. The defendants never had a partnership agreement with DW or its owner, Angela Jayes.[43] Jayes was never an employee, manager, or member of any defendant entity.[44] Meek and Thomas were never employees, managers, or members of DW.[45] Summit's and Biologics' operating agreements do not mention DW[46] and were never amended and always included solely Thomas and Meek as the defendants' members, owners, and managers.[47] Further, the defendants did not share business profits and losses with DW and Jayes.[48]

The only written contract defining the roles of the defendants and DW was a service level agreement.[49] The agreement provided that DW would provide nurse practitioners to administer the product the defendants advertised and sold. Per the service level agreement, the defendants generally paid DW "$4,500 per month, per state and per nurse practitioner."[50] DW invoiced the defendants for the "services" it provided to them each month.[51]

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[43] Trial Tr. Vol. 3, 140:18-24.
[44] Trial Tr. Vol. 2, 27:11-20.
[45] Trial Tr. Vol. 2, 27:21-28:4.
[46] D0145, Trial Ex. 23; D0146, Trial Ex. 24.
[47] Trial Tr. Vol. 3, 80:8-83:13.
[48] D0150, Trial Ex. 28; Trial Tr. Vol. 3, 141:21-23; D0151, Trial Ex. 29.
[49] D0150, Trial Ex. 28; Trial Tr. Vol. 2, 30-31.
[50] D0150, Trial Ex. 28; Trial Tr. Vol. 3, 141:21-23.
[51] D0151, Trial Ex. 29.

Jayes did not believe she could bind the individual or corporate defendants to anything without their express consent.[52] She did not allow the defendants to bind her without her express consent.[53] Jayes did not consider herself and DW to be equals with the defendants.[54]

The court finds that DW acted as an independent contractor with respect to the defendants to provide nurse practitioner services. It was not an agent of any of the defendants' advertisement and sale of stem cell therapies and was not authorized to conduct business on behalf of the defendants. DW could not enter into legally binding agreements on behalf of the defendants.

D. Iowa Attorney General's Investigation of the Defendants

The Consumer Protection Division ("CPD") of the Iowa Attorney General's Office began its investigation of the defendants after receiving complaints from Iowa consumers concerning their stem cell business. In January 2020, Redfield resident Kenneth Hurt submitted a complaint to CPD.[55] In December 2020, Norwalk resident Ruth Draper-Helland submitted a complaint to CPD.[56] Her complaint also included advertising documents provided by the defendants and

[52] Trial Tr. Vol. 2, 28:9-12.
[53] Trial Tr. Vol. 2, 28:13-16.
[54] Trial Tr. Vol. 2, 22:23-23:14.
[55] D0127, Trial Ex. 5 at 120.
[56] D0128, Trial Ex. 6.

copies of other forms.[57] Following these complaints, the CPD initiated an investigation[58] and issued several subpoenas to the defendants and other parties[59] as authorized by the CFA.[60] The subpoenaed parties responded with narratives under oath and documents relating to the defendants' sales and advertising activities with Iowa consumers.[61]

E. Methods of Stem Cell Therapies

The defendants sold Iowa consumers stem cell therapies administered in two ways: injections in various body parts and general wellness IVs.[62]

The defendants advertised and sold injections while they operated in Iowa.[63] Initially, the defendants offered and sold general wellness IVs this practice ceased following the hiring of a chief medical officer, Dr. Zaid Fadul, who advised against continuing this treatment.[64] Also, Jayes was unable to validate whether people were having good results after receiving these treatments for general wellness.[65]

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[57] D0128, Trial Ex. 6 at 133-144.
[58] Trial Tr. Vol. 1, 130:3-13.
[59] D0142, Trial Ex. 11; D0133, Trial Ex. 12; D0134, Trial Ex. 13; D0135, Trial Ex. 14.
[60] The CFA authorizes CPD to issue investigative subpoenas prior to bringing lawsuits. Iowa Code 714.16(3)-(4).
[61] D0142, Trial Ex. 11; D0133, Trial Ex. 12; D0134, Trial Ex. 13; D0135, Trial Ex. 14.
[62] D0024, Amended Answer ¶¶35, 83; Trial Tr. Vol. 3, 135:13-136:25.
[63] Trial Tr. Vol. 3, 135:13-18.
[64] Trial Tr. Vol. 3, 136:21-137:1-12; Trial Tr. Vol. 2, 78:24-79:1.
[65] Trial Tr. Vol. 2, 78:4-8.

The defendants never refunded Iowa consumers who received general wellness IVs.[66]

F. Stem Cell Products Sold to Iowans

The defendants did not sell autologous therapies in which one's own cells or other bodily materials are extracted, processed and reintroduced inside his or her body.[67] The therapies the defendants sold Iowans used allogeneic tissue and cellular materials, meaning all materials were sourced from individuals other than the individual receiving the products.[68]

The defendants used four different product manufacturers to source cellular and tissue products used with Iowa consumers at differing periods of time: Liveyon, Biogenix, Invitrx, and Regenative.[69] Specifically, the defendants used Liveyon Pure, Liveyon PurePro, and Liveyon Restore from February 2019 through September 2019.[70] The defendants used Biogenix's Bio 10 and Bio 30 from June 2019 through October 2019.[71] The defendants used Invitrx's CB 0100, CB 0200, CB 0300, CB 0400, and CB 030 mil from October 2019 through February 2020.[72]

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[66] Trial Tr. Vol. 3, 138:17-20.
[67] D0024, Amended Answer ¶26(a)-(d); Trial Tr. Vol. 1, 55:1-56:1; Trial Tr. Vol. 6, 48:3-8.
[68] D0024, Amended Answer ¶26(a)-(d); Trial Tr. Vol. 1, 55:1-56:1; Trial Tr. Vol. 6, 48:3-8.
[69] D0024, Amended Answer ¶26(a)-(d).
[70] D0024, Amended Answer ¶26(a).
[71] D0024, Amended Answer ¶26(b).
[72] D0024, Amended Answer ¶26(c).

Finally, the defendants used Regenative's Protext and Coretext products from February 2020 through at least May 2020.[73] In response to a subpoena, the defendants described Regenative's Protext and Coretext products as being derived from Wharton's Jelly while the other products were derived from umbilical cords.

According to PowerPoint presentations given by Meek, Thomas and their salespersons to Iowa consumers, these products were advertised as containing mesenchymal stem cells ("MSCs"), collagen, growth factors, structural proteins, cytokines, and hyaluronic acids.[74] Thomas believed all of these ingredients were related to the effectiveness of the therapies the defendants sold and told Iowa consumers these ingredients would help the stem cells be effective.[75]

The defendants never verified the precise types and measures of all these contents in any of the products they sold.[76] The defendants did not verify the information regarding the ingredients in the products they sold at different times during their Iowa operations. They failed to verify: (1) the number of MSCs in their products, (2) the number of any other cells, (3) the amount of any type of cell, (4) the type or amount of cytokines, (5) the type or amount of growth factors, (6)

[73] D0024, Amended Answer ¶26(d).
[74] D0145, Trial Ex. 23 at 1000; D0146, Trial Ex. 24 at 1011.
[75] Trial Tr. Vol. 3, 107:2-16.
[76] Trial Tr. Vol. 3, 127:3-128:20.

the amount of structural proteins, the amount of collagens, or the amount of hyaluronic acids.[77]

The defendants' expert witness, Dr. Scott Martin did not cite any internal or external analysis, testing or peer-reviewed clinical research regarding the specific products the defendants used with Iowans - as opposed to other substances studied in the sources he did cite.[78] Further, Dr. Martin was not able to cite or disclose any analysis or verification of the specific products sold to Iowans.[79]

The defendants failed to present any credible evidence or testimony regarding the ingredients in the products they sold Iowans. The defendants introduced some documentary information from the product manufacturers in the form of manufacturer pamphlets.[80] This evidence was only for half of the four manufacturers they used. The information had minimal, information substantiating the types and amount of the product ingredients advertised and sold by the defendants that made it an effective treatment option.[81] Moreover, neither the defendants nor Dr. Martin possessed documentation from all the product

[77] Trial Tr. Vol. 3, 127:3-128:20.
[78] Trial Tr. Vol 6, 10-20.
[79] Trial Tr. Vol. 3, 127:3-15; Trial Tr. Vol 6, 10-20.
[80] D0211, Trial Ex. 59 (Liveyon "Pure" products); Def. Ex. 69 (Regenative Labs Wharton Jelly products); Def. Ex. 71 (Regenative Labs "amniotic membrane allograft" products).
[81] D0211, Trial Ex. 59 (Liveyon "Pure" products); Def. Ex. 69 (Regenative Labs Wharton Jelly products); Def. Ex. 71 (Regenative Labs "amniotic membrane allograft" products).

manufacturers confirming the precise types and amounts of each of the alleged contents for the products advertised and sold to Iowans.[82]

Consequently, the defendants could not verify the ingredients or their amounts in the products Iowans received from June 2019 through October 2019[83] or from October 2019 through February 2020.[84] Meek and Thomas[85] helped select the products sold to consumers despite their lack of information regarding the product's contents.[86]

Thomas testified he did not believe there were any major differences between the various products the defendants sold.[87] In other words, he believed the Wharton Jelly-derived products from manufacturer Regenative were interchangeable with the umbilical cord-derived products of other manufacturers the defendants used. Jayes had a different opinion than Thomas. Jayes believed Invitrx's umbilical cord-derived products were "less effective" than Regenerative's products.[88] She also testified she believed cost was the driver for selecting products.[89]

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[82] Trial Tr. Vol. 3, 127:3-15; Trial Tr. Vol 6, 10-20.
[83] D0024, Amended Answer ¶26(b).
[84] D0024, Amended Answer ¶26(c).
[85] Trial Tr. Vol. 2, 33:12-34:6 (Thomas assumed the role of "Quality Assurance.").
[86] Trial Tr. Vol. 2, 37:5-7.
[87] Trial Tr. Vol. 3, 111:20-24.
[88] Trial Tr. Vol. 2, 93:15-94:3.
[89] Trial Tr. Vol. 2, 37:8-12.

G. Summary of the Defendants' Advertising Claims to Iowa Consumers

The defendants used several mediums to advertise stem cell therapies to Iowa consumers.[90] Typically, the defendants sent Iowa consumers direct mail solicitations inviting them to attend dinner sales seminars in various Iowa locations.[91] The defendants' salespersons gave attendees a PowerPoint presentation discussing the alleged benefits of stem cell therapies they offered for sale.[92] The consumers received handouts at the seminars with various claims, such as: "Stem Cells – The Future of Medicine, Personal Health and Longevity."[93] Another handout included several positive consumer testimonials, "What people are saying about stem cell therapy."[94] Following the seminar presentation, salespersons made appointments to meet one-on-one with consumers to close sales.[95] The defendants also had a website where they touted advertising claims about the stem cell therapies they sold Iowa consumers.[96]

1. <u>The defendants claim stem cells seek out health problems</u>.

   The defendants advertised to Iowa consumers that:

   > Regenerative Medicine uses stem cells to regenerate and repair tissues in your body that are damaged due to age, disease and defects. Stem

[90] D0024, Amended Answer ¶34.
[91] D0024, Amended Answer ¶39; D0142, Trial Ex. 11 at 259-261.
[92] D0024, Amended Answer ¶45; D0145; D0146, Trial Exs. 23, 24.
[93] D0149, Trial Ex. 27.
[94] D0148, Trial Ex. 26.
[95] D0024, Amended Answer ¶61.
[96] D0024, Amended Answer ¶¶36-37.

> cells have the power to go to these damaged areas and generate new cells, rebuilding and repairing the area.[97]

"Stem cells are our body's natural repair system. In short, stem cells seek damage in the body and work to regenerate damaged tissue."[98] One sales seminar PowerPoint slide read: "Cells go where the body needs them."[99] Another slide read the products could: "control inflammation" and "modulate the immune system."[100]

2. The defendants claim stem cells could repair damaged tissues.

The defendants admitted that their marketing materials contained statements that stem cells could regenerate tissue and repair damage caused by the aging process and illness in all areas of the body.[101] The defendants admitted that their marketing materials claimed that "Stem cells have the power to go to these damaged areas and generate new cells, rebuilding and repairing the area."[102] During seminars, they also claimed their products would stimulate regeneration.[103]

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[97] D0144, Trial Ex. 22 at 990.
[98] D0142, Trial Ex. 11 at 250.
[99] Trial Tr. Vol. 3, 109:22-24.
[100] D0145, Trial Ex. 23 at 998 (slide 28); D0146, Trial Ex. 24 at 1009 (slide 28).
[101] D0001, Petition, ¶108, D0024, Amended Answer ¶108.
[102] D0024, Amended Answer ¶109; D0142, Trial Ex. 11, 261.
[103] Trial Tr. Vol. 3, 109:11-13; D0145, Trial Ex. 23 at 998 (slide 28); D0146, Trial Ex. 24 at 1009 (slide 28).

3. The defendants advertised that stem cell therapy could treat many health problems.

The defendants claimed in their mail solicitations: "Stem cell therapy has been shown to improve a variety of conditions and injuries including arthritis, osteoporosis, joint pain, sports injuries and more."[104] During sales seminars the defendants' salespersons gave consumers examples of the health problems the stem cell therapies they sold could treat. These examples included:

> Neck pain, joint pain/injury, shoulder pain, tennis elbow, tendonitis, back pain, low back pain, knee pain, ACL/MCL tears, degenerative arthritis, plantar fasciitis, degenerative joint disease, arthritis joint pain or injury, degenerative cartilage/ligaments, neuropathy, osteoarthritis of the knee, ligament strains and bursitis.[105]

The defendants eventually removed "neuropathy" and "tendonitis" from their list.[106] The defendants' admitted their website listed specific "conditions this may help" which included meniscus injuries in the knees to labrum tears in the hips and rotator cuff tears in the shoulder.[107] Iowa consumers also received therapy to address other health problems the defendants were aware salespersons could discuss directly with them, but were not overtly advertised.

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[104] D0144, Trial Ex. 22 at 991.
[105] D0001, Petition, ¶56, D0024; Amended Answer ¶56; D0145, Trial Ex. 23 at 992; D0146, Trial Ex. 24 at 1003.
[106] D0146, Trial Ex. 24 at 1003.
[107] D0001, Petition, ¶¶36-37; D0024, Amended Answer ¶¶36-37.

4. The defendants advertised various doses of stem cells were appropriate.

The defendants advertised and sold Iowa consumers various doses of stem cells at different costs even though they knew there were no uniform or objective dosing criteria for umbilical cord-driven stem cells that has been proven or established in the field of regenerative medicine. [108] Jayes testified that the dosing amount for additional product was determined by cost. [109] Also, Dr. Martin, did not cite or explain any scientific evidence elaborating the appropriate effective dosing in regenerative medicine any of the health conditions the defendants touted in their advertising. He did not explain how dosing would differ, or whether it differed if the product was injected or provided by IV.

The consumers who testified indicated that the number of injections they received was dependent upon the amount they wanted to spend. The court finds the dosing protocols used with Iowa consumers were not guided by medical or scientific criteria. The dosing depended upon the price the consumer was willing to spend.

[108] D0001, Petition, ¶119; D0024, Amended Answer ¶119.
[109] Trial Tr. Vol. 2, 58:6-24.

5. The defendants claim their stem cell procedures sold to Iowa consumers were safe.

The defendants told consumers the stem cell therapies they sold were safe.[110] In the mail solicitation inviting consumers to attend seminars, they claimed: "Stem cells offer a *risk-free* solution that heals the body naturally to deliver long-term relief from pain."[111] In the slideshow presentation Meek, Thomas and their salespersons, the defendants claimed the therapies were: "Simple, fast, SAFE…"[112] The defendants further claimed during sales seminars that the products they sold "were screened and tested for infectious disease, sterility and endotoxins."[113] Also, the defendants told Iowa consumers they would experience "no HLA/immune response to the cells."[114]

In handout materials provided to consumers during the seminars, the defendants claimed:

> 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.[115]

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[110] Trial Tr. Vol. 3, 107:17-108:3.
[111] D0144, Trial Ex. 22 at 991. (emphasis added).
[112] D0001, Petition, ¶¶2, 3, 52, 53, 123; D0024, Amended Answer ¶¶2, 3, 52, 53, 123; D0145, Trial Ex. 23 at 992; D0146, Trial Ex. 24 at 1003.
[113] Trial Tr. Vol. 3, 107:22-108:2.
[114] Trial Tr. Vol. 3, 108:4-7.
[115] D0142, Trial Ex. 11 at 250.

H. Defendants' Sales Seminars

The defendants admitted their marketing strategy included group sales seminars at Iowa restaurants, where they offered a free meal and made a sales presentation using PowerPoint presentation that touted the alleged benefits of stem cell therapy.[116] The defendants admitted they held over 200 seminars across Iowa between June 2019 and February 2020.[117]

To fill the seminar rooms with prospective buyers, the defendants sent Iowa consumers direct mail solicitations inviting them to hear from stem cell industry experts.[118] The defendants sent approximately 6,000 mail solicitations per seminar event. They hoped to receive a 1% response rate or 60 consumers attending each event.[119] According to Meek, if the defendants gave 160 presentations, they sent approximately 350,000 mailers to Iowa consumers.[120]

Both Meek and Thomas were directly involved in the mail solicitations the Iowa consumers received.[121] The defendants paid the costs to have the mailers sent

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[116] D0001, Petition, ¶45; D0024, Amended Answer ¶45.
[117] D0001, Petition, ¶48; D0024, Amended Answer ¶48. Defendants provided a comprehensive summary of their sales seminar events in Iowa including the dates, times, locations, addresses and presenters in response to one of the State's investigatory subpoenas. They can be found at: D0142, Trial Ex. 11 at 262-263.
[118] D0001, Petition, ¶47; D0024, Amended Answer ¶47; D0144, Trial Ex. 22; Trial Tr. Vol. 5, 8:19-20.
[119] Trial Tr. Vol. 5, 8:20-25.
[120] Trial Tr. Vol. 5, 8:19-9:2.
[121] Trial Tr. Vol. 3, 91:9-19.

to Iowans.[122] Thomas testified he reviewed and approved all of the statements appearing on the defendants' mail solicitation before they were sent to Iowans.[123] Thomas wanted consumers to "imagine a life without pain," "discover the healing power of stem cells," believe that "stem cell therapy has been shown to improve a variety of health conditions and injuries," and believe they could receive "long-term pain relief," among many other things.[124] Meek and Thomas included individuals over 50 years of age to receive their direct mail campaigns.[125]

Both Meek and Thomas were involved in the sales seminars. The defendants paid the costs of hosting the seminars.[126] Both Meek and Thomas presented at seminars.[127] Thomas testified he personally reviewed the PowerPoint presentation shown during seminars and given it to consumers over 100 times.[128] Meek personally gave the presentation to consumers more times than Thomas.[129] Meek and Thomas also trained salespersons how to give the PowerPoint presentation.[130]

The court finds these facts demonstrate that Meek and Thomas were directly involved in the advertisement and sale of stem cell therapies, including all claims

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[122] Trial Tr. Vol. 3, 91:20-22.
[123] Trial Tr. Vol. 3, 92:15-20.
[124] Trial Tr. Vol. 3, 92:15-95:6.
[125] Trial Tr. Vol. 3, 92:2-14.
[126] Trial Tr. Vol. 3, 98:13-15.
[127] D0001, Petition, ¶¶52, 53; D0024, Amended Answer ¶¶52, 53.
[128] Trial Tr. Vol. 3, 96:6-12.
[129] Trial Tr. Vol. 3, 96:17-25.
[130] Trial Tr. Vol. 3, 97:2-98:12.

made about those therapies. The court also finds the defendants' misled Iowa consumers by touting the results of articles Thomas admits he never read.[131] The defendants featured only the titles, but not the substance, of various periodical, internet and scientific articles attributing amazing results to stem cell therapies.[132] For example, the titles read: "Scientists are developing new ways to treat disease with cells, not drugs"; "Meet the only person to be cured of HIV"; "Second man is HIV-free after stem cell transplant"; "First paralyzed human treated with stem cells has now regained his upper body movement"; and "Stem cell therapy for heart disease."[133] The net impression of this messaging was that Iowa consumers could expect similar results from therapies they purchased from the defendants or that the therapies the defendants advertised had a similar potential.

The defendants did not verify whether the types of stem cell therapies presented in these articles matched the products the defendants were selling to Iowans.[134] Thomas was unable to summarize the contents of the articles.[135] The impression created by using these article titles was to imply that the therapies the defendants sold Iowans could accomplish similar results. The court finds Meek and Thomas failed to investigate and understand the basic information about the claims

[131] Trial Tr. Vol. 3, 105:25-106:6.
[132] Trial Tr. Vol. 3, 105:1-106:6.
[133] D0145, Trial Ex. 23 at 994-97; D0146, Trial Ex. 24 at 1005-1008.
[134] Trial Tr. Vol. 3, 105:13-24.
[135] Trial Tr. Vol. 3, 105:25-106:6.

they told Iowans regarding stem cell therapies for the health conditions they alleged to treat.

The defendants provided a handout to the consumers during their sales seminars that contained testimonials about the relief individuals received.[136] Thomas admitted he never contacted any of the endorsers touting stem cell therapies, did not possess the individual's contact information, and did not verify whether the statements were true.[137] He also admitted there was no process to verify whether the people reflected by the testimonials continued to feel the same way long after receiving the therapies.[138] Nor was Thomas able to verify the type of stem cells the endorsers received or the method in which they received them.[139] The court finds that the defendants did not verify any testimonial or whether the statements were true or accurate.

The defendants' PowerPoint presentation contained a list of the health problems stem cell therapy could help.[140] The examples were very general such as neck pain, joint pain, shoulder pain, back pain, low back pain, neuropathy, degenerative arthritis and so forth. The defendants also used a cheat sheet of health conditions with consumers featuring numerous health conditions they did not

[136] D0148, Trial Ex. 26; Trial Tr. Vol. 3, 116:1-14.
[137] Trial Tr. Vol. 3, 116:18-117:6.
[138] Trial Tr. Vol. 3, 117:7-11.
[139] Trial Tr. Vol. 3, 117:12-118:9.
[140] Trial Ex. 23 at 992 (slide 2); Trial Tr. Vol. 3, 99:3-19.

advertise in seminars.[141] However, medical records showed consumers purchased therapy to address COPD,[142] tinnitus[143] and scarring[144] – which were in the cheat sheet but not featured in health conditions in the slideshow. These practices indicate that the defendants were marketing their products as treatment for many common everyday ailments consumers could be suffering without providing the how and why these therapies treated these conditions.

Initially, when they operated as Summit the defendants advertised that their therapies could be used to treat neuropathy and tendonitis.[145] Later when they operated as Biologics these conditions were removed.[146] However, the defendants never refunded consumers or investigated whether consumers had purchased therapy for neuropathy and tendinitis.[147]

I. Defendants' Door-to-Door Sales Activities with Iowa Consumers

The defendants' salespersons met directly with Iowa consumers following their seminar presentations to close sales.[148] The defendants only had a virtual

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[141] D0168, Trial Ex. 33. The "cheat sheet" addressed other health conditions like rheumatoid arthritis, autoimmune, celiac disease, Parkinson's, Grave's disease, MS, bronchial asthma, cardiovascular disease, COPD, diabetes, and traumatic brain injury.
[142] D0207, Trial Ex. 55 at 1725, 1727, 1735; D0168, Trial Ex. 33 at 1052.
[143] D0207, Trial Ex. 55 at 1755.
[144] D0207, Trial Ex. 55 at 1712-13.
[145] Trial Tr. Vol. 3, 99:20-102.
[146] Trial Tr. Vol. 3, 99:20-102:18.
[147] Trial Tr. Vol. 3, 100:9-101:21.
[148] D0001, Petition, ¶61; D0024, Amended Answer ¶61.

office in Des Moines and never a physical clinic location in Iowa.[149] Salespeople were hired and trained by Meek and Thomas.[150] During the one-on-one meeting between the defendants' salespersons and Iowa consumers, salespersons would discuss each consumer's health concerns.[151] The defendants' salespersons were provided a cheat sheet to help explain to consumers which health problems stem cell therapy could alleviate.[152] This cheat sheet included various information including each health "condition," and information that identified what a "Can Stem Cells treat?", and the "Recommended Protocol."[153]

The medical information conveyed by consumers to the defendants' salespersons would be written down on a sales form.[154] This form allowed the salesperson to fill in the contact information for each consumer, the body areas each consumer wanted treated, and payment information.[155] The defendants' salespersons used another document to determine the dosage the consumer could purchase for the medical problems based on each consumer's perception of where their bodies needed treatment.[156]

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[149] D0001, Petition, ¶151; D0024, Amended Answer ¶151.
[150] Trial Tr. Vol. 3, 97:2-14.
[151] D0001, Petition, ¶61; D0024, Amended Answer ¶61.
[152] D0168, Trial Ex. 33.
[153] D0168, Trial Ex. 33 at 1049-1058.
[154] D0140, Trial Ex. 19.
[155] D0140, Trial Ex. 19.
[156] D0169, Trial Ex. 34.

The form also provided:

> I/We understand that this Agreement constitutes the entire understanding between the parties, and that there are no verbal understandings changing or modifying any of the terms of this Agreement.[157]

It also provided:

> I/We hereby acknowledge that no guarantees have been made and that the practice of regenerative medicine is not an exact science and that the treatment of any ailment may involve risks.[158]

This form contradicted the defendants' mail solicitation that claimed stem cells "offer a *risk-free* solution that heals the body naturally."[159] The form did not set forth the purpose of the injection or IV procedures, any specific risks, or the known risk probabilities.[160] It did not inform consumers whether they had a 3-day right to cancel the transactions.[161]

J. The Contract Was Completed in Each Iowan's Home

While in the consumer's home, salespersons would enter into sales contracts and receive payments during the one-on-one meetings with consumers.[162] Iowa

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[157] D0140, Trial Ex. 19.
[158] D0140, Trial Ex. 19.
[159] D0144, Trial Ex. 22 at 991 (emphasis added).
[160] D0140, Trial Ex. 19; *See* Iowa Code §147.137 (containing statutory requirements for when a written consent "creates a presumption that informed consent was given" from patients, including by disclosing the nature and purpose of the procedure with known risks, acknowledging that information has been disclosed and questions answered, and is signed by the patient).
[161] D0140, Trial Ex. 19.
[162] D0001, Petition, ¶61; D0024, Amended Answer ¶ 61.

consumers typically paid between $3,000 to $20,000 for the therapies.[163] The defendants admitted neither they or their salespersons ever provided any Iowa consumers written notices of 3-day cancellation rights or other statutory notices reflected by the Iowa Door-to-Door Sales Act under Iowa Code section 555A ("DDSA").[164] The court finds the defendants failed to notify Iowa consumers of their DDSA cancellation rights.

K. The Alleged Medical Board

After each sale, the defendants claimed a medical board reviewed the salespersons' notes to determine whether Iowa consumers should be approved or denied for stem cell therapy.[165] The defendants did not keep and did not produce any record of the medical board's rationale approving or denying purchased therapies nor did they disclose the individuals on this board.[166] Thomas testified he did not know who the individuals on the board were.[167]

Jayes testified there was no medical board that approved or denied the purchases made by Iowa consumers."[168] Jayes further testified that the defendants claimed that certain individuals constituted a medical board on their website and in

[163] D0001, Petition, ¶75; D0024, Amended Answer ¶75.
[164] D0001, Petition, ¶¶ 154-56; D0024, Amended Answer ¶¶ 154-56.
[165] Trial Tr. Vol. 3, 128:21-130:10.
[166] Trial Tr. Vol. 3, 130:25-132:12.
[167] Trial Tr. Vol. 3, 129:11-130:4.
[168] Trial Tr. Vol. 2, 60:11-15.

their seminars who were not on a medical board.[169] The court finds that the defendants' claim that a medical board reviewed each consumer's specific circumstance to determine whether stem cell therapy was appropriate is not credible.

L. In-Home Stem Cell Therapies and Nurse Decker

Stem cells therapies were administered in the customers' homes by nurse Lisa Decker. Before each appointment to provide stem cell therapy, Ms. Decker received a spreadsheet in her email box simply listing each consumer's name, address, amount to inject, and which body location.[170] Ms. Decker never exercised independent medical judgment to assess whether any Iowa consumer should receive the stem cell therapy the defendants sold them.[171]

Further, she did not know who determined whether each Iowan was an appropriate therapy candidate.[172] She never completed health histories, physicals, range of motion testing or strength testing with any Iowa consumers before giving them therapy.[173] She was not trained to do that.[174] She did not determine appropriate dosing and was unaware who did.[175] She was unaware of all

[169] Trial Tr. Vol. 2, 60:16-25.
[170] Trial Tr. Vol. 5, 119:21-120:6.
[171] Trial Tr. Vol. 5, 120:7-121:21.
[172] Trial Tr. Vol. 5, 119:3-6.
[173] Trial Tr. Vol. 5, 116:14-20.
[174] Trial Tr. Vol. 5, 116:21-22.
[175] Trial Tr. Vol. 5, 119:16-20.

consumers' health histories.[176] She did not know if consumers were on medications.[177] And although Ms. Decker gave consumers an informed consent form before she injected them, she admitted she would not have been able to answer any questions about information contained within the informed consent form.[178]

M. The Defendants' Profits

The defendants admitted in response to the State's petition they received at least $1.5 million dollars from their Iowa-focused sales.[179] In response to a prelitigation investigatory subpoena, the defendants provided the State with a spreadsheet of at least 175 Iowa consumers who paid them at least $1,649,080.50 for stem cell therapies. [180]

N. The Consumers' Experiences

The State called eight Iowa consumer witnesses who purchased therapies from the defendants to testify. The defendants did not call any of the other 175 Iowa consumers to testify.

[176] Trial Tr. Vol. 5, 119:7-9.
[177] Trial Tr. Vol. 5, 120:13-15.
[178] Trial Ex. 37; Trial Tr. Vol. 5, 125:9-129:15.
[179] D0001, Petition, ¶22; D0024, Amended Answer ¶22.
[180] D0204, Trial Ex. 52; D0142, Trial Ex. 11 at 178-179.

1. Consumer Witness Gerry Gilmore

The State's first consumer witness was Gerry Gillmore.[181] Mr. Gillmore was born in June 1953. He was at least 65 years old when the defendants first began doing business in Iowa in June 2019.[182] Mr. Gillmore was married to Nancy Gillmore.[183] Nancy Gillmore was born in November 1944, making her 74 years old when the defendants first began doing business in Iowa.[184] Mrs. Gillmore passed away from cancer on February 5, 2020.[185]

The Gillmores purchased stem cell therapy from the defendants to address Mrs. Gillmore hip problems and pains.[186] In addition to alleviating Mrs. Gillmore's hip problems, they hoped the therapy would improve her general quality of life.[187] The sale for Mrs. Gillmore's therapy occurred at the Gillmore's home.[188] Mr. Gillmore was present with his wife during the sale.[189] Mr. Gillmore testified that the defendants' salesperson was aware Mrs. Gillmore had cancer because the salesperson directly discussed it with the Gillmores.[190] The defendants' salesperson

[181] Trial Tr. Vol. 1, 156.
[182] Trial Tr. Vol. 1, 157:1-2; D0001, Petition, ¶34; D0024, Amended Answer ¶34.
[183] Trial Tr. Vol. 1, 157:12-14.
[184] Trial Tr. Vol. 1, 157:25-158:1.
[185] Trial Tr. Vol. 1, 158:2-3.
[186] Trial Tr. Vol. 1, 159:17-23.
[187] Trial Tr. Vol. 1, 163:13-18.
[188] Trial Tr. Vol. 1, 160:16-18.
[189] Trial Tr. Vol. 1, 160:19-20.
[190] Trial Tr. Vol. 1, 161:13-162:1.

never indicated that, according to the defendants' established policies, Mrs. Gillmore's cancer should automatically disqualify her from receiving stem cell therapy.[191]

Mr. Gillmore witnessed Mrs. Gillmore's therapy.[192] Mrs. Gillmore ultimately received a shot in each hip, as well as a general wellness IV.[193] Mr. Gillmore's perception of the general wellness IV was that it was a general, whole body option.[194] His understanding of the general body shot was that "it's supposed to cover most everything on your body . . . ."[195] They also believed it could help Mrs. Gillmore's arthritis.[196] The Gillmores perceived the chance of a successful outcome as positive because the defendants' salesperson informed them that umbilical cord-derived cells Mrs. Gillmore received were the best stem cells.[197] The Gillmores paid the defendants $26,090 for her treatment.

During cross-examination Mr. Gillmore testified that the State did not offer him compensation in exchange for his testimony, and he was unaware he could be

[191] Trial Tr. Vol. 1, 161:13-162:22.
[192] Trial Tr. Vol. 1, 164:20-21.
[193] Trial Tr. Vol. 1, 163:19-22.
[194] Trial Tr. Vol. 1, 163:23-24.
[195] Trial Tr. Vol. 1, 163:25-164:16.
[196] Trial Tr. Vol. 1, 164:5-7.
[197] Trial Tr. Vol. 1, 170:4-9.

reimbursed if the State won the case.[198] The court finds Mr. Gillmore's testimony credible.

Consumer Witness Mark Frese

The State's second consumer witness was Mark Frese.[199] Mr. Frese was born in 1950, or approximately 68 years old when the defendants began doing business in Iowa.[200] Mr. Frese lives in Davenport.[201] Prior to retiring in 2011, he was a firefighter.[202] He also did physically demanding part-time work hanging sheetrock.[203]

Mr. Frese experienced a great deal of knee pain, which he attributed to years of manual labor.[204] Mr. Frese feared the prospect of having to undergo knee replacement surgery.[205] He hoped for an alternative solution.[206] Mr. Frese received the defendants' flyer in the mail, which invited him to attend a seminar.[207] He

[198] Trial Tr. Vol. 1, 167:24-168:4.
[199] Trial Tr. Vol. 2, 159.
[200] Trial Tr. Vol. 2, 159:25-160:1.
[201] Trial Tr. Vol. 2, 160:9-10.
[202] Trial Tr. Vol. 2, 160:2-8.
[203] Trial Tr. Vol. 2, 160:25-161:10.
[204] Trial Tr. Vol. 2, 161:11-13.
[205] Trial Tr. Vol. 2, 162:11-13.
[206] Trial Tr. Vol. 2, 162:8-12.
[207] Trial Tr. Vol. 2, 165:3-7.

attended the defendants' seminar in December 2019.[208] Seth Berge was the salesperson who presented the seminar he attended.[209]

One of the defendants' seminar messages that appealed to Mr. Frese was the idea that stem cell therapy could be the knee replacement surgery alternative Mr. Frese hoped to find.[210] According to Mr. Frese,

> It was presented to me as this would be a solution for your knee problems and that any limitations you have would possibly go away because of the stem cells.[211]

Based upon the defendants' presentation of the therapy, Mr. Frese perceived it was not experimental, but that "this was a tried and tested procedure to alleviate pain" for his knees.[212] He testified: "I thought they had this down. It was going to be the next mode of treatment for arthritic knees, shoulders."[213]

After the sales seminar, Mr. Berge went to Mr. Frese's home to finalize the sale. Mr. Frese purchased the stem cell therapy for $8,995.00.[214]

On the day Mr. Frese received his knee injections, the nurse practitioner had a difficult time injecting one of his knees.[215] He testified the injection needle "got

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[208] Trial Tr. Vol. 2, 165:19-21.
[209] Trial Tr. Vol. 2, 166:17-19.
[210] Trial Tr. Vol. 2, 166:25-167:11.
[211] Trial Tr. Vol. 2, 167:3-5.
[212] Trial Tr. Vol. 2, 168:6-11.
[213] Trial Tr. Vol. 2, 182:10-12.
[214] Trial Tr. Vol. 2, 170:19-23.
[215] Trial Tr. Vol. 2, 173:9-13.

stuck," and the nurse "kept moving it around."[216] He experienced intense pain when "she poked through."[217]

Within 24 hours of the shot, Mr. Frese was on his back from intense pain.[218] He attempted to communicate this unexpected pain to Summit and Ms. Decker.[219] They claimed it was possible Mr. Frese was simply experiencing a healing crisis.[220] Mr. Frese interpreted a healing crisis to mean that his pain was not a sign that he could be experiencing a dangerous health complication requiring medical attention, but was instead an expected and potentially normal part of his recovery from stem cell therapy.[221]

In the meantime, Mr. Frese diligently followed the advice that he should drink more water.[222] He felt as if he drank "half of the Mississippi" river.[223] Yet, Mr. Frese was so immobilized he was confined to using a wheelchair.[224] And drinking more water was not solving the problem.[225]

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[216] Trial Tr. Vol. 2, 173:14-16.
[217] Trial Tr. Vol. 2, 173:16-18.
[218] Trial Tr. Vol. 2, 174:3-10.
[219] Trial Tr. Vol. 2, 174:21-175:3.
[220] Trial Tr. Vol. 2, 175:4-7.
[221] Trial Tr. Vol. 2, 175:8-14.
[222] Trial Tr. Vol. 2, 175:21-23.
[223] Trial Tr. Vol. 2, 175:19-21.
[224] Trial Tr. Vol. 2, 176:14-16.
[225] Trial Tr. Vol. 2, 175:24-176:1.

Mr. Frese was admitted to a hospital, where doctors cleaned what Mr. Frese believed to be an infection out of his knees.[226] Regardless of Mr. Frese's understanding of his diagnosis, the court finds Mr. Frese received medical treatment on his knees shortly after the injections. Mr. Frese was admitted to and remained hospitalized for thirty (30) days.[227]

The court finds Mr. Frese's testimony credible. The court does not find that the stem cell shots Mr. Frese received caused what he believed to be his knee infections 24 hours later. However, the court does find that the healing crisis message Mr. Frese received was dangerous because it suggested to him that this was normal and discouraged seeking medical care. The defendants produced no evidence that drinking water after the injections was medically appropriate.

2. Consumer Witness Larry Franz

The State's third consumer witness was Larry Franz.[228] Larry was 74 years old at trial, making him about 69 years old when the defendants began doing business in Iowa.[229] Mr. Franz lived in Adel for about a decade preceding trial.[230]

[226] Trial Tr. Vol. 2, 176:20-177:7.
[227] Trial Tr. Vol. 2, 178:2-3.
[228] Trial Tr. Vol. 3, 4:16.
[229] Trial Tr. Vol. 3, 5:11-12.
[230] Trial Tr. Vol. 3, 5:13-16.

Mr. Franz had health problems and pains. He testified his right knee was bone-on-bone.[231] He also had torn both rotator cuffs during a fall.[232]

These problems significantly impacted Mr. Franz's quality of life for many years.[233] Mr. Franz is unable to do some of things [he] used to be able to do.[234] Mr. Franz's shoulders pop," and he has no strength when he lifts his arms above his head.[235] He is unable to throw a ball or play basketball.[236] When he does his laundry in his downstairs basement, he carries the clothes hamper backwards down the stairs to lift it only a few steps at a time due to his limitations.[237]

Mr. Franz received the defendants' mail solicitation –that read, "Imagine a life without pain – Yes, it's possible." [238] Mr. Franz described this as a wonderful message because he believed it would rid him of his ongoing and limiting pain.[239] Mr. Franz reviewed all the other claims appearing on the defendants' mail solicitation, such as: "Stem cell therapy is not the future. It's today."[240] "Regenerative medicine uses stem cells to regenerate and repair tissues in your

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[231] Trial Tr. Vol. 3, 7:4-6.
[232] Trial Tr. Vol. 3, 7:7-9.
[233] Trial Tr. Vol. 3, 8:19-22.
[234] Trial Tr. Vol. 3, 9:2-5.
[235] Trial Tr. Vol. 3, 8:6-14.
[236] Trial Tr. Vol. 3, 8:15-18.
[237] Trial Tr. Vol. 3, 9:6-9.
[238] D0144, Trial Ex. 22; Trial Tr. Vol. 3, 10:10-11:21.
[239] Trial Tr. Vol. 3, 11:3-6.
[240] *Id.* at Vol. 3, 11:7-12

body that are damaged due to age, disease and defects."[241] "Stem cells have the power to go to these damaged areas and generate new cells, rebuilding and repairing the area.[242] That he would learn at the defendants' seminars "Why stem cells heal so many things."[243] He believed the word heal meant the defendants' treatment would fix his problems.[244]

Mr. Franz attended the defendants' seminar in Winterset at the Sports Page Grill.[245] There were about 20 to 30 consumers present during the seminar.[246] He described the crowd as older because no one appeared to be kids or around 20 years old.[247]

The presenter that day was Seth Berge.[248] One of Mr. Berge's messages to the audience was that the stem cells they would receive were "brand-new cells as opposed to the cells in me that would be 65, 70 years old; that these would do more things and have more healing."[249] In other words, there was an important association between how young a cell was and how effective it could be for Mr.

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[241] *Id.* at Vol. 3, 11:13-16.
[242] *Id.* at Vol. 3, 12:1-2.
[243] *Id.* at 12:8-11.
[244] Trial Tr. Vol. 3, 12:8-14.
[245] Trial Tr. Vol. 3, 12:17-25.
[246] Trial Tr. Vol. 3, 13:14-16.
[247] Trial Tr. Vol. 3, 13:17-23.
[248] Trial Tr. Vol. 3, 14:3-4.
[249] Trial Tr. Vol. 3, 14:8-15.

Franz and other consumers.[250] Mr. Franz also got the impression he "would grow new cartilage and maybe attach my parts on my shoulders that aren't attached."[251]

During the seminar Mr. Franz received the defendants' handout, "Stem Cells: The Future of Medicine, Health and Longevity." [252] Mr. Franz took this handout "at its word" – "I was very hopeful."[253]

Based on the defendants' messaging, Mr. Franz believed he would receive "30 million" stem cells in his therapy – not 30 million other types of cells.[254] He expected every one of the 30 million stem cells to be alive at the time of his therapy.[255] He also believed the 30 million stem cells would effectively be received by his own body – not destroyed by his body's immune system.[256] He believed the cells would be in his body "forever."[257] If anyone had informed Mr. Franz that the cells would be destroyed within hours or days, Mr. Franz would not have purchased the therapy.[258] Additionally, Mr. Franz would not have purchased the

[250] Trial Tr. Vol. 3, 14:19-21.
[251] Trial Tr. Vol. 3, 14:16-18.
[252] D0149, Trial Ex. 27; Trial Tr. Vol. 3, 14:22-15:4.
[253] Trial Tr. Vol. 3, 15:17-20.
[254] Trial Tr. Vol. 3, 15:21-16:7.
[255] Trial Tr. Vol. 3, 16:11-13.
[256] Trial Tr. Vol. 3, 16:14-16.
[257] Trial Tr. Vol. 3, 24:24-25:2.
[258] Trial Tr. Vol. 3, 24:20-23.

therapy if he believed it was potentially unsafe and would hurt rather than help him.[259]

Based upon these representations, Mr. Franz purchased stem cell therapy from the defendants hoping it would help his knee and his rotator cuffs.[260] Seth Berge, the person who gave Mr. Franz's seminar, finalized the sale.[261] Mr. Franz paid $7,495.00 for the therapy.[262] He testified that that was a lot of money to him.[263]

Mr. Berge nor anyone from the defendants discussed Mr. Franz's medical history or reviewed his medical records to determine if the therapy was appropriate given Mr. Franz's individual circumstances.[264] Additionally, Mr. Franz testified no one orally informed him he had a 3-day right to cancel Mr. Berge's sale to him.[265] He did not know whether he had a right to cancel.[266]

Mr. Franz received a voicemail from Mr. Berge after the sale in which Mr. Berge informed him a medical board had approved Mr. Franz receiving therapy.[267] Mr. Franz never spoke to a medical board, so he was surprised and confused what

[259] Trial Tr. Vol. 3, 25:14-17.
[260] Trial Tr. Vol. 3, 7:6-12.
[261] Trial Tr. Vol. 3, 17:2-4.
[262] Trial Tr. Vol. 3, 18:21-23.
[263] Trial Tr. Vol. 3, 18:24-25.
[264] Trial Tr. Vol. 3, 17:11-20.
[265] Trial Tr. Vol. 3, 18:16-18.
[266] Trial Tr. Vol. 3, 18:19-20.
[267] Trial Tr. Vol. 3, 19:1-11.

that meant.[268] However, Mr. Franz assumed the voicemail meant the idea of him receiving therapy "went through some doctors and they okayed it . . ."[269] He was unsure how or why that had occurred because he had not yet spoken to anyone besides Mr. Berge.[270]

Mr. Franz received therapy inside his home in September 2019.[271] He believed it was weird to receive the therapy inside his house rather than in a clinical setting.[272]

Lisa Decker injected the product into Mr. Franz's right knee and both shoulders.[273] Decker did not use any other equipment to guide placement of the injection needle, but that did not seem strange because Mr. Franz believed the defendants' claim: "It was supposed to find where it was needed."[274]

Mr. Franz did not experience any relief following the therapy.[275] None of the lifestyle limitations he experienced were abated.[276] He did not request a refund or complain to the Attorney General.[277] He did not believe the defendants would

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[268] Trial Tr. Vol. 3, 20:6-14.
[269] Trial Tr. Vol. 3, 20:15-18.
[270] Trial Tr. Vol. 3, 20:18-22.
[271] Trial Tr. Vol. 3, 22:6-15.
[272] Trial Tr. Vol. 3, 21:1-9.
[273] Trial Tr. Vol. 3, 21:10-19.
[274] Trial Tr. Vol. 3, 21:20-22:2.
[275] Trial Tr. Vol. 3, 24:10-12.
[276] Trial Tr. Vol. 3, 24:13-16.
[277] Trial Tr. Vol. 3, 23:18-24:3.

refund his money.[278] He regrets spending his money on the therapy because he felt "it was for nothing."[279] The court finds Mr. Franz's testimony credible.

3. Consumer Witness Stephen Sells

The State's fourth consumer witness was Stephen Sells.[280] Mr. Sells resides in Altoona.[281] He is retired.[282] Prior to retiring, Mr. Sells held several jobs. He served in the Marine corps, was a truck driver, worked in a Goodridge Corporation factory where he handled heavy steel, and was a mechanic for Ruan Transportation.[283] Most of his jobs were physically demanding.[284]

Mr. Sells suffered from degenerative disc disease as well as arthritis throughout his body.[285] These problems began in 1993 and got worse as he grew older.[286] Mr. Sells experienced back problems while he drove trucks.[287]

Mr. Sells' back problems impacted his life. He had little mobility and walked stooped over.[288] He described two instances that essentially immobilized

[278] Trial Tr. Vol. 3, 23:18-21.
[279] Trial Tr. Vol. 3, 25:22-25.
[280] Trial Tr. Vol. 3, 29.
[281] Trial Tr. Vol. 3, 29:18-19.
[282] Trial Tr. Vol. 3, 29:24-25
[283] Trial Tr. Vol. 3, 30:1-11.
[284] Trial Tr. Vol. 3, 30:14-15.
[285] Trial Tr. Vol. 3, 30:18-21.
[286] Trial Tr. Vol. 3, 30:22-25.
[287] Trial Tr. Vol. 3, 31:23-25.
[288] Trial Tr. Vol. 3, 32:1-4.

him.[289] In both instances the pain Mr. Sells experienced was incredibly intense. He testified: "I've had to pass a kidney stone, and it was just as bad."[290]

The physical pain impacted Mr. Sells' mental condition.[291] As a former Marine, his limitations made him feel "useless."[292] Mr. Sells testified there were "multiple times I thought of suicide."[293] He sought psychiatric help.[294] In therapy he described his pain and how he contemplated killing himself to alleviate the pain.[295]

These were Mr. Sells' circumstances when the defendants solicited him. Mr. Sells received the defendants' mail solicitation inviting him to attend their seminar at the Waterfront Seafood Restaurant in Ankeny.[296] Mr. Sells attended with his wife.[297] There were about 22 people in the room, including Mr. Sells, his wife and the two speakers.[298] Mr. Sells' perceived he was one of the youngest individuals in

[289] Trial Tr. Vol. 3, 32:4-22
[290] Trial Tr. Vol. 3, 32:23-33:3.
[291] Trial Tr. Vol. 3, 33:4-7.
[292] Trial Tr. Vol. 3, 33:8-12.
[293] Trial Tr. Vol. 3, 33:8-9.
[294] Trial Tr. Vol. 3, 33:16-18.
[295] Trial Tr. Vol. 3, 33:18-21.
[296] Trial Tr. Vol. 3, 34:20-23.
[297] Trial Tr. Vol. 3, 35:16-17.
[298] Trial Tr. Vol. 3, 36:6-8.

the audience.[299] The majority of the audience members "had silver or gray hair."[300] There were no 20-year-olds present.[301]

One of the two seminar presenters that day was Scott Thomas. Mr. Sells identified Thomas in the courtroom during trial.[302] He testified that Thomas presented most of the seminar Mr. Sells attended.[303]

He testified that Thomas appeared "knowledgeable about the product," was "well-mannered," and "very informative and convincing."[304] Mr. Sells had the impression that Thomas "knew a lot about stem cells."[305] He testified Thomas spoke medically about "how it would help and the things that it could do and the possibilities."[306]

One message given to the audience that made an impression on Mr. Sells was about the pain that had tormented him:

> when you have pain in your body, it [the stem cells] sends a message to the brain. And should you have stem cell injections, it's like a little ambulance is going to go rushing to that area where the pain is, and it's going to support that tissue that—those cells of your body and help rebuild it with the products….[307]

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[299] Trial Tr. Vol. 3, 41:21-23.
[300] Trial Tr. Vol. 3, 41:24.
[301] Trial Tr. Vol. 3, 41:25-42:1.
[302] Trial Tr. Vol. 3, 36:9-15.
[303] Trial Tr. Vol. 3, 36:19-21.
[304] Trial Tr. Vol. 3, 37:3-7.
[305] Trial Tr. Vol. 3, 37:8-10.
[306] Trial Tr. Vol. 3, 37:11-15.
[307] Trial Tr. Vol. 3, 37:16-25.

Additionally, Mr. Sells remembered another message given during the seminar about the younger age of the cells he could purchase:

> …if they use the cells from your own body at the age you are, you're just, in turn, getting old cells put back into your body. Whereas, these new cells, because they were supposedly harvested from umbilical cords and those cells were infantile, so to speak, and they were like brand-new, and as they are working in your body, they adapt to your body, and they help your body to heal and to start to grow and grow stronger.[308]

Mr. Sells was convinced that the defendants had physical clinic locations where the stem cell therapy was provided.[309] Having clinic locations reinforced his belief the defendants' business was legitimate.[310] "It told me that it was an established business, that they've dealt with medical situations or medical procedures for some time . . ."[311]

Mr. Sells believed the claims made during his seminar.[312] He "was looking for something that was on the newer edge of medical sciences that could help with [his] situation because [he] dealt with so much pain."[313]

Mr. Sells also heard testimonials during the seminar from people who claimed they received stem cell therapy with successful results.[314] The testimonials

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[308] Trial Tr. Vol. 3, 38:1-11.
[309] Trial Tr. Vol. 3, 38:17-21.
[310] Trial Tr. Vol. 3, 38:22-25.
[311] Trial Tr. Vol. 3, 39:1-6.
[312] Trial Tr. Vol. 3, 38:12-14.
[313] Trial Tr. Vol. 3, 38:12-16.
[314] Trial Tr. Vol. 3, 40:22-41:2.

influenced Mr. Sells' decision to purchase the therapy from the defendants.[315] He believed it was likely he could receive the same good result as the satisfied customers.[316]

Mr. Sells did not purchase the minimum dosage the defendants offered.[317] Mr. Sells worried the minimum option would not be enough to bring him relief.[318] And during the seminar presentation Thomas gave the message that "the more stem cells you had, . . . the more good it's going to do to your body,"[319] even though the defendants admitted in response to the State's petition:

> [T]here are no uniform or objective dosing criteria for umbilical cord derived cells for the conditions Biologics purported to treat that have been proven or otherwise established in the field of regenerative medicine.[320]

As a result, Mr. Sells purchased six treatments.[321] It was possible to buy even more, but that depended "on how big your wallet is."[322]

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[315] Trial Tr. Vol. 3, 41:6-13.
[316] Trial Tr. Vol. 3, 41:3-5.
[317] Trial Tr. Vol. 3, 40:13-15.
[318] Trial Tr. Vol. 3, 40:5-10.
[319] Trial Tr. Vol. 3, 40:16-21.
[320] D0001, Petition, ¶119; D0024, Amended Answer ¶119.
[321] Trial Tr. Vol. 3, 40:11-12.
[322] Trial Tr. Vol. 3, 40:13-15.

Mr. Sells received his therapy from Lisa Decker in his home.[323] Mr. Sells video recorded the therapy and took some photographs.[324] Mr. Sells explained why he recorded the procedure.

> I did it so that should my regular doctor need to know what went on, I would have proof to show, if they so desired to. It was a big expense, and I just thought it was important to keep this as a reminder of what happened. It's like keeping a sales receipt for something special that you buy. You want to have proof that something did happen.[325]

The State also admitted photographs taken by Mr. Sells.[326] The photographs demonstrated that Ms. Decker did not use sterile clinical procedures for administering the injections. She did not use gloves. The syringes were placed on Mr. Sells' uncovered kitchen table. The kitchen table was not sterilized prior to the injections.[327]

Ms. Decker did not tell Mr. Sells where she would be injecting him with stem cells; rather, she asked for instructions from him.[328] She states: "Show me on your neck where you want me to go."[329] Mr. Sells testified he thought it was strange for the nurse to ask him where the stem cell injection should be administered: "they should have known I was having spinal injections. It should

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[323] Trial Tr. Vol. 3, 42:12-16.
[324] D0130, Trial Ex. 8.
[325] Trial Tr. Vol. 3, 43:20-44:4.
[326] D0131, Trial Ex. 9.
[327] D0131, Trial Ex. 9 at 147; Trial Tr. Vol. 3, 51:8-10.
[328] Trial Tr. Vol. 3, 45:-11.
[329] D0130, Trial Ex. 8 (approx. 50 to 55 seconds).

have been mapped out before this clinician came to my home."[330] That was not the only time Ms. Decker looked to her patient for direction on where to inject the stem cell products. Later, Ms. Decker felt around Mr. Sells' back and Mr. Sells told her where he believed the injections should be administered on specific portions around his spine stating that "would be a good spot."[331] The video demonstrated the multiple areas that Ms. Decker injected the stem cell therapy and the pain that Mr. Sells endured.[332]

During the procedure Ms. Decker told Mr. Sells: "There's so many research trials out there that have shown that this is so effective. And big pharma companies don't want to pay for it."[333] Mr. Sells believed Ms. Decker's statements.[334]

Mr. Sells described his understanding of what the stem cell products he received could accomplish:

> It's knowing where to go. All the ambulances are going to the right spot. That was the other explanation they gave to me – your body has been calling for ambulances to come deal with the pain and there are slow getting there. These little friends are gonna get there quicker and are gonna replicate a lot quicker, too.[335]

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[330] Trial Tr. Vol. 3, 44:19-25.
[331] D0130, Trial Ex. 8 (approx. 3:42 to 4:40).
[332] D0130, Trial Ex. 8.
[333] D0130, Trial Ex. 8 (approx. 6:22-6:34).
[334] Trial Tr. Vol. 3, 45:12-46:7.
[335] D0130, Trial Ex. 8 (approx. 14:46 to 15:10).

Ms. Decker informed Mr. Sells that 15% of patients experience flu-like symptoms.[336] However, those symptoms would go away after a couple weeks.[337] Ms. Decker also informed Mr. Sells that "some patients experience what we call a healing crisis," and that he may experience "inflammation" or a "deep ache" at "the injection site."[338] However, that would be completely normal because that is "when the cells are uptaking into those areas of inflammation and they're doing their job. They send out chemicals to other cells to come help out and repair the cells that need to be repaired."[339] "When they send out those chemical signals, you get a little bit of inflammation at the site as the chemicals come to the area that they need to come to and you might have a little bit of achiness..."[340]

Mr. Sells paid the defendants $19,795.00 for this therapy.[341] That was a lot of money to Mr. Sells.[342]

Mr. Sells testified there were several assumptions about the stem cell procedure that were material to his decision to purchase it. First, he did not believe

[336] D0130, Trial Ex. 8 (approx. 15:31 to 15:35).
[337] D0130, Trial Ex. 8 (approx. 15:35 to 15:40).
[338] D0130, Trial Ex. 8 (approx. 15:52 to 16:03).
[339] D0130, Trial Ex. 8 (approx. 16:03 to 16:15).
[340] D0130, Trial Ex. 8 (approx. 16:15 to 16:22).
[341] Trial Tr. Vol. 3, 54:8-10.
[342] Trial Tr. Vol. 3, 54:11-13.

his own immune system would kill stem cells he received within hours or days.[343] He believed the defendants' claims that the opposite would occur:

> I was told at the seminar that once injections are applied, … that those cells would double after 24 to 48 hours, and then after another certain amount of time they would double again. They continued to increase…[344]

Second, Mr. Sells believed every product he received contained live cells that would be biologically effective and the numbers of cells the products contained mattered in terms of how efficacious the therapy could be.[345]

> I was under the impression the more …stem cells, that you would have, the better your operational chance of recuperating or improving would be much greater.[346]

Third, Mr. Sells believed his therapy was clearly FDA-approved.[347]

> If it was legal, if it was safe, I wanted to try it. And having been in pain for so many years, you're willing to do a lot of things to alleviate that pain, suicide included.[348]

Mr. Sells was a dissatisfied customer.[349] He felt let down and developed a gray feeling when he realized he would not receive any more contact after the final 6-month follow-up call:

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[343] Trial Tr. Vol. 3, 56:13-21.
[344] Trial Tr. Vol. 3, 56:3-9.
[345] Trial Tr. Vol. 3, 56:22-57:5; 58, lines 1-2.
[346] Trial Tr. Vol. 3, 57, lines 23-58:2.
[347] Trial Tr. Vol. 3, 59:19-60:4.
[348] Trial Tr. Vol. 3, 60:1-4.
[349] Trial Tr. Vol. 3, 55:1-12.

> there's nothing more you can do. It's done. It's over. You can't get anything more… I just was hoping for something more, but nothing credible came my way. It was over. Nothing I could do.[350]

The court finds Mr. Sells' testimony credible.

4. Consumer Witness Sharon Ballard

The State's fifth consumer witness was Sharon Ballard. Mrs. Ballard resided in Council Bluffs where she lived for 38 years.[351] She earned a degree in elementary education taught in a Christian school.[352]

Ms. Ballard suffered from back pains.[353] Her back pain originated when she was in high school.[354] She had a successful "fusion" surgery but reinjured it. She had a second surgery but the pain persisted without relief.[355] This pain was also felt in her left foot and two of her toes.[356] Mrs. Ballard described the constant pain she experienced as:

> like, you have your arms crossed wrong, it kind of goes to sleep, and it feels like a tingling, painful sensation. That's what it felt like all the time.[357]

Mrs. Ballard took narcotic pain relievers like Percocet to cope with her pain.[358]

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[350] Trial Tr. Vol. 3, 55:13-20.
[351] Trial Tr. Vol. 4, 20:9-12.
[352] Trial Tr. Vol. 4, 21:2-22.
[353] Trial Tr. Vol. 4, 21:23-25.
[354] Trial Tr. Vol. 4, 22:4-9.
[355] Trial Tr. Vol. 4, 22:10-18.
[356] Trial Tr. Vol. 4, 22:23-23:2.
[357] Trial Tr. Vol. 4, 23:8-12.
[358] Trial Tr. Vol. 4, 23:13-23.

She testified the pain was daily:

> It's, like, always in your head, and it never goes away. It really affects -- for me, at least it just affected every part of my life.[359]

It was difficult for Mrs. Ballard to sit and ride in a vehicle, access items in lower cupboards, and sitting in church.[360]

Mrs. Ballard tried other interventions apart from surgery with no success.[361] For example, she tried acupuncture, chiropractic, steroid injections, and a back brace.[362] She was desperate for relief.[363]

Mrs. Ballard believes her mother received the defendants' mail solicitation advertising their seminars in Council Bluffs.[364] Mrs. Ballard attended the defendants seminar with her parents and her husband.[365] The reason Mrs. Ballard attended in a family group was because both she and her mother were looking for back pain relief, and Mrs. Ballard was going to see if stem cell therapy worked for her before her mother tried it.[366] The seminar Mrs. Ballard attended was held in a

[359] Trial Tr. Vol. 4, 23:24-24:2.
[360] Trial Tr. Vol. 4, 24:3-10.
[361] Trial Tr. Vol. 4, 25:3-14.
[362] Trial Tr. Vol. 4, 25:3-14.
[363] Trial Tr. Vol. 4, 25:15-17.
[364] Trial Tr. Vol. 4, 25:18-25.
[365] Trial Tr. Vol. 4, 25:18-25.
[366] Trial Tr. Vol. 4, 26:8-15.

conference room of a restaurant called Tisha's.[367] The speaker was named "Seth."[368]

Mrs. Ballard testified that the seminar audience of approximately 15 to 20 people were generally older individuals.[369] Mrs. Ballard was in her mid-50s at the time she attended.[370] She did not remember anyone younger than her and her husband.[371]

After attending the seminar, Mrs. Ballard's understood the stem cell therapy would "offer. . .a type of healing that I hadn't had access to."[372] "[She] was desperate for healing at that point, and I was holding onto that hope that it could help heal me."[373]

Seth the same salesperson closed her sale.[374] Mrs. Ballard did not remember Seth informing her she had a 3-day right to cancel the transaction.[375] She also could not recall any person asking her whether she had health conditions that automatically precluded her from receiving stem cell therapy.[376] She denied

[367] Trial Tr. Vol. 4, 26:19-23.
[368] Trial Tr. Vol. 4, 27:2.
[369] Trial Tr. Vol. 4, 28:9-11 and 17-25.
[370] Trial Tr. Vol. 4, 28:9-11 and 17-25.
[371] Trial Tr. Vol. 4, 28:9-11 and 17-25.
[372] Trial Tr. Vol. 4, 29:19-25.
[373] Trial Tr. Vol. 4, 30:29-25.
[374] Trial Tr. Vol. 4, 32:25-33:14.
[375] Trial Tr. Vol. 4, 34:16-20.
[376] Trial Tr. Vol. 4, 35:17-20.

completing written forms where she would have to disclose health history or related information and denied familiarity with the defendants' prescreening document.[377]

Mrs. Ballard paid $8,000 for the therapy.[378] This was a considerable amount of money for her. "We were basically surviving on my $13,000 a year at the day care."[379]

Mrs. Ballard received the therapy inside the elementary school building where she worked.[380] She wanted to go to an "office space that was clean and sanitary."[381] She did not feel comfortable getting treatment in the school room.[382] However, she settled for doing the procedure in the school because of staffing issues at the school.[383] Also, she felt it probably was not an option to get her money back by that time because it was too far into the process.[384]

The nurse administered the injections in Mrs. Ballard's lower back.[385] The nurse asked Mrs. Ballard where on her body she thought the injections should

[377] Trial Tr. Vol. 4, 43:9-23; D0199, Trial Ex. 47.
[378] Trial Tr. Vol. 4, 34:21-23.
[379] Trial Tr. Vol. 4, 27:20-28:5.
[380] Trial Tr. Vol. 4, 35-37.
[381] Trial Tr. Vol. 4, 35-37.
[382] Trial Tr. Vol. 4, 37:14-16.
[383] Trial Tr. Vol. 4, 37:5-13.
[384] Trial Tr. Vol. 4, 37:21-38:2.
[385] Trial Tr. Vol. 4, 38:21-22.

go.[386] Mrs. Ballard was taken aback that the administering nurse looked to her for direction on where the injections should go but went with it.[387]

The factors that swayed Mrs. Ballard's purchase included: She did not believe her own immune system would destroy any cells introduced into her body and would not have purchased them had she believed otherwise.[388] She believed she could potentially receive a benefit from the cells for up to a year.[389] She considered the therapy to be safe and would not contain anything that could harm her and this also factored into her decision to buy it.[390] She would not have purchased the therapy if she had believed the cells would not be expected to last more than hours or days.[391]

Mrs. Ballard experienced no relief from her injections.[392] She was disappointed.[393] The court finds Mrs. Ballard's testimony credible.

[386] Trial Tr. Vol. 4, 38:23-39:2.
[387] Trial Tr. Vol. 4, 39:1-5.
[388] Trial Tr. Vol. 4, 40:1-4.
[389] Trial Tr. Vol. 4, 40:1-4.
[390] Trial Tr. Vol. 4, 40:19-41:8.
[391] Trial Tr. Vol. 4, 40:13-18.
[392] Trial Tr. Vol. 4, 40:5-12.
[393] Trial Tr. Vol. 4, 41:9-12.

5. Consumer Witness Sherry Cain

The State's sixth consumer witness was Sherry Cain. Mrs. Cain was 71 years old when she received therapy.[394] She is a resident of Tabor.[395] Before she retired, Mrs. Cain was a nurse.[396]

Mrs. Cain suffered from back pain.[397] The back pain greatly impacted her life. She testified:

> If I stood for very long, it would shoot a pain down my back into the back of my buttock area and down my legs, the back of my legs. Also, if I sat for very long, I would get numbness and tingling in my right leg when I would stand up, and then I couldn't sleep at night for the problems.[398]

This created many limitations for Mrs. Cain:

> I couldn't exercise. I couldn't take a walk for very long without starting to hurt my hip, my back. I couldn't sleep at night. Couldn't get comfortable in any position, and I had a little great-granddaughter, Penny, and I couldn't do a lot of things with her. To get down on the floor and play or if I wanted to pick her up, I couldn't do it. It hurt.[399]

She was desperate for relief.[400]

Mrs. Cain received the defendants' mail solicitation inviting her to attend their sales seminar.[401] One message on the defendants' mailer that stood out to her

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[394] Trial Tr. Vol. 4, 46:20-47:3.
[395] Trial Tr. Vol. 4, 47:4-5.
[396] Trial Tr. Vol. 4, 47:9-15.
[397] Trial Tr. Vol. 4, 47:18-24.
[398] Trial Tr. Vol. 4, 48:15-20.
[399] Trial Tr. Vol. 4, 48:21-49:3.
[400] Trial Tr. Vol. 4, 49:4-5.
[401] Trial Tr. Vol. 4, 49:6-18.

was: "Imagine your life without pain. Yes, It's possible."[402] She testified: "When you're desperate with pain, that caught my eye."[403]

Mrs. Cain read the defendants' claim she could hear from industry experts during the seminar.[404] She interpreted this message to mean the defendants were "specialized, and they had training to be able to give their expertise in stem cells is what it meant to me, that they had specific training in that field."[405]

Mrs. Cain was also interested in the defendants' claim she may avoid surgery by undergoing stem cell therapy.[406] However, Mrs. Cain eventually underwent surgery after she purchased the defendants' stem cells and because she experienced no relief from the pain.[407]

Mrs. Cain attended the seminar, where Rylee Meek was the presenter.[408] The crowd consisted of older individuals and seemed around Mrs. Ballard's age of 71.[409] She did not recall witnessing anyone who appeared in their 20s in the audience.[410]

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[402] Trial Tr. Vol. 4, 49:19-50:1; D0144, Trial Ex. 22.
[403] Trial Tr. Vol. 4, 49:19-50:1.
[404] Trial Tr. Vol. 4, 50:6-16.
[405] Trial Tr. Vol. 4, 50:6-16.
[406] Trial Tr. Vol. 4, 50:22-51:5.
[407] Trial Tr. Vol. 4, 51:1-5.
[408] Trial Tr. Vol. 4, 51:11-23.
[409] Trial Tr. Vol. 4, 52:1-53:2.
[410] Trial Tr. Vol. 4, 52:25-532.

Mrs. Cain received and reviewed one of the defendants' handouts that listed several positive testimonials about stem cell therapy.[411] These testimonials factored into Mrs. Cain's decision to purchase the defendants' therapy:

> They were from real people, and some of them were like, 'immediate relief the next day… And I just thought it was remarkable.[412]

Meek closed the sale with Mrs. Cain at her home following the seminar.[413] The cost to Mrs. Cain was $8,995.00.[414] She paid by credit card and later withdrawing funds from her retirement fund account.[415]

Mrs. Cain received the treatment from Lisa Decker at her home in Tabor.[416] However, she believed it was an option to go to a physical clinic location – but having a nurse practitioner come to her home would be easier than traveling in her car where her back could hurt.[417]

Mrs. Cain received an injection in her lower lumbar and in her right hip.[418] Mrs. Cain – a former nurse – found it odd that the administering nurse did not leave her any paperwork documenting "what injection [she] got…"[419]

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[411] Trial Tr. Vol. 4, 54:14-55:9.
[412] Trial Tr. Vol. 4, 55:1-9.
[413] Trial Tr. Vol. 4, 51:11-23.
[414] Trial Tr. Vol. 4, 53:14-15.
[415] Trial Tr. Vol. 4, 51:21-23; 53:17-20.
[416] Trial Tr. Vol. 4, 55:13-58:7.
[417] Trial Tr. Vol. 4, 55:16-23.
[418] Trial Tr. Vol. 4, 56:9-12.
[419] Trial Tr. Vol. 4, 56:13-22.

Mrs. Cain felt "devastated" to not feel relief.[420]

> I was devastated. It didn't feel any better. And, to be honest, I was embarrassed. I didn't tell my kids. I didn't tell any friends that I had had stem cell injections. I was just totally embarrassed that I spent that much money, and it didn't work.[421]

She testified: "I was so angry, depressed, the whole bit …"[422] The court finds Mrs. Cain's testimony credible.

6. Consumer Witness Julie A. Vander Plas

The State's seventh consumer witness was Julie Vander Plas. Mrs. Vander Plas was born in June 1950, making her about 68 years old at the time the defendants began doing business in Iowa.[423] Mrs. Vander Plas' husband, was about 69 years old at the time the defendants began doing business in Iowa.[424]

Mrs. Vander Plas had some health problems, including a heart murmur and bowel issues.[425] However, her husband Mr. Vander Plas had many more health issues in 2019, including rheumatoid arthritis, tremors, thyroid neuropathy, Type 2 diabetes, high blood pressure, MRSA, incontinence, hearing issues and vision problems.[426] He took "30-plus" prescription medications per day.[427]

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[420] Trial Tr. Vol. 4, 57:9-15.
[421] Trial Tr. Vol. 4, 57:11-15.
[422] Trial Tr. Vol. 4, 59:17.
[423] Trial Tr. Vol. 5, 82:11-12.
[424] Trial Tr. Vol. 5, 97:16-20.
[425] Trial Tr. Vol. 5, 83:4-9.
[426] Trial Tr. Vol. 5, 83:7-14.
[427] Trial Tr. Vol. 5, 83:16, 24-84:1.

The Vander Plas attended the defendants' seminar at "4 Brothers" restaurant in Le Mars on August 27, 2019.[428] One thing the seminar speaker told the audience was that the procedures the defendants sold involved a specific type of stem cell:

> I remember they said that there were four kinds of stem cell treatments that you could use, and the one they used was the one that interested us the most because they used the human umbilical cord from a newborn baby with -- a healthy baby and a healthy parent and that they consented to the use of the cord -- the stem cells from that cord. It was the good stuff, so it didn't have any -- it would take on your body DNA. In other words, it wouldn't have anything that -- that would impair it from helping you.[429]

Mrs. Vander Plas also remembered the seminar speaker tell the audience the procedures the defendants sold had a "90% success rate."[430]

Also Seth Berge, claimed: "One injection to last your lifetime in the area that you got it."[431] Her understanding was: "[I]f they give it in the knees, then it would last in the knees."[432] She testified: "At that time [Mr. Vander Plas'] knees were really bad. His hip was bad. He had all these issues, so we were really excited about that."[433]

Mrs. Vander Plas testified she had received an advertising pamphlet during the seminar with Summit branding.[434] The State had requested the defendants to

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[428] Trial Tr. Vol. 5, 82:19-83:2.
[429] Trial Tr. Vol. 5, 84:15-85:1.
[430] Trial Tr. Vol. 5, 83:2-6.
[431] Trial Tr. Vol. 5, 85:5-87:1.
[432] Trial Tr. Vol. 5, 86:16-20.
[433] Trial Tr. Vol. 5, 85:8-10.
[434] Trial Tr. Vol. 5, 87-91; D0268, Trial Ex. 98.

provide all advertising they presented to Iowa consumers and their response failed to include the pamphlet their salesperson gave to Mrs. Vander Plas.[435] Meek claimed during his testimony he had provided all advertising materials to the State and acknowledged he had been asked to do so during his deposition.[436] However, when confronted with the undisclosed pamphlet Mrs. Vander Plas received, Meek claimed: "This particular piece I've never seen before."[437]

The pamphlet made the following declarations: It stated that stem cells "can become any one of the 220 different cells in the body."

> Because cells are only one day old and from a healthy born umbilical cord, those cell (sic) may turn into ANY cell your body needs (e.g. bone cells, heart cells, liver cells, skin cells, etc.
>
> There's only one kind of stem cell option which fits ALL of the following criteria: Safe, non-surgical, fast recovery time, ethical, trusted by medical practitioners. Answer: Umbilical cord blood stem cells." It further claimed umbilical cord cells were "unlike autologous stem cells obtained through liposuction or bone marrow collection, which have an increased risk, cost and liability.
>
> [MSCs] have a higher proliferative capacity meaning they replicate faster than older cells. This translates in to much faster healing in recipients." Further, "MSCs have a larger amount of different growth factors. Growth factors typically act as signaling molecules between cells…[438]

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[435] D0142, Trial Ex. 11 at 165 (9. Provide exemplar copies of all written materials the Respondents' door-to-door salespersons gave to or otherwise exchanged with Iowa consumers on or after January 1, 2017. Include all advertising materials (brochures, pamphlets, etc.)….")
[436] Trial Tr. Vol. 5, 7:16-22.
[437] Trial Tr. Vol. 5, 28:1-3.
[438] Trial Ex. 98

> Backed by 30 years of research, umbilical cord stem cells have been applied to support people who have symptoms from more than 80 diseases. At Summit Health Centers, our goal is to address the underlying cause of disease and not simply treat symptoms… We offer one of a kind service and customized treatment plans aimed at maximizing results in the shortest amount of time possible.

The pamphlet provided a healing timeline that stated during the first

> 2-6 months: The stem cells are continuing to repair and create new tissue…. 6+ months… it is not uncommon to still experience improvements for up to 18 months.

Finally, the pamphlet claimed

> our licensed doctors will determine your eligibility for the procedure… Once you have been deemed suitable for the procedure, we will schedule an appointment for your restorative therapy.[439]

Both Mrs. Vander Plas and her husband received therapy.[440] Mr. Vander Plas received one injection in each knee, one injection in his hip, and a general wellness IV, while Mrs. Vander Plas received a general wellness IV for her overall health.[441] The salesperson claimed the general wellness IV "would go to the part of your body that needed it the most, so whatever part that was."[442]

Mrs. Vander Plas and her husband paid the defendants $28,395.00. Mr. Vander Plas' treatments were $19,400.00 and Mrs. Vander Plas' therapies were

[439] D0268, Trial Ex. 98.
[440] Trial Tr. Vol. 5, 93:12-18.
[441] Trial Tr. Vol. 5, 93:12-18.
[442] Trial Tr. Vol. 5, 94:8-10.

$8,995.00 for Mrs. Vander Plas' IV therapy.[443] The court finds Mrs. Vander Plas' testimony credible.

7. Consumer Witness Leyla Rose Shrunk

The State's eighth consumer witness was Leyla Rose Shrunk. Mrs. Shrunk was born in December 1948.[444] Mrs. Shrunk is married to James Francis Shrunk.[445] Mr. Shrunk was born in March 1962.[446]

In August 2019, Mrs. Shrunk was suffering from joint pain and osteoarthritis.[447] The Shrunks attended one of the defendants' sales seminars alongside Julie Vander Plas and her husband, Duane Vanderplas.[448] Mrs. Shrunk summarized the mail solicitation she received as follows:

> Well, the invitation said that you could be free of pain, and they could take the pain away, and it regenerated your cells, or they could go to different parts of your body and make new tissue repair…[449]

Mrs. Shrunk verified that she also received the same pamphlet from the defendants' salesperson that Mrs. Vander Plas received.[450]

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[443] Trial Tr. Vol. 5, 94:20-22.
[444] Trial Tr. Vol. 5, 99:1-2.
[445] Trial Tr. Vol. 5, 99:8-9.
[446] Trial Tr. Vol. 5, 99:10-11.
[447] Trial Tr. Vol. 5, 99:18-21.
[448] Trial Tr. Vol. 5, 100:9-11.
[449] Trial Tr. Vol. 5, 100:16-20.
[450] Trial Tr. Vol. 5, 102:13-25.

Mr. Shrunk received a knee injection.[451] Mrs. Shrunk received a general wellness IV.[452] She testified about her understanding of what the general IV could accomplish for her:

> All I know is that it would go to any part of your body. I think that even the injections could go to different parts. They didn't know if it would stay exactly where. The reason I had a push was so that it could go to any part of my body to fix me.[453]

It took Mrs. Shrunk over a year to pay off the balance on her credit card.[454] The amount the Shrunks paid the defendants was substantial and impacted the Shrunks' financial stability and comfort:

> We didn't go on vacations, not like that, like that wasn't an important thing anyway. But we, you know, didn't do things that we could have done if we didn't have to pay for that, but we figured this was – I think I should say I figured it was pretty important and well worth the try for something to be that miraculous.[455]

The court finds Mrs. Shrunk's testimony credible.

O. The Defendants False and Misleading Claim Stem Cell Therapy Was "Risk-free" and "SAFE"

At least four circumstances demonstrate there were reasons the defendants knew the therapies they sold were not risk-free and safe as they repeatedly claimed to Iowans: 1. The cytomegalovirus indifference; 2. Failure to screen consumers for

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[451] Trial Tr. Vol. 5, 104:22-24.
[452] Trial Tr. Vol. 5, 104:12-21.
[453] Trial Tr. Vol. 5, 104:12-21.
[454] Trial Tr. Vol. 5, 105:14-24.
[455] Trial Tr. Vol. 5, 106:2-7.

chronic kidney disease; 3. The misleading "healing crisis" message; and 4. FDA scrutiny into the products.

1. Indifference to cytomegalovirus contamination.

The defendants advertised their therapies were risk-free and SAFE, they stated in their advertising that their products did not contain harmful ingredients. Specifically, the defendants claimed that the "mothers & cords" were "screened/tested for infectious disease, sterility, & endotoxins."[456] Also, the defendants claimed there would be "no HLA[human leukocyte antigen]/immune response to cells."[457]

The defendants' messaging implied their products were safe because they were uncontaminated by substances that could harm them. Several witnesses confirmed they had this perception based on the defendants' advertising.[458] They also testified that the perceived safety of the stem cell products were safe and uncontaminated was a material reason for making their purchases.[459] They would not have purchased the products had they believed otherwise.

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[456] D0145, Trial Ex. 23, 998 (slide 26); D0146, Trial Ex. 24, 1009 (slide 26); Trial Tr. Vol. 3, 108:4-7.
[457] D0145, Trial Ex. 23 at 998 (slide 27); D0146, Trial Ex. 24 at 1009 (slide 27); Trial Tr. Vol. 3, 108:4-7.
[458] Trial Tr. Vol. 3, 25:14-17; 60:1-4; Trial Tr. Vol. 4, 40:19-41:1-8.
[459] Trial Tr. Vol. 3, 25:14-17; 60:1-4; Trial Tr. Vol. 4, 40:19-41:1-8.

This messaging was not accurate. In October 2019, two Iowa consumers received injections of Invitrx products that were "positive" for cytomegalovirus ("CMV").[460] CMV is an infection caused by a common virus that can cause serious issues and even be fatal in those with weakened immune systems.[461] According to Ms. Decker: she believed it was a health emergency to inject immunocompromised people with CMV+ products.[462] The consumers' medical records contain no information regarding whether anyone had inquired if either of the Iowans were immune compromised prior to these events.[463] Ms. Decker testified she had no knowledge whether Iowans were notified they had received CMV+ products.[464] Both impacted Iowans were older. M.H. was 61 at the time she received the CMV+ product, and L.S. was 72.[465]

This result was easily avoidable. A testing sheet was typically provided for the products used with consumers.[466] It was supposed to be common practice for

[460] D0209, Trial Ex. 57 at 1768 and 1776; D0135, Trial Ex. 14 at 395.
[461] *See* "Cytomegalovirus (CMV) infection, MAYO Clinic, at https://www.mayoclinic.org/diseases-conditions/cmv/symptoms-causes/syc-20355358.
[462] Trial Tr. Vol. 5, 175:14-20.
[463] D0209, Trial Ex. 57.
[464] Trial Tr. Vol. 5, 175:21-176:1.
[465] D0209, Trial Ex. 57.
[466] D0209, Trial Ex. 57 at 1768 and 1776; D0135, Trial Ex. 14 at 395.

nurse practitioners to check these testing sheets to ensure they were negative for harmful ingredients.[467]

This apparently was not happening with Iowa consumers because a nurse practitioner operating in a different state discovered that the product had positive CMV.[468] That nurse's testing paperwork stated: "CMV is a common virus infecting people of all ages. Invitra CBSC is not recommended for use in immunocompromised patients."[469] According to DW: "Once Definitive Wellness learned the product was positive, it refused to inject patients."[470]

At the time of the discovery of this problem, the defendants advertised and sold Iowans, and DW injected at least two Iowa consumers by the time DW learned this was the case.[471]

Thomas and Meek were aware these events transpired, but they reacted with indifference. The defendants and Jayes texted one another about the CMV incident.[472] Thomas' reaction to this serious news was: "It's more perception than actual… we don't want any liability… I want them all to be negative."[473] In response, Jayes replied:

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[467] D0135, Trial Ex. 14 at 395.
[468] D0135, Trial Ex. 14 at 395.
[469] D0209, Trial Ex. 57 at 1768 and 1776; D0135, Trial Ex. 14 at 395.
[470] D0135, Trial Ex. 14 at 395.
[471] D0209, Trial Ex. 57 at 1768 and 1776; D0135, Trial Ex. 14 at 395.
[472] D0195, Trial Ex. 43.
[473] D0195, Trial Ex. 43 at 1078.

> I am concerned with injecting any product with anything positive. If they are immune compromised we are putting a virus in them that could kill them or make them really sick…[474]

Thomas was on notice for concern months before the defendants ceased business in Iowa at the request of the Attorney General.

In response to Jayes' concern, Meek's implied Jayes should quit or be terminated for raising issues about product safety.[475] In an email to Jayes, Meek wrote:

> If this is you giving us notice of your departure, then please put that formally in writing, and we will work on our transition.[476]

Jayes interpreted this as Meek asking for her resignation for trying to have safe products used with consumers.[477] Jayes did not interpret Meek to be concerned: "I guess they were comfortable with the fact of giving CMV-positive products."[478]

Jayes further testified the defendants' ultimate solution to their CMV problem escalated from one of indifference to lying by omission. The defendants wanted to address the issue as follows:

> We'll just remove the CMV testing from the product completely, and we won't have it on there, so Angela doesn't need to worry about it because that testing won't be on the product listing, or we just won't provide the

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[474] D0195, Trial Ex. 43 at 1078.
[475] D0176, Trial Ex. 41 at 1072; Trial Tr. Vol. 2, 83:6-25.
[476] D0176, Trial Ex. 41 at 1072; Trial Tr. Vol. 2, 83:6-25.
[477] D0176, Trial Ex. 41, 1072; Trial Tr. Vol. 2, 83:6-25.
[478] Trial Tr. Vol. 2, 84:1-5.

> producing testing with the cells. Then we don't have to worry about it at all.[479]

The defendants knew their solution would not solve the problem of the Iowa consumers who had already received the CMV+ product or future purchases.[480]

The Iowans were not contacted by the defendants or anyone associated with them and informed they had received CMV+ products into their bodies despite all parties' ignorance of the status of the Iowans' immune systems.[481] The defendants kept doing business in Iowa after these events occurred in October 2019.

2. <u>The failure to screen Iowans with water intake restrictions.</u>

Medical records and trial testimony confirmed consumers were consistently informed they should drink lots of water following their therapies. This was also documented in a stem cells handout, which read: "Drink a lot of water (cells need the hydration to survive)."[482] Based on her education, training, and experience, Ms. Decker believed it was inappropriate to counsel consumers to drink lots of water "in every circumstance.[483]

Ms. Decker testified consumers suffering from "congestive heart failure that has difficulty pumping blood to keep up with their body demand and you introduce

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[479] Trial Tr. Vol. 2, 86:5-21.
[480] Trial Tr. Vol. 2, 86:22-87:2.
[481] D0209, Trial Ex. 57.
[482] D0203, Trial Ex. 51 at 1491.
[483] Trial Tr. Vol. 5, 139:20-140:2.

fluid, they will start retaining it in their legs or lungs and cause significant breathing and heart problems."[484] Another potential issue is: "if you introduce a lot of water to a patient with chronic kidney disease, (sic) is not able to filter the amount of water or fluid that the body takes on due to their inability to filter that it can cause fluid retention, which, again, can cause breathing problems, leg swelling, edema and heart problems."[485]

Jayes admitted that before December 31, 2019, there was no formal process to screen all consumers from receiving instructions to increase water intake if they were suffering from chronic kidney disease.[486]

Meek and Thomas prevented effective screening mechanisms to avoid the sorts of medical injuries and emergencies about which Ms. Decker was concerned. Jayes believed it would be too difficult to implement an effective screening mechanism addressing water intake restrictions given the sales-focused approach of Thomas and Meek. She testified:

> So, anytime we would start asking more questions of the patients… it could discourage the patient from continuing on with the services or continuing on with the purchase. So if I was starting to ask more medical questions, they didn't want any negative leading questions. [Meek and Thomas] only wanted positive leading questions because if you did a negative leading question, then that might put a bad taste in the patient's mouth—or in their mind. They might want a refund, or this isn't working, or it's not going to work.

[484] Trial Tr. Vol. 5, 140:3-9.
[485] Trial Tr. Vol. 5, 140:10-15.
[486] Trial Tr. Vol. 2, 95:1-6.

> So, it would be the same on the front end. If we're starting to ask negative questions or ask medical history, then that might put a negative thought in their mind. Then they may not want to continue with this process.[487]

Failure to properly screen and/or alert consumers to this potential health issue is supportive of the conclusion that the defendants deceived consumers regarding the safety or risk-free nature of its products by omission.

3. The dangerous healing crisis message.

Testimony and medical records confirmed consumers were consistently told they may experience a healing crisis following therapy. Thomas and Meek directly told consumers about the potential of a alleged healing crisis during the sales seminars.[488] The message was also reflected in the post instruction handout given to consumers, which read:

> Healing crisis-not everyone experiences but a lot will. You might experience increased symptoms and/or increased pain. Can last a day to 2 weeks and can occur today and up to 90 days.[489]

Jayes explained her understanding that a healing crisis is when, "during the healing process, [consumers] can have an increased inflammatory process. It usually can be from day one to 90 days. And it is actually—it can be a good

[487] Trial Tr. Vol 2, 95:15-96:6.
[488] D0145, Trial Ex. 23, 1001 (slide 39); D0146, Trial Ex. 24, 1012 (slide 37); Trial Tr. Vol. 3, 113:11-17.
[489] D0203, Trial Ex. 51 at 1491.

thing."[490] Ms. Decker testified she was trained to explain to consumers that it is "basically all of your body's inflammatory processes go[ing] into the [injection] site and helping support the replication of the stem cells."[491] However, Ms. Decker had never heard the term healing crisis in her many years of formal education prior to the activities involved in this case.[492]

This message made it difficult for consumers to self-assess whether they are experiencing a healing crisis they were told was a positive result as opposed to a serious health emergency following body injections and IVs. As discussed earlier, at least one consumer, Mark Frese was hospitalized for 30 days shortly after his knee injections after being counseled he was experiencing a healing crisis before he was admitted. The court finds this messaging had a capacity to delay or prevent consumers from seeking timely medical care in the event they needed it, which could lead to injury.

III. CONCLUSIONS OF LAW

A. Count I – Consumer Fraud Act Violations

The State alleged various instances of the defendants' stem cell therapy advertising lacked a reasonable basis and that the defendants engaged in deceptive

[490] Trial Tr. Vol. 2, 123:2-9.
[491] Trial Tr. Vol. 5, 132:13-17.
[492] Trial Tr. Vol. 5, 132:18-20.

and unfair conduct. While all three standards are violations of the Iowa Consumer Fraud Act ("CFA") – they entail different standards of proof.

B. Background: Consumer Fraud Act

The legislature enacted the CFA in 1965 to protect the public from deceptive and unfair business practices.[493] The principal purpose of the CFA is to safeguard Iowans from fraud and deception in the sale and advertisement of products and services.[494] The CFA is a remedial statute "designed to infuse flexible equitable principles into consumer protection law so that it may respond to the myriad of unscrupulous business practices modern consumers face."[495] The courts give the CFA "a liberal interpretation, not an illusory one."[496]

CFA actions are not the same as common law fraud actions.[497] "The [CFA] provides broader protection to the citizens of Iowa by eliminating common law fraud elements of reliance and damages."[498] Also, "there is no requirement under

[493] *State ex rel. Miller v. Hydro-Mag, Ltd.*, 436 N.W.2d 617, 620-22 (Iowa 1989).
[494] *Hydro-Mag, Ltd.*, 436 N.W.2d at 621 ("The historical development of consumer law reveals that the Consumer Fraud Act was enacted to better protect consumers from fraud").
[495] *State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 528 (Iowa 2005); *State ex rel. Miller v. Vertrue*, 834 N.W.2d 12, 34 (Iowa 2013).
[496] *Vertrue*, 834 N.W.2d at 132.
[497] *State ex rel. Att'y Gen. of Iowa v. Autor*, 991 N.W.2d 159, 167 (Iowa 2023).
[498] *Id.* (quoting *Hydro Mag, Ltd.*, 436 N.W.2d at 622).

the statute that a violator have knowledge of the falsity of his or her representations."[499]

The CFA defines an unlawful practice as:

> 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.[500]

The CFA prohibits deceptive and unfair conduct and there is a third category of per se deception when merchants fail to possess a reasonable basis for performance-based advertising claims.[501] A single act or practice can be both deceptive and unfair.[502]

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[499] *State ex rel. Miller v. Pace*, 677 N.W.2d 761, 771 (Iowa 2004).
[500] Iowa Code section 714.16(2)(a).
[501] Iowa Code section 714.16(2)(a): "*It is deceptive advertising within the meaning of this section* for a person to represent . . . that the advertised merchandise has certain performance characteristics, accessories, uses, or benefits . . . if, at the time of the representation, no reasonable basis for the claim existed." (emphasis added).
[502] "[D]eceptive and unfair practices are distinct lines of inquiry.... [W]hile a practice may be both deceptive and unfair, it may be unfair without being deceptive." *State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 527 (Iowa 2005).

C. Legal Standards and Burden of Proof: Unsubstantiated Advertising Claims

The CFA requires sellers and advertisers to have a reasonable basis ("substantiation") for their performance claims before making them.[503] The burden of proof for truthful advertising is on the person making the claim – not the State.[504] The substantiation requirement is:

> 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.[505]

Our appellate courts have not defined what constitutes a reasonable basis. At a minimum it appears there must be competent and reliable scientific evidence to support the claim being made and that scientific testing be conducted to establish that the product functions as claimed.[506]

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[503] Iowa Code section 714.16(2)(a).
[504] *Id.; State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004).
[505] Iowa Code § 714.16(2)(a) ("The burden is on the person making the representation to demonstrate that a reasonable basis for the claim existed."). *See also State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004).
[506] *Id.* at 596 ("The defendants presented no credible expert evidence that the device was adequately tested or that reliable evidence would substantiate the claims made for it.").

In *New Womyn*, the court found that the defendant "presented no credible expert evidence that the device was adequately tested or that reliable evidence would substantiate the claims made for it."[507] The defendant produced no medical or scientific input into the test the defendant conducted on himself and his wife. He could not establish he had the qualifications to design the device or determine if it properly functioned.[508] The device had also been deemed a quack design by the FDA.[509] Accordingly, the court concluded "that the defendants have failed to show a reasonable basis for their claims" and affirmed the district court's ruling that defendants violated the CFA.[510]

1. Competent and reliable scientific evidence.

In addition to *New Womyn*, and *Hydro-Mag*, the Iowa Supreme Court has considered decisions regarding actions by the Federal Trade Commission[511] enforcing the Federal Trade Commission Act ("FTCA") persuasive authority.[512]

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[507] *New Womyn*, 679 N.W.2d. at 596-97.
[508] *Id.* at 597.
[509] *Id.*
[510] *Id.*
[511] The FTC Act prohibits deceptive or unfair acts or practices like the CFA. The CFA is a so-called "little FTC" statute commonly enforced by state attorneys general around the United States. § 3:7. Liability under state and federal antitrust and trade regulation laws—State antitrust laws, Dir. & Off. Liab § 3:7
[512] *See State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d 12, 37, 39 (Iowa 2013) (The Iowa Supreme Court cited several cases brought by the Federal Trade Commission, such as: "*FTC v. Tashman*, 318 F.3d 1273, 1278 (11th Cir. 2003) (holding the district court erred in focusing "on a few satisfied customers" when overwhelming evidence demonstrated misleading representations)"; "*FTC v.*

Federal courts reviewing allegations that health-related claims violated the FTCA because they lacked a reasonable basis have stated that for such health-related claims, the "advertiser must possess 'competent and reliable scientific evidence' to substantiate that claim."[513] "'Competent and reliable scientific evidence' has been defined in various contexts, including in published FTC guidelines,[514] as 'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.'"[515]

Randomized controlled human clinical trials ("RCTs") should be used to substantiate health-related claims.[516] Evidence for claims falling short of

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Kuykendall, 371 F.3d 745, 757–58 (10th Cir. 2004) (finding a violation of the Telemarketing Sales Rule sufficient to support violation of injunction entered in previous FTC enforcement action when, inter alia, telemarketers used "rapid fire and confusing language" in a magazine subscription sales pitch").

[513] *FTC v. Natural Solution, Inc*., 2007 WL 8315533 *3 (C.D. Cal. Aug. 7, 2007).

[514] Health Products Compliance Guidance, FED. TRADE COMM'N, https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance

[515] *F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1186 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009).

[516] *See, e.g., Roca Labs, Inc.*, 345 F. Supp. 3d at 1387 (requiring a randomized controlled human clinical trial ("RCT") to substantiate weight-loss claims). *Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d at 303 ("[I]t seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims."); *Removatron Int'l Corp*., 111 F.T.C. 206 (1988), *aff'd*, 884 F.2d 1489, 1498 (1st Cir. 1989) (requiring "adequate and well-controlled clinical testing" to substantiate claims for hair removal product); *Thompson Med. Co.*, 104 F.T.C. at

RCTs, such as scientific testing of health products with animals instead of humans[517] and anecdotal testimonials,[518] are insufficient. Finally, advertisers "should make sure that the scientific research on which they rely isn't just internally valid, but also relevant to their specific product and to the specific advertised benefit."[519]

2. Requirement of scientific substantiation prior to advertising.

Advertisers' "speculative" and "experimental" claims still require adequate scientific support before their products are sold to the public based on their claims.

826 (requiring well-controlled clinical studies to substantiate certain analgesic drug claims).

[517] *See, e.g., Nat'l Urological Grp., Inc.*, 2017 U.S. Dist. LEXIS 182256 at *95-98.

[518] *FTC v. QT, Inc.*, 512 F.3d 858, 862 (7th Cir. 2008) (testimonials "are not a form of proof because most testimonials represent a logical fallacy: post hoc ergo propter hoc," i.e., "[a] person who experiences a reduction in pain after donning the bracelet may have enjoyed the same reduction without it.").

[519] *Id.* ("If there are significant discrepancies between research conditions and the real-life use being promoted, advertisers must evaluate whether it is appropriate to extrapolate from the research to the claimed effect."); *See also Ranes v. Adams Lab'ys, Inc.*, 778 N.W.2d 677, 692 (Iowa 2010) ("Dr. Thoman reasoned, from this [case-control] study, PPA can likely cause stroke, and since Ranes likely suffered a 'stroke-like event,' this study tended to show a relevant causal connection. This study is simply not relevant to the case before us. It excludes men and only references hemorrhagic stroke in women. Moreover, the study does not describe an injury following PPA ingestion called 'stroke-like event.' In fact, stroke does not appear to be the injury at issue in this case at all.")

In *Hydro Mag*, the Iowa Attorney General brought a CFA action against the seller of an "electromagnetic" water treatment system that made several claims about it.[520] The Iowa Supreme Court opined,

> Based on the scientific record, we conclude that the electromagnetic treatment of water is a speculative area which is, at best, in an embryonic stage of future development. . . . [Hydro Mag] made several very specific claims . . . These wide ranging claims were based solely on [the seller's] personal opinions and speculation. None of these advertising claims were substantiated by scientific testing. . . [H]e misrepresented the extremely experimental nature of the electromagnetic treatment of water. . . .[521]

The court continued:

> We understand that many of today's ideas will eventually develop into tomorrow's realities. The necessity for experimentation does not, however, provide justification for marketing products without the proper support for claims made to the public.[522]

3. Testimony from satisfied customers is not reliable scientific evidence.

Hydro Mag also establishes that testimonials from satisfied customers do not meet the criteria of competent and reliable scientific evidence. In that case, the court held that consumer satisfaction is insufficient scientific proof of advertising claims because the reported satisfaction was not scientifically controlled for other variables that may have caused the changes.[523] Proof of advertising claims must be

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[520] *State ex rel. Miller v. Hydro Mag, Ltd*., 436 N.W.2d 617, 618 (Iowa 1989).
[521] *Id*. at 622.
[522] *Id*. at 623.
[523] *State ex rel. Miller v. Hydro Mag, Ltd.*, 436 N.W.2d at 623 ("We also find Mr. Van Gorp's lay witnesses to be unpersuasive. Each of these customers testified as to their beliefs concerning Hydro–Mag, however, none were able to say with any

based on objective scientific evidence. Satisfied customer testimonials do not meet this criterion.

D. Expert Testimony

The State and the defendants each designated one expert witness to opine whether the defendants could substantiate their advertising claims about regenerative medicine therapies. Both gave testimony regarding their qualifications and presented their opinions. A fact finder is not bound to accept expert testimony, even if uncontradicted by other expert testimony.[524] The weight given to the expert opinion is determined by the fact finder.[525] Additionally, "[a]lthough generally 'the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility,' ... if an expert's opinion is 'so fundamentally unsupported ... it can offer no assistance to the [fact finder]...,' it *must* be excluded.[526]

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degree of confidence that the Hydro–Mag, and not any other changes, caused the improvement. Also, establishing that there were satisfied customers is not a complete defense to this type of action.").

[524] *In Int. of L.G.*, 532 N.W.2d 478, 481 (Iowa Ct. App. 1995).

[525] *In re Marriage of Dennis*, 467 N.W.2d 806, 809 (Iowa Ct. App. 1991) ("The trial court is free to consider any and all evidence of the value of Dennis Parking Lot Maintenance, Inc. including the credibility of the expert witness' testimony, the credibility of the parties, and each party's opinion as to the value of the corporation.").

[526] *Ranes v. Adams Laboratories, Inc.*, 778 N.W.2d 677, 693 (Iowa 2010) (emphasis added).

1. State's Witness - Dr. Sean J. Morrison.

The State designated Dr. Sean J. Morrison as its expert witness.[527] Dr. Morrison received his BSc degree with honors in biology and chemistry from Dalhousie University.[528] He received his PhD in immunology from Stanford University.[529] Upon completing his PhD, he was a postdoctoral scholar at California Institute of Technology, where he studied neural stem cells.[530]

Dr. Morrison holds multiple positions as a professor and scientist. For example, he is a Howard Hughes Medical Institute Investigator.[531] This is one of the world's largest biomedical research organizations that funds around 300 laboratories across the United States that Howard Hughes Medical Institute regards as being leaders in their scientific fields.[532]

Also, Dr. Morrison is the Founder and Director of the Children's Medical Center Research Institute at University of Texas Southwestern.[533] The Institute focuses on the interface of stem cells, cancer, and metabolism.[534] Dr. Morrison operates a laboratory studying various aspects of stem cells and cancer.[535]

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[527] D0028, State's Designation of Expert Witness Dr. Sean J. Morrison.
[528] D0108, State Trial Ex. 2, at 5; Trial Tr. Vol. 1, 36:24-37:1.
[529] D0108, Trial Ex. 2, at. 5; Trial Tr. Vol. 1, 37:4-6.
[530] D0108, Trial Ex. 2, at 6; Trial Tr. Vol. 1, 37:7-12.
[531] D0108, Trial Ex. 2, at 5; Trial Tr. Vol. 1, 38:7-9.
[532] Trial Tr. Vol. 1, 38:11-15.
[533] D0108, Trial Ex. 2, p. 5.
[534] Trial Tr. Vol. 1, 38:22-25.
[535] Trial Tr. Vol. 1, 39:10-19.

Dr. Morrison authored a significant number of articles about regenerative medicine. Over 150 of his studies have been published peer-reviewed journals.[536]

Dr. Morrison serves on the United States Food and Drug Administration's Cellular Tissue and Gene Therapies Advisory Committee.[537] The FDA regularly seeks the Advisory Committee's advice when the FDA has concerns about companies' claims of product efficacy and safety, as well as issues relating to product manufacturing and quality control.[538] The FDA tends to ask the Committee about the "tough" cases it evaluates.[539] Thus Dr. Morrison has insight into the FDA's approval process for regenerative medicine therapies.[540]

In addition to studying efficacy claims, Dr. Morrison studies the scientific literature of regenerative medicine to assess safety.[541] He also evaluates informed consent documents submitted for institutional review board ("IRB") approval in connection with regenerative medicine studies.[542] Dr. Morrison has been the recipient of numerous honors and awards for his work in regenerative medicine.

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[536] Trial Tr. Vol. 1, 40:20-23.
[537] Trial Tr. Vol. 1, 43:19-23.
[538] Trial Tr. Vol. 1, 44:2-22.
[539] Trial Tr. Vol. 1, 44:25-45:5.
[540] Trial Tr. Vol. 1, 43:25-44:4.
[541] Trial Tr. Vol. 1, 45:10-24.
[542] Trial Tr. Vol. 1, 46:1-14.

Dr. Morrison is an expert in the field of regenerative medicine and in the science of stem cells. The court finds that Dr. Morrison is qualified to render opinions on the defendants' regenerative medicine advertising claims.

2. Defendants' Witness - Dr. Scott M. Martin.

The defendants designated Dr. Scott M. Martin as their expert witness to substantiate the reasonable basis for their claims.[543] Dr. Martin's practice varied throughout his career. He is presently an interventional pain doctor. He previously operated a regenerative aesthetics clinic, served as a consultant on a medical advisory board for a biotech and other biotech-related companies.[544] He also indicated he did clinical research, some publishing, and starting his own IRB.[545]

Dr. Martin received his medical degree from the American University of the Caribbean.[546] He did an interventional pain fellowship at the University of Michigan.[547] He is board certified in physical medicine and rehabilitation.[548] After December 2014 he moved to Las Vegas, Nevada and began practicing in nonnarcotic pain practice which involved herbal medications, diagnostic injections, ancillary therapy, physical therapy, occupational therapy, and acupuncture.[549] He

[543] D0046, Defendants' Designation of Expert Witness Dr. Scott M. Martin.
[544] Trial Tr., Vol. 6, 9:17-24.
[545] Trial Tr., Vol. 6, 9:25-10:2.
[546] Trial Tr. Vol. 6, 21:8-10.
[547] Trial Tr. Vol. 6, 21:8-15
[548] Trial Tr. Vol. 6, 21:18-19.
[549] Trial Tr. Vol. 6, 28:3-29:2.

began using allogenic biologics at this time.[550] This involved using the patient's blood and "spinning it down" and using the growth factor to inject back into the patient to facilitate healing.[551] In March 2022 he moved to Florida and was the vice president of clinical development at Regenerative Labs where he was the liaison at Regenerative Labs and medical providers who were using allografts.[552] Dr. Martin authored articles on observational research for Regenerative Labs, which is one of the product manufacturers the defendants used to source stem cell products with Iowans.[553] Dr. Martin operated a regenerative aesthetics clinic to compliment another provider's Botox and fillers practice.[554]

The State challenged Dr. Martin's opinions and his qualifications to render opinions in pretrial motions in limine and at trial.[555] Specifically, the State challenged his opinions since he did not conduct any studies on the products sold by the defendants and failed to identify any scientific studies establishing the efficacy of the products on the claims made by the defendants. Dr. Martin agreed that he had "no report or clinical research study or peer-reviewed journal article

[550] Trial Tr. Vol. 6, 29:13-16.
[551] Trial Tr. Vol. 6, 29:25-30:7.
[552] Trial Tr. Vol. 6, 32:1-33:2.
[553] Trial Tr. Vol. 6, 33:3-34:3.
[554] Trial Tr. Vol. 6, 34:10-15.
[555] Trial Tr. Vol. 6, 10:8-21:5.

regarding any of the products manufactured by the manufacturers from whom the defendants obtained their products that were sold to Iowans."[556]

The court finds that Dr. Martin was unable to provide the kind of competent and reliable scientific evidence necessary to support the defendants' claim they had a reasonable basis for making the claims they made in their advertising. Several of Dr. Martin's statements during trial were contrary to the defendants' advertising claims.

> Under section 361, whether you're using PRP or Wharton's jelly, you cannot make claims. You cannot say that any of those are going to ***diagnose, treat, cure, prevent disease***.[557]
>
> If you apply an allogeneic allograft, a Wharton's jelly allograft to the cartilage-based defect of the right knee, ***not only should there be no systemic administration of that product, you also cannot claim that there's going to be some magical systemic activity with that product***.[558] Drugs have a systemic effect. ***Human cell tissue products have a local focal effect***.[559]
>
> FDA guidance – ***cannot make claims that any human cell and tissue product could be used to diagnose, treat, cure, or prevent disease.***[560]
>
> There's zero uniformity between stem cell products outside of the United States and human cell and tissue products within the United States. There's also no conformity between one PRP application and a second PRP application, even within the same individual.[561]

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[556] Trial Tr. Vol. 6, 15:10-15.
[557] Trial Tr. Vol. 6, 45:7-12 (emphasis added).
[558] Trial Tr. Vol. 6, 52:9-14 (emphasis added).
[559] Tial Tr. Vol. 6, 52:23-24 (emphasis added).
[560] Trial Tr. Vol. 6, 77:6-21 (emphasis added).
[561] Trial Tr. Vol. 6, 86:19-87:1

Dr. Martin provided no scientific studies that demonstrated that the defendants' products could provide the relief that they claimed could be relieved in their marketing materials. He conducted no tests with the defendants' products to establish they could accomplish what the defendants claimed. He produced no tests or studies conducted by the manufacturers or any other scientist that demonstrated the defendants' products could accomplish what the defendants claimed in their marketing materials.

Dr. Martin's opinion is unreliable because it did not consider (and could not have considered) the most basic types and amounts of all the ingredients relevant to the stem cell products the defendants sold. There was no evidence presented by the defendants that established what was in any of the vials they sold to Iowa consumers. The defendants failed to establish there were stem cells, or living stem cells that would effectively treat any condition they informed Iowans they would. The defendants failed to provide any product testing completed by the manufacturer, neutral third parties, or from their own expert.

In this case, the defendants advertised a host of product ingredients were active and would help MSCs to be more effective.[562] The ingredients list included: collagen, growth factors, structural proteins, cytokines, and hyaluronic acids. Dr.

[562] D0145, Trial Ex. 23, 1000; D0146, Trial Ex. 24, 1011; Trial Tr. Vol. 3, 107:2-16.

Martin provided no scientific research or studies that demonstrated these ingredients could accomplish what the defendants claimed.

Dr. Martin admitted his opinions did not rest on any internal or external analysis, testing or peer-reviewed clinical research regarding the specific products the defendants used that could verify the types and measures of all the ingredients the defendants advertised and sold.[563]

One of the claims made by the defendants'' was that their products contained large or significant number of live stem cells. Dr. Morrison debunked this claim.

> [I]n umbilical cord blood, only one out of every 100 million cells in the cord blood is a stem cell. And so if you were really interested in using [MSCs] from umbilical cord blood, you would put the umbilical cord blood cells into culture, 99.9999 percent of the cells would die, and those extraordinarily rare [MSCs] could grow out, and then you could transplant them into somebody. But based on the information I've seen from the defendants, in no cases were their products cultured. They were using crude extracts of cells in which [MSCs] would be expected to be rare or nonexistent.[564]

> [W]hat we know about umbilical cord blood is that only one out of every 100 million cells is a MSC, and the largest Liveyon product contained 30 million cells in it. So we wouldn't expect most vials – we would expect two-thirds of the vials of this Liveyon product to not contain any [MSCs] at all and one-third of the vials to contain a single MSC rather than millions of [MSCs]…[565]

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[563] Trial Tr. Vol 6, 10-20.
[564] Trial Tr. Vol. 1, 56:9-25.
[565] Trial Tr. Vol. 1, 81:16-82:5.

> Invitrx claimed to generate a product that contained [MSCs] and growth factors from umbilical cord blood, but the same concern applies as the Liveyon product… [W]e would expect Invitrx products to contain few or no [MSCs].[566]

Dr. Martin provided no testimony or evidence to rebut this opinion.

Dr. Morrison further testified one important consideration of his review methodology was analyzing evidence relating to the same broad type of allogeneic stem cells the defendants sold to account for meaningful biological differences with other cell types. Specifically, Dr. Morrison testified it is important to review controlled clinical trials "in which the effectiveness and the safety of the product, the *exact product* that's been sold for the exact indication that it's claimed to be able to treat…" is studied.[567]

> That's because:
>
> Each of these cells have very different properties. There is no kind of stem cell that's a one-size-fits-all cure than can be injected into somebody and can be expected to around their body healing their diabetes and their Parkinson's disease, their heart disease, and other orthopedic conditions… That would be like suggesting that because one car part could be used to fix a problem in another car, than any car part could be used to fix the same problem.[568] [Y]ou wouldn't expect products that had very different cellular compositions to have the same effect once they're injected into a patient.[569]

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[566] Trial Tr. Vol. 1, 82:12-82:3.
[567] Trial Tr. Vol. 1, 63:7-13 (emphasis added).
[568] Trial Tr. Vol. 1, 77:8-11.
[569] Trial Tr. Vol. 1, 85:12-17.

It is undisputed that the defendants marketed and sold allogeneic stem cells sourced from individuals apart from the recipient of the product in therapy. This is different than autologous cells in which cells are extracted from the therapy recipient's own body. In other words, you cannot extrapolate studies done on autologous cells and allogenic because you are comparing apples to oranges. Dr. Martin produced no evidence to rebut this opinion.

The defendants' answer admitted that there were no protocols for determining the therapeutic level of stem cell therapy for their advertised health conditions in regenerative medicine. Dr. Martin did not contest or otherwise address the defendants' admission. He did not address how the products were effective for each health problem in the amounts the defendants sold Iowans. Also, he did not address the defendants' internal disagreement with Jayes whether some consumers over 300 or 250 pounds should receive additional product volume to be effective.

Dr. Martin ignored an advertising claim the defendants made about how long the alleged stem cells in each product could last inside consumers' bodies. The defendants claimed consumers could experience relief over a year after receiving therapy. Consumers testified their perception was the cells would entail long-term effects. However, Dr. Morrison testified that the allogeneic products the

defendants used with Iowans would be cleared by each consumer's immune system within hours or days.

> Q. So I want to make sure that's clear. Does that mean all the products that Defendant sold to Iowans were cleared from their immune systems within hours or days?
> A. Yes. That's what we would expect.[570]

The defendants and Dr. Martin presented no evidence that contradicted this opinion.

While the State had no burden to disprove the defendants' substantiation claim, Dr. Morrison's testimony debunked the defendants' argument that they had a reasonable basis to believe their products could provide relief, treat, or heal any of the medical conditions they advertised. He demonstrated there was nothing in the scientific community to establish that the defendants could have a reasonable belief regarding the claims they made.

> Q So we've talked about considerations. What is the scientific level of proof required by qualified experts in the field of regenerative medicine to substantiate a claim about therapy?
> A We would expect at least one controlled clinical trial with enough patients to be able to rigorously test safety and effectiveness and that in which the exact product that's being -- that's the subject of the claims is tested for the exact indication in which the claims that are being made.[571]

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[570] Trial Tr. Vol. 1, 56:2-5
[571] Trial Tr. Vol. 1, 70:22-71:6.

He explained how he determined whether there was scientific proof that would substantiate the claims the defendants made.[572]

> It's based on -- first of all, they were asked to provide substantiation for the claims they made. I examined the documents they produced, and in no case did they provide clinical evidence that any of the products they used were safe or effective for the treatment of any of the conditions featured in their advertising. Finally, the Food and Drug Administration has not approved either these products or any similar products for the treatment of any of the conditions featured in their advertising. And then, finally, I also evaluated the rationale they articulated for why they thought these products would be effective, and they made many false claims in their advertising. There is no stem cell that would be capable of doing the things that they claim that their products could do; that is, traveling around the body, seeking out areas of damage in different kinds of tissues, and treating those areas by replacing the cells. 50:8-51:9 there's not enough evidence to claim that mesenchymal stem cells would be effective for the treatment of the kinds of indications that were featured in their advertising.[573] 51:21-24

> First I looked at the advertising to see what the claim was, and then I looked at the substantiation provided by the defendants. And they provided no evidence from clinical trials that any of their products they used could be effective for the treatment of any of the conditions featured in their advertising. Then I looked in the scientific literature to see if anybody else had done clinical trials to test those products or similar products and, again, didn't find evidence from clinical trials, controlled clinical trials, that those products or any similar product is effective for the treatment of any of the conditions. And then I looked at their rationale for why they were proposing that those products would be effective. I found many false claims that, obviously, didn't fit with the biology of the cells that we understand.[574]

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[572] Trial Tr. Vol. 1, 49:24-50:6.
[573] Trial Tr. Vol. 1, 50:8-51:9.
[574] Trial Tr. Vol. 1, 78:4-20.

He further noted there was "abundant evidence against it in the scientific literature."[575]

There was no reasonable basis to assert that stem cells, whether given by injection or IV, would travel to sites within the body to fix the problem that existed.

> In this case we would not expect mesenchymal stem cells to be able to travel around the body and repair lots of different organs. We wouldn't expect them to persist for long periods of time, as the defendants claimed. We wouldn't expect them to be able to make new pancreatic cells with someone with diabetes, new heart cells with somebody with heart disease, new liver cells with somebody with liver damage. Based on what we understand of the biology of these cells, the major claims that the defendants made in their advertising and in their website and in their seminars for patients are just not true.[576]

> Q Is the concept of a general witness IV scientifically plausible?
> A No, because it's predicated on the false idea that was really one of the central false claims in the defendants' advertising, that once injected, the cells in their products would travel around the patient's body, fixing whatever needed to be fixed. Again, there is no stem cell therapy that would be capable of doing that in different kinds of conditions for very different medical problems.[577]

There was no evidence that the stem cell therapy would provide relief.

> Q So let's set aside the issues of quantities of the components. If there are sufficient quantities of components, is it possible for them to be -- to give long-lived effects in the person?
> A We would not expect injections of growth factors to have long-lived effects. So in their advertising, the defendants commonly claimed that their

[575] Trial Tr. Vol. 1, 51:10-24.
[576] Trial Tr. Vol. 1, 70:10-21.
[577] Trial Tr. Vol. 1, 91:5-14.

> products would persist in patients for weeks or months and continue and to continue traveling around their body, healing whatever tissues need to be healed. But growth factors are just proteins, and they would be cleared within hours or a few days of being injected. In patients that are treated with growth factors, either the effect of the growth factor is expected to be very short-lived or patients are given that growth factor in a repeated manner so the effect will persist.
> Q Is there any reason to believe consumers would benefit from the growth factors, cytokines, or extracellular matrices that were claimed to be contained in these products?
> A No.[578]

The court finds that the defendants failed to substantiate that they had a reasonable basis to believe the claims they made in their advertising materials and the statements they made to the Iowa consumers when they were presenting their products for sale.

E. Legal Standards and Burden of Proof: Deceptive Acts and Practices

The CFA provides that the "act, use or employment by a person of . . . deception . . . in connection with[579] the lease, sale or advertisement of any merchandise . . . whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice."[580] Deception means an act or practice which has the tendency or capacity to mislead a substantial number of consumers as to a

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[578] Trial Tr. Vol. 1, 86:19-87:15.
[579] *State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 526 (Iowa 2005) (To show a "practice is 'in connection with' the sale of merchandise, … the attorney general need only show some relation or nexus between the two.").
[580] Iowa Code § 714.16(2)(a).

material fact or facts.[581] The State has the burden to prove the defendants engaged in deceptive acts or practices by a preponderance of clear, convincing, and satisfactory evidence.[582]

To ascertain whether a practice may mislead the courts evaluate the overall or net impression created by the representation.[583] A solicitation may be likely to mislead, for purposes of deception, by virtue of the net impression it creates, even though the solicitation also contains truthful disclosures.[584] The presence of a disclosure or request for consent does not alone cure a misleading solicitation if the net impression remains deceptive because material elements of the transaction remain obscured.[585] Evidence that consumers were in fact misled is relevant to determining whether a solicitation had a tendency to mislead for purposes of establishing deception.[586]

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[581] Iowa Code §714.16(1)(c). *See also State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d 12, 34 (Iowa 2013) ("A misleading impression created by a solicitation is material 'if it involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product.'").
[582] *State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 524 (Iowa 2005).
[583] *Vertrue*, 834 N.W.2d at 34.
[584] *Id.*
[585] *Id.* at 37.
[586] *Id.* at 36.

F. Analysis: Defendants' Deceptive Acts and Practices

1. Threshold questions.

The State alleged specific advertisements the defendants made about their product efficacy, safety, and their testimonials, were deceptive practices in violation of the CFA. The court first addresses whether these acts and practices were in connection with the defendants' advertisements and sales, and whether they had a tendency or simply a capacity to mislead a substantial number of consumers.

All these acts and practices were in connection with the defendants' sales because there is a nexus between them. To demonstrate a deceptive practice is in connection with the sale of merchandise, the State need only show "some relation or nexus between the two."[587] The defendants' advertisements allowed them to make sales to Iowa consumers. Their claims the therapies were safe helped placate consumer doubts about buying the therapies. The defendants' testimonials also helped convince consumers they should buy their therapies because they were successful. There is a clear nexus between the defendants' advertisements and the sales they made to Iowans.

[587] *State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 526 (Iowa 2005).

The State established that the defendants' acts and practices could also mislead a substantial number of Iowa consumers. Meek testified that the defendants sent 6,000 mail solicitations per seminar event. The defendants ultimately expected to reach at least 350,000 Iowa consumers with the mailers. Even presuming only 60 consumers showed up to 160 seminar events, that equals 9,600 Iowans that could have received the defendants' advertisements and seminar handout materials. The defendants, in responding to the State's subpoena documented many seminar events held across Iowa. These seminars involved a substantial number of Iowans. The court finds that the defendants had a capacity to mislead a substantial number of consumers.

2. The defendants' deceptive advertising claims.

The defendants and their advertisements fostered a deceptive net impression about results Iowa consumers could expect. For example, consumers testified they believed the defendants' claims they were purportedly receiving cells that could migrate around their bodies to fix whatever needed fixed. They believed these cells would be accepted by their bodies and would multiply, not be destroyed by their bodies. These claims influenced their decisions to buy the therapy.

Dr. Morrison testified that none of the products the defendants claimed to have used were shown to be safe and effective in controlled clinical trial for any of

the indications that were features in their advertising.[588] He reviewed the literature provided by the defendants and it provided no substantiation. He reviewed the medical literature and he could not find any clinical trials that tested the products the defendants sold or similar products, and the claims the defendant were making did not fit the biology of the cells.[589] He further testified that the defendants produced no clinical evidence to demonstrate that the products they used were safe and effective for the conditions featured in their advertising. There was no evidence that the FDA approved the products for their use on the conditions advertised. There was no evidence that stem cells were capable of traveling around the body seeking out damage in different cells and repairing them. There was no evidence to support the claim that mesenchymal stem cells would be effective for the treatment of the kinds of health problems that were featured in their adverting.[590]

Dr. Martin produced no evidence from any controlled clinical trial for any of the defendants' products that treated any of these products in the context of the conditions that were featured in the defendants' advertising.[591]

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[588] Trial Tr. Vol. 1, 50:3-6.
[589] Trial Tr. Vol. 1, 78:4-20
[590] Trial Tr. Vol. 1, 50:8-51:24.
[591] *Id.*, 88:1-5.

The defendants sold general wellness IVs. Dr. Morrison testified this was not scientifically plausible. This claim was premised on a central false claim that their products would travel around the body and fix the patient's body where it was needed. There is no stem cell therapy that is capable of doing this with different kinds of conditions or different medical problems.[592]

Dr. Morrison testified that there was no one-size stem cell that you could inject that would cure multiple conditions. He also testified that there were very few things that stem cell therapies available.[593] The defendants and Dr. Marttin produced no evidence to rebut this opinion. Dr. Morrison confirmed the allogeneic product would be destroyed by consumers' immune systems. Any stem cells that could migrate would be so few as to have no clinical effect. Further. Dr. Martin testified that the only relief that could be obtained from allogenic products were at the site of the cartilage defect.[594] These facts were withheld from the consumers.

Consumers testified they believed the defendants' claims that the therapy could have long-lasting effects. Indeed, many were hoping for long-term pain relief and to avoid surgery because the defendants told them it was possible. This influenced their decision to buy products from the defendants. Dr. Morrison

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[592] *Id.*, 91:5-92:7
[593] Trial Tr. Vol. 1, 54:1-6.
[594] Trial Tr. Vol. 6, 68:13-16.

confirmed this claim was not credible because the cells consumers received would be destroyed within hours or days.[595]

Dr. Morrison testified that testimonials or endorsements by users of the products were notoriously unreliable. First, there is the impact of the placebo effect where the patient perceives that they obtained relief because they believe what their doctor gives them will be effective. Studies show that when controlled with one group getting the drug and the placebo group indicates they obtained relief. Second, people may be receiving other therapies or treatments which will impact the results. You cannot tell if it was the drug being tested or the other therapies or drugs the patient might be receiving. A testimonial or endorsement that the stem cell therapy cured my osteoarthritis proves nothing.[596] Likewise, the use of stem cell therapy in one cannot be extrapolated to its use elsewhere.[597]

Another deception was that consumers believed they would receive millions of stem cells into their bodies. They did not believe only one out of every three vials would contain a single MSC. Their perception that the products contained millions of MSCs was material to their decision to buy therapies. Yet, Dr. Morrison confirmed only one out of every three products vials would contain a single stem cell. Dr. Martin did not contradict this testimony. The types of cells

[595] Trial Tr. Vol. 1, 84:9-25; 86:19-87:10; 92:23-93:20.
[596] Trial Tr. Vol. 1, 74:12-15.
[597] Trial Tr. Vol. 1, 77:5-11.

contained in the products in high numbers were likely white blood cells – not stem cells. This information was never presented to the consumers.

The defendants also told consumers they had received approval to get therapy by a medical board. The consumers were never informed that a medical board did not review their case and approve their individual treatment. The court finds the defendants' advertising claims were deceptive in violation of the CFA.

The defendants claim that the consumers accepted the risk when they signed their informed consent form. Dr. Morrison testified that a fundamental principle of informed consent is that it must be informed with accurate information. In these cases the defendants provided lots of misinformation thus their consent is not informed.[598] For instance, the form's central idea was they were receiving stem cells when they were few or no stem cells in the products being administered.[599] In addition, the person who provided the informed consent form provided the same misleading information. Such as once injected the stem cells would travel where they needed to be. The body would repair itself over months with the new cells.[600]

[598] *Id.*
[599] *Id.* at 97:1-11.
[600] *Id.* at 97:1-98:6.

G. The Defendants' Deceptive Claims Their Therapies Were Safe.

The consumers testified their belief that the therapies they received were safe materially influenced their decisions to move purchase. All the facts summarized by the court in its findings discussing the defendants' various safety shortcomings always remained obscured to consumers. In fact, the defendants failed to advise two Iowa consumers who received CMV+ products and were indifferent about taking precautions to prevent this from happening in the future. The court finds the defendants' claim their therapies were safe is deceptive in violation of the CFA.

H. The Defendants' Deceptive Testimonials.

The defendants' testimonial handout was provided directly to consumers who attended the defendants' sales seminars. The defendants admitted the seminars were a key feature of their advertising strategy seeking prospective therapy buyers.

The handout features many positive messages and claims regarding what stem cell therapy could allegedly accomplish in improving pain and health conditions. These messages were viewed as outcomes they would experience if they bought the defendants' therapies. Iowa consumers testified the handout encouraged them to purchase the defendants' stem cell therapies and that the testimonials played a factor in their buying decision.

The defendants' handout was deceptive because it had a capacity to mislead consumers as to at least one material fact. Iowa consumers were likely to place less, if any, weight on the defendants' handout if they knew the several material facts the defendants concealed. Further, the defendants were unable to verify whether the listed people providing testimonials were real, how they had received therapy, and whether the therapies allegedly received by the endorsers were the same products being sold the Iowa consumers.

Also, Dr. Morrison confirmed it is well established there are placebo effects with cell therapies that could change a therapy recipient's initially positive view over time. Testimonials are particularly unreliable. Yet, the defendants did not have any process in place to verify whether the endorsers continued to feel the way they allegedly did long after the therapy.

Finally, Jayes admitted only one of the listed people was reflected in medical records as having received treatment from the relevant parties. So, it is unknown and the defendants did not prove the endorsers received therapies the Iowa consumers received or that these endorsers existed.

Each of these examples were material facts that were withheld from Iowa consumers. The State carried its burden to prove the defendants' use of the handout in this manner was a deceptive practice in violation of the CFA.

I. Legal Standards and Burden of Proof: Unfair Acts and Practices

The CFA also outlaws "unfair" acts and practices in connection with the sale and advertisement of merchandise.[601] An "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.[602] The State has the burden to prove the defendants engaged in unfair acts or practices by a preponderance of clear, convincing, and satisfactory evidence.[603]

Statutes that prohibit "unfair practices" are designed to infuse flexible equitable principles into consumer protection so that it may respond to the myriad of unscrupulous business practices modern consumers face.[604] Determining what constitutes an unfair practice is a "highly fact-specific inquiry" that depends upon the circumstances of each case.[605] "A course of conduct contrary to what an ordinary consumer would anticipate contributes to a finding of an unfair practice."[606]

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[601] Iowa Code § 714.16(2)(a).
[602] Iowa Code §714.16(1)(i).
[603] *State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 524 (Iowa 2005).
[604] *Id.* at 525.
[605] *Id.*
[606] *State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d at 37 (Iowa 2013) (*citing Cutty's*, 694 N.W.2d at 530).

J. Analysis: Defendants' Unfair Acts and Practices

The defendants' acts and practices caused unavoidable financial and physical consumer harm. The consumers that testified spent thousands of dollars that were worthless. They all testified their expenditure was significant and caused financial harm to them.

The court recognizes the desperation of consumers who tried various legitimate therapies for their pain and suffering but did not find success. The defendants presented themselves in these circumstances involving vulnerable Iowans to exploit them.

The court finds there is no consumer or competitive benefits the defendants practices produced. Consequently, it need not weigh Iowa consumers' injuries against alleged benefits.

K. Count 2 – Background and Legal Standards: Door-to-Door Sales Act Violations

"[H]ome solicitation sales can often involve unfair, high-pressure tactics."[607] The DDSA provides important consumer protections for high-pressure sales made outside of typical storefront settings. It requires that sellers provide Iowa consumers a 3-day right to cancel transactions for any reason, notices of their cancellation rights, and a simple means to effectuate their rights.[608]

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[607] *State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d 12, 21 (Iowa 2013).
[608] *See* Iowa Code § 555A.

> A "door-to-door sale" means:
> [A] sale, lease, or rental of consumer goods or services with a purchase price of twenty-five dollars or more, whether under single or multiple contracts, in which the seller or the seller's representative personally solicits the sale, including those in response to or following an invitation by the buyer, and the buyer's agreement or offer to purchase is made at a place other than the place of business of the seller.[609]

The DDSA further defines "place of business of the seller" as "the main or permanent branch office or local address of a seller."[610]

Iowa's DDSA makes compliance simple by setting forth the text, language, font, and placement of the required cancellation notice to be included in the DDSA receipt or contract and the text, language, font, and placement of the separate and required "Notice of Cancellation" form.[611] What is required of the seller and what he may not do is likewise spelled out.[612] The DDSA provides a step-by-step guide for sellers to follow to ensure their actions comply within the statute.

For example, sellers engaged in door-to-door sales must comply with several requirements including providing a receipt or copy of the contract which includes the date of the transaction; the name and address of the seller; a prescribed statement regarding the consumer's right to cancel within no less than three business days; and a separate, more-detailed notice of the consumer's cancellation

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[609] Iowa Code § 555A.1(3)(a).
[610] Iowa Code § 555A.1(4).
[611] Iowa Code §§ 555A.2-.3.
[612] Iowa Code § 555A.4.

rights.[613] Additionally, the DDSA places certain duties upon the seller including, but not limited to, providing two copies of the cancellation notice to the consumer and honoring a notice of cancellation.[614]

The right to cancel is the cornerstone of the DDSA. The consequences for noncompliance - voiding of the contract and a complete defense to any action brought upon it - is a significant feature designed to impress upon sellers the importance of compliance with the law.[615]

L. Burden of Proof: DDSA Violations

The legislature declared that each failure to comply with the DDSA is a per se "unlawful practice" in violation of the CFA.[616] The State must prove all violations of the CFA by a preponderance of clear, convincing and satisfactory evidence.[617]

M. Analysis: Application of the DDSA

The court must determine whether the DDSA applied to the defendants' sales activities in Iowa and whether the State proved the defendants failed to abide the DDSA's requirements.

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[613] Iowa Code §§ 555A.2-.3.
[614] Iowa Code § 555A.4.
[615] Iowa Code § 555A.5.
[616] Iowa Code § 555A.6(2) ("A violation of this chapter is a violation of section 714.16, subsection 2, paragraph 'a.'").
[617] *State ex rel. Miller v. Cutty's Des Moines Camping Club, Inc.*, 694 N.W.2d 518, 524 (Iowa 2005).

1. The DDSA applied to the defendants' sales activities.

In analyzing this claim, the court must determine whether the defendants sold consumer goods and services costing over $25 and whether Iowa consumers' agreements to purchase merchandise from the defendants occurred "at a place other than the place of business of the seller."

As to the first question, all the defendants' merchandise[618] cost more than $25. First, Thomas admitted each stem cell therapy sold to Iowa consumers cost more than $25.[619] Second, the defendants admitted their therapies cost over $25 in response to discovery.[620] Third, the defendants' documents provided in response to the State's subpoenas verify all therapies sold to Iowa consumers cost more than $25.[621]

a. Iowa consumers' agreements to purchase therapies occurred outside the defendants' places of business.

The defendants operated in at least 15 other states apart from Iowa.[622] The defendants' mission was to "offer patients non-surgical and non-opiate options to

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[618] The CFA defines merchandise broadly to include "any objects, wares, goods, commodities, intangibles, securities, bonds, debentures, stocks, real estate or services." Iowa Code section 714.16(1)(e).
[619] Trial Tr. Vol. 3, 87:10-12.
[620] D0105, Trial Ex. 1.
[621] D0142, Trial Ex. 11 at 178-179.
[622] D0140, Trial Ex. 19 (According to a form provided by Defendants to consumers, the other states in which Defendants also operated included: Arizona, Florida, Illinois, Indiana, Kansas, Kentucky, Minnesota, Michigan, Missouri, Nebraska, Ohio, Pennsylvania, South Dakota, Tennessee, and Wisconsin).

improve their pain, mobility and quality of life all in the convenience of a *home setting*…"[623] Their advertising and sales model depended upon home sales throughout the United States and Iowa instead of sales in traditional brick-and-mortar storefronts.

For purposes of applying the DDSA, a seller's "place of business" 'means the main or permanent branch office or local address.[624] The defendants' place of business could not temporarily migrate from home-to-home throughout the United States simply depending upon where the defendants' salespersons happened to be located during their sales activities. "A corporation has no residency in the sense that a natural person does. It is an artificial being, operating through its officers, directors, and agents."[625] However, a "corporation is not ambulatory."[626] "The prevailing view is that a corporation's 'residency' is where its principal place of business is located."[627] "A corporation, unlike a natural person, has a stationary legal domicile in the state and county of its creation, which may not be changed at

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[623] D0142, Trial Ex. 11 at 176.
[624] Iowa Code § 555A.1(4).
[625] *Iowa Pub. Serv. Co. v. Iowa State Com. Comm'n*, 263 N.W.2d 766, 769 (Iowa 1978).
[626] *State v. Dist. Ct. in & for Winnebago Cnty.*, 191 Iowa 244, 182 N.W. 211, 213 (1921).
[627] *Iowa Pub. Serv. Co. v. Iowa State Com. Comm'n*, 263 N.W.2d 766, 769 (Iowa 1978) (*citing Cannon v. Century Construction Co.*, 252 Iowa 88, 89, 106 N.W.2d 65, 66 (1960), 18 C.J.S. Corporations s 176(b), p. 583 (1939), *770 18 Am.Jur.2d Corporations s 160, p. 694 (1965).

will, but only as authorized by statute. It is not migratory. It is a legal entity, and as such its existence, its name, and its residence are born of the law."[628] Thus, the defendants must have a corporate home for purposes of determining whether the DDSA applied.

Keeping these principles in mind, the court finds that three facts demonstrate Iowa consumers agreed to purchase merchandise from the defendants at locations other than the defendants' place of business. First, the operating agreements of both Summit and Biologics indicate that their places of business were outside of Iowa, so all Iowa sales were not in the defendants' place of business.[629] Second, the defendants admitted the State's allegations that none of the defendants' sales occurred within their permanent, main or local places of business.[630] Third, the defendants admitted none of their sales occurred in their principal places of business.[631]

2. The defendants violated the DDSA.

Having determined the DDSA's requirements applied to the defendants, the court turns to the question of whether the defendants complied with the DDSA.

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[628] *State v. Dist. Ct. in & for Winnebago Cnty.*, 182 N.W. 211, 213 (1921).
[629] D0024, Amended Answer ¶4; D0141, Trial Ex. 20, 944; D0024, Amended Answer ¶5; D0143, Trial Ex. 21 at 967.
[630] D0024, Amended Answer ¶¶151-153.
[631] D0105, State Trial Ex. 1, 0002, 0004.

In their amended answer and at trial, the defendants conceded they violated nearly every DDSA provision. Thomas conceded the defendants' 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.[632] The defendants' sales contracts did not include a notice of cancellation.[633] The defendants did not furnish two completed copies of a notice of cancellation to Iowa buyers.[634]

The defendants testified they orally apprised all consumers of their 3-day cancellation rights even though the defendants admit they did not follow any of the written requirements.[635] Thomas testified that while he did not abide by any written notice requirements of the DDSA, all the defendants' salespersons orally apprised consumers of their 3-day cancellation rights.[636] The court does not find this testimony credible. No consumer witness verified Thomas' assertion that they were told they could cancel. In addition, Thomas was not at every sales seminar so he cannot assure this occurred.[637] Therefore, the court finds the defendants also failed

[632] D0024, Amended Answer ¶154; Trial Tr. Vol. 3, 87:22-88:5.
[633] D0024, Amended Answer ¶155; Trial Tr. Vol. 3, 88:6-10.
[634] D0024, Amended Answer ¶156; Trial Tr. Vol. 3, 88:11-16.
[635] Trial Tr. Vol. 3, 88:17-89:9.
[636] Trial Tr. Vol. 3, 89:10-17.
[637] Trial Tr. Vol. 3, 90:3-25.

to orally apprise all Iowa consumers of their DDSA rights to cancel the stem cell therapy sales contracts the defendants initiated.

N. Count 3 – Older Iowans Act Violations: Background and Legal Standards

The Older Iowans Act ("OIA") augments the CFA by allowing the court to impose additional civil penalties up to $5,000 per violation for consumer frauds committed against older[638] Iowans.[639] The court "has latitude when determining whether and to what degree remedies under the CFA and OIA are appropriate."[640]

In determining whether to impose additional penalties under the OIA, the court considers whether the defendant's conduct was in willful disregard of the rights of the older individual; whether the defendant knew or should have known that the defendant's conduct was directed to an older individual; whether the older individual was substantially more vulnerable to the defendant's conduct because of age, poor health, infirmity, impaired understanding, restricted mobility, or disability, than other persons; and any other factors the court deems appropriate.[641]

OIA "remedies are aimed at equitable and remedial goals of making victims whole, extracting ill-gotten gains, and 'protecting Iowa consumers' by encouraging

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[638] "Older individual" means an individual who is sixty years of age or older. Iowa Code § 714.16A(3).
[639] Iowa Code § 714.16A(1)(a).
[640] *State ex rel. Att'y Gen. of Iowa v. Autor*, 991 N.W.2d 159, 167 (Iowa 2023).
[641] Iowa Code § 714.16A(2)(a)-(d).

compliance with the law."[642] The OIA does not indicate that any single mandatory or permissive consideration must bear greater weight than the others, so the court need not weigh the considerations equally in applying the OIA to the facts of this matter.

O. Analysis: Application of the OIA to Defendants

The court determined the defendants violated section 714.16. Having considered all the OIA's mandatory and permissive factors, the court finds it appropriate to levy additional penalties up to $5,000 per violation for the following reasons.

First, defendants admitted that they targeted older age demographics when sending mail solicitations to prospective dinner sales seminar attendees. The State need not prove intentional conduct that targets Iowa consumers over sixty; rather, proving the defendants "evinced negligent or reckless indifference to the rights of elderly Iowans" is sufficient.[643] Thomas admitted that he and Meek targeted mail solicitations to those over the baseline age of fifty.[644] The defendants directed their own assistant, Gail Honeycutt, to contact the mail services company the defendants

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[642] *Att'y Gen. of Iowa v. Autor*, 991 N.W.2d at 168. *See, e.g.*, *State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d 12, 45 (Iowa 2013) (noting the OIA's "self-evident goal of protecting Iowa consumers who are vulnerable to unfair sales tactics because of their age").
[643] *State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d 12, 44 (Iowa 2013).
[644] Trial Tr. Vol. 3, 92:5-14.

used called "Leading Response" to implement these age demographics.[645] The defendants were not only aware they were targeting older Iowans but personally engaged in targeting them. The defendants knew or should have known using a demographic solicitation baseline of age fifty would naturally result in a significant number of Iowa consumers over sixty receiving solicitations. Such activities at least evinced a negligent or reckless indifference to the rights of older Iowans.

Second, witness testimony and medical records confirmed older Iowans bore the brunt of the defendants' conduct. The Iowa consumer witnesses universally claimed most individuals at the seminars were older individuals such as themselves. They did not see young people attending the seminars. The defendants' salespersons, and the defendants themselves made presentations and sales to Iowans in Iowa, thus they witnessed this phenomenon. The defendants knew or should have known their conduct disproportionally impacted older Iowans.

Third, the marketing claims the defendants approved gave older Iowa consumers the wrong impression the alleged younger stem cells consumers would receive would be more effective than consumers' own older and decreasing stem cells. "To ascertain whether a practice is likely to mislead in the consumer protection context, courts typically evaluate the overall or 'net impression' created

[645] Trial Tr. Vol. 3, 92:2-4.

by the representation."[646] "A misleading impression created by a solicitation is material if it 'involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product.'"[647] The defendants created a misleading net impression by highlighting the alleged relationship between the impotency of older individuals' own stem cells as compared to newer umbilical cord cells of babies Iowa consumers would purportedly receive.

For example, the defendants admitted their own website contained the following language:

> 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.[648]

The defendants admitted the mail solicitation they approved read: "[s]tem cells rapidly decline with age" and included graphics showing that the relative amount of stem cells shrinks with age.[649] Iowa consumer witnesses testified they believed they would receive newer, younger and more potent stem cells that would entail

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[646] *State ex rel. Miller v. Vertrue, Inc.*, 834 N.W.2d 12, 34 (Iowa 2013).
[647] *Id.*
[648] D0024, Amended Answer ¶163.
[649] D0024, Amended Answer ¶162.

good results. This was false and misleading information that further convinced older Iowa consumers to purchase therapies from the defendants.

Fourth, the defendants sold products they knew would be introduced to consumers' bodies to allegedly ameliorate chronic health problems and pains generally associated with aging populations. The defendants' examples of specific health problems highlighted during the seminar presentations are the kind of degenerative health problems they knew or should have known are commonly associated with older individuals. The defendants believed, without evidence, that "older consumers tended to have a better chance of success with stem cell therapies..."[650] Such messaging was crafted toward, and would be more successfully received by, older Iowa consumers than younger ones.

Fifth, some of the defendants' most serious actions directly impacted older Iowans' safety and their financial circumstances. The court finds the State convincingly carried its burden to show the defendants violated the OIA.

IV. AFFIRMATIVE DEFENSES

Having determined the defendants violated the CFA, DDSA, and the OIA, the court now addresses the defendants' affirmative defenses. The defendants in their proposed findings of fact and conclusions of law did not address several of their affirmative defenses. They did not discuss or present argument regarding their

[650] D0024, Amended Answer ¶161.

defense of laches, estoppel, waiver, and jurisdiction. Further the court finds that the evidence presented by the defendants did not establish any of those defenses.

A. Consumers Gave Informed Consent

The defendants claim that all their unsubstantiated, deceptive, and unfair advertisements and other practices were cured when Iowa consumers signed an informed consent form[651] immediately before receiving therapy. The court is unaware of any Iowa authority allowing informed consent under Iowa Code section 147.137 as an affirmative defense to consumer fraud actions brought by the State. The defendants cite no authority for the adoption of this defense in a consumer fraud action.

The defendants assert that under section 147.137 the requirements of this defense are that the written consent must:

> (1) set forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any;
> (2) acknowledges that the disclosure of that information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner; and
> (3) is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent, is signed by a person who has legal authority to consent on behalf of that patient in those circumstances.[652]

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[651] D0172, Trial Ex. 37.
[652] D0405, Defendants' Findings of Fact, Conclusions of Law, and Ruling, at 21-22 (Polk Cty Dist. Ct. Iowa Code Sep. 26, 2025) (citing Iowa Code § 147.137).

The defendants contend their form met these requirements. The court rejects the defendants' informed consent argument because it is: 1. nnot a recognized defense to a consumer fraud action, and 2. inapplicable given the facts of this case even presuming it were a valid defense to CFA actions.

1. Informed consent is unavailable as a defense to CFA actions.

The defendants argue that because Iowa consumers signed an informed consent,[653] the court must dismiss the State's CFA action. The defendants cite statutory text entirely outside of the CFA regarding what "creates a presumption" of informed consent in medical malpractice cases.[654] However, the cited statutory text applies only "to any medical or surgical procedure or course of procedures in patient care," not to advertising and sales activities that are at the heart of this consumer fraud case against the defendants salespersons.[655] The defendants cite to no other authority for their proposition. The court finds this is not a recognized defense to a statutory consumer fraud claim.

[653] D0172, Trial Ex. 37.
[654] Iowa Code § 147.137.
[655] Iowa Code § 147.137.

2. Iowa consumers could not have given informed consent after the defendants consistently misled them.

If informed consent under section 147.137 could be applied to a consumer fraud action, the informed consent form here was insufficient to provide informed consent because the known risks were not presented to the consumers.

It was not possible for Iowa consumers to give informed consent given the misinformation the defendants gave consumers before receiving therapy. Dr. Morrison best summarizes the problem with the argument that Iowa consumers gave informed consent for their therapies:

> The most fundamental principle of informed consent is that it has to be informed with accurate information. And when leading up to the consent there's lots of misinformation provided to these patients then consent can't be informed.
>
> Even the document itself, the central – the central idea in the consent document is that patients are about the receive a stem cell therapy. Whereas, there's reason to believe that there were few or no cells in the products that the defendants were administering.[656]

In addition, the informed consent form did not warn immunocompromised Iowa consumers that the stem cell products could contain cytomegalovirus or other pathogens.[657] This was not undisclosed and was ignored by the defendants when they discovered two Iowans received contaminated products.[658]

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[656] Trial Tr. Vol. 1, 97:1-11.
[657] D0172, Trial Ex. 37.
[658] D0172, Trial Ex. 37.

Also, the form did not warn Iowa consumers experiencing chronic kidney disease or heart failure that they should disregard the advice they should drink more water to aid the efficacy of the alleged stem cells they received. Consumers were not warned that having cancer disqualified them from the treatment.

3. The nurse practitioner who implemented therapies the defendants sold was not qualified to provide informed consent.

Iowa consumers were not informed that Ms. Decker, who gave the defendants' therapies was not formally and sufficiently qualified or knowledgeable about stem cell therapy. A "physician's experience or training with the proposed treatment can be information material to the decision of a reasonable person in the patient's position to or not to undergo the proposed treatment."[659] The defendants could not have provided consumers informed consent because they admitted they are salesmen, not medical professionals, so the person who would have had to be qualified to provide it was the nurse practitioner who implemented the therapies. Furthermore, in this context the defendants advertised that the consumers would meet industry experts at the seminar. That never occurred.

The only person who had any medical training was Ms. Decker, who was a nurse. However, she was not qualified to discuss accurately stem cell therapies. Ms. Decker did not have any education, training or experience with stem cells prior

[659] *Andersen v. Khanna*, 913 N.W.2d 526, 542 (Iowa 2018).

to her activities in this case.[660] Apart from an approximately 2-hour "zoom" training and a few days of job shadowing, DW did not provide Ms. Decker any other training in regenerative medicine.[661] The defendants' informed consent did not disclose any of this material information to Iowa consumers.

Furthermore, she simply reiterated the deceptive statements the defendants made that the stem cells would travel in the body and fix what needed to be fixed. It was obvious she had no training as to how or where the therapies should be injected. Instead, she asked the recipient where they wanted it.

The defendants did not establish that they provided the known risks to the Iowa consumers. In summary, the informed consent argument the defendants advanced is an attempt to shift blame for their own conduct onto Iowa victims and the informed consent form, along with the statements from the defendants, did not accurately and adequately disclose the known risks or the truth about stem cell therapies.

B. Corporate Veil Protects Individual Defendants from Personal Liability

The State is not required to pierce the corporate veil because personal liability for CFA violations arises from one's "complete control of [an entity] and

[660] Trial Tr. Vol. 5, 113:3-5.
[661] Trial Tr. Vol. 5, 114:1-10.

his own personal acts in perpetrating consumer fraud."[662] "A corporate shield does not insulate a nonresident defendant from jurisdiction of an Iowa court for personal acts causing injury to residents of Iowa. To immunize a defendant from jurisdiction merely because that defendant is associated with a corporation would allow the corporate shield to be used as a sword."[663]

Additionally, the defendants, Meek and Thomas, conceded in pretrial briefing: "A court may disregard the corporate structure by piercing the corporate veil only under circumstances where the corporation is a mere shell, serving no legitimate business purpose, and used primarily as an intermediary to perpetuate fraud or promote injustice."[664] Defendants also admitted that a factor supporting the piercing of the corporate veil is "the business's promotion of fraud or illegality."[665]

There is no legitimate business purpose in making material misrepresentations to Iowa consumers about an expensive, invasive, dangerous and

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[662] *State ex rel. Miller v. Santa Rosa Sales & Mktg., Inc.*, 475 N.W.2d 210, 220 (Iowa 1991).
[663] *State ex rel. Miller v. Grodzinsky*, 571 N.W.2d 1, 6 (Iowa 1997), as amended on denial of reh'g (Dec. 11, 1997) (internal citations omitted).
[664] D0247, Defendants' Trial Brief, at 19 (citing *In re Marriage of Ballstaedt*, 606 N.W.2d 345, 349 (Iowa 2000); *C. Mac Chambers Co. v. Iowa Tae Kwon Do Academy, Inc.*, 412 N.W.2d 593, 597 (Iowa 1987) (quoting *Briggs Transp. Co. v. Starr Sales Co.*, 262 N.W.2d 805, 810) (Iowa 1978)).
[665] D0247, Defendants' Trial Brief, at 20.

unproven product introduced into their bodies while violating Iowa's consumer fraud acts and the DDSA.

Further, the court finds the State is not required to pierce the corporate veil based upon the court's ruling in *Santa Rosa.* In *Santa Rosa* the court held that an individual may be personally liable for consumer fraud violations if he (1) exercised complete control of the defendant entities and; (2) engaged in personal acts perpetuating consumer fraud.[666]

1. The individual defendants' control over the corporate entities.

The defendants Meek and Thomas were the only ones in positions to control the defendant entities, their activities, and their sales agents and contractors. Both Summit and Biologics are member-managed LLCs.[667] Meek and Thomas are the only members of both defendant entities.[668] They never transferred their membership interests to any other individual.[669] Likewise, Meek and Thomas are the only managers of both defendant entities.[670] They never added additional managers to either defendant entity.[671] According to both the Summit and

[666] *State ex rel. Miller v. Santa Rosa Sales and Marketing, Inc.*, 475 N.W.2d 210, 220 (Iowa 1991).
[667] D0141, Trial Ex. 20 at 945; D0143, Trial Ex. 21 at 968.
[668] D0141, Trial Ex. 20 at 944-45, 965-66; D0143, Trial Ex. 21at 967-68; 988-89.
[669] D0141, Trial Ex. 20 at 945; D0143, Trial Ex. 21 at 968; Trial Tr. Vol. 3, 80:19-24.
[670] D0141, Trial Ex. 20 at 945; D0143, Trial Ex. 21 at 968.
[671] Trial Tr. Vol. 3, 80:25-81:1-2.

Biologics operating agreements, only Meek and Thomas could make binding decisions on behalf of the defendant entities and direct their salespersons as the only company members and managers.[672]

There were no other conceivable persons to direct and decide the upfront sales and advertising acts of the defendant entities. The defendant entities are closely held by Meek and Thomas with a small number of other salespersons.[673] In response to the State's prelitigation investigatory subpoenas, the defendants provided a list of other past and present salespersons affiliated with Summit and Biologics.[674] The defendants' response indicated that the only employees were Meek and Thomas, and the other salespersons were considered as independent contractors.[675] The court finds the Meek and Thomas controlled the corporate defendant entities Summit and Biologics.

2. Scott Thomas and Rylee Meek were involved at every level of the fraudulent advertising and sales activities.

Having determined Meek and Thomas controlled the corporate defendants, the court turns to the question whether Meek and Thomas personally perpetuated consumer fraud. The court finds Meek and Thomas personally perpetuated consumer fraud for the following reasons.

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[672] D0141, Trial Ex. 20, 952-54; D0143, Trial Ex. 21 at 975-77.
[673] D0142, Trial Ex. 11 at 163-64, 172-73.
[674] D0142, Trial Ex. 11 at 163-64, 172-73.
[675] D0142, Trial Ex. 11 at 163-64, 172-73.

Meek and Thomas were involved at every level in making fraudulent claims and sales with Iowa consumers in Iowa, including: 1. the social dynamic selling system used to solicit Iowans; 2. mail solicitations Iowans received; 3. seminar sales dinner Iowans attended; and 4. sales Meek and Thomas personally finalized with Iowans. Each of these examples justify the court holding them personally liable.

First, Meek and Thomas developed the marketing system they implemented to sell stem therapies to Iowans. They claimed to the co-founders of the social dynamic selling system. Meek took successful portions of other existing selling systems to create the social dynamic selling system. Both used the system with other products and services before starting the stem cell business. They used the social dynamic selling system to sell stem cell therapies to Iowa consumers. Before using it with Iowans, they tested their system in Ohio and compared it to cold internet advertising for stem cell therapies. They found their system was more effective in generating interest for stem cell therapies than cold advertising. Therefore, both defendants are directly implicated in the sales model used with all Iowa consumers to sell their therapies.

Second, Meek and Thomas were involved in the mail solicitations.[676] The corporate defendants paid the costs to send the mailers. Meek and Thomas

[676] D0144, Trial Ex. 22.

determined the consumer demographics the mail services company would target. Meek and Thomas approved the design and wording of the mailer, including all claims about stem cell therapies contained within it. Thomas admitted he reviewed the mailer before it was sent. Every message it reflected was a message Thomas wanted. Meek and Thomas directly developed, approved, and sent the advertising messages Iowa consumers received.

Third, Meek and Thomas created, implemented, and managed all aspects of the dinner seminars. Thomas admitted he created the PowerPoint presentation shown to attendees. Their independent contractor salespersons traveled with Meek and Thomas to learn the presentations before conducting seminars independently. Meek and Thomas trained their salesperson with training lasting approximately four weeks.

Meek and Thomas personally gave seminar presentations in Iowa. Meek admitted he gave Iowa seminars on at least nine occasions, including in Atlantic, Muscatine, and Charles City. Thomas admitted he gave one seminar presentation in Fort Dodge. However, Iowa consumer witness Stephen Sells testified that Thomas personally gave at least one other seminar in Ankeny that Sells attended. Accordingly, Meek and Thomas integrally managed and participated in dinner seminars where Iowans purchased therapies.

Fourth, Meek and Thomas closed sales with Iowa consumers in Iowa. Meek and Thomas made commissions based on sales they personally completed in addition to drawing profits from the corporate defendants.[677] They admitted all these sales - including the ones they personally made - violated the DDSA. Consequently, Meek and Thomas made unsubstantiated advertising claims directly to Iowa consumers and violated the DDSA while making sales in Iowa.

Thomas and Meek controlled the corporate defendants and personally perpetuated consumer fraud, the court rules they are personally liable for any judgment issued by the court.

C. The Defendants Were Included in Prior Settlement with Other Parties

The defendants amended their October 11, 2023, answer on March 11, 2024, alleging they were covered by a May 10, 2023, settlement agreement they did not sign. The defendants contend the settlement agreement enacted between the Iowa Attorney General and other parties prior to the filing of this lawsuit was also applicable to them. This issue was previously raised in a motion for summary judgment. The court denied that motion. In denying the motion the court held "[t]he defendants have a burden to prove 'the contract was made for his express benefit.'"[678] The court concluded that as a matter of law the defendants did not

[677] Trial Tr. Vol. 3, 143:17-25; Vol. 5, 6:13-14.
[678] D0048, Order re: Defendants' Motion for Summary Judgment, at 14 (Polk Cty Dist. Ct. Dec. 27, 2024).

establish this fact. There was no evidence presented at trial that changes the court's decision on this issue. The evidence at trial did not establish that the settlement with the other parties was made for the benefit of the individual and corporate defendants here. In so finding the court incorporates its findings and conclusions from its summary judgment decision and concludes that the State's settlement with others precludes the present claims against the defendants.

D. Successor Corporations

The court addresses the relationship between the two corporate defendants, Summit and Biologics. The court will decide whether the entities remained distinct or if Biologics was a successor corporation to Summit.

The court concludes Biologics was a continuation of Summit, so it can be held responsible for Summit's debts. "A successor will be liable for the predecessor's debts when:. . . the successor is a 'mere continuation' of the predecessor. . . One theme of these cases is that a successor is liable when it is not distinct from its predecessor."[679] Again, Thomas and Meek, continued to be the

[679] *Ostrem v. Prideco Secure Loan Fund, LP*, 841 N.W.2d 882, 898 (Iowa 2014). *See also Nelson v. Pampered Beef–Midwest, Inc.*, 298 N.W.2d 281, 287–88 (Iowa 1980) (explaining the application of the "mere continuation" and merger exceptions); *Arthur Elevator Co.*, 236 N.W.2d at 392 (citing cases from other jurisdictions that focused on the sameness of the predecessor and successor); *In re Bellingham Ins. Agency, Inc*., 702 F.3d 553, 572 (9th Cir.2012) (explaining that in Washington, which recognizes the general rule of successor liability and the continuation exception, "[t]he nub of the inquiry is whether the purchaser represents merely a new hat for the seller" (internal quotation marks omitted)).

owners and managers of the defendant Biologics entity. There were no operational, strategic, or other changes in the business because of the name change. The defendants conducted the same sort of business and made basically the same claims as "Biologics" as it was with "Summit." The operating agreements of both entities were nearly identical. No contractual agreement was presented into evidence by any party indicating that Biologics disclaimed the debts and obligations of Summit. And, the defendants admitted in response to the State's Petition, "Biologics is the successor to Summit."[680]

The court finds Biologics Health, LLC, is a successor corporation to Summit Health Centers, LLC, and Biologics can be held liable for Summit's debts.

V. LIABILITIES

A. Count I – Consumer Fraud Act Violations

The court finds the following advertising claims the defendants made to Iowa consumers were unsubstantiated. The defendants failed to carry their burden to show a reasonable basis for the claims at the time the defendants made them, thus the claims were per se deceptive practices violating Iowa Code section 714.16(2)(a):

[680] D0024, Amended Answer ¶19.

1. The alleged stem cell therapies the defendants sold seek out inflammation, degeneration, and damage throughout the body and migrate to those areas to fix them, could impart general wellness.

2. The alleged stem cell therapies the defendants sold "regenerate and repair tissues in consumers' bodies that are damaged due to age, disease and defects" or "generate new cells."

3. The differing dosages of alleged stem cells the defendants sold at different prices could help Iowa consumers with each consumer's specific health problem.

The court finds the State proved by a preponderance of clear, convincing and satisfactory evidence that these advertising claims were deceptive and misleading practices in violation of Iowa Code section 714.16(2)(a). The advertising claims the defendants made were acts and practices that had a tendency or capacity to mislead a substantial number of Iowa consumers as to the material facts. The advertising claims were in connection with the defendants' sales of stem cell therapies because they were related to or there existed a nexus between them.

Further, the court finds the State proved by a preponderance of clear, convincing and satisfactory evidence that the defendants advertising claims were unfair practices in violation of Iowa Code section 714.16(2)(a) because each advertisement was an act or practice which caused substantial, unavoidable injury to Iowa consumers that is not outweighed by any consumer or competitive benefits which the practice produces. The court could find no consumer or competitive benefit.

The court finds the additional 18 advertising claims listed below and which the defendants made to Iowa consumers were unsubstantiated. The defendants failed to carry their burden to show a reasonable basis for the claims at the time the defendants made them to Iowa consumers, so the claims were per se deceptive practices violating Iowa Code section 714.16(2)(a).

4. Neck Pain
5. Joint Pain / Injury
6. Shoulder Pain
7. Tennis Elbow
8. Tendonitis
9. Back Pain
10. Low Back Pain
11. Knee Pain
12. ACL/MCL Tears
13. Degenerative Arthritis
14. Plantar Fasciitis
15. Degenerative Joint Disease
16. Arthritis Joint Pain or Injury
17. Degenerative Cartilage / Ligaments
18. Neuropathy
19. Osteoarthritis of the Knee
20. Ligament Strains
21. Bursitis

The court finds the State proved by a preponderance of clear, convincing and satisfactory evidence that the above-referenced advertising claims were also deceptive, misleading, and unfair practices in violation of Iowa Code section 714.16(2)(a), for the same reasons as the advertising claims #1-3 outlined above.

The court finds the defendants engaged in unsubstantiated, deceptive, misleading and unfair acts and practices in violation of the CFA for the same

reasons outlined for claims #1-21 when the defendants claimed the stem cell therapies, they sold Iowans were generally safe. The defendants failed to carry their burden to substantiate their claim the therapies they sold were safe. The State proved by a preponderance of clear, convincing and satisfactory evidence that the defendants' safety claim was deceptive, misleading and unfair. This is the 22nd violation.

Finally, the court finds the defendants' testimonial practices were unsubstantiated, deceptive, misleading and unfair acts and practices. The defendants failed to carry their burden to substantiate that consumers could expect the same or similar results as those touted by the alleged endorsers. The State further proved by a preponderance of clear, convincing and satisfactory evidence the defendants' testimonials were deceptive, misleading and unfair acts and practices. This is the 23rd violation.

B. Count II – Door-to-Door Sales Act Violations

The court finds the State proved by a preponderance of clear, convincing and satisfactory evidence that the defendants violated the Iowa Door-to-Door Sales Act in Iowa Code chapter 555A, in the five following ways constituting additional per se violations of Iowa Code section 714.16:

24. The defendants failed 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 in violation of Iowa Code section 555A.2;

25. The defendants failed to furnish a form that contained a "Notice of Cancellation" that also contains the required statutory notice in violation of Iowa Code section 555A.3;

26. The defendants failed 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 in violation of Iowa Code section 555A.4(1);

27. The defendants failed to orally apprise Iowa consumers of their rights to cancel in violation of Iowa Code section 555A.4(3); and

The court identifies these twenty-seven (27) violations of the CFA for purposes of fashioning appropriate remedies, including the Older Iowans Act (OIA) civil penalty enhancements.

VI. REMEDIES

Having found the defendants violated the CFA, DDSA, and OIA, the court now determines the appropriate remedies. The CFA's "remedies are aimed at equitable and remedial goals of making victims whole, extracting ill-gotten gains, and 'protecting Iowa consumers' by encouraging compliance with the law."[681] "By authorizing monetary consequences, these statutes advance equitable and remedial purposes, including protecting Iowans by encouraging compliance with the law."[682]

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[681] *Id.* at 168.
[682] *State ex rel. Att'y Gen. of Iowa v. Autor*, 991 N.W.2d 159, 166–67 (Iowa 2023).

Even if the CFA and OIA remedies were to be characterized as "punitive," "'punitive damages' are 'within the purview of the equity court' . . . [which may] punish the wrongdoer and set an example."[683]

The State requests: (1) permanent injunctive relief, (2) consumer reimbursement (both for all known consumers and a claims-made process for unknown consumers), (3) civil penalties, (4) enhanced civil penalties under the OIA, and (5) reasonable costs and attorney fees.

A. Permanent Injunctive Relief

"If it appears to the attorney general that a person has engaged in . . . a practice declared to be unlawful by this section [of the CFA], the attorney general may seek and obtain in an action in a district court a . . . 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 . . ."[684] The court finds a permanent injunction should be granted.

[683] *Id.* (internal citations omitted).
[684] Iowa Code section 714.16(7).

B. Consumer Reimbursement

"The court may make orders or judgments as necessary . . . to restore to any person in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section."[685] "A claim for reimbursement may be proved by any competent evidence, including evidence that would be appropriate in a class action."[686]

The State requested the court: (a) order reimbursement of all known Iowa consumers who purchased stem cell therapies from the defendants; and (b) to allow for a claims-made process for unknown consumers, if any. The court now addresses each request.

1. Reimbursement of Known Iowa Consumers

The court finds it is appropriate to award reimbursement to all Iowa consumers who purchased stem cell therapies from the defendants.

The court orders the defendants reimburse all the 175 Iowa consumers reflected in the defendants' subpoena responses to the Iowa Attorney General. This amount equals $1,649,080.50.

[685] Iowa Code section 714.16(7).
[686] Iowa Code section 714.16(7).

2. Claims-Made Reimbursement Process for Unknown Iowa Consumers

The court provides for a claims-made reimbursement process accounting for unknown or missing Iowa consumers, if any, in part because the defendants failed to adequately account for all consumers during the State's investigation.

In April 2020, State issued subpoena 2896 to the defendants.[687] The subpoena's request #3 asked the defendants to provide a spreadsheet reflecting information for "each Iowa consumer from which Respondents received payment of any kind on or after January 1, 2017."[688] Information the State requested included each consumer's name, contact information, an itemization of purchases with amounts paid, and the "total amount the Respondent ever refunded to the consumer, if any."[689] Because the defendants claimed they ceased business in Iowa by the time of the subpoena issuance, their response to the subpoena's request for all Iowa consumer information should have included every single Iowa consumer who purchased therapies from the defendants. The defendants' response to the subpoena was under oath.[690]

The defendants responded to the subpoena in June 2020.[691] The defendants provided a spreadsheet with information for each Iowa consumer who purchased

[687] D0142, Trial Ex. 11.
[688] D0142, Trial Ex. 11 at 0164.
[689] D0142, Trial Ex. 11 at 0164.
[690] D0142, Trial Ex. 11 at 266-267.
[691] D0142, Trial Ex. 11 at 0266.

stem cell therapies responsive to request #3.[692] The spreadsheet listed 175 Iowa consumers.[693] It reflected only one Iowa consumer named Kenneth Hurt was provided a partial refund of $4,400.[694]

The State issued a separate subpoena, #2925, on Green Sky requesting all finance agreements and payment histories for Iowa consumers who financed purchases of stem cell therapies from the defendants.[695] Green Sky's response, and Thomas' trial testimony, showed Iowa consumers who financed purchases but who were not included among the 175 Iowa consumers in the defendants' response to State's subpoena 2896 under oath.[696] Additionally, at trial in March 2025, the defendants entered several exhibits obtained from Green Sky reflecting Iowa consumers they claimed were reimbursed or refunded. Therefore, it appears the defendants never adequately reported all Iowa consumers who paid them in response to the State's in April 2020 subpoena.

The court may make necessary reimbursement orders to repay all consumer fraud victims, including a claims-made process. "The court may make orders or judgments . . . which are necessary to restore to any person in interest any moneys .

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[692] D0142, Trial Ex. 11 at 0179.
[693] D0142, Trial Ex. 11 at 0179; D0204, Trial Ex. 52.
[694] D0142, Trial Ex. 11 at 0179; D0204, Trial Ex. 52 at 1495.
[695] D0254, D0251, D0252, Trial Exs. 93-95 at 3719-3720.
[696] Trial Tr. Vol. 3, 162:1-163:9 (e.g. Grayden Lau, Peggy Gorsuch, and Roger Beneke); D0142, Trial Ex. 11 at 179; D0204, Trial Ex. 52.

. . which have been acquired by means of a practice declared to be unlawful by this section."[697] This statutory authorization allows the court to do what is necessary to ensure all Iowa fraud victims are completely reimbursed.

Additional statutory language gives the court flexibility to fashion appropriate reimbursement orders under the circumstances: "A claim for reimbursement may be proved by any competent evidence, including evidence that would be appropriate in a class action."[698] "Where consumer identities are unknown or individual harm is uncertain, courts have generally approved a 'claims-made' process in which the class certification/settlement notice requires consumers to complete and file a claim form to receive redress."[699] In this case, the total scope of harm is uncertain because of the defendants' failure to provide a complete list of all their Iowa consumers to the State under oath in 2020. A combination of direct refunds to all known Iowa consumers allowing for a separate claims-made process for unknown consumers will account for all individual harms Iowans suffered.

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[697] Iowa Code §714.16(7).
[698] Iowa Code § 714.16(7).
[699] Federal Trade Commission., *Consumers and Class Actions: A Retrospective and Analysis of Settlement Campaigns. An FTC Staff Report*, https://www.ftc.gov/system/files/documents/reports/consumers-class-actions-retrospective-analysis-settlement-campaigns/class_action_fairness_report_0.pdf (last visited Sep. 18, 2025).

Finally, the court sitting in equity wields broad powers it may use to remedy the defendants' consumer fraud on Iowans.[700] The court's innate equitable power reinforces the CFA's express statutory permission for the court to craft appropriate reimbursement orders. The court finds it is appropriate to enact a process enabling unknown Iowa consumers to be reimbursed.

Therefore, the defendants must create a claims-made process for all unknown Iowa consumers. By July 1, 2026, the defendants shall hire a claims administrator. The time for Iowa consumers to submit claims shall be January 1, 2027. Iowa consumers may submit claims by: 1) Showing they were residents at the time they purchased therapies from the defendants; and 2) Showing evidence of their purchase(s). The defendants shall pay all claims by April 1, 2027. The defendants shall pay all the administrator's costs. The claim process shall be published in the newspapers in Des Moines, Iowa City, Davenport, Dubuque, Sioux City, Fort Dodge, Counsel Bluffs, Cedar Rapids and may be published on the Iowa Attorney General's website. The claims process and forms applicable shall be approved by the Attorney General's Office. The court retains jurisdiction to implement this process if disputes arise.

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[700] *See State ex rel. Att'y Gen. of Iowa v. Autor*, 991 N.W.2d 159 (Iowa 2023) (discussing the equitable character of Consumer Fraud Act actions brought by the Iowa Attorney General); *In re Marriage of Gallagher*, 539 N.W.2d 479, 481 (Iowa 1995) (en banc) ("Courts of equity may exercise broad powers in applying equitable principles.").

C. Civil Penalties

> 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.[701]

The court must set a deterrent example for others thinking about repeating the same activities with other Iowans. The court considered the defendants' actions to halt their sales in Iowa when the Attorney General sent its notice to cease and desist. The court finds that that $30,000 per violation is sufficiently deterrent and appropriate under the circumstances.

For these reasons, the court finds the defendants are jointly and severally liable and subject to civil penalties for all 27 CFA violations. Each civil penalty shall be $30,000. This equals $810,000. This civil penalty shall be deposited into the Consumer Education and Litigation Fund established by Iowa Code section 714.16C.

D. Enhanced Civil Penalties under the Older Iowans Act

For the reasons stated in the court's analysis applying the OIA to the defendants' actions, the court finds that all 27 CFA violations should each be increased by $5,000. This equals an additional $135,000 in civil penalties. All the

[701] Iowa Code §714.16(7).

defendants are jointly and severally liable for this amount, which shall be deposited into the Elderly Victim Fund established by Iowa Code section 714.16A.

E. State's Reasonable Costs and Attorney Fees

The CFA "provides that '[i]n an action brought under [section 714.16], the attorney general is entitled to recover costs of the court action and any investigation which may have been conducted, including reasonable attorneys' fees, for the use of this state.'"[702] The Iowa Supreme Court "held that this language precluded any discretion to deny the State's request for 'reasonable attorney fees and investigative costs incurred by the State in successfully prosecuting [a] consumer fraud action.'"[703] The State succeeded on the merits of its CFA, DDSA and OIA claims, so it is entitled to its reasonable attorney fees and costs.

The State shall file affidavits, an attorney fee affidavit, itemized billing statements, and receipts for its reasonable attorney fees and costs. The State shall submit its proposed fees and costs by May 15, 2026. The defendants have until May 30, 2026, to file any resistance to the amount of the requested attorney fees and costs.

IT IS THEREFORE ORDERED, ADJUDGED, AND DECREED:

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[702] Iowa Code § 714.16(11) (emphasis added).
[703] *State ex rel. Att'y Gen. of Iowa v. Autor*, 991 N.W.2d 159, 167 (Iowa 2023) *citing State ex rel. Miller v. Fiberlite Int'l, Inc.*, 476 N.W.2d 46, 48 (Iowa 1991).

The court finds a permanent injunction shall issue.

PERMANENT INJUNCTIVE RELIEF

I. DEFINITIONS

1. The *Act* is the Iowa Consumer Fraud Act, Iowa Code § 714.16.
2. The *Attorney General* means the Office of the Iowa Attorney General.
3. *Defendants* means Rylee John Meek, Scott David Thomas, Summit Partners Group, LLC, and Biologics Health, LLC, as individuals, collectively, jointly and severally, or in any combination.
4. *Regenerative Medicine Treatment* means any product, therapy, or treatment that falls under the definition of either: (a) *Stem Cell Therapy*; or (b) *Essentially Equivalent Regenerative Medicine Treatments or Products*.
5. *Stem Cell Therapy* means any product, therapy, or treatment that involves or is claimed to involve the use of stem cells derived from amniotic tissues, fluids or allografts, the placenta, Wharton's Jelly, umbilical cord blood, adipose tissue, or bone marrow, regardless of the manner in which the substance is harvested or kept (including via cryopreservation, dehydration or any other method).
6. *Essentially Equivalent Regenerative Medicine Treatments or Products* means any product, therapy or treatment that involves, is claimed to involve, contains or is derived from amniotic tissues, fluids or allografts, the

placenta, Wharton's Jelly, umbilical cord blood, adipose tissue, or bone marrow – including exosomes, growth factors, and any other extracellular matrices, regardless of whether the product, therapy or treatment is administered by intramuscular injection, intravenously, through nebulization, or any other method or means.

7. *Iowa consumer* means a resident of the State of Iowa.
8. *Means and Instrumentalities* means any information, including, but not limited to, any advertising, labeling, promotional, or purported substantiation materials, for use by healthcare clinics or other entities or individuals offering any Regenerative Medicine Treatment.
9. *Door-to-Door Sale* means a sale, lease or rental of consumer goods or services with a price of twenty-five dollars or more, whether under single or multiple contracts, in which the seller or the seller's representative personally solicits the sale, including those in response to or following an invitation by the buyer, and the buyer's agreement or offer to purchase is made at a place other than the place of business of the seller. *Door-to-Door Sale* also means a sale of funeral services or funeral merchandise regulated under chapter 523A and a sale of a social referral service or an ancillary service. ("Social referral service" means a service for a fee providing matching or introduction of individuals for the purpose of dating,

matrimony, or general social contact not otherwise prohibited by law, and "ancillary service" means goods or services directly or indirectly related to or to be provided in connection with a social referral service.)

a. "Consumer goods or services" means goods or services purchased, leased, or rented primarily for personal, family, or household purposes, including courses of instruction or training regardless of the purpose for which they are taken.

b. "Place of business" means the main or permanent branch office or local address of a seller.

c. "Purchase price" means the total price paid or to be paid for the consumer goods or services, including all interest and service charges.

d. "Seller" means any person engaged in the door-to-door sale of consumer goods or services.

II. PARTIES, JURISDICTION AND VENUE

10. The Attorney General is authorized to bring actions on behalf of the State of Iowa under § 714.16(7) of the Act.

11. The court has subject matter jurisdiction over this matter under Iowa Code § 714.16(7).

12. The court has personal jurisdiction over the defendants because they solicited and did business with Iowa consumers in Iowa.

13. Venue is proper in Polk County pursuant to Iowa Code § 714.16(7) because the defendants solicited and sold merchandise to residents of Polk County.

III. INJUNCTIVE RELIEF

A. Cessation of Regenerative Medicine in Iowa

14. **IT IS ORDERED** that the defendants, whether acting directly or through an intermediary — including by owning, providing services, consulting, planning, participating, facilitating, or advising — are permanently restrained and enjoined from the: (1) advertising, (2) marketing, (3) promotion, (4) offering for sale, or (5) sale of any Regenerative Medicine Treatment in Iowa or to any Iowa consumer, through any means, including through the use of a computer or computer network.

15. **IT IS FURTHER ORDERED** that the defendants are permanently restrained and enjoined from providing the Means and Instrumentalities with which to make, expressly or by implication, any false or misleading statement of material fact about Regenerative Medicine Treatment that could affect an Iowa consumer.

B. Compliance with Door-to-Door Sales Act

16. **IT IS FURTHER ORDERED** that the defendants, to the extent any one of them or a combination of them conduct door-to-door sales in Iowa, must comport with all the following requirements:

a. 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, the following statement: "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."

b. Every seller shall furnish each buyer, at the time the buyer signs the door-to-door sales contract or otherwise agrees to buy consumer goods or services from the seller, a completed form in duplicate, captioned "Notice of Cancellation", which shall be attached to the contract or receipt and easily detachable, and which shall contain in ten point boldface type the information and statements reflected in Iowa Code § 555A.3 (2025) in the same language as that used in the contract.

c. Every seller shall 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.

d. Every seller shall not include in any contract or receipt any confession of judgment or any waiver of any of the rights to which the buyer is entitled by way of this injunctive relief.

e. Every seller shall 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.

f. Every seller shall not misrepresent in any manner the buyer's right to cancel or the other obligations of this injunctive relief.

g. Every seller shall honor any valid notice of cancellation by a buyer and within ten business days after the receipt of notice shall refund all payments made under the contract or sale, return any goods or property traded in, in substantially as good condition as when received by the seller, and cancel and return any negotiable instrument executed by the buyer in connection with the contract or sale and take any action necessary or appropriate to terminate promptly any security interest created in the transaction.

h. Every seller shall 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.

i. Every seller shall, within ten business days of receipt of the buyer's notice of cancellation, notify the buyer whether the seller intends to repossess or to abandon any shipped or delivered goods.

C. Other Injunctive Relief

17. **IT IS FURTHER ORDERED** that the defendants must not violate the Act.

18. **IT IS FURTHER ORDERED** that the defendants must not participate, directly or indirectly, in any activity to use, form or proceed as a separate corporation, trust or other entity for the purpose of engaging in, or benefitting from, acts from within any Iowa location or directed at Iowa consumers that are prohibited by this Consent Judgment as ordered by the court, or for any other purpose which circumvents any part of this judgment as ordered by the court.

19. **IT IS FURTHER ORDERED** that Defendants must comply with reasonable requests from the Attorney General for information relating to compliance with this Judgment.

20. **IT IS FURTHER ORDERED** that nothing in this order diminishes the requirements, duties, obligations, or powers set forth in the Act.

21. **IT IS FURTHER ORDERED** that, in addition to whatever other legal remedies may be available, a violation of this permanent injunctive relief constitutes a violation of the Act. Each such violation by Defendants, if established by a preponderance of the evidence in an enforcement action by the Attorney General, gives rise to all the remedies provided in the Act and, in the case of door-to-door sales violations, also gives rise to the court's ability to declare void any contract, note, instrument, or other evidence of indebtedness Defendants executed or entered into that violates the injunctive requirements set forth in this opinion.

22. **IT IS FURTHER ORDERED** that the court retains jurisdiction to enforce this Judgment.

REIMBURSEMENT

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that judgment is entered in favor of the State and against the defendants, jointly and severally, for $1,649,080.50 plus interest at the rate of 5.72%.

CLAIMS MADE REIMBURSEMENT

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that the defendants, jointly and severally, will implement a claims made process as outlined above to reimburse any Iowa consumer not previously identified by the defendants.

CIVIL PENALTIES

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that the defendants shall pay civil penalties of $810,000 to the Consumer Education and Litigation Fund. The defendants are jointly and severally liable for these civil penalties plus interest at the rate of 5.72%.

CIVIL PENALTIES UNDER THE OLDER IOWANS ACT

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that the defendants shall pay civil penalties of $135,000 to the Elderly Victim Fund. The defendants are jointly and severally liable for these civil penalties plus interest at the rate of 5.72%.

ATTORNEY FEES AND COSTS

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that the State has judgment against the defendants, jointly and severally, for the State's attorney fees and costs. The State shall submit its claim for fees and costs by May 15, 2026. The defendants shall file any response by May 30, 2026.

COURT COSTS

IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that the defendants shall pay jointly and severally the court costs.

State of Iowa Courts

Case Number	**Case Title**
EQCE089356	STATE OF IOWA VS BIOLOGICS HEALTH ET AL
Type:	ORDER FOR JUDGMENT

So Ordered

Lawrence P. McLellan, District Court Judge,
Fifth Judicial District of Iowa

Electronically signed on 2026-04-29 08:30:39