# IN THE IOWA DISTRICT COURT FOR POLK COUNTY

STATE OF IOWA ex rel.
THOMAS J. MILLER,
ATTORNEY GENERAL OF IOWA

Plaintiff,
v.

TRAVIS AUTOR,

EMILY AUTOR,

MICHAEL PAVEY,

REGENERATIVE MEDICINE AND ANTIAGING INSTITUTES OF OMAHA, LLC,

OMAHA STEM CELLS, LLC, and

STEM CELL CENTERS, LLC,

Defendants.

COMES NOW the State of Iowa ex rel. Attorney General Thomas J. Miller, by and through Assistant Attorneys General Amy Licht and J. Andrew Cederdahl, and states as follows in this enforcement proceeding against the above-named Defendants under the Iowa Consumer Fraud Act, Iowa Code section 714.16 and the Older Iowans Law, Iowa Code section 714.16A:

# **INTRODUCTION**

According to the U.S. Food and Drug Administration (FDA), stem cells are "[s]ometimes called the body's 'master cells.'" They are the cells that "develop into blood, brain, bones, and

<sup>&</sup>lt;sup>1</sup> FDA Warns About Stem Cell Therapies, U.S. FOOD & DRUG ADMIN., <a href="https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies">https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies</a> (last visited July 13, 2020).

all of the body's organs" and "have the potential to repair, restore, replace, and regenerate cells, and could *possibly* be used to treat many medical conditions and diseases" (emphasis in original).<sup>2</sup> Researchers "hope stem cells will one day be effective in the treatment of many medical conditions and diseases."3

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

Exosomes are in the beginning stage of scientific study. Exosomes are not cells. They are extracellular vesicles released from stem cells.<sup>7</sup> Exosomes were first described by scientists in the late 1980s<sup>8</sup> and less is understood about exosomes than stem cells. There are no FDAapproved exosome products for any medical condition.<sup>9</sup>

The potential of stem cell therapy and exosome therapy has created significant opportunity for the proliferation of false, deceptive and misleading claims. Indeed, in a

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

<sup>&</sup>lt;sup>2</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> Peter W. Marks et al., Clarifying Stem-Cell Therapy's Benefits and Risks, 376 New Eng. J. Med. 1007, 1008

<sup>&</sup>lt;sup>6</sup> See FDA Warns About Stem Cell Therapies, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies (last visited July 13, 2020). <sup>7</sup> James R. Edgar, Q&A: What are exosomes, exactly?, BMC BIOLOGY, 1 (2016), https://bmcbiol.biomedcentral.com/track/pdf/10.1186/s12915-016-0268-z.

<sup>&</sup>lt;sup>8</sup> Michael Eisenstein, *Inside the stem-cell pharmaceutical factory*, SCIENTIFIC AMERICAN (June 17, 2020), https://www.scientificamerican.com/custom-media/nature-outlook-extracellular-rna/inside-the-stem-cellpharmaceutical-factory/.

<sup>&</sup>lt;sup>9</sup> Public Safety Notification on Exosome Products, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/yaccinesblood-biologics/safety-availability-biologics/public-safety-notification-exosome-products (last visited July 13, 2020).

September 2019 consumer update, the FDA warned consumers: "Stem cells have been called everything from cure-alls to miracle treatments[,]" and implored them: "don't believe the hype. Some unscrupulous providers offer stem cell products that are both unapproved and unproven." Former FDA Commissioner Scott Gottlieb stated that, "some actors are leveraging the widespread belief in the eventual promise of [stem cell] products, flouting the statutes and [FDA] regulations, and deceiving patients by illegally... selling purported therapies, and falsely promoting their benefits." The FDA has also issued warnings about unapproved exosome therapies. In a December 2019 public safety notification, the agency cautioned consumers about "serious adverse events" suffered by patients treated with "unapproved products marketed as containing exosomes" in Nebraska and advised that unsubstantiated claims about exosomes are deceptive and risky. 12

Defendants Travis Autor, Emily Autor, Michael Pavey and the Defendant companies are an example of the sorts of "unscrupulous providers" the FDA and Dr. Gottlieb caution against. Starting in April 2018 and through at least fall 2019, Defendants ran a stem cell clinic in Omaha, Nebraska. At their clinic and in advertisements directed to Iowans, including at over 90 live events throughout the state, Defendants advertised and sold unproven stem cell and exosome treatments they claimed could treat, cure, prevent, or reverse a wide variety of medical conditions. They even claimed they could turn back the process of aging itself.

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<sup>&</sup>lt;sup>10</sup>FDA Warns About Stem Cell Therapies, U.S. FOOD & DRUG ADMIN.,

https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies (last visited July 13, 2020). 

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

<sup>&</sup>lt;sup>12</sup> Public Safety Notification on Exosome Products, U.S. FOOD & DRUG ADMIN. (Dec. 6, 2019), <a href="https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products">https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products</a>.

Regardless of the ailment, Defendants sought to be the costly cure-all. They targeted older Iowans, many afflicted with serious medical problems involving painful and chronic symptoms, with claims consumers could "get your life back!" For consumers without any apparent health issues, Defendants claimed they could slow or prevent illnesses that had not been detected. They charged victims thousands of dollars for these treatments, which are not covered by insurance.

Under the Iowa Consumer Fraud Act, Iowa Code section 714.16 ("CFA"), those who make performance claims for a product or service must have a reasonable basis for those claims at the time they make them. Defendants lacked the required substantiation to support their claims about stem cell therapy and exosome therapy and engaged in false, misleading, and deceptive conduct and unfair practices in the sale and advertisement of stem cell and exosome therapy in Iowa. Throughout their operations, Defendants conflated the *potential* for stem cell and exosome therapy with the *present* in their efforts to separate as many Iowans as possible from their money through unproven stem cell therapies. This lawsuit under the CFA and the Older Iowans Law seeks a permanent injunction against Defendants to stop them from swindling additional Iowa victims; an order directing them to reimburse money victims spent on bunk treatments and imposing civil penalties for their false, misleading, and deceptive conduct and unfair practices; and other relief.

### PARTIES AND VENUE

- 1. Thomas J. Miller is the Attorney General of the State of Iowa, and is expressly authorized to enforce the CFA under Iowa Code section 714.16(7).
- 2. Defendant Omaha Stem Cells LLC (OSC) is a Nebraska Limited Liability Company with its principal place of business at 9839 South 168<sup>th</sup> Avenue, Suite 2E in Omaha, Nebraska.

- OSC did business in Iowa under the name Stem Cell Centers, LLC. At all times relevant hereto, OSC advertised and sold stem cell therapy and exosome therapy that it claimed could treat, cure, prevent, or reverse various medical conditions and the aging process to consumers in Iowa. OSC was administratively dissolved by the Nebraska Secretary of State on June 29, 2019.
- 3. Defendant Regenerative Medicine and Anti-Aging Institutes of Omaha, LLC (RMAI) is a Nebraska Limited Liability Company with its principal place of business at 9839 South 168<sup>th</sup> Avenue, Suite 2E in Omaha, Nebraska. Upon information and belief, RMAI took over OSC's operations and is a successor to OSC. At all times relevant hereto, RMAI advertised and sold stem cell therapy and exosome therapy that it claimed could treat, cure, prevent, or reverse various medical conditions and the aging process to consumers in Iowa.
- 4. Defendant Stem Cell Centers, LLC is an Alaska Limited Liability Company located at 200 West 34<sup>th</sup> Avenue, #977 in Anchorage, Alaska. Stem Cell Centers, LLC is the sole member of Defendant RMAI and the sole member of Defendant OSC.
- 5. Defendant Travis Autor is a resident of Las Vegas, Nevada. Along with Defendant Emily Autor, he owns 80% of Defendant RMAI and he is its Chief Executive Officer. Defendant Travis Autor formulated, directed, participated in, and authorized OSC and RMAI's advertisement and sale of stem cell therapy and exosome therapy in Iowa, including training company salespersons who conducted seminars in Iowa and treatment providers who provided services to Iowa consumers at the Omaha clinic. At all times relevant hereto, he knew or should have known about the acts and practices of RMAI and OSC in Iowa and with Iowa consumers.

- 6. Defendant Emily Autor is a resident of Las Vegas, Nevada. Along with Defendant Travis Autor, she owns 80% of Defendant RMAI. Upon information and belief, Defendant Emily Autor hired staff and conducted essential business operations for OSC and RMAI.
- 7. Defendant Michael Pavey is a resident of Spokane Valley, Washington. He owns 10% of Defendant RMAI, is its Chief Operating Officer and was a key participant in OSC and RMAI's advertisement and sale of stem cell therapy and exosome therapy in Iowa, including having oversight of day-to-day operations for the company and leadership of the company's marketing and creative staff.
- 8. Venue is proper in Polk County pursuant to Iowa Code section 714.16(10) because

  Defendants have directed advertising for their services into Polk County and sold their services to residents of Polk County.

# **KEY LEGAL PROVISIONS**

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

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

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

- 10. The CFA at Iowa Code section 714.16 (1) provides the following definitions (among others):
  - a) The term "advertisement" includes the attempt by publication, dissemination, solicitation, or circulation to induce directly or indirectly any person to enter into any obligation or acquire any title or interest in any merchandise.
  - (f) "Deception" means an act or practice which has the tendency or capacity to mislead a substantial number of consumers as to a material fact or facts.
  - (i) The term "merchandise" includes any objects, wares, goods, commodities, intangibles, securities, bonds, debentures, stocks, real estate or services.
  - (n) "Unfair practice" means an act or practice which causes substantial, unavoidable injury to consumers that is not outweighed by any consumer or competitive benefits which the practice produces.
- 11. In further describing what the attorney general must allege and prove under the CFA, Iowa Code section 714.16 (7) provides, in pertinent part:

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

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

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

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

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

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

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

- 14. Subsection 714.16A (2) provides that, in determining whether to impose a civil penalty under the Older Iowans Law, and the amount of any such penalty, the court shall consider the following:
  - a. Whether the defendant's conduct was in willful disregard of the rights of the older person;
  - b. Whether the defendant knew or should have known that the defendant's conduct was directed to an older person;
  - c. Whether the older person was substantially more vulnerable to the defendant's conduct because of age, poor health, infirmity, impaired understanding, restricted mobility, or disability, than other persons;
  - d. Any other factors the court deems appropriate.

### FACTUAL BACKGROUND

- 1. <u>Defendants' Marketing Campaign in Iowa</u>
- 15. At their Omaha stem cell clinic Defendants offered a variety of services, including treatment with stem cells derived from bone marrow, amniotic fluid, umbilical cord blood, and "Wharton's jelly" and with exosomes.
- 16. Defendants typically administered stem cells and exosomes that they obtained from an outside supplier, rather than using stem cells from the consumer.
- 17. Defendants employed nurse practitioners to administer these treatments to consumers in the Omaha office by injection, by intravenous administration, and/or through inhalation using a nebulizer.

- 18. Through direct mail, newspaper and television ads, and on their websites, Defendants targeted older Iowans with claims that stem cell therapy and exosome therapy could treat, cure, prevent, or reverse many medical conditions, such as osteoarthritis, neuropathy, chronic obstructive pulmonary disease (COPD), Alzheimer's disease, chronic pain, joint pain, and other ailments.
- 19. The newspaper and TV ads appeared in numerous media outlets commonly reaching large swaths of the Iowa public, such as the *Des Moines Register*, the *Ames Tribune*, the *Sioux City Journal*, KCCI-TV, and WHO-TV.
- 20. Defendants' advertisements typically invited consumers to attend in-person "educational seminars" at local hotels. These presentations were a key part of Defendants' marketing strategy and were usually scheduled twice daily on 4-5 consecutive days in differing regions of Iowa. For example, during the week of July 15, 2019, Defendants held two seminars per day at a hotel in each of the following locations: Fort Dodge (Monday), Waterloo (Tuesday), Cedar Rapids (Wednesday), Coralville (Thursday), and Clive (Friday).
- 21. Following this pattern, Defendants held 93 seminars in Iowa between April 2018 and September 2019. During the same period, they held numerous additional seminars in Omaha and surrounding towns near the Nebraska-Iowa border.
- 22. While these events were billed as "educational" they were, in fact, extended sales pitches carefully designed to part all older Iowans who attended from as much of their money as possible including through high-interest-rate financing options for those older Iowans unable to pay Defendants out of pocket.

- 23. At each seminar a live speaker trained by Defendants presented a PowerPoint slideshow created by Defendants covering a wide range of ailments for which Defendants could purportedly provide a "revolutionary" solution.
- 24. Seminar speakers reiterated and elaborated on Defendants' unfounded claims that stem cell therapy and exosome therapy could treat, cure, prevent or reverse many medical conditions.
- 25. Defendants recognized they could impart a semblance of medical legitimacy to their seminars and increase sales of their unproven treatments by quoting from and citing to scientific studies throughout the seminar presentation. Indeed, as Defendant Travis Autor once explained to his sales staff during a company training session: "The more of these studies I can quote and stuff it gives me more authority . . . that I know what I'm talking about."
- 26. As discussed in greater detail in Section 2 below, the studies Defendants touted did not necessarily stand for the propositions they extrapolated from them, were often limited in application, and taken out of context.
- 27. Defendants' seminars were laden with high-pressure sales techniques focused on, among other things, selling bigger, more expensive stem cell and exosome packages to consumers who did not need them. They included "pre-suasion" and "psychology of sales" rhetorical tactics that the Defendants believed predisposed seminar attendees to buy their products.
- 28. Hundreds of Iowans attended Defendants' live seminars, and many ultimately paid thousands of dollars for stem cell therapy or exosome therapy, with prices ranging from \$1,400 to over \$27,000. Consumers who financed some or all of their stem cell purchase

through an on-site third-party lender incurred significant additional expense in the form of finance charges and interest payments.

- 2. <u>Defendants' Misrepresentations About Stem Cell Therapy and Exosome</u>
  <u>Therapy for Specific Medical Conditions</u>
  - a. Stem Cells and Exosomes as a "Healing Solution"
- 29. Defendants made broad claims that stem cells and exosomes were essentially a panacea for a broad range of ailments.
- 30. For example, Defendants claimed in their direct mail ads:
  - a. "Today's regenerative medicine offers a revolutionary treatment that helps to heal your injured tissue." <sup>13</sup>
  - b. "If you suffer from injured or degenerative conditions in your back, knees, hips, shoulders or have arthritic joints or suffer from neuropathy or respiratory diseases like COPD, Stem Cell Therapy can help get you out of pain and discomfort!"
  - c. "Experience healing with regenerative stem cell therapy at Stem Cell Centers!"
  - d. "Get relief without costly and painful surgery!"
- 31. Defendants made similarly broad claims in their television commercials. The commercials focused on a variety of conditions, but always claimed that stem cells and exosomes could provide a "solution" for pain and discomfort. For example,

<sup>&</sup>lt;sup>13</sup> At times, Defendants used the term "regenerative medicine" to refer to their stem cell and exosome services and products. The term regenerative medicine "refers to cell therapies, gene therapies, and medical treatment intended to repair or replace damaged, diseased, or dysfunctional cells, tissues and organs." *See FDA's Framework for Regulating Regenerative Medicine Will Improve Oversight*, PEW CHARITABLE TR. (Oct. 17, 2019), <a href="https://www.pewtrusts.org/en/research-and-analysis/reports/2019/10/17/fdas-framework-for-regulating-regenerative-medicine-will-improve-oversight">https://www.pewtrusts.org/en/research-and-analysis/reports/2019/10/17/fdas-framework-for-regulating-regenerative-medicine-will-improve-oversight</a>. "Regenerative medicine" is generally understood to include treatment with stem cells.

- a. In a commercial featuring neuropathy, Defendants stated, "now there is relief and finally a healing solution for your painful neuropathy with revolutionary stem cell therapy."
- b. In a commercial about chronic knee and hip pain and osteoarthritis, Defendants stated, "now there is hope and finally a solution for your pain with revolutionary stem cell therapy."

### b. Chronic Obstructive Pulmonary Disease

- 32. COPD is a group of progressive lung diseases including emphysema and chronic bronchitis. <sup>14</sup> According to the Centers for Disease Control, COPD makes breathing difficult for 16 million Americans. <sup>15</sup> In 2018 there were over 24,000 COPD emergency room visits in Iowa alone. <sup>16</sup>
- 33. Defendants identified COPD as one of the conditions they treated and Defendants' advertisements regularly claimed that stem cell therapy or exosome therapy could treat, cure, prevent, or reverse COPD.
- 34. One of Defendants' television commercials that aired in Iowa told viewers that "Stem cell therapy has the ability to reverse your COPD..."
- 35. Defendants also claimed in their seminars that stem cell therapy could repair lung tissue in COPD patients. One seminar slide stated:

Chronic Obstructive Pulmonary Disease:

The Good News

- > Stem Cells can heal damaged lung tissue.
- > Stem Cells can grow new blood vessels

 $<sup>^{14}</sup>$  What is COPD?, CTRS. FOR DISEASE CONTROL AND PREVENTION, <a href="https://www.cdc.gov/copd/index.html">https://www.cdc.gov/copd/index.html</a> (last visited July 13, 2020).

<sup>&</sup>lt;sup>15</sup> <u>*Id*.</u>

<sup>&</sup>lt;sup>16</sup> Iowa Dep't Pub. Health, *COPD Emergency Department Visits Data* – 2018, https://tracking.idph.iowa.gov/Health/COPD/COPD-ED-Visits-Data (last visited July 13, 2020).

# ➤ Healing similar to Neuropathy<sup>17</sup>

- 36. Through a Civil Investigative Demand (CID)<sup>18</sup> issued to Defendants in March 2020, the Attorney General asked Defendants to provide the substantiation required by Iowa law for the claims shown in Paragraphs 34 and 35 that stem cell therapy can "reverse" COPD, heal damaged lung tissue, grow new blood vessels and provide healing similar to neuropathy.
- 37. Defendants responded by stating that most stem cells in the bloodstream get "lodged in the patient's lungs," where they can release "secretomes" and heal native cells over a sustained time period, though they provided no further information or reference for this statement. Defendants also identified a "COPD Trial" cited in their seminar slideshow as a reasonable basis for these claims.
- 38. The COPD Trial was led by a Kansas physician<sup>19</sup> and consisted of providing an initial stem cell therapy treatment to seven people with COPD and repeating that treatment after three and six months. Participants were subject to a pulmonary function screening and other tests before the initial procedure, and were to be reassessed again after the initial treatment.
- 39. The results of the COPD Trial were not formally written up, published in a journal, or subject to peer review.
- 40. Although some participants recorded a benefit in the COPD trial, it does not constitute a reasonable basis for Defendants' dramatic claims for several reasons, including:

 $<sup>^{17}</sup>$  At times, Defendants used the word "exosome" or the term "Regenerative Medicine" in place of "Stem Cells" on this slide.

<sup>&</sup>lt;sup>18</sup> A Civil Investigative Demand is an information-gathering tool authorized by subsections (3) and (4) of the Consumer Fraud Act. It is comparable to an investigative subpoena. *See State ex rel. Miller v. Smokers Warehouse Corp.*, 737 N.W.2d 107, 109-10 (Iowa 2007).

<sup>&</sup>lt;sup>19</sup> The Kansas physician did not authorize Defendants to use his research.

- a. The COPD Trial consisted of a very small sample size of seven patients, two of whom completed only one treatment.
- b. All participants were already diagnosed with COPD before their participation in the Trial, although Defendants' claims target people without COPD.
- c. The COPD Trial was not blinded or randomized, meaning that the medical professionals and participants knew what treatment each participant received.
- d. There was no placebo arm, meaning there was no way to compare results between participants who received stem cell therapy and those who received a placebo.
- e. Participants in the COPD Trial were treated with stromal vascular fraction (SVF).

  SVF is a substance created in a laboratory procedure when the patient's own adipose (fat) tissue is extracted from their body and processed to isolate and concentrate certain cells. The SVF is then re-introduced to the body.
- f. In the COPD Trial, each participant's own SVF was combined with platelet-rich plasma and administered to the patient intravenously and through a nebulizer. However, upon information and belief, Defendants did not offer or provide SVF to patients. Instead, Defendants typically obtained the stem cell or exosome products from outside suppliers.
- g. Upon information and belief, participants were given an anti-inflammatory regimen of a nutritional supplement and glutathione, an antioxidant. It is unclear what impact these additional substances had on the participants' health condition.
- 41. Defendants do not have a reasonable basis to support their claims that stem cell therapy is effective to heal damaged lung tissue or otherwise treat or cure COPD.

# c. Neuropathy

- 42. Peripheral neuropathy "refers to the many conditions that involve damage to the peripheral nervous system..." Peripheral neuropathy can have many causes and sources, including physical injury, diabetes, and a range of other medical conditions.<sup>21</sup>
- 43. Defendants identified neuropathy as another condition they treated, and their promotional materials claimed that stem cell therapy or exosome therapy was effective to treat, cure, prevent, or delay neuropathy.
- 44. For example, in a mailer highlighting neuropathy, Defendants stated, "There is now an option that can cure your problem and give you relief from the pain Stem Cell Therapy!"
- 45. In their seminars, Defendants stated that stem cell treatment could turn back the process that causes neuropathy. One slide stated:

# **NEUROPATHY Originates From:**

- Lack of a blood supply means lack of oxygen getting to the nerves
- No oxygen causes the nerves to die
- > Stem cells can grow new blood vessels
- > Stem cells can grow new peripheral Nerves and reverse this process <sup>22</sup>
- 46. The Attorney General's CID asked Defendants for the legally-required substantiation for the claim shown in Paragraph 45 that "Stem cells can grow new Peripheral nerves and reverse this process" (when "this process" refers to neuropathy).
- 47. Defendants summarily responded that "Numerous Stem Cell studies have shown [sic] to be able to regenerate peripheral nerves as well as re-myelinate damaged peripheral

<sup>&</sup>lt;sup>20</sup> Peripheral Neuropathy Fact Sheet, NAT'L INST. NEUROLOGICAL DISORDERS & STROKE (Aug. 2018), <a href="https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Peripheral-Neuropathy-Fact-Sheets">https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Peripheral-Neuropathy-Fact-Sheets</a>

<sup>&</sup>lt;sup>21</sup> See id.

<sup>&</sup>lt;sup>22</sup> At times, Defendants substituted "Regenerative Medicine" for "Stem cells" on this slide.

- nerves." Defendants did not identify any specific studies or provide any further explanation to support their neuropathy claims.
- 48. Defendants lack a reasonable basis that for their claim that stem cell therapy can "reverse" the process that causes neuropathy by growing new peripheral nerves.

# d. Anti-Aging

- 49. Defendants claimed their stem cell therapy and exosome therapy could reverse the effects of growing older.
- 50. For example, in the "anti-aging" segment of their seminar presentation, Defendants asked attendees: "Anyone Wish They Could Turn Back The Hands Of Time?" On the next slide, they reassured consumers, "Stem Cell Therapy Can Do Just That."<sup>23</sup>
- 51. To support the claim that their treatments could "turn back the hands of time" in their seminar presentation Defendants cited a clinical study in which people diagnosed with frailty received stem cell therapy ("Frailty Study"). Participants in the Frailty Study received one intravenous dose of either (a) 100 million stem cells, (b) 200 million stem cells, or (c) a placebo. Participants were evaluated on whether they experienced serious adverse events after one month and on physical performance, patient-reported outcomes, and various other tests and immune markers after six months.
- 52. The Frailty Study does not substantiate Defendants' dramatic claims that stem cell therapy or exosome therapy can reverse the aging process. It reaches a far more conservative conclusion that the, "findings suggest" that human stem cells, "may be an

Double-Blind, Placebo-Controlled Clinical Trial, 72 Js. GERONTOLOGY, 1513, 1513-1522 (2017).

<sup>&</sup>lt;sup>23</sup> At times, Defendants used the term "Regenerative Medicine" in place of "Stem Cell Therapy" on this slide.
<sup>24</sup> Bryon A. Tompkins et al., *Allogeneic Mesenchymal Stem Cells Ameliorate Aging Frailty: A Phase II Randomized*,

- effective biological modifier of aging frailty, and support ongoing investigation" of stem cell therapy by itself or with other strategies for frailty.<sup>25</sup>
- 53. Moreover, the study itself noted that it was "limited by a small sample size" of 30 people, that the lack of difference between treatment groups meant it had "limit[ed] statistical power," and a larger number of participants would be required, "for appropriate statistical power to detect a difference between [treatment] groups."<sup>26</sup>
- 54. Additional reasons that the Frailty Study does not provide the required substantiation for Defendants' broad claims that stem cell or exosomes can reverse the aging process include:
  - a. All study participants showed signs of the medical condition of frailty as confirmed by physician assessments.<sup>27</sup> However, Defendants did not restrict their claims to people with frailty, but claimed that stem cell therapy could "reverse" the aging process for "Anyone."
  - b. Study participants who received a treatment product (not the placebo) were given particularly high doses of 100 million or 200 million stem cells. Upon information and belief, Defendants did not offer such high doses to consumers.
- 55. Defendants do not have a reasonable basis for their claims that stem cell therapy can "turn back the hands of time."

<sup>&</sup>lt;sup>25</sup> *Id.* at 1517.

<sup>&</sup>lt;sup>26</sup> Id. at 1520. See also David G. Le Couteur et al., Stem Cell Transplantation for Frailty, 72 Js. GERONTOLOGY: BIOLOGICAL SCI. 1503, 1503-04 (2017) (guest editorial in the journal issue containing the Frailty Study and describing it as an "early-phase trial" with a "small number of participants, designed primarily to assess safety, so conclusions about efficacy need to be treated with caution").

<sup>&</sup>lt;sup>27</sup> Frailty is a formal diagnosis described as "a clinically recognizable state of older adults with increased vulnerability, resulting from age-associated declines in physiologic reserve and function across multiple organ systems, such that the ability to cope with everyday or acute stressors is compromised." Xujiao Chen et al., Frailty syndrome: an overview, 9 CLINICAL INTERVENTIONS AGING 433, 434 (2014).

- 56. Another slide in Defendants' seminar presentation claims that their stem cell therapy can reverse aging by three years: "Anti-Aging: Mesenchymal Stem Cell infusions turned back the hands of Father Time about *three* years! Would you like to get back three years?" (emphasis in original).<sup>28</sup>
- 57. The Attorney General's CID asked Defendants for the reasonable basis for the claim in Paragraph 56 that stem cell treatment can "turn back" time by three years.
- 58. In their sworn response, Defendants stated that a "company called Longeveron, which is comprised of a number of university professors is in phase 2b with the FDA with a treatment for frailty. One of the professors spoke about this at the World Stem Cell Summit in Miami." Defendants did not provide any more information about the Longeveron efforts.
- 59. Longeveron is a Florida life sciences company that describes itself as developing "biological solutions for aging and aging-associated diseases" by testing of human mesenchymal stem cells derived from bone marrow of young, healthy donors.
- 60. Upon information and belief, based in part upon a review of www.clinicaltrials.gov (the federal database of privately and publicly funded clinical studies), Defendants are referring to an ongoing Longeveron-sponsored clinical trial on the use of stem cells in people with aging frailty that is not yet complete and for which final trial results are expected to become available in 2021.<sup>29</sup>

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<sup>&</sup>lt;sup>28</sup> "Mesenchymal" stem cells are adult stem cells that can be isolated from human and animal sources. Imran Ullah et al., *Human mesenchymal stem cells- current trends and future prospective*, BIOSCIENCE REP., Apr. 2015 at 1, 1. <sup>29</sup> See Phase IIb Trial to Evaluate Longeveron Mesenchymal Stem Cells to Treat Aging Frailty, NAT'L LIBR. MED., https://clinicaltrials.gov/ct2/show/NCT03169231 (last visited July 14, 2020); see also Longeveron LLC Announces Completion of Enrollment in Phase 2b Clinical Trial of Longeveron Allogeneic Mesenchymal Stem Cells in Aging Frailty, Longeveron (Feb. 11, 2020), http://longeveron.com/longeveron-llc-announces-completion-of-enrollment-in-phase-2b-clinical-trial-of-longeveron-allogeneic-mesenchymal-stem-cells-lmscs-in-aging-frailty/.

61. The Longeveron clinical trial does not provide a reasonable basis for Defendants' claims that stem cell therapy "turned back the hands of Father Time about *three* years!" or that they can provide such results for consumers.

### e. Knee Pain

- 62. Defendants focused on joint pain as a condition they commonly treated and stated that they successfully treated many consumers for knee pain, back pain, and other similar conditions.
- 63. In their seminar slideshow, Defendants claimed that knee replacement surgery presents a high risk of serious side effects, including infection and death, and is very expensive.

  They presented stem cells or exosomes as the better if not the only alternative.
- 64. One presentation slide showing four images of what appears to be a knee joint stated, "It Does Not Matter What Level of Knee Degeneration You Have For This Treatment. The results are the same!"
- 65. The Attorney General's CID asked for the reasonable basis for the knee degeneration treatment claim in Paragraph 64.
- 66. In response, Defendants stated, "When analyzing the data from the first 1000 patients, we learned that age nor [sic] stage of OA did not affect the outcomes in knee patients."
- 67. In response to an earlier CID, Defendants described the data they kept on the "first 1000 patients" as people, "treated for either OA [osteoarthritis] or Neuropathy from the time the clinic opened." According to Defendants, the 1000-patient data set, "was collected based on reported pain scores. It was not peer reviewed or published."
- 68. Upon information and belief, Defendants no longer possess the 1000-person data set or any summary or analysis of it.

69. The 1000-person data set results that Defendants cite do not provide a reasonable basis for their claims that stem cell therapy or exosome therapy provide the same beneficial results for any consumer, regardless of their level of knee degeneration.

### f. Alzheimer's Disease

- 70. Although Defendants did not typically list Alzheimer's disease as one of the conditions they purportedly treated, the illness figured prominently in their seminar presentation.

  There, Defendants claimed that stem cell therapy or exosome therapy is effective to reduce the symptoms of Alzheimer's disease and to delay or prevent its onset. Defendants made these claims to persuade Iowa consumers to rely upon their irresponsible statements in buying the Defendants' products and services.
- 71. In their seminar slideshow, Defendants made the following claims regarding Alzheimer's disease:
  - a. "IV Stem Cell Treatment Improves Brain Function in Alzheimer's Patients"
  - b. "According to research, Stem Cells can break down the plaquing BEFORE you get symptoms, possibility delaying or even preventing this disease. Be
     Proactive!" (emphasis in original).<sup>30</sup>
- 72. The Attorney General's CID asked Defendants for a reasonable basis for the statements in Paragraph 71.
- 73. Defendants cited a "4 person study" referenced in their slideshow as one source of a "reasonable basis" for the Alzheimer's disease claims.

<sup>&</sup>lt;sup>30</sup> At times, Defendants used the term "Regenerative Medicine" in place of "Stem Cell(s)" in the claims in Paragraphs 71(a) and (b).

- 74. The "4-person study" is a set of case studies led by the same Kansas physician on four patients diagnosed with mild-to-moderate Alzheimer's disease. <sup>31</sup> Participants underwent up to three IV infusions of SVF (as described above in Paragraph 40(e)) at 90-day intervals over a 180-day period. <sup>32</sup> They were given a mental status evaluation, brain imaging and other testing before and after the treatment. <sup>33</sup>
- 75. While two of the four participants saw some positive result from the treatment, the case studies do not provide a reasonable basis for Defendants' far-reaching assertions that stem cell therapy improves brain function in Alzheimer's patients or delays or prevents the illness.
- 76. The outcomes of the case studies were limited. The studies' authors stated, "Our study design and sample of convenience provides limited results" because, among other things, participants received the same dosage regardless of body mass, the preferred or required duration between treatments was unknown, and "appropriate treatment frequency is unclear."<sup>34</sup>
- 77. Additional reasons that the case studies do not provide the needed substantiation for Defendants' claims regarding Alzheimer's disease in Paragraph 71 include:
  - a. The case studies involved a very small sample size of only four patients, which provide a limited basis that precludes definitive conclusions, such as Defendants' sweeping claims.

<sup>&</sup>lt;sup>31</sup> See Kipp A. Van Camp et al., Intravenously Administered Autologous Bone Marrow and Adipose-Derived Stromal Cells in the Treatment of Alzheimer Disease: Case Studies, 24 J. AM. PHYSICIANS & SURGEONS 8, 8-12 (2019). Again, the Kansas physician did not authorize Defendants to use this research in their presentation.

<sup>32</sup> Id. at 9.

<sup>&</sup>lt;sup>33</sup> *Id*.

<sup>&</sup>lt;sup>34</sup> *Id.* at 11.

- All participants were already diagnosed with mild-to-moderate Alzheimer's disease before their enrollment, though Defendants' claims target people without the illness.<sup>35</sup>
- c. The case studies were not blinded or randomized, meaning that the medical professionals and participants knew what treatment each participant received.<sup>36</sup> Participants were also required to pay for the cost of their treatment, plus ten percent, in order to take part in the study, potentially impacting their assessment of the treatment.<sup>37</sup>
- d. There was no placebo arm, meaning that there was no way to compare results between participants that received treatment and those who did not.<sup>38</sup>
- e. As with the COPD Trial, the patients in the Alzheimer's case studies were treated with SVF sourced from their own body.<sup>39</sup> However, upon information and belief, Defendants did not offer or provide stem cell therapy utilizing SVF.
- 78. The Alzheimer's case studies do not provide a reasonable basis for Defendants' sweeping claims that stem cell therapy can improve brain function in Alzheimer's patients or delay or prevent development of Alzheimer's disease.
- 79. As an additional response to the Attorney General's CID requesting a reasonable basis for the claims described in Paragraph 71 Defendants stated, "Japan has already approved a treatment for Alzheimer's utilizing stem cells IV infusions" and referenced a "Japan

<sup>&</sup>lt;sup>35</sup> *Id.* at 9.

<sup>&</sup>lt;sup>36</sup> *Id*.

<sup>&</sup>lt;sup>37</sup> *Id.* at 12.

<sup>&</sup>lt;sup>38</sup> *Id*. at 9.

<sup>&</sup>lt;sup>39</sup> *Id*.

- study" on their seminar slideshow. Defendants did not provide any identifying information for or any materials related to the "Japan study."
- 80. Upon information and belief and based on information in their slideshow, Defendants are referring to developments described in an April 2018 press release from a South Korean company announcing it was to begin providing, "Stem Cell-Based Regenerative Treatment for Alzheimer's Disease in Japan." According to the press release, the company planned to administer intravenous stem cell therapy derived from the patient's own tissue to patients diagnosed with mild-to-moderate Alzheimer's disease. The results of the treatment described in the press release were not released.
- 81. The "Japan study" does not provide a reasonable basis for Defendants' claims that stem cell therapy can improve brain function in Alzheimer's patients or delay or prevent development of Alzheimer's disease.
  - 3. <u>Defendants Pressured Consumers to Buy Larger, More Expensive Doses of Stem Cell</u>
    Therapy, Even When They Had No Medical Problems.

#### a. More Doses

- 82. Defendants made unfounded claims that bigger and more expensive stem cell and exosome packages were more effective to stop or slow down diseases and medical conditions.
- 83. For example, on a consumer "sell sheet" highlighting COPD Defendants described the largest option of 6 treatment doses or 24 units (priced at \$15,997 or \$16,997 at different times) as follows: "The bad news is this is the most expensive option but the good news is it should be the most effective. Six treatments will give you the greatest chance at restoring your lung function by 'turning off' or substantially slowing the debilitating progression." Defendants made very similar claims that more doses of stem cells or

- exosomes were "most effective" to slow down or stop spine and disc pain, osteoarthritis, and neuropathy in sell sheets focused on those conditions.
- 84. Defendants' slideshow reiterated claims that larger, more expensive doses would purportedly be more effective in preventing, delaying or mitigating the chance of disease.
  - a. One slide described the option for the maximum dose of "24 Units Stem
     Cells" as follows (emphasis in original):
    - ✓ 79% of patients choose this plan
    - ✓ Potential significant improvement in **Pulmonary Function.**
    - ✓ "You have the **BEST** [sic] of **helping or curing many other** ailments.
    - ✓ Best Chance at reaching **Maximum Medical Improvement**.
    - The **Bad news** More expensive option
    - The Good news Most effective option

      Up to three (3) separate treatments

      Used for Anti Aging, Dementia or

      Alzheimer's.
  - b. Another slide discussing treatment with exosomes, Defendants stated, "More
     Exosomes = Better Results."
- 85. Defendants also encouraged consumers to buy larger doses of stem cells or exosomes in order to have them administered using more than one method. One seminar slide stated, "OUR Stem Cell Therapy: Two Birds, One Stone. **Both** an injection and an IV. Our results show this is **the most successful and effective treatment** and can treat the whole body vs. 1 area" (emphasis in original).
- 86. The Attorney General's CID asked Defendants for the legally-required substantiation for the claim in Paragraph 85. In response, Defendants stated, "We find the best outcomes when we do both," but provided no other basis for their claims.

- 87. Internally, Defendants acknowledged that they did not know how to determine the volume of stem cells or exosomes to administer to a consumer. In an email exchange with an Omaha employee concerned that the company's treatment protocols were designed only to advance sales, Defendant Travis Autor admitted, "It is impossible to know how much each person needs when it comes to Stem Cells."
- 88. Defendants lacked substantiation for their claims that larger doses of stem cells or exosomes would yield a greater benefit for consumers, and their high-pressure sales tactics based on those claims were false, misleading, deceptive, and constitute an unfair practice.

# b. Fewer Symptoms

- 89. Defendants targeted consumers who did not have health problems with unfounded claims that stem cells or exosomes could prevent or allay undetected medical conditions. They pressured consumers to take "proactive" steps to treat illnesses or conditions for which they had no symptoms. For example:
  - a. Defendants claimed in their slideshow that stem cells or exosomes "can reverse and repair the damage caused by COPD whether you know you have it or not...**Be ProActive**" (emphasis in original).<sup>41</sup>
  - b. As mentioned in Paragraph 71(b), Defendants told consumers that stem cells or exosomes could "break down plaquing BEFORE you get

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<sup>&</sup>lt;sup>40</sup> Defendants' own source highlights the uncertainty about appropriate dose levels. For example, the Frailty Study, discussed *supra* at Section 2(d), concluded that 100 million cells were a "superior dose level" compared to 200 million cells, though "the reasons underlying the inverse dose relationship noted here remain incompletely understood." Bryon A. Tompkins et al., *Allogeneic Mesenchymal Stem Cells Ameliorate Aging Frailty: A Phase II Randomized, Double-Blind, Placebo-Controlled Clinical Trial*, 72 Js. GERONTOLOGY, 1513, 1513-1522 (2017).

<sup>41</sup> At times, Defendants substituted "Regenerative Medicine" for "Stem cells" on this slide.

symptoms [of Alzheimer's disease], possibly delaying or even preventing this disease. **Be Proactive!**" (emphasis in original).

- 90. To attract symptom-less people who accompanied their partners and spouses to seminars, Defendants offered \$1,000 discounts when those consumers immediately scheduled a future clinic visit before leaving the seminar, as well as \$500 discounts "if both Spouse and Loved One receive Treatment" (emphasis in original).
- 91. Defendants trained their employees and sales representatives to sell treatments to people without medical problems. For example, in a training session for seminar speakers on how to present Defendants' slideshow, Defendant Travis Autor explained that:

I am talking in this slide because I want people to be aware that they need to buy a 24-unit treatment.<sup>42</sup> Just because you don't have symptoms, does not mean you don't have problems. And I'll say, I will look around the room and say ...'every single person in this room knows one or two people who have died suddenly from a heart attack that didn't even know they had heart problems, correct?' Everybody [is] like – 'uh huh, yeah'

Discussing pushing consumers to be "proactive" he said,

The reason I ask that question [about whether consumers have other health problems] is I want to upsell them to the 24-dose treatment. . . You may have lots of other things going on inside you you [sic] don't know about. . .That's why I ask that question.

92. When training and instructing company employees, Defendant Travis Autor further described the "upsell" tactics he sought to foster as follows:

<sup>&</sup>lt;sup>42</sup> As noted above in Paragraph 83, 24 units was typically the largest and most expensive treatment Defendants offered.

[E]very joint should be an upsell. So we are going to go over these techniques this morning on how to get a person to a 'yes' on stem cells and then say, 'Hey, we highly suggest . . . to maximize your chance of success and maximize amount of success, that you get a [platelet rich plasma]<sup>43</sup> treatment with your joint, or with your knee pain, or with your back pain, or whatever we're doing.' And it's not that hard. Once somebody has, you know, agreed to 9,000 or to 15,000, getting another 1,000 is easy. It really is. So, the psychology of sales: ah, once a person commits to a large purchase, they get a huge endorphin rush in the pleasure spot of our brain, called the brain reward cascade system. And the endorphins are released, and we are like 'ah...' Same pleasure we get from drinking, getting high, having sex, having an orgasm. It's the same area, right, but we like it. That's why we keep doing it. Um, so, when a patient gets to 15,000 dollars and they get that rush, we're gonna offer them a second ability to have that rush again. And the brain is wired to want that rush again.

- 93. Defendants' focus on selling to consumers without health problems, aggressive "upselling" tactics, used in combination with their unfounded claims about stem cell treatment, were false, misleading, deceptive, and constitute an unfair practice.
  - 4. <u>Defendant Pavey's Testimonial Was Deceptive, Misleading and an Unfair Practice.</u>
- 94. Defendants included a video testimonial by Defendant Michael Pavey in their seminar slideshow. In the video, Defendant Pavey is pictured with a caption stating, "Mike Pavey 25 years of BACK PAIN." He describes recovering from years of chronic back pain after undergoing stem cell injections at Stem Cell Centers and advises viewers to "give stem cell therapy a long, solid look."
- 95. Defendants do not disclose in the testimonial or anywhere else in their promotional materials that Defendant Pavey owns 10% of Defendant RMAI, has been its Chief

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<sup>&</sup>lt;sup>43</sup> Platelet-rich plasma treatment is an additional treatment Defendants offered, often as a complement to stem cell or exosome therapy.

- Operating Officer since 2015 and that he oversees day-to-day operations for the company, including the internal marketing and creative staff.
- 96. The U.S. Federal Trade Commission (FTC) had issued guidance on use of testimonials and endorsements. *See* 16 C.F.R section 255. Under the FTC's guidance when there is a, "connection between the endorser and the seller of the advertised product that might materially affect the weight or credibility of the endorsement...such connection must be fully disclosed." 16 CFR section 255.5.
- 97. Defendant Pavey's ownership stake and role as an RMAI executive is a connection that could materially impact the weight or credibility of his endorsement and should have been disclosed. Defendants' failure to disclose Defendant Pavey's connection to RMAI was deceptive, misleading, and constitutes an unfair practice.
- 5. Defendants' Own Disclaimers Were Insufficient and They Downplayed FDA Warnings.

# a. Defendants' Disclaimers

- 98. Some of Defendants' promotional materials contain disclaimers or warnings such as, 
  "These statements have not been evaluated by the FDA," "Stem cell therapy is still 
  considered experimental by the FDA," and, "[o]ur products are not intended to diagnose, 
  treat, cure or prevent any disease."
- 99. Defendants at times made limiting statements that while most consumers would respond to stem cell or exosome therapy, not all do. For example, in some promotional materials Defendants stated that "not everyone responds to therapy. A high enough percentage of patients do respond favorably and are satisfied with their results, that we feel this is a very viable treatment option for conditions we treat."

100. These disclaimers, warnings, and limiting statements (or any other such disclaimer, warning, or statement associated with Defendants' products or promotional activities) were not sufficient to overcome the net impression Defendants created that stem cell or exosome therapy were effective to treat, cure, delay, or prevent many medical conditions and reverse the aging process.

### b. FDA Warnings

- 101. In their seminar presentations Defendants minimized and undermined a September 2019
  FDA consumer warning that cautioned the public about using unfounded stem cell therapy.
- 102. The FDA warning stated that, "unproven stem cell therapies can be particularly unsafe."

  It identified "potential safety concerns for unproven treatments" as:
  - Administration site reactions,
  - The ability of cells to move from placement sites and change into inappropriate cell types or multiply,
  - Failure of cells to work as expected, and
  - The growth of tumors.<sup>44</sup>
- 103. In seminars Defendants downplayed these warnings, telling consumers that the adverse effects or lack of efficacy that the FDA warns about were rare.
- 104. In an internal company training session Defendant Travis Autor minimized and made light of the warning that injected stem cells can "move from placement sites," telling employees: "What that means is if you inject stem cells into the knee it could travel down to your ankle and turn an ear. That doesn't happen. Never seen that happen."

<sup>&</sup>lt;sup>44</sup> FDA Warns About Stem Cell Therapies, U.S. FOOD & DRUG ADMIN., <a href="https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies">https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies</a> (last visited July 13, 2020).

105. In the same September 2019 consumer update, the FDA further cautioned consumers considering stem cell treatments, as follows:

To do your part to stay safe, make sure that any stem cell treatment you are considering is either:

- FDA-approved, or;
- Being studied under an Investigational New Drug Application (IND), which is a clinical investigation plan submitted and allowed to proceed by the FDA.
- 106. In seminars, Defendants undercut this FDA consumer guidance by contending that the FDA is "caught in the middle" of different companies involved in the stem cell field, and implied that the guidance unfairly disfavors clinics such as theirs.
- 107. Defendants' efforts to undermine and misrepresent the FDA's consumer guidance about stem cell therapy, used in combination with their unfounded claims about stem cell treatment, were false, misleading, deceptive, and constitute an unfair practice.
  - 6. Defendants' Conduct Had a Disproportionate Impact on Older Iowans
- 108. Defendants deliberately targeted older Iowans in the advertising and sale of their stem cell therapy and exosome therapy by, among other things, targeting virtually all of their direct mail advertisements to consumers age 60 and older.
- 109. In employee training sessions, Defendant Travis Autor explicitly acknowledged that most or all of Defendants' consumers were older persons
- 110. Defendants knew the consumers they targeted and who attended their seminars were likely to suffer from medical problems.
- 111. Defendants' conduct was in willful disregard of the rights of older people. Defendants knew or should have known that such conduct was directed to older people and older people are substantially more vulnerable to such conduct on account of age and other

factors. For these and other reasons, each qualifying civil penalty assessed to Defendants under the CFA should be increased by \$5,000.00 (or by such lesser amount as the Court deems appropriate).

### MISCELLANEOUS ALLEGATIONS

- 112. Neither all nor any part of the application for injunctive relief herein has been previously presented to and refused by any court or justice. Iowa R. Civ. P. 1.1504.
- 113. In an action by the State, no security shall be required of the State. Iowa R. Civ. P. 1.207.

# COUNT 1

# CONSUMER FRAUD ACT VIOLATIONS

- 114. The introduction and Paragraphs 1-113 are incorporated herein.
- 115. Defendants' acts and practices violate the prohibitions of Iowa Code section 714.16(2)(a) against misleading, deceptive, and unfair acts and practices, and otherwise violate that subsection of the CFA.
- 116. Although it is not necessary to establish reliance, damages or intent to deceive to obtain injunctive relief or reimbursements under the CFA, establishing these factors (particularly intent) is nevertheless relevant *inter alia* to the Court's determination of the appropriate scope of injunctive relief and the appropriate amount of civil penalties. Those acts and practices of Defendants in violation of subsection (2)(a) of the CFA alleged in this Court would in fact induce reliance on the part of consumer victims, would in fact cause damage to consumers, and/or were in fact intentional.

### **COUNT II**

### **OLDER IOWANS ACT VIOLATIONS**

117. The introduction and Paragraphs 1- 116 are incorporated herein by reference.

118. Defendant's violations of the CFA were committed against older Iowans within the meaning of Iowa Code section 714.16A, and give rise to the penalties set forth in that provision.

### **PRAYER**

Plaintiff prays the Court grant the following relief:

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

D. Pursuant to Iowa Code section 714.16(7) enter judgment against Defendants, jointly and severally, for such additional funds as are necessary to ensure complete disgorgement of all ill-gotten gain traceable to the unlawful practices alleged herein.

E. Pursuant to Iowa Code section 714.16(7), enter judgment against each Defendant for up to \$40,000.00 for each separate violation of the Consumer Fraud Act.

F. Pursuant to Iowa Code section 714.16A, the Older Iowans Law, enter judgment against each Defendant for a civil penalty of up to \$5,000.00, to be added to each civil penalty imposed under the Consumer Fraud Act.

G. Award Plaintiff interest as permitted by law.

H. Pursuant to Iowa Code section 714.16(11), enter judgment, jointly and severally, against Defendants for attorney fees and state's costs.

I. Retain jurisdiction as necessary to ensure full compliance with the pertinent provisions of the Consumer Fraud Act and the Older Iowans Law, and with the Court's orders.

J. Assess court costs against Defendants.

K. Grant such additional relief as the Court deems just and equitable.

Respectfully submitted,

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