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7 **STATE OF WASHINGTON**
8 **KING COUNTY SUPERIOR COURT**

9 STATE OF WASHINGTON,

10 Plaintiff,

11 v.

12 US STEMOTOLOGY, LLC, a Washington
13 limited liability company; and TAMI
14 MERAGLIA, M.D., individually and as
part of the marital community comprised
of TAMI MERAGLIA, M.D. and ROCCO
MERAGLIA.

15 Defendants.

NO.

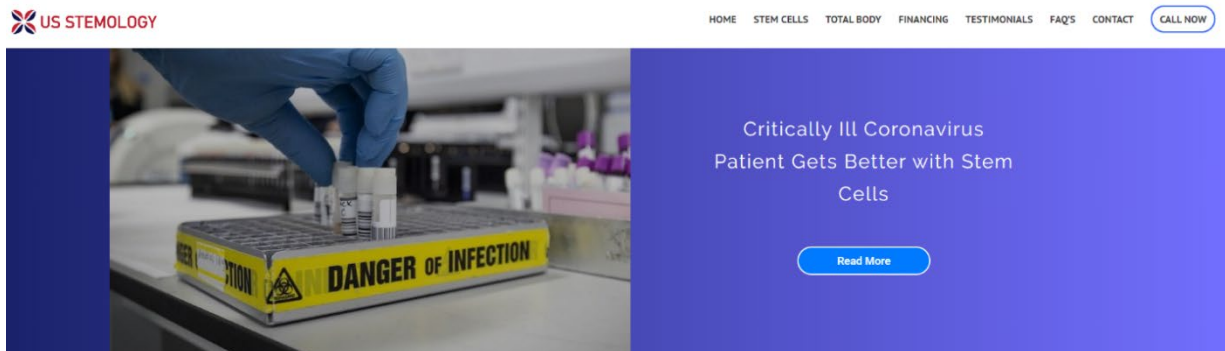
COMPLAINT FOR INJUNCTIVE AND
OTHER RELIEF

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17 Plaintiff, State of Washington, by and through its attorneys Robert W. Ferguson,
18 Attorney General, and Daniel Davies and Logan Starr, Assistant Attorneys General, brings this
19 action against Defendants US Stemology, LLC and Tami Meraglia, M.D. (collectively,
20 “Defendants”). The State alleges that Defendants engaged in unfair or deceptive acts or practices
21 in violation of the Consumer Protection Act (CPA), RCW 19.86, by marketing unsubstantiated
22 stem cell treatments for serious medical conditions, including COVID-19, and by misrepresenting
23 these unproven treatments as legitimate scientific research. The State alleges the following on
24 information and belief:
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I. INTRODUCTION

1.1 From their Seattle clinic, Defendants US Stemology and Tami Meraglia, M.D. marketed unproven stem cell treatments for COVID-19 infection, diabetes, lupus, Parkinson's disease, multiple sclerosis, and a host of other serious medical conditions. Marketed under the names US Stemology and Seattle Stem Cell Center, Defendants' clinic offered patients essentially the same stem cell procedure as a cure-all for all of these conditions. Defendants marketed this cure without any reasonable substantiation for its effectiveness, in violation of Washington's Consumer Protection Act.

1.2 During the early stages of the global COVID-19 pandemic, when many Washingtonians were fearful and searching for answers, Defendants capitalized on that fear by advertising stem cell treatments to prevent or treat COVID-19 infection based on anecdotal information from a few news articles. For instance, during early 2020, Defendants' websites featured a prominent banner informing consumers, "Critically Ill Coronavirus Patient Gets Better with Stem Cells," under an icon encouraging consumers to "CALL NOW."



<https://ustemology.com> (last visited Apr. 30, 2020).

1.3 This statement regarding the ability to treat COVID-19 with stem cell procedures, in concert with the invitation to call now, gave consumers the net impression that Defendants were offering stem cell procedures at their clinic to treat COVID-19. At the time Defendants advertised stem cell procedures to treat COVID-19, Defendants lacked any competent and

1 reliable scientific evidence to support the effectiveness of those procedures. Nor did any such
2 evidence exist.

3 1.4 Defendants' incautious response to the global pandemic is demonstrative of their
4 recklessness in marketing stem cell treatments for serious cardiopulmonary, neurological, and
5 autoimmune diseases to consumers. Since at least 2018, Defendants have charged over one hundred
6 patients over \$740,000 to administer stem cell treatments for which Defendants lacked any
7 competent and reliable scientific evidence regarding efficacy.

8 1.5 While charging patients thousands of dollars for unproven stem cell treatments,
9 Defendants also led these patients to believe that they were participating in legitimate clinical trials.
10 However, Defendants failed to follow basic principles of human clinical research, such as the use
11 of a control group or a standard course of treatment across study participants, and the individuals
12 purportedly independently reviewing the research were the researchers themselves, causing an
13 irreconcilable conflict of interest.

14 1.6 Defendants' misleading and unsubstantiated claims regarding the ability of stem cell
15 procedures to treat a wide range of serious medical conditions had the capacity to deceive and cause
16 significant injury to a substantial number of consumers in Washington and nationwide.

17 1.7 As a result of their repeated violations of the CPA, Defendants are liable for civil
18 penalties, injunctive relief, restitution, and other appropriate relief, as set forth below.

19 II. PARTIES

20 2.1 The Plaintiff is the Attorney General on behalf of the State of Washington. The
21 Attorney General is authorized to commence this action pursuant to RCW 19.86.080 and
22 RCW19.86.140. The Washington State Attorney General's Office created the Consumer
23 Protection Division to detect, investigate, and prosecute any act prohibited or declared to be
24 unlawful under the Washington Consumer Protection Act.

25 2.2 Defendant US Stemology, LLC ("US Stemology"), is a Washington limited
26 liability company with its principal place of business located at 311 West Republican Street, Seattle,

1 WA 98119. It is registered to do business in Washington and its Unified Business Identifier
2 Number is 604 307 477. US Stemology is wholly owned by Tami Meraglia, M.D. US Stemology
3 operates a clinic in Seattle, Washington which is simultaneously marketed using the names US
4 Stemology and Seattle Stem Cell Center.

5 2.3 Defendant Tami Meraglia, M.D. (“Meraglia”) is a married individual residing in
6 Seattle, King County, Washington. All acts of Defendant Meraglia alleged herein were taken on
7 behalf of herself and her marital community. At all times material to this Complaint, Defendant
8 Meraglia was governor of US Stemology and its sole owner. Defendant Meraglia personally
9 participated in the conduct described herein, and with knowledge approved of such conduct.

10 III. JURISDICTION AND VENUE

11 3.1 The State files this Complaint and institutes these proceedings under the
12 provisions of the Consumer Protection Act, RCW 19.86.

13 3.2 Defendants have engaged in the conduct set forth in this Complaint in King
14 County and elsewhere in the State of Washington.

15 3.3 Venue is proper in King County pursuant to RCW 4.12.020 and 4.12.025, and
16 Court Rule 82 because Defendants reside in and transact business in King County.

17 3.4 The Attorney General has the authority to commence this action as conferred by
18 RCW 19.86.080 and RCW 19.86.140.

19 IV. FACTS

20 A. Defendants’ Unsubstantiated Stem Cell Treatments

21 4.1 Sometimes called the body’s “master cells,” stem cells “develop into blood, brain,
22 bones, and all of the body’s organs.”¹ Stem cells “have the potential to repair, restore, replace, and
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25 ¹ “FDA Warns About Stem Cell Therapies,” [https://www.fda.gov/consumers/consumer-updates/fda-](https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies)
26 warns-about-stem-cell-therapies (Sept. 29, 2019), attached hereto as Exhibit A.

1 regenerate cells,” and in the future, “could *possibly* be used to treat many medical conditions and
2 diseases.”² Currently, however, these treatments remain unproven.

3 4.2 The Food and Drug Administration (FDA) regulates stem cell products in the United
4 States.³ With limited exceptions, the FDA requires new stem cell products or therapies to go through
5 a review process by submitting an Investigational New Drug Application (IND) and obtaining the
6 FDA’s approval for clinical trials to proceed.⁴ The only stem-cell products currently approved by
7 the FDA are blood-forming cells (hematopoietic progenitor cells) derived from cord blood, for
8 limited uses relating to disorders of the body systems involved in the production of blood.⁵ The
9 FDA warns consumers that stem cell treatments which are neither FDA-approved nor in clinical
10 trials under an IND pose serious safety risks, even where the treatments use a patient’s own stem
11 cells.⁶ For this reason, RCW 18.130.420 requires Washington providers of stem cell therapies to
12 give written notice to patients if they perform treatments not approved by the FDA or subject to an
13 IND.⁷

14 4.3 However, in recent years, stem cell clinics like Defendant US Stemology have
15 proliferated throughout the country, advertising stem cell treatments outside the FDA’s approval
16 process as a cure-all for a myriad of medical conditions. Defendants made such representations to
17 consumers despite the fact that no adequate scientific substantiation exists to support the
18 effectiveness of these treatments.

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20 ² *Id.*

21 ³ *Id.*

22 ⁴ *Id.*

23 ⁵ *Id.*

24 ⁶ *Id.*

25 ⁷ RCW 18.130.420 also exempts clinical trials under the auspices of “the foundation for the accreditation
26 of cellular therapy, the national institutes of health blood and marrow transplant clinical trials network, or AABB
[Association for the Advancement of Blood & Biotherapies].” RCW 18.130.420(5)(b).

1 4.4 Starting in at least 2018, Defendants promoted and performed stem cell
2 treatments using adipose-derived mesenchymal stromal cells (AD-MSCs),⁸ which are cells
3 harvested from a patient's own fat tissue in a procedure similar to liposuction. Typically,
4 Defendants' AD-MSC treatments for cardiopulmonary, neurological, and autoimmune diseases
5 consisted of manufacturing a product referred to as Stromal Vascular Fraction (SVF) from the
6 patient's AD-MSCs and injecting the SVF into the patient intravenously or via soft tissue.

7 4.5 Defendants also promoted and performed stem cell treatments using lab-
8 manufactured stem cell products known as exosomes and cord cells. Defendants purchased the
9 exosome products, isolated from neonatal mesenchymal stromal cells, from Kimera Labs in
10 Miramar, Florida. Defendants purchased the cord cell products, derived from umbilical cord
11 blood, from FIOR Bioscience in Sandy, Utah. Defendants then injected these exosome and cord
12 cell products into patients intravenously, either in conjunction with AD-MSC treatments or as
13 standalone treatments.

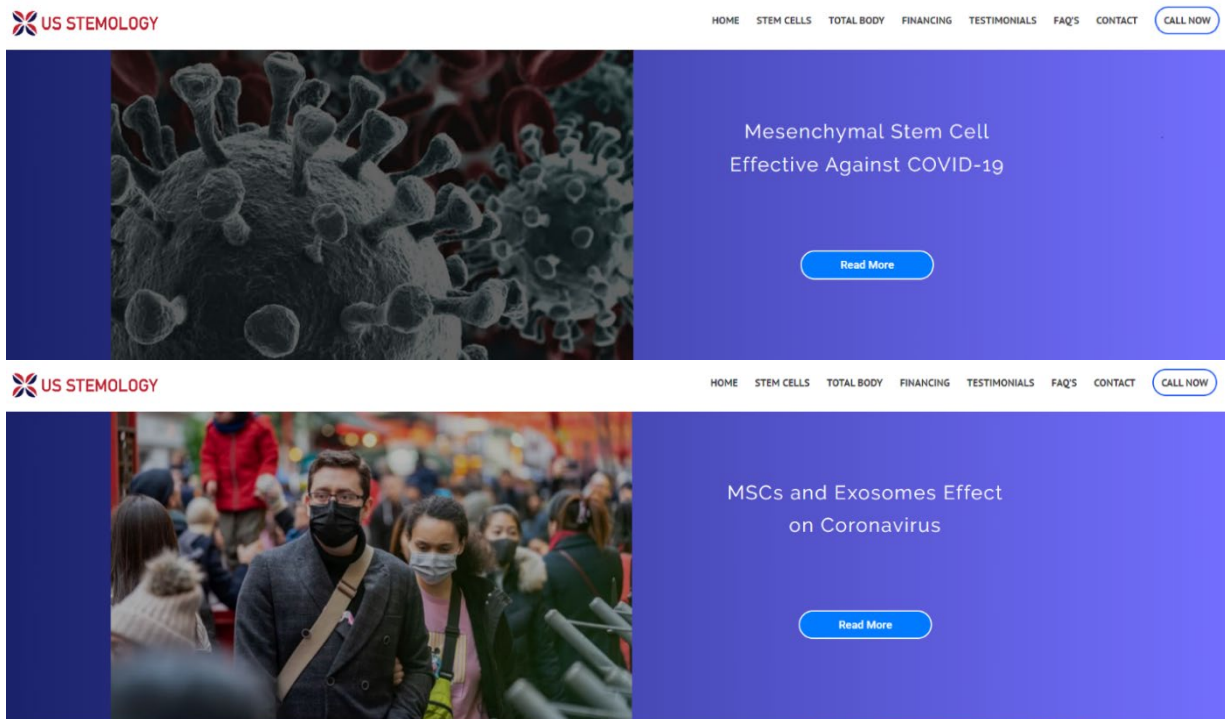
14 4.6 Defendants' website seattlestemcellcenter.net and Facebook page referred to their
15 stem cell treatments as part of a "US Based Clinical Trial" and claimed that this purported research
16 was being conducted under the oversight of an Institutional Review Board (IRB). However,
17 Defendants did not submit an IND application or obtain the FDA's approval to perform their
18 unproven treatments on patients.

19 4.7 Defendants charged patients \$8,900 for a single AD-MSC treatment, or \$13,500
20 for a "package" of three AD-MSC treatments. Defendants charged patients \$5,000 for standalone
21 exosome or cord cell treatments and charged patients \$2,200 to add an exosome or cord cell
22 treatment to their AD-MSC treatment.

25 ⁸ The terms "mesenchymal stromal cells" and "mesenchymal stem cells" refer to the same cell type and
26 are often used interchangeably.

B. Defendants’ Deceptive Claims Regarding the Prevention or Treatment of COVID-19 Infection with Stem Cell Procedures.

4.8 During at least three months in early 2020, in the early stages of the global COVID-19 pandemic, Defendants’ websites usstemology.com and seattlestemcellcenter.net featured prominent banners that rotated between the following three statements concerning the ability of stem cell procedures to treat COVID-19 infections: (1) “Critically Ill Coronavirus Patient Gets Better with Stem Cells,” (2) “Mesenchymal Stem Cell Effective Against COVID-19;” and (3) “MSCs and Exosomes Effect on Coronavirus.” These banners appeared directly under a “CALL NOW” icon.



<https://ustemology.com> (last visited Apr. 30, 2020)

4.9 These statements regarding the ability to treat COVID-19 with stem cell procedures gave consumers the net impression that Defendants were offering stem cell procedures to patients at their clinic to prevent or treat COVID-19.

1 4.10 During the same time period, usstemology.com featured a pop-up advertisement
2 which encouraged website visitors to download a “Free Coronavirus ~~Survival~~ THRIVING
3 Guide” (Thriving Guide). The pop-up stated, “I want to share with you a few things that you
4 may not have heard regarding the Coronavirus and ways to protect yourself and loved ones.”

A screenshot of a pop-up advertisement. On the left is a thick red vertical bar. To its right, the text "FREE Coronavirus ~~Survival~~ THRIVING Guide" is displayed in a large, bold, black font. Below this, a smaller line of text reads: "I want to share with you a few things that you may have not heard regarding the Coronavirus and ways to protect yourself and loved ones." Underneath this text are three input fields: "Your Name *" with a placeholder "Name", "Your Email *" with a placeholder "Email", and "Phone Number" with a placeholder "Phone". Below these fields is a wide red button with the text "Download Now" in white.

15 <https://ustemology.com> (last visited Apr. 30, 2020)

16 4.11 The Thriving Guide itself lists “Stem Cell Therapy” as the first topic listed under
17 the heading “Prevention and Protection,” before listing Centers for Disease Control
18 recommended preventative measures such as handwashing and wearing face masks. The
19 Thriving Guide further states: “you can get a Stem Cell treatment in the summer or early fall as
20 your personalized ‘vaccine’ against getting sick with COVID-19. The reason for this is because
21 stem cell therapy treats the lungs first and has long term anti-inflammatory and immune
22 modulating properties.”

Prevention and Protection

Since COVID-19 can not enter our bodies without our help there is a lot we can do to protect ourselves.

Stem Cell Therapy: The FDA recently approved a study using Stem Cells from your own fat as a Preventative treatment against COVID-19. That means you can get a Stem Cell treatment in the summer or early fall as your personalized “vaccine” against getting sick with COVID-19. The reason for this is because stem cell therapy treats the lungs first and has long term anti-inflammatory and immune modulating properties

<https://ustemology.com> (last visited Apr. 30, 2020)

4.12 Defendants also promoted stem cell procedures for the prevention or treatment of COVID-19 directly to the recipients of their email marketing lists. On April 5, 2020, Defendant Meraglia sent an email blast to her marketing list with the subject heading, “Stem Cells and Coronavirus—what you need to know.” The email stated, “Did you know that Stem Cells are being used to treat Covid-19 positive patients successfully around the world and are being investigated as a possible preventative measure?” and further stated, “And... we as members of the Cell Surgical Network, have received an IRB approval for this!”

4.13 Defendants’ representations in the Thriving Guide and their email marketing communication regarding stem cell treatments to prevent COVID-19 infection gave consumers the net impression that Defendants’ clinic was offering those treatments and that those treatments were effective.

4.14 During the course of the State’s investigation, Defendants were unable to provide any adequate prior scientific substantiation to support their claims that COVID-19 could be prevented or treated with AD-MSC, exosome, or cord cell procedures. Nor did any adequate scientific substantiation exist to support those claims at the time they were made.

1 4.15 At the time Defendants made the above-referenced claims on their websites and
2 elsewhere regarding the prevention or treatment of COVID-19, Defendants possessed no
3 adequate scientific substantiation to support those claims.

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5 **C. Defendants’ Deceptive Claims Regarding the Treatment of Cardiopulmonary,
6 Neurological, and Autoimmune Diseases with Stem Cell Procedures.**

7 4.16 Starting in 2018 or earlier, Defendants promoted stem cell procedures to treat
8 various cardiopulmonary, neurological, and autoimmune diseases on their websites
9 usstemology.com and seattlestemcellcenter.net.

10 4.17 The seattlestemcellcenter.net homepage featured a prominent graphic near the top
11 of the page which stated, “We Help You Put the LIFE Back in Your Years: Could Stem Cell
12 therapy change your life?” Immediately below, the graphic asked, “Do you have?” and listed the
13 following six conditions: Arthritis, Parkinsons, Traumatic Brain Injury, Chronic Obstructive
14 Pulmonary Disease, Stroke, and Multiple Sclerosis. Beneath this list, the graphic invited
15 consumers to “Call Now For a FREE Consultation.”
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<https://seattlestemcellcenter.net> (last visited Apr. 23, 2020)

4.18 Both the ustemology.com and seattlestemcellcenter.net website homepages listed cardiopulmonary, neurological, and autoimmune conditions under a heading stating “Conditions We Are Investigating,” followed by invitations to “Call Now for a Free Consultation” (on seattlestemcellcenter.net) and to “Book a free consult NOW” (on ustemology.com).

4.19 Relevant to the State’s Complaint, Defendants’ websites promoted stem cell procedures to treat the following cardiopulmonary conditions: (1) asthma; (2) cardiomyopathy; (3) chronic obstructive pulmonary disease and other lung disease; (4) congestive heart failure; and (5) post myocardial infarction.

4.20 Relevant to the State’s Complaint, Defendants’ websites promoted stem cell procedures to treat the following neurological conditions: (1) amyotrophic lateral sclerosis;

(2) multiple sclerosis; (3) muscular dystrophy; (4) neuropathy; (5) Parkinson's; (6) spinal cord injury; (7) stroke; and (8) traumatic brain injury.

4.21 Relevant to the State's Complaint, Defendants' websites promoted stem cell procedures to treat the following autoimmune conditions: (1) autoimmune neuropathy and chronic inflammatory demyelinating polyneuropathy; (2) diabetes; (3) Crohn's disease; (4) lupus; (5) myasthenia gravis; (6) polymyalgia rheumatica; (7) relapsing polychondritis; and (8) scleroderma.

4.22 During the course of the State's investigation, Defendants were unable to provide any adequate prior scientific substantiation to support their representations that any of the above-listed cardiopulmonary, neurological, or autoimmune conditions could be effectively treated with AD-MS, exosome, or cord cell procedures. Nor did any adequate scientific substantiation exist to support those representations at the time they were made.

4.23 Despite Defendants' representations regarding conducting investigations and research, Defendants' websites repeatedly used the terms "treatment" and "therapy"⁹ to refer to their stem cell procedures.

4.24 The usstemology.com and seattlestemcellcenter.net home pages both promised consumers a "customized stem cell treatment plan."

THE US STEMOTOLOGY ADVANTAGE

So many clinics start and end with stem cell therapy. US Stemology believes in a holistic, ongoing approach to your health and healing. From a free consultation and customized stem cell treatment plan to the actual procedure and follow-up nutrition-health optimization, the team at US Stemology is committed to a happier, healthier you.

<https://usstemology.com> (last visited Apr. 30, 2020)

⁹ The Oxford English Dictionary defines "therapy" as "treatment intended to relieve or heal a disorder."

1 4.25 Defendants’ Facebook page similarly promised consumers, “A customized stem
2 cell therapy program, instead of simply a procedure.”



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16 <https://www.facebook.com/SeattleStemCellCenter/> (last visited January 10, 2022)

17 4.26 Defendants’ websites ustemology.com and seattlestemcellcenter.net featured
18 patient testimonials in which patients describe the success of stem cell treatments performed by
19 Defendants. Specifically, a patient identified as “Deborah M” stated, “I know that they are
20 bringing a treatment to patients that can be life changing, and they do it because they sincerely
21 want to help people live their best and healthiest life.” A patient identified as “Bruce G” stated,
22 “After years of frustration I’m enjoying real results and looking forward to the next two Stem
23 Cell treatments.” A patient identified as “Donna B” stated, “Stem cell treatment for my mama’s
24 COPD (emphysema) is working! We now have the evidence to back up the science!”

1 4.27 Medical treatment, which is intended to benefit the individual patient, is distinct
2 from clinical research, which is intended to benefit future patients.¹⁰ According to the FDA,
3 medical treatment “[u]ses products and procedures accepted by the medical community as safe
4 and effective,” whereas clinical research “[t]ests products and procedures of unproven benefit to
5 the patient.”¹¹

6 4.28 Defendants’ repeated statements on their websites regarding “stem cell
7 treatment” and “stem cell therapy,” as well as the promise to customize treatment to meet
8 individual needs, gave consumers the net impression that Defendants were offering stem cell
9 procedures to treat the conditions listed on Defendants’ websites and that those procedures are
10 effective.

11 4.29 Relevant to the State’s Complaint, Defendants’ clinic actually performed stem
12 cell procedures on patients to treat the following conditions: (1) asthma; (2) cardiomyopathy; (3)
13 chronic obstructive pulmonary disease and other lung disease; (4) congestive heart failure; (5)
14 amyotrophic lateral sclerosis; (6) multiple sclerosis; (7) muscular dystrophy; (8) neuropathy; (9)
15 Parkinson’s; (10) spinal cord injury; (11) stroke; (12) traumatic brain injury; (13) diabetes; (14)
16 Crohn’s disease, (15) lupus; (16) myasthenia gravis; and (17) scleroderma. Defendants charged
17 over one hundred patients in excess of \$700,000 in the aggregate for various stem cell procedures
18 to treat these 17 conditions.

19 4.30 Defendants advertising of stem cell procedures for serious cardiopulmonary,
20 neurological, and autoimmune conditions specifically targeted individuals or communities based
21 on the presence of a sensory, mental, or physical disability by advertising stem cell procedures
22 for chronic and sometimes incurable medical conditions. Such targeted advertising preyed on
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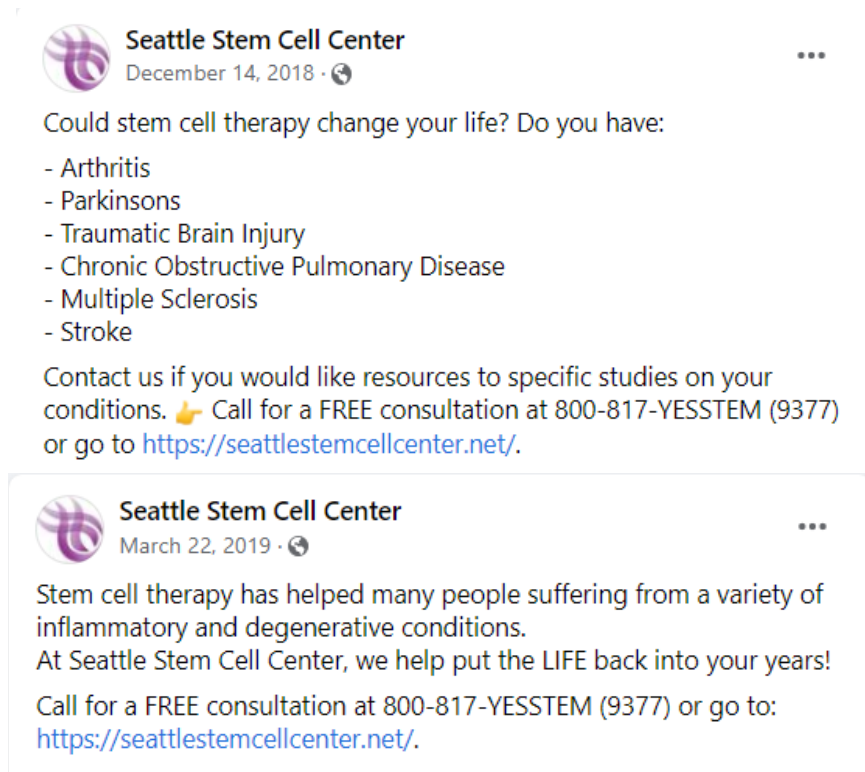
24 ¹⁰ “Clinical Research Versus Medical Treatment,” [https://www.fda.gov/patients/clinical-trials-what-](https://www.fda.gov/patients/clinical-trials-what-patients-need-know/clinical-research-versus-medical-treatment)
25 patients-need-know/clinical-research-versus-medical-treatment (Mar. 22, 2018), attached hereto as Exhibit B.

26 ¹¹ *Id.*

1 individuals with disabilities by giving them false hope as to Defendants' unsubstantiated stem
2 cell procedures.

3 4.31 Defendants published posts to their Facebook page which stated, "STEM CELL
4 THERAPY is an exciting potential therapeutic option for those who have reached the end of
5 traditional medical options or who are wanting to explore using their own cells for treatment."

6 4.32 Defendants also targeted their Facebook posts toward individuals with specific
7 chronic or incurable conditions, such as Parkinson's, multiple sclerosis, or degenerative
8 conditions generally.

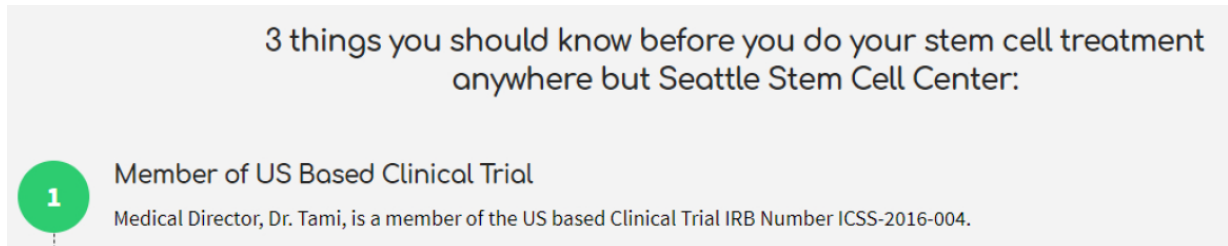


26 <https://www.facebook.com/SeattleStemCellCenter/> (last visited January 10, 2022)

4.33 On information and belief, Defendants' deceptive representations about their
stem cell procedures had an outsize impact on individuals or communities based on the presence
of a sensory, mental, or physical disability, who were more likely to pursue stem cell treatments
for chronic or incurable conditions.

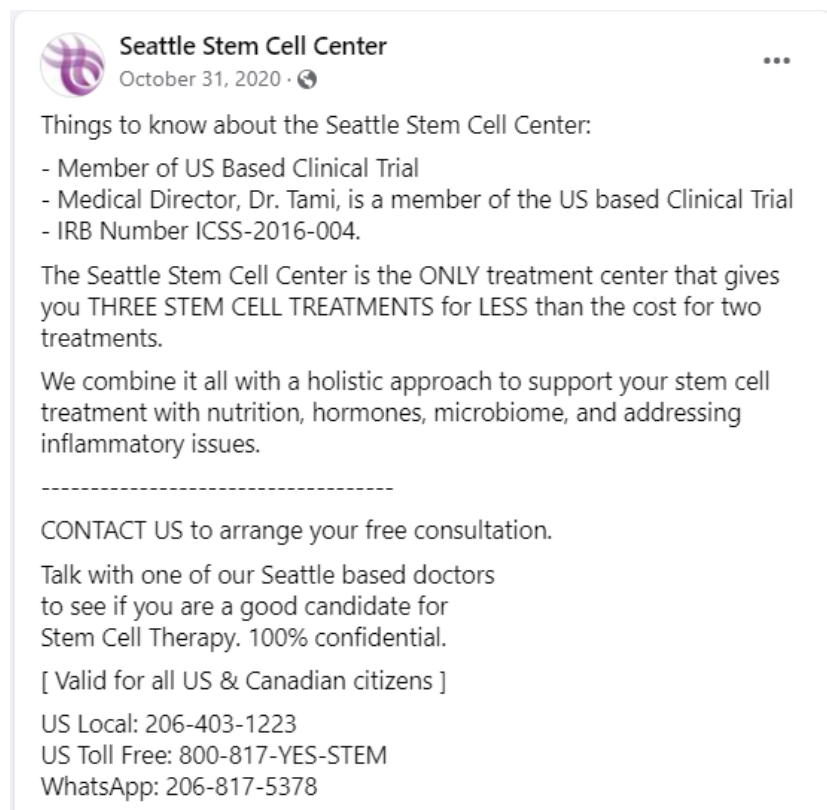
1 **D. Defendants’ Deceptive Claims Characterizing their Patient-Funded Treatments as**
2 **Legitimate Clinical Research.**

3 4.34 Defendants’ website seattlestemcellcenter.net stated on the home page, under a
4 list of reasons that consumers should choose Defendants’ clinic, that Defendants were part of a
5 “US Based Clinical Trial” and referenced an Institutional Review Board (IRB) number “ICSS-
6 2016-004.”



11 <https://seattlestemcellcenter.net> (last visited Apr. 23, 2020)

12 4.35 Defendants’ Facebook page for Seattle Stem Cell Center also promoted
13 Defendants’ clinic and Defendant Meraglia as a “Member of US Based Clinical Trial.”



1 <https://www.facebook.com/SeattleStemCellCenter/> (last visited January 10, 2022)

2 4.36 FDA regulations require that human clinical trials be approved and monitored by
3 an Institutional Review Board (IRB) to ensure protection of the rights and welfare of human
4 research subjects. FDA regulations impose various restrictions on the membership of IRBs,
5 including the requirement that “No IRB may have a member participate in the IRB’s initial or
6 continuing review of any project in which the member has a conflicting interest, except to
7 provide information requested by the IRB.” 21 C.F.R. § 56.107(e) (“IRB membership”).
8 Customarily, IRBs are operated by universities and other large research institutions.

9 4.37 Defendants purport to be conducting human studies under the supervision of an
10 IRB operated by the International Cell Surgical Society (ICSS), a tax-exempt organization
11 located in Palm Desert, California. Relevant to the State’s Complaint, the ICSS approved IRB
12 proposals for the following categories: (1) “Clinical Efficacy of Autologous Stromal Vascular
13 Fraction SVF for Acute COVID-19 Infection,” (2) “Clinical Efficacy of Adipose Derived SVF
14 for Cardiac Conditions,” (3) “Clinical Efficacy of Adipose Derived SVF for Chronic Obstructive
15 Pulmonary Disease and Asthma,” (4) “Clinical Efficacy of Adipose Derived SVF for
16 Degenerative Neurological Conditions,” and (5) “Clinical Efficacy of Adipose Derived SVF for
17 Autoimmune Conditions.”

18 4.38 The primary researchers listed on all five of these ICSS-approved IRB proposals
19 are Eliot B. Lander M.D. and Mark Berman M.D. Dr. Lander and Dr. Berman operate the
20 California Stem Cell Treatment Center in Rancho Mirage, California. Neither Defendant
21 Meraglia nor Defendant US Stemology are listed as investigators on these five IRB proposals.

22 4.39 Dr. Lander and Dr. Berman are also the founders of the Cell Surgical Network, a
23 group of affiliated stem cell treatment providers across the United States. Defendants are
24 affiliates of the Cell Surgical Network.
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1 4.40 IRS Form 990 Series Return filings by ICSS, which are publically available on
2 the IRS website, indicate that for the tax years 2015 through 2020, Dr. Berman was the President
3 of ICSS and Dr. Lander was its Secretary.

4 4.41 Accordingly, Dr. Berman and Dr. Lander were principal officers of ICSS when
5 it approved the five above-referenced IRB proposals for Dr. Berman and Dr. Lander to conduct
6 stem cell research on human subjects. This arrangement was an impermissible conflict of interest
7 in violation of FDA regulations.

8 4.42 On information and belief, the IRB operated by the ICSS exists solely to provide
9 approval of purported research studies conducted by Dr. Lander and Dr. Berman and their Cell
10 Surgical Network affiliates, including Defendants.

11 4.43 On information and belief, Defendants' cord cell and exosome procedures were
12 not performed pursuant to any IRB-approved protocol.

13 4.44 Defendants were not performing legitimate clinical research when they
14 performed stem cell procedures on patients based on the five above-referenced IRB proposals.
15 In that regard, Defendants did not follow a standard course of treatment for patients who
16 participated in their purported research studies, instead letting patients determine which stem
17 cell treatments to receive (AD-MSC, cord cell, or exosome) and how many treatments to receive.

18 4.45 Defendants purported research studies did not make use of a control group to
19 determine whether any recorded results occurred as a result of the stem cell treatments
20 performed.

21 4.46 Defendants relied solely on anecdotal evidence in the form of patient surveys to
22 assess the results of the stem cell treatments performed.

23 4.47 Instead of performing legitimate clinical research, Defendants used the existence
24 of these self-interested IRB protocols to mislead patients to believe that they were participating
25 in clinical research when they were simply paying to receive unproven and potentially unsafe
26 medical treatments.

1 4.48 Defendants performed these unproven and potentially unsafe procedures absent
2 the supervision of a legitimate IRB and the accompanying protections that are intended to ensure
3 patient safety and minimize adverse events.

4 4.49 Defendants' unfair and deceptive acts and practices in marketing stem cell
5 treatments without adequate prior scientific substantiation and making deceptive claims
6 regarding their purported patient-funded research have impacted the public interest and are likely
7 to continue without relief from this Court.

8 4.50 Defendants, at all times relevant to this action, have been engaged in trade or
9 commerce within the meaning of RCW 19.86.010(2), by marketing various stem cell procedures
10 to consumers in Washington and nationwide. Defendants conduct business in the state of
11 Washington.

12 **V. CAUSE OF ACTION**
13 **(Unfair and Deceptive Claims Regarding Stem Cell Treatments**
14 **in Violation of the Consumer Protection Act, RCW 19.86.020)**

15 5.1 Plaintiff re-alleges Paragraphs 1.1 through 4.50 and incorporates them as if set fully
16 herein.

17 5.2 Defendants engaged in "trade" or "commerce" within the meaning of the
18 Consumer Protection Act, RCW 19.86.010(2), by marketing stem cell procedures to consumers
19 in Washington and nationwide and by charging patients for those services.

20 5.3 Through statements on their websites and elsewhere, Defendants represented that
21 stem cell procedures could prevent or treat COVID-19 without possessing any competent and
22 reliable scientific evidence to substantiate those representations.

23 5.4 Through statements on their websites and elsewhere, Defendants represented that
24 stem cell procedures could treat various cardiopulmonary, neurological, and autoimmune
25 conditions without possessing any competent and reliable scientific evidence to substantiate
26 those representations.

1 5.5 Defendants' claims regarding the ability of various stem cell procedures to
2 prevent or treat COVID-19, cardiopulmonary, neurological, and autoimmune conditions had the
3 capacity to deceive a substantial portion of the public.

4 5.6 Defendants' practice of claiming various stem cell procedures could prevent or
5 treat COVID-19, cardiopulmonary, neurological, and autoimmune conditions was unfair. Through
6 statements on their websites and elsewhere, Defendants misrepresented their paid stem cell
7 treatments as legitimate clinical research, when Defendants were not conducting legitimate
8 clinical research.

9 5.7 Defendants' misrepresentations of their paid stem cell treatments as legitimate
10 clinical research had the capacity to deceive a substantial portion of the public.

11 5.8 Defendants' misrepresentations of their paid stem cell treatments as legitimate
12 clinical research were unfair.

13 5.9 Defendants' unfair and deceptive acts and practices in promoting stem cell
14 treatments to prevent or treat COVID-19, as well as cardiopulmonary, autoimmune, and
15 neurological conditions, without adequate scientific substantiation have impacted the public
16 interest and are likely to continue without relief from this Court.

17 5.10 Based on the above deceptive acts and practices, Plaintiff is entitled to relief
18 under the Consumer Protection Act including injunctive relief and restitution pursuant to
19 RCW 19.86.080, civil penalties pursuant to RCW 19.86.140 for each and every violation of
20 RCW 19.86.020, and reimbursement of the costs of this action, including reasonable attorneys'
21 fees, pursuant to RCW 19.86.080.

22 **VI. PRAYER FOR RELIEF**

23 Wherefore, the State prays for the following relief:

24 6.1 That the Court adjudge and decree that the Defendants have engaged in the conduct
25 complained of herein.
26

1 6.2 That the Court adjudge and decree that the conduct complained of constitutes
2 unfair or deceptive acts or practices and is unlawful in violation of the Consumer Protection Act,
3 RCW 19.86.

4 6.3 That the Court issue a permanent injunction pursuant to the Consumer Protection
5 Act, RCW 19.86.080, enjoining and restraining Defendants and their representatives, successors,
6 assigns, offices, agents, servants, employees, and all other persons acting or claiming to act for,
7 on behalf of, or in concert or participation with Defendants, from continuing or resuming the
8 unlawful conduct complained of herein.

9 6.4 That the Court assess civil penalties, pursuant to RCW 19.86.140, against
10 Defendants in the amount of \$7,500 for each and every violation of RCW 19.86.020 caused by
11 the conduct complained of herein.

12 6.5 That the Court assess enhanced civil penalties, pursuant to RCW 19.86.140, against
13 Defendants in the amount of \$5,000 for each and every violation of RCW 19.86.020 which targeted
14 or impacted individuals or communities based on the presence of any sensory, mental, or physical
15 disability.

16 6.6 That the Court, as an equitable remedy, disgorge Defendants of money or property
17 acquired by Defendants as a result of the conduct and violations complained of herein.

18 6.7 That the Court make such orders pursuant to RCW 19.86.080 as it deems
19 appropriate to provide for restitution to consumers of money or property unlawfully acquired by
20 Defendants as a result of the conduct complained of herein.

21 6.8 That the Court make such orders pursuant to RCW 19.86.080 to provide that the
22 Plaintiff, State of Washington, have and recover from Defendants the costs of this action,
23 including reasonable attorneys' fees.

24 6.9 That the Court award prejudgment interest on any order of restitution.

25 6.10 For such other relief as the Court may deem just and proper.
26

1 DATED this 14th day of March, 2022.

2
3 ROBERT W. FERGUSON
4 Attorney General

5
6 /s/ Logan Starr

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