|   | Case 8:18-cv-01838 Document 1 Filed  | 10/12/18 Page 1 of 23 Page ID #:1                                      |
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| 1<br>2<br>3<br>4<br>5<br>6<br>7<br>8<br>9<br>10<br>11<br>12 | ALDEN F. ABBOTT<br>General Counsel<br>ANNETTE SOBERATS<br>FL Bar No. 93934; asoberats@ftc.gov<br>TAWANA E. DAVIS<br>DC Bar No. 435896; tdavis@ftc.gov<br>Federal Trade Commission<br>600 Pennsylvania Avenue, NW, CC-10528<br>Washington, DC 20580<br>Tel: (202) 326-2921; -2755 / Fax: (202) 32<br>Local Counsel<br>DELILAH VINZON<br>CA Bar No. 222681; dvinzon@ftc.gov<br>10990 Wilshire Blvd. #400<br>Los Angeles, CA 90024<br>Tel: (310) 824-4328 / Fax: (310) 824-4380 |  |
| 13  | UNITED STATES DISTRICT COURT<br>CENTRAL DISTRICT OF CALIFORNIA   |  |
| 14<br>15  |  |  |
| 16  | FEDERAL TRADE COMMISSION,  |  |
| 17  | Plaintiff,   | Case No. <u>8:18-cv-01838</u>  |
| 18  | v.   |  |
| 19<br>20<br>21  | REGENERATIVE MEDICAL GROUP, INC., a corporation;   | COMPLAINT FOR<br>PERMANENT INJUNCTION<br>AND OTHER EQUITABLE<br>RELIEF |
| 22<br>23  | TELEHEALTH MEDICAL GROUP, INC<br>a corporation; and  | ••   |
| 24  | BRYN JARALD HENDERSON, D.O.,   |  |
| 25  | individually and as an officer of REGENERATIVE MEDICAL   |  |
| 26  | GROUP, INC. and TELEHEALTH   |  |
| 27  | MEDICAL GROUP, INC.,   |  |
| 28  | Defendants.  |  |

Plaintiff, Federal Trade Commission ("FTC" or "Commission"), for its complaint alleges:

 The FTC brings this action pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to obtain permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendants' acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of stem cell therapy to treat, cure, and mitigate various diseases and health conditions.

### JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b).

3. Venue is proper in this district under 28 U.S.C. § 1391(b)(1), (b)(2),
(c)(1), (c)(2), and (d) and 15 U.S.C. § 53(b).

### **PLAINTIFF**

4. The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. §§ 53(b) and 56(a)(2)(A).

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### **DEFENDANTS**

6. Defendant Regenerative Medical Group, Inc. ("RMG") is a California corporation with its principal place of business at 615 E. Chapman Avenue,
Orange, CA 92866. RMG transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, RMG has advertised, marketed, or sold stem cell therapy to treat, cure, and mitigate various diseases and health conditions to consumers throughout the United States.

7. Defendant Telehealth Medical Group, Inc. ("TMG") is a California corporation with its principal place of business at 615 E. Chapman Avenue, Orange, CA 92866. TMG transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, TMG has advertised, marketed, or sold primary care medical services, including services related to stem cell therapy, to treat, cure, and mitigate various diseases and health conditions to consumers throughout the United States.

8. Defendant Bryn Jarald Henderson, D.O., J.D., is the founder, CEO, and sole owner and shareholder of RMG and TMG. At all times material to this Complaint, acting alone or in concert with others, he has formulated, directed, controlled, had authority to control, or participated in the acts and practices of RMG and TMG, including the acts and practices set forth in the Complaint. Defendant Henderson resides in this district and, in connection with the matters alleged herein, transacts or has transacted business in this district and throughout the United States. Defendant Henderson's family trust owns RMG's and TMG's main office at 615 E. Chapman Avenue, Orange, California 92866.

9. Defendant Henderson is featured prominently in RMG's advertising,including its websites and social media platforms, where he often appears in awhite lab coat discussing the benefits of amniotic stem cell therapy. He speaks

with all prospective patients during which he discusses the benefits of amniotic stem cell therapy. Defendant Henderson is aware that the vast majority of amniotic stem cell research has been conducted on animal models. There are no human clinical studies in the scientific literature showing that amniotic stem cell therapy cures, treats, or mitigates diseases or health conditions in humans, and the medical community considers amniotic stem cell therapy to be an experimental and unproven treatment. He also has not conducted any studies demonstrating that amniotic stem cell therapy cures, treats, or mitigates diseases or health conditions in humans.

10. Defendant Henderson maintains final approval for all information posted on the RMG website and Facebook page. He has the login credentials for all of RMG's advertising platforms, including the website and social media pages. In addition, Defendant Henderson has employed physicians and pharmacists to work at RMG and TMG who have no experience with stem cell therapy and lack appropriate licenses to practice medicine.

11. Defendants RMG and TMG (collectively "Corporate Defendants") have operated as a common enterprise while engaging in the deceptive acts and practices alleged below. These Corporate Defendants have conducted the business practices described below through interrelated companies that have common ownership, officers, managers, business functions, employees, and office locations. Because these Corporate Defendants have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below. Defendant Henderson has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the Corporate Defendants that constitute the common enterprise.

### **COMMERCE**

12. At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

### **DEFENDANTS' BUSINESS ACTIVITIES**

13. Defendants advertise, offer for sale, sell, and distribute stem cell therapy to treat, cure, and mitigate various diseases and health conditions.Defendants use stem cells derived from the amniotic fluid of women who have had full-term pregnancies and elected to undergo caesarean sections.

14. Defendants have advertised stem cell therapy through social media and other internet marketing. Defendants also marketed and sold stem cell therapy through websites owned by RMG including, but not limited to, www.stemcell.life and www.cerebralpalsy.healthcare.

15. To induce consumers to undergo stem cell therapy, Defendants have disseminated or caused to be disseminated advertisements and promotional materials including, but not limited to, the attached Exhibits A through F. The cost of the initial stem cell therapy Defendants sell ranges from approximately \$9,500 to \$15,000. From January 2014 to December 2017, Defendants generated at least \$3.31 million in U.S. net sales for all of their stem cell therapy products. Dr. Henderson and RMG's other physicians encourage patients to undergo multiple stem cell treatments. A follow-up "booster" of stem cells can cost between \$5,000 to \$8,000.

16. The advertisements and promotional materials referenced inParagraphs 14 and 15 contain the following statements and depictions, among others:

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A. A letter from Defendant Henderson posted on the stemcell.life website and disseminated from January 1, 2015 to present (Ex. A):



Please Share this with your Healthcare Providers If you wish we would like you to invite your physician to learn about the advances in stem cells. We recognize that it is a challenge to keep up with all the advances in medicine but stem cells are special. This is the only treatment that allows your body to determine how and where to make new cells. Stem cell therapies are already playing a significant role in the treatment of many illnesses. As often the case due to strict regulations and powerful health care companies America lags the world in stem cell therapies. Lives are being saved, the blind see, the crippled walk and the patients with heart, lung, kidney and nerve diseases can alter the course of their suffering with a simple therapy the lasts for years and impacts their lives NOW! We currently use the most advanced stem cells - Amniotic stem cells - derived from a process approved by the FDA in a FDA licensed lab in Scottsdale, AZ. This company is licensed to sell these stem cells globally. Amniotic stem cells are immune privileged which means that our bodies do not recognize them as foreign and therefore do not reject them. There has never been any side effects reported from administering amniotic stem cells. Please review the following links and encourage those you love as well as your physicians to do the same in an effort to help you make the best decisions regarding your care. We also encourage you to create a 'Google alert' with the topic of 'adult stem cells' and track the advances daily as we have done for the past five years. This is one of the most exciting advances in medicine since the discovery of antibiotics ! www.StemCell.life is our web site with a direct link to our Facebook page where you will find many testimonials and answers to common questions. It is also a place where you can ask other patients who have preceded you in these powerful treatments. We welcome your questions, we discuss stem cell therapies daily with physicians from all over the world. We recognize that stem cell therapies are not for everyone and welcome learning from others in our efforts to help patients. We have a diverse team of healthcare professionals; physicians, dentists, pharmacists, chiropractors, naturopaths, and therapists from all over the world. Bryn (). Henderson DO, JD, FACPE, CIME Executive leader of Regenerative Medical Group https://www.stemcell.life/uploads/3/0/0/9/30093761/dr letter.pdf

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B. Defendant RMG's website, www.stemcell.life, disseminated from January 2015 to present (Ex. B):



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### Can Stem Cell therapy help patients with chronic kidney disease?



Yes it can. Stem Cells can make new cells that replace damaged cells and reverse chronic kidney disease symptoms. RMG offers patients access to chronic kidney disease Stem Cell therapy using amniotic Stem Cells. These Stem Cell treatments improve complications in patients with chronic kidney disease. These procedures help patients who don't respond to typical drug

treatments, want to reduce their reliance on medication, or are looking to try Stem Cell therapy before starting a lifelong drug treatment.

Ex. B(9).

Find Out About Treatment Of Parkinson's Disease - by StemCell.Life

# Yes, we can treat Parkinson s

Parkinson's Disease (PD) belongs to a group of conditions called motor system disorders, which are the result of the loss of dopamine-producing brain cells.

The four primary symptoms of PD are:

- Tremor: trembling in hands, arms, legs, jaw, and face
- Rigidity: stiffness of the limbs and trunk
- Bradykinesia: slowness of movement
- Postural instability: impaired balance and coordination.



Ex. B(12).



C. Defendant RMG's Facebook pages disseminated from January 2015 to present (Ex. C - E ):







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D. Defendant RMG's Fact Sheets, authored at least in part by Dr.

Henderson, disseminated from January 2015 to present (Ex. F - G):

## Stem Cell Therapy for Macular Degeneration Fact Sheet

### Can Stem Cell Therapy help patients who have macular degeneration?

Yes it can. It can make new cells that replace damaged cells and reverse macular degeneration symptoms.

RMG offers patients access to macular degeneration stem cell therapy using amniotic Stem Cells.

These Macular Degeneration Stem Cell Treatments have been shown to improve sight in patients with macular degeneration. These procedures help patients who don't respond to typical drug treatment. These patients often have better results if stem cell therapy is begun early in the illness.



Ex. F(2).

Stem Cell Therapy for Chronic Kidney Disease

## Fact Sheet



### Can stem cell therapy help patients with chronic kidney disease?

Yes it can. It can make new cells that replace damaged cells and reverse chronic kidney disease symptoms.

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Stem cells have been shown to help avoid and reduce dialysis. This allows patients to work and continue as productive citizens. This also allows family members and friends more free time because patients regain independence.

The financial benefits of eliminating dialysis and its consequences greatly outweigh the costs of stem cells. The long-term expense of dialysis is replaced by a short protocol of stem cells, which in all likelihood will eventually be a covered benefit of some insurance plans.

Ex. G(2) – (3).

E. Defendant RMG's YouTube channel, available from January 2015 to present (Ex. H):



F. Defendant RMG's video titled "Avoid Surgery! Osteoarthritis Regenerative Therapy," available on Defendant RMG's website stemcell.life from January 2015 to present (Ex. I):

**UNIDENTIFIED MALE**: For years, surgery for osteoarthritis has been seen as unavoidable. In order to get better and gain mobility, it would involve going under the knife. What if surgery was no longer required? What if you could avoid surgery entirely?

At the Regenerative Medical Group, stem cell therapy is being used to improve osteoarthritis conditions. It's a cutting-edge treatment that offers regeneration making new cells. Ultimately, stem cells and the patient's own

blood is used in order to create an injection (misspelled in transcript) into the joints.

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Instead of having knee surgery, injections help. Patients have been calling this a miracle. The process takes about two hours in the office and very little down time is required. There is no surgery and no overnight stays in a hospital. Within a few days, you can start to see results. Within a few weeks, you can get off the painkillers that you have been dependent on [sic], possible for years.

Ex. I(4) - (5).

Defendants have not conducted any studies to assess the efficacy of amniotic 17. stem cell therapy, including its ability to cure, treat, or mitigate any disease or health condition. Moreover, there are no studies in the scientific literature establishing that amniotic stem cell therapy cures, treats, or mitigates diseases or health conditions in humans. 16

### **VIOLATIONS OF THE FTC ACT**

18. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

19. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

20. Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), prohibits the dissemination 23 of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or 24 cosmetics. For the purpose of Section 12 of the FTC Act, 15 U.S.C. § 52, stem cell therapy is a "drug" as "drug" is defined in Section 15(c) of the FTC Act, 15 U.S.C. 26 § 55(c).

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### COUNT ONE

### **False or Unsubstantiated Efficacy Claims**

21. Through the means described in Paragraphs 13 – 16, including, but not
limited to, the statements and depictions contained in the advertisements attached
as Exhibits A through I, Defendants have represented, expressly or by implication,
that their stem cell therapy:

A. Cures, treats, or mitigates specific diseases or health conditions, including Parkinson's disease, autism, multiple sclerosis, cerebral palsy, traumatic brain injury, heart disease, macular degeneration, chronic kidney disease, osteoarthritis, and stroke; and

B. Is comparable to or superior to conventional medical treatments in curing, mitigating, or treating specific diseases or health conditions, including Parkinson's disease, autism, multiple sclerosis, cerebral palsy, traumatic brain injury, heart disease, macular degeneration, chronic kidney disease, osteoarthritis, and stroke.

22. The representations set forth in Paragraph 21 are false or were not
substantiated at the time the representations were made. In fact, many of these
diseases are considered to be currently incurable by medical professionals.

23. Therefore, the making of the representations as set forth in Paragraph 21 of this Complaint constitute deceptive acts or practices and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

### **CONSUMER INJURY**

24. Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

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### THIS COURT'S POWER TO GRANT RELIEF

25. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, Federal Trade Commission, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

A. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies;

B. Enter a permanent injunction to prevent future violations of the FTC Act by Defendants; and

C. Award Plaintiffs the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Dated 10/12/13

Respectfully submitted,

ANNETTE SOBERATS TAWANA E. DAVIS Federal Trade Commission 600 Pennsylvania Avenue, NW Mail Drop CC-10528 Washington, DC 20580 202-326-2921; -2755 202-326-3259 (Fax) asoberats@ftc.gov; tdavis@ftc.gov

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