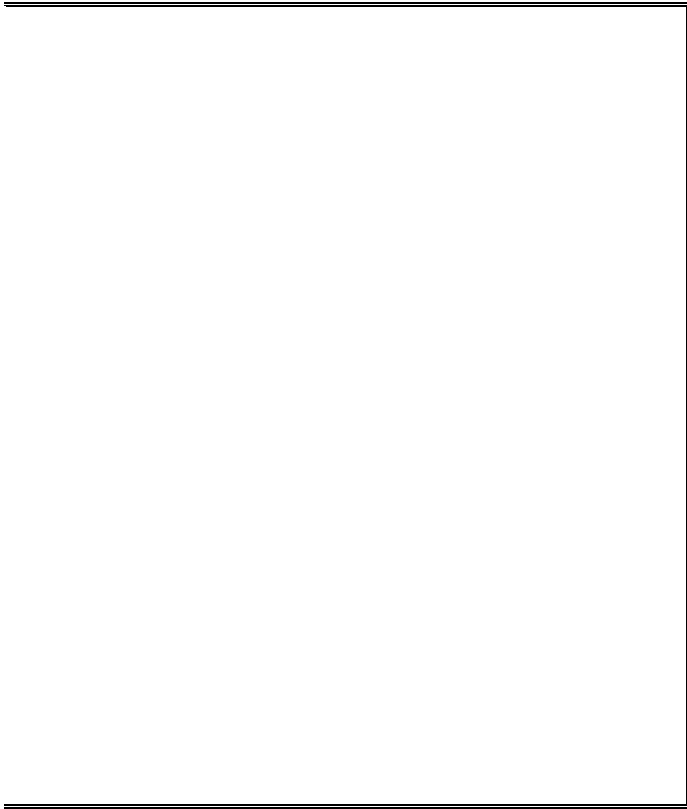


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1 Plaintiff, the Federal Trade Commission (“Commission”), filed its  
2 Complaint for a permanent injunction and other equitable relief in this matter,  
3 pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15  
4 U.S.C. § 53(b). The Commission and Defendants stipulate to the entry of this  
5 Stipulated Order for Permanent Injunction and Monetary Judgment (“Order”), to  
6 resolve all matters in dispute in this action.

7 **THEREFORE, IT IS ORDERED** as follows:

8 **FINDINGS**

9 1. This Court has jurisdiction over this matter.

10 2. The Complaint charges that Defendants participated in deceptive and unfair  
11 acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45  
12 and 52, in the advertising, marketing, and sale of stem cell therapy to treat, cure,  
13 and mitigate various diseases and health conditions.

14 3. Defendants neither admit nor deny any of the allegations in the Complaint,  
15 except as specifically stated in this Order. Only for purposes of this action, s(it nor deny any )a

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1 3. **“Defendants”** means the Individual Defendant and the Corporate  
2 Defendants, individually, collectively, or in any combination.

3 A. **“Corporate Defendants”** means the Regenerative Medical Group,  
4 Inc., the TeleHealth Medical Group, Inc., and their successors and assigns.

5 B. **“Individual Defendant”** means Bryn Jarald Henderson, D.O.

6 4. **“Device”** means an instrument, apparatus, implement, machine, contrivance,  
7 implant, in vitro reagent, or other similar or related article, including any  
8 component, part, or accessory, which is (1) recognized in the official National  
9 Formulary, or the United States Pharmacopeia, or any supplement to them; (2)  
10 intended for use in the diagnosis of disease or other conditions, or in the cure,  
11 mitigation, treatment, or prevention of disease, in humans or other animals; or (3)  
12 intended to affect the structure or any function of the body of humans or other  
13 animals; and which does not achieve any of its principal intended purposes through  
14 chemical action within or on the body of humans or other animals and which is not  
15 dependent upon being metabolized for the achievement of any of its principal  
16 intended purposes.

17 5. **“Dietary Supplement”** means (1) any product labeled as a dietary  
18 supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet,  
19 capsule, powder, softgel, gelcap, liquid, or other similar form containing one or  
20 more ingredients that are a vitamin, mineral, herb or other botanical, amino acid,  
21 probiotic, or other dietary substance for use by humans to supplement the diet by  
22 increasing the total dietary intake, or a concentrate, metabolite, constituent, extract,  
23 or combination of any ingredient described above, that is intended to be ingested,  
24 and is not represented to be used as a conventional food or as a sole item of a meal  
25 or the diet.

26 6. **“Drug”** means (1) articles recognized in the official United States  
27 Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or  
28 official National Formulary, or any supplement to any of them; (2) articles

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1 them, who receive actual notice of this Order, whether acting directly or indirectly,  
2 in connection with the manufacturing, labeling, advertising, promotion, offering  
3 for sale, sale, or distribution of any Covered Product or Covered Service, are  
4 permanently restrained and enjoined from making, or assisting others in making,  
5 expressly or by implication, including through the use of a product or service  
6 name, endorsement, depiction, or illustration, any representation that such product  
7 or service:

8       A. Cures, mitigates, or treats any disease or health condition, including  
9 Parkinson's disease, autism, multiple sclerosis, cerebral palsy, traumatic brain  
10 injury, heart disease, macular degeneration, chronic kidney disease, osteoarthritis,  
11 and stroke; or

12       B. Is comparable or superior to conventional medical treatments in  
13 curing, mitigating, or treating any disease or health condition;  
14 unless the representation is non-misleading, and, at the time of making such  
15 representation, they possess and rely upon competent and reliable scientific  
16 evidence substantiating that the representation is true. For purposes of this  
17 Section, competent and reliable scientific evidence shall consist of human clinical  
18 testing of the Covered Product or Covered Service or, in the case of a food, drug,  
19 or dietary supplement, of the Covered Product or of an Essentially Equivalent  
20 Product, that is sufficient in quality and quantity based on standards generally andards gred on st

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1 and Reliable Human Clinical Tests or Studies must be available for inspection and  
2 production to the Commission. Persons covered by this Section have the burden of  
3 proving that a product satisfies the definition of Essentially Equivalent Product.

4 **II.**

5 **PROHIBITED REPRESENTATIONS:**

6 **OTHER HEALTH-RELATED CLAIMS**

7 **IT IS FURTHER ORDERED** that Defendants, Defendants' officers,  
8 agents, and employees, and all other persons in active concert or participation with  
9 any of them, who receive actual notice of this Order, whether acting directly or  
10 indirectly, in connection with the manufacturing, labeling, advertising, promotion,  
11 offering for sale, sale, or distribution of any Covered Product or Covered Service,  
12 are permanently restrained and enjoined from making, or assisting others in  
13 making, expressly or by implication, including through the use of a product or  
14 service name, endorsement, depiction, or illustration, any representation, other than  
15 representations covered under the Section of this Order entitled Prohibited  
16 Representations: Health-Related Claims Requiring Human Clinical Testing for  
17 Substantiation, about the health benefits, performance, efficacy, safety, or side  
18 effects of any Covered Product or Covered Service, unless the representation is  
19 non-misleading, and, at the time of making such representation, they possess and  
20 rely upon competent and reliable scientific evidence that is sufficient in quality and  
21 quantity based on standards generally accepted by experts in the relevant disease,  
22 condition, or function to which the representation relates, when considered in light  
23 of the entire body of relevant and reliable scientific evidence, to substantiate that  
24 the representation is true.  
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26 For purposes of this Section, competent and reliable scientific evidence  
27 means tests, analyses, research, or studies (1) that have been conducted and  
28 evaluated in an objective manner by experts in the relevant disease, condition, or

1 function to which the representation relates; (2) that are generally accepted by such  
2 experts to yield accurate and reliable results; and (3) that are randomized, double-  
3 blind, and placebo-controlled human clinical testing of the Covered Product or  
4 Covered Service or, in the case of a food, drug, or dietary supplement, of the  
5 Covered Product or of an Essentially Equivalent Product, when such experts would  
6 generally require such human clinical testing to substantiate that the representation  
7 is true. In addition, when such tests or studies are human clinical tests or studies,  
8 all underlying or supporting data and documents generally accepted by experts in  
9 the field as relevant to an assessment of such testing as set forth in the Section  
10 entitled Preservation of Records Relating to Competent and Reliable Human  
11 Clinical Tests or Studies must be available for inspection and production to the  
12 Commission. Persons covered by this Section have the burden of proving that a  
13 product satisfies the definition of Essentially Equivalent Product.

14 **III.**

15 **FDA-APPROVED CLAIMS**

16 **IT IS FURTHER ORDERED** that nothing in this Order prohibits  
17 Defendants, Defendants' officers, agents, and employees, or all other persons in  
18 active concert or participation with any of them from:

19 A. For any drug, making a representation that is approved in labeling for  
20 such drug under any tentative final or final monograph promulgated by the Food  
21 and Drug Administration, or under any new drug application approved by the Food  
22 and Drug Administration; and

23 B. For any product, making a representation that is specifically  
24 authorized for use in labeling for such product by regulations promulgated by the  
25 Food and Drug Administration pursuant to the Nutrition Labeling and Education  
26 Act of 1990, s. author.3[pployees, or all other10persons in  
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1 **IV.**

2 **PRESERVATION OF RECORDS RELATING TO**  
3 **COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES**

4 **IT IS FURTHER ORDERED** that, with regard to any human clinical test  
5 or study (“test”) upon which Defendants rely to substantiate any claim covered by  
6 this Order, Defendants shall secure and preserve all underlying or supporting data  
7 and documents generally accepted by experts in the field as relevant to an  
8 assessment of the test, including:

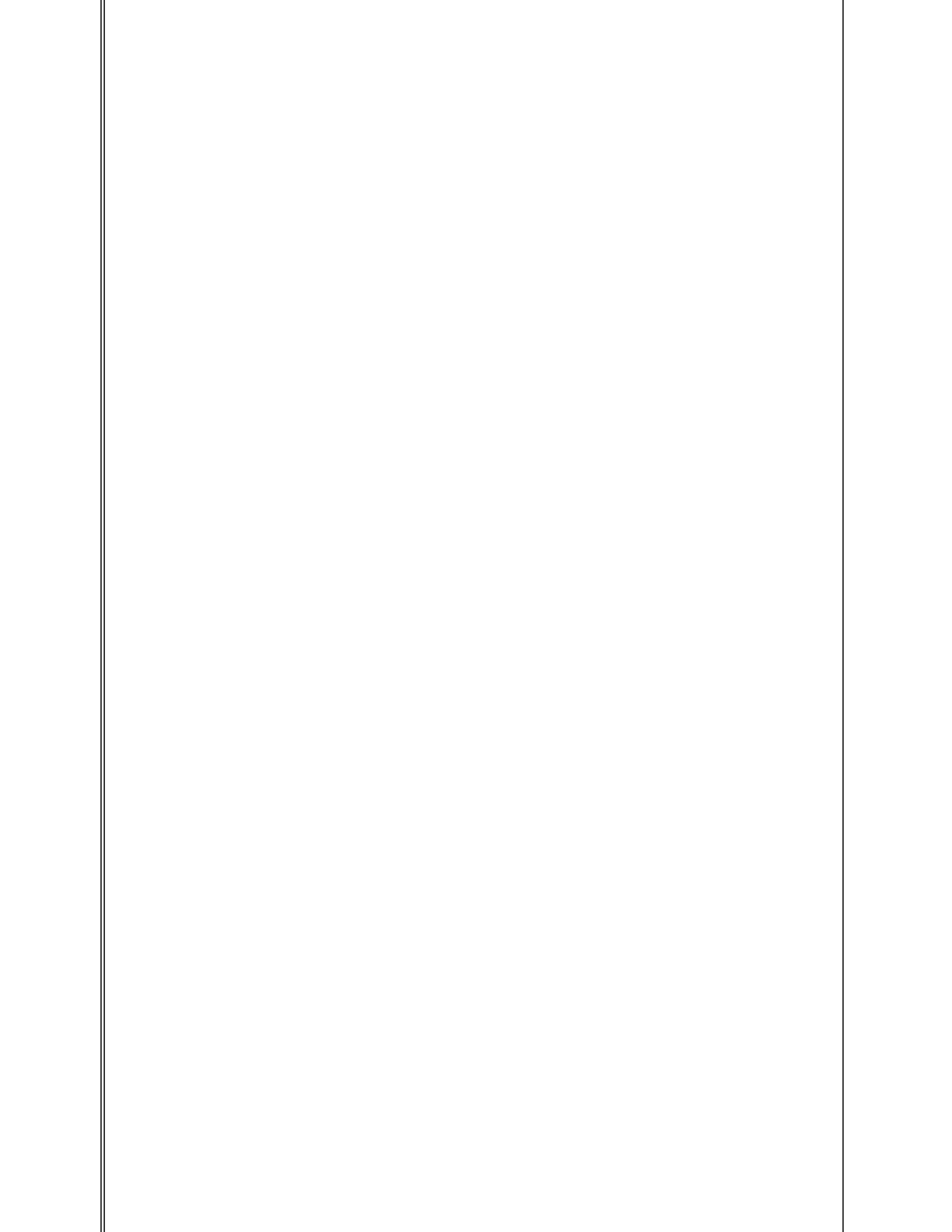
9 A. All protocols and protocol amendments, reports, articles, write-ups, or  
10 other accounts of the results of the test, and drafts of such documents reviewed by  
11 the test sponsor or any other person not employed by the research entity;

12 B. All documents referring or relating to recruitment; randomization;  
13 instructions, including oral instructions, to participants; and participant  
14 compliance;

15 C. Documents sufficient to identify all test participants, including any  
16 participants who did not complete the test, and all communications with any  
17 participants relating to the test; all raw data collected from participants enrolled in  
18 the test, including any participants who did not complete the test; source  
19 documents for such data; any data dictionaries; and any case report forms;

20 D. All documents referring or relating to any statistical analysis of any  
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1 Regenerative Medical Group, Inc. signed by Bryn Jarald Henderson, CEO, on May  
2 16, 2018, including the attachments; and

3 3. Financial Statement of Cor  
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1 estoppel effect for such purposes.

2 D. Defendants acknowledge that their Taxpayer Identification Numbers  
3 (Social Security Numbers or Employer Identification Numbers), which Defendants  
4 previously submitted to the Commission, may be used for collecting and reporting  
5 on any delinquent amount arising out of this Order, in accordance with 31 U.S.C.  
6 §7701.

7 E. All money paid to the Comm

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1           B.     For 10 years after entry of this Order, Individual Defendant for any  
2 business that such Defendant, individually or collectively with any other

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1 own involvement); (d) describe in detail whether and how that Defendant is in  
2 compliance with each Section of this Order; and (e) provide a copy of each Order  
3 Acknowledgment obtained pursuant to this Order, unless previously submitted to  
4 the Commission.

5           2.       Additionally, Individual Defendant must: (a) identify all  
6 telephone numbers and all physical, postal, email and Internet addresses, including  
7 all residences; (b) identify all business activities, including any business for which  
8 such Defendant performs services whether as an employee or otherwise and any  
9 entity in which such Defendant has any ownership interest; and (c) describe in  
10 detail such Defendant's involvement in each such business, including title, role,  
11 responsibilities, participation, authority, control, and any ownership.

12           B.       For 10 years after entry of this Order, each Defendant must submit a  
13 compliance notice, sworn under penalty of perjury, within 14 days of any change  
14 in the following:

15           1.       Each Defendant must report any change in: (a) any designated  
16 point of contact; or (b) the structure of any Corporate Defendant or any entity that  
17 Defendant has any ownership interest in or controls directly or indirectly that may  
18 affect compliance obligations arising under this Order, including: creation,  
19 merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that  
20 engages in any acts or practices subject to this Order.

21           2.       Additionally, Individual Defendant must report any  
22 change in: (a) name, including aliases or fictitious names, or residence address; or  
23 (b) title or role in any business activity, including any business for which such  
24 Defendant performs services whether as an employee or otherwise and any entity  
25 in which such Defendant has any ownership interest, and identify the name,  
26 physical address, and any Internet address of the business or entity.

1 C. Each Defendant must submit to the Commission notice of the filing of  
2 any bankruptcy petition, insolvency proceeding, or similar proceeding by or  
3 against such Defendant within 14 days of its filing.

4 D. Any submission to the Commission required by this Order to be  
5 sworn under penalty of perjury must be true and accurate and comply with 28  
6 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under  
7 the laws of the United States of America that the foregoing is true and correct.  
8 Executed on: \_\_\_\_\_” and supplying the date, signatory’s full name, title (if  
9 applicable), and signature.

10 E. Unless otherwise directed by a Commission representative in writing,  
11 all submissions to the Commission pursuant to this Order must be emailed to  
12 DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to:  
13 Associate Director for Enforcement, Bureau of Consumer Protection, Federal  
14 Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The  
15 subject line must begin: FTC v. Regenerative Medical Group, Inc., No. \_\_\_\_\_.

16 **XI.**

17 **RECORDKEEPING**

18 **IT IS FURTHER ORDERED** that Defendants must create certain records  
19 for 10 years after entry of the Order, and retain each such record for 5 years.  
20 Specifically, each Defendant, for any business that such Defendant, individually or  
21 collectively with any other Defendants, is a majority owner or controls directly or  
22 indirectly, must create and retain the following records:

23 A. accounting records showing the revenues from all goods or services  
24 sold;

25 B. personnel records showing, for each person providing services,  
26 whether as an employee or otherwise, that person’s: name; addresses; telephone  
27 numbers; job title or position; dates of service; and (if applicable) the reason for  
28 termination;





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D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. §1681b(a)(1).

**XIII.**

**RETENTION OF JURISDICTION**

**IT IS FURTHER ORDERED** that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

**SO ORDERED:**

**DATED:**

\_\_\_\_\_  
**United States District Judge**

1 ATTACHMENT A  
2 [On Regenerative Medical Group letterhead]

3 [on envelope]

4 **IMPORTANT NOTICE ABOUT COURT SETTLEMENT**

5 [content of letter, 16-point font]

6  
7 Dear [Recipient]:

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9 The Federal Trade Commission (FTC), the nation's  
10 consumer protection agency, has sued us for deceptive  
11 advertising related to our promises that our stem cell therapy  
12 treats a variety of serious diseases and health conditions. To  
13 settle the lawsuit we have agreed to:

- 14 x stop claiming that stem cell therapy treats or cures any  
15 disease or health condition, including Parkinson's disease,  
16 autism, multiple sclerosis (MS), cerebral palsy, traumatic  
17 brain injury, heart disease, macular degeneration, chronic  
18 kidney disease, osteoarthritis, and stroke; and
- 19 x stop claiming that stem cell therapy is comparable or superior  
20 to conventional medical treatments in curing, mitigating, or  
21 treating these diseases or health conditions.

22 The FTC says these claims are not currently backed by competent  
23 and reliable scientific evidence. Therefore, we can't make these claims  
24 in the future unless they can be supported by scientific proof.

25 You can find out more about the FTC's lawsuit at [URL].

26  
27 Sincerely,  
28 [Regenerative Medical Group signatory]