IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

STATE OF GEORGIA *ex rel.* CHRISTOPHER M. CARR, Attorney General State of Georgia, Plaintiff, v. ELITE INTEGRATED MEDICAL, LLC, f/k/a Superior Healthcare of Woodstock, LLC d/b/a Superior Healthcare Group, Superior Healthcare Sandy Springs, and Superior Healthcare Morrow, and JUSTIN C. PAULK, individually, Defendants.	:	CIVIL ACTION NO. 1:20-cv-4946-AT

OPINION AND ORDER

Plaintiff State of Georgia *ex rel.* Christopher M. Carr, Attorney General of the State of Georgia ("State of Georgia" or "State") brought this action against Defendants Elite Integrated Medical, LLC ("Elite") and Justin C. Paulk for violations of the Georgia Fair Business Practices Act, O.C.G.A. § 10-1-390 *et seq.* ("GFBPA") in the Superior Court of Fulton County in September 2020. The suit alleges that Defendants made false and/ or misleading representations to the public concerning the regenerative medicine products Elite offered. Defendants removed the case to federal court in December 2020. (Doc. 1.) After removing the case, Defendants filed a motion to dismiss for failure to state a claim. (Doc. 8.)

Shortly thereafter, the State of Georgia filed the instant Motion to Remand [Doc. 13] for lack of subject matter jurisdiction. For the reasons that follow, the State of Georgia's motion [Doc. 13] is **GRANTED**.

I. FACTUAL AND PROCEDURAL BACKGROUND

The Regenerative Medicine Industry:

This action arises against the backdrop of the regenerative medicine industry. Generally speaking, regenerative medicine involves replacing, engineering, or regenerating human cells, tissues, or organs to establish, restore or enhance normal cell function. (Complaint, Doc. 1-2 ¶ 9.) This can be accomplished with cell therapies, therapeutic tissue-engineering products, human cell and tissue products, and certain combination products involving cells and devices. (*Id.*) Regenerative medical products and procedures are regulated by the U.S. Food and Drug Administration ("FDA") under the 1938 Food, Drug and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA"). (*Id.* ¶ 10.) At present, the FDA has approved the use of stem cell products only for certain types of stem cells, "blood-forming" stem cells, and for specific disorders, such as ones that affect the production of blood. (*Id.*) Non-approved stem cell products are "investigational" products that are currently involved in FDA review processes which includes investigations into the product's effectiveness and safety, such as through clinical trials. (*Id.* ¶ 11.)

Over the last few years, the FDA, its Commissioner, its Director of the Center for Biologics Evaluation and Research, and industry physicians, scientists, and

regulatory experts have warned about unproven and unapproved regenerative medicine products — including stem cell, exosome, or other similar products — that are "uncontrolled experimental procedures" that cost patients both financially and physically. (*Id.* ¶¶ 11-13.) The FDA has issued "consumer alerts" concerning certain stem cell products, including ones derived from human umbilical cord blood, Wharton's Jelly, or amniotic fluid, notifying consumers that none of these products have been approved to treat any orthopedic condition, neurological disorder, or cardiovascular or pulmonary disease. (*Id.* ¶ 12.) These authorities have also condemned the practice of advertising and offering of unproven stem cell products, stating that the "aggressive marketing approach" by certain companies, which claim that their particular stem cell products are safe and effective, is not supported by the existing scientific literature. (*Id.* ¶ 13.) Similarly, the Federal Trade Commission has warned that marketers should not create confusion by playing "fast and loose" with the facts, as the phrase "stem cell treatment" covers a broad range of therapies, from promising research to fraud. (*Id.* ¶ 14.)

Elite's Business:

During the relevant time period, Defendant Elite operated a medical practice that advertised and offered regenerative medicine products to Georgia consumers to treat, cure, and mitigate various diseases and health conditions. (*Id.* ¶ 4.)

(*Id.* ¶ 34.) Defendant Paulk owned and managed the day-to-day operations of Elite, had the sole authority to approve all marketing content relating to the regenerative medicine products offered by Elite, and regularly communicated with the company that disseminated marketing content on behalf of Elite. (*Id.* ¶ 5.)

The regenerative medicine products Elite advertised and offered were not ones it manufactured or produced; rather, Elite purchase these products from third-party manufactures. (*Id.* ¶ 17.) These third-party products were processed or derived from placental tissue and Wharton's jelly of the umbilical cord. (*Id.* ¶¶ 18-21.) The manufactures have identified these products as human cellular and tissue products ("HCT/P") that are regulated by the FDA. (*Id.* ¶ 23.) None of the products offered by Defendants have been approved by the FDA. (*Id.* ¶ 27.)

According to the Complaint, Defendants made false and misleading representations regarding their products' safety and effectiveness on their website, in video-taped "testimonials," in newspapers, on social media, in brochures, by email, and at seminars. (*Id.* ¶¶ 34,40,41,45,50.) For example, as alleged,

Defendants represented, expressly or by implication, that their products were safe and effective by citing to studies and reports for *other*, *different* stem cell therapies and products. (*Id.* ¶ 30.) These other stem cell products are derived from different sources (such as bone marrow), do not contain the same ingredients, and are not processed or manufactured using the same processes. (*Id.* ¶ 32.)

In addition, the State alleges that Elite made a series of other misrepresentations in promoting its products. The Complaint alleges that Elite advertised as having a staff of medical doctors involved in providing the regenerative therapies — for example, posting a video with a paid actor purporting to be a medical doctor — when in reality Elite only employed medical doctors as independent contractors for the limited purpose of administering injections to consumers. (*Id.* ¶¶ 37-38.) Seminars were conducted by chiropractors wearing white lab coats who introduced themselves as "doctor." (*Id.* ¶ 49.) Defendants also allegedly sent out emails to consumers with success stories from professional athletes to substantiate their products; however, the stem cell therapies/ products used by the athletes were different that the ones provided by Elite. (*Id.* ¶ 46.) As another example cited in the Complaint, Defendants' seminar materials included PowerPoint presentations, indicating that Human Cellular Tissue is not regulated by the FDA, as shown below. (*Id.* ¶ 51.)

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