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,<br><br>Plaintiff,<br><br>v.<br><br>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,<br><br>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.)

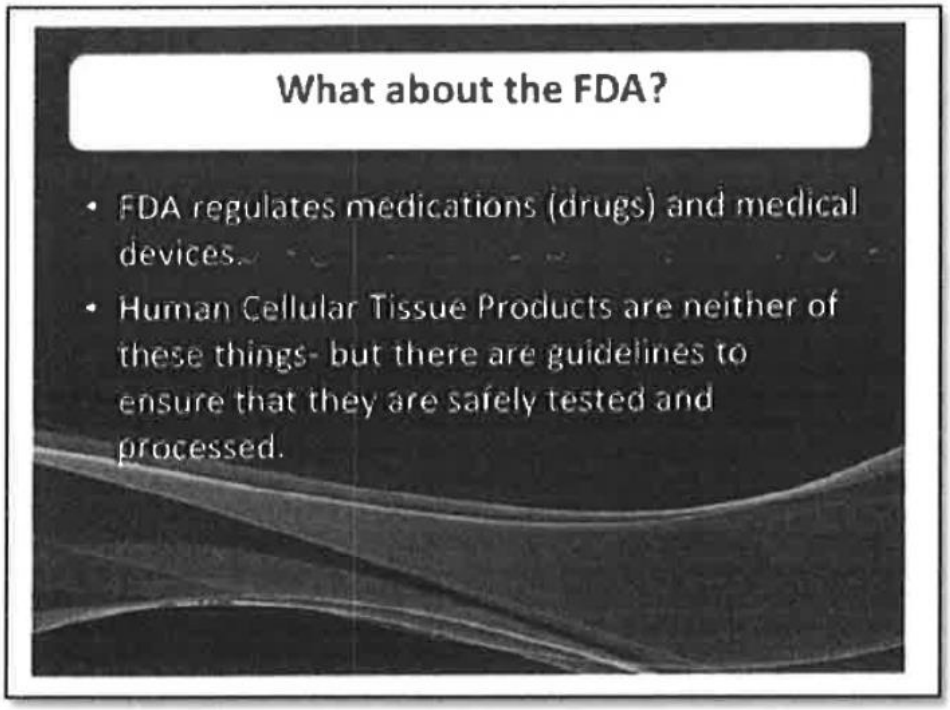

(*Id.* ¶ 34.) Defendant Paulk owned and managed the day-to-day operations of Elite, had the sole authority to approve all marketing content relating to the regenerative medicine products offered by Elite, and regularly communicated with the company that disseminated marketing content on behalf of Elite.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




The advertising material also represented that Elite's products were as safe and effective as alternative treatments, such as surgery. (*Id.* at 12-13, ¶ 50.) In advertising this content, the State alleges that Defendants specifically targeted older and disabled consumers by focusing on diseases and health conditions that limit certain consumers' major life activities, such as orthopedic conditions like osteoarthritis. (*Id.* ¶¶ 57-58.)

Asserted Causes of Action:

Based on the above facts, the Attorney General brings the four following claims under the Georgia Fair Businesses Practice Act ("GFBPA"), in his official capacity pursuant to O.C.G.A. § 10-1-397. In Count I, the State alleges that Defendants made false and misleading representations that their regenerative medicine products treat, cure, or mitigate diseases and health conditions when

these representations are not substantiated by reliable and competent scientific evidence. (*Id*. ¶ 60.) Similarly, in Count II, the State alleges that Defendants made false and misleading representations that their products were comparable or superior to conventional medical treatments without reliable scientific evidence. (*Id*. ¶ 63.) Count III asserts that Defendants misrepresented to consumers that their products are not regulated by the FDA or that the products do not require FDA approval. (*Id*. ¶ 66.) The fourth GFBPA claim asserted is for use of a computer or computer network to disseminate false and misleading representations about the regenerative medicine products. (*Id*. ¶ 69.) According to the State, Defendants' targeting of vulnerable populations subjects them to additional civil penalties under the GFBPA, *see* O.C.G.A. § 10-1-851.

Procedural Background:

Plaintiff State of Georgia filed this lawsuit in Fulton County State Court on September 14, 2020. Defendants did not file an answer in state court but removed this lawsuit to federal court on December 7, 2020. (Doc. 1.) A week later, Defendants filed a motion to dismiss on December 14, for failure to state a claim. (Doc. 8.) Now, the State has filed the present Motion to Remand (Doc. 13), to which Defendants have responded (Doc. 21), and Plaintiff has replied (Doc. 23).

## II. LEGAL STANDARD

A defendant may remove to federal court any civil action "arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. §§ 1331 (detailing original/ federal question jurisdiction); 1441(a) (outlining removal); *see also,*

*Kemp v. IBM*, 109 F.3d 708, 711 (11th Cir. 1997) ("A defendant may remove a case to federal court only if the district court would have had jurisdiction over the case had the case been brought there originally"). "To remove a case as one falling within federal-question jurisdiction, the federal question ordinarily must appear on the face of a properly pleaded complaint." *Jefferson County v. Acker*, 527 U.S. 423, 430-31 (1999); *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987) ("[F]ederal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint. The rule makes the plaintiff the master of the claim; he or she may avoid federal jurisdiction by exclusive reliance on state law.")

A case "aris[es] under" federal law within the meaning of § 1331 if "a well-pleaded complaint" establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 689-90 (2006) (quoting *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 27-28 (1983)); s*ee also Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (noting that "the vast majority of cases brought under the general federal-question jurisdiction of the federal courts are those in which federal law creates the cause of action"). *But see, Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005) (explaining that even if federal law does not create the cause of action, a case may nonetheless arise under federal law where a state law claim turns on

substantial questions of federal law). In assessing whether a case arises under federal law, potential defenses involving the Constitution or laws of the United States are ignored. *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 6 (2003).

Under rare circumstances, the complete preemption doctrine provides an "independent corollary" to the well-pleaded complaint rule for determining whether a federal court has subject matter jurisdiction. *See Caterpillar*, 482 U.S. at 393. Where "the pre-emptive force of a [federal] statute is so 'extraordinary' that it 'converts an ordinary state common-law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule,'" such a claim "arises under" federal law and thus provides the court with subject matter jurisdiction. *Id.* (quoting *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 65 (1987)).[1]

"A removing defendant bears the burden of proving proper federal jurisdiction." *Adventure Outdoors, Inc. v. Bloomberg*, 552 F.3d 1290, 1294-95 (11th Cir. 2008) (quoting *Leonard v. Enterprise Rent a Car*, 279 F.3d 67, 972 (11th Cir. 2002)). "[T]o meet their burden, the defendants must show that the plaintiffs' complaint, as it existed at the time of removal, provides an adequate basis for the exercise of federal jurisdiction." *Id.* at 1295. As federal district courts are courts of limited jurisdiction, in deciding a motion to remand where the plaintiff and defendant disagree as to jurisdiction, any doubts about the propriety of federal

[1] The Supreme Court has only recognized complete preemption of state law claims under three federal laws: (1) the Labor Management Relations Act, s*ee Avco Corp. v. Aero Lodge No. 735, Int'l Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557, 560-62 (1968); (2) the Employee Retirement Income Security Act, *see Metro. Life*, 481 U.S. at 65-66; and (3) the National Bank Act, *see Beneficial*, 539 U.S. at 7-11.

jurisdiction should be resolved in favor of remand to state court. *Burns v. Windsor Ins. Co.*, 31 F.3d 1092, 1095 (1994); *Adventure Outdoors*, 552 F.3d at 1294.

## III. DISCUSSION

Here, the State contends that federal question jurisdiction — the basis for removal — is lacking because the State's complaint does not assert any federal claims and no claims are dependent on an actual, disputed federal question. (Motion to Remand ("Mot.") at 2.)[2] Defendants' responsive argument is twofold. First, Defendants argue that federal question jurisdiction exists because there is a disputed issue of federal law: namely, whether the FDA regulates regenerative medicine products. (Def. Resp. at 12.) Second, Defendants contend that there is federal question jurisdiction because the State's claims are preempted by the FDCA. (*Id.*) The Court addresses these arguments in turn.

### A. Whether the State's claims depend upon resolution of a substantial question of federal law

The State's Complaint asserts four counts, all for violations of the Georgia Fair Businesses Practices Act ("GFBPA"), a state statute intended to "protect consumers and legitimate business enterprises from unfair or deceptive practices in the conduct of any trade or commerce in part or wholly in the state." O.C.G.A. § 10-1-391(a). Without question, there is no federal cause of action at issue here.[3] In arguing that the State's claims nevertheless "arise under" federal law, Defendants

[2] Defendants do not argue that diversity jurisdiction exists here.
[3] As noted above, the Supreme Court reiterated in *Merrell*, 478 U.S. at 808, that "the vast majority of cases brought under the general federal-question jurisdiction of the federal courts are those in which federal law creates the cause of action."

hang their hat on the "longstanding, if less frequently encountered, variety of federal 'arising under' jurisdiction," that recognizes that "in certain cases[,] federal-question jurisdiction will lie over state-law claims that implicate significant federal issues." *Grable*, 545 U.S. at 312. This flavor of federal question jurisdiction applies only to a "special and small category" of cases. *Gunn v. Minton*, 568 U.S. 251, 258 (2013) (citing *Empire Healthchoice*, 547 U.S. at 699).

In articulating a standard by which courts should determine whether a case fits into this "slim category," the Supreme Court's past guidance has been scattered. *See, Gunn*, 568 U.S. at 258 ("In outlining the contours of this slim category, we do not paint on a blank canvas. Unfortunately, the canvas looks like one that Jackson Pollock got to first.") Thus, to "bring some order to this unruly doctrine," the Court in *Grable*, 545 U.S. at 314, condensed prior cases "into the following inquiry: Does the 'state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.'?" *Gunn*, 568 U.S. at 258 (quoting *Grable*, 545 U.S. at 314). The Court in *Gunn* reiterated that "federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258. All of these requirements must be met to support federal jurisdiction. *Id.*

Here, the Parties' dispute surrounds Count III of the Complaint, for "false and misleading representations regarding regulation of regenerative medicine products." (Compl. at 33.) In this claim, the State alleges:

> 66.
>
> Defendants misrepresented to consumers that the regenerative medicine products they offer, including Surforce, CoreCyte, and GeneXStem, are not regulated for use by the FDA and/ or that the products are not required to be approved by the FDA.
>
> 67.
>
> Defendants' acts and practices violate O.C.G.A. § 10-1-393(a), the FBPA's general prohibition against unfair and deceptive acts and practices; O.C.G.A. § 10-1-393(b)(2) that prohibits causing actual confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services; O.C.G.A. § 10-1-393(b)(3) that prohibits causing actual confusion or actual misunderstanding as to affiliation, connection, or association with or certification by another; and O.C.G.A. § 10-1-393(b)(5), which prohibits representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have.

(Compl. ¶¶ 66-67.) This claim thus gives rise to Defendants' argument that the State's lawsuit implicates the federal question of whether the FDA regulates regenerative medicine products. (Def. Resp. at 7) ("Here, if the FDA does not regulate regenerative medicine products, there can be no state law violation based on marketing stating that the products are not regulated by the FDA. If the FDA *does* regulate regenerative medicine products, a set of facts exists in which a state law claim could stand.")

In order to prove Count III, that Defendants made false and misleading representations regarding the regulation or approval of regenerative medicine

products in violation of the GFBPA, the State must establish (1) that a representation was made, (2) that the representation was likely to mislead consumers acting reasonably under the circumstance, and (3) that the representation was material. *See FTC v. Tashman*, 318 F.3d 1273, 1277 (11th Cir. 2003) (construing the FTCA[4]). Under the first requirement here, the State must show that Defendants made the representations asserted in the complaint, *i.e.*, that the advertisements and related marketing materials in fact stated that Elite's products were not regulated by the FDA or did not require FDA approval. In assessing whether the State has made out this element, the evaluating court will look to "the advertisement's overall, net impression rather than the literal truth or falsity of the words in the advertisement." *F.T.C. v. National Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1188-89 (N.D. Ga. 2008) (Pannell, J.), *aff'd* 356 F. App'x. 358 (11th Cir. 2009) (noting that the meaning of the advertisement is a fact

[4] In passing the GFBPA, the General Assembly explained that it intended that the GFBPA "be interpreted and construed consistently with interpretations given by the Federal Trade Commission in the federal courts pursuant to Section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. Section 45(a)(1)), as from time to time amended." *See* O.C.G.A. § 10-1-391(b). *See also*, *Zeeman v. Black*, 273 S.E.2d 910, 913 (Ga. Ct. App. 1980). The GFBPA may be enforced through both governmental and private action, each with its own remedies. *Quattroccki v. State*, 850 S.E.2d 432, 436 (Ga. Ct. App. 2020) (detailing the parallel enforcement scheme which provides for "damages" as a remedy for private litigations but not as a remedy available to the government). However, unlike with a private action, the state enforcement scheme allows the Attorney General to take action "whether or not any person has actually been misled." O.C.G.A. § 10-1-397(b). *See also, Moore-Davis Motors, Inc. v. Joyner*, 556 S.E.2d 137, 139 (Ga. Ct. App. 2001) ("Although the FBPA provides administrative remedies for any violation of the Act, a private right of action is only available to a person 'who suffers injury or damage as a result of a violation.'") Thus, the requirements for the State to show a GFBPA violation are different than in the case of a private litigant bringing suit under the GFBPA. *See e.g., Tiismann v. Linda Martin Homes Corp.*, 637 S.E.2d 14, 17 (Ga. 2006) ("A private FBPA claim has three elements: a violation of the Act, causation, and injury.").

question that "may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey").

Second, the State must demonstrate that the representation was likely to mislead consumers. It can make this showing under a "falsity theory," a "reasonable basis theory," or both. *Id*. at 1190; *see also, F.T.C. v. Pantron,* 33 F.3d 1088, 1096 (9th Cir. 1994); *F.T.C. v. Direct Marketing Concepts, Inc*., 624 F.3d 1, n. 6 (1st Cir. 2010); *Beardsall v. CVS Pharmacy, Inc*., 953 F.3d 969, 977 (7th Cir. 2020); *Federal Trade Commission v. Roca Labs, Inc*., 345 F.Supp.3d 1375, 1386 (M.D. Fla. 2018). While the "falsity theory" requires that the State show that the express or implied message conveyed by the ad is false, the "reasonable basis theory" only requires that the State show that Elite lacked a reasonable basis, or adequate substantiation, for asserting that the message was true. *National Urological Group*, 645 F. Supp. 2d at 1188-89; *Pantron,* 33 F.3d at 1096. Third, the State must show that the representation at issue was material, *i.e*., if it "is the kind usually relied on by a reasonably prudent person." *National Urological Group*, 645 F. Supp. 2d at 1188-89;(citing *FTC v. Windward Marketing*, 1997 WL 33642380, at *9 (N.D. Ga. Sept. 30, 1997)).

As noted above, "federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, **and** (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 568 U.S. at 258 (emphasis added).

*i. Necessarily raised*

Under this framework, the State argues that the resolution of a federal question is not *necessary* for it to prove its case because the purported federal question is only relevant to Count III and, under that claim, the State has pled both a "falsity theory" and a "reasonable basis theory." Thus, the issue of whether the FDA in fact regulates regenerative medicine products does not dictate its right to relief. (Mot. at 19-20). As the State further explains:

> [T]he State may proceed under a reasonable basis theory entirely, in which case additional evidence referenced in the complaint may be considered without any consideration of the provisions of the FDCA. The state court factfinder may contemplate how Defendants could claim that their products are not regulated by the FDA and/or that the products are not drugs when the FDA issued press releases and consumer alters stating otherwise, the manufacturers of the products represented otherwise, and the studies and reports represented by Defendants to be substantiation for efficacy appear to involve products that are regulated by the FDA as drugs. The state court factfinder could find that Defendants did not have a reasonable basis for making the representation in the power point slide and therefore violated Sections 393(a), 393(b)(2), and/or 393(b)(3) of the FBPA, without deciding whether the FDA in fact regulated the products and/or whether the products were in fact drugs under the FDCA. *Because a state court factfinder could find liability without deciding any issue involving the FDCA, the State's cause of action does not depend necessarily on a question of federal law*.

(*Id*.) (emphasis added). Though acknowledging the State's above position — that a resolution of the alleged federal issue is not necessary under the "reasonable basis theory" — Defendants do not substantively engage with this argument or attempt to refute it, other than by repeating that "the question of whether the FDA may

regulate regenerative medicine products is dispositive in this case." (Def. Resp. at 7, 10.)

In *Merrell Dow*, *supra,* the Supreme Court — also addressing a situation where the plaintiff's state law claim arose in connection with the FDCA — affirmed and cited the decision of the Sixth Circuit, which had reasoned that:

> Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief *depended necessarily* on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' cause of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court.

478 U.S. at 807 (quoting *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 766 F.2d 1005, 1006 (6th Cir. 1985)). *See also, Christianson,* 486 U.S. at 810 (addressing § 1338(a) jurisdiction for patent cases[5], explaining that "a claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories") (citing *Franchise Tax Board*, 463 U.S. at 26); *Manning v. Merrill Lynch Pierce Fenner & Smith, Inc.*, 772 F.3d 158, 164 (3d Cir. 2014) (concluding that federal jurisdiction was lacking and remanding to state court, noting that "even if Plaintiffs' claims were partially predicated on federal law, federal law would still not be necessarily

[5] Although *Christianson* concerned 28 U.S.C. § 1338, dealing with actions "arising under" the patent laws, rather than § 1331, the Supreme Court has referenced the "identical language" in the two provisions and has applied the "same test" to both. 486 U.S. at 808; *see also, Gunn,* 568 U.S. at 257.

raised" where plaintiff could prevail upon state-law claims without need to prove or establish a violation of federal law); *New Mexico ex rel. Balderas v. Purdue Pharma L.P.*, 323 F. Supp. 3d 1242, 1252 (D.N.M. 2018) (finding no federal jurisdiction, and thus remanding, in suit brought by state Attorney General where defendants' liability, if any, did not hinge exclusively on federal law, since state law provided alternate theories of recovery) (citing *Christianson,* 486 U.S. at 810)[6]. As in these cases, the State's right to relief does not "depend necessarily" on a question of federal law since a jury could find liability on the part of Defendants "without finding a violation of the FDCA." *Merrell Dow,* 478 U.S. at 807. That the State will use the FDA regulations "as evidence" in support of Defendants' allegedly false or misleading statements is "not the same thing as raising a substantial" question of federal law. *Russo*, 550 F.3d at 1009, *supra* at n. 6.

Defendants' argument that the FDA does not regulate their regenerative medicine products as a *defense* to Count III does not confer federal jurisdiction since the Court's role is to examine *only* the well-pleaded complaint and "ignore potential defenses." *Beneficial Nat'l Bank*, 539 U.S. at 6 (citing *Louisville & Nashville R. v. Mottley*, 211 U.S. 149, 152 (1908)). Consequently, applying the analysis articulated in *Gunn* to the present situation, federal jurisdiction cannot lie

[6] *See also Russo v. Ballard Medical Products*, 550 F.3d 1004, 1009 (10th Cir. 2008) (Gorsuch, J.) (assessing jurisdiction under § 1338(a) in patent case, finding no jurisdiction where state claims did not necessarily depend on resolution of substantial question of federal patent law where patents were mentioned in the complaint *as evidence* showing *how* defendant misappropriated designs but fact that patents could be used as evidence in aid of claim is "not the same thing as raising a substantial (or really, any) question of federal patent law").

because the federal issue in question is not "necessarily raised" by the State's Complaint. *Gunn*, 568 U.S. at 258.

*ii. Substantiality*

In addition, the Court finds that any federal issues raised in the State's complaint are not "substantial" federal questions. The "substantiality inquiry" looks to "the importance of the issue to the federal system as a whole." *Gunn*, 568 U.S. at 260. In assessing the "importance to the federal system," courts primarily "focus not on the interests of the litigants themselves, but rather on the broader significance" of the alleged federal question. *Id.* at 260-61. ("As our past cases show, however, it is not enough that the federal issue be significant to the particular parties in the immediate suit; that will *always* be true when the state claim 'necessarily raise[s]' a disputed federal issue, as *Grable* separately requires.") For example, in *Grable*, the Court "emphasized the Government's 'strong interest' in being able to recover delinquent taxes through seizure and sale or property;" in *Smith v. Kansas City Title & Trust Co.*, the Court focused on the general importance "of a determination that the Government 'securities were issued under an unconstitutional law, and hence of no validity.'"[7] *Gunn*, 568 U.S. at 260-61

[7] Defendants' reliance on *Kansas City Title & Trust*, 255 U.S. 180 (1921), is inapposite. In that case, from 1921, the plaintiff brought suit to enjoin a company from issuing bonds under the Federal Farm Loan Act by claiming the statute itself was unconstitutional, and thus the crux of plaintiff's case depended on showing a federal constitutional violation. This case does not involve a comparable issue of whether the FDCA is unconstitutional and the State's case, which arises entirely under Georgia law, does not depend on its ability to show a violation of federal law.

(citing *Grable*, 545 U.S. at 310-11; *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921)).

In this case, Defendants contend that the "determination of the FDA's regulation of regenerative medicine products would have a significant impact on the manufacturers of those products and their compliance programs." (Def. Resp. at 10.) Again, Defendants do not expound on their conclusory statement.

The State's claims are for unfair and deceptive practices: specifically, for allegedly false and misleading misrepresentations in advertising their stem cell products in violation of the GFBPA. This case does not involve an alleged violation of the FDCA, such as allegations that Defendants misbranded a product in violation of FDA regulations or made fraudulent representations in the FDA approval process. To the extent that the Complaint touches on the FDA's regulations under the FDCA, "any interpretation will be done in the context of state law when analyzing Defendant[s]" alleged misrepresentations to the public. *Kentucky ex rel. Conway v. Janssen Pharm., Inc.*, 978 F. Supp. 2d 788, 794–95 (W.D. Ky. 2013) (remanding case brought by Kentucky Attorney General against drug company for unfair, deceptive, and misleading labeling of prescription antipsychotic drug). Moreover, here, the issue of Defendants' alleged misrepresentations concerning FDA approval are "only part of the [State's] larger state-law claim" and any potential federal question in this case "will be resolved in the context of whether Defendants'" conduct constitutes a violation of *Georgia* law. *Id.* at 795; *see also*, *In re Vioxx Prods. Liab. Litig.*, 843 F.Supp.2d 654, 669 (E.D.

La. 2012) (remanding and finding that action did not raise federal question where complaint brought by Attorney General alleged facts regarding Merck's conduct vis-à-vis the FDA, but those facts were only some allegations among many); *Durack v. MTC Fin., Inc.,* 2012 WL 2047731, at *2 (D. Nev. June 5, 2012) (noting that while plaintiff asserted that defendants were in violation of the FDCA, that was "not the principal claim[ ] on the face of Plaintiff's pleading; the stated federal claim[ ][is] not substantial and [is] not clearly raised for dispute in this action. Plaintiff's complaint is limited to ... Nevada's Deceptive Trade Practices Act. While Plaintiff may have alleged that Defendants violated federal law, the alleged violation is not pivotal.")

Contrary to Defendants' conclusory position, any ruling involving the FDCA and FDA regulations here would be "fact-bound and situation specific" to Defendants' own products and the particular representations they made about those products. *See Janssen Pharm.*, 978 F. Supp. 2d at 796-7 (explaining that the FDA will continue to enforce its labeling standards and its ability to do so would not be affected by the court's ruling in that consumer protection case); *see also Oregon ex rel. Kroger v. Johnson & Johnson,* 832 F.Supp.2d 1250, 1257 (D. Or. 2011) (remanding case where Oregon Attorney General brought action for violations of the Oregon Unlawful Trade Practices Act, noting that "the Supreme Court has recognized that state courts have traditionally handled state claims with embedded FDCA standards.... [E]ven a *novel* FDCA issue raised as part of a state cause of action would not typically justify the exercise of federal jurisdiction.")

This issue is therefore not a substantial federal issue and is insufficient to establish federal "arising under" jurisdiction. *Gunn*, 568 U.S. at 263 (citing *Empire Healthchoice*, 547 U.S. at 701); *see also, Bender v. Jordan*, 623 F.3d 1128, 1130 (D.C. Cir. 2010) ("[F]ederal jurisdiction is disfavored for cases that are 'fact-bound and situation specific' or which involve substantial questions of state as well as federal law."); *see also*, *Merrell Dow*, 478 U.S. at n. 12.

*iii. The federal-state balance approved by Congress*

The final requirement in the jurisdictional analysis set out in *Grable* and rearticulated in *Gunn* — whether the federal issue is "capable of resolution in federal court without disrupting the federal-state balance approved by Congress" — is also not met here. In *Merrell Dow*, the Supreme Court recognized that there is no federal private cause of action for a violation of the FDCA.[8] As there was no cause of action for such a violation, the *Merrell Dow* Court held that it would "flout, or at least undermine, congressional intent to conclude that the federal courts might … exercise federal-question jurisdiction … for violations of [the FDCA] solely because the violation of the federal statute is said to be a 'rebuttable presumption' or a 'proximate cause' under state law, rather than a federal action under federal law." 478 U.S. at 812. The *Grable* Court later clarified that "*Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the 'sensitive judgments about

[8] As articulated in the FDCA, all proceedings for the enforcement or to restrain violations of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

congressional intent' that § 1331 requires." *Grable*, 545 U.S. at 318. (further explaining that, in the case of *Merrell Dow*, "if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases.")

The State points to several cases in which courts have determined, in light of *Merrell Dow,* that it would upset the balance of judicial responsibilities to allow state law claims that touch on the FDCA to proceed in federal court. *See e.g., Janssen Pharm.*, 978 F.Supp.2d at 798 (finding that exercising federal jurisdiction would upset balance of judicial responsibilities in context of claim brought by Kentucky Attorney General against pharmaceutical company); *Marcus v. Medical Initiatives, Inc.*, 2013 WL 718630, at *5-6 (M.D. Fla. Feb. 27, 2013) (granting motion to remand and explaining that federal jurisdiction would disrupt balance struck by Congress in case where plaintiff alleged that defendants violated Florida's Deceptive and Unfair Trade Practices Act by participating in the manufacture, sale, and distribution of counterfeit pharmaceuticals and representing them to be original, name-brand drugs); *Johnson & Johnson*, *supra*, 832 F.Supp.2d at 1257-58 (remanding and holding that recognizing federal jurisdiction over State of Oregon's claims for violations of the Oregon Unlawful Trade Practices Act would disrupt balance between state and federal judicial responsibilities) (citing *Wyeth v. Levine*, 555 U.S. 555, 574 (2009)) ("Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs

in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers.") (citing legislative history). The Court finds similarly here.

The Supreme Court instructed that federal jurisdiction over a state law claim will lie only if a federal issue meets all four of the following requirements, that it is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress. *Gunn*, 568 U.S. at 258. For the reasons explained above, Defendants cited federal issue is not necessarily raised, substantial, or capable of resolution without disrupting the federal-state balance approved by Congress. The State's claims thus do not depend upon a substantial question of federal law.

### B. Whether the State's claims are preempted by the FDCA and the PHSA

Defendants next assert that removal was proper because the State's claims are preempted by the FDCA and the PHSA under a theory of "field preemption" and "therefore, federal question jurisdiction exists under 28 U.S.C. § 1331." (Def. Resp. at 12-13.) The State argues that Defendants erroneously misrepresent the State's claims as ones for relief under the FDCA when they are not, and also contends that Defendants have not shown that the FDCA completely preempts state-law claims, as required to establish federal question jurisdiction. (Reply at 14.)

In general, when a state-law claim is brought in state court, preemption is insufficient to support removal of the case to federal court. *See e.g., Behlen v.*

*Merrill Lynch*, 311 F.3d 1087, 1090 (11th Cir. 2002) ("[A] case may not be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue") (quoting *Caterpillar*, 482 U.S. at 393). The doctrine of "complete preemption" is an exception to the well-pleaded complaint rule that allows for the removal of certain types of cases where the "pre-emptive force of federal law is so extraordinary that it converts an ordinary state common-law complaint into one stating a federal claim." *Caterpillar*, 482 U.S. at 393 (citation and punctuation omitted); *see also, Kemp*, 109 F.3d at 712; *Ervast v. Flexible Products Co.*, 346 F.3d 1007, 1012 (11th Cir. 2003).

Courts rarely find complete preemption. The Supreme Court has applied the complete preemption doctrine to only three federal statutes: (1) § 301 of the Labor Management Relations Act, s*ee Avco Corp. v. Aero Lodge No. 735, Int'l Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557, 560-62 (1968); (2) the Employee Retirement Income Security Act ("ERISA"), *see Metro. Life*, 481 U.S. at 65-66; and (3) the National Bank Act, *see Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7-11 (2003). *See Atwater v. Nat'l Football League Players Ass'n*, 626 F.3d 1170, 1176 n. 7 (11th Cir. 2010). The Supreme Court "has cautioned that complete preemption can be found only in statutes with 'extraordinary' preemptive force[,], which "must be manifest in the clearly expressed intent of Congress." *Geddes v. Am. Airlines, Inc.*, 321 F.3d 1349, 1353 (11th Cir. 2003) (citing *Metro. Life*, 481 U.S.

at 65-66); *Metro. Life*, 481 U.S. at67-68 ("[T]he prudent course for a federal court that does not find a clear congressional intent to create removal jurisdiction will be to remand the case to state court.") (Brennan, J., concurring).

"Complete preemption is distinct from 'ordinary' or 'defensive' preemption." *Community State Bank v. Strong*, 651 F.3d 1241, 1260 n. 16 (11th Cir. 2011). "Ordinary preemption simply allows a defendant to defeat a plaintiff's state-law claim on the merits by asserting the supremacy of federal law as an affirmative defense." *Id.* (citing *Blab T.V. of Mobile, Inc. v Comcast Cable Commc'ns, Inc.*, 182 F.3d 851, 855 (11th Cir. 1999)). In "contrast to complete preemption, 'defensive preemption does not furnish federal subject-matter jurisdiction under 28 U.S.C. § 1331.'" *Id.* (citing *Butero v. Royal Maccabees Life Ins. Co.*, 174 F.3d 1207, 1212 (11th Cir. 1999)).

Here, Defendants' arguments concern defensive preemption and thus cannot furnish federal subject matter jurisdiction. *Id.* Defendants' cited authority bears this out. In *Bellsouth Telecommunications, Inc. v. Nuvox Commc'ns, Inc.*, 2006 WL 2617123, at *12 (N.D. Ga. Sept. 12, 2006), the court explained that complete preemption "inheres where a particular area is so thoroughly covered by federal law that there is nothing left for the state to regulate without running afoul of the federal scheme," before finding that the federal telecommunications act in question did *not* completely preempt state law since it expressly created room for state regulation in the telecommunications field. Likewise here, the Supreme Court

has explained that Congress created room for state-law remedies to further consumer protection under the FDCA:

> Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 [FDCA] statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.

*Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (citing legislative history, explaining that in the first version of the bill that later became the FDCA, witnesses testified that a private right of action for consumers was unnecessary because common-law claims were available under state law); *Johnson & Johnson, supra*, 832 F. Supp. 2d at 1258-59 (remanding, finding that the state law consumer protection claims were not completely preempted by the FDCA, and noting that the "fact that there is no private right of action under the FDCA does not, however, displace all other causes of action that incorporate FDCA standards.")

Defendants also cite to *Cotton v. Massachusetts Mut. Life Ins. Co.*, 402 F.3d 1267, 1281 (11th Cir. 2005). Yet, not only does this case involve a different statute, ERISA, which has its own separate test for complete preemption under that statute, *see id.* at 1281, but in *Cotton*, the Eleventh Circuit held that the plaintiff's claims were *not* completely preempted and indeed emphasized that defensive preemption will not provide a basis for removal to federal court. *Id.* at 1281-82. *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707 (1985), a case that did not address preemption in the context of supplying subject matter jurisdiction,

also does not help Defendants: there, the Court determined that FDA regulations related to blood plasma did *not* preempt local ordinances by way of either field preemption or conflict preemption. *Id*. at 720, 723.[9]

Defendants' attempt to recast the State's claims as "fraud-on-the-FDA" claims in efforts to establish preemption is likewise unavailing. A "fraud-on-the-FDA" claim is one in which the manufacturer of a device or product makes fraudulent representations to the FDA. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347 (2001) (finding that plaintiffs' claims conflicted with, and thus were preempted by, the FDCA) ("The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration."). Defendants' reliance on *Buckman,* however, is misplaced both factually and legally. In *Buckman*, the plaintiffs alleged that the regulatory consultant to the manufacturer of orthopedic bone screws made fraudulent representations to the FDA to obtain approval to market the screws, which ultimately caused the plaintiffs' injuries. *Id*. at 343, 346-47.

Here, the State makes no comparable allegations. The State does not allege that Defendants engaged in fraud in the FDA approval process or made false statements or misrepresentations to the FDA, as in *Buckman*.[10] Rather, the State

[9] Defendants also cite *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597 (1991). That case involved a different statute, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which the Court found did not preempt a local ordinance through complete ("field") preemption or by way of conflict preemption. *Id*. at 611-614.

[10] The *Buckman* Court noted that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally held.'" That is clearly not the goal in this case where the State is attempting to "police" alleged misrepresentations made to the general public.

alleges claims arising under the GFBPA for misrepresentations to the *public*, not to the FDA. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (explaining that the *Buckman* Court instructed that "traditional state tort law causes of action that … did not implicate a duty owed to the FDA, are generally not impliedly preempted" and finding that plaintiff's manufacturing defect theory was not preempted because it involved a duty defendant owed to the plaintiff as opposed to the FDA); *See also Johnson & Johnson, supra*, 832 F. Supp. 2d at 1258-59 (explaining that "Defendants' attempt to recast Plaintiff's claims" to be ones that merely recite an FDCA violation was unavailing as Attorney General's claims were that defendants "knowingly misled distributors and consumers into believing that their products met FDA standards and that this misrepresentation harmed Oregon consumers.")

Besides the clear factual differences, *Buckman* also did not assess the issue of whether preemption was sufficient to furnish federal jurisdiction but instead considered preemption as a defense. *Buckman*, 531 U.S. at 348, n. 2 ("Given this analytical framework, we hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. In light of this conclusion, we express no view on whether these claims are subject to express pre-emption.") As noted, complete preemption sufficient to bestow federal jurisdiction is rare. Defendants have not met their burden to show that the instant case presents such an exceptional situation.

## IV. Conclusion

Defendants' arguments in justification of removal based on federal question jurisdiction are unavailing. The State's claims do not depend on the resolution of a substantial issue of federal law, nor are they completely preempted by the FDCA sufficient to create federal jurisdiction. Accordingly, this case is not appropriately removed and filed in this Court. The State's Motion to Remand [Doc 13] is **GRANTED**. This case is **REMANDED** to the Superior Court of Fulton County. Defendants' pending Motion to Dismiss [Doc. 8] is **DENIED AS MOOT**. The Clerk is **DIRECTED** to close the case.

**IT IS SO ORDERED** this 12th day of April 2021.

**Honorable Amy Totenberg**
**United States District Judge**