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

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| CHRISTA BLEVINS-ELLINGTON, et al., | : | |
| Plaintiffs, | : | |
| v. | : | CIVIL ACTION NO. 1:22-cv-00197-LMM |
| COOPERSURGICAL, INC., et al., | : | |
| Defendants. | : | |

**ORDER**

This case comes before the Court on Defendants' motions for summary judgment, Dkt. Nos. [163, 164, 165]; Defendants' motions to exclude the opinions of several of Plaintiffs' expert witnesses, Dkt. Nos. [166, 167, 168, 169]; and Plaintiffs' motion for partial summary judgment of Defendants' affirmative defenses, Dkt. No. [171]. After due consideration, the Court enters the following Order.

## I. LEGAL STANDARD

Rule 56 of the Federal Rules of Civil Procedure provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute is genuine if the evidence would

allow a reasonable jury to find for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is "material" if it is "a legal element of the claim under the applicable substantive law which might affect the outcome of the case." Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997).

The moving party bears the initial burden of showing the Court, by reference to materials in the record, that there is no genuine dispute as to any material fact that should be decided at trial. Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260 (11th Cir. 2004) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)). The moving party's burden is discharged merely by " 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support [an essential element of] the nonmoving party's case." Celotex Corp., 477 U.S. at 325. In determining whether the moving party has met this burden, the district court must view the evidence and all factual inferences in the light most favorable to the party opposing the motion. Johnson v. Clifton, 74 F.3d 1087, 1090 (11th Cir. 1996).

Once the moving party has adequately supported its motion, the non-movant then has the burden of showing that summary judgment is improper by coming forward with specific facts showing a genuine dispute. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.' " Id. All reasonable doubts, however,

are resolved in the favor of the non-movant. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993).

The same standard of review applies to cross-motions for summary judgment, but the Court must determine whether either of the parties deserves judgment as a matter of law on the undisputed facts. S. Pilot Ins. Co. v. CECS, Inc., 52 F. Supp. 3d 1240, 1242-43 (N.D. Ga. 2014); see also Gerling Glob. Reinsurance Corp. of Am. v. Gallagher, 267 F.3d 1228, 1233-34 (11th Cir. 2001). Each motion must be considered "on its own merits, [with] all reasonable inferences [resolved] against the party whose motion is under consideration." CECS, Inc., 52 F. Supp. 3d at 1243; accord Gerling Glob. Reinsurance Corp. of Am., 267 F.3d at 1233-34.

## II. BACKGROUND

Between 2011 and 2013, Plaintiffs Christa Blevins-Ellington, Kimyania Smith, and Amanda Jo Venenga each underwent tubal-ligation procedures using "Filshie Clips." Dkt. No. [180-2] ¶¶ 6-7. The Filshie Clip is a birth-control device that consists of small titanium clips lined by silicone rubber. Id. ¶ 1. They are designed to be used in tubal-ligation procedures to block the fallopian tubes and serve as a long-term form of birth control. Id. At the time, Defendant Femcare, Ltd., manufactured Filshie Clips; Defendant Utah Medical Products, Inc., was Femcare's parent company; and Defendant CooperSurgical, Inc., distributed Filshie Clips. Dkt. No. [188-1] ¶¶ 1-3.

In 1996, Femcare had received conditional premarket approval from the Food and Drug Administration ("FDA") for Filshie Clips as a Class III device, the most dangerous and most rigorously tested class of medical devices. Dkt. No. [180-2] ¶ 2. As part of the application process, Femcare had reported that Filshie Clips had a 0.13% migration rate. Dkt. No. [186-1] ¶ 3; Dkt. No. [180-6] at 3. The FDA-approved warnings for Filshie Clips disclosed potential adverse side effects of pain, "adverse" clip migration at 0.13%, and asymptomatic migration at an unknown frequency. Dkt. No. [180-2] ¶ 2.

Following their procedures, Ms. Blevins-Ellington, Ms. Smith, and Ms. Venenga experienced severe pain and other adverse symptoms. Dkt. No. [186-1] ¶¶ 14-16. They, and Ms. Venenga's husband, David Raymond Venenga, subsequently filed this action against Femcare, Utah Medical Products, and CooperSurgical. Dkt. No. [17]. They assert claims for design defect (Count One); manufacturing defect (Count Two); failure to warn (Count Three); strict liability (Count Four); negligence (Count Five); deceptive trade practices in violation of consumer-protection laws (Count Six); gross negligence (Count Seven); punitive damages (Count Eight); and attorneys' fees (Count Nine). Dkt. No. [17] ¶¶ 97-194. Although Mr. Venenga's claim is not set out in a separate count, it appears that he asserts a claim for loss of consortium.[1] See id. ¶ 84.

[1] The complaint also suggests a claim for negligent infliction of emotional distress based on Mr. Venenga's mental pain and suffering from observing his wife's suffering. Dkt. No. [17] ¶ 84. However, Georgia generally follows the "impact rule" and therefore does not permit such recovery. See

Defendants now move for summary judgment, Dkt. Nos. [163, 164, 165], and seek to exclude the opinions of several of Plaintiffs' expert witnesses, Dkt. Nos. [166, 167, 168, 169]. Plaintiffs, in turn, move for partial summary judgment of Defendants' affirmative defenses. Dkt. No. [171].

## III. DISCUSSION

Defendants move for summary judgment on all of Plaintiffs' claims. They argue, among other things, that federal law preempts all of the claims. They also challenge Plaintiffs' ability to establish causation on some of them. Dkt. No. [163] at 10-26; Dkt. No. [164] at 14-15; Dkt. No. [165] at 10.

Plaintiffs counter the motion for summary judgment with evidence suggesting that by the time they were implanted with Filshie Clips, Defendants knew that the risk of migration is significantly higher than reported to the FDA—up to an estimated 25% migration rate—and that Defendants received complaints of adverse events from patients and reports of safety concerns from medical experts that they either downplayed to the FDA or failed to report at all. Dkt. No. [180-2] ¶¶ 2-3, 5; Dkt. No. [186-1] ¶¶ 1-10. On this basis, they assert three theories of liability: (1) that Defendants should have issued more extensive warnings about the dangers of Filshie Clips; (2) that Defendants overstated the safety of Filshie Clips in marketing materials; and (3) that Defendants defectively

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Benson v. Krystal Koach, Inc., Civ. Action No. 1:08-CV-2841-CAP, 2010 WL 11597751, at *6 (N.D. Ga. Nov. 17, 2010) (citing McCunney v. Clary, 576 S.E.2d 635, 636-37 (Ga. Ct. App. 2003)).

designed or manufactured Filshie Clips. See generally Dkt. No. [17]. Plaintiffs also argue that the Court already resolved the preemption issues in their favor and therefore should grant them summary judgment of the preemption defenses. Dkt. No. [171] at 7-8.

Below, the Court first discusses relevant background on preemption in the medical-device context and then analyzes the parties' arguments.

**A. Background on Preemption**

Because Defendants argue that Plaintiffs' claims are preempted under federal law, the Court begins by reviewing the federal regulatory scheme governing Filshie Clips. The Court organizes its discussion into background on: (1) the Medical Device Amendments of 1976 ("MDA"); (2) express preemption under the MDA; (3) implied preemption under the MDA; and (4) the combined effect of express and implied preemption.

***1. The Medical Device Amendments of 1976***

Congress passed the MDA, an amendment to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c, et seq., to create a uniform regulatory scheme for medical devices. The MDA fashioned three distinct classes of devices based on their potential risks. Riegel v. Medtronic, Inc., 552 U.S. 312, 316-17 (2008). Class III applies to the most dangerous devices, characterized as such because the controls used for Classes I and II are not sufficient to ensure these devices' safety. 21 U.S.C. § 360c(a)(1)(C).

Filshie Clips are a Class III medical device. Dkt. No. [180-2] ¶ 2. To gain Class III status, Filshie Clips had to pass the FDA's "rigorous" premarket-approval testing. See Riegel, 552 U.S. at 317-18; 21 U.S.C. § 360e. To receive premarket approval, applicants must submit detailed reports of studies and investigations of the device's safety and efficacy; full descriptions of the device's components, methods, packaging, and more; and proposed labeling, among other things. Riegel, 552 U.S. at 318 (citing 21 U.S.C. § 360e(c)(1)). Based on these materials, the FDA must determine whether there is "reasonable assurance" of the device's safety and effectiveness. 21 U.S.C. § 360e(d). To do so, the FDA may consult outside experts, request additional data, and conduct other reviews in weighing the health benefits against the risks of injury and illness presented by the device. Riegel, 552 U.S. at 318; 21 U.S.C. § 360c(a)(2)(C).

If, based on this evidence, the FDA decides to grant premarket approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Riegel, 552 U.S. at 319. Devices with premarket approval are also subject to ongoing reporting requirements: manufacturers must "inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of," and they must "report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or

serious injury if it recurred." Id. The FDA has authority to withdraw premarket approval based on new or existing information, and it "must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Id. at 319-20. Thus, manufacturers who are granted premarket approval for their devices must comply with specific regulations promulgated by the FDA, as necessary to sustain approval.

***2. Express Preemption***

The MDA was enacted in part to standardize the varied requirements states impose on manufacturers. Id. at 315-16. To ensure nationwide standardization, Congress included an *express* preemption provision in the MDA:

> Except as provided in subsection (b) [of this section], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has held that the MDA protects manufacturers from liability when they comply with federal law, but the Amendments do not foreclose state claims based on breaches of common-law duties that parallel existing federal requirements. Medtronic, Inc. v. Lohr, 518 U.S. 470, 487-88 (1996) (plurality opinion); Riegel, 552 U.S. at 330; see also Jacob v. Mentor Worldwide,

LLC, 40 F.4th 1329, 1335-36 (11th Cir. 2022). Further, the Supreme Court has set forth a two-part preemption test, which requires courts to consider: (1) whether federal government requirements apply to the device at issue and (2) whether Plaintiffs' state-law claims relate to the device's safety and effectiveness and rest on requirements that are "different from, or in addition to," the federal requirements. Riegel, 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)(1)).

Here, Plaintiffs' claims relate to the clips' safety and effectiveness. See generally Dkt. No. [17]. And "any device that goes through premarket approval will necessarily have federally established requirements."[2] Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1326 (11th Cir. 2017). Thus, the only remaining question with respect to express preemption is whether Plaintiffs' claims rest on requirements that are different from or in addition to the federal requirements.

### *3. Implied Preemption*

The MDA also provides for the *implied* preemption of state-law claims implicating core FDA functions within the MDA framework. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 347-48 (2001). One example, relevant here, is that state-law claims based on a manufacturer's failure to meet its ongoing

[2] Filshie Clips' premarket approval distinguishes this case from Lohr, where the court found no express preemption of the state-law tort claims. FDA approval of the device in Lohr was based on substantial equivalency to a grandfathered device already on the market, rather than on the rigorous premarket approval process Filshie Clips underwent. Lohr, 518 U.S. at 480. Thus, the device in Lohr, unlike Filshie Clips, was subject only to generic federal MDA standards and not to specific requirements particular to the device, as necessary to trigger § 360k(a). Id. at 501.

reporting requirements—"state-law fraud-on-the-FDA claims"—conflict with federal law and are impliedly preempted, because allowing such claims would hamper the FDA's ability to punish and deter fraud perpetuated against it. Id. at 347-53. In other words, "a plaintiff cannot seek to privately enforce a duty that is owed to the FDA." Jacob, 40 F.4th at 1336. "So, even if a plaintiff's claim is not expressly preempted, it is impliedly preempted if it is cognizable only because of duties owed to the FDA." Id.

***4. Express and Implied Preemption Applied***

Applying express preemption and implied preemption together, the Eleventh Circuit has explained that "[t]o avoid having his claims preempted, a plaintiff must carefully plead a claim that implicates the safety or effectiveness of a federally-regulated medical device." Mink, 860 F.3d at 1327. Where a state-law claim imposes on the medical device "a requirement different from or additional to federal requirements," the claim will be barred by express preemption, and "implied preemption prohibits state-law claims that seek to privately enforce duties owed to the FDA." Id.

This leaves a "narrow gap" for Plaintiffs to avoid preemption: "a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption) but cannot sue *only* because the conduct violated that federal requirement (avoiding implied preemption)." Id. (cleaned up; emphasis added). In other words, "a plaintiff may proceed on her claim so long as she claims the breach of a well-recognized duty owed to her under state law and so long as she

can show that she was harmed by a violation of applicable federal law." Id. (internal quotation marks omitted).

**B. Analysis**

As described above, three theories of recovery underpin Plaintiffs' claims: (1) that Defendants are liable for their failure to warn about the dangers of Filshie Clips; (2) that Defendants are liable for overstating the safety of Filshie Clips in marketing materials; and (3) that Defendants are liable for defects in the design and manufacturing of Filshie Clips. The Court first addresses Plaintiffs' motion for summary judgment of Defendants' preemption defenses and then considers each theory separately.

***1. Plaintiffs' Motion for Summary Judgment of Preemption Defenses***

Plaintiffs have moved for summary judgment of Defendants' preemption defenses. Dkt. No. [171] at 7-8. In support of the motion, Plaintiffs point out that the Court determined—at the pleadings stage of this litigation—that preemption did not apply. Id. They assert that "[d]iscovery did not yield any new information which would show that Plaintiffs' claims are preempted by federal law" and that the Court should therefore grant Plaintiffs summary judgment of the defenses. Id. at 8.

The issue is not so simple. Unlike at the motion-to-dismiss stage, Plaintiffs' claims "are now subject to an evidentiary standard, not self-described careful drafting." Mack v. CooperSurgical, Inc., No. 1:22-cv-54-RAH, 2024 WL 4427846,

at *8 (M.D. Ala. Oct. 4, 2024). While the Court determined that Plaintiffs' claims survived preemption on their well-pleaded allegations, see Dkt. No. [66] at 37-38; Dkt. No. [104] at 5-6, on summary judgment, those allegations must be reevaluated with the benefit of evidence obtained during discovery. In other words, Plaintiffs are no longer entitled to the leniency courts typically afford plaintiffs at the pleadings stage with respect to preemption. See Mack, id.; cf. Anderson, 477 U.S. at 256 ("[A] party opposing a properly supported motion for summary judgment may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial."). The Court therefore cannot summarily grant Plaintiffs' motion and instead must proceed with a theory-by-theory analysis on the evidence now before it.

***2. Failure to Warn***

The Court begins with Plaintiffs' failure-to-warn theory. Defendants contend that the theory is both expressly and impliedly preempted. Dkt. No. [163] at 16-26. In response, Plaintiffs acknowledge that Defendants did not deviate from the warnings approved by the FDA but argue that Defendants are liable because they failed to report adverse events to the FDA, and the FDA therefore was not aware that a more accurate warning was necessary. Dkt. No. [180] at 19-20. Defendants reply that, to the extent Plaintiffs' claims rely on a duty owed to the FDA rather than Plaintiffs, those claims are impliedly preempted. Dkt. No. [186] at 5-7.

Defendants have the better argument. As described above, express preemption bars state-law claims that impose a requirement different from or additional to federal requirements. Mink, 860 F.3d at 1325-26. Here, Plaintiffs have not pointed to any evidence that Defendants used different warnings or instructions than those previously approved by the FDA. To the contrary, Plaintiffs have acknowledged that Defendants did not deviate from the approved language. See Dkt. No. [180] at 19-20; Dkt. No. [180-2] ¶ 11. Without evidence of such a deviation, Plaintiffs' failure-to-warn claims would impose different requirements on Defendants than those established by federal law. Thus, Plaintiffs' claims are expressly preempted to the extent they rely on the theory that Defendants should have provided a different or more extensive warning for Filshie Clips than the warning approved by the FDA.

In arguing against preemption, Plaintiffs contend that—by refusing to disclose to the FDA adverse events and other information indicating that the reported 0.13% migration rate was significantly underestimated—Defendants have "robbed" the FDA of an opportunity to update the warnings for Filshie Clips. Dkt. No. [180] at 7-24. If Defendants had done so, Plaintiffs posit, the FDA would have updated the warnings for Filshie Clips.[3] Id. Defendants respond that, because this theory relies on an alleged failure to report adverse events to the

[3] Plaintiffs hinge most of their briefing on this issue, arguing that Defendants violated federal law by failing to disclose scientific articles to the FDA, submit annual reports to the FDA, and report other adverse events to the FDA. See Dkt. No. [180] at 10-24.

FDA—a duty owed to the FDA rather than to Plaintiffs—Plaintiffs' claims are impliedly preempted. Dkt. No. [163] at 20-26.

Defendants are correct. The Eleventh Circuit has held that claims based on failure to report adverse events to the FDA are impliedly preempted. See Mink, 860 F.3d at 1330 (affirming the dismissal of the plaintiff's state-law negligence claim to the extent that it relied on allegations that the defendant failed to report adverse events to the FDA); see also Mack, 2024 WL 4427846 at *8 (granting summary judgment to the defendant because the plaintiff failed to "actually present evidence that their failure to warn claims consist of more than a failure to report adverse events to the FDA"). Because Plaintiffs' failure-to-warn theory "is based on a duty to file a report with the FDA, it is very much like the 'fraud-on-the FDA' claim the Supreme Court held was impliedly preempted." Mink, 860 F.3d at 1330 (citing Buckman, 531 U.S. at 348).

Additionally, while some courts have upheld failure-to-warn claims based on an independent state-law obligation to report to the FDA,[4] Plaintiffs have identified no such duty under Georgia law: although Plaintiffs contend that a parallel duty exists under Georgia common law, Plaintiffs' cited authority reflects only the general principle that Defendants owe a duty to warn *users* of their product—not the FDA or another third-party regulatory body—of the product's

[4] See, e.g., Glover v. Bausch & Lomb Inc., 43 F.4th 304, 305-07 (2d Cir. 2022) (finding that a Connecticut statute creates a duty for medical device manufacturers to report adverse events to the FDA).

dangers. See Dkt. No. [180] at 14-15. To the contrary, it appears that Georgia common law does not recognize a duty to report adverse events to third-party regulatory bodies. See Swinney v. Mylan Pharms., Inc., No. 4:22-cv-90-MLB, 2023 WL 2090702, at *5 (N.D. Ga. Feb. 17, 2023) ("[C]ourts in Georgia consistently reject as preempted claims based only on the defendant's purported failure to comply with FDA reporting requirements.").

Simply put, Plaintiffs' failure-to-warn claims are based only on reporting duties owed to the FDA under federal law. See, e.g., 21 C.F.R. § 814.84 (requiring, as a matter of federal law, reporting to the FDA). Without an independent state-law basis for Plaintiffs' failure-to-report claims, those claims are impliedly preempted. See Jacob, 40 F.4th at 1336 ("State-law claims based on conduct that violates the [Food, Drug, and Cosmetic] Act can escape implied preemption only if the alleged wrongdoing would give rise to liability under state law even if the Act did not exist." (citing Mink, 860 F.3d at 1330)); see also Swinney, 2023 WL 2090702 at *4 ("A manufacturer's failure to report adverse events to [the] FDA is not a 'traditional state-law tort claim' because it 'seeks to enforce a duty owed to the FDA.' " (cleaned up) (quoting Frey v. Bayer Corp., 499 F. Supp. 3d 1283, 1288 (M.D. Ga. 2020))). Thus, Defendants are entitled to summary judgment of the failure-to-warn claims on preemption grounds.

### *3. Deceptive Marketing*

The Court next turns to Plaintiffs' deceptive-marketing theory. To the extent that the claims rely on the theory that marketing communications were

within the scope of language approved by the FDA but were misleading in light of information Defendants failed to report to the FDA, the claims are preempted for the same reason as the failure-to-warn claims. See supra Part III.B.2. Viewing the complaint in the light most favorable to Plaintiffs, however, Plaintiffs also at least arguably alleged that Defendants made false and misleading safety claims in marketing materials that exceeded the scope of the language approved by the FDA, Dkt. No. [17] ¶ 51, claims that would not be preempted.

Even so, the claims do not survive summary judgment. To assert a claim for deceptive marketing, the plaintiff must establish that the deceptive messaging led to her injury. See, e.g., Grand Master Contracting, LLC v. Lincoln Apartment Mgmt. Ltd. P'ship, 724 S.E.2d 456, 458 (Ga. Ct. App. 2012) (setting out the "five essential elements" of fraudulent misrepresentation: the defendant's false representations; the defendant's knowledge that the representations were false; the defendant's intent to deceive the plaintiff and induce the plaintiff to act; the plaintiff's justifiable reliance; and resulting injury to the plaintiff); Tiismann v. Linda Martin Homes Corp., 637 S.E.2d 14, 17 (Ga. 2006) ("A private [Georgia Fair Business Practices Act] claim has three elements: a violation of the Act, causation, and injury." (alteration adopted)).

Defendants contend that "there is no evidence that Plaintiffs or any of their implanting physicians saw or reviewed a Filshie Clip brochure or other sales or marketing materials, much less evidence anyone relied on [the materials]" and that Plaintiffs therefore cannot establish causation. Dkt. No. [163] at 27. Indeed,

in response to Defendants' statements of material fact, Plaintiffs concede that "none of the Plaintiffs reviewed any warnings, brochures, instructions, marketing materials, or other literature regarding the Filshie Clip" and that there is no record evidence that their physicians "reviewed any Filshie Clip warnings, instructions, brochures, or other evidence." Dkt. No. [180-2] ¶¶ 12, 14.

As a consequence, Plaintiffs cannot, in fact, establish the causation element of their deceptive-marketing claims. Defendants are therefore entitled to summary judgment of these claims as well.

#### *4. Design & Manufacturing Defects*

Defendants also argue that the claims premised on liability for design and manufacturing defects are preempted. Dkt. No. [163] at 14-16. The Court agrees.

Plaintiffs concede that there is no record evidence that the Filshie Clips deviated from the FDA-approved design or were manufactured in a way that violated the premarket-approval requirements. Dkt. No. [180-2] ¶¶ 9-10. Instead, they rely on the theory that Defendants violated federal requirements to report adverse events, thereby misleading the FDA as to the safety of Filshie Clips' design and manufacturing specifications and robbing it of the opportunity to amend the specifications or remove the device from the market. See generally Dkt. No. [180].

This is yet another variation of the "fraud-on-the-FDA" theory the Court has already considered and rejected on preemption grounds. Thus, these claims are also preempted for the same reasons discussed above. See supra Part III.B.2.

The Court has also reviewed the cases Plaintiffs cite where negligent design or manufacturing claims were not preempted, see Dkt. No. [180] at 11 n.6 (citing Frey v. Bayer Corp., 499 F. Supp. 3d 1283 (M.D. Ga. 2020); Cooksey v. Medtronic, No. 1:20-cv-00805-ELR, 2020 WL 10090793 (N.D. Ga. 2020); and In re Wright Med. Tech. Inc., Conserve Hip Implant Prods. Liability Litig., 127 F. Supp. 3d 1306 (N.D. Ga. 2015)), but they are all materially distinguishable because none of them deal with claims arising from a defendant's alleged fraud on the FDA. Indeed, in Frey and Cooksey, the courts expressly noted that such claims *would* be preempted. See Frey, 499 F. Supp. 3d at 1288 ("[T]he Food Drug and Cosmetic Act impliedly preempts fraud-on-the-FDA claims, even if they are labeled as something else, like a negligence claim based on a manufacturer's failure to investigate adverse events and report them to the FDA."); Cooksey, 2020 WL 10090793 at *9 (finding that the claims were not based on fraud-on-the-FDA allegations and therefore were not impliedly preempted).[5] Therefore,

[5] The courts' analysis in the cases also follows the MDA framework set out in Part III.A. above. In Frey and Cooksey, the plaintiffs' negligent-manufacturing claims were not preempted because they were based on both a violation of the defendant's duty to exercise reasonable care in manufacturing its products so as to make them safe for their intended use *and*—unlike in the present case—an alleged violation of federal manufacturing requirements, which placed the claims in the narrow gap between express and implied preemption. Frey, 499 F. Supp. 3d at 1289-90; Cooksey, 2020 WL 10090793 at *9. And in In re Wright, as in Lohr, discussed supra at n.2, the court determined that the defendants' arguments for express preemption failed because—again, unlike in the present case—there was insufficient evidence that the device at issue had been through the premarket-approval process and was thus subject to FDA requirements specific to the device, as necessary to trigger § 360k(a). In re Wright, 127 F. Supp. 3d at 1353-56.

nothing in these cases suggests that design or manufacturing claims arising from the defendants' alleged failure to meet FDA reporting requirements escape preemption.

Consequently, the Court concludes that Defendants are entitled to summary judgment on the claims based on a design-defect or manufacturing-defect theory.

### *5. Derivative Claims*

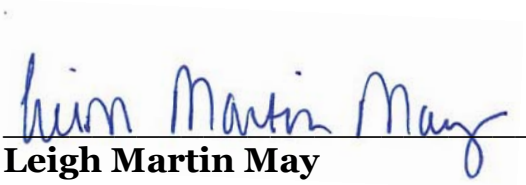
Without a surviving substantive claim, Mr. Venenga's derivative claim for loss of consortium and all of the plaintiffs' derivative claims for attorneys' fees and punitive damages fail as a matter of law. See Stuart v. Hatcher, 757 F. App'x 807, 811 (11th Cir. Dec. 4, 2018) (" '[A]wards of punitive damages and attorney fees are derivative of underlying claims; where those claims fail, claims for punitive damages and attorney fees also fail.' " (quoting Popham v. Landmark Am. Ins. Co., 798 S.E.2d 257, 264 n.1 (Ga. Ct. App. 2017)); Priester v. Turner, 896 S.E.2d 710, 712 (Ga. Ct. App. 2023) (holding that a claim for loss of consortium is dependent on the spouse having a viable personal-injury claim). Thus, Defendants are entitled to summary judgment on these claims as well.

## IV. CONCLUSION

In accordance with the foregoing, Defendants' motions for summary judgment, Dkt. No. [163, 164, 165], are **GRANTED**; Plaintiffs' motion for partial summary judgment, Dkt. No. [171], is **DENIED** as to Defendants' preemption defense and is otherwise **DENIED AS MOOT**; Defendants' motions to exclude

expert-witness opinions, Dkt. Nos. [166, 167, 168, 169], are **DENIED AS MOOT**; and all claims are **DISMISSED WITH PREJUDICE**. The Clerk is **DIRECTED** to enter judgment in Defendants' favor and close the case.

**IT IS SO ORDERED** this 8th day of August, 2025.



**Leigh Martin May**
**United States District Judge**