IN THE THIRD JUDICIAL DISTRICT COURT
SALT LAKE COUNTY, STATE OF UTAH

CHELSEA GARTRELL, *et al.*, Plaintiffs, vs. UTAH MEDICAL PRODUCTS, INC. and its U.K.-based subsidiary FEMCARE, LTD.; and COOPERSURGICAL, INC, Defendants.	MEMORANDUM DECISION AND ORDER Case No. 220906025 Judge Coral Sanchez

This matter is before the Court on Defendants' Motion to Dismiss. Oral argument was held July 5, 2023. The Court took the matter under advisement. The Court, having considered the motions and memoranda; the facts, argument, and legal authority therein; the arguments of counsel; and being otherwise fully informed, hereby rules and orders as follows.

BACKGROUND

Plaintiffs are 50 women who were injured when the birth control device, Filshie Clip, migrated from the fallopian tubes into other parts of the body. Defendants are the manufacturer, promotor, distributor, and seller of the Filshie Clip. In 1996, Defendants applied for and received a Class III medical device rating for the Filshie Clip from the Food and Drug Administration (FDA). Classification as a Class III medical device requires a rigorous process.[1] At the time, Defendants reported a clip migration rate of .13%.

[1] The Tenth Circuit Court of Appeal summarized the Class III approval process here:
In 1976, Congress passed the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetics Act (FDCA). Through that legislation,

In their Complaint, Plaintiffs assert that as early as 2001, the Filshie Clip migration rate was as high as 25%. Plaintiffs bring claims against Defendants for: (1) Strict Products Liability – Manufacturing Defect, (2) Strict Products Liability – Design Defect, (3) Strict Products Liability – Failure to Warn, (4) Negligence, (5) Gross Negligence, and (6) Punitive Damages. Plaintiffs assert that Defendants "had a duty to [P]laintiffs to avoid injuring them with their defective products" and "were required to comply with and not deviate from federal statutory and regulatory requirements." The Complaint alleges that Defendants breached several requirements under the Food, Drug and Cosmetics Act (FDCA) for Class III medical devices.[2]

> Congress standardized and regulated the safety and effectiveness of medical devices. Class III devices—those subject to the strictest controls—must go through a premarket approval (PMA) process, administered by the Food and Drug Administration (FDA). The PMA process begins with a rigorous application, involving extensive research and testing and usually requiring a multi-volume submission. [] Only upon "reasonable assurance" of the device's safety and effectiveness, weighing any probable benefit to health against any probable risk of injury or illness, may the FDA approve a Class III device. Part of every PMA review involves warnings and labeling. And the FDA may only approve labels and warnings if it determines they are not false or misleading. The FDA may condition premarket approval on adherence to performance standards, restrictions on sale or distribution, or further research. After approval, a manufacturer may not change "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Furthermore, the FDA may subject approved devices to ongoing reporting obligations and can revoke approval based on new or existing data and must do so when "it determines that a device is unsafe or ineffective."

Brooks v. Mentor Worldwide, LLC, 985 F.3d 1272, 1277-78 (10th Cir. 2021) (citations omitted).

[2] *See* 21 C.F.R. § 814.80 (prohibits distribution of device in a manner inconsistent with the PMA process); *id.* at § 814.82 (post-approval process requires continuing evaluation and reporting of device's safety); *id.* at § 814.84 (periodic reports to FDA must include scientific literature and unpublished clinic study data); *id.* at § 820.20 (management must ensure quality system procedures); *id.* at § 820.100 (management must establish "corrective and preventative" process to address problems); *id.* at § 820.198 (manufacturer to maintain file of complaints and evaluate whether to report to FDA); *id.*

DISCUSSION

Defendants move the Court to dismiss Plaintiffs' claims with prejudice for lack of subject matter jurisdiction and for failure to state a claim. *See Tuttle v. Olds*, 2007 UT App 10, ¶ 6, 155 P.3d 893 ("Rule 12(b)(6) dismissals are appropriate only where the court concludes that the plaintiff has failed to state a claim upon which relief can be granted, after accepting all the factual allegations made in the complaint as true and drawing all reasonable inferences in a light most favorable to the plaintiff.").

Defendants argue that the FDCA grants the FDA the exclusive right to enforce a Class III medical device's compliance with the FDCA, and thus this Court lacks subject matter jurisdiction over Plaintiffs' preempted claims. The FDCA provides,

> [N]o 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.A. § 360k(a). In *Brooks v. Mentor Worldwide, LLC*, the Tenth Circuit Court of Appeals summarized this and another preemption provision, citing the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

> The Supreme Court established a two-part test to evaluate a claim for express preemption. First, we must ask "whether the federal government has established requirements applicable to" the implants. [] Second, we must determine whether the state-law claims impose a requirement that relates to the safety or effectiveness of the implant and differs from or adds

---

at § 803.1 (manufacturer, importer, distributor and "device user facilities" must submit annual report to FDA listing deaths and serious injuries); *id.* at § 803.10 (specifies reporting requirements of adverse effects for each of importers, manufacturers, and device user facilities); *id.* at § 803.40 (importers must report deaths, serious injuries, and reports of malfunctions); and *id.* at § 803.58 (reporting requirements for foreign manufacturers).

to the federal requirements. Federal law preempts a tort claim "unless the federal requirements impose duties that are at least as broad as those" imposed by the state law.

The second preemption statute provides that

> Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. ...

21 U.S.C. § 337.

Interpreting and applying this requirement is easier than the first. "Congress intended that the MDA be enforced exclusively by the Federal Government." Thus, the FDCA preempts "any state tort claim that exists 'solely by virtue' of an FDCA violation." Along with express preemption, this implied preemption provision leaves only a narrow gap of possible state tort claims. Any such claim must be *predicated on* conduct that violates the FDCA but may not be brought *solely because* that conduct violates the FDCA—the conduct must also violate a parallel state-law requirement.

Put differently, to survive preemption, a plaintiff must plead conduct that (1) violates the FDCA (because state law may not impose additional or different duties) and (2) would be actionable under state law independently of the FDCA (because a plaintiff may not seek to enforce the FDCA). And when the pleader misses the gap—that is, when federal law preempts a claim—the court should dismiss that claim.

Brooks, 985 F.3d 1272, 1278-79 (10th Cir.) (emphasis in original).

Brooks clarifies that in order for Plaintiffs to survive preemption, they must show that their state-based claims are equivalent to the requirements under the FDCA. And in fact, Plaintiffs' Complaint repeatedly states: "Any deviation from [federal law] is a violation of federal law and also a violation of Utah common law duties as a manufacturer, importer, distributor and seller, but only to the extent that they are parallel to and not different from or in addition to the requirements of federal law."

Defendants point to the only Utah case on this subject. In *Burningham v. Wright Med. Tech., Inc.,* the plaintiff sued the manufacturer of hip implants, a Class III medical device, for strict liability - design defects. 2019 UT 56, 448 P.3d 1283. The Utah Supreme Court cited to *Riegel:* "For devices that go through the more rigorous premarket approval

process, the United States Supreme Court has held that federal law preempts any state law tort claims, so we do not opine on whether such devices might be unavoidably unsafe as a matter of law because they are already exempt from design defect claims." *Id.* at ¶ 2. "*Riegel* holds that all state law tort claims, including strict liability design defect claims, involving a PMA-approved device are preempted by the MDA." *Id.* at ¶ 25.

Plaintiffs retort that *Burningham* is conclusory, and in fact it is. But *Burningham's* conclusion correctly assumed that the plaintiff's Utah-based claim for strict products liability did not parallel the FDCA's related rules. To spell it out, Utah has adopted the Restatement of Torts for strict products liability claims. *See House v. Armour of Am., Inc.*, 929 P.2d 340, 343 (Utah 1996) (citing to adoption of Restatement). Section 402A states:

> One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Restatement (Second) of Torts (1965) § 402A. In turn, Utah's Product Liability Act defines "unreasonably dangerous" as:

> [D]angerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer, or user of that product in that community considering the product's characteristics, propensities, risks, dangers, and uses together with any actual knowledge, training, or experience possessed by that particular buyer, user, or consumer.

Utah Code § 78B-6-702. Utah law requires a manufacturer to adequately warn the consumer of dangerous products. "[U]nder Utah law, a manufacturer may be held strictly liable for any physical harm caused by its failure to provide adequate warnings regarding the use of its product. Moreover, a manufacturer who knows or should know of a risk associated with its product may be directly liable to the user if it falls to warn adequately

of the danger." *Feasel v. Tracker Marine LLC*, 2021 UT 47, ¶ 20, 496 P.3d 95 (citation and quotations omitted). "The jury should decide whether a party's warnings were reasonable." *Shipley v. Forest Labs., Inc.*, 2015 WL 4199739, at *14 (D. Utah July 13, 2015).[3]

In comparison, the FDCA does not use the term "unreasonably dangerous" or an equivalent, and the FDCA provides for the FDA to make safety decisions, not a trier of fact. The FDCA also imposes no duty upon manufacturers to the ultimate consumer. Utah law does not have equivalent requirements to report adverse events to the FDA, nor does it provide damages for a violation of FDA regulations. As Utah's strict products liability laws impose independent duties from the FDCA, Plaintiffs' first three claims are preempted.

Without a valid duty to warn claim due to federal preemption of Plaintiffs' products liability claims, Plaintiffs cannot support their claims for negligence and gross negligence. What would otherwise be a duty owed by Defendants to Plaintiffs under state law, the FDCA preempts so that all duties are owed to the FDA. If no duty to warn is owed to

---

[3] Both parties provided numerous case citation from jurisdictions outside Utah. The majority favor Defendants' position here. *See, e.g., Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340 (10th Cir. 2015) (stating a viable state law claim regarding an FDA-approved medical device is like "navigating between Scylla and Charybdis."); *In re Medtronic, Inc., Sprint Fidelis.*, 623 F.3d 1200 (8th Cir. 2010) (failure to warn of unreasonably dangerous risk of Class III device is preempted by § 360k of the FDCA); *Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129 (D.D.C. 2018) (a failure to warn claim is not the functional equivalent of manufacturer's failure to report adverse incidents to FDA); *Poozhikala v. Medtronic Inc.*, 2022 WL 1076173, at *4 (C.D. Cal. Apr. 7, 2022) ("the overwhelming majority of state law tort claims, including claims based on negligence, design defect, manufacturing defect, failure to warn, ... are preempted."); and *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 930 (5th Cir. 2006) (to permit a jury to second-guess the design approval by applying the state standard for unreasonably dangerous design would risk interference with the federally-approved design standards and criteria.).

Plaintiffs, then they cannot support a claim for negligence. *See Gonzalez v. Russell Sorenson Const.*, 2012 UT App 154, ¶ 20, 279 P.3d 422 (A negligence claim requires: (1) a duty owed to the plaintiff, (2) breach, (3) causation, and (4) injury.).

In sum, Plaintiffs' claims for strict product liability and negligence, including the failure to warn claim, fail as preempted by the FDCA. Utah's tort claims do not parallel federal law, and they add to the federal requirements. Defendants move the Court to dismiss the Complaint with prejudice, asserting that no amendment could cure the lack of subject matter jurisdiction over a federally-preempted Class III medical device. The Court agrees. Plaintiffs' products liability and negligence claims are founded in violations of federal law. Plaintiff's products liability and negligence claims are well-defined under Utah law, and they do not parallel federal law—rather they contain different standards and requirements. Under *Burningham*, these claims are clearly preempted, and this Court lacks subject matter jurisdiction.

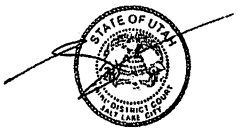
Order

Accordingly, the Court hereby rules as follows:

1. The Defendants' Motion to Dismiss, filed pursuant to Rule 12(b) of the Utah Rules of Civil Procedure, is **GRANTED**.
2. The Complaint is dismissed with prejudice.

This Order fully and finally resolves this matter. This Order constitutes a final and appealable Order. This is the order of the Court, and no further writing is necessary to effectuate this decision.

So ORDERED this 29th day of August 2023.



Judge Coral Sanchez
Third District Court of Utah

CERTIFICATE OF NOTIFICATION

I certify that a copy of the attached document was sent to the following people for case 220906025 by the method and on the date specified.

MANUAL EMAIL: BEAU BURBIDGE BEAU@BURBIDGEMITCHELL.COM

MANUAL EMAIL: RICHARD BURBIDGE RBURBIDGE@BURBIDGEMITCHELL.COM

EMAIL: CLANCEY HENDERSON CHENDERSON@BURBIDGEMITCHELL.COM

MANUAL EMAIL: EDWARD HAVAS EHAVAS@DKOWLAW.COM

MANUAL EMAIL: DANIEL R GRIFFIN dan@griffinpurnell.com

MANUAL EMAIL: SIMON B PURNELL simon@griffinpurnell.com

08/29/2023 /s/ ALEXANDER GUARDADO

Date: _____ _____

Signature