UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

KATELYN DICKSON	**CASE NO. 2:24-CV-00121**
VERSUS	**JUDGE JAMES D. CAIN, JR.**
DEXCOM INC	**MAGISTRATE JUDGE LEBLANC**

MEMORANDUM RULING

Before the court is a second Motion to Dismiss and Motion to Compel Arbitration [doc. 28] filed by defendant Dexcom Inc., in response to the Second Amended Complaint filed by plaintiff Katelyn Dickson. Plaintiff opposes the motion. Doc. 31.

I. BACKGROUND

A. Plaintiff's Allegations

This products liability suit arises from plaintiff's use of the Dexcom G6 System ("G6"), a continuous glucose monitor. The court incorporates the extended factual background in its prior ruling. *See* doc. 25. To summarize, in March 2018 the FDA approved the request and allowed the G6 to enter the market as a Class II medical device, subject to certain mitigation measures for its identified risks. *See* 87 Fed. Reg. 9237. The G6 consists of three main components: a sensor, a transmitter, and a display device. Doc. 19, att. 2, ¶ 4. The user can view glucose data on her display device by using either a Dexcom receiver or the G6 App, a mobile medical phone application that allows the user to view data on a compatible personal mobile device such as an iPhone. *Id.*

Plaintiff, a 29-year-old woman diagnosed with Type 1 diabetes mellitus, began using the G6 in December 2021 on the advice of her physician, even though she was pregnant. The G6 User Guide advises:

- **Don't Use If . . .**

  Do not use the G6 if you are pregnant, on dialysis, or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the system. G6 readings may be inaccurate in these populations.

Doc. 16, att. 6, p. 24. Plaintiff's physician received over $145,000.00 in compensation from Dexcom, maker of the G6, between 2019 and 2022.[1] Doc. 27, ¶¶ 72–77.

Plaintiff was still using the G6 on October 27, 2022, when she became involved in a motor vehicle accident after her blood glucose levels suddenly dropped to dangerously low levels. *Id.* at ¶ 102. Specifically, she states that she struck a concrete driveway and culvert at 65 miles per hour, causing her airbags to deploy and trapping her in her vehicle. *Id.* At that time plaintiff was between twelve and fourteen weeks pregnant and traveling with a small infant in her car. *Id.* She further alleges that emergency responders recorded her blood glucose as 53 mg/dl, which the CDC defines as severely low.[2] *Id.* at ¶ 106.

Plaintiff filed suit in this court on January 30, 2024. Doc. 1. In her First Amended Complaint, she raised state law claims for design defect, failure to warn, and breach of

[1] The figure is $145,415.61, derived from entries for plaintiff's physician on the Open Payments database. The database is a program of the Centers for Medicare & Medicaid Services, which collects and publishes information about the financial relationship between health care providers and certain drug and medical device companies. *See* Open Payments, *available at* https://openpaymentsdata.cms.gov/.

[2] According to the CDC, low blood sugar is defined as below 70 mg/dl and severe low blood sugar is below 54 mg/dl. *See* Treatment of Low Blood Sugar (Hypoglycemia), https://www.cdc.gov/diabetes/treatment/treatment-low-blood-sugar-hypoglycemia.html (last visited June 10, 2024).

express warranty under the Louisiana Products Liability Act ("LPLA"), as well as redhibition, rescission due to error, and rescission due to fraud. Doc. 16.

B. First Motion to Compel Arbitration and Motion to Dismiss

Defendant moved to compel arbitration of all claims under an arbitration clause in the Dexcom app's Terms of Use. Doc. 19. Alternatively, it moved to dismiss plaintiff's claims under Federal Rule of Civil Procedure 12(b)(6) on the following grounds:

1. Plaintiff's claims are preempted by federal law
2. Plaintiff's claims are deficiently pled or barred by Louisiana law
3. Plaintiff's allegations establish that she was misusing her G6
4. Plaintiff's punitive damages claim is precluded by Louisiana law

Id. Plaintiff opposed both motions. Doc. 19.

The court denied the motion to compel arbitration, finding that the language in the Terms of Use only indicated that the user was consenting to arbitration for claims arising from her use of the app—which was not required for use of the G6 device. Accordingly, the terms "fail[ed] to provide a reasonable user with notice that she is waiving her right to pursue any claims arising from a medical device merely by installing the associated app." Doc. 25, p. 9.

Under the motion to dismiss, the court dismissed the rescission and redhibition claims. *Id.* at 10. As to the LPLA claims, the court held that the FDA's Class II de novo classification and approval of the G6 were entitled to preemptive effect. Accordingly, any claims under the LPLA would be preempted by the Medical Device Amendments to the FDCA, codified at 21 U.S.C. § 360, to the extent they imposed requirements that are

"different from, or in addition to the federal ones" and related to the device's safety and efficacy. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008). The court further determined that plaintiff's LPLA claims fit this mold and must be dismissed, except for her failure to warn claim. As to this claim, the court allowed leave to amend for "that claim alone" so plaintiff could show whether it fit the exception for post-approval label changes under the FDA's Changes Being Effected regulation. Doc. 25.

C. Second Amended Complaint, Motion to Compel, and Motion to Dismiss

Plaintiff amended her complaint as instructed, asserting only a failure to warn claim under the LPLA. Doc. 27. She attached articles reviewing case reports on continuous glucose monitors from the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. Doc. 27, atts. 1–3. Based on these reports, plaintiff alleges that the FDA-approved label was inadequate and should have been amended to fully apprise users of the device's risks. Doc. 27.

Dexcom now reasserts its motion to compel arbitration and, in the alternative, moves to dismiss this claim under Federal Rule of Civil Procedure 12(b)(6). Doc. 28. Under the first motion, it maintains that the court erred in its original ruling and that the dispute is subject to arbitration because it arises from plaintiff's use of the app. Under the second, it argues that plaintiff's LPLA claim is expressly and impliedly preempted, and that arguments based on the Changes Being Effected ("CBE") regulation have no impact because (1) the regulation does not apply to Class II medical devices and (2) the studies on which plaintiff relies are not "newly acquired" information. In the alternative, Dexcom maintains that plaintiff's claim is barred by her misuse of the G6. Finally, it moves for

dismissal of her claim for punitive damages because such a claim is not authorized under Louisiana law. Plaintiff does not address the argument on punitive damages but opposes the motions in all other respects. Doc. 31.

II.
Law & Analysis

The court has already ruled that arbitration should be denied and finds no reason to revisit that ruling. Additionally, the court has ruled that plaintiff's sole remaining claim is preempted unless she can show that the CBE regulation applies. Accordingly, the court first considers this argument of the motion to dismiss and only precedes to the others if there is no basis for preemption.

Defendant argues that plaintiff's claim is preempted by the Medical Device Amendments ("MDA") to the FDCA, codified at 21 U.S.C. § 360. The MDA preempts state law claims when: (1) the federal government has established specific requirements applicable to the device and (2) the claims are based on state requirements that are "different from, or in addition to the federal ones" and relate to the device's safety and efficacy. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008). The court determined in its previous ruling that the first requirement was met through the "special controls" established by the FDA for the design, testing, manufacture, and labeling of the G6 through its Class II de novo approval. Under the second requirement, the court further held that a failure to warn claim allowing a jury to second-guess the adequacy of FDA-approved materials under state law "would displace the FDA's exclusive role and expertise . . . and risk imposing inconsistent obligations on [the defendant]." *Gomez v. St. Jude Medical Diag. Div., Inc.*,

442 F.3d 919, 931 (5th Cir. 2006). Plaintiff pled a loophole through the CBE regulation, however, and the court has allowed plaintiff to expand on those allegations through her amended complaint.

Generally speaking, a manufacturer can only change a drug or device label if the FDA approves a supplemental application. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). A manufacturer may also unilaterally alter the label under the CBE regulation, if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction" in order to "reflect newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii). "Newly acquired information" is that which "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions" to the FDA. 21 C.F.R. § 314.3(b). It includes both new data and new analyses of submitted data. *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019).

The CBE regulation only applies to drugs and devices approved through the premarket approval process. *See* 21 C.F.R. § 814.39(d). The G6, on the other hand, received approval through the FDA's de novo classification process and was not subject to the more rigorous PMA for Class III devices. *See, e.g.*, *Tuttle v. Dexcom, Inc.*, 2021 WL 8998920, at *3 (N.D. Ga. May 20, 2021). Plaintiff maintains that Dexcom could have requested a change to the label by submitting a new § 510(k) notice to the FDA. The § 510(k) process refers to the premarket review through which the FDA determines if a new device is substantially equivalent to an existing device. This process encompasses only a limited review focused on equivalence rather than safety; "substantially equivalent" devices may be marketed without further regulatory analysis. *Lohr*, 518 U.S. at 478–79.

Yet again, the G6 entered the market through de novo classification because it had no substantial equivalent. *Tuttle*, 2021 WL 8998920, at *3. Plaintiff points to FDA guidance on when a new § 510(k) must be submitted after a change to an existing device—but she alleges no changes made by Dexcom to the G6 between its approval and her accident. Doc. 31, pp. 20–21; *see* doc. 22, att. 8.

Even if plaintiff could show a mechanism like the CBE regulation requiring Dexcom to independently reevaluate and amend its label, she has twice failed to show sufficient "newly acquired information" to trigger any relevant change to the existing warnings. First off, the burden is on plaintiff to point to the existence of such information. *Utts v. Bristol-Myers Squibb Co.*, 251 F.Supp.3d 644, 661 (S.D.N.Y. 2017), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). The information is limited to "data, analyses, or other information not previously submitted to the Agency[.]" 21 C.F.R. § 314.3(b). This information may include "new analyses of previously submitted data . . . if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to [the] FDA." *Id.* The information must also "demonstrate 'reasonable evidence of a causal association with a drug . . . ." *Gayle v. Pfizer Inc.*, 452 F.Supp.3d 78, 88 (S.D.N.Y. 2020) (citing 21 C.F.R. § 201.57). Accordingly, "adverse event reports, without any analysis indicating causality, cannot constitute 'newly acquired information.'" *Id.* Likewise, it is insufficient to assert that a manufacturer "could have or should have done more studies" to create such "newly acquired information." *Holley v. Gilead Sciences, Inc.*, 2023 WL 6390598, at *8 (N.D. Cal. Sep. 28, 2023).

Plaintiff relies on two analyses based on adverse event reports for continuous glucose monitors ("CGMs"). One of these, published by Jan S. Krouwer in 2023,[3] did not emerge until after plaintiff's 2022 accident. Therefore, it cannot support plaintiff's claim of information showing the need for a label change before her injuries occurred. At any rate, the article highlighted the challenges of analyzing CGM adverse event reports but did not identify a greater incident or different type of injury than previously considered by the FDA. The other, also authored by Krouwer,[4] was based on adverse event data for 2019. For the G6, the author graphed the results of the CGM versus a blood glucose meter following incidents reported as malfunctions or injuries. The results showed that glucose readings could be grossly inaccurate even for events reported as "malfunctions" rather than "injuries." The author disavowed any implication, however, "that Dexcom brands are more inaccurate than other brands." He also acknowledged the limitations of the adverse event database, namely that "[t]he number of events is misleading without rates (the denominator of usage)" and "[t]here is no way to know if all events that should be reported have been reported and have been properly classified." He thus recommended that the FDA enforce medical device reporting regulations and that researchers obtain usage information to understand the error rates. These conclusions likewise fail to show a rising incidence of adverse events or any other evidence of a new risk that should have supported an independent label change, if the mechanism existed to make one. Accordingly, plaintiff

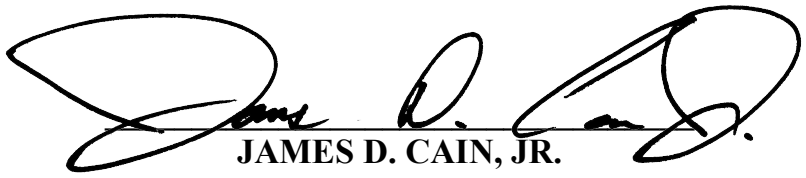
[3] Jan S. Krouwer, *Adverse Event Causes From 2022 for Four Continuous Glucose Monitors*, J. OF DIABETES SCI. AND TECH., 1–4 (2023).
[4] Jan S. Krouwer, *An Analysis of 2019 FDA Adverse Events for Two Insulin Pumps and Two Continuous Glucose Monitors*, J. OF DIABETES SCI. AND TECH., 228–32 (2022).

fails to show an exception and her failure to warn claim is preempted. *Accord Higginbottom v. Dexcom, Inc.*, __ F.Supp.3d __, 2024 WL 3823023 (S.D. Cal. Aug. 13, 2024). The court finds no basis to grant her request for further discovery into the issue.

III.
CONCLUSION

For the reasons stated above, the Motion to Compel Arbitration [doc. 28] will be **DENIED**, the Motion to Dismiss [doc. 28] will be **GRANTED**, and plaintiff's remaining claim will be **DISMISSED WITH PREJUDICE**.

THUS DONE AND SIGNED in Chambers on the 25th day of September, 2024.



JAMES D. CAIN, JR.
UNITED STATES DISTRICT JUDGE