

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

MARTHA HAWKINS

CIVIL ACTION

VERSUS

NO: 20-2962

ABBOTT DIABETES CARE SALES
CORPORATION ET AL.

SECTION: "J"(3)

ORDER AND REASONS

Before the Court is a *Motion to Dismiss* (**Rec. Doc. 25**) and a *Request for Judicial Notice* (**Rec. Doc. 26**) filed by Defendants, Abbott Diabetes Care Sales Corporation, Abbott Laboratories, Abbott Laboratories International LLC, and Abbott Laboratories, Inc. Plaintiff, Martha Hawkins filed an opposition to the request for judicial notice. (Rec. Doc. 27). Defendants filed a reply (Rec. Doc. 30). Having considered the motion and legal memoranda, the request for judicial notice, the record, and the applicable law, the Court finds that the motion and request for judicial notice should be **GRANTED**.

FACTS AND PROCEDURAL HISTORY

Defendants own FreeStyle Libre, which is a continuous glucose monitoring device designed to replace blood glucose testing, detect trends and tracking patterns, aid in the detection of episodes of hyperglycemia and hypoglycemia, and facilitate both acute and long-term therapy adjustments in persons age 18 and older with diabetes. The sensor uses a thin, flexible filament inserted just under the skin to measure glucose every minute.

On September 27, 2019, Plaintiff alleges that she used the FreeStyle Libre device, at which time she claims she removed the sensor from her arm and discovered a burn. As a result of this incident, on September 16, 2020, Plaintiff filed a Petition for Damages against Defendants in the 24th Judicial District Court for Jefferson Parish, which was subsequently removed to this Court. In response, Defendants filed the present motion to dismiss, arguing that Plaintiff's claim was pre-empted, and a request for judicial notice, asking the Court to take notice of FreeStyle Libre's premarket approval by the FDA.

LEGAL STANDARD

Under the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The complaint must "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 346 (2005) (internal citations omitted). The allegations "must be simple, concise, and direct." Fed. R. Civ. P. 8(d)(1).

"Under Rule 12(b)(6), a claim may be dismissed when a plaintiff fails to allege any set of facts in support of his claim which would entitle him to relief." *Taylor v. Books A Million, Inc.*, 296 F.3d 376, 378 (5th Cir. 2002) (citing *McConathy v. Dr. Pepper/Seven Up Corp.*, 131 F.3d 558, 561 (5th Cir. 1998)). To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead enough facts to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the

plaintiff pleads facts that allow the court to “draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* A court must accept all well-pleaded facts as true and must draw all reasonable inferences in favor of the plaintiff. *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 232 (5th Cir. 2009); *Baker v. Putnal*, 75 F.3d 190, 196 (5th Cir. 1996). The court is not, however, bound to accept as true legal conclusions couched as factual allegations. *Iqbal*, 556 U.S. at 678. “[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.” *Taylor*, 296 F.3d at 378.

DISCUSSION

Under 21 U.S.C. § 360k(a), premarket approval of medical devices by the FDA preempts state law claims challenging the safety or performance of that device. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). However, Plaintiff did not file an opposition to the motion to dismiss, but instead, opposed the request for judicial notice of FreeStyle Libre’s premarket approval. Thus, the only contested issue before the Court is whether the Court should take judicial notice of FreeStyle Libre’s premarket approval.

Under Federal Rule of Evidence 201, a court may take judicial notice of adjudicative facts that are not subject to reasonable dispute. In the context of a motion to dismiss, a court “may take judicial notice of and consider the public records of the FDA . . . without transforming [the motion to dismiss] into a motion for summary judgment.” *Sons v. Medtronic, Inc.*, 915 F. Supp. 2d 776, 781 (W.D. La. 2013). More specifically, a court may take judicial notice of FDA records reflecting

that the FDA granted premarket approval to a medical device in the context of a motion to dismiss raising federal preemption grounds. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (finding that the district court took appropriate judicial notice of a premarket approval letter while granting a defendant's motion to dismiss).

In this case, the Court sees no merit in refusing Defendants' request to take judicial notice of FreeStyle Libre's premarket approval by the FDA. Further, since the premarket approval of this product preempts Plaintiff's state law claims, Defendants' motion to dismiss should be granted.


CONCLUSION

Accordingly,

IT IS ORDERED that Defendants' *Request for Judicial Notice (Rec. Doc. 26)* is **GRANTED**.

IT IS FURTHER ORDERED that Defendants' *Motion to Dismiss (Rec. Doc. 25)* is **GRANTED**, and Plaintiff's claims are hereby **DISMISSED WITH PREJUDICE**.

New Orleans, Louisiana, this 2nd day of March, 2021.



CARL J. BARBIER
UNITED STATES DISTRICT JUDGE