IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
October 29, 2018
Lyle W. Cayce
Clerk

No. 18-50380
Summary Calendar

PETER B. CASEY,

Plaintiff - Appellant

v.

BRISTOL-MYERS SQUIBB COMPANY; OTSUKA AMERICA PHARMACEUTICAL, INCORPORATED,

Defendants - Appellees

Appeal from the United States District Court
for the Western District of Texas
USDC No. 5:17-CV-1175

Before JOLLY, COSTA, and HO, Circuit Judges.

PER CURIAM:*

Peter Casey alleges that he began taking Abilify in 2011, after it was prescribed to him by his psychologist. In June 2016, he stopped taking Abilify following a three week "tapering off" period. He alleges that withdrawal symptoms manifested two weeks later. These allegedly included headaches, weight loss, insomnia, impotence, and, most importantly, Tardive Dyskensia,

* Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

a neurological disorder that causes repetitive, unintentional movements. Casey filed suit against defendants, manufacturers and marketers of Abilify, in Texas state court asserting a state law failure-to-warn claim. The defendants removed the case to federal district court. The district court then dismissed the case, finding that the defendants were entitled to a judgment on the pleadings because, under Texas law, there is a presumption that warnings approved by the United States Food and Drug Administration (FDA) are "adequate." *See* Tex. Civ. Prac. & Rem. Code § 82.007.

Casey makes two arguments on appeal. First, he suggests that the defendants misled or withheld from the FDA material information causally related to the side effects that he suffered, thus rebutting the state law presumption and plausibly stating a cognizable claim. Fraud on the FDA is one of the exceptions set forth in the Texas statute as capable of rebutting the presumption against liability. Tex. Civ. Prac. & Rem. Code § 82.007(b)(1). We have previously held, however, that federal law requires a plaintiff suing under a state law failure-to-warn cause of action to show that the FDA itself has found that defendants behaved fraudulently. *Loften v. McNeil Consumer & Specialty Pharms.,* 672 F.3d 372 (5th Cir. 2012). Despite conclusory statements in his brief, Casey's complaint does not allege this, let alone contain any specific factual matter to support it. Therefore, the district court did not err in its ruling concerning fraud on the FDA.[1]

[1] The district court presumed that Casey was required to plead facts to rebut the Texas law presumption in his complaint. We have not previously decided in a published opinion whether Tex. Civ. Prac. & Rem. Code § 82.007 establishes an additional element of a failure-to-warn claim that must be adequately pled by the plaintiff, or an affirmative defense, which does not. We have presumed the former, however, in at least one unpublished opinion. *Thurston v. Merck & Co.,* 415 F. App'x 585 (5th Cir. 2011). Because Casey does not raise this issue on appeal, we need not address it.

Second, Casey argues that the district court erred because, by labeling his symptoms "side effects" rather than "withdrawal" symptoms, the defendants gave per se inadequate warnings. We see no merit to this argument. Leaving aside whether there is a meaningful difference between labeling the symptoms generally as "side effects" or explicitly attaching the "withdrawal" label to them, this is not a decision for us to make. The FDA has approved the warning provided by the defendants, and Texas law has made this approval sufficient to forestall any products liability claim absent the existence of a specified exception. Since Casey has not adequately pled any of these exceptions, we have no basis for finding that the defendants may be held liable.

Therefore, we AFFIRM the judgment of the district court.