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decisions issued on or after Jan. 1, 2007.
See also U.S. Ct. of App. 11th Cir. Rule 36-2.
United States Court of Appeals, Eleventh Circuit.

Robert N. MARKLAND, as the Personal Representative of the Estate of Carolyn S. Markland, Deceased, Plaintiff-Appellant,
v.
INSYS THERAPEUTICS, INC., a Delaware Corporation, Defendant-Appellee.

No. 17-14607
|
Non-Argument Calendar
|
(December 19, 2018)

Attorneys and Law Firms

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Appeal from the United States District Court for the Middle District of Florida, D.C. Docket No. 3:16-cv-00997-MMH-PDB

Before MARCUS, WILLIAM PRYOR, and ANDERSON, Circuit Judges.

Opinion

PER CURIAM:

***1** Plaintiff Robert Markland appeals the district court's dismissal of his wrongful death claim against Insys Therapeutics, Inc. In his complaint, Markland alleged that his wife, Carolyn Markland ("Carolyn"), died shortly after receiving a prescription drug manufactured by Insys, and he brought a single claim of "negligent marketing" under Florida law. On appeal, Markland argues the district court erred in finding the claim preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–399h. After careful review, we affirm.

The tragic facts of this case are these. [1] Insys Therapeutics is a pharmaceutical company that manufactures, among other things, a prescription painkiller called Subsys. Subsys is a spray form of Fentanyl, a powerful opioid that is a Schedule II controlled substance. See 21 U.S.C. § 812(c), sched. II (b)(6). The intended use of Subsys is to treat cancer patients with "breakthrough pain," i.e., sharp, sudden episodes of pain that occur despite constant treatment with other pain medications. While this is the sole FDA-approved use of Subsys, Markland alleges that Insys engaged in a "fraudulent" and "unlawful" marketing scheme to push doctors to prescribe Subsys "off label" for patients with other kinds of pain.

Carolyn Markland received Subsys, in what the complaint alleges is a prime example of an off-label use of the drug. At the time, she was receiving treatment for chronic back pain resulting from a degenerative disc disease. She regularly took a different opioid, Exalgo, and her pain management physician prescribed Subsys for pain on an as-needed basis. One morning after her physician administered a dose of Subsys, Carolyn suffered respiratory distress and died. Subsys is known to cause respiratory problems, and the medical examiner identified the cause of death as drug toxicity. Robert Markland filed this wrongful death suit as the personal representative of his wife's estate.

We review de novo the grant of a Rule 12(b)(6) motion to dismiss for failure to state a claim. Ray v. Spirit Airlines, Inc., 836 F.3d 1340, 1347 (11th Cir. 2016). We accept the allegations in the complaint as true and view them in the light most favorable to the plaintiff. Id. Regardless of the district court's reasoning, "we are free to affirm the district court's decision on any ground that is supported by the record." United States v. Elmes, 532 F.3d 1138, 1142 (11th Cir. 2008).

As a starting point, we note that the FDCA says that its requirements may only be enforced by the United States government. 21 U.S.C. § 337(a). In Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), the Supreme Court explained how

this bar on private enforcement of the FDCA interacts with the background of state tort law. There, patients injured by a medical device sued a consulting company for allegedly making false representations to the FDA in order to get approval to market the device. Id. at 343, 121 S.Ct. 1012. The plaintiffs' theory was that if the defendant had not made those false statements, the devices would not have been approved and they never would have been injured. The Supreme Court held that these "fraud-on-the-FDA" state tort claims were in conflict with federal law and were therefore preempted. Id. at 348, 121 S.Ct. 1012. The conflict "stem[med] from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against" it in pursuit of a "somewhat delicate balance of statutory objectives." Id. In other words, Congress made a specific choice to allow only the government to enforce the FDCA's requirements, and allowing private litigants to sue for misrepresentations made to the FDA would conflict with that policy decision. Id. at 348-51, 121 S.Ct. 1012.

***2** After Buckman, this Court noted a distinction between claims that rely on FDCA violations and claims derived from "traditional state tort law that predated the federal enactments in question." Mink v. Smith & Nephew, Inc., 860 F.3d 1319, 1327 (11th Cir. 2017) (quotations and modifications omitted). Traditional state-law tort claims are not preempted "so long as they don't seek to privately enforce a duty owed to the FDA." Id. The Court's different treatment of two claims in that case is instructive: a claim based on the defendant's failure to file a required report with the FDA was held to be preempted, but a traditional manufacturing defect products liability claim was not. Id. at 1330. The key distinction was that a manufacturing defect claim involves a duty that both predates the FDCA and is owed to the individual patient, not to the FDA. Id.

Here, Markland's claim is styled as a "negligent marketing" claim, which is not a recognized tort under Florida law. Markland alleges that after Subsys was approved to treat pain in cancer patients, Insys "unlawfully and negligently began an aggressive marketing campaign to get physicians to prescribe Subsys for other uses including relieving chronic back pain." More specifically, Markland asserts that Insys made payments to physicians and other medical professionals who prescribed the drug, at the same time urging them to write off-label prescriptions. Among other things, he alleges that Insys paid health care professionals through a sham "Speakers Bureau," which rewarded physicians who prescribed Subsys under the guise of providing compensation for travel and speeches. He adds that Insys "intentionally violated requirements imposed by the FDA" regarding the proper use of the drug.

The district court "read the substance of Mr. Markland's complaint as alleging that Insys violated federal law" and held that his claim was preempted. We agree. A critical premise of Markland's complaint is that Insys's promotion of off-label uses was improper, a proposition that can only be established by pointing to federal law. Although the FDCA does not expressly regulate off-label prescriptions, the FDA has penalized companies for the promotion of off-label uses under the misbranding provisions of the Act. See, e.g., United States v. Caronia, 703 F.3d 149, 154 (2d Cir. 2012) ("The government has repeatedly prosecuted -- and obtained convictions against -- pharmaceutical companies and their representatives for misbranding based on their off-label promotion."). At the same time, however, the FDA also generally permits the off-label prescription of drugs by physicians. See 21 U.S.C. § 396; cf. Buckman, 531 U.S. at 350, 121 S.Ct. 1012 (explaining that the off-label use of medical devices "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine").

Notably, Markland has not pointed to any traditional state-law duty owed by Insys to Carolyn that was breached by the company's marketing of Subsys for off-label use. It is only because of the FDCA and FDA enforcement decisions that the promotion of off-label uses is prohibited. Indeed, the very concept of a drug use being "off-label" is derived from the FDCA and FDA policymaking decisions.

Markland is correct that under Florida tort law, a negligence claim can be premised on a duty created by a federal statute or regulation. See Godfrey v. Precision Airmotive Corp., 46 So.3d 1020, 1023 (Fla. Dist. Ct. App. 2010). But preemption is an issue of federal law, and a duty derived from a federal statute is insufficient to prevent preemption. One cannot say that a claim based on a federal statutory duty "rel[ies] on traditional state tort law which [predates] the federal enactments in question[ ]." Buckman, 531 U.S. at 353, 121 S.Ct. 1012. As with the Buckman plaintiffs, Markland seeks to enforce a duty that

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"exist[s] solely by virtue of the FDCA." Id. That kind of claim is preempted.

***3** Because we affirm on the ground that Markland's claim is preempted, we need not express any view on the viability of a negligent marketing claim under Florida law or the application of the learned intermediary doctrine to this case.

AFFIRMED.

All Citations

--- Fed.Appx. ----, 2018 WL 6666385

Footnotes

1 Because the district court decided this case on a motion to dismiss, we take the facts alleged in the complaint as true. See Furry v. Miccosukee Tribe of Indians, 685 F.3d 1224, 1226 n.2 (11th Cir. 2012).

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