9-7-2022

Phyllis Bennett v. Teva Pharmaceuticals USA Inc

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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Nos. 21-1642 & 21-2304

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PHYLLIS BENNETT, Executor of the Estate of Harvey Bennett; ARTHUR J. OLSTAD; KATHLEEN OLSTAD; ROBERT PERKINS; ELIZABETH CLARK; WILLIAM MURPHY; BONNIE MURPHY; RITA WEAVER; MARVIN BAUMAN; ROWENA BAUMAN; HENRY ACKERMAN; GENIEVE ACKERMAN; DONALD HACKERSON; CAROLYN HACKERSON; JAMES WALZ; MARY BETH WALZ; JUDITH COTE; THEODORE ALMOND; EDWARD J. MILLER, JR.; THOMAS HEPLER; BARBARA KING; SAMUEL KING; RICKEY THOMAS; CAROLYN THOMAS; JOHN ACKERMAN; KIM ACKERMAN; ALBERT DELSANTRO; CHARLOTTE DELSANTRO; RICHARD BRESETTE; RALPH BOOTH; HANS OMASTA; WINONA OMASTA; EDDIE BATES; LINDA BATES; CHARLES DAVID SMEDLEY; MARCHETTE COOK, Personal Representative of the Estate of Alice Southerland; TY BEARD; VERNON DEBOARD, Personal Representative of the Estate of Katherine DeBoard; JOHN A. DAVIS, JR.; DEBORAH DAVIS; KENNETH COLLINS; KIM COLLINS; CAROLYN HARRISON, Personal Representative of the Estate of Gerald Harrison; KAY ANN RICE; ROBERT RICE; LOIS RONCAL; DARLENE HERONEMA; KATHERINE WOLLASTON; DANIEL WOLLASTON; GEORGE CHOSICH; ELIZABETH CHOSICH; PEGGY BROWN; MARY ANN MINASIAN; LEE ALVIN SMITH; MARY PARKER; BRIAN SUKENIK; LINDA BRUNNER; DENNIS WORKMAN; MARY WATERS; GEORGE SCHMIDT; SHARON SCHMIDT; CLINTON HUMPHREY; TENNA HUMPHREY; BETTY BOSTIC; JIMMY BOSTIC; GEORGIA SUTTON; BRAHA JACKSON; ROBERT MASON; NOEL CLECKLER; FRANCES CLECKLER; MARK LAGANELLI, Personal Representative of the Estate of Lawrence Laganelli; NEILS DAVIS; DON AMBURGEY; JOYCE AMBURGEY; ELBERT CROWDER; TIMOTHY LEROSE; MARGARET LEROSE; DOYLE TURNER, Personal Representative of the Estate of Carolyn Turner; MELVIN KINNEY; ISABELLA

KINNEY; BALDEMAR MARTINEZ; ANNA MARTINEZ; ALBERT SHEPHERD, Personal Representative of the Estate of Emily Shepherd; DORIS JOHNSON; FRED BURROUGH; MONA WINDHAM; RONNIE WINDHAM; WILLIAM HUNT; PHYLLIS HUNT; PINK JONES; ANNIE JONES; MARY DAVIS; JAMES MASON; CATHY MASON; CECIL THOMAS; DEBBIE THOMAS; MARTHA SUE DIXON; BELVA WARD; DONALD BARD; JUDY BARD; JOHN SPAULDING, JR.; LINDA SPAULDING; SHIRLEY MILLER; RONALD MILLER; JACQUELINE FABBRI, Personal Representative of the Estate of Frank Fabbri; INGA REYNOLDS, Personal Representative of the Estate of Gerwin Hermenau; CARLETTA WILLIAMS, Personal Representative of the Estate of James C. Williams, III; TRIO CALDWELL; BEVERLY CALDWELL; EDWIN STREED; MARGARET STREED; DIANNE CRUCE; DOUG HYAK; DAMEON ALBRITTON; JI YONG AHN ALBRITTON; LAUREL TURLEY; ROGER TURLEY; DIANE MANCINELLI; CONNIE LUYE, Personal Representative of the Estate of Evelyn Moss; ROBERT E. SMITH; DORLIS LYLE, Personal Representative of the Estate of James Lyle; GEORGE L. BUSH; EDWIN MARTIN; CHARLES HERSHISER; MARY FRANCES HERSHISER; SHELBY CAMPBELL; PENNY WATSON, Personal Representative of the Estate of Darwin Watson; JOHN HENDRIX; LINDA PERRY,

Appellants in No. 21-1642

JAMES JORDAN; SHARON JORDAN; BOBBY HUGHES, PERSONAL REPRESENTATIVE OF THE ESTATE OF MIRIAM HUGHES; BILLY KARR; SHANNON DAY; CINDY DAY; PATRICIA ALBRECHT RHODES, PERSONAL REPRESENTATIVE OF THE ESTATE OF REX RHODES; BRUCE WEHLING, PERSONAL REPRESENTATIVE OF THE ESTATE OF LEONARD WEHLING, JR.,

Appellants in No.21-2304

v.

TEVA PHARMACEUTICALS USA INC

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
(D.C. Civil Nos. 1-19-cv-02126 and 1-20-cv-01209)
District Judge: Honorable Colm F. Connolly

Argued May 4, 2022

Before: CHAGARES, *Chief Judge*, GREENAWAY, JR. and PORTER, *Circuit Judges*

(Opinion Filed: September 7, 2022)

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OPINION*

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* This disposition is not an opinion of the full Court and, pursuant to I.O.P. 5.7, does not constitute binding precedent.

GREENAWAY, JR., *Circuit Judge*.

Prescription drugs are generally a boon to the health of our populace. Their ability to address maladies is something we have accepted and embraced societally. But unfortunately, prescription drugs often carry a risk of side effects. That risk—and a pharmaceutical company's obligation to warn of the risk of side effects—gives rise to this litigation.

Amiodarone, which is manufactured by Teva Pharmaceuticals USA Inc. ("Teva" or "Appellee"), is a generic version of a prescription drug named Cordarone (produced by Wyeth Pharmaceuticals). Appellants are patients, spouses, heirs, and the estates of decedents who used the drug for its off-label use to treat atrial fibrillation ("a-fib"). They commenced two actions against Teva relating to Teva's manufacture and distribution of Amiodarone.

Appellants allege Teva violated its state law duties, as a generic manufacturer, to warn users regarding Amiodarone's off-label use. Specifically, Teva did not provide federally mandated Medication Guides, and it failed to report all adverse events to the FDA. Also, according to Appellants, Teva either directly or through omission misrepresented that Amiodarone was safe and effective as a treatment for a-fib.

In this consolidated appeal, we will affirm the District Court's dismissal of Appellants' claims because Appellants fail to adhere to the requirements of Rules 8 and 9 of the Federal Rules of Civil Procedure.

I. BACKGROUND

A. Statutory and Regulatory Framework

The Food, Drug, and Cosmetic Act ("FDCA"), Ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 *et seq.*), provides the regulatory framework for prescription drugs in the United States. Under the FDCA, drug manufacturers must seek approval from the United States Food and Drug Administration ("FDA") to bring a new drug to market. The approval processes for brand-name drugs and generic drugs differ significantly.

Brand-name drug manufacturers must first file a New Drug Application. 21 U.S.C. § 355(b)(1), (d). Thereafter, they must prove the drug's safety and efficacy and propose accurate and adequate labeling. *Id.* "As the Supreme Court has recognized, '[m]eeting those requirements involves costly and lengthy clinical testing.'" *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, 751 F.3d 150, 153 (3d Cir. 2014) (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011)).

By contrast, pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282, generic drugs can "gain FDA approval simply by showing equivalence to a . . . drug that has already been approved by the FDA." *In re Fosamax*, 751 F.3d at 153 (quoting *Mensing*, 564 U.S. at 612); *see also* 21 U.S.C. § 355(j)(2)(A)). To do so, generic drug manufacturers must file an Abbreviated New Drug Application. The FDA will provide its approval if the generic drug manufacturer sufficiently demonstrates that "the generic drug and the FDA-approved brand-name drug are

bioequivalent[, and] . . . hav[e] the same active ingredients, . . . route of administration, dosage form, dosage form, dosage strength, and labeling." *In re Fosamax*, 751 F.3d at 153 (citing 21 U.S.C. § 355(j)(2)(A)(ii)-(v)). The purpose of the Hatch-Waxman Act is to "allow[ ] manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *Id.* (quoting *Mensing*, 564 U.S. at 612.).

For drugs with serious side effects, the FDA also requires patient labeling. 21 C.F.R. § 208.1(c) ("Patient labeling will be required if the FDA determines that . . . [t]he drug product is one for which patient labeling could help prevent serious adverse effects."). For those drugs, the manufacturer must provide Medication Guides or the means to produce them to distributors, packers, or authorized dispensers. 21 C.F.R. § 208.24(b).[1] In turn, distributors or packers must provide those guides or the means to produce them to authorized dispensers. 21 C.F.R. § 208.24(c). At the time that a drug is dispensed, these dispensers must then provide the Medication Guide to patients or their agents. 21 C.F.R. § 208.24(e). The FDA approves Medication Guides "to ensure [they

[1] Specifically, § 208.24(b) provides: "[e]ach manufacturer who ships a container of drug product for which a Medication Guide . . . is responsible for ensuring that Medication Guides are available for distribution to patients by either: (1) [p]roviding Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or (2) [p]roviding the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product."

are] consistent with [the information contained] in the package insert." 63 Fed. Reg. at 66386.

Beyond drug approval and labeling, the FDCA and FDA impose other requirements. As relevant here, the FDCA "generally prohibits manufacturers from marketing, advertising, or otherwise promoting drugs for . . . unapproved or 'off-label' uses" (*i.e.*, "therapeutic uses other than their FDA-approved indications"). *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239–40 (3d Cir. 2012) (citing 21 U.S.C. § 331(a) and (d)). However, because "the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for [such] off-label uses." *Id.* (citation omitted). Drug manufacturers must also report adverse drug experiences to the agency.[2] 21 C.F.R. § 314.80(c). Pursuant to Section 314.80, adverse drug experiences are defined as "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." *Id.*

B. Factual and Procedural History

Appellants either are patients who were injured by the drug Amiodarone or sue on behalf of their relatives who were injured by the drug Amiodarone. Although the facts differ slightly among them, the general allegations are the same. Each patient suffered from a-fib and was prescribed Amiodarone. Appellants allege that the patients suffered

[2] Examples of adverse drug experiences include: "[a]n adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action." 21 C.F.R. § 314.80(a).

significant side effects (such as pulmonary fibrosis, pulmonary toxicity, and respiratory failure) as a result of using Amiodarone, including, in some cases, death.

Amiodarone is the generic form of the brand-name drug Cordarone. Teva is a manufacturer of generic Amiodarone. Amiodarone is a drug of "last resort" for patients suffering from ventricular fibrillation and tachycardia. Appendix ("App.") 322. The FDA has not approved Amiodarone for the treatment of a-fib, but physicians prescribe it for this "off-label" purpose. App. 58.

The plaintiffs bring seven claims under Delaware state law: strict liability and negligent failure to warn (Counts 1–2); negligent marketing and sale (Count 3); negligence *per se* (Count 4); strict liability for defective manufacturing under Del. Code § 3302 (Count 5); fraud (Count 6); and a derivative claim for wrongful death (Count 7). Appellants' claims broadly fall into three theories of liability. First, Appellants allege that they did not receive Medication Guides when their Amiodarone prescriptions were dispensed, as required by federal regulations, because Teva failed to make them available to pharmacists in sufficient numbers. Second, Appellants allege that Teva failed to report known adverse events to the FDA. Third, Appellants allege that Teva negligently and fraudulently promoted Amiodarone as approved for the treatment of a-fib or benefitted from others' fraudulent promotion of the off-label use of the drug.

Teva moved to dismiss both cases pursuant to Federal Rule of Civil Procedure 12(b)(6). The District Court granted both motions, holding that the plaintiffs' claims were impliedly preempted by the FDCA. In opposing the motions to dismiss, Appellants concluded by briefly requesting leave to amend their complaints should the District Court

be inclined to grant the motions. However, because the District Court held that the claims were preempted as a matter of law, the court dismissed both complaints with prejudice. Appellants timely appealed. This Court consolidated the appeals on July 21, 2021. Appellants in *Jordan v. Teva Pharmaceuticals USA Inc*, No. 21-2304, adopted the brief filed by Appellants in *Bennett v. Teva Pharmaceuticals USA, Inc.*, No. 21-1642, on October 19, 2021.

After observing a potential issue regarding the District Court's subject matter jurisdiction over these cases, we remanded the orders of the District Court. Specifically, we instructed the District Court to consider whether the Doe defendants were merely nominal defendants that may be dismissed without prejudice or whether to permit the Appellants to amend the *Bennett* complaint to assert jurisdiction under CAFA. Subsequently, the parties filed a joint motion to dismiss the Doe defendants and a petition for rehearing. We granted both requests on August 26, 2022, and now reach the merits.

II. STANDARD OF REVIEW

We review "a district court's decision granting a party's motion to dismiss *de novo*." *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Zuber v. Boscov's*, 871 F.3d 255, 258 (3d Cir. 2017) (quoting *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Pursuant to Rule 8 of the Federal Rules of Civil Procedure, a plaintiff is required to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In addition, under Rule 9, fraud claims are subject to a heightened pleading standard. Fed. R. Civ. P. 9(b); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997) (citation omitted) ("boilerplate and conclusory allegations will not suffice" and "[p]laintiffs must accompany their legal theory with factual allegations that make their theoretically viable claim plausible.").

III. DISCUSSION

As a preliminary matter, we shall address whether Appellants' claims are sufficiently pled pursuant to Rules 8 and 9. "[A]lthough the District Court did not address [the sufficiency of the pleadings], we can affirm based on any grounds supported by the record." *Ridley Sch. Dist. v. M.R.*, 680 F.3d 260, 282 (3d Cir. 2012) (citing *Chambers ex rel. Chambers v. Sch. Dist. Of Philadelphia Bd Of Educ.*, 587 F.3d 176, 183–34 (3d Cir. 2009)).

A. Medication Guide Claim

Appellants allege that "Defendants failed to ensure the Medication Guide was provided to all consumers, including Plaintiffs, in the manner required by law." App. 352 ¶ 188. Not only is this allegation conclusory insofar as it fails to articulate how Teva's provision of the Medication Guide was purportedly deficient, *see Iqbal*, 556 U.S. at 678, but also 21 C.F.R. § 208.24(b)(2) does not impose a requirement that drug manufacturers deliver Medication Guides directly to patients. Rather, § 208.24 permits manufacturers to "[p]rovid[e] the means to produce Medication Guides in sufficient numbers to

distributors, packers, or authorized dispensers." 21 C.F.R. § 208.24(b). Appellants make no factual allegations that support the inference that Appellee failed to do so. Thus, their Medication Guide claim is not plausibly alleged.

B. Failure to Report Claim

Appellants allege "Defendants also failed to report thousands of serious adverse medical events in their exclusive possession to the FDA, health care professionals, and consumers, including Plaintiffs." App. 352. These pleadings are conclusory. Appellants cannot rely on the assumption that because millions of patients are diagnosed with a-fib and Amiodarone is prescribed off-label to treat it, Appellee failed to report or otherwise concealed adverse events. At the very least, Appellants would need to provide examples of countless adverse events that Appellee knew or should have reasonably known about but failed to report to the FDA. Appellants' failure to sufficiently plead such claims necessarily means that their pleadings, to the extent they allege fraud, likewise fail to satisfy the heighted pleading standard of Rule 9.

C. Off-Label Promotion Claim

Appellants allege "Teva 'provided or failed to correct false and misleading information about the indications and uses of Amiodarone provided to physicians via reference materials like the PDR and Epocrates, that are used by physicians in prescribing situations and which the prescribing physicians read and rely on in prescribing Amiodarone to Plaintiffs.'" Appellants' Br. at 49 (citing App. 363). Such allegations are similarly insufficient under Rule 9's heightened pleading standard. Appellants do not identify any specific misrepresentations and instead, generally assert that the information

provided in the reference materials, which Appellants characterize as labeling, was false and misleading.

In addition, Appellants do not plead sufficient factual allegations to support the inference that Teva is responsible for or otherwise contributed to these reference materials. Teva, as a generic drug manufacturer, does not have any control over labeling—that was solely Wyeth's responsibility. *See Mensing*, 564 U.S. at 613 (citation omitted) (explaining that a generic drug manufacturer must "ensur[e] that its warning label is the same as the brand name's").

D. Leave to Amend

Although Rule 15 provides that leave to amend should be "freely give[n] when justice so requires," we will not grant Appellants leave in this case. Fed. R. Civ. P. 15(a)(2). Where, as here, a plaintiff includes a "single sentence, lacking a statement for the grounds for amendment and dangling at the end of her memorandum" in opposition to a motion to dismiss, "a motion for leave to amend was never properly before [the District Court]." *Ramsgate Ct. Townhome Ass'n v. W. Chester Borough*, 313 F.3d 157, 161 (3d Cir. 2002). Thus, the District Court did not abuse its discretion when it dismissed Appellants' claims with prejudice.

IV. CONCLUSION

For the foregoing reasons, we will affirm the District Court's dismissal of Appellants' complaints.