7-24-2023

Christine Jankowski v. Zydus Pharmaceuticals USA Inc

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 22-2212

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CHRISTINE JANKOWSKI; KIRK ALBRECHT; HEIDI ALBRECHT; PATSY ALDRED;
PAUL ALDRED; JOHN ALEXANDER; DON AMBURGEY;
JOYCE AMBURGEY; MAX AUSTIN; CHRISTINE AUSTIN;
MARVIN BAUMAN; ROWENA BAUMAN; TY BEARD;
TOM BELL; NANCY BELL; MARY BLEVINS; RALPH BOOTH;
BETTY BOSTIC; JIMMY BOSTIC; TIMOTHY BRAWLEY;
SUSAN BRAWLEY; SHIRLEY BRINKLEY; JACK BRINKLEY;
TIFFANY BROOKS; LINDA BRUNNER; FRED BURROUGH;
SONJA BUTLER; JAMES D. CALVIN; HELEN CALVIN;
DELBERT CARTER; BOBBIE CARTER; KARMEN CARUSO;
RANIERE CASERTA; COUCHITA CASERTA; JOHN CHAPMAN, SR.;
LOIS CHILDS; NOEL CLECKLER; FRANCES CLECKLER;
JO ANN COLLINGS; KENNETH COLLINS; KIM COLLINS;
RACHEL COOK; JENNITH COONTZ; DONALD COONTZ;
MARY COX; MARY DAVIS; VERNON DEBOARD;
SUSAN FEDORSHA; CHARLES FENDLEY; PATRICIA FENDLEY;
ANDREW FANCHER; DIANE ZAREMBO; MICAH GARTMAN;
PAMELA GIBSON; RUTH GLASCOE;
BARBARA GRANTHAM INDIVIDUALLY;
FRANCIS GROMADZKI; LEE ANN GROMADZKI;
CAROLYN HALE; EUGENE HAMILTON;
JOANN HAMILTON; SHIRLEY HART; DEBORAH HENSLEY;
HENRY HENSON; REX HESS; DELBERT HINKLE;
SARA HUFF; CLINTON HUMPHREY;
TENNA HUMPHREY BRAHA JACKSON; DORIS JOHNSO;
MICHAEL JOHNSTON; PINK JONES; ANNIE JONES;
STEPHANIE KIBODEAUX; BARBARA KING; SAMUEL KING;
DENNIS KOCH; BARBARA KOCH; MARK LAGANELLI;
BEVERLY LANDRUM; DANIEL LEONG; LAURAN LEONG;
FRANCIS LOMBARDI; ANGELA LOMBARDI;
NANCY LOVVORN; KIM LEE LOWE; BERNICE MANZO;
ROBERT MASON; GLENDA MCGUFFIE; BRENDA MEDLER;

GEORGE MILLER; JOHN L. MORRIS; ELIZABETH MORRIS;
LONNIE MYERS; BARBARA MYERS; HANS OMASTA;
WINONA OMASTA; ROBERT PERKINS; LISA PULLEN;
RICHARD REED; VICKI REED; SANDRA RHODES;
CHARLES RHODES; BOBBIE ROBERTS; TROY ROBERTS;
LARRY E. ROBINSON; LOIS RONCAL; JIMMIE ROSS;
KAREN ROTH; RICHARD RYAN; MOHAMMAD SALEEM;
ALBERT SHEPHERD; CYNTHIA SKILES; RAYMOND SKILES;
JEANETTE SMITH-AKYOL; IEDA STURGILL; BRIAN SUKENIK;
GEORGIA SUTTON; WILLIAM TEESCH; CECIL THOMAS;
DEBBIE THOMAS; JOHN NATHAN TIMM; LAUREL TURLEY;
ROGER TURLEY; DOYLE TURNER; JANICE UPTON;
MARTHA VERNON; GEORGE VIOLA; MARY WATERS;
STEWART WILKINS; MARY WILKINS; NANCY WILLIAMS;
JIM WILLIAMS; KATHERINE WOLLASTON;
DANIEL WOLLASTON; JAMES MASON; CATHY MASON;
JACQUELINE FABBRI; ROBERT KIZANIS; VELOMY KIZANIS;
CARLETTA WILLIAMS; ELMO WAYNE DUNCAN;
JOHN BLACKFORD; MAXINE BLACKFORD;
DARLENE GLASGOW; DIANNE CRUCE; DOUG HYAK;
BILL WORTHINGTON; BIRGITTA BENGTSSON;
VERONICA ITANO; DIANE MANCINELLI; JAMES VINSON, JR.;
ROBERT E. SMITH; AMY MILLER; DORIS LYLE;
DAVID WAYNE GORBETT; NORMA GORBETT;
ROBERT GHISELIN; GERI GHISELIN; GEORGE L BUSH;
EDWIN MARTIN; BRENDA BAREFOOT; MARY PARKER;
DON ASH; JANNA ASH; IMOGENE BERRY; FRANCIS DODD;
THERESA GRAVES; ANN MORISEY; CHARLES MORISEY;
HARSHARAN SANDHU; JOHN HENDRIX; LINDA PERRY;
JAMES JORDAN; SHARON JORDAN; CHARLES PRICE;
JAMES ROADCAP, SR.; EDNA ROADCAP; PATRICIA SOPP;
BARBARA CLARK; KRIKOR PECHAKJIAN; DEBRA LISTER;
RAYMOND WRIGHT; JACQLYN CARTER; MARSHA MCCRORY;
CARLA ELLIS; NANCY BARBER; RITA PENNINGTON;
ROBERTA SCHROEDER; CARL SCHROEDER; LOYCE PARR;
THE ESTATE OF MICHAEL BLEVINS, BY AND THROUGH MARY BLEVINS;
THE ESTATE OF MINNIE DARISAW, BY AND THROUGH TIFFANY BROOKS;
THE ESTATE OF RAYMOND BUTLER, BY AND THROUGH SONJA BUTLER;
THE ESTATE OF ROBERT COLLINGS, BY AND THROUGH JO ANN COLLINGS;
THE ESTATE OF KATHERINE DEBOARD, BY AND THROUGH VERNON DEBOARD;
THE ESTATE OF JOSEPH FEDORSHA, BY AND THROUGH SUSAN FEDORSHA;
THE ESTATE OF JULIANNE WINTKER, BY AND THROUGH ANDREW

FANCHER;
THE ESTATE OF WILLIAM GLASCOE, BY AND THROUGH RUTH GLASCOE;
THE ESTATE OF LARRY GRANTHAM, BY AND THROUGH BARBARA GRANTHAM;
THE ESTATE OF BENNY HALE, BY AND THROUGH CAROLYN HALE;
THE ESTATE OF JANE HENSON, BY AND THROUGH HENRY HENSON;
THE ESTATE OF MILDRED CAGLE, BY AND THROUGH SARA HUFF;
THE ESTATE OF PATRICIA JOHNSON, BY AND THROUGH MICHAEL JOHNSTON;
THE ESTATE OF LATUIS KIBODEAUX, BY AND THROUGH STEPHANIE KIBODEAUX;
THE ESTATE OF LAWRENCE LAGANELLI, BY AND THORUGH MARK LAGANELLI;
THE ESTATE OF JOHN LAMDRUM, JR., BY AND THROUGH BEVERLY LANDRUM;
THE ESTATE OF FRANK LOVVORN, BY AND THROUGH NANCY LOVVORN;
THE ESTATE OF JOANN LOWE, BY AND THROUGH KIM LEE LOWE;
THE ESTATE OF ROBERT MEDLER, BY AND THOUGH BRENDO MEDLER;
THE ESTATE OF DORIS HILDEBRAND, BY AND THROUGH KAREN ROTH;
THE ESTATE OF EMILY SHEPHERD, BY AND THROUGH ALBERT SHEPHERD;
THE ESTATE OF CAROLYN TURNER, BY AND THROUGH DOYLE TURNER;
THE ESTATE OF JANICE COVINGTON, BY AND THROUGH JANICE UPTON;
THE ESTATE OF FRANK FABBRI, BY AND THROUGH JACQUELINE FABBRI;
THE ESTATE OF KENNETH GLASGOW, BY AND THROUGH DARLENE GLASGOW;
THE ESTATE OF BETTYE WORTHINGTON, BY AND THROUGH BILL WORTHINGTON;
THE ESTATE OF PHILLIP ITANO, BY AND THROUGH VERONICA ITANO;
THE ESTATE OF LARRY MILLER, BY AND THROUGH AMY MILLER;
THE ESTATE OF JAMES LYLE, BY AND THOUGH DORIS LYLE;
THE ESTATE OF CLARK BAREFOOT, BY AND THROUGH BRENDA BAREFOOT;
THE ESTATE OF ROBERT GRAVES, BY AND THROUGH THERESA GRAVES;
THE ESTATE OF GURDIP SANDHU, BY AND THROUGH HARSHARAN SANDHU;
THE ESTATE OF PHILIP SOPP, BY AND THROUGH PATRICIA SOPP;
THE ESTATE OF ROY L. CLARK, BY AND THROUGH BARBARA CLARK;
THE ESTATE OF MARK ANTHONY, BY AND THROUGH DEBRA LISTER;
THE ESTATE OF SARIANNE WRIGHT, BY AND THROUGH RAYMOND WRIGHT;
THE ESTATE OF JACK CARTER, BY AND THOUGH JACQLYN CARTER;
THE ESTATE OF IVA WALKER, BY AND THROUGH CARLA ELLIS;
THE ESTATE OF JOHN GLYNNE BARBER, BY AND THROUGH NANCY

BARBER;
THE ESTATE OF DELMAS PARR, BY AND THROUGH LOYCE PARR;
ROBERT VINING, 20-13439; ROSLYN VINING, 20-13439;
WILLIAM RAMSAY, 20-13439; SUSAN RAMSAY, 20-13439;
JULENE HARDIN, 20-13439; THE ESTATE OF BENNIE MIKE HARDIN, 20-13439;
BY AND THROUGH JULENE HARDIN; NANCY HANSON, 20-13439;
THE ESTATE OF CLAYTON HANSON, 20-13439; BY AND THROUGH NANCY HANSON,
Appellants

v.

ZYDUS PHARMACEUTICALS USA, INC.

On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3-20-cv-02458)
U.S. District Judge: Hon. Michael A. Shipp

Submitted Under Third Circuit L.A.R. 34.1(a)
July 10, 2023

Before: SHWARTZ, RESTREPO, and CHUNG, Circuit Judges.

(Filed: July 24, 2023)

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.

SHWARTZ, Circuit Judge.

Plaintiffs appeal the District Court's order dismissing their failure to warn claim against generic drug manufacturer Zydus Pharmaceuticals USA, Inc. ("Zydus"). Because the claim is preempted, we will affirm.

I

Zydus manufactures Amiodarone, which is the generic version of Cordarone, a brand-named drug sold by non-party Wyeth Pharmaceuticals, Inc. Wyeth obtained Food and Drug Administration ("FDA") approval to market and sell Cordarone "only as a drug of last resort for patients suffering from documented, recurrent, life-threatening, ventricular fibrillation [("v-fib")], and ventricular tachycardia [("v-tac")]." App. 418 (SAC ¶¶ 166-67). Plaintiffs allege that Wyeth aggressively marketed Cordarone for "off-label" use as a "first line" treatment for non-life-threatening atrial fibrillation ("a-fib"). App. 419 (SAC ¶ 168). According to Plaintiffs, Zydus "directly benefited" from this marketing campaign because physicians began prescribing Amiodarone to those with non-life-threatening a-fib. App. 419-20 (SAC ¶ 168).

In their Second Amended Complaint ("SAC"), Plaintiffs allege that they, their spouses, or the decedents they represent were injured or died after taking Amiodarone to treat a-fib.[1] They sued Zydus claiming that, although it included the FDA-approved warnings regarding Amiodarone's side effects in the drug's packaging and the content of those warnings was adequate, it violated New Jersey's Products Liability Act

[1] Amiodarone's most serious side effect is "pulmonary toxicity/lung disease." App. 424-25 (SAC ¶ 180).

("NJPLA")[2] because it failed to take additional steps to communicate the warnings to Plaintiffs' physicians, such as sending Dear Doctor letters[3] or placing the FDA-approved information in physician reference sources.[4] The District Court dismissed the SAC, holding that Zydus had fulfilled its duty to warn Plaintiffs' physicians by placing the FDA-approved warnings in Amiodarone's packaging. Jankowski v. Zydus Pharms. USA, Inc., No. 20-cv-02458, 2022 WL 1748061, at *4-5 (D.N.J. May 31, 2022).

Plaintiffs appeal.

II[5]

We need not determine whether Zydus fulfilled its duty to warn under New Jersey state law because Plaintiffs' state law claim is preempted by the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. The preemption doctrine stems from the Supremacy Clause of the Constitution, which provides that "the Laws of the United

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[2] The District Court dismissed Plaintiffs' negligence and wrongful death claims because the NJPLA "subsume[d]" them. Jankowski v. Zydus Pharms USA, Inc., No. 20-cv-02458, 2022 WL 1748061, at *3 (D.N.J. May 31, 2022). Plaintiffs do not contest that conclusion on appeal.

[3] A Dear Doctor letter is a mailing "[m]anufacturers and distributors of drugs and the [FDA] occasionally" use to communicate information about drugs to "physicians and others responsible for patient care" when it concerns "a significant hazard to health . . . important changes . . . [or] a correction to [advertising or labeling]." 21 C.F.R. § 200.5.

[4] Plaintiffs also alleged that Zydus had a duty to correct allegedly inaccurate information about Amiodarone in the third-party physician reference sources. The District Court rejected this claim, Jankowski v. Zydus Pharms USA, Inc., No. 20-cv-02458, 2022 WL 1748061, at *5-6 (D.N.J. May 31, 2022), and Plaintiffs do not challenge the Court's conclusion on appeal.

[5] The District Court had jurisdiction under 28 U.S.C. § 1332. We have jurisdiction under 28 U.S.C. § 1291. We review a district court's order granting a motion to dismiss de novo. Krieger v. Bank of Am., N.A., 890 F.3d 429, 437 (3d Cir. 2018). "[W]e may affirm on any ground supported by the record." Laurel Gardens, LLC v. McKenna, 948 F.3d 105, 116 (3d Cir. 2020).

States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Congress may exert its supremacy" through either express or implied preemption. Sikkelee v. Precision Airmotive Corp., 822 F.3d 680, 687 (3d Cir. 2016) ("Sikkelee I"). Because "Congress has not enacted [an express preemption] provision for prescription drugs," we consider only implied preemption. Wyeth v. Levine, 555 U.S. 555, 574 (2009). One way a federal law impliedly preempts a state law is when "compliance with both state and federal regulations is impossible." Sikkelee I, 822 F.3d at 688 (citing PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011)).

Plaintiffs assert that Zydus failed to warn doctors of Amiodarone's risks. The scope of Zydus's duty to warn is impacted by the Hatch-Waxman Amendment to the FDCA. That amendment facilitates the prompt market entry of generic drugs by permitting generic drug manufacturers to file Abbreviated New Drug Applications ("ANDA") in which they "piggyback off of a previously-approved brand-name drug, but [are] required by federal law to match the preapproved brand-name analogue's labeling and composition exactly."[6] Sikkelee I, 822 F.3d at 703 n.20 (emphasis omitted); see 21 C.F.R. § 314.105(c) ("FDA will approve . . . an ANDA after it determines that the drug

[6] On the other hand, entities seeking approval of a brand-name drug must file a New Drug Application ("NDA"), which the FDA will approve "only if it determines that the drug in question is safe for use under its proposed labeling and the drug's probable therapeutic benefits outweigh its risk of harm." Sikkelee I, 822 F.3d at 703 n.20; see 21 C.F.R. § 314.105(c) ("FDA will approve an NDA after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling.").

meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence."). Under this framework, the brand-name manufacturer is responsible for the adequacy and accuracy of its drug's labeling, while a generic drug manufacturer is subject to a "duty of sameness," which requires its label to be identical to the brand-name's label.[7] PLIVA, Inc. v. Mensing, 564 U.S. 604, 613, 616 (2011). The definition of labeling in the prescription drug context is "expansive," Schrock v. Wyeth, Inc., 727 F.3d 1273, 1287-88 (10th Cir. 2013), and includes:

> [b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor . . . ,

21 C.F.R. § 202.1(l)(2) (referring to items the content of which are subject to mislabeling provisions of the FDCA). This indicates that almost every communication with a medical professional concerning a drug and its warnings constitutes "labeling" under FDA regulations.

In Mensing, the Supreme Court held that a state law failure-to-warn claim against a generic drug manufacturer is preempted by the FDCA when the alleged state law duty would violate the duty of sameness by requiring the manufacturer to unilaterally

[7] A generic manufacturer may only change its drug's label "to match an updated brand-name label or to follow the FDA's instructions." PLIVA, Inc. v. Mensing, 564 U.S. 604, 614 (2011).

strengthen or alter its label. 564 U.S. at 618; accord In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II), 751 F.3d 150, 162-63 (3d Cir. 2014). Therefore, given the federal duty of sameness, it would be impossible for a generic manufacturer to comply with any state law obligation requiring it to change its label. Mensing, 564 U.S. at 618.

Plaintiffs' state law failure to warn claim is preempted under Mensing. Plaintiffs do not assert that Zydus's label lacks the FDA-approved warnings concerning Amiodarone. Rather, Plaintiffs allege that New Jersey law required Zydus to take affirmative steps to further alert doctors as to those side effects by, for example, sending the FDA-approved warning information via Dear Doctor letters or placing this same information in other physician reference sources. These communications, however, constitute labeling that is subject to the duty of sameness,[8] and Plaintiffs do not allege that Wyeth warned of its drug's side effects using these means. Thus, if Zydus had unilaterally engaged in such communications, its labeling would have surpassed the labeling provided by Wyeth and run the risk of "inaccurately imply[ing] a therapeutic difference between the brand and generic drugs . . . and be[ing] impermissibly 'misleading.'" Mensing, 564 U.S. at 615. The apparent mismatch would have violated the duty of sameness. Morris v. PLIVA, Inc., 713 F.3d 774, 776-77 (5th Cir. 2013) (holding that a generic manufacturer could not be liable for "failing to convey FDA-

[8] See Mensing, 564 U.S. at 615 (deferring to the FDA's view that Dear Doctor letters qualify as labeling); 21 C.F.R. § 202.1(l)(2) (defining "labeling" to include "references published . . . for use by medical practitioners, pharmacists, or nurses").

approved information" because "the duty of sameness prohibits the generic manufacturers from taking such action unilaterally"); Guarino v. Wyeth, LLC, 719 F.3d 1245, 1249-50 (11th Cir. 2013) ("Whether a warning is placed on the label on the bottle or in letters to distributors, any state law duty requiring generic manufacturers to act unilaterally in this area is preempted by federal law." (quoting Morris, 713 F.3d at 777)); In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 932-33 (6th Cir. 2014) (same). As such, Plaintiffs' claim is preempted.[9]

III

For the foregoing reasons, we will affirm.[10]

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[9] Nothing herein, however, should be read to relieve generic manufacturers of their duty to monitor the safety and effectiveness of their drugs. See, e.g., 21 C.F.R. §§ 314.80, 314.98 (imposing a duty on generic manufacturers to report adverse drug experiences to the FDA). Moreover, we do not comment on other factual scenarios in which a state law duty to warn may not contravene the federal duty of sameness. See, e.g., Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 584 (6th Cir. 2013) (holding that a state tort claim requiring a generic manufacturer to update its label was not preempted where the FDA had previously approved updated brand-name labeling and, thus, federal law also required the generic to update its label). Instead, our holding is limited to the situation here where plaintiffs do not plead that (1) the content of the branded label was inadequate, (2) the brand-name's label changed in any way during the relevant time period, or (3) the brand-name took any additional action to alert doctors to the side effects of the drug. As such, the FDA did not require—and in fact its regulations would not allow—a generic manufacturer to take such action in these circumstances.

[10] Judge Chung concurs in the judgment and reaches this outcome on failure to state a claim grounds. In the context of drugs, the New Jersey Products Liability Act ("NJPLA") creates a rebuttable presumption that a warning is adequate when the warning has been approved by the federal Food and Drug Administration. N.J. Stat. Ann. § 2A:58C-4. "[A]ny duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling." Perez v. Wyeth Lab'ys Inc., 734 A.2d 1245, 1259 (N.J. 1999). Plaintiffs do not allege that Zydus's warnings failed to comply with any federal requirement, either in contents (e.g., using the FDA-approved warning text) or communication (e.g., complying with federal regulations about distributing warnings). Thus, in Judge Chung's view, the NJPLA's rebuttable presumption of adequacy applies to Zydus' warnings. Although the rebuttable

presumption can be overcome in certain "appropriate circumstances," In re Accutane Litig., 194 A.3d 503, 531 (N.J. 2018), in Judge Chung's view, Plaintiffs have not done so. Because in her view Plaintiffs failed to state a claim, Judge Chung does not address whether possible state requirements are preempted under federal law.