7-24-2009

Colleen Grobelny v. Baxter Healthcare

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 08-3475

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COLLEEN MARY GROBELNY;
ROBERT GROBELNY,
Appellants

v.

BAXTER HEALTHCARE CORPORATION; THE AMERICAN RED CROSS; DR. GLENN DUBOV; R.N. NURSE JAYSHE DOE, last name being fictitious; ROBERT WOOD JOHNSON HOSPITAL; JOHN DOES 1-5, said names being fictitious

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On Appeal From the United States District Court
For the District of New Jersey
(D.C. Civ. No. 05-cv-04645)
District Judge: Honorable Peter G. Sheridan

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Submitted Pursuant to Third Circuit LAR 34.1(a)
JULY 22, 2009

Before: RENDELL, FUENTES AND ALDISERT, Circuit Judges

(Opinion Filed: July 24, 2009)

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OPINION

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PER CURIAM

Colleen Mary Grobelny and Robert Grobelny, wife and husband, appeal pro se

from the District Court's entry of summary judgment in favor of Baxter Healthcare Corporation ("Baxter") and The American Red Cross (the "Red Cross"). For the following reasons, we will affirm.

I.

The Grobelnys were represented by counsel at all relevant times prior to this appeal. In 2005, they filed a complaint in the New Jersey Superior Court for Middlesex County, alleging that Colleen suffered severe adverse reactions to intravenous immunoglobulin ("IGIV") treatments administered on February 7 and 8, 2002. Her treating physician, Dr. Bruno Fang, prescribed those treatments in preparation for the removal of her spleen, which Dr. Fang recommended to combat a bleeding disorder called Idiopathic Thrombocytopenic Purpura ("ITP"). The treatments caused her to suffer multiple "thrombotic events"—i.e., the formation of blood clots in a blood vessel, artery or vein. Those events resulted, inter alia, in the permanent reduction of her left kidney function and a pulmonary embolism.

Among the defendants named in the complaint were Baxter and the Red Cross, which allegedly manufactured and distributed the IVIG treatment at issue,[1] and Dr. Fang.

[1]There is some question regarding which precise product Colleen received. She first alleged that she was given either Baxter's Gammagard S/D or the Red Cross's Polygam S/D. She later claimed to have identified the lot number of the IGIV treatment as containing Polygam, but defendants claim that that lot was not cleared for release until the month after she received the treatment. In any event, the warnings for both Gammagard and Polygam are contained in the record and the operative language of each is identical. The defendants and the District Court thus assumed that Colleen received Polygam as plaintiffs assert, and so will we.

Plaintiffs alleged that Baxter and the Red Cross failed to adequately warn of the IVIG treatment's potential adverse reactions and that Dr. Fang committed malpractice in various respects. The state court dismissed the claims against Dr. Fang for noncompliance with New Jersey's affidavit of merit requirement, N.J.S.A. 2A:53A-27, and two other defendant physicians were dismissed in state court as well. The Red Cross, after later being served with the complaint, timely removed the suit to federal court under 28 U.S.C. §§ 1441 and 1446 pursuant to the terms of its federal charter. See 36 U.S.C. § 300105(a)(5) (formerly 36 U.S.C. § 2); American Nat'l Red Cross v. S.G., 505 U.S. 247, 257 (1992); Doe v. American Red Cross, 14 F.3d 196, 197-98 (3d Cir. 1993). Thereafter, plaintiffs voluntarily dismissed their claims against all remaining defendants except Baxter and the Red Cross.

Baxter and the Red Cross filed a motion for summary judgment, arguing that the warnings they issued had been approved by the Food and Drug Administration, that such warnings were thus presumed adequate under New Jersey law, see N.J.S.A. 2A:58C-4, and that plaintiffs had failed to present evidence sufficient to rebut that presumption.[2] Plaintiffs opposed the motion, and to their response attached the report of their expert, Dr. John N.D. Wurpel, who opined that the IVIG treatment caused Colleen's injuries but offered no opinion on the adequacy of the warnings. The District Court denied defendants' motion by order entered August 12, 2007, after finding, in an oral opinion

[2]Defendants renew this argument on appeal. In light of our disposition, we need not reach it.

rendered on Aust 3, 2007, that defendants had presented no proof that the warnings had been approved by the FDA.

Defendants moved for reconsideration, arguing that plaintiffs were required to support their inadequate warning claim with expert testimony but that Dr. Wurpel had offered no opinion on that issue. By order entered April 7, 2008, the District Court concluded that expert testimony was indeed required to show that the warnings were inadequate. The District Court also construed defendants' motion for reconsideration as "more akin" to a motion in limine and scheduled a Daubert hearing, see Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), at which it directed plaintiffs to proffer Dr. Wurpel's testimony.

The hearing was conducted on May 15, 2008, and the District Court entered an opinion and order on May 23, 2008.[3] The District Court ruled once again that expert testimony was required to demonstrate the inadequacy of the warnings. The District Court further ruled that Dr. Wurpel was qualified to testify that the IVIG treatment caused Colleen's injuries and to "explain technical aspects" of the warnings, such as defining the relevant terms, but not to offer an opinion on their overall adequacy. The District Court concluded, however, that plaintiffs could meet their burden of proof with Dr. Wurpel's testimony in conjunction with the expected factual testimony of Dr. Fang (the treating physician, whom the state court had dismissed as a defendant) regarding his

[3]The operative order is docketed at Docket No. 55 and states that it supercedes the order dated May 22, 2008, and docketed at Docket No. 54.

understanding of the warnings. (The District Court wrote that plaintiffs' counsel had made certain representations to it about Dr. Fang's expected testimony. Those representations do not appear of record, and defendants state that they were "not privy" to them.)

Thereafter, the parties deposed Dr. Fang. Defendants then renewed their motion for summary judgment, arguing that Dr. Fang's testimony demonstrates that the warnings were adequate and that plaintiffs had presented no evidence to the contrary. Defendants filed their motion on July 16, 2008, requesting that the District Court hear argument on July 18, 2008 (three days before the case was scheduled for trial). Plaintiffs' counsel did not file a brief in opposition or submit any additional documents to the District Court, but he did not object to this procedure and the parties presented oral argument on July 18. The District Court granted defendants' motion from the bench that same day.[4] Plaintiffs appeal.

II.

We have jurisdiction under 28 U.S.C. § 1291. "Our review of the District Court's decision is plenary, and we apply the same standard as the District Court to determine whether summary judgment was appropriate. A grant of summary judgment is appropriate 'if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant

[4]The transcript of the argument and the District Court's oral ruling erroneously refers to Dr. Fang as "Dr. Frank" throughout.

is entitled to judgment as a matter of law.'" State Auto Prop. & Cas. Ins. Co. v. Pro Design, P.C., 566 F.3d 86, 89 (3d Cir. 2009) (quoting Fed. R. Civ. P. 56(c)) (internal citation omitted). In response to a properly-supported motion for summary judgment, "the non-moving party must point to some evidence in the record that creates a genuine issue of material fact" and "must rebut the motion with facts in the record and cannot rest solely on assertions made in the pleadings, legal memoranda, or oral argument." Berckeley Inv. Group, Ltd. v. Colkitt, 455 F.3d 195, 201 (3d Cir. 2006) (citations omitted). Our plenary review is necessarily limited to the record that was before the District Court. See Caver v. City of Trenton, 420 F.3d 243, 257 (3d Cir. 2005); Fassett v. Delta Kappa Epsilon (New York), 807 F.2d 1150, 1165 (3d Cir. 1986). We review the District Court's rulings regarding the admissibility of expert testimony for abuse of discretion. See Pineda v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008).

The parties and the District Court assumed that this case is governed by the substantive law of New Jersey, where the Grobelnys reside and Colleen received the treatments at issue, and we see no basis to question that assumption. "[T]he New Jersey Product Liability Act . . . is 'the sole basis of relief under New Jersey law available to consumers injured by a defective product.'" Port Auth. of N.Y. & N.J. v. Arcadian Corp., 189 F.3d 305, 313 (3d Cir. 1999) (citations omitted). The Act provides in relevant part:

> [T]he manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning. . . . An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the

> danger and that communicates adequate information on the dangers and safe use of the product, . . . in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

N.J.S.A. 2A:58-C-4. This provision codifies the "learned intermediary" doctrine, under which "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Niemiera v. Schneider, 555 A.2d 1112, 1117 (N.J. 1989).[5] Accordingly, the crucial question is whether the warning was adequate to apprise a physician, not a consumer, of the risks. See id.

We agree that plaintiffs failed to present the District Court with evidence on that question sufficient to raise a genuine issue for trial. The warnings at issue, contained in a package insert, read in relevant part:

> **Precautions**
> **General**
> There is clinical evidence of a possible association between Immune Globulin Intravenous (Human) (IVIG) administration and thrombotic events. The exact cause of this is unknown; therefore, caution should be exercised in the prescribing and infusion of IVIG in patients with a history of cardiovascular disease or thrombotic episodes.
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> ***
> **Adverse Reactions**

[5]The New Jersey Supreme Court has held that this doctrine does not apply to pharmaceutical products that manufacturers market directly to consumers, see Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1257 (N.J. 1999), but there has been no suggestion that the IVIG product at issue here qualifies for that exception.

> ***
> In general, reported adverse reactions to . . . Polygam ®, in patients with either congenital or acquired immunodeficiencies are similar in kind and frequency. Various minor reactions, such as headache, fatigue, chills, backache, leg cramps, lightheadedness, fever, urticaria, flushing, slight elevation of blood pressure, nausea and vomiting may occasionally occur.
>
> ***
> **Idiopathic Thrombocytopenic Purpura (ITP)**
> During the clinical study of Polygam ® for the treatment of [ITP], the only adverse reaction reported was headache which occurred in 12 out of 16 patients (75%).

(Defs.' Mot. for Summ. J., Richard I. Schiff, M.D., Ph.D. Declaration, Ex. 1 at 6-7.)

Plaintiffs argue that these warnings are insufficient because they (1) limit the risk of thrombotic events to patients "with a history of cardiovascular disease or thrombotic episodes," neither of which Colleen had, and (2) convey the impression that the only potential adverse reactions are mild ones such as headaches, which was the only reported reaction for those, like Colleen, with ITP. The question, however, is not how an ordinary consumer might have read these warnings, but how a prescribing physician would read them, "taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician." N.J.S.A. 2A:58-C-4. The District Court properly concluded that evidence in addition to the warnings themselves was necessary to answer that question. The District Court concluded that plaintiffs could meet their burden with (1) the expert testimony of Dr. Wurpel regarding the meaning of terms contained in the warnings (though not their adequacy), and (2) the testimony of Dr. Fang, apparently as a fact witness, regarding his understanding of the warnings. On appeal, plaintiffs challenge

neither the District Court's ruling that expert testimony was required nor its preclusion of Dr. Wurpel from testifying as to the adequacy of the warnings, and we perceive no error in those rulings.[6]

Those rulings left Dr. Fang's still-unreceived testimony as the only evidence potentially relevant to the adequacy of the warnings. Plaintiffs' counsel apparently represented to the District Court that Dr. Fang would testify that he believed the warnings were inadequate. Dr. Fang, however, did not testify to that effect at his deposition. Instead, he testified that, before he prescribed IVIG treatment for Colleen, he had read the warnings and knew, both from the warnings and from other medical sources, that there was an association between IVIG treatment and thrombotic events. (Defs.' Renewed Mot. for Summ. J., Ex. 1 at 15:18-16:9, 17:5-9, 55:21-56:2, 75:6-12.) He further testified

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[6]Dr. Wurpel's report offers no opinion on the adequacy of the warnings. Plaintiffs quote a portion of Dr. Wurpel's deposition testimony, in which he later opined that "I don't believe that these warnings . . . would be sufficient to adequately alert the physician that thrombotic events and renal events were highly likely." That portion of Dr. Wurpel's deposition is not contained in the record, but he testified to the same effect during the Daubert hearing. (May 15, 2009 Trans. at 23.) He also testified, however, that pharmaceutical warnings were not within his expertise, that he has no experience with the FDA or applicable regulations, and that he is not a clinician and has never prescribed medication. (Id. at 27-33.) Moreover, he "waffled" (as the District Court characterized it) on his opinion of the warnings' adequacy, and his final words on the subject were that "it's difficult to make an opinion." (Id. at 51.) For those reasons, the District Court did not abuse its discretion in precluding Dr. Wurpel from testifying to the adequacy of the warnings. Cf. Pineda, 520 F.3d at 254 & n.12 (holding that District Court abused its discretion in preventing engineer from testifying to the necessity of a warning where no warning was given, but opining that if plaintiff's claim was "that an existing warning or instruction was ineffective, misleading, or otherwise defective, a true 'warnings' expert might be required").

that, contrary to plaintiffs' argument, he did not understand the warnings to limit that risk to patients with a history of cardiovascular disease or thrombotic episodes, but read them instead to state that the risk was present for all patients, "with or without" that history. (Id. at 113:8-114:7.) Finally, he testified that he prescribed IVIG treatment notwithstanding the risk of thrombotic events because Colleen had responded positively to the treatment in the past and he believed the risks of treatment were outweighed by the benefits. (Id. at 53:1-54:18, 55:21-56:11, 125:17-126:5.)[7]

In sum, there is no testimony from Dr. Fang in the record that the warnings at issue were inadequate in any way, and the only reasonable inference from his testimony is to the contrary. Plaintiffs came forward with no evidence that might have undermined that testimony, and it raises no issue regarding Dr. Fang's credibility on its face. See Waskovich v. Morgano, 2 F.3d 1292, 1296 (3d Cir. 1993) (facts testified to in "'deposition testimony . . . if there is no contradictory evidence . . . may be accepted as true for summary judgment purposes without an assessment of the credibility of the witness'") (citation omitted). We agree that, in light of Dr. Fang's testimony, and plaintiffs' failure to present any other evidence regarding the adequacy of the warnings, defendants were entitled to summary judgment.

Plaintiffs raise three arguments on appeal. First, plaintiffs assert that Dr. Fang

[7]The record contains only those portions of the transcript of Dr. Fang's deposition testimony that defendants filed with their renewed motion for summary judgment. Plaintiffs did not file any other portions of the transcript with the District Court, and did not argue that any other portion of Dr. Fang's testimony supported their case.

initially believed that Colleen's adverse reaction was caused by a kidney stone. They further assert that Colleen then presented him with an FDA warning regarding the link between IVIG and "clot-related problems," and that Dr. Fang said the information was "very interesting" and that he previously had not been aware of it. On appeal, plaintiffs have presented Dr. Fang's July 17, 2002 note of the office visit memorializing that exchange. Plaintiffs also purport to quote in their reply brief from a portion of Dr. Fang's deposition, at which he apparently acknowledged the contents of that note. Plaintiffs, however, submitted neither Dr. Fang's office note nor that portion of his deposition to the District Court. Plaintiffs nevertheless argue that Dr. Fang's note and other documents are part of the record, apparently because they were produced during discovery or marked as exhibits at depositions. Because none of the parties filed these documents with the District Court, however, they are not included in the record on appeal. See Fed. R. App. P. 10(a). Thus, we may not consider them. See, e.g., Fassett, 807 F.2d at 1165.[8] In addition, plaintiffs did not raise these arguments in the District Court, so they are waived on appeal. See In re Stone & Webster, Inc., 558 F.3d 234, 241 n.8 (3d Cir. 2009).

Second, plaintiffs rely on McNeil v. Wyeth, 462 F.3d 364 (5th Cir. 2007), in which the court reversed the entry of summary judgment after a district court found a pharmaceutical warning label adequate as a matter of law. In that case, however, the

[8]For that reason, defendants' motion to strike portions of plaintiffs' appellate appendix, including Dr. Fang's office note and other documents presented for the first time on appeal, is granted. Plaintiffs' motion to expand the record on appeal is denied.

treating physician gave conflicting testimony about whether he would have prescribed the drug at issue if the pharmaceutical defendant had given him the warnings that the plaintiff claimed it should have given. See id. at 372. The record contains no such conflicting testimony by Dr. Fang here. The legal context is also distinct. In McNeil, the plaintiff presented substantial evidence on the issue of whether the warnings were adequate, and the treating physician's testimony did not relate to that issue. Instead, it related to the issue of causation—i.e., whether the physician would have prescribed the medication if he had been given an adequate warning. In this case, the District Court did not reach that issue, and we need not do so, because plaintiffs failed to present sufficient evidence that the warning was inadequate in the first place.

Finally, plaintiffs devote much of their briefs to arguing that Dr. Fang's decision to prescribe IVIG treatment was unreasonable. Dr. Fang, however, was dismissed as a party before this suit was removed to federal court and that dismissal is not before us for review. Those arguments are not relevant to any issue on appeal, and we express no opinion on them.

Accordingly, the judgment of the District Court will be affirmed.