NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15-2059

IN RE: AVANDIA MARKETING, SALES PRACTICES
AND PRODUCTS LIABILITY LITIGATION

Linda Schatz; John Schatz,
Appellants

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(D.C. Nos. 2:12-cv-01588, 2:07-md-01871)
District Judge: Honorable Cynthia M. Rufe

Submitted Under Third Circuit LAR 34.1(a)
January 29, 2016

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

(Opinion Filed: February 12, 2016)

OPINION*

SHWARTZ, Circuit Judge.

Linda and John Schatz appeal from the orders: (1) striking their sur-reply and physician's affidavit submitted in opposition to Glaxosmithkline LLC's ("GSK") motion

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

for summary judgment and (2) granting GSK's summary judgment motion. For the reasons that follow, we will affirm both orders.

I

Mrs. Schatz suffers from Type II diabetes. Her physician, Dr. Scott McKimm, prescribed her Avandia, a GSK diabetes medication, starting in 2002. Mrs. Schatz responded well to Avandia and continued on the medication for several years. In February 2007, GSK informed doctors of a 2006 study that found women taking Avandia had increased risk of bone fractures, and in March 2007, GSK updated the Avandia Package Insert and the Patient Information Leaflet to include a warning about fractures.[1] Dr. McKimm testified that he regularly read letters from pharmaceutical companies and considered label warnings in making prescription decisions. Dr. McKimm could not recall whether or when he read the letter GSK issued in response to the 2006 study, but he testified that the updated Avandia label would have been available to him as of March 2007.

In May and October 2007, respectively, Mrs. Schatz had accidents and fractured first her spine, and then her ribs and scapula. According to Mrs. Schatz's medical records, she ceased taking Avandia at some point in 2007,[2] but in November 2007 she

[1] In December 2006, the New England Journal of Medicine published a diabetes study which found that women taking Avandia had an increased risk of fractures in the upper arm, hand, and foot.

[2] According to Mrs. Schatz's medical records, she stopped taking Avandia sometime between March and July 2007, although the Amended Complaint, Avandia litigation Plaintiff Fact Sheet, and expert report indicate that she continuously took Avandia between March and November 2007.

resumed taking the drug for approximately four weeks before Dr. McKimm switched her to a different medication due to the risk of bone fractures from Avandia use.

The Schatzes filed suit against GSK, asserting claims of negligence, negligent misrepresentation, strict products liability, breach of warranty, fraud, and unjust enrichment arising out of Mrs. Schatz's use of Avandia, which allegedly made her bones more susceptible to fracture. During discovery, GSK deposed Dr. McKimm. Dr. McKimm testified that even if GSK had warned of the risks of bone fracture associated with Avandia, he would still have prescribed the drug to Mrs. Schatz. The Schatzes' counsel did not ask Dr. McKimm any questions. Following the close of discovery, GSK moved for summary judgment. After the Schatzes filed a response in opposition to GSK's motion, GSK filed a motion for leave to file a reply in accordance with the District Court's case management rules. While GSK's motion for leave was pending, the Schatzes filed a sur-reply, to which they attached an affidavit from Dr. McKimm ("McKimm Affidavit"),[3] without seeking leave of court. Two days later, the District Court granted GSK's motion for leave and deemed the reply filed.

Thereafter, GSK filed a motion to strike the Schatzes' sur-reply, or in the alternative, for leave to re-depose Dr. McKimm. The District Court granted both GSK's motion to strike and its motion for summary judgment and dismissed all of the Schatzes' claims with prejudice. The Schatzes appeal the orders granting these two motions.

[3] In his affidavit, which was filed seven months after his deposition, Dr. McKimm stated that had GSK provided a different and more thorough warning of the risks of bone fracture associated with Avandia, he never would have prescribed the drug to Mrs. Schatz.

II[4]

A

The Schatzes contend that the District Court abused its discretion in granting GSK's motion to strike their sur-reply and the accompanying McKimm Affidavit.

Fed. R. Civ. P. 16 authorizes a court to enter orders that govern pretrial proceedings. To this end, the District Court's individual case management rules notify parties that the District Court will issue a scheduling order directing them to use one of two methods to file a motion for summary judgment. The rules explain that the District Court will generally direct the parties to use an "alternative" method and that a "traditional" method will be used in rare cases. Under the District Court's alternative method, a moving party must identify the issues in outline form in no more than five double-spaced pages, and replies and sur-replies are permitted as of right. By contrast, its traditional method permits a motion for summary judgment to reach twenty-five double-spaced pages, and provides that any reply or sur-reply "may be filed only after obtaining leave of Court." App. 414. In its scheduling order, the District Court did not specify the

[4] The District Court had jurisdiction pursuant to 28 U.S.C. § 1332. We have jurisdiction under 28 U.S.C. § 1291. We review the District Court's decision to strike the Schatzes' sur-reply and accompanying affidavit for abuse of discretion. See Meditz v. City of Newark, 658 F.3d 365, 367 n.1 (3d Cir. 2011). We review the District Court's decision on summary judgment de novo. Dee v. Borough of Dunmore, 549 F.3d 225, 229 (3d Cir. 2008). Summary judgment is appropriate where, drawing all reasonable inferences in favor of the non-moving party, "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). "An issue is genuine only if there is a sufficient evidentiary basis on which a reasonable jury could find for the non-mov[ant.]" Kaucher v. Cnty. of Bucks, 455 F.3d 418, 423 (3d Cir. 2006) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)).

method to be used, directing only that "[a]ll Daubert or dispositive motions shall be filed by May 30, 2014." Schatz v. GSK, No. 12-1588, ECF No. 5 at 3 (E.D. Pa. Feb. 11, 2014).

When GSK moved for summary judgment, it chose the traditional method, filing a fourteen-page memorandum that did not use the alternative outline format, which the District Court accepted and to which the Schatzes did not object. Consistent with the traditional method, GSK also moved for leave to file a reply to the Schatzes' response, a request the District Court ultimately granted. The Schatzes, however, deviated from the District Court's case management rules when they filed their sur-reply without seeking leave of court. The District Court granted GSK's motion to strike because the Schatzes failed to comply with the traditional method's requirement that they seek leave of court to file a sur-reply, and because they sought to offer a contradictory affidavit from Dr. McKimm even though they had the opportunity to elicit testimony from him at his deposition.

Because the traditional method was employed, the Schatzes had no basis to unilaterally attempt to use the alternative method to file their sur-reply and the McKimm Affidavit, and the District Court acted within its discretion to strike them for failure to comply with its rules. Cf. Knoll v. City of Allentown, 707 F.3d 406, 411 (3d Cir. 2013)(finding no abuse of discretion where the trial court dismissed post-trial motions for failure to comply with local rules). It was also within the District Court's discretion to strike the sur-reply because it sought to introduce the McKimm Affidavit, which contradicted Dr. McKimm's deposition testimony.

When a deponent's post-deposition affidavit conflicts with his prior testimony, a district court may disregard the affidavit to prevent a party from "creat[ing] a material issue of fact to defeat summary judgment by filing an affidavit disputing his or her own sworn testimony without demonstrating a plausible explanation for the conflict."[5] Baer v. Chase, 392 F.3d 609, 625 (3d Cir. 2004) (citation omitted); EBC, Inc. v. Clark Bldg. Sys., Inc., 618 F.3d 253, 269-70 (3d Cir. 2010); Jiminez v. All Am. Rathskeller, Inc., 503 F.3d 247, 253 (3d Cir. 2007). A district court may strike such an affidavit based upon the timing of the affidavit, whether any other record evidence supports the affidavit, and whether there is a plausible explanation for the contradiction. See Clark Bldg. Sys., 618 F.3d at 269-70; Jiminez, 503 F.3d at 253; see also In re Fosamax Prods. Liab. Litig., 707 F.3d 189, 195 (2d Cir. 2013) ("The timing of the testimony recanting the prior sworn testimony clearly increased the likelihood that it was intended solely to defeat the motion for summary judgment.").

Each of these considerations supports striking the McKimm Affidavit. The McKimm Affidavit was produced more than seven months after the doctor's deposition. Moreover, the Schatzes could have, but did not, question Dr. McKimm at his deposition. Furthermore, Dr. McKimm was informed that he had thirty days to review his deposition

[5] This is known as the "sham affidavit" doctrine. This Court defines a "sham affidavit" as "a contradictory affidavit that indicates only that the affiant cannot maintain a consistent story or is willing to offer a statement solely for the purpose of defeating summary judgment." Jiminez v. All Am. Rathskeller, Inc., 503 F.3d 247, 253 (3d Cir. 2007); see also Martin v. Merrell Dow Pharm., Inc., 851 F.2d 703, 706 (3d Cir. 1988) ("If a party who has been examined at length on deposition could raise an issue of fact simply by submitting an affidavit contradicting his own prior testimony, this would greatly diminish the utility of summary judgment." (internal quotation marks omitted)).

transcript and submit any changes. He submitted none. While the Schatzes claim before us that "the sur-reply and affidavit directly address arguments made by GSK in its reply brief that Dr. McKimm's testimony was unequivocal in GSK's favor," Appellants' Br. 20, GSK argued this point in its opening brief before the District Court, see App. 52-53, and thus the Schatzes were on notice of GSK's position and had the opportunity to present their arguments in their response. Additionally, the Schatzes admit that Dr. McKimm did not author his affidavit until the day they filed their sur-reply, suggesting that the affidavit might simply be a belated attempt to avoid a damaging admission made by their witness. Finally, the Schatzes failed to provide an "explanation for the conflict between the prior deposition and the affidavit." Jiminez, 503 F.3d at 253 (internal quotation marks omitted). For these reasons, the District Court did not abuse its discretion in striking the Schatzes' sur-reply and McKimm Affidavit.

B

The Schatzes also challenge the District Court's order granting GSK's motion for summary judgment. The Schatzes allege that GSK failed to warn of the risk of bone fractures posed by taking Avandia. A drug manufacturer has a duty to warn a prescribing physician of a drug's dangerous side effects, rather than the patient taking the drug. Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971). A manufacturer is subject to liability for failure to warn only where it "fails to exercise reasonable care to inform [the physician] of the facts which make the product likely to be dangerous." Lineberger v. Wyeth, 894 A.2d 141, 150 (Pa. Super. Ct. 2006).

To prove a failure to warn claim, a plaintiff must establish proximate cause by showing that had the manufacturer issued a proper warning to the plaintiff's prescribing physician, the physician would not have prescribed the drug to the plaintiff and the injury would have been avoided.[6] Demmler v. Smithkline Beecham Corp., 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996); Lineberger, 894 A.2d at 150 (explaining that a prescribing physician "is expected to make an independent medical judgment in determining whether a given drug is appropriate for a particular patient"); see Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super. Ct. 2010) (describing physician's duty to understand a drug's characteristics). Summary judgment is properly granted on a failure to warn claim where the record "is devoid of evidence to support [the] argument that a different warning would have altered [the physician's] prescribing methods . . . ." Lineberger, 894 A.2d at 150; Demmler, 671 A.2d at 1156.

The Schatzes contend, among other things,[7] that the District Court erred in granting summary judgment because Dr. McKimm's testimony that he would have prescribed Avandia to Mrs. Schatz notwithstanding the risk of fractures was equivocal.[8]

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[6] This is known as the "learned intermediary" doctrine. Lineberger, 894 A.2d at 150.

[7] The Schatzes do not appeal the District Court's ruling that all of their claims were grounded in GSK's alleged failure to warn. Because we conclude that the Schatzes' failure to warn claim fails, we need not address other arguments, such as their argument that GSK failed to exercise reasonable care because it did not conduct safety studies related to skeletal risks in a timely manner, and therefore did not disclose a complete risk profile to prescribing physicians.

[8] Because the District Court properly struck the Schatzes' sur-reply and the McKimm Affidavit, the affidavit does not impact the proximate cause analysis. The Schatzes' expert's opinion also has no impact on this subject. The expert opined that the Avandia label should have warned of the risk of hip and spine fractures in older women,

The record, however, shows that his testimony was clear. At his deposition, Dr. McKimm was asked "[c]onsidering what you know about Avandia today, do you have any reason to believe that a different warning would have changed your decision to prescribe Avandia to Mrs. Schatz?" App. 279. In response, Dr. McKimm first discussed how a black box warning "certainly would have caught [his] eye."[9] App. 279. When counsel rephrased the question to ask "[i]f a patient presented to you today with the same clinical course as Mrs. Schatz presented to you with back in 2002 . . . would you prescribe Avandia to that patient today?" App. 279-80, Dr. McKimm responded "to be honest with you, I would." App. 280.

The context demonstrates that counsel's question was aimed at ascertaining what Dr. McKimm would do based on his current knowledge of Avandia's fracture risks, not his knowledge when he initially prescribed the drug to Mrs. Schatz. Dr. McKimm unequivocally testified that he would prescribe Avandia today to a patient who presented as Mrs. Schatz did in 2002. Moreover, beyond referencing the usefulness of a black box warning, Dr. McKimm never suggested that any other type of warning would have impacted his prescribing decision. Although Dr. McKimm may have taken Mrs. Schatz

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but his opinion was based upon studies published after Mrs. Schatz stopped taking Avandia, and dealt with a population of which Mrs. Schatz was not a part, namely older women. See Leibowitz v. Ortho Pharm. Corp., 307 A.2d 449, 458 (Pa. Super. Ct. 1973) ("A warning should not be held improper because of subsequent revelations."); see App. 240 (2011 letter from Dr. McKimm to the Schatzes' counsel describing Mrs. Schatz as a "young female").

[9] Only the FDA may issue a black box warning, however, so GSK could not have included such a warning absent a directive from the FDA. See PLIVA Inc. v. Mensing, 131 S. Ct. 2567, 2577 (2011) (holding that a finding of liability may not be based on a manufacturer's alleged failure to strengthen a warning label where FDA regulations prohibit it from doing so).

off of Avandia for some period in 2007, the record is clear that Dr. McKimm prescribed it to her again in November 2007—after she had sustained multiple fractures, after the publication of a fracture study, after GSK informed physicians like Dr. McKimm of the risk of fractures, and after GSK updated the Avandia Package Insert and Patient Information Leaflet.[10]

Because the Schatzes failed to adduce evidence sufficient to establish "some reasonable likelihood that an adequate warning would have prevented [Mrs. Schatz] from receiving the drug," Demmler, 671 A.2d at 1155 (internal quotation marks omitted), the District Court appropriately granted summary judgment in favor of GSK.

III

For the foregoing reasons, we will affirm the orders of the District Court granting GSK's motion to strike the Schatzes' sur-reply and McKimm Affidavit and granting GSK's motion for summary judgment.

[10] The Schatzes also argue that the fact that Dr. McKimm took Mrs. Schatz off of Avandia "immediately after" discovering the increased risk of fractures through his own research creates a genuine issue of material fact regarding his prescribing decision. Appellants' Br. 23-27. This assertion fails to account for the fact that Dr. McKimm continued to prescribe Avandia after GSK disseminated information about fracture risks, and even after Mrs. Schatz experienced fractures.