10-5-2016

William Bock v. Novartis Pharmaceuticals Corp

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15-3696

WILLIAM M. BOCK

v.

NOVARTIS PHARMACEUTICALS CORPORATION

BRUCE E. BOCK; BONNIE J. BOCK, As personal representatives of the Estate of William M. Bock, Deceased,
Appellants

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
(D.C. Civ. No. 2-10-cv-01338)
District Judge: Honorable Mark R. Hornak

Submitted Under Third Circuit L.A.R. 34.1(a)
September 13, 2016

Before: CHAGARES, GREENAWAY, JR., and RESTREPO, *Circuit Judges*.

(Opinion Filed: October 5, 2016)

OPINION*

GREENAWAY, JR., *Circuit Judge*.

The Estate of William M. Bock ("Appellant") appeals from the District Court's grant of summary judgment in favor of Novartis Pharmaceuticals Corporation ("Novartis") with respect to Appellant's failure-to-warn claim.[1] Specifically, Appellant argues that Novartis failed to provide adequate warning to doctors that two of its drugs—Aredia and Zometa—contribute to the risk of developing osteonecrosis of the jaw ("ONJ"), a condition Mr. Bock developed. For the following reasons, we will affirm the grant of summary judgment.

I. BACKGROUND

Aredia and Zometa are intravenously administered bisphosphonates, or drugs that inhibit bone resorption in patients suffering from hypercalcemia of malignancy ("HCM"), a "potentially life-threatening" complication of cancer caused by "the release of calcium into the blood from increased bone resorption that is uncoupled from bone formation." (JA 57.) In 2003, scientific studies began to suggest a potential link between bisphosphonate therapy and the development of ONJ in some patients.

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

[1] Mr. Bock passed away from colon cancer on July 18, 2011. His estate, represented by two of his children, Bruce Bock and Bonnie Bock, is pursuing this action.

In 2003 and 2004, Novartis revised the packaging of Aredia and Zometa to include notice that cases of ONJ had been reported and that caution with respect to dental procedures for patients on these medications was advisable. Novartis sent out a "Dear Doctor" letter in 2004 to apprise the medical community that the package inserts for both drugs had been amended to contain the following language:

> **Precautions**
>
> Osteonecrosis of the Jaw
>
> Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis.
>
> A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g., cancer, chemotherapy, corticosteroids, poor oral hygiene).
>
> While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

(JA 131.) The letter also noted that the "Adverse Reactions" section of the inserts for both drugs had been revised to include the following notice:

> **Post-Marketing Experience**
>
> Cases of osteonecrosis (primarily involving the jaws) have been reported in patients treated with bisphosphonates. The majority of the reported cases are in cancer patients attendant to a dental procedure. Osteonecrosis of the jaw has multiple well documented risk factors including a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids) and co-morbid conditions (e.g., anemia, coagulopathies, infection, pre-existing oral disease). Although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged. (See PRECAUTIONS)

(JA 132.) In May 2005, Novartis sent out a second "Dear Doctor" letter, which reminded doctors of the changes to the Precautions section of the package inserts for Aredia, provided some information about ONJ, and stressed that, during "treatment, invasive dental procedures should be avoided, if possible." (JA 133.)

Mr. Bock, who had a history of prostate and colon cancer, was diagnosed with progressive anemia, leukopenia, hypercalcemia of malignancy, and multiple myeloma in August and early September 2005. To treat Mr. Bock's HCM, oncologist Dr. Mohammed Islam prescribed Aredia. Dr. Islam noted that he had planned to switch Mr. Bock to Zometa, a bisphosphonate considered more potent than Aredia, but that Mr. Bock ceased treatment with Dr. Islam before the drug switch occurred.

Dr. Islam was on Novartis's list of "Dear Doctor" letter recipients. (JA 136.) In his deposition, Dr. Islam stated that he was aware, back in 2005, "that osteonecrosis of the jaw was a potential side effect of Aredia," and that he believed that he would have discussed this potential side effect with Mr. Bock given that it was his practice to discuss

the risk of ONJ with his patients. (JA 151.) Dr. Islam added that it was the standard of care in 2005 to prescribe Aredia or Zometa to treat patients with multiple myeloma, and that, if he were treating a patient similar to Mr. Bock today, he would still prescribe Aredia or Zomeda to that patient.

In September 2005, in light of his multiple myeloma, Mr. Bock began to see Dr. Mounzer Agha, a hematologist who was also on Novartis's list of "Dear Doctor" letter recipients. Dr. Agha noted that, by September 2005, he was prescribing bisphosphonates for all his patients with multiple myeloma, in keeping with the established standard of care for that condition. Dr. Agha's records dated March 23, 2006, state that Mr. Bock would "continue on Zometa indefinitely to protect his bones" and counter his myeloma. (JA 207.) The records further indicate that "[i]t was also explained to the patient that, if he had any problems with his teeth, he needs to inform us right away. It was also explained that any dental surgery can cause necrosis of the jaw, which is rare, but he may need to be on prophylactic antibiotics." (*Id.*) The records specify that "[t]his was explained in detail to the patient and the family." (*Id.*)

Dr. Agha testified that ONJ in myeloma patients receiving bisphosphonate therapy "is a rare complication" that, "cumulatively, can be up to three percent with ongoing use." (JA 177.) Dr. Agha noted the severity of ONJ and stated that, "if you recognize it, you should stop the drug." (JA 177.) Dr. Agha explained, however, that this does not mean that he would discontinue bisphosphonate therapy for fear of ONJ. Rather, he testified that, "even today," he "believe[s] that bisphosphonates are very important, so

[he] would not stop the drugs." (JA 180.) He explained, "What I usually do is hold the drug for a month before any dental procedures, and I have them get the dental procedure, and then I have them restart the drug." (*Id*.)

Dr. Agha added that, "unless [patients] have a real significant dental issue[], usually the treatment benefit [of bisphosphonates] outweighs any potential risk of osteonecrosis" (JA 181), and that it is "very critical to move ahead" with bisphosphonate treatment. (JA 182.) With respect to ONJ, Dr. Agha observed: "The risk is so small, and, for the most part, it is not life threatening or anything compared to the tremendous benefit people get from the [bisphosphonate therapy]." (JA 191.) Dr. Agha affirmed that bisphosphonates are "still the standard of care of multiple myeloma patients" (JA 197), and that, in the intervening years, the "bisphosphonate therapy recommended for patients like Mr. Bock [has not] changed at all." (JA 198.)

Dr. Agha's records indicate that he did not see Mr. Bock between January 2008 and March 2009. On May 26, 2009, Dr. Agha noticed that Mr. Bock had a lesion. Mr. Bock had undergone a "dental extraction without telling anybody," and, in light of the lesion that he developed afterward, Dr. Agha "wanted [Mr. Bock] to go see an osteonecrosis specialist which is Dr. Kail." (JA 195.)

Dr. Kent Galey was the dentist who performed two extractions on Mr. Bock, one in 2008 and one in 2009, along with two other dental surgeries. Dr. Galey testified that he was aware that Mr. Bock was taking Zometa. Galey noted that he was not familiar with that drug or bisphosphate therapy when he began treating Bock, so he "would have

looked [it] up." (JA 219.) Although Dr. Galey had no recollection of discussing Zometa and ONJ with Mr. Bock, Galey believed that he would probably have discussed the potential risk of ONJ with Mr. Bock, in keeping with his "general practice [of] informing patients of potential risks of medications they may be on that might affect your treatment of them." (JA 218.) Dr. Galey agreed that, "[r]egardless of the recommendation to avoid extraction in patients taking bisphosphonates like Zometa," he believed it appropriate to perform the extractions "because leaving the tooth in could pose more significant risks for Mr. Bock than taking the tooth out," particularly since "cancer patients are particularly susceptible to infections." (JA 230.)

Dr. Michael Kail, to whom Dr. Agha referred Mr. Bock upon spotting the lesion he had developed, is an oral surgeon who specializes in osteonecrosis. Dr. Kail's May 2009 records indicate that he diagnosed Mr. Bock with osteonecrosis, that Mr. Bock needed to have one tooth extracted and the area surrounding that tooth debrided, and that Dr. Kail planned to confer with Dr. Agha about placing Mr. Bock's Zometa treatment on hold. Those records also state: "[Mr. Bock] is aware that surgery could potentially aggravate the problems of the left maxilla secondary to osteonecrosis. This was reviewed extensively with him." (JA 238.) In November 2010, Dr. Kail extracted another of Bock's teeth and removed necrotic bone from the surrounding area. Dr. Kail testified that, in his "opinion within a reasonable degree of medical certainty," Mr. Bock's bisphosphonate treatment "was a component in him developing osteonecrosis." (JA 251.)

On October 10, 2010, Mr. Bock filed a five-count complaint against Novartis in the United States District Court for the Western District of Pennsylvania,[2] alleging: strict liability (Count One); negligent manufacture (Count Two); negligent failure to warn (Count Three); and breach of express and implied warranties (Counts Four and Five). On April 9, 2015, Appellant moved to dismiss Counts One, Four, and Five without prejudice; this motion was granted the next day.

Meanwhile, on March 19, 2015, the District Court issued an order directing Novartis to "file any summary judgment motion on matters not requiring or related to expert discovery on or before April 18, 2015." (JA 262.) Novartis moved for summary judgment on the remaining counts on April 17, 2015. The District Count granted summary judgment in favor of Novartis on October 7, 2015. Appellant filed a timely notice of appeal on November 4, 2015, to challenge the District Court's disposition of the failure to warn claim.

II. JURISDICTION & STANDARD OF REVIEW

The District Court had jurisdiction over this case pursuant to 28 U.S.C. § 1332. This Court has jurisdiction under 28 U.S.C. § 1291.

We exercise plenary review over a grant of summary judgment and we apply the same legal standards as the District Court. *Faush v. Tuesday Morning, Inc.*, 808 F.3d 208, 215 (3d Cir. 2015). A court grants summary judgment when "there is no genuine

[2] The case was transferred to the Middle District of Tennessee on November 17, 2010, but was conditionally remanded to the Western District of Pennsylvania by the Judicial Panel on Multi-District Litigation on September 26, 2014.

dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Facts are "material" for purposes of Rule 56 if their "existence or nonexistence might impact the outcome of the suit under the applicable substantive law." *Santini v. Fuentes*, 795 F.3d 410, 416 (3d Cir. 2015) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Disputes over material facts are "genuine" when "a reasonable jury could return a verdict for the nonmoving party." *Id.* (quoting *Anderson*, 477 U.S. at 248).

It is the moving party's burden to demonstrate that the record reflects no genuine dispute of material fact. *Goldenstein v. Repossessors Inc.*, 815 F.3d 142, 146 (3d Cir. 2016). Once this occurs, the burden shifts to the nonmovant to "identify facts in the record that would enable them to make a sufficient showing on essential elements of their case for which they have the burden of proof." *Willis v. UPMC Children's Hosp. of Pittsburgh*, 808 F.3d 638, 643 (3d Cir. 2015) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). In assessing whether the parties have carried their respective burdens, courts must "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 (3d Cir. 2016) (quoting *Montone v. City of Jersey City*, 709 F.3d 181, 189 (3d Cir. 2013)).

III. DISCUSSION

As with other claims sounding in negligence, negligent failure-to-warn claims require showing a duty, a breach, and causation:

> Assuming that a plaintiff has established both duty and a failure to warn, a plaintiff must further establish proximate causation by showing that had defendant issued a proper warning [ ], he would have altered his behavior and the injury would have been avoided. To create a jury question, the evidence introduced must be of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug.

Maya v. Johnson & Johnson, 97 A.3d 1203, 1213–14 (Pa. Super. Ct. 2014), *reargument denied* (Sept. 25, 2014), *appeal denied*, 112 A.3d 653 (Pa. 2015) (alterations in original) (quoting *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676–77 (Pa. Super. Ct. 2010)). Pennsylvania law recognizes that "[p]roximate cause is an essential element in a failure to warn case," and defines proximate cause "as a substantial contributing factor in bringing about the harm in question." *Id.* (quoting *Cochran*, 3 A.3d at 676).

In cases that "involv[e] the failure to warn of risks associated with prescription drugs, Pennsylvania applies the learned intermediary doctrine," pursuant to which "a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the facts which make the drug likely to be dangerous." *Cochran*, 3 A.3d at 676 (citations omitted). Proximate causation may be shown in learned intermediary cases through evidence that, if properly warned, the doctor either would have declined to prescribe a particular drug or would have detailed the known risks for the patient, who would then have declined the medication. *See Daniel v. Wyeth Pharm., Inc.*, 15 A.3d 909, 925 (Pa. Super. Ct. 2011) ("Sufficient evidence of record exists in this case permitting the jury to find that if Wyeth had issued adequate warnings regarding the risk

of breast cancer, Dr. Haggard would have altered his prescribing practices for Prempro (by specifically advising Daniel of the risk of breast cancer), and Daniel's injury would have been avoided since Daniel would have declined the prescription.").

The District Court granted summary judgment in favor of Novartis after finding that Appellant could not demonstrate causation. The Court observed that Mr. Bock's death precluded any testimony that he would have declined to take bisphosphonates if he had received more or different information about the risk of ONJ. (JA 18.) The Court also emphasized the treating physicians' testimony that they

> were well aware of the risk of ONJ at the time that they prescribed the drugs[,] . . . that they would certainly have discussed that risk with Bock, . . . and that they would still prescribe the drug today if presented with a patient such as Bock because, in their medical judgment, the benefits of the drug significantly outweigh the risks.

(JA 17–18 (citations and internal citations omitted).)

We agree with the District Court's assessment that the evidence in this case, described at length above, precludes a showing of proximate causation. Appellant has not made the requisite prima facie showing that Mr. Bock would have received a different treatment—either through his own informed decision or through his doctors' determinations—if the warnings provided by Novartis had been more detailed. Indeed, the evidence mustered paints the opposite picture, particularly the fact that Mr. Bock, though informed by Dr. Agha of the risks of dental procedures and the concomitant need to inform his doctor of the need for any dental work, scheduled tooth extractions without

consulting Dr. Agha. Also compelling is the testimony that the considerable threat of infection rendered the dental procedures unavoidable and that, even to this day, the doctors would not have managed Mr. Bock's treatment any differently. Because proximate causation is an essential element of a failure-to-warn claim, we conclude that summary judgment was appropriate in this matter.

In so concluding, we reject Appellant's challenge not only to the consistency and credibility of the medical testimony,[3] but also to the contents of the warning at issue. Appellant contends that summary judgment was inappropriate because it is not clear what "information . . . should have been disclosed by an adequate warning, including the degree or extent of the actual risk of developing ONJ, and the many factors that no doubt affect the degree of risk, such as degree, frequency, and duration." (Appellant Br. 13.) Appellant adds that, because the grant of summary judgment preceded the introduction of any expert testimony, there is no way to determine what Mr. Bock's physicians "would

[3] Appellant argues that Dr. Agha's testimony reveals that he has, in fact, changed his prescribing practices since 2005 and that he did not always withhold Zometa from patients prior to dental procedures. This assertion is controverted by Dr. Agha's response that what he stated of bisphosphonate treatment was both "[t]rue today" and "true back in 2005." (JA 182.)

Appellant's argument that "there is a high probability that Mr. Bock's injuries would have been avoided" if Dr. Galey had been adequately warned of the risks of ONJ that accompany Zometa treatment is similarly undercut by the record. First, Dr. Galey stated that he would have researched Zometa when Mr. Bock notified him that he was on Zometa, and the record has established that the potential risk of dental procedures for patients taking Zometa was known by the time Mr. Bock underwent the extractions. Even more salient is Dr. Galey's testimony that, even today, he would perform the extractions given the dangers posed by the risk of infection.

have done if they had been provided with different or additional information that an adequate warning would have disclosed." (*Id.*)

Because Mr. Bock's doctors testified that they would prescribe the same course of treatment for him today that they did at the time, this argument could have merit only if, even today, the doctors have not been adequately warned of the risk of bisphosphonate treatment. However, under Pennsylvania law, "[a] warning should not be held improper because of subsequent revelations." *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 458 (Pa. Super Ct. 1973); *accord Lance v. Wyeth*, 4 A.3d 160, 167 (Pa. Super. Ct. 2010), (applying same principle in context of a post-sale duty-to-inform claim), *rev'd in part on other grounds*, 85 A.3d 434 (Pa. 2014). Appellant relies not on facts tending to show failure to adequately disseminate knowledge of actual risk by Novartis, but rather on the possibility that expert testimony will reveal that the risks of bisphosphonate treatment are actually greater than they are presently known to be and that, in response to those potential greater risks, the doctors would have altered their practice.

Such speculation cannot stave off summary judgment; "[t]o the contrary, 'summary judgment is essentially "put up or shut up" time for the non-moving party' who 'must rebut the motion with facts in the record and cannot rest solely on assertions made in the pleadings, legal memoranda, or oral argument.'" *Wiest v. Tyco Elecs. Corp.*, 812 F.3d 319, 330 (3d Cir. 2016) (quoting *Berckeley Inv. Group, Ltd. v. Colkitt*, 455 F.3d 195, 201 (3d Cir. 2006)). Because Appellant has not adduced sufficient record facts with

respect to causation, we conclude that the District Court did not err in granting summary judgment in favor of Novartis.

IV. CONCLUSION

For the foregoing reasons, we will affirm the judgment of the District Court.