UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 10-1019

JAMES MACK, Individually, and as Surviving Parent and Personal Representative of the Estate of Crystal Ann Mack; SYLVIA MACK, Surviving Parent of Crystal Ann Mack,

Plaintiffs – Appellants,

v.

AMERISOURCEBERGEN DRUG CORPORATION, d/b/a Amerisource Bergen; JOHNSON & JOHNSON; CENTOCOR, INCORPORATED,

Defendants – Appellees,

and

LISA S. PICHNEY, MD; LISA S. PICHNEY, MD PA; ST. JOSEPH'S MEDICAL CENTER, INCORPORATED; REBECCA EVE MANCOLL; GREATER BALTIMORE MEDICAL CENTER,

Defendants.

Appeal from the United States District Court for the District of Maryland, at Baltimore. Richard D. Bennett, District Judge. (1:08-cv-00688-RDB)

Argued: January 26, 2011 Decided: April 26, 2011

Before MOTZ, KING, and GREGORY, Circuit Judges.

Affirmed by unpublished per curiam opinion. Judge Gregory wrote a separate concurring opinion.

ARGUED: Governor Jackson, III, LAW OFFICE OF GOVERNOR E. JACKSON, III, LLC, Baltimore, Maryland; Donald Ray Huskey, LAW OFFICE OF DONALD R. HUSKEY, Baltimore, Maryland, for Appellants. John Winter, PATTERSON, BELKNAP, WEBB & TYLER, New York, New York, for Appellees. **ON BRIEF:** William H. Robinson, Jr., LECLAIR RYAN, PC, Alexandria, Virginia, for Appellees.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

In this products liability action filed in state court but removed to the District of Maryland pursuant to 28 U.S.C. § 1441(a), removal being based on the diversity of citizenship of the opposing parties, see 28 U.S.C. § 1332(a)(1), Plaintiffs James and Sylvia Mack, as surviving parents of Crystal Ann Mack, and Mr. Mack in his capacity as personal representative of his daughter's estate, appeal the district court's award of summary judgment to Defendants AmerisourceBergen Drug Corporation and Johnson & Johnson, along with the latter's subsidiary, Centocor, Inc. The appeal also encompasses the court's interlocutory rulings denying the Macks' motion to remand and excluding from consideration the expert testimony of one of their witnesses as the result of an evidentiary assessment prompted by the Supreme Court's decision in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

The Macks allege that their daughter's death was caused by Remicade, a drug manufactured by Centocor and distributed by AmerisourceBergen. Remicade is typically prescribed, as it was in Crystal's case, to treat Crohn's disease. The medical examiner, following an autopsy, opined that Crystal died from an intestinal hemorrhage attributable to her underlying disease, exacerbated by her diabetes. The Macks contend that Crystal instead succumbed to cardiac arrhythmia stemming from her

treatment regimen, and that the Defendants misrepresented the safety and efficacy of Remicade.

The district court, however, declined to reach the question of causation, ruling that the Macks had not adduced sufficient evidence at the summary judgment stage to support a threshold showing that Remicade was defective in its design or manufacture, such that a reasonable juror could determine that the drug was "unreasonably dangerous" as defined by Maryland law. See Phipps v. General Motors Corp., 363 A.2d 955, 959 (Md. 1976). The court also concluded that the Macks had failed to identify any actionable misrepresentation or to demonstrate their detrimental reliance thereon.

Having considered the parties' written submissions and the arguments of counsel, we now affirm the judgment of the district court for the reasons it stated from the bench and set forth in its written opinions and orders. See Transcript of Motions Hearing at 69-88, Mack v. AmerisourceBergen Drug Corp. (D. Md. Aug. 20, 2009) (No. 1:08-cv-00688) (granting Defendants' motion in limine to exclude testimony of James T. O'Donnell); Mack v. AmerisourceBergen Drug Corp., No. 1:08-cv-00688, Letter Order at 1 (D. Md. Aug. 25, 2009) (memorializing oral rulings of August 20, 2009 hearing); Mack v. AmerisourceBergen Drug Corp., No. 1:08-cv-00688, Memorandum Order at 4 (D. Md. Aug. 25, 2009) (denying Macks' motion for remand to Circuit Court for Baltimore

City); Mack v. AmerisourceBergen Drug Corp., No. 1:08-cv-00688, Memorandum Opinion at 6-12 (D. Md. Nov. 24, 2009) (granting Defendants' motion for summary judgment as to products liability and misrepresentation claims).

AFFIRMED

GREGORY, Circuit Judge, concurring:

I concur in the opinion, however I write separately to express a more fulsome perspective on the standard of proof surrounding this tragic case. It bears restating that we need not reach the issue of causation – namely, whether Remicade caused Mack's death – since there is evidence in the record that could arguably survive summary judgment on such a standard. See, e.g., S.A. 243, 284-85 (Mack suffered a ventricular fibrillation arrhythmia immediately prior to her death); S.A. 271, 287, 291 (testimony of Dr. Marks that the death was more likely the result of an arrhythmia than Crohn's disease); S.A. 214-15 (testimony of Dr. Marks that there is a correlation between Remicade and arrhythmias).

Rather, the key issue is whether, as a threshold matter, Remicade is an unreasonably dangerous drug under Maryland law. Because the plaintiffs failed to prove that the drug's risks outweigh its benefits, the district court's holding that the drug is not unreasonably dangerous was supported by the record, even assuming that Remicade caused Mack's fatal arrhythmia. Under Maryland law, to prevail on a products liability claim the plaintiff's must show: (1) the existence of a defect; (2) the attribution of the defect to the seller; and (3) a causal relation between the defect and the injury. Jensen v. American Motors Corp., 50 Md. App. 226, 234 (1981); see also Banks v.

Iron Hustler Corp., 59 Md. App. 408 (1984) (adopting § 402A of the Restatement (Second) of Torts).

Here, the plaintiffs have not met their burden to show that Remicade was defective. The cited study – which the defendants criticize as studying patients with arthritis, not Crohn's – does not call into question the efficacy of the drug as a whole. Mack herself initially noted significant improvement after taking the drug. Furthermore, Remicade was initially approved for the treatment of Crohn's disease back in 1998 and has subsequently been approved by the FDA for use in alleviating the symptoms of a variety of other conditions, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, and plaque psoriasis, among others. In total, Remicade has undergone evaluation by the FDA fourteen times and has been found to be a safe and effective treatment whose benefits outweigh its risks. The plaintiffs conceded at the hearing for summary judgment that Dr. Marks would not view the drug as unreasonably dangerous since he has supervised its administration to other patients. J.A. 272. There are many drugs that are high risk – a quintessential example would be

chemotherapy – yet ultimately may be justified.[*] Accordingly, I concur in the opinion.

[*] The plaintiffs have not brought a failure to warn case against the manufacturer. The drug contained a statement that it should not be used unless conventional therapy has failed. I take no position on whether Remicade was properly prescribed to treat Mack.