

UNPUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

NANCY CHERYL WEHLING, formerly
known as Nancy Cheryl Strowd,
Plaintiff-Appellant,

v.

SANDOZ PHARMACEUTICALS

No. 97-2212

CORPORATION, a Delaware
Corporation; CAREMARK,
INCORPORATED, a California
corporation,
Defendants-Appellees.

Appeal from the United States District Court
for the Eastern District of North Carolina, at Wilmington.
James C. Fox, District Judge.
(CA-96-84-F)

Argued: June 5, 1998

Decided: August 20, 1998

Before NIEMEYER and LUTTIG, Circuit Judges, and
SMITH, United States District Judge for the
Eastern District of Virginia, sitting by designation.

Affirmed by unpublished per curiam opinion.

COUNSEL

ARGUED: David Henry Rogers, Raleigh, North Carolina, for Appel-
lant. Hayden Judson Silver, III, MOORE & VAN ALLEN, P.L.L.C.,

Raleigh, North Carolina; William Howard Moss, SMITH, ANDERSON, BLOUNT, DORSETT, MITCHELL & JERNIGAN, Raleigh, North Carolina, for Appellees. **ON BRIEF:** Curtis J. Shipley, MOORE & VAN ALLEN, P.L.L.C., Raleigh, North Carolina; Deanna L. Davis, SMITH, ANDERSON, BLOUNT, DORSETT, MITCHELL & JERNIGAN, Raleigh, North Carolina, for Appellees.

Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

OPINION

PER CURIAM:

Plaintiff appeals the district court's ruling barring plaintiff's expert witness from testifying. Plaintiff also appeals the grant of summary judgment on all claims. Because we find no abuse of discretion and determine that summary judgment was appropriate, we affirm.

I.

These facts, drawn from the record, are expressed in the light most favorable to plaintiff as the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Plaintiff, Nancy Cheryl Wehling (Wehling), brought suit against defendants alleging claims of negligence, breach of implied warranty, and negligent infliction of emotional distress for injuries stemming from an alleged interaction of the prescription drug "Clorazil," a drug manufactured and distributed by defendants, and the prescription drug "Klonopin," a type of benzodiazepine (BZD).

Plaintiff has suffered from severe and chronic paranoid schizophrenia for approximately twenty-five years. She has been institutionalized for this illness at least twenty-seven times, including numerous admissions to Dorothea Dix Hospital (Dix Hospital) in Raleigh, North Carolina. On March 1, 1991, plaintiff was admitted to Dix Hospital

for treatment of her schizophrenia. From the time of her admission on March 1, 1991, through March 21, 1991, plaintiff was administered several types of prescription drugs commonly used to treat paranoid schizophrenia, namely, Prolixin, Cogentin, Ativan (a BZD), and Klonopin (a BZD). These more traditional antipsychotic medications failed to improve plaintiff's condition. Accordingly, on March 20, 1991, plaintiff's treating physician initiated treatment with Clorazil, an antipsychotic medication manufactured by defendant Sandoz Pharmaceuticals Corporation (Sandoz) and distributed by defendant Caremark, Incorporated (Caremark).

Plaintiff received her first 25-milligram dose of Clorazil at approximately 10:30 a.m. on March 20, 1991. Approximately two hours later, plaintiff allegedly suffered respiratory arrest while eating lunch in the cafeteria at Dix Hospital. An emergency team was summoned to the scene and woke plaintiff by stimulating her breastbone. Plaintiff was placed in the critical care unit, from which she was discharged approximately two weeks later. Plaintiff claims that her condition has worsened since the March 20, 1991, incident. However, two physicians on staff at Dix Hospital contend that plaintiff suffered no permanent injury as a result of the incident.

Clorazil was created as a chemical compound in 1960. Psychiatrists in Europe have prescribed the drug since 1974. The drug was first marketed in the United States in February, 1990. Prior to plaintiff's incident on March 20, 1991, Clorazil had been administered to approximately 10,000 patients in the United States. In 1991, the possibility of an interaction between Clorazil and BZD medications was not widely known. Two articles by German authors were published in 1990, describing six anecdotal cases of cardiorespiratory arrest in patients who had simultaneously received BZD medications and clozapine (the generic name for Clorazil). However, the authors emphasized that no statistically valid and controlled clinical studies had been performed, and only a small number of patients were involved. Consequently, the authors could not conclude that an interaction between BZD medications and clozapine had been established.

Despite the inconclusive nature of these articles, defendant Sandoz, at the suggestion of the Food and Drug Administration, added a warning to Clorazil's package insert in January, 1991. The revised package

insert advised physicians that orthostatic hypotension in patients taking clozapine could be accompanied by profound collapse and respiratory depression, and in some cases, concomitant BZD medications had been administered, although it had not been established there was a drug interaction.

Plaintiff filed the complaint in this action on April 5, 1996. The complaint alleged that the warning added to Clorazil's package insert in January, 1991, did not adequately warn physicians of the risk of cardiorespiratory collapse when Clorazil was used with BZD medications. The complaint further alleged that defendants did not adequately test Clorazil for use in the United States, or require that its usage be subject to necessary safety precautions, thus causing plaintiff's collapse on March 20, 1991.

Defendant Sandoz filed a motion to exclude the proposed testimony of plaintiff's expert, Arthur J. McBay, Ph.D. (McBay), and a motion for summary judgment pursuant to Federal Rule of Civil Procedure 56. Defendant Caremark filed a motion to dismiss for failure to state a cause of action pursuant to Federal Rule of Civil Procedure 12(b)(6), or alternatively, for summary judgment pursuant to Federal Rule of Civil Procedure 56. Following a hearing on defendants' motions, the court determined that McBay's testimony was not sufficiently reliable to be admissible as expert opinion testimony. Accordingly, the court excluded McBay's testimony in its entirety and granted defendants' motions for summary judgment, from which rulings this appeal results.

II.

Plaintiff challenges the court's ruling excluding McBay's testimony in its entirety. The district court applied the criteria set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and ruled that McBay's testimony was obviously relevant to the issues of negligence and causation, but his testimony was insufficiently reliable to be admissible into evidence.

A trial court has broad discretion in determining whether to admit expert testimony and should not be reversed absent a clear abuse of discretion. Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 799

(4th Cir. 1989), cert. denied, 493 U.S. 1073 (1990). An appellate court should not apply a more stringent standard of review where the court's ruling regarding the admissibility of expert testimony results in summary judgment. General Elec. Co. v. Joiner, ___ U.S. ___, 118 S. Ct. 512, 517-19 (1997). In applying the abuse of discretion standard, the appellate court may not categorically distinguish between rulings that allow expert testimony and rulings that disallow it. Id. at 517.

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert opinion testimony. Under Rule 702,

[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702. The touchstone of admissibility is whether the testimony will assist the trier of fact. Fox v. Dannenberg, 906 F.2d 1253, 1256 (8th Cir. 1990).

In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), the Supreme Court established a test for trial courts to apply in exercising their "gatekeeping responsibility" under Rule 702. The standard is designed to ensure that admitted expert testimony is both relevant and reliable. In order to meet the reliability prong of the Daubert test, "[p]roposed testimony must be supported by appropriate validation." Daubert, 113 S. Ct. at 2795. Toward this end, the Court in Daubert provided these guidelines for lower courts to follow in making reliability determinations: (1) whether the expert's theory or technique has been or can be tested; (2) whether the expert's theory or technique has been subjected to "peer review and publication;" (3) whether the expert's theory or technique has a known or potential rate of error; (4) whether standards exist to control the technique's operation; and, (5) whether the technique is generally accepted in the scientific community. Id. at 2796-97, 2799; see Cavallo v. Star Enter., 100 F.3d 1150, 1158-59 (4th Cir. 1996), cert. denied, ___ U.S. ___, 188 S. Ct. 684 (1998).

Courts have also looked to the qualifications of the witness in determining whether his proffered opinions are reliable. See, e.g., In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 749 (3d Cir. 1994), cert. denied sub nom., General Elec. Co. v. Ingram, ___ U.S. ___, 115 S. Ct. 1253 (1995). Another significant fact weighing against admitting the testimony is where, as here, the expert developed his opinions expressly for the purposes of testifying. See, e.g., Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1317 (9th Cir.), cert. denied, 516 U.S. 869 (1995).

Plaintiff relied primarily on the testimony of McBay to establish the elements of negligence and causation. Specifically, McBay proposed to testify that Clorazil interacted with the BZD Klonopin in plaintiff's body, causing plaintiff to experience respiratory arrest; the Clorazil label and package insert were inadequate to warn plaintiff's physician of Clorazil's potential interaction with BZDs; and, had the warning been more explicit regarding a possible interaction with BZDs, plaintiff would not have suffered respiratory arrest, or alternatively, her physicians would have responded to her collapse more quickly.

Having carefully reviewed the entire record, we find that the district court did not abuse its discretion in excluding McBay's testimony in its entirety. McBay is a retired pharmacist and toxicologist; he is neither a pharmacologist nor a medical doctor. His background focuses on assisting medical examiners in determining causes of death. He has also developed an expertise in drug and alcohol testing, particularly in the context of automobile accidents. None of this experience is relevant to the issues of causation and negligence in the context of an alleged drug interaction. As the trial court concluded, McBay was not qualified to testify on the issues in dispute in this suit.

Further, McBay has no education, training, or experience in the treatment of patients with schizophrenia, or in the prescription, use, or administration of Clorazil. He has not published articles or conducted research in the treatment of schizophrenia, or the two prescription drugs in question. In fact, McBay testified that he has no knowledge of how Clorazil works in the brain, or how it could interact with a BZD medication. He testified that he knows very little about Klonopin, the drug that allegedly interacted with Clorazil and

caused plaintiff's collapse. McBay further testified that he does not consider himself an expert in the pharmacological treatment of schizophrenic patients, and he has never been involved in any way with the treatment of a schizophrenic patient. Without prior training, education, or experience in the field, McBay's review of the literature, after he was retained as an expert witness in this suit, was insufficient to qualify him as an expert on the issues in dispute.

The record supports the conclusion that McBay was unqualified to testify as to the adequacy of the warning appearing on Clorazil's package insert. McBay testified that he has never been involved with the drafting, regulation, or approval of product labeling for any prescription medication, and he has no training in this area. Without more, his experience as a pharmacist, reading prescription labels and dispensing drugs, does not qualify him to testify about the adequacy of drug warnings. McBay expressed the opinion that Clorazil's label should have recommended an initial dosage of 12.5 milligrams, rather than 25 milligrams as plaintiff received, but his opinion is primarily based on defendants' revision of the Clorazil label in 1992. As this is not the type of subsequent remedial measure reasonably relied upon by experts in the field in forming their opinions or inferences, the district court properly concluded that the methodology and reasoning underlying McBay's opinions are not scientifically valid.

McBay was likewise unqualified to testify as to whether plaintiff's physician would have followed a different course of action, had defendants provided a more explicit warning regarding a possible interaction between Clorazil and BZD medications. To create a jury question, the evidence must be of sufficient weight to establish, by the preponderance of the evidence, at least some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug. Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 812 (5th Cir.), cert. denied, 504 U.S. 956 (1992). Lacking any sound basis whatsoever, McBay's opinion that plaintiff's treating physician would have followed a different course of treatment is purely speculative. McBay testified that he had no knowledge about the standard practices of physicians treating patients with Clorazil.

The Court in Daubert defined the "scientific knowledge" requirement of Rule 702 as "establish[ing] a standard of evidentiary reliabil-

ity" or "trustworthiness," which essentially means "scientific validity." 113 S. Ct. at 2795 n.9. To be scientifically valid, an expert's opinion must be "ground[ed] in the methods and procedures of science" and "supported by appropriate validation." Id.; see United States v. Dorsey, 45 F.3d 809, 813 (4th Cir.), cert. denied, 515 U.S. 1168 (1995).

In the instant case, the reasoning and methodology underlying McBay's opinions regarding negligence and causation were speculative and not scientifically valid. An "expert" opinion is considered unreliable and inadmissible under Daubert where, as here, the expert has developed the opinions expressly for purposes of testifying in the case, has himself performed no tests or studies that support his opinions, has cited no peer-reviewed, controlled studies substantiating his opinions, and fails to "point to some objective source . . . to show that [he has] followed the scientific method." Daubert, 43 F.3d at 1316-18; see Cabrera v. Cordis Corp., 134 F.3d 1418, 1420 (9th Cir. 1998). McBay based his opinion regarding causation primarily on the correlation in time between the administration of Klonopin to plaintiff, and the administration of Clorazil. Since conjecture, hypothesis, subjective belief, or unsupported speculation are impermissible grounds on which to base an expert opinion, such "expert" opinions as McBay's must be excluded. See Daubert, 509 U.S. at 589.

For the foregoing reasons, we find the court did not abuse its discretion in excluding McBay's testimony in its entirety.

III.

We review a grant of summary judgment de novo. See Higgins v. E.I. DuPont de Nemours & Co., 863 F.2d 1162, 1167 (4th Cir. 1988). Summary judgment is appropriate only when the court, viewing the record as a whole and in the light most favorable to the non-moving party, finds there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see, e.g., Celotex Corp. v. Catrett, 477 U.S. 317, 322-24 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-50 (1986); Terry's Floor Fashions, Inc. v. Burlington Indus., 763 F.2d 604, 610 (4th Cir. 1985).

Plaintiff relied almost exclusively on the proffered testimony of McBay in establishing negligence and causation, two essential elements of her claims against defendants. We have already determined that the district court properly excluded McBay's testimony in its entirety. The only other evidence offered by plaintiff on the element of causation would have been inadmissible at trial, or was insufficient to raise a genuine issue of material fact. For example, plaintiff submitted, as an exhibit to her response to defendants' motions for summary judgment, articles published by two German authors. This academic literature might have been admissible at trial under the learned treatise exception to the hearsay rule. However, as previously discussed, the articles were not based on statistically valid and controlled clinical studies, and only a small number of patients were involved. Consequently, the authors could not conclude that an interaction between BZD medications and clozapine had been established.

The other evidence offered by plaintiff on the issue of causation, namely her medical records, also failed to raise a genuine issue of material fact. While these records likely would have been admissible at trial as an exception to the hearsay rule, they did not tend to establish that plaintiff's injuries were caused by an interaction between a BZD medication and Clorazil.

Finally, the press releases submitted as an exhibit to plaintiff's response to defendants' motion for summary judgment would have been inadmissible at trial, as would the evidence of subsequent remedial measures taken by defendant Sandoz, also submitted as an exhibit to plaintiff's response to defendants' summary judgment motions. Likewise, the correspondence between plaintiff's treating physician and various European physicians, in which they discuss their opinions on the topic, would be inadmissible hearsay at trial.

Thus, even viewing the record in the light most favorable to plaintiff as the non-moving party, there are no genuine issues of material fact and defendants are entitled to judgment as a matter of law. Accordingly, the court properly granted summary judgment in favor of defendants on all claims.

IV.

Because we determine that the court did not abuse its discretion in excluding McBay's testimony in its entirety, and that summary judgment on all claims was appropriate, we affirm.

AFFIRMED