United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 07-1822

In re: Prempro Products Liability Litigation,	*	
Helene Rush,	*	
Appellant,	*	
v.	*	Appeal from the United States District Court for the Eastern District of Arkansas.
Wyeth, doing business as Wyeth, Inc., doing business as Wyeth Pharmaceuticals,	*	
Appellee.	*	

Submitted: October 18, 2007
Filed: January 31, 2008

Before RILEY, MELLOY, and COLLOTON, Circuit Judges.

RILEY, Circuit Judge.

Helene Rush (Rush) was prescribed the Wyeth, Inc. (Wyeth) estrogen products Premarin and Prempro for symptoms related to menopause. Rush took the drugs for nearly ten years, beginning in August 1989. Rush was diagnosed with breast cancer in June 1999. Six years later, in March 2005, Rush filed this lawsuit alleging Wyeth's

products caused her breast cancer. Rush's case is part of the multi-district litigation (MDL) on Hormone Replacement Therapy (HRT). A jury found Rush failed to prove: (1) Wyeth inadequately warned about the drugs' risks, (2) the drugs were defective in design, and (3) Wyeth was negligent, or (4) any of these claims proximately caused her breast cancer. Rush moved for a new trial which was denied.

On appeal, Rush argues the district court[1] erred by (1) giving incorrect instructions to the jury, (2) allowing undisclosed and improper expert testimony, (3) disallowing Rush's expert opinions, and (4) failing to instruct the jury on fraud.

The jury also found against Wyeth on Wyeth's statute of limitations defense, finding Wyeth failed to prove Rush either knew, or should have discovered by the exercise of reasonable diligence, the causal connection between the Wyeth estrogen products and her breast cancer. Wyeth asserts (1) Rush's claims are time barred, and (2) her labeling claim was preempted by federal law.

We affirm without reaching Wyeth's issues.

I. BACKGROUND

In 1989, at age 55, Rush began taking prescribed estrogen products manufactured by Wyeth for symptoms related to menopause. Rush's physician, Dr. Cynthia Frazier (Dr. Frazier), prescribed HRT for the treatment of vaginal atrophy. Before beginning the therapy, Dr. Frazier discussed with Rush the benefits and risks of the medications.

In 1992, an abnormality was discovered in Rush's breast. At that time, Dr. Frazier discussed with Rush the association between breast cancer and HRT and that

[1]The Honorable William R. Wilson, Jr., United States District Judge for the Eastern District of Arkansas.

Rush "may want to stop hormones." After another breast abnormality was found the next year, Rush stopped the HRT treatment for eight months before deciding to resume HRT.

Rush took the product Premarin until 1996, when her new gynecologist, Dr. Karen Kozlowski (Dr. Kozlowski), switched Rush to Prempro. Dr. Kozlowski told Rush with HRT "there was a slight risk of cancer." Rush took these drugs for nearly ten years until, in June 1999, she was diagnosed with breast cancer.

Rush relied solely on her doctors' advice in deciding to take HRT. Rush did not rely on any product advertisements. Rush did receive patient information sheets with her monthly Premarin and Prempro prescriptions. These information sheets explicitly warned that some studies suggested breast cancer was a possible danger or risk of the medications if taken "for prolonged periods of time and especially if higher doses are used." While Rush admits receiving the information sheets, she denies ever reading them.

During the entire time Rush was taking Premarin and Prempro, and continuing to this day, these drugs were approved by the Federal Drug Administration (FDA) as safe and effective. Before the FDA approved Prempro, the FDA specified the wording and placement of breast cancer warnings on the product labeling.

On March 18, 2005, Rush filed her lawsuit alleging Wyeth's hormone drugs caused her breast cancer. The case filing was nearly six years after Rush was diagnosed with breast cancer.

II. DISCUSSION

A. Jury Instructions

Jury instructions are reviewed for abuse of discretion. Slidell, Inc. v. Millennium Inorganic Chems., Inc., 460 F.3d 1047, 1054 (8th Cir. 2006). "We afford the district court broad discretion in choosing the form and language of the instructions" and "will reverse a jury verdict only if the erroneous instruction affected a party's substantial rights." Id. "[O]ur review is limited to a determination of whether the instructions, taken as a whole and viewed in the light of the evidence and applicable law, fairly and accurately submitted the issues to the jury." Id.

1. Assumption of Ordinary Care Instruction

Arkansas Model Jury Instruction (AMI) 602 states, "Every person using ordinary care has a right to assume, until the contrary is or reasonably should be apparent, that every other person will use ordinary care. To act on that assumption is not negligence." Rush asserts the district court erred in giving this instruction because only a plaintiff—but never a defendant—may assume that others will use ordinary care based upon the Arkansas Supreme Court's interpretation in England v. Costa, 216 S.W.3d 585, 590 (Ark. 2005) ("Generally speaking, when the instruction is utilized in a contributory negligence case, the phrase 'every person' in the instruction is intended to refer to the plaintiff.").

Wyeth counters that Justice Imber's concurring opinion in England specified "[t]he instruction is not limited to plaintiffs alleging negligence against defendants." Id. at 592 (Imber, J., concurring). Further, Wyeth notes the AMI's commentary states, "England . . . held that [AMI 602] should only be given where there is evidence of negligence on the part of a party claiming damages." Ark. Model Jury Instr., Civil AMI 602 cmt.

Wyeth asserts evidence of Rush's negligence was presented, thereby rendering this instruction proper. Specifically, Wyeth asserts Rush's admission, that she never

read the warnings Wyeth included with each prescription, was evidence of negligence. Furthermore, reading England to restrict the instruction only to a case where a plaintiff is alleging contributory negligence may be overly restrictive. In any event, England does not apply directly to the facts of this case and is not controlling.

Even if giving the assumption of ordinary care instruction was erroneous under England's logic, this instruction did not affect Rush's substantial rights. The instruction did not direct the jury to find Wyeth was not negligent if Rush did not read the warnings. Instead, the instruction only explained Wyeth was not negligent in assuming Rush *would read* the warnings. The jury could still have found Wyeth negligent and Wyeth's warnings were inadequate. Thus, assuming this instruction was given in error, the instruction was not unfairly prejudicial and any error was harmless. The district court's decision to include this instruction was not an abuse of discretion.

2. Failure to Warn Instruction

Rush challenges Instruction 14, regarding the failure to warn, because this instruction directed the jury that it must find for Wyeth if the jury found Rush was aware of the dangers posed by using Premarin (with progestin) or Prempro before Rush's breast cancer diagnosis. In an action for negligent failure to warn, this court has held, "if a user is already aware of the dangers, the lack of warning is not the proximate cause of the injury." Crook v. Kaneb Pipe Line Operating P'ship, 231 F.3d 1098, 1103 (8th Cir. 2000). As such, the focus is on whether or not Rush was aware of the dangers posed by the Wyeth drugs, Premarin (with progestin) and Prempro.

Arkansas recognizes the existence of the Learned Intermediary Doctrine. See Hill v. Searle Labs., 884 F.2d 1064, 1070 (8th Cir. 1989). Under this doctrine, a physician acts as a learned intermediary between a pharmaceutical manufacturer and the physician's patient. As such, "a warning to the physician is deemed a warning to the patient." Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004)

(internal brackets omitted). "[A]dequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly." Id.

While the Learned Intermediary Doctrine provides that adequate warning to a patient's physician can suffice to defeat a patient's failure to warn claim, this doctrine does not preclude informing a patient directly. "[I]f a user is already aware of the dangers, the lack of warning is not the proximate cause of the injury." Crook, 231 F.3d at 1103. The goal is to assure either the patient or the patient's physician, as a proxy for the patient, is aware of the dangers. If the patient is independently aware of the dangers, then a failure of the manufacturer to warn adequately of the danger is irrelevant.

The district court's instruction accurately reflects Arkansas law and did not prejudice Rush. Rush's assertion, that this portion of the law created "a total bar to recovery" under the doctrines of assumption of risk and contributory negligence, is incorrect. Rush's claim is a negligence claim based upon Wyeth's failure to warn. The district court's jury instruction accurately reflected Arkansas law because the jury was only directed to find for Wyeth if the jury determined Rush *was aware* of the dangers *before* her diagnosis with breast cancer. The trial court did not abuse its discretion.

3. Failure to Instruct on Fraud

Wyeth moved for summary judgment on Rush's fraud claim, which the district court granted. Rush does not appeal the grant of summary judgment, but instead asserts the district court erred in failing to instruct the jury on Rush's fraud claim because evidence offered in support of other claims was sufficient to warrant this instruction.

To prove fraud, Rush must show a justifiable reliance on a false representation of a material fact. Tyson Foods, Inc. v. Davis, 66 S.W.3d 568, 577 (Ark. 2002). Rush

does not claim she relied upon false statements from Wyeth, but claims that her doctors so relied. To the contrary, both Dr. Frazier and Dr. Kozlowski testified at trial they relied "very little," if at all, upon anything said by Wyeth in making the prescription decisions for Rush, instead relying on their own knowledge independent of any drug company. Rush asserts her doctors' testimony is subject to a credibility determination so that if her doctors' testimony is sufficiently discredited, the jury could conclude the doctors relied upon false representations by Wyeth. "[D]iscredited testimony is not normally considered a sufficient basis for drawing a contrary conclusion." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256-57 (1986) (internal brackets omitted). Instead, there must be some affirmative evidence to support a claim. See id. Here, no such affirmative fraud evidence exists.

The district court's refusal to instruct the jury on fraud was not an abuse of discretion.

B. Expert Testimony

We review the district court's decision to admit or exclude expert testimony for abuse of discretion. See Torbit v. Ryder Sys., Inc., 416 F.3d 898, 903 (8th Cir. 2005). In the context of admitting evidence, an abuse of discretion occurs "only where the error is clear and prejudicial to the outcome of the proceeding." Id.

1. Expert Testimony Allowed

a. Dr. Lewis Chodosh

Rush asserts the district court erred in allowing a defense expert, Dr. Lewis Chodosh (Dr. Chodosh), to give case specific testimony. Wyeth asserts Dr. Chodosh's testimony was necessarily implied by his testimony as to general causation and, as such, was properly admitted or harmless.

One of the key opinions set forth in Dr. Chodosh's report and deposition, and reiterated at trial, was his opinion that "the lower limit of latency for breast cancer from

initiation to detection is in the range of twelve years." Dr. Chodosh's opinion was substantially based on extensive studies of radiation exposure and the onset time of breast cancer for women in Hiroshima and Nagasaki. Dr. Chodosh opined twelve years was the minimum time period between exposure to a causative element and detection of breast cancer. At trial, Dr. Chodosh was asked to consider a hypothetical situation based on Rush's situation. Specifically, Dr. Chodosh was asked to assume Rush was diagnosed with breast cancer at age 65, and had been taking hormone therapy for nine plus years with a seven month period when no HRT occurred. Based upon those hypothetical facts, Dr. Chodosh was asked his opinion as to whether Rush's breast cancer was present before she began her HRT.

Dr. Chodosh's "opinion is [Rush's] breast cancer almost certainly was present prior to the time when she began to use [HRT]." His opinion was based on knowing how long it takes for breast cancers to grow and "given that the risks of breast cancer associated with [HRT] are small, the math alone would suggest that more probably than not Ms. Rush's breast cancer was unrelated to her use of hormone therapy."

Dr. Chodosh's trial testimony clearly reflects the application of his opinion, that it takes a minimum of twelve years from exposure to detection of breast cancer, to Rush's situation. Where Rush's exposure to HRT began less than ten years before she was diagnosed, Dr. Chodosh's conclusion that the HRT drugs could not have caused the breast cancer is an exercise in basic math using simple deductive reasoning. As such, the admission of this opinion was not an abuse of discretion.

b. Dr. Lisa Rarick

Rush objects to the defense testimony of Dr. Lisa Rarick (Dr. Rarick) regarding the correlation of hormonal blood levels with menopausal symptoms. Dr. Rarick was asked, "[c]an you tell us what hormone therapy taken by a menopausal woman adds to her circulating blood levels?" Dr. Rarick responded estrone levels "go up to about the range you would expect in the low range for a premenopausal woman." This

testimony went beyond Dr. Rarick's report, but was elicited in response to an opinion of Rush's expert, Dr. Suzanne Klimberg (Dr. Klimberg), an opinion which also had not previously been disclosed. In answer to a juror's question, Dr. Klimberg testified HRT brings estrone levels that are "not quite at the level that you would get pre-menopausal." Essentially, Dr. Rarick's testimony echoed Dr. Klimberg's earlier testimony. Rush was not prejudiced, and the district court did not abuse its discretion in allowing this testimony.

c. Dr. Michael Dey

Rush asserts reversible error occurred when Dr. Michael Dey (Dr. Dey) testified by giving his definition of the word *promote*. Dr. Dey said, "[m]y definition of promotion is, they stimulate an existing cancer to grow in some tumors, in some women, or some tissues. But they do not cause cancer because they do not take a normal cell and make it a cancerous cell." There was no objection to this testimony. Dr. Dey was then asked if he understood "the term 'promotion' is used differently by different scientists." Dr. Dey agreed. Next, Dr. Dey was asked, "What other meanings of promotion have you heard in connection with this subject matter?" Only when Dr. Dey attempted to answer this question was an objection made. The objection was based solely on hearsay. The district court overruled this objection, telling the jury, "I'm going to allow the witness to give his understanding of the word 'promote' in the scientific field. I want you to keep in mind, though, that at the end of this trial, I am going to give you my understanding of the word 'promote' as Arkansas law applies, and that definition will be the one you'll have to follow."

In the closing charge, the district court instructed the jury as to the definition of "promote" under Arkansas law, noting the jury was to consider the evidence in light of the definition provided by the court. A jury is presumed to follow the instructions given. See Weeks v. Angelone, 528 U.S. 225, 234 (2000). Thus, we must presume any confusion that may have existed because of differences between the definitions of "promote" given by Dr. Dey and the district court was resolved by the jury instruction

which defined "promote" for the jury and specified the evidence should be considered in light of the trial court's definition of the term.

2. Expert Opinions Disallowed

Rush asserts the district court abused its discretion when it excluded portions of the testimony of Rush's expert, Dr. Donald F. Austin (Dr. Austin). Rush attempted to have Dr. Austin testify regarding new data garnered from the SEER[2] database. The new testimony was intended to prove causation and contradicted Dr. Austin's prior testimony.[3] Rush cites to Farmland Indus. v. Morrison-Quirk Grain Corp., 54 F.3d 478, 482 (8th Cir. 1995), for the proposition that it is proper for the court to permit testimony like Dr. Austin's where Dr. Austin previously gave the same opinions in a prior trial between the same parties. In Farmland, this court affirmed the district court's decision allowing the causation testimony stating, "As with all discovery matters, the district court maintains broad control over Rule 26(e) issues regarding the disclosure of the substance of an expert's testimony. We will not reverse a district court's decision in this area absent a gross abuse of discretion resulting in fundamental unfairness in the trial of the case." Id. (internal quotations and citations omitted).

Unlike Farmland, where the district court admitted the causation expert testimony, the district court excluded Rush's causation expert testimony. Farmland does not stand for the proposition this testimony *must* be admitted. Rather, Farmland simply expresses the unremarkable proposition that the district court's decision, whether or not to allow testimony, is reviewed "in this area" for "a gross abuse of

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[2]SEER is an acronym for the Surveillance Epidemiology and End Results program of the National Cancer Institute. The SEER program "is an authoritative source of information on cancer incidence and survival in the United States." Overview of the SEER Program, at http://seer.cancer.gov/about/ (last visited Jan. 4, 2008).

[3]In his deposition, Dr. Austin testified it would be fallacious to use the SEER database study to prove causation.

discretion resulting in fundamental unfairness." Id. (internal quotations and citations omitted). The district court did not abuse its broad discretion when it excluded this testimony, particularly as here, where Dr. Austin previously testified such a study could not be used to prove causation.

Rush also asserts the district court erred in excluding the causation testimony of her expert Dr. Graham Colditz (Dr. Colditz) based upon recent data in the SEER database. After the district court excluded the testimony of Dr. Austin regarding this new data, Rush attempted to permit Dr. Colditz to testify to the same data. The district court excluded Dr. Colditz's testimony regarding this new data because Dr. Colditz had never referenced this data in his expert report nor testified about this data before his December 18, 2006, preservation deposition. The district court found this new testimony would be subject to Daubert[4] and the deadline for raising Daubert issues was September 21, 2006. The district court noted, "this specific testimony by Dr. Colditz was not designated until after I ruled that Dr. Austin could not use the very same information." The district court did not abuse its discretion when it excluded Dr. Colditz's testimony regarding the new, and previously undisclosed, SEER database data.

C. Wyeth Appeal Issues

Having affirmed the decision of the district court on other grounds, we do not reach the issues of whether Rush's claims are barred by the statute of limitations or whether Rush's labeling claim is preempted by federal law.

III. CONCLUSION

For the foregoing reasons, we affirm the decision of the district court.

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[4]Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).