

In the
United States Court of Appeals
For the Seventh Circuit

No. 07-3149

JACQUELYN GILES, individually and as
Special Administrator of the Estate of
Jeff L. Giles, Deceased,

Plaintiff-Appellant,

v.

WYETH, INC., and WYETH PHARMACEUTICALS,
formerly known as AMERICAN HOME PRODUCTS
CORPORATION,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Illinois.
No. 04 C 4245—**J. Phil Gilbert, Judge.**

ARGUED FEBRUARY 14, 2008—DECIDED FEBRUARY 12, 2009

Before MANION, ROVNER, and WILLIAMS, *Circuit Judges.*

WILLIAMS, *Circuit Judge.* This case arises out of a tragic event, the death of Jeff Giles, a forty-six-year-old married father who took his life in the fall of 2002. His widow filed a wrongful death suit against Wyeth, the manufac-

turer of Effexor, the antidepressant Mr. Giles began taking two days before his death. A jury found in favor of Wyeth. On appeal, Mrs. Giles argues that she should have been allowed to introduce warnings that accompanied Effexor in the years following Mr. Giles's death. Because these later warnings focused on the risk of suicide in younger persons, not adults of Mr. Giles's age, and there is no evidence that Wyeth knew or should have known the information contained in the later warnings at the time of Mr. Giles's death, the district court did not abuse its discretion when it excluded the later warnings. We therefore affirm the judgment of the district court.

I. BACKGROUND

Jeff Giles worked as a coal miner. He suffered a serious injury on the job in the mid-1990s, and, in the years that followed, continued to experience neck pain that limited his ability to move. In July 2002, the coal mine laid Mr. Giles off from his job. A few months later, on September 12, he had neck surgery in an attempt to alleviate the effects of his neck injury. Unfortunately, he did not heal as quickly from the surgery as he hoped, and he also learned around the same time that the coal mine from which he had been laid off would close permanently.

On October 28, 2002, Mr. Giles visited his primary care physician. Mr. Giles told him that he felt tired and depressed, lacked motivation, and had insomnia. His doctor diagnosed him with major depressive disorder and prescribed the antidepressant Effexor. Mr. Giles took three Effexor pills over the next two days. On the morning of

October 30, 2002, he pulled over to the side of an isolated road and died from a self-inflicted gunshot wound. Mr. Giles was forty-six years old at the time and left behind a wife and son.

Various warnings accompanied the Effexor Mr. Giles took. Among them, in accordance with a United States Food and Drug Administration requirement, was a suicide precaution that stated:

Suicide—The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Effexor should be written for the smallest quantity of capsules consistent with good patient management in order to reduce the risk of overdose.

In June 2003, the FDA announced it was reviewing reports of a possible relationship between Paxil, an antidepressant not manufactured by Wyeth, and an increased risk of suicidal thinking and suicide attempts in children and adolescents. The FDA's statement also said there was no evidence that Paxil was associated with an increased risk of suicidal thinking in adults. The FDA then began collecting data from antidepressant manufacturers' pediatric clinical trials. In August 2003, Wyeth changed Effexor's labeling to reflect that its pediatric clinical trials showed an increased risk of suicidal ideation in children using the drug.

In the spring of 2004, the FDA issued a new antidepressant warning, and Wyeth adjusted its Effexor warnings

accordingly. Effexor's 2004 warning stated that "Patients with major depressive order, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs." The warning also stated that although a causal role for antidepressants in inducing suicidality had not been established, "patients being treated with antidepressants should be observed closely for clinical trial worsening and suicidality, especially at the beginning of a course of drug therapy"

In August of 2004, the FDA completed its analysis of all antidepressant manufacturers' pediatric clinical trial data. As a result of this analysis, in January 2005, the FDA issued a suicide-related "black box" warning for antidepressants and modified the antidepressant warnings' language. (The FDA requires that certain contraindications or serious warnings, particularly those that might lead to death or serious injury, be presented in a box that explains the risk and refers to more detailed information elsewhere in the labeling. *See* 21 C.F.R. § 201.57(c)(1)). Wyeth modified the Effexor warnings in compliance. Effexor's 2005 labeling contained a black box captioned "Suicidality in Children and Adolescents." Inside the black box, in bold, the warning stated that "Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders." It also said that analyses of short-term placebo-controlled trials in children and adolescents

with major depressive disorder, obsessive compulsive disorder, or other psychiatric disorders revealed a greater risk of adverse events representing suicidality during the first few months of treatment in those receiving antidepressants. Outside of the black box, the 2005 warnings included that "Adults with MDD or co-morbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases."

The FDA finalized a study of all antidepressant manufacturers' clinical trials involving adults in 2006. It concluded that for adults aged 25 to 64, no increase in suicidal behavior was demonstrated among those taking antidepressants. The next year, the FDA issued a new black box warning that expanded its previous suicidality black box warning to include adults younger than twenty-five. The 2007 black box also stated that "[s]hort-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24." The warnings section advised that all patients being treated with antidepressants should be monitored for suicidality and other changes in behavior, especially during the first few months on the drug.

Before the trial in this case, Wyeth filed a motion in limine asking the district court to exclude: (1) all suicide-related warnings that accompanied Effexor after Mr. Giles's death in 2002, and (2) scientific data related to suicidality in pediatric patients taking antidepressants. The

district court granted the motion in part, ruling that evidence of post-2002 suicide-related warnings was not admissible. It also denied the motion in part and allowed the use of scientific evidence relating to pediatric patients, including such evidence from after Mr. Giles's death.

After a three-week trial, the jury returned a verdict in Wyeth's favor. Mrs. Giles appeals the judgment against her on her claim that Wyeth was strictly liable for failing to provide adequate warnings for Effexor.

II. ANALYSIS

A. Basis for exclusion of later warnings

Mrs. Giles's principal argument on appeal is that the district court should not have precluded her from introducing the warnings that accompanied Effexor after her husband's death. The parties first disagree about the basis of the district court's decision to exclude the later warnings. Mrs. Giles maintains that the district court excluded this evidence only upon its determination that FDA-mandated warnings were "subsequent remedial measures" within the scope of Federal Rule of Evidence 407. This determination, she argues, was a legal one that we should review *de novo*.

Wyeth, on the other hand, maintains that the district court excluded the evidence under not just Rule 407, but also under Federal Rule of Evidence 403, which allows a district court to exclude relevant evidence when its "probative value is substantially outweighed by the

danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." We agree with Wyeth. Before trial, Wyeth filed a motion in limine to exclude suicide-related warnings given after Mr. Giles's suicide and to exclude scientific data relating to suicidality in pediatric patients taking antidepressants. Wyeth argued in the motion that Rule 403 and Rule 407 each independently supported exclusion of both types of evidence. The district court heard argument on the motion and ruled orally. It denied Wyeth's motion in part, as it allowed the use of scientific evidence relating to pediatric patients. The district court also granted the motion in part, stating that "[p]ost remedial measures will not be—they're not admissible. The Court is exercising its discretion not to admit that."

During trial, Mrs. Giles's counsel asked the district court to revisit its pre-trial ruling that excluded evidence of the warnings that accompanied Effexor after Mr. Giles's death. The district court declined to allow the evidence of later warnings, stating that its ruling was "the same. Under 403, although relevant, the Court's going to exclude this evidence finding that its probative value is substantially outweighed by the confusion of the issues before this . . . jury." In its ruling at trial, then, the district court invoked Rule 403 by name and used the language of Rule 403 to explain its decision to keep out the later warnings. Even if the district court's pre-trial ruling could be taken to mean it had decided on the basis of Rule 407, the district court clearly ruled during trial that the warnings

were excluded under Rule 403. We proceed, then, to analyze whether exclusion under Rule 403 was proper.

B. Exclusion under Rule 403

We review a district court's decision to exclude evidence under Rule 403 for an abuse of discretion. *Chlopek v. Federal Ins. Co.*, 499 F.3d 692, 700 (7th Cir. 2007). In doing so, we give the district court's decision significant deference. *Milhailovich v. Laatsch*, 359 F.3d 892, 906 (7th Cir. 2004). Mrs. Giles's claim is that Wyeth is strictly liable under Illinois law for failure to provide adequate warnings concerning Effexor, and that taking Effexor caused Mr. Giles to take his life. In a strict liability case based on a failure to warn in Illinois, "the plaintiff must allege and prove that defendant knew or should have known of the danger and this is tested on knowledge existing at the time of production." *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 344 (Ill. 1990). We find no abuse of discretion in the district court's decision to exclude the later warnings on the basis that their probative value was substantially outweighed by the danger of confusing the jury.

The warnings that accompanied Effexor after Mr. Giles's death had little, if any, probative value in this case. First, and most significantly, the excluded warnings did not help establish that Wyeth knew or should have known about an increased risk of suicidality in adults of Mr. Giles's age. Mr. Giles was forty-six years old when he took Effexor. The excluded post-2002 warnings, however, focused on children and adults younger than twenty-

five years old. The “black box” in the 2005 warning, for example, was entitled “Suicidality in Children and Adolescents” and warned that antidepressants had increased the risk of suicidal thinking and behavior in *children and adolescents* with major depressive disorder and other psychiatric disorders. But it made no such statement about adults. The 2007 warning expanded the 2005 black box warning to “young adults,” meaning persons younger than twenty-five, but Mr. Giles did not fall within this age group either.

Instead of suggesting an increased risk of suicidality, the Effexor warnings after 2002 actually more directly disclaimed any increased risk of suicidality in adults of Mr. Giles’s age. The 2007 black box warning, the most recent one at issue, made explicit that for a person in Mr. Giles’s age group, no increased risk of suicidality had been shown. It unambiguously stated: “Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24.” Warnings of an increased risk of suicidality that pertained only to much younger persons did not tend to show Wyeth’s knowledge of an increased risk for persons of Mr. Giles’s age.

Mrs. Giles also points us to other language in the excluded warnings, untied to age, such as that stating that “patients” should be observed closely for suicidality, especially at the beginning of a course of drug therapy. And it is true that Mr. Giles took his life two days after he began taking Effexor. The precaution in place at the time Mr. Giles took Effexor, however, already warned that the possibility of a suicide attempt was inherent in

depression and that close supervision should accompany initial therapy for high risk patients.

But even if the later warnings could be seen as materially different from the 2002 precaution, Mrs. Giles identifies no evidence that the excluded post-2002 warnings were based on information Wyeth knew or reasonably could have known at the time of Mr. Giles's death. *See N. Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1038 (Ill. App. Ct. 1991). The 2007 warning was based on conclusions the FDA drew in 2006. Moreover, it drew these conclusions from an analysis of adult clinical trial data from *all* antidepressant manufacturers, not just from Wyeth. Similarly, the bases for the 2004 warning and 2005 warning were pediatric trial results and the 2004 FDA Pediatric Analysis, which the FDA did not begin until after Mr. Giles's death. Like the 2006 FDA analysis of antidepressant use in adults, the 2004 FDA Pediatric Analysis was based on an examination of *all* antidepressant manufacturers' clinical trial data. And there was no testimony that data other than that for Effexor was available to Wyeth before October 2002. Finally, although Mrs. Giles argues that the burden was on Wyeth to analyze its data and then to add an appropriate warning of the association between Effexor and increased suicidality, she does not point us to any evidence suggesting that analyzing Effexor's clinical trial data would have yielded results requiring additional warnings for adults of Mr. Giles's age.

The tendency of the later warnings to prove that Wyeth knew of an increased risk of suicidality in persons of Mr. Giles's age was essentially nil in this case. Although

the later warnings might therefore seem to help Wyeth in that they disclaim any relationship for adults of Mr. Giles's age, admitting these warnings which focused on children, adolescents, and persons who were much younger than Mr. Giles could have confused the jury. That is, the jury might have thought that the warnings that antidepressants had increased suicidal thinking and behavior in certain adolescents and young adults also had application to Mr. Giles, when there was no evidence to support that. As a result, we do not find an abuse of discretion in the district court's determination that the probative value of the post-2002 warnings was substantially outweighed by the danger of confusing the jury. *See Chlopek*, 499 F.3d at 700 (finding no abuse of discretion in district court's determination that evidence of a changed warning label was excludable as unfairly prejudicial).

C. Admission of scientific evidence

Finally, Mrs. Giles argues that the district court's rulings prevented the jury from hearing "the whole truth." She maintains that it was error to let Wyeth introduce scientific knowledge gained after Mr. Giles's suicide, including the FDA's later data analyses, but not the subsequent warnings. Mrs. Giles's claim at trial was that taking Effexor led her husband to commit suicide on October 30, 2002. The jury therefore had to determine whether Effexor caused Mr. Giles's death, and scientific evidence after 2002 that showed no increased risk of suicidality when adults took Effexor was relevant to

whether Effexor caused Mr. Giles's suicide. The question at trial was not whether scientific knowledge in existence in 2002 demonstrated that Effexor caused Mr. Giles to take his life, it was whether Effexor caused him to take his life. If later studies shed light on that answer, all the better.

Whether Effexor's warnings were adequate, on the other hand, *was* time-dependent. Illinois law holds a manufacturer responsible for failing to warn only regarding dangers it knew or should have known about at the time it made the drug. *See Smith*, 560 N.E.2d at 344. It does not hold a manufacturer liable for failure to warn about dangers that might be revealed later if the manufacturer had no reason to foresee them. It was therefore not inconsistent to allow post-2002 evidence on causation while keeping out post-2002 warnings that did not pertain to adults and was not based on information known when Mr. Giles took Effexor.¹

¹ We note that the district court denied Wyeth's request that it be granted summary judgment on preemption grounds, and Wyeth did not develop a preemption argument on appeal. "[P]reemption is a defense and thus does not affect subject-matter jurisdiction," *Baker v. IBP, Inc.*, 357 F.3d 685, 687 (7th Cir. 2004), so we needed not address it here. Cf. *Wyeth v. Levine*, 128 S. Ct. 1118 (2008) (granting petition for writ of certiorari on question of whether FDA drug labeling requirements imposed on manufacturers preempt state law claims premised on the theory that different labeling judgments were needed to make the drugs reasonably safe for use). In light of our
(continued...)

III. CONCLUSION

The judgment of the district court is AFFIRMED.

¹ (...continued)

decision, we also need not address Wyeth's other arguments in favor of upholding the verdict.
