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In the
Indiana Supreme Court

No. 71S03-0409-CV-417

STEPHEN A. AND SUZAN M. COX,

Appellants (Plaintiffs below),

v.

WILLIAM E. PAUL, D.D.S.,

Appellee (Defendant below).

Appeal from the St. Joseph Circuit Court, No. 71C01-9801-CP-000135
The Honorable Terry A. Crone, Judge

On Petition To Transfer from the Indiana Court of Appeals, No. 71A03-0303-CV-92

June 14, 2005

Boehm, Justice.

We hold that a health care provider who receives notice of possible dangerous side effects of a treatment is not strictly liable for failure to warn a patient who received the treatment from the provider, but may be held liable for failure to make reasonable efforts to warn the patient. If there is credible evidence that the patient did not receive notice, it is the burden of the provider to establish that reasonable steps were taken. In this case, the provider did not carry that burden.

Factual and Procedural Background

In 1983, Suzan Cox consulted Dr. William Paul, an oral and maxillofacial surgeon, for problems in her temporomandibular joints which connect the jaw to the skull. On March 20, 1984, Paul performed a surgical replacement of Suzan's right and left temporomandibular joints using Vitek dental implants. After the surgery, Suzan underwent a course of physical therapy and enjoyed an uneventful recovery. Suzan's last appointment with Paul was on June 18, 1984. In late 1989, Suzan began to experience vertigo, neck pain, headaches, fatigue, and insomnia. The severity of these symptoms "escalated" with each year, but her family doctor could not identify their source.

In September 1991, the Food and Drug Administration announced a recall of Vitek implants. As is customary in recalls, Paul received a "Dear Doctor" letter advising that Vitek implants were potentially defective. The FDA requested that doctors discuss the risk of implant failure with their patients who had received the implants, conduct a clinical follow-up with those patients, and encourage the patients to enroll in the Medic Alert Foundation International Implant Registry. The FDA also requested that doctors respond within thirty days, informing the FDA through Medic Alert, of the actions that they had taken, and complete a form with information for each of the Vitek implant patients the doctor had or may have had.

In early 1992 Paul instructed his staff to search his patient charts, identify patients who had received the implants, and inform them of the dangers. The record contains no indication that Paul responded to the FDA as requested. Paul's staff performed a second search in 1994. Paul explains that he conducted this second search "simply to try and be thorough and continue to try to notify patients." Suzan's record was not identified in either the 1992 or the 1994 search.

In 1996, Suzan was identified by Paul's office as a Vitek patient under circumstances not revealed by the record. She was then notified of Vitek issues. Paul testified that he does not know why Suzan was not identified until 1996. He hypothesizes that her file might not have been in his office at the time of the two "sweeps" of his records. Paul explains that he had been in a partnership with Dr. David Harris, but the two separated and Paul started an individual practice near the end of 1989, before he received the "Dear Doctor" letter. Paul points out that when the separation occurred, charts were divided between the two doctors, so it is possible that

Suzan's chart had been moved to Harris's office. Paul states that he does not know whether Suzan's chart was ever actually moved to Harris's office or how her chart came to his attention in 1996. After Paul's staff notified Suzan, she met with Paul who recommended that she have an MRI. The MRI revealed that Suzan's Vitek implants were extensively damaged and had disintegrated. In November 1996, she underwent surgery to remove the implant remnants.

Suzan and her husband filed a complaint against Paul in January 1998, alleging that Suzan was injured as a result of Paul's breach of his duty to warn her of the dangers associated with Vitek. The Coxes also submitted the proposed complaint to the Indiana Department of Insurance as required by the Medical Malpractice Act. As the MMA provides, a medical review panel was convened, and the panel found that the evidence did not support the conclusion that Paul failed to meet the applicable standard of care. The Coxes then moved in the trial court for partial summary judgment on the issue of liability, arguing that "Paul totally failed to ever notify, or even identify, Suzan Cox for nearly five years after his duty to do so first existed. Such failure is a breach of his duty as a matter of law." Paul responded that this breach of duty to Suzan turned on a genuine issue of material fact, specifically, "whether the steps taken by Dr. Paul in conducting the two searches was reasonable." The trial court denied the Coxes' motion and certified its ruling for interlocutory appeal. The Court of Appeals reversed, Cox v. Paul, 805 N.E.2d 901 (Ind. Ct. App. 2004), and this Court granted transfer. Cox v. Paul, 822 N.E.2d 976 (Ind. 2004).

The standard of review of a grant or denial of a motion for summary judgment is the same as that used in the trial court: summary judgment is appropriate only where the designated evidence shows there is no genuine issue of material fact and the moving party is entitled to a judgment as a matter of law. All facts and reasonable inferences drawn from those facts are construed in favor of the nonmoving party. Corr v. Am. Family Ins., 767 N.E.2d 535, 537-38 (Ind. 2002) (citing Bemenderfer v. Williams, 745 N.E.2d 212, 215 (Ind. 2001)).

Liability for Failure to Notify Patient of Newly Discovered Risks

In Harris v. Raymond, 715 N.E.2d 388 (Ind. 1998), this Court faced an almost identical set of facts. In 1986 Dr. David Harris[1] surgically replaced Mary Raymond's temporomandibular joints with Vitek implants. Id. at 390. In 1991, Harris received the Vitek "Dear Doctor" letter from the FDA. Id. at 391. Harris's staff attempted to compile a list of patients with Vitek implants, but Raymond was not contacted even though Harris's staff had access to Raymond's current address, received phone calls from her, and responded to her request for copies of her medical records, all after 1991. In 1993, Raymond sought medical care when she developed a severe earache and began bleeding from the ear. A CT scan revealed that her Vitek implants had shattered. Id. Raymond subsequently sued Harris, alleging that he failed to warn her that the implants were defective and that she suffered damages including a perforated eardrum and muffled hearing as a result.

Harris moved for summary judgment contending that Raymond's claims were barred by the statute of limitations provided in the Medical Malpractice Act. Id. Raymond responded that the two-year statute of limitations was unconstitutional. The trial court denied Harris's motion and the Court of Appeals affirmed. Id. On transfer, before addressing the statute of limitations question, this Court noted "two preliminary issues" that were not raised by the parties on appeal. Id. at 392. One of those was the validity of Raymond's claim that Harris had breached his duty to warn her of the safety issues related to Vitek. This Court stated that "it is essential that the health care provider disclose material facts to the patient at appropriate times during the course of the patient's treatment." Id. at 394. This Court pointed out that the physician was best positioned to maintain patient records so that patients may be contacted if "significant new information" becomes available bearing on the safety of a treatment. Id. This Court concluded that, "as a matter of law, defendant had a duty to warn both current and former patients, including plaintiff, of safety issues highlighted by the manufacturer and/or the FDA, and that, based on the undisputed facts, defendant has breached that duty here." Id. at 395. This Court went on to state that "at the very least" a safety alert "triggers the need to make reasonable efforts" to notify patients. Id.

[1] The record does not reveal whether this is the same Dr. David Harris who at one time practiced with Dr. Paul.

In this case, the parties, following Harris, agree that the plaintiffs' claim requires duty, breach, injury, and proximate cause. At this stage of the litigation the issue is solely whether breach is established by the agreed fact that Paul failed to communicate the dangers of Vitek implants until some five years after he was informed of the product's recall. Whether a defendant has a duty to conform conduct to a certain standard for the benefit of the plaintiff is generally a question of law. Id. at 393. The question of the breach of a duty is usually one for the trier of fact. Id. However, if any reasonable jury would conclude that a specific standard of care was or was not breached, the question of breach becomes a question of law for the court. Id. at 394. The Coxes argue that under Harris Paul had a duty to warn Suzan of the recall and breached that duty as a matter of law. Paul agrees that he had a duty to make "reasonable efforts" to identify those patients who had received the Vitek implants, but contends that whether he made reasonable efforts is a fact for resolution by a jury.

The Coxes argue that under Harris, breach is established as a matter of law by a showing that Paul did not notify Suzan. In effect, this calls for strict liability for failure to notify Suzan. We agree that Paul had a duty to warn Suzan of the risks associated with her dental implants, but we do not think that the duty is absolute. In Harris we stated that on that record Harris breached his duty to Raymond as a matter of law. Id. We also explained, "at the very least, a safety alert issued by the manufacturer or the FDA triggers the need to make reasonable efforts to contact all current and former patients with the implants." Id. at 395. We adopt the latter formulation as the general rule, and expressly hold that the applicable standard is a requirement to exercise reasonable care to communicate to the patient but not necessarily to ensure that the patient received notification.

Although Paul is not subject to strict liability for failure to notify, as Harris observed, the doctor is in the best position to know who received what treatment. Id. at 395. The doctor is also in the best position to establish the efforts to notify patients. We think that in this case, an analysis similar to *res ipsa loquitor* should apply. The plaintiff in a negligence action ordinarily bears the burden of proving the failure of the defendant to conform to a specified standard of conduct. Restatement Torts (Second) § 328A (1965). However, in some situations the plaintiff is able to raise an inference that the defendant was negligent from the facts known to the plaintiff, but proof of the specific negligent act or omission may be difficult or impossible. "The

general rule of *res ipsa loquitor* merely permits the trier of fact to infer negligence as the cause of harm without proof of specific acts of negligence when the facts fairly analyzed show that, more likely than not, (a) the plaintiff's harm was caused by negligence, even though the specific act of negligence is not identified, and (b) the defendant was the author of the negligence." Dan B. Dobbs, The Law of Torts § 154, at 371 (2001).

Here, the Coxes have raised an inference that Paul was negligent by showing that he did not notify Suzan until several years after he received the FDA notice. *Res ipsa loquitor*, in some circumstances, merely permits the trier of fact to infer negligence. In others, it may function "as a rule of policy which goes beyond the probative effect of circumstantial evidence, and requires the defendant to explain the event of circumstantial evidence or be liable." Restatement Torts (Second) § 328D, cmt. b. If so, *res ipsa loquitor* may be "given a greater procedural effect" by shifting the burden of proof to the defendant or creating a presumption of negligence. Id.

We think this reasoning is appropriate here. A showing that no communication was received is sufficient to shift the burden to Paul to explain what steps he took to notify Suzan or why no steps were taken. The Restatement points out that cases in which the defendant is required to explain an event frequently involve special responsibility of the defendant to the plaintiff. Id. This is the case here. Paul undertook a special responsibility toward Suzan when she became his patient and he performed her surgery. "The relationship between a health care provider, such as a physician or oral surgeon, and a patient is special and particularly important in that the patient relies heavily on the expertise of that health care provider in making decisions that may greatly impact the patient's health and well-being." Harris, 715 N.E.2d at 394; see also Dobbs, supra at § 242, at 631 ("the duty of care owed by medical and other professionals is usually expressed and applied in a special way"). Equally important, Paul, either directly or through one of his employees, was in exclusive control of the patient records. He, therefore, is fairly charged with responsibility for explaining the steps he took to give notice and why they were reasonable under the circumstances. If he shows reasonable steps, the trier of fact may find him not liable despite the failure of those steps to accomplish the goal of completing the communication to the patient.

There are a number of explanations that might be found by the trier of fact to be sufficient to explain lack of notice. For example, there may be no liability if it can be shown that some catastrophe has befallen the doctor's office through no fault of the doctor, and the relevant files had been destroyed, rendering identification of all patients impossible. Moreover, failure of receipt does not establish lack of reasonable steps to send notice. But only the sender can maintain a record of the patients identified and the means of notification. It is therefore appropriate to place the burden on the sender to show what was done to give notice if the claim is that reasonable steps were taken, even if notice was not received.

The Coxes claim that Suzan was not given notice of the FDA warning until nearly five years after Paul received it. Paul does not dispute that, but argues that he made reasonable efforts to contact her because he directed his staff to make two sweeps of his office and because he contacted her as soon as he discovered her file. Of course, if the sweeps were negligently performed by Paul's staff, his civil tort liability is the same as for his personal negligence. See, e.g., Stropes v. Heritage House Childrens Center, Inc., 547 N.E.2d 244, 247 (Ind. 1989). Although he explains that Suzan's file might have been moved or misplaced when Paul left his partnership with Harris and started his own office, he does not know whether this occurred, and if it did, he does not explain how it was not a result of negligence.[2] There is no evidence of any attempt to notify Suzan in this record and no claim of an office fire or other intervening event that might have frustrated reasonable efforts to give notice. Only speculation, not evidence, is offered to support any explanation for lack of notice, and that explanation even if it were supported by evidence is not free of the inference of negligence. In short, the facts the Coxes have established leave room for no explanation other than negligence attributable to Paul or one of this employees or a non-negligent explanation as to which Paul has the burden of proof but failed to carry that burden. This is enough for the Coxes to make their *res ipsa loquitor* case. The Coxes are therefore entitled to partial summary judgment as a matter of law.

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[2] The Chief Justice addresses only the reasonable care in the design of the overall search of Dr. Paul's records. Reasonable care is also required in the recording of each individual patient's records and in identifying those to whom notice is required. In a products liability case, one can establish liability either by showing negligent design or negligent manufacture. See Hoffman v. E.W. Bliss Co., 448 N.E.2d 277, 281 (Ind. 1983). Similarly, Paul or those in his employ may have designed a reasonable process to identify the affected patients. But if that is the case there is no apparent explanation for failure of notice other than negligent execution of that design or failure to keep records of what the process was and how it was implemented.

Conclusion

The order of the trial court on the parties' cross motions for partial summary judgment is vacated. This case is remanded with instructions to grant the plaintiffs' motion for partial summary judgment.

Dickson, Sullivan, and Rucker, JJ., concur.

Shepard, C.J., concurs and dissents with separate opinion.

SHEPARD, C.J., concurring and dissenting.

I agree with the Court's description of the physician's duty to make reasonable efforts to notify patients of safety issues identified by manufacturers and the FDA.

I think the Court's disposition of the motion for summary judgment, however, places the law declared by this case much closer to strict liability than to reasonable efforts, notwithstanding the majority opinion's disclaimer to the contrary.

The evidence before us on summary judgment is that Dr. Paul initiated an examination of all his patient files after receiving the FDA notice. This campaign involved the reading of every chart to identify which of his patients received Vitek implants. The records were a veritable mountain, some 13,000 files in all. It took several months to examine them all in search of the .8% that ultimately turned out to be Vitek patients who needed notification.

The doctor directed his staff to do this search not once but twice, and they conducted another examination of files in 1994. Indeed, it is apparent that they were still on the lookout even after that, as Mrs. Cox's implant was ultimately identified in 1996.

The majority opinion says nothing about the extent of the doctor's efforts to identify and notify these patients. This omission is appropriate, taken in light of the straightforward observation that any such effort that does not succeed in identifying every patient and generating a notice for every patient is likely the product of negligence that would constitute breach of duty as a matter of law. (Slip op. at 7.) Only a fire or other catastrophe is said to be a defense. (Id.)

By the time the Court travels to this point, claiming that the doctor has not offered "any explanation for lack of notice," (id.), it has wandered off the legal standard we set seven years ago for such matters: "a safety alert 'triggers the need to make reasonable efforts.'" (Slip op. at 4, quoting Harris v. Raymond, 715 N.E.2d 388, 305 (Ind. 1998).

If, under Harris v. Raymond, the legal question is whether the doctor made "reasonable efforts," I would say that this record makes summary judgment for either party inappropriate. I would direct the denial of both motions and have the case submitted to a jury.