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NOT TO BE PUBLISHED

Commonwealth Of Kentucky

Court Of Appeals

NO. 1999-CA-000548-MR

MATTIE BERNARD — APPELLANT

v.

APPEAL FROM HARDIN CIRCUIT COURT
HONORABLE HUGH ROARK, JUDGE
ACTION NO. 93-CI-01259

JEFFREY B. RICHARDSON, M.D. — APPELLEE

OPINION
AFFIRMING
** ** ** ** **

BEFORE: COMBS, KNOPF, AND TACKETT, JUDGES.

KNOPF, JUDGE: Mattie Bernard appeals from a February 9, 1999, summary judgment of the Hardin Circuit Court dismissing her medical negligence action against Jeffrey B. Richardson, M.D. Bernard contends that her claim should be excepted from the general rule requiring expert testimony to support a cause of action for malpractice and that the trial court erred by concluding otherwise. Being persuaded that the trial court applied the general rule correctly, we affirm.

At some point in the late 1980's, apparently, Bernard began suffering from bouts of a hive-like rash. The rash would appear without warning at different places on her body and would

last for several days. It was physically and mentally distressing, and on occasion it affected Bernard's eyes, making them so painfully sensitive to light that she was unable to leave her house. Bernard's family physician tried various remedies, without success, and referred Bernard to several specialists. In early August 1992, her condition still unresolved, Bernard was referred by an allergist to the appellee, Dr. Richardson, who is a dermatologist.

Dr. Richardson's initial prescriptions seem to have fared no better than the others that had been tried. In late August 1992, Dr. Richardson prescribed Dapsone, an antibacterial drug, which Bernard took orally once per day. When she had taken the medicine for about two weeks, she began to experience a sore throat; fever; generalized pains, some of them sharp; weakness; and labored breathing. Consequently, on about September 6 or 7, 1992, Bernard was seen in the emergency room at Hardin Memorial Hospital. Apparently she was treated for pneumonia and sent home. Her symptoms worsened, however, particularly her shortness of breath, and she returned to the emergency room on September 9, 1992.

She was admitted to the hospital, where it was determined that she was suffering from an adverse reaction to Dapsone. That medicine was discontinued, and gradually Bernard's acute symptoms subsided. The rash, too, the parties seem to agree, appears now far less often than it did and in episodes far less severe. Nevertheless, Bernard claims that, as a result of her exposure to Dapsone, she is permanently weakened and sore;

that persistent troubled breathing severely curtails her activities; and that her liver, spleen, and lungs are permanently damaged.

In September 1993 Bernard filed suit against Dr. Richardson. She alleged, among other things not pertinent to this appeal, that he had breached his duty to monitor her response to Dapsone. In September 1998, and by renewed motion a few weeks later, Dr. Richardson moved for summary judgment on the ground that Bernard, after more than adequate time for discovery, had failed to proffer expert testimony concerning the existence and nature of the duty alleged to have been breached. Bernard responded by arguing that expert testimony was not necessary in this case because other evidence, particularly the drug manufacturer's warnings, adequately defined Dr. Richardson's duty. The trial court's rejection of this argument prompted Bernard's appeal.

As the parties have noted, summary judgments involve no finding of disputed fact. Rather, the record is to be construed so as to give the benefit of all reasonable doubts to the non-movant. Steelvest, Inc. v. Scansteel Service Center, Inc., Ky., 807 S.W.2d 476 (1991). Accordingly, although the record is far from clear on this point, we shall assume that Dr. Richardson made no attempt to monitor Bernard's response to the Dapsone during the entire two weeks of her treatment and learned of her hypersensitivity to the drug only upon her adverse reaction.

As the parties have also noted, this Court reviews summary judgments *de novo*, in the sense that we owe no deference

to the conclusions of the trial court. As did the trial court, we ask whether material facts are in dispute and whether the party moving for judgment is clearly entitled thereto as a matter of law. Under this state's rules of practice, summary judgments are to be granted cautiously; they are appropriate only when it appears impossible for the non-movant to prove facts establishing a right to relief or release, as the case may be. *Id*.

Medical providers do not guarantee the success of their treatments, and the law does not require them to do so. Many treatments, in fact, involve a substantial risk of harm regardless of anything the provider does or does not do. In most cases, therefore, medical negligence is not to be inferred simply from an adverse result. Perkins v. Hausladen, Ky., 828 S.W.2d 652 (1992); Neal v. Wilmoth, Ky., 342 S.W.2d 701(1961). The plaintiff alleging medical negligence must show, rather, that the physician (or other provider of medical services) probably caused the alleged injury by failing to meet a pertinent standard of care or skill. Perkins, *supra*. Moreover, because non-experts are frequently incapable of determining the degree of care or skill required in a particular instance, the rule has developed in medical negligence cases "that negligence must be established by medical or expert testimony unless the negligence . . . [is] so apparent that laymen with a general knowledge would have no difficulty in recognizing it." Harmon v. Rust, Ky., 420 S.W.2d 563, 564 (1967). *See also* Keel v. St. Elizabeth Medical Center, Ky., 842 S.W.2d 860 (1992).

Bernard acknowledges this "expert testimony" rule, and acknowledges further that the "common knowledge" exception to the rule has ordinarily been applied only when virtually no technical knowledge is required to recognize the wrongfulness of the plaintiff's injury--cases, for example, of sponges sewn up within surgical wounds. Laws v. Harter, Ky., 534 S.W.2d 449 (1976); Jarboe v. Harting, Ky., 397 S.W.2d 775 (1965); Butts v. Watts, Ky., 290 S.W.2d 777 (1956). Discussing this exception in Perkins, *supra*, however, our Supreme Court recognized that, in some malpractice cases

> an inference of negligence [is] sufficiently supplied by medical testimony of record even though the plaintiff had no expert witness to opine that the conduct fell below the standard of acceptable professional care. . . . [I]n determining whether the evidence was sufficient to support an inference of negligence, both common knowledge and the testimony of medical witnesses could be relied on, separately and in combination.

828 S.W.2d at 655 (citing Cho v. Kempler, 2 Cal.Rptr. 167 (1960)).

Relying on these notions from Perkins, Bernard argues that the 'common knowledge' exception should be extended to cases in which there is a reliable albeit non-testamentary source of technical information on the basis of which laymen could readily recognize both the physician's standard of care and its breach. In particular, she maintains that the drug descriptions and warnings pharmaceutical companies distribute with their products, and which are collected and periodically reprinted in the

Physicians' Desk Reference[1] (PDR), can, and in this case do, obviate expert testimony to establish the practitioner's standard of care.

This narrow issue is apparently one of first impression in Kentucky although our sister states have addressed it extensively. Annotation, "Liability for Drug Side Effects," 47 ALR5th 433 (1997). At least two states have recognized the rule Bernard urges and permitted PDR entries to suffice as *prima facie* evidence of the physician's duty. Mulder v. Parke Davis, 181 N.W.2d 882 (Minn. 1970); Ohligschlager v. Proctor Community Hospital, 303 N.E.2d 392 (Ill. 1973). The more prevalent rule, however, is that PDR entries, like passages from learned texts in general,[2] may sometimes be admitted in conjunction with expert testimony, but do not alone satisfy the malpractice plaintiff's burden of proving the pertinent standard of care or skill.[3]

We find little with which to quarrel in this latter statement of the rule, but the issue may be resolved slightly less categorically, we believe, under this state's precedents. As noted above, the rule in Kentucky has long been that expert testimony is required for every element of a malpractice

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[1]See Comment, "Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits," 44 U. Chi. L. Rev. 398 (1977); Lawrence, "Drug Manufacturers' Recommendations and the Common Knowledge Rule to Establish Medical Malpractice," 63 Neb. L. Rev. 859 (1984).

[2]See KRE 803(18).

[3]Spensieri v. Lasky, 701 N.Y.S.2d 689 (Ct.App. 1999); Morlino v. Medical Center, 706 A.2d 721 (N.J. 1998); Craft v. Peebles, 893 P.2d 138 (Hawaii 1995); Mears v. Marshall, 905 P. 2d 1154 (Or.App. 1995); Ramon v. Farr, 770 P.2d 131 (Utah 1989).

plaintiff's case unless the circumstances are such that a layperson could readily recognize the existence of a particular element without it. It is conceivable that a PDR entry or package insert could have such a clear and unmistakable import as to amount to such a circumstance: "Caution! Because of a high risk of birth defects, under no circumstances administer this product to a pregnant woman." We are unwilling, therefore, to rule categorically that the "common knowledge" exception could never apply in such a case.[4] In the vast majority of cases, however, expert testimony would be necessary to interpret the PDR entry, and so the general rule requiring expert testimony would remain in effect.

That is the case here. The manufacturer's warnings upon which Bernard relies provide in pertinent part as follows:

> The patient should be warned to respond to the presence of clinical signs such as sore throat, fever, pallor, purpura or jaundice. Deaths associated with the administration of Dapsone have been reported from agranulocytosis, aplastic anemia and other blood dyscrasias. Complete blood counts should be done frequently in patients receiving Dapsone. The FDA Dermatology Advisory Committee recommended that, when feasible, counts should be done weekly for the first month, monthly for six months and semi-annually thereafter.

Bernard maintains that, in light of this warning, a lay person could readily recognize that Dr. Richardson had a duty to perform weekly blood counts during the first two weeks of Bernard's Dapsone treatment and that he breached that duty.

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[4]We of course express no opinion concerning the admissibility of such evidence under the hearsay rules.

The warning, however, calls for "frequent" blood counts, and notes an independent recommendation that blood counts be taken weekly when it is "feasible" to do so. We are not persuaded that this is the sort of clear and unmistakable warning from which a lay person can readily infer the physician's standard of care. Plainly, the warning is serious and is to be taken seriously, but its precautions are vague or are merely recommendations. They are subject, to the conditions of the particular case, which it is the doctor's responsibility to assess. Whether Dr. Richardson's assessment and handling of this case was inadequate cannot be determined, therefore, from the PDR recommendations alone. That determination required expert testimony interpreting the PDR and reasonably suggesting that in these circumstances Dr. Richardson should have responded otherwise than he did. Absent such testimony, Bernard's claim failed as a matter of law, and summary judgment was appropriate. Accordingly, we affirm the February 9, 1999, judgment of the Hardin Circuit Court.

TACKETT, JUDGE, CONCURS.

COMBS, JUDGE, DISSENTS BY SEPARATE OPINION.

COMBS, JUDGE, DISSENTING: It is impossible to determine from the short record before us whether Dr. Richardson — as a matter of <u>fact</u> — properly monitored the patient's response to Dapsone. That material fact remains in dispute and should be resolved at trial — where the failure to call an expert witness would very likely be fatal. However, the patient should be allowed to proceed to trial and to have the chance to produce an

expert witness at that time to testify as to the proper standard of care and whether or not it was breached. She should not have to make her case in chief at this preliminary stage of the proceedings. I believe that summary judgment was premature and, therefore, incorrect under these circumstances.

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