Fusco v. Shannon, 438 Md. 24 (Md. 2014)

Topics Covered: Expert Witnesses

Outcome: Favorable

Issue

The issues in this case were whether (a) a trial judge abused his discretion by refusing to allow a pharmacist to testify in a liability suit brought against a physician that the physician had failed to obtain his patient's informed consent, and (b) whether the physician's failure to disclose that a drug was not FDA approved for the patient's condition was a material risk that should have been disclosed to the patient.

AMA Interest

The AMA believes that an expert witness who testifies against a physician in a medical liability case should have comparable education, training, and occupational experience in the same field as the defendant or have specialty expertise in the disease process or procedure at issue in the case. The AMA further believes that the official labeling statements approved by the FDA establish the parameters governing advertising or promotion of the drug product but should not be regarded as a legal standard of acceptable or accepted medical practice.

Case Summary

Anthony Fusco was diagnosed with prostate cancer. After two years of "watchful waiting," Mr. Fusco, with the advice of his regular urologist, elected a combination of radiotherapy and hormone treatment. Following various referrals, he consulted with Kevin Shannon, MD, a hematologist/oncologist.

Dr. Shannon suggested that Mr. Fusco be treated with Amifostine, a drug that would reduce the risk of radiation damage to Mr. Fusco's bladder and rectum. Dr. Shannon advised Mr. Fusco that Amifostine could cause potential side effects, including "a local or slightly more extensive skin reaction." Dr. Shannon informed Mr. Fusco that there were no alternatives to Amifostine. Although Amifostine had not been FDA-approved for protection against injury arising from radiation therapy treatment, Dr. Shannon did not advise Mr. Fusco of this non-approval.

Mr. Fusco received the radiation therapy, and he was also treated with Amifostine. Unfortunately, he developed, first, an acute systemic rash and lip swelling, then a more severe skin reaction, known as Stevens - Johnson Syndrome, and then a yet more severe skin condition known as Toxic Epidermal Necrolysis Syndrome. He died of a stroke, with the medical examiner listing Toxic Epidermal Necrolysis Syndrome as a contributing cause of death.

Mr. Fusco's estate and his widow sued Dr. Shannon and his practice group. The plaintiffs claimed that Dr. Shannon had failed to obtain Mr. Fusco's informed consent prior to administration of the Amifostine, and the Amifostine therapy had been a factor in Mr. Fusco's demise. As an expert witness, they proffered a doctor of pharmacy, who was not a medical

doctor. The pharmacist was prepared to testify: (a) It was inappropriate for Dr. Shannon to have used Amifostine for a patient, such as Mr. Fusco, who was undergoing treatment for radiation therapy for prostate cancer. Amifostine therapy was only successful in patients diagnosed with head, neck, and kidney cancer, but not prostate cancer, and (b) The FDA had not approved Amifostine to protect against injury arising from radiation therapy treatment. Thus, the plaintiffs alleged, FDA non-approval was a material risk associated with the Amifostine treatment, and Mr. Fusco should have been advised of that risk.

The defendants challenged the pharmacist's qualifications as an expert witness, and the trial judge barred his testimony. The judge found that the pharmacist's putative testimony would have been more aligned with negligence than informed consent and, further, the pharmacist was unqualified to give expert testimony against a physician, because the pharmacist lacked a medical degree. The case was subsequently tried before a jury, which rendered a verdict in favor of the defendants. The plaintiffs then appealed to the Maryland Court of Special Appeals, the intermediate-level appellate court in Maryland.

The Court of Special Appeals noted that the sufficiency of expert witness qualifications ordinarily falls within the discretion of the trial judge. The court further noted that "[w]e have not found any Maryland cases concerning whether a pharmacist is qualified to testify regarding a prescription drug in an informed consent action [and] this issue is one of first impression in Maryland." However, it then observed that similar situations had arisen in other states; sometimes pharmacists had been allowed to testify as expert witnesses in professional liability cases against physicians and sometimes not. Generally, the court concluded, pharmacists were allowed to testify in claims based on lack of informed consent, but they were not allowed to testify in claims based on other aspects of negligence.

The Court of Special Appeals concluded that the trial judge here had erred in barring the pharmacist's testimony. The court held that the pharmacist should have been allowed to testify about "the material risks associated with a regimen of Amifostine therapy in connection with radiation therapy, particularly for this patient, including that the use of this drug under these circumstances was not previously approved by the FDA." However, it would be impermissible for the pharmacist to testify that Dr. Shannon was negligent for having prescribed Amifostine for Mr. Fusco. The case was reversed and remanded.

Dr. Shannon and his practice group have appealed the Court of Special Appeals decision to the Maryland Court of Appeals, which is the highest court in Maryland.

On April 24, 2014, the Court of Appeals reversed the Court of Special Appeals and affirmed the trial court. It held that the adequacy of the informed consent had to be measured by the disclosure of the materiality of the risks associated with the administration of Amifostine. This depended not only on the existence of potential side effects but also with the likelihood that those side effects might occur and their severity if they did occur.

In this case, proffered testimony of the pharmacist would have addressed the existence of the side effects but not the likelihood of their occurrence or their severity. Thus, the pharmacist's testimony would not have shown that Dr. Shannon failed to advise Mr. Fusco about the material risks associated with the administration of Amifostine. Further, the Supreme Court held, it was immaterial whether the FDA had approved the Amistofine for the purposes of Dr. Shannon's treatment of Mr. Fusco. Accordingly, it was within the discretion of the trial judge to bar the pharmacist's testimony.

Litigation Center Involvement

The Litigation Center, along with Med Chi, the Maryland State Medical Society, and Medical Mutual Liability Insurance Society of Maryland filed an *amicus* brief in support of the defendants.

Maryland Court of Appeals brief