



Zito v. Zabarsky, 812 N.Y.S.2d 535 (N.Y. Sup. Ct., App. Div. 2006)

Topics Covered: Expert Witnesses

Outcome: Very Unfavorable

Issue

The issue in this case was whether an appropriate legal standard was applied in determining the admissibility of expert witness testimony in a medical malpractice case.

AMA Interest

The AMA believes that the testimony of medical expert witnesses should reflect current scientific thought and standards of care that have gained acceptance among peers in the relevant field.

Case Summary

Pamela Zito, sued her physician, Dr. Gary Zabarsky, for medical malpractice, alleging that she had developed polymyositis, an autoimmune disease, as a result of Dr. Zabarsky's improper prescription of the statin drug Zocor, a cholesterol lowering medication. Dr. Zabarsky had prescribed Zocor at the highest recommended daily dose of 80 milligrams. Soon thereafter, Zito began experiencing pain in her joints, weakness, and shortness of breath. When her blood samples exhibited elevated levels of creatine phosphokinase ("CPK"), Dr. Zabarsky discontinued the Zocor therapy. She was then diagnosed with polymyositis.

Zito alleged that Dr. Zabarsky had departed from accepted medical practice by prescribing an "excessive dose" of Zocor, thereby causing her polymyositis. As Zito's theory of causation involved a question of "scientific novelty," the trial court held a *voir dire* hearing to determine the admissibility of her proffered expert testimony. At this hearing, Zito's medical expert employed a causation theory involving multiple steps and inferences. He first testified that one of the possible side-effects of statin drugs is myopathy, a muscular disease characterized by increased levels of CPK. Following her use of Zocor, Zito had elevated levels of CPK, which may have caused the release of certain intracellular constituents. These intracellular constituents in turn caused a release of antigens, and Zito's immune system responded by producing "anti-jo-1" antibodies. These antibodies led to the onset of polymyositis.

Zito's medical expert claimed, without citing any scientific literature, that it was "established to a degree of pharmacological certainty" that: (1) statins cause myopathy and (2) myopathy is characterized by increased levels of CPK. Based on these "generally accepted scientific principles," Zito "reasoned" that the release of CPK would be concurrent with the release of

other intracellular constituents, which would ultimately cause an immune system reaction leading to polymyositis.

In support of his reasoning, Zito cited a single case study published in *The Lancet* in 1997 that recounted the onset of polymyositis in “one patient” after he had received a 20-milligram dose of Zocor. This case study, however, contained several notable differences from Zito’s case. For instance, in the case study, the patient had *transitory* polymyositis, which went into remission after a few days of steroid treatment without relapse. Zito’s condition was *permanently* disabling polymyositis. The case study patient had also tested negative for the “anti-jo-1” antibody, which was a critical component of the hypothesis espoused by Zito’s medical expert. Finally, the case report patient revealed “considerable variation in fibre size, muscle-fibre necrosis and fragmentation, and abundant inflammatory cell infiltration.” Zito’s biopsy, however, was unremarkable and showed no evidence of inflammation or drug-induced toxicity.

The trial court ultimately disallowed the testimony of Zito’s medical expert, because no scientific literature expressly reported a causal nexus between excessive doses of Zocor and the onset of polymyositis. The single case study, the court found, was insufficient to support the claimed nexus. As a result of the preclusion of Zito’s medical expert, the trial court entered a judgment in Dr. Zabarsky’s favor. Zito then appealed the decision precluding her medical expert to the Appellate Division of the New York Supreme Court.

The Appellate Division reversed and remanded for trial, holding that an expert need not base his or her opinion on medical causation on established scientific literature. A single case study, coupled with “scientifically accepted methodology and reasoning” is sufficient. The court indicated its concern that plaintiffs who sue defendants based on new medical theories would be disadvantaged, as there would be few studies in the scientific community to support their allegations. Dr. Zabarsky then asked the Appellate Division to reconsider its decision reversing the trial court’s ruling. In the alternative, Dr. Zabarsky requested certification for appeal to the New York Court of Appeals.

The Appellate Division denied the motion for reconsideration or certification, without discussion.

Litigation Center Involvement

The Litigation Center joined with the Medical Society of the State of New York in an *amicus curiae* brief that opposed the admission of “junk science” in a medical malpractice lawsuit against a physician. The *amicus* brief, which was submitted in support of Dr. Zabarsky’s motion for reconsideration or certification, pointed out: (1) the lone case study did not support Zito’s theory of causation, as it pertained to a single, distinguishable incident, (2) there was no scientific proof of Zito’s theory of causation, (3) the medical expert made no attempt to rule out alternative causes, (4) the decision conflicted with existing New York legal standards of scientific reliability, and (5) Zocor was well established and was far from the type of “new drug” that might arguably justify a relaxation of existing legal standards.