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PROFESSIONAL LIABILITY

Easier Times Ahead for Plaintiffs In Informed Consent Cases

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In the landmark decision of *Largey v. Rothman* 110 N.J. 204 (1988), the state Supreme Court revitalized informed consent cases. The *Largey* decision has been expanded by a continuum of cases, including four recently published opinions, *Caputa v. Antiles*, 296 N.J. Super. 123 (App. Div. 1996), *Canesi v. Wilson,* 295 N.J. Super. 354 (App. Div. 1996), *cert. granted* 149 N.J. 139 (1997); *Lombardo v. Borsky*, 298 N.J.Super. 658 (App. Div. 1997) and *Kimmel v. Dayrit*, A-6323-94T5 (N.J. Super. Ct. App. Div., approved for publication June 5, 1997). These decisions should be studied carefully for the guidance they provide.

A brief review of the evolution of the law of informed consent will assist in fully understanding these recent developments. Before *Largey*, the law of informed consent was stated in *Kaplan v. Haines* 96 N.J. Super. 242 (App. Div. 1967) *aff'd* 51 N.J. 404 (1968), which held that the plaintiff in an informed consent case must "prove what a reasonable medical practitioner of the same school and same or similar community, under the same or similar circumstances, would have disclosed to his patient." Id., at 257. This holding became known as the "reasonable physician" standard. Since many doctors provided only limited information to the patient, the "reasonable physician" standard made it virtually impossible for plaintiffs to prevail in informed consent cases.

Largey overruled *Kaplan* and imposed on the physician a duty to disclose all "material" risks associated with the proposed treatment. *Largey, supra,* 110 N.J. at 211-213, citing the seminal case of *Canterbury v. Spence,* 464 F.2d 772 *(D.C. Cir.) cert. denied* 409 U.S. 1064 (1972). *Largey* explained that a risk is "material when a reasonable patient, in what the physician knows or should know to be the *patient's position*, would be likely to attach significance to the risk . . . in deciding whether to forego the proposed therapy or to submit to it." Id. at 211-212. (Emphasis added). This has come to be known as the "prudent patient" standard. Id. at 212.

Largey quoted Canterbury's holding that the "the law must itself set the standard for adequate disclosure," and, therefore, whether a particular risk must be disclosed should be determined as a matter of law by the trial court. Id. at 211. The decision started an evolutionary process of rethinking the doctrine of informed consent. Two years after *Largey* was decided, *Battenfeld v. Gregory,* 247 N.J. Super. 538 (App. Div. 1991), held that a doctor must not only warn a patient of the risks associated with treatment but must also warn of "the potential hazards of refusing the recommended treatment." *Battenfeld, supra,* 247 N.J. Super. at 552. Also in 1991, in the *Estate of Behringer v. The Medical Center at Princeton* 249 N.J. Super. 597 (Law Div. 1991), the court concluded that an HIV- positive surgeon must disclose even a remote risk of transmitting the virus to the patient:

> Where the ultimate harm is death, even the presence of a low risk of transmission justifies the adoption of a policy which precludes invasive procedures when there is "any" risk of transmission . . . If there is to be an ultimate arbiter of whether the patient is to be treated invasively by an AIDS-positive surgeon, the arbiter will be the fully-informed patient. The ultimate risk to the patient is so absolute — so devastating — that it is untenable to argue against informed consent combined with a restriction on procedures which present "any risk" to the patient.

Behringer, supra, 249 N.J. Super. at 657- 658.

Expert Testimony

Several post-*Largey* cases have analyzed the requirement of

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expert testimony in informed consent cases. Since the standard for disclosure is determined by the court as a matter of law, the expert opinions that are required in the informed consent case differ from the opinions needed in other types of malpractice cases. *Febus v. Barot*, 260 N.J. Super. 322 (App. Div. 1992), explicitly held that an expert witness is not needed to establish whether a risk must be disclosed:

> The sufficiency of disclosure under the prudent patient standard requires that the disclosure be viewed through the mind of the patient, not the physician. Implicit in this shift of emphasis is the recognition that *expert testimony is no longer required in order to establish the medical community's standard for disclosure* and whether a physician failed to meet that standard.

Id. at 327 [Emphasis added].

However, the court hastened to add that the need for expert testimony was not totally eliminated since it still "must first be shown that the risk . . . was recognized within the medical community." Id. at 327. However, in *Adamski v. Moss* 271 N.J. Super. 513 (App. Div. 1994) the court recognized that in most circumstances the plaintiff could use learned treatises to prove that the risk was known in the medical community. See *Jacober v. St. Peter's Medical Center*, 128 N.J. 475 (1992). The court even observed that the plaintiff probably could have compelled the defendant to qualify a text as reliable during a deposition. *Adamski*, supra, 271 N.J. Super. at 520.

Extending the Largey Doctrine

Largey has been further expanded in *Caputa v. Antiles*, 296 N.J. Super. 123 (App. Div. 1996), which involved treatment for a kidney stone. Plaintiff's expert testified that a kidney stone such as the size of plaintiff's had a "90% chance to pass without intervention." Id. at 130. However, plaintiff was not informed of any treatment option other than surgery, and he sustained severe injuries during five operations to remove the stone. The defendant conceded that he did not provide plaintiff with the option of consumption of fluids and observation before attempting to surgically remove the stone.

Defendant's expert anachronistically testified that the defendant had complied with the standard of care, explaining: "The doctor has to make the decision and the patient has to agree to it." Id. at 132. The defendant's expert also testified that defendant had exercised good judgement and "did the appropriate thing in not informing the patient about possibly observing the stone longer." Id. at 132. The trial court denied the plaintiff's motion for a directed verdict as to the informed consent claim and the jury found that the defendant was not negligent. The Appellate Division reversed and remanded with instructions that the plaintiff was entitled to a directed verdict on liability. The court explained:

> We conclude there was no dispute that observation existed as a reasonably available medical alternative of which plaintiff had to be advised. Whether the doctor had the duty to disclose such an alternative is a legal question — neither the treating doctor nor the medical profession is the final arbiter. The defense expert's opinion that it was the physician's job to make the decision and present the best alternative is in direct conflict with the holding in *Largey*, which states that "it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie." *Largey*, supra, 110 N.J. at 214.

Caputa, supra, 296 N.J. Super. at 135.

The court deemed it significant that the surgical procedure was not emergent and plaintiff "was not in danger of losing his life or suffering serious bodily injury in the absence of immediate surgery." Id. at 136. Therefore, "the jury should have been instructed, that as to the initial procedure, plaintiff had established that defendant failed to offer the alternative treatment of observation without intervention and thereby breached his duty to obtain plaintiff's informed consent." Id.at 137.

Most recently, in *Kimmel v. Dayrit*, A-6323-94T5, (N.J. Super. Ct. App. Div. approved for publication June 5, 1997), the court, in a wide-ranging opinion written by Judge Wecker, held, inter alia, that a physician has a duty to inform a patient of the availability of diagnostic testing. In *Kimmel*, the plaintiff's husband was under the care of the defendant, a gastroenterologist, after undergoing a resection of the sigmoid colon in January of 1984. Plaintiff's husband continued under the care of the defendant through April of 1989 when the defendant ordered a CEA test which would have revealed the recurrence of the tumor, but the defendant did not receive the results.

In August of 1989 plaintiff's husband learned that the April 1989 CEA test was indicative of metastatic cancer. Plaintiff's husband died in October 1989. Plaintiff contended that the defendant was negligent for failing to do regular CEA testing after the colon surgery, and failing to obtain the results of the 1989 CEA test. The defendant denied that the standard of care required regular CEA testing, but admitted that it was a deviation from the standard of care not to obtain the results of the 1989 CEA test.

Nevertheless, the defendant argued that knowing the results in April as opposed to August of 1989 would not have made any difference because the cancer was not treatable. Plaintiff responded that even if earlier diagnosis would not have extended her husband's life, it "would have given him the opportunity to plan his remaining time." Id. slip op. at 8. Plaintiff demonstrated that due to the short notice, her husband was not able to sell his optometry practice and suffered other damages. The jury found that the defendant was not negligent. The Appellate Division reversed, observing that:

> With respect to Dr. Dayrit's failure to obtain the abnormal results of the CEA test he ordered in April 1989, and that Dr. Kimmel did not learn until August, the experts all agreed that Dr. Dayrit had a duty to obtain the test result within a reasonable time. Dr. Dayrit himself testified that it was a mistake for him not to notice that he did not have the test report . . . The experts agreed that while chemotherapy is not a cure, it can shrink a tumor that responds, thereby palliating symptoms and improving the quality of the patient's remaining life . . . The jury verdict of no negligence is contrary to the undisputed evidence that defen-

> dant's failure to obtain the CEA test result in 1989 was a deviation."

Id. at 10-11. The court, therefore, held that the verdict constituted a miscarriage of justice and reversed.

However, the court did not stop there, but rather pushed into uncharted territory. As noted above, the plaintiff also asserted that the defendant was negligent in not performing follow up CEA testing after the surgery to detect a recurrence of the cancer at the earliest possible opportunity. The defendants contended that the standard of care did not require follow up CEA testing, and one of the defendant's experts rendered the opinion that "a patient with an untreatable but dormant disease is better off not knowing it." Id. at 17. The court disagreed:

> Plaintiff's expert opined that the appropriate standard required defendant to prescribe regular CEA tests after the colon cancer surgery, whereas defendant's experts opined that it was a matter of medical judgment whether or not to do such regular testing. With differing opinions among experts, we would not normally interfere with a jury's choice of the appropriate standard of care. However, defendant's experts offered a value judgment, not a medical judgment, by testifying that a patient has no need to know he has a terminal condition. By offering that testimony, defendant opened the door to the real issue regarding regular CEA testing following surgery: the patient's right to be informed about the availability, the benefits, and the limitations of repeat CEA testing . . . *Negligence, however, can be inferred where Dr. Dayrit denied Dr. Kimmel the opportunity to make his own choice. Deciding for the patient rather than giving him the choice reflects the same paternalistic approach that the Supreme Court rejected in* Largey v. Rothman, *110 N.J. 204 (1988)."*

Id. at 18-19. (Emphasis added.)

The court cited *Caputa* for its holding that the admitted failure to disclose the availability of a treatment option is "a deviation from the standard of care as a matter of law." Id. at 21. After then noting that expert testimony is not necessary to support a claim of a breach of the duty to provide informed consent, the court held that the jury could have found a breach of the duty to advise the patient of the option of CEA testing.

> The physician's failure to inform the patient about an available test may well be negligence. On retrial, plaintiff must have the opportunity for a jury to determine whether a prudent patient would have wanted full information about regular, repeat CEA testing in order to decide how to proceed after cancer surgery such as Dr. Kimmel had.

Id. at 24.

Judge Burrell Ives Humphreys concurred and dissented in part, noting the defendant conceded he committed malpractice in 1989 and that under those circumstances the verdict of no deviation was a miscarriage of justice. However, Judge Humphreys disagreed with the holding that plaintiff had a valid cause of action based on an informed consent theory because it was "not presented at trial nor was it briefed and argued before us." Id. at 31. Judge Humphreys also opined:

> Presumably, my colleagues conclude that the monitoring physician must obtain the patient's consent *not* to use the test. Failure to obtain the patient's consent not to use the test would apparently render the physician liable under the doctrine of informed consent. I doubt that the doctrine of informed consent does or should reach that far. The majority has not cited any case which so holds. No doctor in this case testified that any such requirement was accepted medical practice in the period 1984 to 1989.

Id. at 32. (Emphasis in original.)

Judge Stern concurred and agreed that "a physician must generally advise a patient of treatment alternatives in non-emergent circumstances." Id. at 34.

Proximate Cause

Largey held that the burden of proof regarding proximate causation is satisfied by demonstrating "that the prudent person *in the patient's position* would have decided differently if adequately informed." *Largey,* supra, 110 N.J. at 215. (Emphasis supplied.) The Court again relied on *Canterbury,* supra, which held "if adequate disclosure could reasonably be expected to have caused that person to decline the treatment because of the revelation of the kind of risk or danger that resulted in harm, causation is shown." *Largey, supra,* 110 N.J. at 216, quoting *Canterbury,* supra, 464 F.2d at 791.

After concluding that plaintiff was entitled to a directed verdict on liability, the *Caputa* Court quoted the *Largey* causation test and held that on remand the jury must decide whether a reasonable person "in the plaintiff's condition would have gone through with the surgery after having been properly informed of the available option." *Caputa,* supra, 296 N.J. Super. at 138. *Kimmel* reiterated the *Largey* objective standard of proximate cause, and similarly instructed that on remand the issue of proximate causation as to the informed consent claim must be submitted to the jury. Id. at 26.

However, another recent case holds that the failure to obtain the patient's informed consent to treatment must still be the cause in fact of the plaintiff's injury. In *Canesi by Canesi v. Wilson,* 295 N.J. Super. 354 (App. Div. 1996), plaintiff was prescribed Provera after being overdue for her menstrual period. Plaintiff took the Provera for eight days and then learned she was pregnant. The defendant, an obstetrician, admitted that he had not warned plaintiff about any risks associated with the medication.

Furthermore, the defendant admitted he knew at the time the Provera was prescribed that there was a warning in the *Physician's Desk Reference* that the use of Provera during the first four months of pregnancy was associated with the possibility of "limb reduction defects." Plaintiff's child was born with limb reduction of the hands and fingers.

However, after the birth of the child, the warning in the *PDR* was changed to eliminate the language about the risk of limb reduction. Plaintiff's experts testified that the defendant was obligated to warn the plaintiff of the risk of limb reduction due to

administration of Provera so that plaintiff would have had the choice of terminating the pregnancy. However, neither of plaintiff's experts was able to testify that the Provera caused limb reduction abnormalities. *Canesi,* supra, 295 N.J. Super. at 359. The trial court dismissed plaintiff's claim that the failure to warn of the risk of limb reduction associated with Provera deprived plaintiff of the possibility of terminating the pregnancy. The Appellate Division affirmed, rejecting plaintiff's argument that if warned of the risk she would have terminated the pregnancy. The court explained:

> While we agree with plaintiffs' assertion that breach of a standard of care must be measured by the standard in effect at the time it was allegedly breached, we hold that in these circumstances causation is to be determined by up to date medical and scientific evidence. Thus, current knowledge is highly relevant to the issue of whether defendants' acts or omissions 'caused' the plaintiff harm. Causation in these circumstances is not time-related, it must be viewed for our purposes as an absolute truth, subject to discovery by proper investigation.

Canesi, supra, 295 N.J. Super. at 361.

The court noted that if the pregnancy had been terminated because of the *PDR* warning, the abortion would have been "based on a medical premise now found to be fallacious." *Canesi,* supra, 295 N.J. Super. at 362. Since the plaintiff was not able to show that the Provera had in fact caused the limb reduction, the plaintiff is not entitled to damages "for a 'chance occurrence' that was not caused by defendant's failure to warn." *Canesi,* supra, 295 N.J. Super. at 364.

Statute of Limitations

In another recent case, *Lombardo v. Borsky,* 298 *N.J. Super.* 658 (App. Div. 1997), the court discussed the statute of limitations in an informed consent case. In *Lombardo, supra,* the defendant implanted an experimental intraocular lens into plaintiff's eye in March of 1982. Plaintiff was advised in 1985 and 1987 that the lens was the wrong size and improperly installed. In 1990, the plaintiff discovered that the lens implanted by the defendant was experimental and had not been approved by the Food and Drug Administration, and she filed suit in 1991, asserting only a breach of the duty of informed consent.

The trial court concluded that plaintiff was aware in January of 1988 that she had a potential cause of action for malpractice and, therefore, the complaint that she filed in May of 1991 was barred by the statute of limitations. Id. at 663. The Appellate Division reversed, concluding that the informed consent cause of action was distinct from the cause of action for medical malpractice. Id. at 663.

Indeed, the court seemed to suggest that an informed consent case is not even a medical malpractice case. Id. at 663-664. Since the plaintiff did not know of the potential informed consent cause of action until 1990, the court concluded that the filing of the claim for informed consent in 1991 was timely. The court disregarded the argument that the entire controversy doctrine would have compelled the plaintiff to bring the medical malpractice claim by 1988 at the latest, simply holding that since plaintiff had not filed a prior action, the entire controversy doctrine did not apply.

Four Big Cases

Caputa, Kimmel, Canesi, and *Lombardo* are significant for several reasons. *Caputa* is the latest chapter in the development of the *Largey* doctrine and firmly confirms the holding that where a health care provider does not provide the patient with all treatment options, the trial court should rule as a matter of law that the defendant has breached the duty imposed by the doctrine of informed consent.

Kimmel has expanded the duty of informed consent to include the duty to advise of the availability of diagnostic testing. This opinion will have a major impact on any case involving a failure to make a timely diagnosis of a disease such as cancer or a condition such as a myocardial infarction. The plaintiff must still demonstrate proximate causation in the context of an informed consent case — that if fully informed a reasonably prudent patient in the plaintiff's position would have chosen an alternative treatment and thereby avoided the injury.

Canesi, nevertheless, requires the plaintiff to demonstrate that the failure to advise of a risk was the cause in fact of the injury. This holding is important in cases involving the administration of medications which are associated with side effects, such as neurological injuries, that have many causes, and may or may not be related to the medication.

Lombardo suggests that an informed consent case is not a medical malpractice case at all, and that the informed consent case may be subject to an entirely distinct statute of limitations governed by separate discovery considerations. Indeed, *Lombardo* explicitly holds that a patient could discover a medical malpractice cause of action and fail to assert it within the time period required by the statute of limitations and, nevertheless, bring an informed consent cause of action years later, without even the entire controversy doctrine posing a barrier to recovery.

It is clear that the trend is strongly in favor of informed consent cases. Where the plaintiff has submitted to elective surgery or treatment, without being informed of all of the risks of treatment, and sustains a severe injury, and where there was at least one other way of treating the condition, juries will be inclined to find that a reasonable person in the plaintiff's condition would have rejected the treatment. Furthermore, it is clear that informed consent cases can be pursued at far less cost than other malpractice cases because plaintiff can use medical literature to prove that the risk which occurred was known in the medical community.

This is so since expert testimony is not necessary to establish the standard for disclosure *which is imposed by law* and not medical consensus. The defendant's only viable defense in such cases is that the treatment was not elective; rather, that the plaintiff had no choice but to accept the proposed treatment, or that the injury was not in fact caused by the treatment. Plaintiffs are now in a position to begin winning informed consent cases which involve elective procedures, the failure to make a timely diagnosis of disease, or the use of medications which result in serious injuries. ■