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Health Law

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Battery Claim Arising from Use of New Medical Device Dismissed

The Illinois Appellate Court First District recently decided a case involving the insertion of a newly developed medical device into a patient during cardiac surgery. In *Obermeier v. Northwestern Memorial Hospital*, 2019 IL App (1st) 170553, patient Maureen Obermeier filed a 12-count complaint against Northwestern Memorial Hospital, cardiologist Dr. Patrick McCarthy, heart valve products manufacturer Edwards LifeSciences, LLC (Edwards), and various others. Obermeier claimed that Dr. McCarthy used a medical device during her heart surgery which had not been approved by the FDA and inserted the device without her informed consent. *Obermeier*, 2019 IL App (1st) 1070553, ¶ 1. The case highlights important aspects of Illinois law pertaining to post-trial appeals of claims dismissed prior to trial, as well as issues pertaining to informed consent claims.

Trial Court Proceedings

Obermeier suffered from a condition called myxomatous valve disease, which prevents the mitral valve in the heart from opening and closing smoothly. *Id.* ¶¶ 4-10. The condition can be treated surgically by implanting an "annuloplasty ring," which stabilizes the repaired tissues and improves the function of the mitral valve leaflets so they can open and close properly. *Id.* ¶ 8. Obermeier underwent surgery to repair the mitral valve, performed by Dr. McCarthy, a cardiologist who specialized in these surgeries. *Id.* ¶¶ 7-8. During the procedure, Dr. McCarthy implanted an annuloplasty ring called a "Myxo ring" that he had invented. *Id.* ¶¶ 9-10.

Dr. McCarthy admitted that it was his decision to select the Myxo ring used during Obermeier's mitral valve repair surgery from various annuloplasty rings that were available to him. *Id.* ¶ 9. He explained that for years, he and his colleagues had been using larger rings and bending them to the shape needed by different patients who suffered from myxomatous valve disease. *Id.* ¶ 10. Dr. McCarthy approached manufacturer Edwards and suggested that it create a ring that was pre-bent to the shape he utilized in his patients. *Id.* Edwards provided Dr. McCarthy with prototypes, and around eight months before Obermeier's surgery, Edwards supplied the final Myxo ring to use in future surgeries. *Id.* ¶ 11.

At issue in the litigation was whether the Myxo ring was an investigational device. By the time of Obermeier's surgery, Dr. McCarthy considered the Myxo ring a marketed device and did not treat it as he would an investigational device. *Id.* ¶¶ 13-14. Dr. McCarthy admitted he had previously been involved with the invention process of two other annuloplasty rings manufactured by Edwards. *Id.* ¶ 12. However, Dr. McCarthy had not discussed the FDA clearance process or been involved in the FDA clearance process for those inventions. *Id.* Likewise, Dr. McCarthy was uninvolved in any FDA clearance processes for the Myxo ring. *Id.*

Obermeier subsequently learned of the insertion of the Myxo ring and filed suit, claiming she was injured by the lack of adequate informed consent with the use of the ring. *Id.* ¶¶ 40, 49. Obermeier later retained a cardiology expert who

opined at trial that Obermeier might have been injured by the ring if it had pinched an artery or a suture being placed in an artery. *Id*. ¶ 35.

At the outset of litigation, the court dismissed the strict liability, informed consent, medical battery, and battery counts against the defendants pursuant to a motion to dismiss. *Id.* ¶ 3. The court later entered summary judgment in favor of the hospital and Edwards on four counts, finding in the hospital's favor on the medical battery claim, as well as strict liability, informed consent, and battery. *Id.* Three counts remained against Dr. McCarthy: (1) informed consent, (2) battery, and (3) medical battery. *Id.*

During the 14-day jury trial, the jury considered Obermeier's evidence that the Myxo ring was investigational, that she was not informed that Dr. McCarthy would utilize the investigational device, that the Myxo ring caused her injury, and that Dr. McCarthy was improperly conducting a clinical study of the Myxo ring. *Id.* ¶ 49. The jury determined there was conflicting testimony on many issues and found in favor of the defendants on all counts. *Id.*

Appellate Court Proceedings

On appeal, Obermeier sought reversal of the dismissals and summary judgment on certain counts so that she could return to the trial court and try those counts against the hospital and Edwards. *Id.* ¶ 50. Specifically, Obermeier argued that strict liability, informed consent, medical battery, and battery were improperly dismissed because the hospital and Edwards' actions "indirectly caused" her to come into contact with the Myxo ring in a manner that was "reasonably regarded as offensive" and "without consent or at substantial variance with the consent she gave." *Id.* ¶¶ 43, 45-46.

Relitigation of a plaintiff's claims against a defendant is generally precluded by estoppel by verdict, which prohibits a party from pursuing a claim again that raises factual issues identical to those already decided by a jury. *Id.* ¶ 50. (citing *Francisco v. Jordan*, 43 Ill. App. 2d 344, 351 (2d Dist. 1963)). The principle of estoppel by verdict dictates that where some controlling fact or question material to the determination of both causes has been adjudicated in a former suit by a court and the same fact or question is again at issue between the same parties, the adjudication in the first suit will be conclusive on the same question in the latter suit, irrespective of whether the cause of action is the same in both suits. *Obermeier*, 2019 IL App (1st) 1070553, ¶ 50; *see also People ex rel. Justice v. Hickory Hills*, 43 Ill. App. 3d 632, 635-36 (1st Dist. 1976).

Here, Obermeier argued that she was entitled to know that the Myxo ring was not properly cleared by the FDA, that it was investigational, and that Dr. McCarthy was using the ring during her surgery as part of a study he was conducting. *Obermeier*, 2019 IL App (1st) 1070553, ¶¶ 46, 49. She claimed that the failure to provide her this information violated her right to informed consent. *Id.* She further argued that the actions of the hospital and Edwards indirectly caused her to come in contact with the ring, and that conduct was offensive and without consent. *Id.*

The First District rejected these contentions. It observed that the theories upon which those counts were based were substantially the same as the theories that were already rejected by the jury in finding Dr. McCarthy was not liable. *Id.* ¶ 48. Consistent with estoppel by verdict, which prohibits a party from pursuing a claim again that raises factual issues identical to those already decided by a jury, the court found that relitigation of the issues against the hospital and Edwards was precluded by estoppel. *Id.* ¶ 50.

Independently of the estoppel issues, the court also addressed the informed consent and battery claims. Regarding informed consent, the general rule is that a hospital can be held liable where it adopted policies to ensure that the consent forms complied with the applicable FDA and Department of Health and Human Services regulations. *Id*. ¶ 56 (citing *Kus*

v. Sherman Hosp., 268 Ill. App. 3d 771, 780 (2d Dist. 1995)). "The rationale underlying this rule is that the physician has the technical knowledge and training necessary to advise each patient of the risks, and that the hospital does not know the patient's medical history, nor the details of the particular surgery to be performed." *Obermeier*, 2019 IL App (1st) 170553, ¶ 56 (citing *Kus*, 268 Ill. App. 3d at 780). An exception to the general rule exists which provides that physicians are responsible for obtaining informed consent from patients in cases of experimental surgery or clinical trial where the hospital specifically undertakes an obligation to ensure the patient's informed consent. *Obermeier*, 2019 IL App (1st) 170553, ¶ 59. In this case, neither Dr. McCarthy, the hospital, nor Edwards believed that the Myxo ring was an investigational device, so the hospital did not undertake a specific obligation to obtain informed consent. *Id.* ¶ 60. Therefore, the court concluded that the dismissal of the informed consent count against the hospital was proper. *Id*.

The court also upheld the dismissal of the medical battery claim, noting that Obermeier consented to Dr. McCarthy's mitral valve surgery. *Obermeier*, 2019 IL App (1st) 170553, ¶ 64. Obermeier admitted that Dr. McCarthy specifically informed her that a ring would be used in the procedure to repair the valve. *Id.* Therefore, the court held that the circumstances did not support the "total lack of consent" necessary to maintain a claim of medical battery. *Id.* The court noted that although she may not have been aware of the particular type of ring that was used, the choice of ring could not be made until surgery was underway and the plaintiff was under anesthesia at that time. *Id.* Therefore, the court found that the trial court did not err in dismissing the battery claim against the hospital. *Id.*

Obermeier argued that Edwards' role in its distribution of the ring made it complicit in civil battery because Edwards failed to proceed through the proper regulatory pathway to ensure that the Myxo ring was properly authorized for use by the FDA. *Id.* ¶ 68. The court disagreed, noting that the United States Supreme Court previously ruled that a private litigant may not sue a medical device manufacturer for violating the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 § *et seq*.). *Id.* ¶ 69. Furthermore, Obermeier failed to allege that the ring was defective in its design or manufacture or that it malfunctioned. *Id.* ¶ 80. Therefore, the court held that, like the hospital, the medical battery claim against Edwards was also properly dismissed. *Id.* ¶ 64.

Practical Takeaways

Obermeier illustrates how summary judgment decisions can essentially be appeal-proofed by positive trial outcomes on related claims by virtue of estoppel. It also serves as an important reminder to individuals in the healthcare field to exercise caution in utilizing newly developed medical devices–particularly devices they helped develop. *Id.* More comprehensive efforts in connection with providing pre-surgery information and obtaining informed consent could have precluded this litigation in its entirety and these issues should always be considered when surgical procedures with new devices are contemplated.

About the Authors

Roger R. Clayton is a partner in the Peoria office of *Heyl, Royster, Voelker & Allen, P.C.*, where he chairs the firm's healthcare practice group. He also regularly defends physicians and hospitals in medical malpractice litigation. Mr. Clayton is a frequent national speaker on healthcare issues, medical malpractice, and risk prevention. He received his undergraduate degree from Bradley University and law degree from Southern Illinois University in 1978. He is a member of the Illinois Association of Defense Trial Counsel (IDC), the Illinois State Bar Association, past president of the

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