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MEDICAL DEFENSE AND HEALTH LAW

DECEMBER 2020

IN THIS ISSUE

This article discusses an Illinois Appellate Court decision that addressed whether a plaintiff can state a battery claim based upon the insertion of a newly developed medical device during a surgical procedure.

Illinois Appellate Court Dismisses Battery Claim Arising From Use of New Medical Device

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The First District Appellate Court of Illinois (First District) recently analyzed a case involving the insertion of a newly developed medical device into a patient during a 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 (the Hospital), cardiologist Dr. Patrick McCarthy, and a heart valve products manufacturer, among various others (Defendants). Obermeier claimed that Dr. McCarthy utilized a medical device during her heart surgery which had not been approved by the FDA and was inserted without her informed consent. *Obermeier*, 2019 IL App (1st) 1070553, ¶ 1.

Factual Background

The record established that Obermeier had a condition called myxomatous valve disease, which prevents the mitral valve in the heart from opening and closing smoothly. *Id.* ¶¶ 4-10. If left untreated, blood can leak backward into the valve as the heart pumps and can lead to further complications. *Id.* ¶ 6. An annuloplasty ring 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 these surgeries. *Id.* ¶¶ 7-8. During the procedure, Dr. McCarthy implanted an annuloplasty ring called a "Myxo ring" that he invented and was subsequently manufactured. *Id.* ¶¶ 9-10.

During his testimony, Dr. McCarthy admitted that he inserted the Myxo ring that was used during Obermeier's mitral valve repair surgery. *Obermeier*, 2019 IL App (1st) 170553, ¶ 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. Following his invention, he approached manufacturer Edwards LifeSciences, LLC (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 later supplied him with the final Myxo ring to use in future surgeries. *Id.* ¶ 11. 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.*

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. *Obermeier*, 2019 IL App (1st) 170553, ¶¶ 13-14. 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.

Analysis

At the outset of litigation, the court dismissed five counts against the Defendants pursuant to a motion to dismiss. *Obermeier*, 2019 IL App (1st) 170553, ¶ 3. The court later entered summary judgment in favor of the Hospital and Edwards on four counts, including the medical battery claim against the Hospital. *Id.* Three counts remained against Dr. McCarthy. *Id.* After a 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.*

On appeal, Obermeier sought to have the dismissals and summary judgment of certain counts reversed so that she could return to the trial court and try those counts against the Hospital and Edwards. *Obermeier*, 2019 IL App (1st) 170553, ¶ 50. Specifically, Obermeier argued that four counts (strict liability, informed consent, medical battery, and battery) were improperly dismissed prior to trial. *Id.* ¶¶ 43, 45. 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. *Id.* ¶¶ 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 initially 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. *Obermeier*, 2019 IL App (1st) 170553, ¶ 48. Therefore, re-litigation of the issues against the Hospital and Edwards was precluded by estoppel. *Id.* ¶ 50.

The court further held, as it related to the informed consent allegation, that 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 (DHHS) regulations. *Obermeier*, 2019 IL App (1st) 170553, ¶ 56, citing *Kus v. Sherman Hospital*, 268 Ill. App. 3d 771, 780 (2d Dist. 1995). 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, the Hospital did not undertake a specific obligation to obtain informed consent from Dr. McCarthy's patients to conduct a clinical trial. Therefore, the court concluded that the dismissal of the informed consent allegation against the Hospital was proper. *Id*. ¶ 60.

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. *Obermeier*, 2019 IL App (1st) 170553, ¶ 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 FDCA. *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.

Conclusion

The *Obermeier* decision serves as an important reminder to individuals in the healthcare field to exercise caution in utilizing newly developed medical devices. *Id.* Furthermore, to the extent possible, proper patient consent should be obtained before performing surgical procedures with new devices to prevent liability.

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