2019 IL App (1st) 170553

FOURTH DIVISION
June 28, 2019

No. 1-17-0553

IN THE APPELLATE COURT OF ILLINOIS
FIRST JUDICIAL DISTRICT

MAUREEN OBERMEIER, Plaintiff-Appellant, v. NORTHWESTERN MEMORIAL HOSPITAL, NORTHWESTERN MEDICAL FACULTY FOUNDATION, PATRICK MCCARTHY, M.D., and EDWARDS LIFESCIENCES, LLC, Defendants-Appellees.	)	Appeal from the Circuit Court of Cook County 08 L 012426 Honorable James M. McGing and William E. Gomolinski, Judges Presiding.

PRESIDING JUSTICE McBRIDE delivered the judgment of the court, with opinion.
Justices Gordon and Reyes concurred in the judgment and opinion.

OPINION

¶ 1 Plaintiff, Maureen Obermeier, brought various claims against defendants, Northwestern Memorial Hospital (NMH), Northwestern Medical Faculty Foundation (NMFF), Patrick McCarthy, M.D. (Dr. McCarthy), and Edwards Lifesciences, LLC (Edwards), arising out of a heart surgery Dr. McCarthy performed on her in November 2006. Plaintiff generally contended that Dr. McCarthy utilized a medical device called a "Myxo ring" during the surgery, which was invented by Dr. McCarthy and manufactured by Edwards. Plaintiff claimed that the Myxo ring had not been approved or cleared by the FDA, that it was investigational, and that Dr. McCarthy

improperly utilized the Myxo ring during her surgery as part of a study. Following a 14-day jury trial, the jury found in favor of defendants and against plaintiff on all counts.

¶ 2 As an initial matter, this court notes that the record in this case is voluminous, consisting of 17 electronic volumes, many of which contain between 3000 and 5000 pages each. Due to the extensive nature of the trial court proceedings and the various issues raised in this appeal, we will initially recite a general overview of the proceedings and the evidence elicited at trial, and we will include a more specific discussion of the facts relevant to the various issues in their respective sections.

¶ 3 Of plaintiff's 12-count third-amended complaint, 5 counts were dismissed pursuant to defendants' motions to dismiss, and summary judgment was entered in favor of defendants on 4 other counts. Those counts included all counts against defendant Edwards, and accordingly, Edwards was dismissed from the case prior to trial. The remaining three counts against NMH, NMFF, and Dr. McCarthy (collectively, the Northwestern defendants), proceeded to trial. The remaining three counts were: Count VII, "Informed Consent versus Dr. McCarthy, with [NMFF] and [NMH] via agency"; Count IX, "Medical Battery versus Dr. McCarthy, with [NMFF] and [NMH] via agency" and Count XII, "Medical Negligence versus Dr. McCarthy, with [NMFF] and [NMH] via agency."

¶ 4 At trial, evidence was presented showing that plaintiff underwent heart surgery to repair her mitral valve on November 6, 2006, at NMH. The mitral valve is a valve in the heart which allows blood to flow from the left atrium to the left ventricle.

¶ 5 Plaintiff had been a long-time patient of cardiologist, Paul Silverman, M.D. Dr. Silverman first treated plaintiff in 2001 in the Emergency Department of Advocate Christ Medical Center. At that time, plaintiff reported a history of mitral valve prolapse, a condition in

which the mitral valve does not close properly. Plaintiff then underwent an echocardiogram which confirmed the existence of that condition.

¶ 6 Dr. Silverman assessed plaintiff periodically with imaging studies to evaluate the progression of her disease. By August 2006, an echocardiogram demonstrated severe mitral regurgitation, meaning that blood was leaking backwards through the mitral valve. Dr. Silverman believed that plaintiff required a surgical consultation to determine whether the valve required repair or replacement.

¶ 7 On September 21, 2006, plaintiff was examined and consulted with Dr. McCarthy, who specialized in the performance of mitral valve surgeries. Dr. McCarthy recommended surgery.

¶ 8 On November 6, 2006, Dr. McCarthy performed surgery on plaintiff's mitral valve. As part of that surgery, he implanted an annuloplasty ring. An annuloplasty ring is utilized during the surgical repair of a diseased mitral valve to stabilize the repaired tissues, thereby improving the function of the mitral valve leaflets so that they open and close properly. Annuloplasty rings are Class II medical devices pursuant to regulations issued by the federal Food and Drug Administration (FDA).

¶ 9 During his testimony, Dr. McCarthy explained the surgery procedures that were performed on plaintiff. Specifically, in order to repair plaintiff's mitral valve, Dr. McCarthy selected a particular type of annuloplasty ring, specifically a 36 millimeter "Myxo ring" from among various annuloplasty rings that were available to him. The decision about what specific size and type of annuloplasty ring to use could not be made until the open heart procedure was underway and the mitral valve was evaluated. Dr. McCarthy testified that at the time of plaintiff's surgery, there were about five or six types of annuloplasty rings in different sizes that were available as possible options.

¶ 10 Dr. McCarthy testified that he invented the Myxo ring that was utilized during plaintiff's mitral valve repair surgery. He had the idea for the Myxo ring because for years he and other valve surgeons had been using larger rings and bending them to the shape needed in patients who suffered from myxomatous valve disease. He approached a manufacturer, Edwards, and suggested that it would be helpful if they could create a ring that was pre-bent to the shape he had been using.

¶ 11 The Edwards engineers created prototypes and showed them to him, and by March 2006, Edwards had supplied the Myxo ring to Dr. McCarthy to utilize in patient surgeries.

¶ 12 Dr. McCarthy had previously been involved in the invention process of two other annuloplasty rings manufactured by Edwards. In those cases, he also explained to engineers at Edwards the shape of the ring that he was looking for, and they created prototypes and showed them to him. Eventually Edwards started manufacturing the rings. Dr. McCarthy was not aware of what the FDA clearance process was, and Dr. McCarthy had not discussed the FDA clearance process or been involved in the FDA clearance process. No clinical trials, "Institutional Review Board" (IRB) process, or special patient consent had been required before the first clinical use with either of those rings.

¶ 13 Dr. McCarthy testified that he had previously been involved in clinical trials of investigational devices, and he knew how to conduct a clinical trial. He was aware that there was a difference between "investigational devices" and "non-investigational devices." In his experience, with an investigational device, the manufacturer contacts the physician and advises the physician that the investigational device must be tested. The manufacturer must obtain an "IDE" [investigational device exemption] from the FDA, and a formal, randomized clinical trial must be set up. The manufacturer must enter into a contract with the University, and the clinical

trial is subjected to an involved IRB process, which includes specific approval of a written consent specifically for the trial, establishing the duration of the trial, and establishing the number of patients that will be involved in the trial. In addition, when a manufacturer provides investigational devices to a physician for use in a human subject, it is shipped in packaging clearly marked "Investigational." Dr. McCarthy testified that there was a "night and day difference" between using an investigational device and a non-investigational device.

¶ 14 Dr. McCarthy further testified that the process that Edwards utilized with the Myxo ring was not at all like the process a manufacturer uses with an investigational device. As with the prior rings that Dr. McCarthy invented and Edwards manufactured, Dr. McCarthy was not aware of what the FDA clearance process for the Myxo ring was. He was not involved in any way in the FDA clearance process, and he did not discuss with Edwards the manner of FDA clearance. Edwards did not utilize the "investigational device" process before it provided the Myxo ring to Dr. McCarthy. There was no clinical trial set up for the Myxo ring. If Dr. McCarthy believed that the Myxo ring was an investigational device, it would not have been a problem for Dr. McCarthy to submit it to the IRB for a clinical trial.

¶ 15 Janice Knuckey, a nurse practitioner at NMFF also testified at trial. She worked in the outpatient cardiac surgery office and met with patients preoperatively to give them instructions. Nurse Knuckey met with plaintiff on October 10, 2006, to review surgical consent forms with plaintiff and witness her signature. She did not present consent forms to plaintiff regarding a Myxo ring study because there was no Myxo ring study. Nurse Knuckey was aware that Dr. McCarthy's custom was to inform patients that an annuloplasty ring would be used during mitral valve repair surgeries, and that it would be used to bring the valve back to its normal shape.

¶ 16 Anna Huskin, R.N, testified that she was employed by Northwestern University as the Research Manager in the Bluhm Cardiovascular Institute (BCI), Clinical Trials Unit. Nurse Huskin works with physicians within the BCI to get their research projects up and running and helps write protocols and IRB approved consent forms. She also works with industry-sponsored projects, where a company approaches a BCI physician to conduct a research study, and she helps get the study up and running, including IRB approval of a consent form for a clinical study.

¶ 17 Nurse Huskin has dealt with many unapproved devices over the years. They take a substantially different path than cleared devices before they can be used within a hospital. If a device has not yet been cleared by the FDA, the manufacturer sends it through the Clinical Trials Unit. If a device is unapproved, the manufacturer must mark the product as an "investigational device." The only devices that come through the doors of Nurse Huskin's unit are investigational devices. The Clinical Trials Unit relies on the manufacturer to tell them when a device is investigational.

¶ 18 Before an investigational device goes to the Clinical Trials Unit, the manufacturer sends a variety of materials, including a study protocol, a draft consent form, instructions how to handle the device, and materials that the patient must review. The materials will also include an IDE number, which is assigned by the FDA. It is the manufacturer who contacts the FDA and asks for an IDE. When Nurse Huskin receives those materials, she submits the materials from the manufacturer to the IRB to obtain their approval and make sure that the IRB is satisfied. Only after full IRB approval is obtained, and after the manufacturer has an executed contract back from Northwestern University, can the investigational devices be shipped to the Clinical Trials Unit.

¶ 19 The investigational devices are only handled by a research team in the Clinical Trials Unit. They are kept in a location separate from commercially available devices that are used in the hospital, and they are labeled in big, bold letters as "Investigational." Nurse Huskin testified that there is no mistaking an investigational device's labeling when it is shipped.

¶ 20 Nurse Huskin further testified that the Myxo ring was never shipped to the Clinical Trials Unit, and it did not come through Nurse Huskin's office. Her understanding was that the Myxo ring was approved, since it was shipped commercially through standard channels. No one from Edwards suggested to her or to anyone else at the Clinical Trials Unit that the Myxo ring had not been cleared by the FDA. If they had been told that, there would have been a completely different process. Neither she nor Dr. McCarthy had any role in deciding whether something is an investigational device. Nurse Huskin testified that there are thousands of FDA-regulated medical devices that are used in a hospital every day. The institution receives those products from manufacturers, assuming that they are being marketed according to FDA requirements. Northwestern University's IRB does not deal with what path a device goes through for FDA clearance. Nurse Huskin and the people at NMH rely on manufacturers to alert them if a device is investigational.

¶ 21 Nurse Huskin was aware that Dr. McCarthy authored a paper on the Myxo ring. She had helped work on it by pulling patient information on patients who underwent myxomatous mitral valve repair surgery. Nurse Huskin testified that she would not characterize it as a "study," but rather a "retrospective chart review." A "study" has more of an organized design where patients are followed at specific intervals. The information that was used for the papers was gathered from the "Outcomes Registry" and there was approval to study or evaluate the data that was within that database.

¶ 22 Plaintiff signed a consent form to be part of the Outcomes Registry at Northwestern University. The Cardiac Surgery Outcomes Registry is a large-scale registry that the Clinical Trials Unit runs. Nurse Huskin has been involved with the Outcomes Registry since its inception. It is a project where they collect information on all cardiac surgery patients who are undergoing cardiac surgery. The Society of Thoracic Surgeons (STS) has a national registry/database, and they encourage teaching institutions across the country to gather information for the purpose of conducting studies after patients receive care, maintaining quality, and to better understand how patients have responded to different modes of treatment. Among the information that is captured on a patient is any device that is used in cardiac surgery.

¶ 23 NMH has a quality assurance initiative to submit data to the STS national database. The Clinical Trials Unit seeks to obtain the consent of all cardiac surgery patients to allow the CTU to maintain the patient's data in the Northwestern University Cardiac Surgery Outcomes Registry as well as the STS national database. The Outcomes Registry has been in existence since 2005, and it is approved by the IRB. After the patient has consented to the Outcomes Registry, all data from the STS database also goes to the Outcomes Registry, which allows Northwestern University to review the database, and to have papers written like that of Dr. McCarthy. Over the years, Nurse Huskin has been involved in over 100 projects similar to the paper that Dr. McCarthy published. In those situations, the physician goes back and searches the database for patients who have already undergone care and puts the information into a publication. In all those cases, the consent that the patient signed that justified going back and pulling their data was the same Outcomes Registry consent form that plaintiff signed in this case.

¶ 24 Allison Curtis testified that she was the global marketing manager for annuloplasty rings for Edwards in 2006, and that she was Dr. McCarthy's primary point of contact with Edwards.

She confirmed that there was no interaction between Edwards and Dr. McCarthy during the regulatory phase of developing the Myxo ring and that she did not discuss the regulatory status of the ring with Dr. McCarthy at any time. She did not describe the available pathways to market or discuss the regulatory pathway that Edwards planned to take with the Myxo ring with Dr. McCarthy. Edwards has very large departments of experts that do nothing but FDA filing and interfacing with the FDA. The ring was made available to Dr. McCarthy in March 2006, after it had gone through the regulatory process. It is customary, and an FDA requirement, for Edwards to place large print labeling on investigational products that says, "For Investigational Use Only." The Myxo ring was never labeled or packaged as "investigational" at any point in time, and nothing about the marketing or handling of the ring by Edwards suggested it was investigational. Ms. Curtis never told Dr. McCarthy that it was investigational. Edwards never considered the Myxo ring to be investigational.

¶ 25 Susan Gamble, Senior Director of Regulatory Affairs for the heart valve therapy division at Edwards also testified at trial. She explained how the "Justification to File" (JTF) pathway to market a product works.

¶ 26 The FDA has prescribed pathways for the marketing of Class II medical devices, including annuloplasty rings, when the device is a minor modification of a substantially equivalent device previously cleared or approved by the FDA. The FDA guidelines, specifically the 1997 guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device," provides that a device which constitutes a minor modification to a device or devices previously cleared by the FDA can be marketed after the manufacturer has completed a comprehensive evaluation of the device as prescribed by the guidance document.

¶ 27 Ms. Gamble testified that, with regard to the Myxo ring, Edwards complied with the guidance document and completed the JTF process on February 27, 2006. The JTF remains in the records of a device manufacturer so it is available for inspection by the FDA.

¶ 28 Ms. Gamble clarified that annuloplasty rings are not "approved" by the FDA, but are "cleared." If a JTF is utilized, there is no requirement that Edwards do anything to tell the FDA it is distributing or marketing the device. It was Ms. Gamble who made the decision regarding the regulatory pathway of the Myxo ring, with the agreement of her senior management. Edwards never considered the Myxo ring to be an investigational product, and it never was an investigational product. Ms Gamble confirmed that Edwards did not involve Dr. McCarthy in the regulatory pathway discussion, and did not talk to Dr. McCarthy about their decision to proceed with the JTF.

¶ 29 Jeffrey Cooper, M.D., testified as a retained expert at trial on behalf of defendants. He is a board-certified physician in Pediatrics and Nuclear Medicine who has also conducted medical research, served as a clinical investigator for industry-sponsored medical research, and served on IRBs and as chairman of an IRB. He is a founder and authored the standards for the Association for the Accreditation of Human Research Protection Programs (AAHRPP), a nonprofit organization that reviews and accredits institutions that conduct human research, including hospital or universities that have IRBs.

¶ 30 Dr. Cooper explained that not all medical research is regulated by the federal government. A "clinical trial" has an investigator who is testing and comparing specific devices or drugs. A characteristic of a clinical trial is that there is a protocol, and the protocol mandates what procedures are done and what care is going to be administered. In a device clinical trial, the protocol will determine which device a patient receives. Two devices will be used, and the

device that is used with a given patient is assigned randomly. In a non-clinical trial, the care is determined by the treating physician. No protocol mandates the use of any particular medical procedure, drug, or device in terms of treatment. When an investigator collects and analyzes specimens or data, that is not a clinical trial. It is also not a clinical trial when the care for each patient is determined by the treating physician, data is collected from patients who have a particular procedure, and the investigator analyzes the data after the fact to see which treatments worked best for which patients. In clinical care, each decision is made for the individual patient, and the actions taken are always for the benefit of the patient.

¶ 31 Dr. Cooper opined that, under FDA regulations, plaintiff was not a human subject involved in a clinical investigation when Dr. McCarthy utilized a Myxo ring in her surgery. Dr. McCarthy implanted the Myxo ring because he felt that it was the best treatment for her. Dr. McCarthy's use of the Myxo ring was not based upon a protocol for evaluating the safety or effectiveness of the device. Accordingly, Dr. McCarthy was not a "clinical investigator" under FDA regulations when he used the Myxo ring, and there was no clinical investigation. Furthermore, under FDA regulations, Dr. McCarthy was not required to treat the Myxo ring as an investigational device. Therefore, Dr. Cooper stated that Dr. McCarthy was not required to obtain research consent under FDA or IRB requirements before he implanted the Myxo ring in plaintiff.

¶ 32 Dr. Cooper also opined that Dr. McCarthy complied with the standard of care when he assumed that the Myxo ring he implanted in plaintiff was legally marketed and cleared by the FDA, because if a manufacturer wishes to have someone use an unapproved device in a clinical investigation, the manufacturer has certain responsibilities that are clearly outlined by the FDA. The manufacturer is obligated to inform the physician that it is an investigational device, which

has an IDE, and provide a proposed protocol for the use of the device, along with a proposed consent. The manufacturer must obtain a signed agreement of how the study is to be conducted from the institution where the study is to be conducted. It must make sure that the physician obtains IRB review of the protocol and the consent, prominently label the device as "investigational," and it cannot charge for an investigational device. Edwards did not do any of these things with the Myxo ring. Edwards treated the Myxo ring as an FDA cleared device, because they believed it was cleared pursuant to FDA guidelines. Furthermore, Dr. Cooper stated that the standard of care did not require Dr. McCarthy to investigate whether the Myxo ring had been cleared by the FDA before he used it.

¶ 33 Dr. Cooper also opined that a physician may study any data pertaining to any clinical care listed in the Outcomes Registry, including devices or drugs, and that plaintiff's consent to include her clinical data in the Outcomes Registry had nothing to do with the use of the Myxo ring during her surgery.

¶ 34 Plaintiff called Bruce Barkalow, Ph.D., as an expert witness on FDA matters and medical devices. He acknowledged that he was neither a physician, nor an expert on anatomy, the mitral valve, mitral valve rings, or surgical techniques. Dr. Barkalow opined that Edwards did not secure proper clearance under FDA procedures to market the Myxo ring before it was used on plaintiff. Dr. Barkalow conceded, however, that it would not surprise him that a physician would defer to a manufacturer as to what is required for FDA clearance. He would expect Dr. McCarthy to rely upon lawyers and FDA experts within Edwards to make that determination. He also acknowledged that it is not unusual for a study using data from a registry to be conducted even after a device has been cleared by the FDA and marketed.

¶ 35 Plaintiff also called Nalini Rajamannan, M.D., as an expert witness. Dr. Rajamannan had previously been employed by NMFF and had previously worked with Dr. McCarthy. Dr. Rajamannan's opinion was that Dr. McCarthy was conducting a clinical trial on the Myxo ring without IRB approval and that he was obligated to obtain IRB-approved consent from plaintiff before implanting the Myxo ring, because it was an investigational device. She opined that "Dr. McCarthy violated the standard of care in regard to his failure to *** obtain informed consent [from plaintiff] on his Myxo ring study." Dr. Rajamannan also testified regarding her theories as how the Myxo ring posed risks not posed by other rings. Dr. Rajamannan believed that one of two possibilities occurred during plaintiff's surgery. Specifically, either the triangular shape of the Myxo ring caused narrowing in the artery, or a suture was placed through the artery causing an obstruction. She acknowledged however, that the risk from suturing was not unique to the Myxo ring, and was present for all annuloplasty rings used in mitral or valve repair surgery.

¶ 36 On cross-examination, Dr. Rajamannan acknowledged that she did not complete a surgical residency or cardiac surgery fellowship. She had also never performed cardiac surgery, or assisted with surgery. She had never worked in an IRB office, and she had never served as an IRB chair, manager, staff member or committee member. Dr. Rajamannan had never made an official determination on behalf of an IRB about whether an activity constituted research.

¶ 37 When asked whether she had been suspended from NMFF in October 2008, Dr. Rajamannan stated, "It was a blessing, yes, I was suspended." She testified that she first raised allegations regarding her concerns about the FDA status of the Myxo ring with legal counsel for NMFF in July of 2007. She testified that she raised concerns that the study was being conducted without an "IDE" or "IRB." In October of 2007, the people in the NMFF legal department and

risk management invited Dr. Rajamannan to review the results and details of their investigation into her allegations, but Dr. Rajamannan declined to meet with them.

¶ 38 Dr. Rajamannan also testified that she reported Dr. McCarthy to the Illinois Department of Professional Regulation, alleging that he "implanted an investigational device in [plaintiff] knowing that it was investigational or experimental." Additionally, Dr. Rajamannan submitted a *qui tam* action in the United States District Court to the Northern District of Illinois asserting the same allegations, and she admitted that the purpose of the action was "to obtain monetary damages." She also made the allegation that Dr. McCarthy implanted an investigational device, knowing that it was investigational, to the FDA.

¶ 39 In addition, Dr. Rajamannan reached out to various media outlets and she wrote several internet blogs regarding her allegations against Dr. McCarthy. Dr. Rajamannan also made these allegations to various bodies of the United States government, including the United States Senate Finance and Judiciary Committee, and the President of the United States. Dr. Rajamannan self-published 13 E-books on Amazon.com regarding her allegations about the Myxo ring. Dr. Rajamannan testified that she became involved in plaintiff's case when plaintiff's counsel contacted her after press reports came out regarding her allegations against Dr. McCarthy.

¶ 40 Plaintiff testified that when she was in her twenties, she was diagnosed with mitral valve prolapse, and since that time, she saw her cardiologist, Dr. Silverman regularly to monitor her health. Around 2005 or 2006, when plaintiff was approximately 50 years old, she began feeling worse and she visited Dr. Silverman to have an echocardiogram performed. When she woke up from the echocardiogram, Dr. Silverman told plaintiff that she was "going to have to get that surgery." Plaintiff subsequently saw Dr. McCarthy, and underwent surgery with him on

November 6, 2006. On cross-examination, plaintiff acknowledged that Dr. McCarthy told her that a ring would be used to accomplish the mitral valve repair.

¶ 41 After the close of evidence and during the jury instruction hearing, counsel for plaintiff indicated that plaintiff had chosen not to send Count IX, "Medical Battery versus Dr. McCarthy, with [NMFF] and [NMH] via agency" to the jury.

¶ 42 After deliberations, the jury returned verdicts finding for defendants and against plaintiff on both of the remaining two counts. On April 1, 2016, the trial court entered a judgment on the verdicts for defendants. On January 30, 2017, the trial court denied plaintiff's post-trial motion. Plaintiff filed a timely notice of appeal on March 1, 2017.

¶ 43 In this court, plaintiff raises several issues. Specifically, plaintiff contends that the circuit court erred in dismissing four counts (Count V, "Strict Liability – Dr. McCarthy as Agent of Edwards"; Count VI, "Informed Consent" against NMH; Count VIII, "Medical Battery" against NMH; and Count X, "Battery" against Edwards), and in granting summary judgment on another count (Count III, "Product Liability – Negligence Failure to Warn or Instruct" against Edwards) prior to trial. Plaintiff also argues that the circuit court erred in barring the use of certain documents at trial, finding them privileged under the Medical Studies Act. Plaintiff further asserts that the court erred in designating one of her witnesses—Dr. Rajamannan—as a Rule 213(f)(3) expert witness. Finally, plaintiff contends that the court abused its discretion in allowing certain cross-examination of Dr. Rajamannan, and in allowing Dr. McCarthy to testify that he donated his proceeds from the Myxo ring to the Chicago Food Depository.

¶ 44 As noted above, the circuit court granted defendants' section 2-615 motions to dismiss as to several counts. A motion to dismiss brought pursuant to section 2-615 of the Code attacks the legal sufficiency of the complaint. *Vitro v. Mihelcic*, 209 Ill. 2d 76, 81 (2004). When ruling on

such a motion, the court must accept as true all well-pleaded facts in the complaint, as well as any reasonable inferences that may arise from them. *Doe v. Chicago Board of Education*, 213 Ill. 2d 19, 28 (2004). However, a court cannot accept as true mere conclusions unsupported by specific facts. *Pooh–Bah Enterprises, Inc. v. County of Cook*, 232 Ill. 2d 463, 473 (2009). A complaint should be dismissed under section 2-615 only if it is clearly apparent from the pleadings that no set of facts can be proven that would entitle the plaintiff to recover. *Bajwa v. Metropolitan Life Insurance Co.*, 208 Ill. 2d 414, 421 (2004). The critical inquiry is whether the allegations of the complaint, when construed in the light most favorable to the plaintiff, are sufficient to establish a cause of action on which relief may be granted. *Sheffler v. Commonwealth Edison Co.*, 2011 IL 110166, ¶ 61. Our review of an order granting a section 2-615 motion to dismiss is *de novo*. *Solaia Technology, LLC v. Specialty Publishing Co.*, 221 Ill. 2d 558, 579 (2006).

¶ 45 Plaintiff asserts that the trial court erred in dismissing four counts (Count V, "Strict Liability – Dr. McCarthy as Agent of Edwards"; Count VI, "Informed Consent" against NMH; Count VIII, "Medical Battery" against NMH; and Count X, "Battery" against Edwards). Because plaintiff's arguments regarding Counts VI, VIII, and X are related, we will consider the court's dismissal of those counts first.

¶ 46 Regarding Count VI, "Informed Consent" against NMH, Count VIII, "Medical Battery" against NMH, and Count X, "Battery" against Edwards, plaintiff contends that these claims are "based on common themes." Specifically, plaintiff alleged that the Myxo ring did not have proper FDA clearance and was investigational, and that Dr. McCarthy was conducting a clinical study using the Myxo ring before it was properly cleared by the FDA. Plaintiff claims she was entitled to know that the Myxo ring was not properly cleared by the FDA and that it was

investigational, and that Dr. McCarthy was utilizing the Myxo ring during her surgery as part of a study he was conducting. Plaintiff claims that the failure to provide her this information violated her right to informed consent. Plaintiff further contends that the actions of NMH and Edwards "indirectly cause[d]" plaintiff to come into contact with the Myxo ring, in a manner "reasonably regarded as offensive" and "without consent or at substantial variance with the consent she gave."

¶ 47 The trial court allowed plaintiff's informed consent and battery claims to go forward against Dr. McCarthy, but found that those claims could not be brought directly against the hospital or Edwards. Accordingly, the trial court dismissed the institutional informed consent and battery claims against NMH (Counts VI and VIII, respectively), and the battery claim against Edwards (Count X).

¶ 48 As an initial matter, we point out that plaintiff's claims against Dr. McCarthy—and against NMH and NMFF via *respondeat superior*—were tried before a jury, which found in favor of defendants. In this appeal, plaintiff does not argue that any aspect of the jury verdicts was against the manifest weight of the evidence, or otherwise challenge the jury verdicts in any way.

¶ 49 The jury in this case heard the evidence presented by plaintiff—and contested by defendants—that the Myxo ring was investigational, that she was not informed that Dr. McCarthy would be utilizing an investigational device, that the Myxo ring caused her injury, and that Dr. McCarthy was improperly conducting a clinical study of the Myxo ring. The jury also heard conflicting evidence from the parties that the consent given by plaintiff was inadequate, and that had she known of the Myxo ring's investigational nature, she would not have consented

to its use. Following the close of evidence, the jury rejected plaintiff's claims, and rendered verdicts in favor of defendants.

¶ 50 In this appeal, plaintiff seeks to have the dismissals and summary judgment of certain counts reversed, so that she can return to the trial court and try those counts against NMH and Edwards. However, it is clear from plaintiff's description of the "themes" underlying those issues, that the theories on which those counts are based are substantially the same as the theories already rejected by the jury. In these circumstances, a relitigation of the issues against NMH and Edwards is 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. *Franciscy v. Jordan*, 43 Ill. App. 2d 344, 351 (1963).

> "When some specific fact or question has been actually and directly in issue and has been adjudicated by a Court of competent jurisdiction in a former suit, and the same fact or question is again put in issue in a subsequent suit between parties or their privities who were parties in the former suit, its determination in the former suit, if properly presented and relied upon, is conclusive upon the parties and their privities in the latter suit, without regard to whether or not the cause of action is the same in both suits, and it cannot be again litigated in the subsequent suit upon the same or a different cause of action whatever may have been the nature of the first action or of the second action in which the estoppel is set up." *Id.*

¶ 51 In this case, the jury returned general verdicts in favor of defendants, and plaintiff did not request that the jury be given any special interrogatories. "When there is a general verdict and more than one theory is presented, the verdict will be upheld if there was sufficient evidence to sustain either theory, and the [moving party], having failed to request special interrogatories,

cannot complain." *Lazenby v. Mark's Construction, Inc*., 236 Ill. 2d 83, 101 (2010). A "general verdict rendered by the jury creates a presumption that the jury found in favor of [a defendant] on every defense raised" (*id.* at 102), as well as a presumption that "all issues of fact upon which proof was offered were found in favor of the prevailing party" (*Holloway v. Sprinkmann Sons Corp. of Illinois*, 2014 IL App (4th) 131118, ¶ 143). Accordingly, we must presume that the jury found against plaintiff on every issue raised in the counts that were before it. In particular, defendants would be entitled to a presumption that the jury rejected plaintiff's claims that the Myxo ring was investigational, that it caused her injury, and that she did not give proper informed consent.

¶ 52 Nevertheless, even if we were to conclude that estoppel by verdict does not preclude plaintiff's claims, we would still conclude that they fail for the reasons that follow.

¶ 53 First, as to Count VI, "Informed Consent" against NMH, Illinois courts have held that, unlike a physician, a hospital generally has no duty to obtain informed consent from a patient. *Kus v. Sherman Hospital*, 268 Ill. App. 3d 771, 780 (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." (Internal quotation marks omitted). *Id*.; see also *Lenahan v. University of Chicago*, 348 Ill. App. 3d 155, 161 (2004).

¶ 54 Plaintiff acknowledges the general rule, but cites to *Kus*, 268 Ill. App. 3d at 779, and *Lenahan*, 348 Ill. App. 3d at 161, as situations in which a hospital may be liable for failing to obtain informed consent from a patient.

¶ 55 In *Kus*, 268 Ill. App. 3d 771, the plaintiff received an intraocular lens implant during cataract surgery. The lens that was used in the surgery was under investigation for safety and

effectiveness by the FDA, and the hospital was involved in a monitored clinical study for the implantation of intraocular lens. The implantation of intraocular lens into human subjects was permitted only under the Medical Device Amendments of 1976 exemption for experimental devices (s*ee generally* 21 U.S.C. § 301, *et seq.* (1988)), and pursuant to federal regulations, the hospital's IRB was charged with the responsibility of assuring that "legally effective informed consent [was] obtained." *Kus*, 268 Ill. App. 3d at 773. Moreover, the federal regulations mandated that certain disclosures be provided to patients involved in the study. Despite the fact that there was a mandated FDA-approved consent form, the physician modified that form, removing a paragraph labeled "clinical investigation," which was intended to inform the patient that the lens was under investigation for safety and efficacy. *Id*. at 774.

¶ 56 The court in *Kus* initially reiterated the general rule that a hospital has no duty to obtain informed consent from a patient, but found in the circumstances before it that the hospital specifically undertook an obligation to assure that informed consent was obtained.

> "By becoming a participating institution in this particular study, Sherman Hospital was charged with assuring that 'legally effective informed consent' was obtained prior to the experimental surgery (21 C.F.R. § 813.66(a)(6) (1993)) and that 'procedures which are experimental' needed to be identified before such surgery occurred. (21 C.F.R. § 50.25(a)(1) (1993).) While we agree that generally a hospital is not in the best position to inform a patient of risks, here it is clear that Sherman Hospital undertook the responsibility to inform the plaintiff of the experimental nature of his surgery. Moreover, a participating institution in the intraocular lens study is required to conduct 'continuing review of research' under the Federal guidelines, which includes the duty to review the informed consent

> process (21 C.F.R. § 56.109 (1993)). Thus, Sherman Hospital also had the minimal duty here of checking to ensure that the form its IRB had promulgated was being used. We determine that the particular facts in the case before us require a determination that a hospital, as well as a physician, may be liable for claims arising from the lack of informed consent in this instance." *Id*. at 780-81.

¶ 57 Similarly, in *Lenahan*, the appellate court reversed the trial court's dismissal of an institutional informed consent claim against a hospital. In that case, a cancer patient participated in a phase I clinical trial, and he died during the course of the clinical trial. *Lenahan*, 348 Ill. App. 3d at 158. The plaintiff, his mother, alleged institutional negligence against the hospital, based on its failure to obtain adequate informed consent to participate in the clinical trial. The plaintiff alleged that her son's death was caused by his participation in the clinical trial, and that the hospital "negligently fail[ed] to disclose in the decedent's consent form all the risks and alternatives to treatment." *Id*. at 160. The plaintiff specifically alleged that the hospital was a signatory to a policy stating that it bore an "independent institutional responsibility to obtain informed consent from all human subjects in the clinical trial, and that such informed consents must comply with applicable [FDA] and Department of Health and Human Services (DHHS) rules and regulations as set forth in Titles 21 and 45 of the Code of Federal Regulations (CFR)." *Id*. Pursuant to this policy, the University and Hospital formed an IRB to ensure that the consent forms complied with the FDA and DHHS regulations.

¶ 58 The *Lenahan* court also noted the general rule, but relied on *Kus* to conclude that the hospital could be held liable where it "adopted policies and established an IRB to ensure that the consent forms complied with the applicable FDA and DHHS regulations." *Id*. at 161.

¶ 59 As these cases illustrate, there is an exception to the general rule that physicians, not hospitals, are responsible for obtaining informed consent from patients in cases of experimental surgery or a clinical trial, where the hospital specifically undertakes an obligation to ensure the patient's informed consent.

¶ 60 *Kus* and *Lenahan*, however, are distinguishable from the instant case. Neither Dr. McCarthy nor NMH believed the Myxo ring to be an investigational device. Edwards, the device manufacturer, also did not believe the Myxo ring to be investigational, and did not classify it as such. Accordingly, NMH did not undertake a specific obligation to obtain informed consent from Dr. McCarthy's patients to conduct a clinical trial. In these circumstances, we find no facts which would support a deviation from the general rule, and therefore, a dismissal of Count VI, "Informed Consent" against NMH was proper.

¶ 61 We next turn to Count VIII, "Medical Battery" against NMH, and Count X, "Battery" against Edwards.

¶ 62 The elements of a claim for civil battery are: (1) an intentional act on the part of the defendant, (2) resulting in offensive contact with the plaintiff's person, and (3) lack of consent to the defendant's conduct. *McNeil v. Brewer*, 304 Ill. App. 3d 1050, 1055 (1999). Specifically, a plaintiff claiming medical battery must establish one of the following: (1) no consent to the medical procedure performed; (2) the procedure was contrary to the injured party's will; or (3) substantial variance of the procedure from the consent granted. *Holzrichter v. Yorath*, 2013 IL App (1st) 110287, ¶ 83; *Fiala v. Bickford Senior Living Group*, LLC, 2015 IL App (2d) 150067, ¶ 26 (citing *McDonald v. Lipov*, 2014 IL App (2d) 130401, ¶ 20). Under any of these circumstances, a battery has occurred, because the person administering the medical treatment touched the person of another without authorization. *Id*. The lack of consent to the medical

treatment is the focus, not the intent of the person administering the medical treatment, and "the law maintains a distinction between a total lack of consent (battery) and a lack of informed consent (negligence)." *Id*.; see also *Mink v. University of Chicago*, 460 F. Supp. 713, 717 (N.D. Ill. 1978) ("battery may be the proper cause of action in certain situations, for example, where there is a total lack of consent by the patient.").

¶ 63 Plaintiff generally contends that her complaint adequately alleged that NMH "intended to indirectly cause [her] to come into contact with a foreign substance (the Myxo ring) in a manner which is reasonably regarded as offensive, and in a manner which was without consent or at substantial variance with the consent she gave." (Emphasis omitted).

¶ 64 Here, it is undisputed that plaintiff consented to Dr. McCarthy's performance of a mitral valve surgery on her. Further, she acknowledged that Dr. McCarthy specifically informed her that a ring would be used to accomplish the mitral valve repair. Moreover, the evidence showed that the decision as to which particular annuloplasty ring was used could not be made until surgery was underway. These circumstances do not support the "total lack of consent" necessary to maintain a claim of medical battery.

¶ 65 Plaintiff relies on *Mink*, 460 F. Supp. 713 (N.D. Ill. 1978), for her conclusion that the dismissal of her battery claim against NMH was improper. In *Mink*, the federal district court for the Northern District of Illinois considered whether the administration of a drug to the plaintiffs without their knowledge or consent constituted a battery under Illinois law. *Id*. at 716. The plaintiffs in *Mink* were approximately 1000 women who were given a drug as part of a medical experiment conducted by the defendants, University of Chicago and Eli Lilly & Company between 1950 and 1952. *Id*. at 715. The drug was administered to the plaintiffs during their prenatal care as part of a double blind study. The women were not told they were part of an

experiment, nor were they told that they were being administered a drug. *Id*. The plaintiffs claimed that as a result of their taking the drug, their children developed various medical issues including an increased risk of cancer. *Id*.

¶ 66 The court initially explained the difference between battery claims, and negligence claims of a lack of informed consent, noting that both were cognizable under Illinois law but that each applied in different situations. *Id*. at 716-17. The court then defined the issue as "whether the instant case is more akin to the performance of an unauthorized operation than to the failure to disclose the potential ramifications of an agreed to treatment," ultimately concluding that the circumstances of that case were "closer to the former." *Id*. at 717. The court pointed out that the plaintiffs did not consent to the drug, and were not even aware that the drug was being administered to them. *Id.* Accordingly, they were the subjects "of an experiment whereby non-emergency treatment was performed upon them without their consent or knowledge." *Id.*

¶ 67 Here, the record shows that plaintiff consented to the mitral valve surgery that Dr. McCarthy's performed on her, and was aware that a ring would be utilized as part of that surgery. Although plaintiff may not have been aware of the particular type of annuloplasty ring that would be used—indeed, the record shows that a choice of ring could not be made until surgery was underway and plaintiff was under anesthesia—the plaintiff's lack of consent to the use of a particular annuloplasty ring cannot be said to be "akin to the performance of an unauthorized operation." *Id.* In these circumstances, we find no error in the trial court's dismissal of the battery claim against NMH.

¶ 68 Specifically as to plaintiff's battery claim against Edwards, plaintiff contends that Edwards' "role in the distribution of the ring *** makes it complicit in the civil battery." She claims that her battery count alleges that Edwards "bore the direct responsibility for registering

the Myxo ring with the FDA and for ensuring that it was properly cleared or approved by the FDA," but that it did not do so. Plaintiff's theory, therefore, is that Edwards failed to proceed through the proper regulatory pathway, ensuring that the Myxo ring was properly cleared by the FDA. This claim, however, is precluded by the Food, Drug, and Cosmetic Act (FDCA), which provides that such alleged violations are the exclusive domain of the FDA. See 21 USC § 337(a) (West 2016) ("all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); see also *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001) (holding that the plaintiffs' state-law claims were pre-empted by the FDCA).

¶ 69 Even if plaintiff could prove that Edwards failed to comply with FDA regulations, plaintiff is unable to recover from Edwards for this failure alone. The United States Supreme Court has conclusively determined that a private litigant may not sue a medical-device manufacturer for violating the FDCA. *Buckman Co.*, 531 U.S. 341, 349 n. 4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"); see also *Martin v. Ortho Pharmaceutical Corp.*, 169 Ill. 2d 234, 241 (1996) (affirming summary judgment in favor of drug manufacturer where the plaintiffs sought "to premise a private cause of action in State court upon defendant's alleged violation of [FDA regulations]."). In these circumstances, we conclude that plaintiff's battery claim against Edwards is preempted by the FDCA, and accordingly, that it was properly dismissed.

¶ 70 Plaintiff also asserts that the trial court erroneously dismissed Count V, "Strict Liability – Dr. McCarthy as Agent of Edwards." Plaintiff specifically alleges that she properly pleaded the following facts to support an agency claim against Edwards—"that Dr. McCarthy served as

Edwards' paid consultant," "that he invented the Myxo ring" and that he "was directly involved in the design and the marketing and promotion of the ring, as Edwards' paid agent."

¶ 71 As an initial matter, it is unclear to this court the import of a dismissal of plaintiff's agency claim against Edwards, alleging that Dr. McCarthy was an agent of Edwards, since the jury found in favor of Dr. McCarthy on all counts. Even assuming an agency relationship, there is no conduct of Dr. McCarthy from which Edwards could be liable as a principal. See *Wilson v. Edward Hospital*, 2012 IL 112898, ¶ 24 ("actual agency and apparent agency are not causes of action" but instead are "merely part of the duty analysis in a case where the plaintiff seeks to hold the principal liable for the agent's alleged negligence."). Nevertheless, plaintiff's claim fails on the merits as well.

¶ 72 Where there exists an agency relationship, a principal may be held vicariously liable for the wrong-doing of its agent. *Anderson v. Boy Scouts of America, Inc.*, 226 Ill. App. 3d 440, 443 (1992). The test of agency is whether the alleged principal has the right to control the manner and method in which work is carried out by the alleged agent and whether the alleged agent can affect the legal relationships of the principal. *Id*. The question of whether a principal-agency relationship existed is generally one of fact, but it becomes one of law where the evidence is not disputed. *Id*. at 444. The burden of proving the existence of an agency relationship and the scope of authority is on the party seeking to charge the alleged principal. *Id*.

¶ 73 Here, the facts alleged by plaintiff to establish an agency relationship are essentially that Dr. McCarthy invented the Myxo ring, which was manufactured by Edwards, and that Edwards paid him. Such facts are insufficient to show that Edwards controlled Dr. McCarthy in his manner and method of work, and accordingly, are insufficient to support a claim of actual agency.

¶ 74 In support of her claim that the dismissal of her agency claim was improper, plaintiff cites *HPI Health Care Services, Inc. v. Mt. Vernon Hospital, Inc.*, 172 Ill. App. 3d 718, 732-35 (1988), in which the fifth district appellate court concluded that the plaintiff's claim based on agency was improperly dismissed. In so holding, the court held that although the inferences raised from the pleadings might be subject to debate, the rule in Illinois is that unless the parties' relationship is so clear as to be undisputed, the existence and scope of an agency relationship are questions of fact to be determined by the trier of fact. Plaintiff compares the circumstances of her case to the circumstances in *HPI Health Care Services, Inc.*, to contend that she adequately pleaded her claim, and that the dismissal of the agency claim should be reversed.

¶ 75 Plaintiff, however, neglects to point out that *HPI Health Care Services, Inc.*, 172 Ill. App. 3d 718, was appealed to the supreme court, which reversed the appellate court's decision on agency, holding that the principle cited by the appellate court "does not free the plaintiff of his obligation to allege specific facts in support of his claim" and "the plaintiff must still allege specific facts regarding the circumstances of the situation from which the existence of the relationship can be inferred." *HPI Health Care Services, Inc. v Mt. Vernon Hospital, Inc.*, 131 Ill. 2d 145, 163 (1989). The supreme court ultimately held that the plaintiff "failed to provide any specific allegations of fact that would give rise to an inference [of an agency relationship]." *Id*.

¶ 76 Moreover, to establish apparent agency, the party alleging the existence of the agency relationship must prove that (1) the principal or its agent acted in a manner that would lead a reasonable person to believe that the individual allegedly at fault was an employee or agent of the principal; (2) the principal had knowledge of and acquiesced in the acts of the agent; and (3) the injured party acted in reliance upon the conduct of the principal or its agent, consistent with

ordinary care and prudence. *Thomas v. Weatherguard Construction Co.*, 2015 IL App (1st) 142785, ¶ 49 (citing *Wilson v. Edward Hospital*, 2012 IL 112898, ¶ 18).

¶ 77 In this case, Plaintiff never alleged any facts that would tend to show that she acted in reliance upon Dr. McCarthy's apparent authority as an agent of Edwards. In fact, as the complaint suggests and the record shows, plaintiff did not know that Dr. McCarthy would use the Myxo ring manufactured by Edwards during her heart surgery. In these circumstances, plaintiff's agency claim fails and we find no error on the part of the trial court in dismissing it.

¶ 78 Plaintiff next contends that the circuit court erred in granting summary judgment on Count III, "Product Liability – Negligence Failure to Warn or Instruct" against Edwards.

¶ 79 Summary judgment is proper when the pleadings, depositions, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. *Nationwide Financial, LP v. Pobuda*, 2014 IL 116717, ¶ 25. We review summary judgment orders *de novo*. *Id*. (citing *Schultz v. Illinois Farmers Insurance Co.*, 237 Ill. 2d 391, 399-400 (2010).

¶ 80 Plaintiff contends that this count "is not a classic failure to warn products liability case" acknowledging that she does not "allege that the Myxo ring was defective." Instead, plaintiff contends that "[s]ince the product was in development and being studied," Edwards was negligent in failing to "ensure that patients were given all pertinent information so the patients could, in turn, give proper informed consents." Plaintiff relies on Dr. Barkalow's testimony to show that Edwards "did not properly follow the rules involving a JTF which renders Edwards' JTFs invalid" and "that the pathway Edwards took to market this device produced a lack of informed consent." Accordingly, plaintiff asserts that "genuine issues of material fact exist[] in

this case as to whether the Myxo ring was investigational, and whether Edwards improperly cut regulatory corners to hastily place the Myxo ring into use by Dr. McCarthy for use in the study."

¶ 81 Like plaintiff's battery claim described above, plaintiff's "failure to warn" claim, is also premised on Edwards's alleged violations of the FDA and its alleged failure to proceed through proper regulatory channels. Plaintiff's argument appears to be that, regardless of whether the Myxo ring was defective in any way, Edwards had a duty to warn patients that it had not been properly cleared by the FDA. To allow plaintiff to recover on her failure to warn claim without any allegation that the Myxo ring was defective would amount to creating a cause of action for a violation of the FDCA, which, as described above, is precluded under *Buckman*, 531 U.S. 341, 349 n. 4 (2001).

¶ 82 Plaintiff next argues that the trial court erred in finding particular documents privileged under the Medical Studies Act (MSA), and barring their use at trial. Plaintiff contends that a "central issue in this case is whether Dr. McCarthy implanted his new Myxo ring on patients as part of a study which required the informed consent of his patients." Plaintiff points to an article authored by Dr. McCarthy regarding the Myxo ring, and states that the article "gave rise to a series of questions," namely, whether the Northwestern IRB allowed a study of the Myxo ring; whether, when getting consent to include their information in the Outcomes Registry, patients were told that "Dr. McCarthy intended to use his new Myxo ring"; and whether Dr. McCarthy informed patients that he "intended to implant a new annuloplasty ring with new features, or that it was larger than other customary rings." The particular documents that plaintiff sought to use, and which are at issue in this appeal are the following—"Protocols," a "New Project Submission Form," and a "Request to Waive Consent." These documents were apparently inadvertently produced to plaintiff by NMH, before Northwestern University, who was not a party at trial or in

this appeal, objected to their disclosure and use in the court proceedings. Plaintiff contends that she seeks to use these documents to "show that [the] IRB *** did not authorize Dr. McCarthy to study the Myxo ring."

¶ 83 The record shows that on December 6, 2013, the parties appeared, along with counsel representing two Northwestern University employees who had upcoming depositions, for hearing on whether the above documents were privileged under the MSA. After argument regarding the applicability of particular case law, the court stated:

> "I'm going to hold that it is MSA. I'm going to say you can't use the protocol. *** [S]o what I found to be MSA privileged are [the 'Protocols,' the 'New Project Submission Form,' and the 'Request to Waive Consent.']"

¶ 84 As an initial matter, in this court the Northwestern defendants contend that plaintiff's claim must be rejected because she "submitted [it] against the wrong entity." The Northwestern defendants point out that it was Northwestern University who invoked the MSA in the circuit court and obtained the order to which plaintiff now objects. Northwestern University, however, was not a party to the trial court proceedings, and it is not a party to this appeal. Accordingly, the Northwestern defendants contend that "[p]laintiff's requested review of [Northwestern University]'s assertion of the MSA privilege is not properly levied against Defendants-Appellees NMH and NMFF in this appeal." The Northwestern defendants contend that they "cannot now take the place of NU in asserting a privilege that they did not advocate for in the lower court and does not belong to them to assert."

¶ 85 Plaintiff replies that all the Northwestern entities, including Northwestern University, were, and are, represented by the same law firm. Accordingly, plaintiff contends that the

"Northwestern lawyers were served with the Notice of Appeal *** [and] could have appeared for the University had they wished to do so."

¶ 86 We conclude that we need not determine whether plaintiff's failure to include Northwestern University in this appeal is fatal to her claim, because it fails on the merits.

¶ 87 The MSA provides, in relevant part, that:

> "All information, interviews, reports, statements, memoranda, *** or other data of *** allied medical societies, health maintenance organizations, medical organizations under contract with health maintenance organizations or with insurance or other health care delivery entities or facilities, *** or committees of licensed or accredited hospitals or their medical staffs, including Patient Care Audit Committees, Medical Care Evaluation Committees, Utilization Review Committees, Credential Committees and Executive Committees, or their designees (but not the medical records pertaining to the patient), used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care or increasing organ and tissue donation, *shall be privileged, strictly confidential and shall be used only for medical research*, increasing organ and tissue donation, the evaluation and improvement of quality care, or granting, limiting or revoking staff privileges or agreements for services[.]" (Emphasis added). 735 ILCS 5/8-2101 (West 2016).

¶ 88 The MSA further provides that any

> "[s]uch information, records, reports, statements, notes, memoranda, or other data, *shall not be admissible* as evidence, nor discoverable in any action of any kind in any court or before any tribunal, board, agency or person. The disclosure of any

> such information or data, whether proper, or improper, shall not waive or have any effect upon its confidentiality, nondiscoverability, or nonadmissibility." (Emphasis added). 735 ILCS 5/8-2102 (West 2016).

¶ 89 The purpose of the MSA is "to encourage candid and voluntary studies and programs used to improve hospital conditions and patient care or to reduce the rates of death and disease." *Niven v. Siqueira*, 109 Ill. 2d 357, 366 (1985). Our supreme court has explained that to promote these goals "the legislature provided that any materials used in such studies or programs shall be confidential." *Id*.

¶ 90 Whether a discovery privilege applies is a matter of law, subject to *de novo* review. *Webb v. Mount Sinai Hospital & Medical Center of Chicago, Inc.*, 347 Ill. App. 3d 817, 825 (2004). However, "whether specific materials are part of an internal quality control or a medical study is a factual determination, which will not be reversed on review unless it is against the manifest weight of the evidence." *Anderson v. Rush-Copley Medical Center, Inc.*, 385 Ill. App. 3d 167, 174 (2008).

¶ 91 Plaintiff does not challenge that the barred documents qualified as any "other data *** used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality, or for improving patient care." Plaintiff contends, however, that the barred documents should have been admitted because allowing a privilege under the MSA here is "inconsistent with the [MSA]'s purpose."

¶ 92 This court addressed the applicability of the MSA to protocols submitted in advance of medical studies in *Doe v. Illinois Masonic Medical Center*, 297 Ill. App. 3d 240, 243-45 (1998). In *Doe*, the plaintiffs were parents who had given birth to child who suffered from cystic fibrosis after participating in the hospital's preimplantation genetic testing procedure. The plaintiffs

brought medical malpractice claims against the doctors and hospital, and sought all protocols submitted to the IRB for the study involving cystic fibrosis. In analyzing the plain language of the MSA, the court determined that it was "clear that the [MSA] applies to the materials in question," and that the "IRB here qualifies as the type of committee covered by the Act." *Id*. at 243-44. In so holding, the court noted that "[w]hile restrictions on discovery may make it difficult in some instances, if not impossible, for plaintiffs to prove otherwise meritorious cases, such restrictions nevertheless represent a considered judgment that interests of litigants must yield to other interests, in this case confidentiality, privacy and candid peer review within medical institutions." *Id*. at 245.

¶ 93 Based on the above, and our review of the documents in question—which, as stated above, were inadvertently disclosed, and are part of the record on appeal—it is clear that the plain language of the MSA applies to the barred documents. In this case, the record shows that plaintiff consented to participate in the Outcomes Registry, agreeing to provide her clinical data for future study. Like in *Doe*, Dr. McCarthy's outcome study protocol documents (including the Protocols, "New Project Submission Form," and "Request to Waive Consent") were submitted to the IRB for approval as part of the required protocol submission process. Accordingly, these documents are subject to the privilege granted by the MSA, and we find no error in the court's exclusion of the documents. *Id*.

¶ 94 Nevertheless, even if we were to find that the court improperly barred the documents described above, plaintiff's claim would still fail, because she has not alleged or shown any prejudice from the trial court's exclusion of the named documents. See *Riehl v. Riehl*, 247 Ill. 475, 477 (1910) ("any error which may have been committed in rulings upon the admission or exclusion of evidence is unimportant if there is competent evidence in the record sufficient to

support the decree, and that the evidence which ought to have been considered would not, if considered, change the result."). Not every erroneous exclusion of evidence suffices to reverse a judgment; instead, the relevant inquiry, on the review of a trial court's exclusion of evidence, is whether the trial court improperly excluded evidence so as to have deprived a party of a fair trial. *Pyskaty v. Oyama*, 266 Ill. App. 3d 801, 814 (1994). An error in the admission or exclusion of evidence will not constitute reversible error unless one party has been prejudiced or the proceedings have been materially affected. *Pister v. Matrix Service Industrial Contractors, Inc.*, 2013 IL App (4th) 120781, ¶ 56.

¶ 95 Here, plaintiff concedes that she was able to utilize alternative evidence—namely, witness testimony—to "make nearly the same point" as she would have made using the barred documents. She contends, however, that this alternative evidence was insufficient because " 'a picture's worth a thousand words,' " and the witnesses' "[m]ere words cannot substitute for [the documents themselves]." Although the alternative evidence may not have been plaintiff's preferred evidence, given plaintiff's concession, she cannot show that she was deprived of a fair trial by her inability to use the barred documents. *Pyskaty*, 266 Ill. App. 3d at 814.

¶ 96 Plaintiff next asserts that the trial court erred in "designating Dr. Rajamannan as plaintiff's Rule 213(f)(3) witness." Illinois Supreme Court Rule 213(f)(3) provides:

> (f) Identity and Testimony of Witnesses. Upon written interrogatory, a party must furnish the identities and addresses of witnesses who will testify at trial and must provide the following information:
>
> * * *
>
> (3) *Controlled Expert Witnesses*. A "controlled expert witness" is a person giving expert testimony who is the party, the party's current employee, or the

> party's retained expert. For each controlled expert witness, the party must identify: (i) the subject matter on which the witness will testify; (ii) the conclusions and opinions of the witness and the bases therefor; (iii) the qualifications of the witness; and (iv) any reports prepared by the witness about the case.

¶ 97 The record shows that on May 10, 2013, the Northwestern defendants filed a motion to deem Dr. Rajamannan a Rule 213(f)(3) witness, requesting that the doctor's testimony be "subject to all of the disclosure requirements of that rule," and "not subject to the payment requirements of Supreme Court Rule 204." The Northwestern defendants complained that they had been surprised by, and had been unable to adequately prepare for, Dr. Rajamannan's two prior depositions, because her testimony included various opinions, and relied on various documents, that had not been previously disclosed. The Northwestern defendants pointed out that Dr. Rajamannan only had a brief encounter with plaintiff while employed by Northwestern, and the majority of the doctor's anticipated testimony was related to that encounter. Instead, Dr. Rajamannan reviewed various records provided by plaintiff in order to form her opinions for trial. Although plaintiff was not paying Dr. Rajamannan, the Northwestern defendants asserted that she should be classified as a Rule 213(f)(3) witness because plaintiff engaged Dr. Rajamannan after discovering that she was critical of defendants, and plaintiff had

> "enjoyed full and continuous cooperation from her over an extended period of time. *** She is a witness whom Plaintiff engaged for the purpose of rendering an expert opinion at trial. She has fully cooperated with Plaintiff in researching his case, preparing his case, preparing her testimony in the case, and preparing exhibits for use at trial."

¶ 98 At the May 28, 2013, hearing on the Northwestern defendants' motion, the Northwestern defendants asked that plaintiff's counsel be required to disclose and seasonably update her opinions consistent with Rule 213(f)(3). The Northwestern defendants also pointed out that Dr. Rajamannan was now seeking to be paid by the Northwestern defendants for her testimony as a 213(f)(2) witness.

¶ 99 At the hearing, plaintiff's counsel acknowledged that Dr. Rajamannan "cooperated in giving opinions that [we]re favorable to [plaintiff's] case," and that her testimony went beyond her treatment of plaintiff, but contended that such cooperation did not rise to the level of being a 213(f)(3) witness. The court pointed out that case law indicated that if a physician sought to "render opinion or give testimony that exceeds her treatment of this individual, then that would be [213(f)(3)]. *** She's now gone beyond that, and *** done animations and she's given opinions, and she's *** read other articles about this and proffered opinion on standards of care."

¶ 100 Plaintiff's counsel ultimately agreed to provide disclosure pursuant to Rule 213(f)(3). Counsel for plaintiff stated:

> "Counsel for the defense is right to have a concern about making sure that everything Rajamannan has to say at trial is aptly disclosed and duly disclosed. I think they're entitled to full disclosure on anything Dr. Rajamannan has to say before she gets to trial under F3 rules no matter what we decide to call her. I think that's fair. So if all we're talking about here is disclosure and supplementing disclosure and making sure that nobody gets sandbagged with what Dr. Rajamannan has to say at trial, I have no problems with that, Judge. Fair is fair, and I think that's fair. But I think the difficulty comes in, though, with her, how

> do you let them run from their own employee? They gave her a paycheck when she was doing this. She's their employee."

¶ 101 The court then stated:

> "I'm going to designate her an F3. I don't do so lightly. I think this is a very different type of situation, one that the court has not [previously] come upon ***. And *** I'm guided by some of the prior cases that I've read that indicate if a person goes beyond these certain things, the treatment and the opinions that are relegated and relating to that treatment, that they move into a—potentially move into this different realm. *** [A]ll of these opinions that are given, all of these conclusions that are given, all of these critiques and criticisms and the animation and the other thing, it just keeps adding to the side in favor of saying I think maybe she's reached that point."

¶ 102 Plaintiff's counsel reiterated that he "agree[d] to be bound by F3 disclosure requirements," but expressed concern that designating Dr. Rajamannan as a 213(f)(3) witness would allow defense counsel to "stand in front of the jury at trial and *** say, that's [plaintiff's counsel]'s witness. *** That's the Plaintiff's hired expert. That's their retained [witness]—and she's not."

¶ 103 Defense counsel agreed that he would not say "she's their hired expert" or "anything other than what I've represented in the court which is the factual truth, which is that they sought her out because they knew she was on a crusade to try to destroy [Dr.] McCarthy. That she wants to blame [Dr.] McCarthy and others that were not her employers for her losing her job at [NMFF]."

¶ 104 The court then found that Dr. Rajamannan was "subject to F3 disclosures" and that, since plaintiff was the one to notice Dr. Rajamannan's deposition, the payment of the deposition fee "[wa]s on [plaintiff]."

¶ 105 In this appeal, plaintiff contends that Dr. Rajamannan should not have been classified as a controlled expert witness because she was formerly employed by NMFF, and had "close ties to" the Northwestern defendants.

¶ 106 As stated above, in the circuit court, plaintiff agreed to provide "full disclosure on anything Dr. Rajamannan has to say before she gets to trial under [Rule 213(f)(3)]." The concern plaintiff's counsel then expressed was regarding whether defense counsel could then argue to the jury that Dr. Rajamannan was plaintiff's "retained," or "hired expert," and defense counsel agreed to not make such statements to the jury.

¶ 107 On appeal, plaintiff continues to maintain that she "did not object to disclosing all of Dr. Rajamannan's opinions consistent with the format of Rule 213(f)(3)." She contends, however that the trial court's order finding Dr. Rajamannan to be plaintiff's Rule 213(f)(3) witness is "contrary to the plain language of *** Rule 213(f)(3)." Plaintiff asserts that the order "adversely affect[ed] Plaintiff because it places obligations on Plaintiff that come with control over an expert, where Plaintiff has no control over this witness."

¶ 108 As an initial matter, we note that the only authority plaintiff cites in support of her argument is the Supreme Court Rule itself, which provides the particular disclosures a party must make regarding controlled expert witnesses. Plaintiff, however, did not object to making such disclosures. Accordingly, it is unclear to this court how the designation of Dr. Rajamannan as a controlled expert witness affected plaintiff, or what relief plaintiff is seeking. Importantly, Dr. Rajamannan testified at trial, and plaintiff does not specify any particular testimony she was

prevented from presenting as a result of the doctor's controlled witness designation. Plaintiff also does not contend that defense counsel improperly referred to Dr. Rajamannan as a hired expert, contrary to counsel's prior representations.

¶ 109 The only way that plaintiff specifically contends that the designation "negative[ly] affect[ed]" her is that in its denial of plaintiff's motion for a new trial, the trial court stated, "Plaintiff chose Dr. Rajamannan as her expert. Although Plaintiff claims she did not control Dr. Rajamannan, she was designated as an (f)(3) witness in this case."

¶ 110 This court has reviewed the order denying plaintiff's motion for a new trial, which plaintiff references. The trial court's comment was made in the context of explaining Dr. Rajamannan's testimony, and the various ways in which her credibility was questionable. We do not find the trial court's statement that plaintiff "chose Dr. Rajamannan as her expert" and the brief reference to the fact that the doctor was designated as a controlled expert witness, to show that she was negatively affected by such designation.

¶ 111 Plaintiff's next challenge concerns certain cross-examination of Dr. Rajamannan. Plaintiff specifically contends that the trial court abused its discretion by allowing cross-examination of Dr. Rajamannan on "collateral matters." Plaintiff asserts that the cross-examination "covered subjects that had no tendency to prove or disprove any of the material issues in Plaintiff's case." Plaintiff specifically objects to cross-examination focusing on Dr. Rajamannan's employment disputes with Northwestern, reports Dr. Rajamannan made to the media about the Myxo ring, Dr. Rajamannan's dealings with governmental agencies, and the *qui tam* action filed by Dr. Rajamannan.

¶ 112 Prior to trial, plaintiff filed several motions *in limine* seeking to bar questioning of Dr. Rajamannan regarding her employment disputes with Northwestern, reports she made to the

media about the Myxo ring, her dealings with governmental agencies, and the *qui tam* action. The trial court denied plaintiff's motions, finding that questioning on these matters was appropriate, as it went to Dr. Rajamannan's bias towards defendants.

¶ 113 During cross-examination, defendants elicited testimony from Dr. Rajamannan that she was suspended from NMFF, that she submitted a *qui tam* action in the United States District Court to the Northern District of Illinois asserting that Dr. McCarthy was improperly using an investigational device during surgeries, and that she reached out to various media outlets regarding her allegations against Dr. McCarthy. Dr. Rajamannan also stated that she wrote several internet blogs, and self-published 13 E-books regarding her allegations about the Myxo ring. Dr. Rajamannan also made these allegations to various bodies of the United States government, including the United States Senate Finance and Judiciary Committee, and the President of the United States.

¶ 114 Plaintiff contends that this line of cross-examination was "an improper attempt to impeach a witness on collateral matters" and that the cross-examination subjects were not relevant. Plaintiff asserts that the testimony was elicited to "create the appearance she was just another hysterical woman who needed these other sources to vent her feelings" and that "her extraordinary experience and prestige should be disregarded because she lacked emotional control."

¶ 115 We note, initially, that plaintiff asserts that eliciting this testimony constitutes "impeachment of a witness on collateral matters." Impeachment, however, occurs where a witness testifies in a certain way, and the opposing party seeks to discredit that testimony through the use of other evidence. Black's Law Dictionary defines "impeach," in relevant part, as, "To discredit the veracity of (a witness)," and "impeachment" as, "The act of discrediting a

witness, as by catching the witness in a lie or by demonstrating that the witness has been convicted of a criminal offense." Black's Law Dictionary 755 (7th ed. 1999). Here, there was no challenge to Dr. Rajamannan's veracity. The relevant testimony was elicited directly from Dr. Rajamannan, who acknowledged these activities willingly during cross-examination. In such circumstances, the rule against impeaching a witness on collateral matters is inapplicable.

¶ 116 Plaintiff's actual challenge appears to be to the relevancy of the above cross-examination. Relevant evidence is evidence which has a tendency to make the existence of any material fact more or less probable than it would be without the evidence. *Worsley v. Farmington Pizza Co.*, 322 Ill. App. 3d 371, 373 (2001). The relevance and admissibility of evidence at trial is within the discretion of the trial court. *Id.* We will not overturn the decision of the trial court absent an abuse of that discretion resulting in substantial prejudice. *Id.*

¶ 117 In this case, the court denied plaintiff's motions *in limine*, and overruled her objections regarding Dr. Rajamannan's suspension from NMFF and subsequent activities, finding that such evidence was admissible because it went to potential bias against defendants. In ruling on plaintiff's motion for a new trial, the trial court explicitly explained its evidentiary ruling, stating:

> "It would have been unfairly prejudicial to the defense and denied Defendants a fair trial if this witness, a former colleague of Dr. McCarthy and former NMFF employee, had been permitted to offer 'expert' opinions that were critical of Defendants without allowing the jury to know that Dr. Rajamannan had been involuntarily terminated from NMFF and that she has claimed quite publicly, in multiple venues, media outlets and in litigation that she was terminated in retaliation for having raised allegations pertaining to the Myxo ring.

> The Court further ruled, however, that Defendants would be extremely limited in the evidence they were permitted to present on this issue. Defendants were limited to demonstrating the fact of Dr. Rajamannan's dismissal, but were prohibited from discussing the details of her dismissal.
>
> As such, the discussion of Dr. Rajamannan's dismissal during the trial of this case was extremely limited. *** This Court agrees with the Defendants that it would have been grossly unfair to Defendants to prohibit them from disclosing Dr. Rajamannan's termination to the jury. This Court ensured, however, that the issue did not dominate the evidence.
>
> * * *
>
> This Court agrees with the Defendants that Dr. Rajamannan's animosity towards the Defendants and the extent of her efforts to attempt to blame Dr. McCarthy for her dismissal from NMFF are significant and relevant areas of inquiry. These activities (particularly her filing her own lawsuit against Dr. McCarthy seeking money damages) are classic examples of bias. It would have been unjust to the Defendants to conceal these activities from the jury. There was no unfair prejudice to Plaintiff that deprived her of a fair trial. This was a relevant area of inquiry for cross examination."

¶ 118 It is well-established that the potential bias of a witness is a relevant topic for cross examination. See *Pierce v. Commonwealth Edison Co.*, 101 Ill. App. 3d 272, 276 (1981) ("the failure to permit an inquiry into the possible bias of the witness would constitute prejudicial error requiring a new trial"); see also Ill. R. Evid. 607 (eff. Jan. 1, 2011) ("credibility of a witness may be attacked by any party"); Ill. R. Evid. 611 (eff. Oct. 15, 2015) (the subject of cross-

examination may include "matters within the knowledge of the witness that explain, qualify, discredit or destroy the witness's direct testimony"). In *Sanchez v. Black Brothers Co.*, 98 Ill. App. 3d 264, 271 (1981), the appellate court explained the particular importance of this rule in cases involving expert testimony:

> "Expert testimony on matters not within common knowledge and experience is sometimes necessary to enable jurors to determine the factual issues submitted to them. However, the expert witness is usually a hired partisan. Moreover, it is unlikely that he could be successfully prosecuted for perjury on the basis of his opinion testimony. Thus, while the expert's opinion has the sanction of an oath, it lacks the substantial safeguard of truth that may be applied to the testimony of other witnesses. For these reasons, counsel must be given the widest possible latitude during cross-examination to demonstrate any interest, bias or motive of the expert witness to testify."

¶ 119 The supreme court has also acknowledged the importance of cross-examination of expert testimony, stating that it has "long recognized that the principal safeguard against errant expert testimony is the opportunity of opposing counsel to cross-examine, which includes the opportunity to probe bias, partisanship or financial interest." *Trower v. Jones*, 121 Ill. 2d 211, 217 (1988).

¶ 120 Here, the trial court concluded that the above testimony regarding Dr. Rajamannan's suspension from NMFF and her subsequent activities critical of defendants were relevant to show her potential bias toward defendants. In these circumstances, we find no abuse of discretion in its decision. *Worsley*, 322 Ill. App. 3d at 373.

¶ 121 Plaintiff also objects to the court's rulings on her objections, which the court overruled, stating that it "Goes to bias. *** Potential bias." Plaintiff contends that by overruling her objections in such a way, the judge "effectively declared before the jury" that Dr. Rajamannan was "a biased witness," and "admonished the jury to consider the evidence as showing that the witness is biased." In support, plaintiff cites *Nastasi v. United Mine Workers of America Union Hospital*, 209 Ill. App. 3d 830, 843-44 (1991), which provides that a "trial judge himself must be fair and impartial, conduct himself so as not to give the jury the impression of his feelings, and not make any comments or insinuations indicative of an opinion on the credibility of a witness." We disagree that the trial judge's brief rulings on plaintiff's objections indicated to the jury any opinion of the credibility of Dr. Rajamannan.

¶ 122 In overruling plaintiff's objections to defendants' cross-examination questions, the trial judge stated that the questions "[went] to bias," later correcting himself to state "potential bias." Such statements cannot reasonably be interpreted to be explicit indications of the trial judge's negative opinion on Dr. Rajamannan's credibility. Instead, it is clear that the trial judge was indicating that the questions were relevant to the question of Dr. Rajamannan's bias, which, as stated above, is a proper subject of cross-examination.

¶ 123 Finally, plaintiff argues that the court abused its discretion in permitting Dr. McCarthy to testify that he donated the royalties he received from sale and use of the Myxo ring to the Greater Chicago Food Depository. She claims that Dr. McCarthy should have been barred from presenting such testimony for two reasons: first, because he did not produce documentation of the donations in response to a written discovery request, and second, because the testimony was "improper evidence of good character."

¶ 124 The record shows that on March 14, 2016, just before opening statements were set to begin, plaintiff presented a motion *in limine* seeking to bar Dr. McCarthy from testifying that he donated the royalties from the Myxo ring. Plaintiff's counsel contended that Dr. McCarthy had been issued a Supreme Court Rule 214 request to produce documents substantiating his donations, and that Dr. McCarthy never produced the requested documents. In response, defendants pointed out that Dr. McCarthy had objected to plaintiff's written discovery request as overly broad and unduly burdensome, and that plaintiff never revisited the request in a 201(k) request, motion to compel, or otherwise, following defendants' objection.

¶ 125 After hearing arguments from the parties, the court stated:

> "There should have been follow-up, though, all along. For me, on the eve of trial, to be presented with, 'I should bar them from being able to say—to even bring that up that he donated it,' I'm not going to bar them from doing that. So you're obviously going to cross-examine him about all of that, but it should have been followed up all through the discovery process, not at the eve of the trial."

¶ 126 At trial, Dr. McCarthy testified as follows regarding his donations of the royalties from the Myxo ring:

> "Q: By the way, what is your share of royalties from the Myxo ring?
>
> A: So the royalties are actually paid to the Cleveland Clinic and then the Cleveland Clinic pays me a portion of that. So it comes *** out to $50 per ring. Now, I don't even want patients even remotely thinking that I would change their treatment based on $50.
>
> PLAINTIFF'S COUNSEL: Objection.
>
> THE COURT: Overruled.

> A: So what I have done is that anytime any surgeon at Northwestern implants any of my rings, I have to accept the money from the Cleveland Clinic because the Cleveland Clinic funds the money from Northwestern, but I then donate that money to charity. I give it to the Greater Chicago Food Depository because I do not want any patient thinking that I might have had a conflict and chose my ring as opposed to some other ring over $50."

¶ 127 In this court, plaintiff first claims that Dr. McCarthy should have been barred from presenting such testimony because he did not produce documentation of the donations in response to her discovery request. Pursuant to Illinois Supreme Court Rule 219(c), a trial court may choose to impose a sanction upon any party who unreasonably refuses to comply with discovery rules. Ill. S. Ct. R. 219(c) (eff. July 1, 2002); see also *Shimanovsky v. Gen. Motors Corp.*, 181 Ill. 2d 112, 120 (1998). The decision as to whether to impose a sanction for the violation of a discovery rule falls within the discretion of the trial court, and only a clear abuse of discretion justifies reversal. *Id.*; *Boyd v. City of Chicago*, 378 Ill. App. 3d 57, 68 (2007). When imposing sanctions, the trial court must consider the surprise to the adverse party, the prejudicial effect of the witness's testimony, the nature of the testimony, the diligence of the adverse party, the timeliness of the objection, and the good faith of the party seeking to offer the testimony. *Santorini Cab Corp. v. Banco Popular North America*, 2013 IL App (1st) 122070, ¶ 21. No single factor is determinative, and each case presents a unique factual situation that the court must consider. *Id.*

¶ 128 The circumstances here support the trial court's conclusion that no discovery sanction was warranted. Plaintiff was not surprised by Dr. McCarthy's testimony regarding his donation of the royalties from the Myxo ring, as she had been aware that he would so testify since his first

deposition in June 2012, almost four years prior to trial. Further, plaintiff sought to present the theory at trial that Dr. McCarthy profited from his decision to use the Myxo ring during her surgery and others. In these circumstances, Dr. McCarthy's testimony would not be prejudicial to plaintiff as it was being presented to rebut plaintiff's theory. Finally, plaintiff never followed up on defendants' objection to producing the supporting documents, and instead waited until the day trial was to begin to seek to bar such testimony. Accordingly, plaintiff's lack of diligence, and the untimeliness of her objection, also weigh in favor of allowing Dr. McCarthy's testimony. In these circumstances, we find no abuse of discretion on the part of the circuit court in choosing not to bar Dr. McCarthy's testimony regarding his donation of the royalties of the Myxo ring.

¶ 129 Similarly, we also reject plaintiff's contention that the trial court should have barred such testimony as "improper evidence of good character."

¶ 130 Initially, we note that in defendants' response brief, they point out that at trial, plaintiff relied only on the theory that such testimony should be barred based on the alleged discovery violation, and she never raised the issue that allowing such testimony would be improper character evidence. Because plaintiff deprived the court of considering this basis, defendants contend that she should be barred from raising this issue on appeal. In plaintiff's reply brief, she presents no response to defendants' contention that she failed to preserve this issue. We agree with defendants.

¶ 131 "It is a fundamental rule of law in Illinois that a party desiring to preserve a question for review must make appropriate objection in the court below, and that a failure to object to preserve a question for review constitutes a waiver." *Brown v. Timpte Inc.*, 137 Ill. App. 3d 1053, 1062-63 (1985). "Objections should be sufficiently specific to inform the court of the ground for the objection, and a general objection, if overruled, will not preserve the issue for

review on appeal." *Carlson v. City Construction Co.*, 239 Ill. App. 3d 211, 239 (1992) (citing *People v. Queen*, 56 Ill. 2d 560, 564 (1974)).

¶ 132 In this case, plaintiff's counsel objected to Dr. McCarthy's testimony that he donated the royalties of the Myxo ring, but stated only "Objection," and did not offer any further specification. Accordingly, the general objection did not suffice to preserve this issue for review, and we consider it waived. Although plaintiff did raise this issue in her motion for a new trial, "issues raised for the first time in a post-trial motion will not be considered." *Zdeb v. Baxter International, Inc.*, 297 Ill. App. 3d 622, 630 (1998).

¶ 133 Nonetheless, even if plaintiff had not waived review of this issue, we would still conclude that it fails on the merits. "[T]he admissibility of evidence is a matter for the sound discretion of the trial court, and its decision will not be reversed on appeal unless that discretion has been clearly abused." *Leonardi v. Loyola University of Chicago*, 168 Ill. 2d 83, 92 (1995).

¶ 134 At trial, it was plaintiff who first introduced the theory that Dr. McCarthy stood to profit by using the Myxo ring. In opening statements, plaintiff's counsel emphasized that Dr. McCarthy "received royalties" from the Myxo ring, and that this fact was not disclosed to his patients. Plaintiff's counsel also elicited testimony from Dr. Rajamannan that Dr. McCarthy violated the standard of care, and that he was "required to give disclosures in regard to his Myxo study that pertain[ed] to conflicts of interest" because he invented the device and stood to benefit from "potential royalties."

¶ 135 Accordingly, Dr. McCarthy's testimony pertaining to his donation of Myxo ring royalties to the Greater Chicago Food Depository was not offered as evidence of good character, but instead was relevant to rebut plaintiff's theory that Dr. McCarthy financially benefited from the Myxo ring. To allow plaintiff to argue that money motivated Dr. McCarthy to use an

"experimental" medical device without allowing Dr. McCarthy to testify that he did not actually profit from the Myxo ring would have been fundamentally unfair. See *Werdell v. Turzynski*, 128 Ill. App. 2d 139, 150 (1970) ("It is a rule of fundamental fairness that evidence that would otherwise be irrelevant or incompetent, if offered by one party in the first instance, may become relevant in rebuttal or to explain evidence offered or injected into the record by the adversary."). In these circumstances, we would find no abuse of discretion by the trial court in allowing such testimony.

¶ 136 For the foregoing reasons, we affirm the judgment of the circuit court of Cook County.

¶ 137 Affirmed.