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2021 IL App (4th) 200490

NO. 4-20-0490

IN THE APPELLATE COURT

OF ILLINOIS

FOURTH DISTRICT

CAROL CLEETON, as Independent Administrator of the Estate of Donald Cleeton, Deceased, Plaintiff-Appellant, v. SIU HEALTHCARE, INC.; CHARLENE YOUNG; ABDULLAH AL SAWAF, M.D.; STEPHANIE WHOOLEY; SUE FERRILL; AND MEDTRONIC, INC., Defendants (Stephanie Whooley, Sue Ferrill, and Medtronic, Inc., Defendants-Appellees).	)	Appeal from the Circuit Court of Sangamon County No. 19L32 Honorable Raylene Grischow, Judge Presiding.

JUSTICE TURNER delivered the judgment of the court, with opinion.

Presiding Justice Knecht and Justice DeArmond concurred in the judgment and opinion.

OPINION

¶ 1 Plaintiff, Carol Cleeton, as the independent administrator of the estate of Donald Cleeton, deceased, appeals the Sangamon County circuit court's August 21, 2020, order granting summary judgment in favor of defendants, Stephanie Whooley, Sue Ferrill, and Medtronic, Inc. (Medtronic) (collectively, Medtronic Defendants), on counts XVI through XXI of plaintiff's amended complaint. On appeal, plaintiff contends the circuit court erred by finding (1) plaintiff's negligence claims based on a failure to warn theory were preempted by federal law and

(2) defendants did not owe a duty to decedent under a voluntary undertaking theory. We affirm.

¶ 2 I. BACKGROUND

¶ 3 When he was 17 years old, decedent sustained a cervical cord injury that left him a quadriplegic. In December 2014, Dr. Jose Espinosa implanted a Medtronic SynchroMed II programmable pump in decedent to reduce the extent of involuntary muscle spasms decedent experienced. The pump delivered Lioresal Intrathecal (baclofen) for spasticity control. After the implantation, decedent's pump was managed by the Southern Illinois University Department of Neurology (SIU Neurology).

¶ 4 On October 25, 2017, decedent, then 25 years old, presented with his mother, Carol Cleeton, at the SIU Neurology clinic for a routine pump refill. He reported his spasms were under good control with the current dose of baclofen. Ashley Kochman, R.N., unsuccessfully attempted to refill decedent's pump three times. One of the attempts resulted in Kochman inserting the full length of the refill needle into decedent's abdomen without making contact with the pump. Kochman sought assistance with the refill from defendant Charlene Young, a nurse practitioner. Young was able to refill decedent's pump on her first or second attempt.

¶ 5 On October 29, 2017, around 8:15 p.m., decedent arrived at the Memorial Medical Center emergency room complaining of abdominal pain and a headache since his pump was refilled. Decedent also noted increased spasms since the refill. He also recently had a urinary tract infection. Decedent was seen in the emergency room by Dr. Richard Austin. At 8:30 p.m., Dr. Austin consulted Dr. Jahangir, a neurology resident. The emergency room notes stated Dr. Jahangir recommended having a Medtronic representative interrogate the device. At 8:46 p.m., Jessica Farley, an emergency department nurse, paged a Medtronic representative. Whooley, a Medtronic sales representative, spoke with Farley, and Farley requested interrogation of decedent's pump.

Sometime between 11 p.m. and midnight, Whooley arrived at the emergency room and interrogated decedent's pump. The interrogation of the pump involved using an electronic device to read the pump to see how the pump was currently functioning and whether an alarm had been activated. The interrogation results showed no functional error with the pump. Whooley also confirmed the pump was programmed correctly. Whooley informed Dr. Austin of the results of the interrogation but did not give him the "on-label" information addressing the signs and symptoms for baclofen withdrawal symptoms and the Medtronic emergency procedures. Whooley also did not discuss the intrathecal catheter that delivered the medication from the pump to the spinal canal. The emergency room notes for decedent contain diagnoses of sepsis and acute urinary tract infection. Dr. Austin admitted decedent to the hospital and transferred decedent's care shortly before midnight. In transferring care of decedent, Dr. Austin spoke with Dr. Nichole Mirocha.

¶ 6 While hospitalized, decedent's condition continued to decline. On October 30, 2017, around 10:45 a.m., a Medtronic employee faxed the emergency procedures for baclofen withdrawal to Memorial Medical Center after receiving a request for troubleshooting assistance with decedent's pump. Sue Ferrill, a clinical specialist with Medtronic, was also contacted on the morning of October 30, 2017. She was informed about the possibility of a dye study on decedent's pump and catheter. The dye study never took place. Also, that morning, defendant Dr. Abdullah Al Sawaf, the neurologist responsible for managing decedent's pump, examined decedent. Decedent was transferred to the intensive care unit where Dr. Mouhamad Bakir took over care for decedent. A code blue was called around 12:09 p.m. Thereafter, numerous physicians were consulted, including Dr. Espinosa, who implanted the pump. Dr. Espinosa recommended intrathecal administration of baclofen, which was done by Dr. Todd Knox. However, after three hours of resuscitation efforts, decedent was declared dead at 3:06 p.m. Later tests revealed the

catheter for decedent's pump had holes in it.

¶ 7 In February 2019, plaintiff filed her wrongful death action against SIU Healthcare, Inc.; Young; and Dr. Al Sawaf. The following were named as respondents in discovery: the Medtronic Defendants, Memorial Medical Center, Dr. Austin, Dr. Knox, Dr. Bakir, Dr. Mirocha, and Farley. In October 2019, plaintiff filed a motion to add the Medtronic Defendants as defendants in this case, which the circuit court granted. Plaintiff added the following counts: (1) a wrongful death claim against Whooley (count XVI), (2) a survival claim against Whooley (count XVII), (3) a wrongful death claim against Ferrill (count XVIII), (4) a survival claim against Ferrill (count XIX), (5) a wrongful death claim against Medtronic under the doctrine of *respondeat superior* (count XX), and (6) a survival claim against Medtronic under the doctrine of *respondeat superior* (count XXI). (We note plaintiff has added other defendants and respondents in discovery during the life of this case and the case is still ongoing.)

¶ 8 The wrongful death claim against Whooley asserted she "undertook the duty to troubleshoot the Baclofen pump and catheter to verify the proper functioning of the device and catheter, including the consideration of the disclosure of Medtronic literature addressing emergency procedures for Baclofen Withdrawal Syndrome." It asserted, on October 29, 2017, Whooley committed the following negligent errors and omissions: (1) failed to troubleshoot the catheter to determine its "patency" and ability to transport the baclofen to its intended location, (2) failed to ask Dr. Austin about his experience and knowledge of the baclofen pump and catheter implanted in decedent, (3) failed to contact a physician with knowledge and expertise with the baclofen pump and catheter implanted in decedent, (4) failed to provide Dr. Austin or any other health care provider or clinician at Memorial Medical Center the emergency procedures contained in the Medtronic literature on label for baclofen withdrawal syndrome, and (5) failed to otherwise

troubleshoot and assist medical personnel with the Medtronic baclofen pump and catheter implanted in decedent.

¶ 9 As to Ferrill, the wrongful death claim alleged she "undertook the duty of troubleshooting the Medtronic Baclofen pump and catheter implanted in [decedent]." The count asserted Ferrill committed one or more of the following negligent acts or omissions: (1) failed to properly troubleshoot the Medtronic baclofen pump and catheter implanted in decedent during his hospital stay of October 29 and 30, 2017, and (2) failed to advise clinicians including physicians and nurses at Memorial Medical Center of the Medtronic emergency procedures on label for baclofen withdrawal syndrome.

¶ 10 In June 2020, the Medtronic Defendants filed a motion for summary judgment and a supporting memorandum with numerous supporting exhibits. Plaintiff filed a response to summary judgment motion with supporting exhibits and a supplement. The supporting exhibits included, *inter alia*, the discovery depositions of Whooley, Ferrill, and Dr. Austin.

¶ 11 In her deposition, Whooley stated she was hired by Medtronic in 2012 as a sales representative. Her degrees were in business. She sold spinal cord stimulators and intrathecal drug pumps. In her position, Whooley received training about the product she was selling, including the SynchroMed II pump implanted in decedent. She also received all of Medtronic's written materials concerning the pump. Whooley was also aware of the withdrawal symptoms of baclofen.

¶ 12 At 9 p.m. on October 29, 2017, Whooley had a telephone call with Farley who informed Whooley decedent was at the hospital and a request for an interrogation had been made. After unsuccessfully looking for a Medtronic employee closer to the hospital, Whooley drove from her home to Memorial Medical Center, a trip of around 1 hour and 15 minutes, to interrogate decedent's pump. Whooley explained interrogation involves using an electronic device to read the

pump. The device reads how the pump is functioning and indicates whether an alarm has been activated, if the pump has stalled, or any other type of system error. The interrogation would not reveal any difficulties in refilling the pump. A clinician is to update the pump's memory after the pump has been refilled.

¶ 13 The interrogation of decedent's pump "revealed that there was no functional error with the pump." Whooley also spoke with decedent's mother and looked at the pump's log. Whooley noted the log's indication of a refill of the pump coincided with the timeline provided by decedent's mother. Whooley further noted a nurse was able to access decedent's medical records, and Whooley confirmed the pump was programmed to be running the way the provider intended the pump to be running. Whooley then provided a pump printout to Dr. Austin and explained to him the steps she took with the emergency room staff and the interrogation of decedent's pump. Whooley did not inquire about Dr. Austin's experience with and knowledge about intrathecal baclofen injections. She also did not provide the emergency procedures for baclofen withdrawal to anyone at Memorial Medical Center on October 29, 2017. Whooley also did not contact Dr. Espinosa or anyone managing decedent's pump.

¶ 14 Whooley stated her role was specifically "to identify whether the pump itself, the computer that drives the delivery of the drug, that computer is intact and programmed accordingly." She did not consider whether the catheter may have been the problem because that was not her role as a Medtronic representative. Whooley did explain the catheter could be tested in a number of ways, including a dye study or fluoroscopy. It was up to the physician to determine the appropriate test and whether to have a Medtronic representative present at the test. If Dr. Austin would have questioned whether the catheter was the source of the problem, Whooley would have explained the options he had for testing a catheter.

¶ 15 In her deposition, Ferrill stated she never saw decedent. On the morning of October 30, 2017, she learned a dye study may have been needed to be performed on decedent's pump and catheter. Ferrill was told she would need to assist and provide equipment if the dye study were to happen. When Ferrill followed up, she was informed decedent's condition had worsened and it was uncertain a dye study would take place.

¶ 16 In his deposition, Dr. Austin stated he had completed his residency four months before treating decedent on October 29, 2017. Before treating decedent, he had seen patients before with pumps but did not learn anything about the specifics of the devices. With the prior patients, he did not have a potential differential diagnosis that involved whether the device was properly working. Dr. Austin acknowledged he had little knowledge about decedent's device. Dr. Austin explained his understanding was that, when a patient presented in the emergency room with a baclofen pump that may or may not be functioning properly, he was to call the "managing team." In decedent's case, it was the SIU Neurology team. Dr. Austin consulted Dr. Jahangir, the neurology resident who was on-call for SIU Neurology. Dr. Jahangir suggested having a Medtronic representative interrogate the device. When asked whether he would have written in his notes a suggestion about any intrathecal baclofen injections, Dr. Austin stated that would be beyond the scope of his practice and he would have included any sort of medication recommendation in his notes.

¶ 17 Dr. Austin further stated he made the associated diagnoses at the end of writing his emergency room note for decedent and listed sepsis and acute urinary tract infection as the associated diagnoses. Dr. Austin explained the diagnoses listed in his note were for things he had been able to definitely diagnose. Thus, while baclofen withdrawal was a differential diagnosis, he did not list it because he did not have enough information to diagnose it. Dr. Austin noted the

Medtronic representative had interrogated the pump and informed him it was functioning appropriately. He did not recall a discussion about the catheter with the Medtronic representative. Dr. Austin relied in part on the Medtronic representative's interrogation results in focusing on a diagnosis of sepsis and a urinary tract infection. Dr. Austin also explained sepsis from a urinary tract infection was an incredibly common condition while sepsis from baclofen withdrawal was a rare condition.

¶ 18 In August 2020, the circuit court held a hearing on the Medtronic Defendants' motion for summary judgment and took the matter under advisement. On August 21, 2020, the court entered a written order granting summary judgment in favor of the Medtronic Defendants. As to a voluntary undertaking, the court found Whooley's limited role did not involve her assuming additional duties of a health-care provider as suggested by plaintiff. It also noted Ferrill never saw decedent and failed to see how she could be held responsible for decedent's care. The court further found the Medtronic Defendants did not owe a duty to diagnose, troubleshoot, inquire about the doctor's experience, offer medical advice, or insert themselves into the middle of the doctor/patient relationship and affirmatively intervene in decedent's care. Regarding the catheter, the Medtronic Defendants had no duty to determine whether it was leaking because they had not been responsible for the pump's implant, the refill procedure, or decedent's care. The court emphasized the physician was responsible for providing medical care. To impose such a duty would require the Medtronic Defendants to monitor the actions of the health-care provider. The court concluded plaintiff had not alleged any facts from which it or a reasonable trier of fact could draw an inference the Medtronic Defendants had or voluntarily undertook any legal duty beyond those they took at the request of decedent's health-care providers.

¶ 19 In finding plaintiff's failure to warn claims were preempted by federal law, the

circuit court commented, no matter how plaintiff's counsel set forth the argument, the argument essentially was the Medtronic Defendants had a duty to advise decedent's medical providers of known information regarding the medical device that was already contained within the on-label warnings. It noted plaintiff failed to identify any federal directive requiring the Medtronic Defendants to deliver a separate copy of the Medtronic emergency procedures for baclofen withdrawal. As such, plaintiff's claims would impose additional requirements above and beyond the on-label warning approved by the Food and Drug Administration, and thus those claims were expressly preempted. On September 11, 2020, the court entered an order stating its August 21, 2020, order granting summary judgment in favor of the Medtronic Defendants was a final and appealable order pursuant to Illinois Supreme Court Rule 304(a) (eff. Mar. 8, 2016) and there was no just reason for delaying enforcement or appeal or both.

¶ 20 On October 6, 2020, plaintiff filed a timely notice of appeal in sufficient compliance with Illinois Supreme Court Rule 303 (eff. July 1, 2017). Accordingly, this court has jurisdiction under Rule 304(a).

¶ 21 II. ANALYSIS

¶ 22 In this case, plaintiff asserted the Medtronic Defendants were negligent under two different theories: voluntary undertaking and failure to warn. The circuit court granted summary judgment in favor of the Medtronic Defendants, finding plaintiff's failure to warn claims were preempted by federal law and no evidence showed the Medtronic Defendants voluntarily undertook any legal duty to take steps beyond those they took at the request of the treating health-care providers. Plaintiff contends the circuit court's grant of summary judgment in favor of the Medtronic Defendants was improper.

¶ 23 A grant of summary judgment is proper when "the pleadings, depositions,

admissions, and affidavits on file establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." *Gillespie v. Edmier*, 2020 IL 125262, ¶ 9 (citing 735 ILCS 5/2-1005(c) (West 2018)). When determining whether a genuine issue of material fact exists, the reviewing court must construe the pleadings, depositions, admissions, and affidavits strictly against the movant. *Gillespie*, 2020 IL 125262, ¶ 9. "We review a motion for summary judgment in the light most favorable to the nonmoving party." *Gillespie*, 2020 IL 125262, ¶ 9. This court reviews *de novo* a circuit court's order granting summary judgment. *Gillespie*, 2020 IL 125262, ¶ 9.

¶ 24 A. Failure to Warn

¶ 25 Plaintiff first contends the circuit court erred by finding her claims of failure to warn were preempted by federal law. She claims she made no allegations that would trigger federal preemption under the Medical Device Amendments of 1976 (the Amendments) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.* (2018)). The Medtronic Defendants contend the circuit court properly found plaintiff's claims preempted because the claims would impose additional requirements above and beyond those approved by the federal Food and Drug Administration.

¶ 26 In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the United States Supreme Court considered whether the preemption clause in the Amendments (21 U.S.C. § 360k(a) (2006)) barred common law claims challenging the safety and effectiveness of a medical device given premarket approval by the federal Food and Drug Administration. The plaintiff's claims included strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the medical device. *Riegel*, 552 U.S. at 320. In analyzing whether the preemption clause applied, the *Riegel* court considered (1) whether the federal government had

established requirements applicable to the medical device and, if so, (2) whether the plaintiff's common law claims for strict product liability and negligence were based on state requirements with respect to the medical device that are " 'different from, or in addition to,' " the federal requirements and related to safety and effectiveness. *Riegel*, 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)(1)).

¶ 27 As to the first consideration, the state requirements are preempted only when the Food and Drug Administration has established specific requirements applicable to a particular device. *Riegel*, 552 U.S. at 322. The *Riegel* Court determined the premarket approval of Class III medical devices is specific to individual devices and constitutes federal safety review. *Riegel*, 552 U.S. at 323. Regarding the second consideration, the Supreme Court rejected the suggestion common-law tort duties are excluded from the scope of preemption. *Riegel*, 552 U.S. at 324-25. It adhered to a prior finding "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. at 323-24. However, state-law claims of strict products liability and negligence are preempted under the Amendments "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). In other words, common-law claims would not be preempted if they were " 'parallel' " to the federal requirements, such as if the claims were for damages premised upon a violation of Food and Drug Administration regulations. *Riegel*, 552 U.S. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). On the facts before it, the *Riegel* Court affirmed the dismissal of the plaintiff's state-law claims against the manufacturer of a Class III premarket approved device because the claims were preempted by the Act. *Riegel*, 552 U.S. at 330.

¶ 28 In this case, plaintiff's claim based on a failure to warn theory asserted the

Medtronic Defendants failed to provide Dr. Austin or any other health-care provider or clinician the emergency procedures contained in the Medtronic literature on label for baclofen withdrawal syndrome. Plaintiff contends *Riegel* provides little guidance in this matter because her claim is outside of the design, manufacturing, and/or labeling of a device. In support of her argument, plaintiff cites a decision by the Indiana Appellate Court, *Medtronic, Inc. v. Malander*, 996 N.E.2d 412, 419, 421 (Ind. Ct. App. 2013), where the reviewing court affirmed the denial of the defendant's motion for summary judgment, finding the plaintiff's negligence claim was not preempted by federal law and a genuine issue of material fact existed as to whether the defendant assumed a duty to the decedent.

¶ 29 In *Malander*, 996 N.E.2d at 414, a physician had implanted a defibrillator and a "Lead" made by the defendant into the decedent (the plaintiffs were the decedent's wife and estate). During a follow-up appointment, the physician learned the device in the decedent had experienced nine episodes of random "short V-V intervals" and scheduled the decedent for a surgery to upgrade the defibrillator and possibly replace the Lead. *Malander*, 996 N.E.2d at 414. The defendant's clinical specialist was present at the surgery and assisted the physician in testing the Lead, which did not reveal any problems. *Malander*, 996 N.E.2d at 414. The physician also called and spoke to two of the defendant's employees in the technical services department and asked for information about the short V-V intervals. *Malander*, 996 N.E.2d at 414. One of the employees told the physician not to worry about it and the employee did not think it was a problem. *Malander*, 996 N.E.2d at 414. The physician did not replace the Lead, and the decedent died following an incident of ventricular tachycardia. *Malander*, 996 N.E.2d at 414. Testing of the device showed short V-V intervals during the two weeks before the tachycardia. *Malander*, 996 N.E.2d at 414. One of the plaintiffs' claims asserted the defendant was negligent for failing to

recommend the Lead be removed or capped off during the decedent's surgery. *Malander*, 996 N.E.2d at 415. The plaintiffs alleged the defendant had distributed memoranda to their technicians prior to the decedent's surgery that indicated short V-V intervals were indicative of lead failure and the technicians should have recommended replacement of the Lead. *Malander*, 996 N.E.2d at 415.

¶ 30 The defendant argued the plaintiffs' failed to allege a parallel claim because plaintiffs' claim was essentially the defendant's technicians should have provided additional warnings above and beyond the warnings on the device's label. *Malander*, 996 N.E.2d at 417. The plaintiffs countered their claim involved negligent oral representations by the defendant's technicians and not the device's labeling. *Malander*, 996 N.E.2d at 417. The reviewing court found the plaintiffs' claim related to oral representations made by the defendant's representatives during a surgical procedure regarding a specific device's performance and not general allegations regarding the labeling, design, or manufacture of the device. *Malander*, 996 N.E.2d at 418. It then addressed several decisions by other courts addressing oral representations by the manufacturer's employees. *Malander*, 996 N.E.2d at 418-19.

¶ 31 Two of the decisions found preemption and one did not. One of the cases finding preemption involved a manufacturer's representative physician informing the physician's nurse the medical pump would continue working for approximately four weeks after the low battery alarm alerted. *Malander*, 996 N.E.2d at 418 (citing *Baker v. Medtronic, Inc.*, No. 2:99-CV-1355, 2002 WL 485013 (S.D. Ohio Mar. 28, 2002)). Four days before the surgery to replace the pump, the battery failed. *Malander*, 996 N.E.2d at 418 (citing *Baker*, 2002 WL 485013, at *1-2). The plaintiff brought an action against the manufacturer and argued, in part, the manufacturer's representative's statements were " 'off label representations' " and not regulated by the Food and

Drug Administration. *Malander*, 996 N.E.2d at 418 (quoting *Baker*, 2002 WL 485013, at *8). The court found the information given to the physician's nurse was consistent with the information in the pump's labeling, and thus the information was not an " 'off label' representation." *Malander*, 996 N.E.2d at 418 (quoting *Baker*, 2002 WL 485013, at *8). The *Malander* court was dismissive of the other case finding preemption because of its lack of analysis and found the third case, *Adkins v. CYTYC Corp.*, No. 4:07CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008), more persuasive. *Malander*, 996 N.E.2d at 419. In *Adkins*, the manufacturer's representative was in the operating room " 'and advised and directed [the doctor] on the proper way' to use the device." *Malander*, 996 N.E.2d at 419 (quoting *Adkins*, 2008 WL 2680474, at *1). "The plaintiff brought an action against the manufacturer 'alleging breach of implied warranty of merchantability, breach of express warranty, negligence through inadequate design and negligent warnings or instruction of the surgeon by [the] defendants' corporate representative.' " *Malander*, 996 N.E.2d at 419 (quoting *Adkins*, 2008 WL 2680474, at *1). The court concluded the plaintiff's cause of action regarding the manufacturer's representative's direct actions " 'during the surgery in negligently instructing the operating physician' were not governed by *Riegel*'s preemption holding." *Malander*, 996 N.E.2d at 419 (quoting *Adkins*, 2008 WL 2680474, at *2). It found the Food and Drug Administration did not regulate interactions between the manufacturer's representatives and physicians on-site at a surgery and such localized situations are traditional matters for the common law. *Malander*, 996 N.E.2d at 419 (citing *Adkins*, 2008 WL 2680474, at *3).

¶ 32 The *Malander* court concluded the plaintiffs' claim was not preempted by the Amendments. *Malander*, 996 N.E.2d at 419. It noted, unlike in *Baker*, the plaintiffs' claim did not involve the mere restatement of information given in the labeling. *Malander*, 996 N.E.2d at 419. Moreover, the *Malander* court found the plaintiffs' claim was similar to *Adkins* since their claim

did not concern the design, manufacture, or labeling of the Lead. *Malander*, 996 N.E.2d at 419.

¶ 33 In this case, the parties agree the first *Riegel* requirement is met. Plaintiff contends the second requirement for preemption is not met because her amended complaint asserts the Medtronic Defendants were negligent based on their own actions or inactions that led to decedent's death. She contends the negligent performance of job duties is not preempted under the Amendments. Plaintiff alleges the court's ruling in *Malander* is instructive. However, the facts of this case are more similar to *Baker* cited in *Malander* than to the facts of *Malander* and *Adkins*. Plaintiff alleged in her amended complaint Whooley and Ferrill should have given decedent's health-care providers the emergency procedures contained in the label for the device. The information contained in the label is clearly controlled by the Food and Drug Administration. To suggest employees had to supply the emergency procedures in addition to the label suggests the label approved by the Food and Drug Administration was insufficient or, stated differently, that additional warnings were required. We agree with the circuit court plaintiff's claim would impose additional requirements above the warnings approved by the Food and Drug Administration. We find no reason why Dr. Austin's lack of knowledge should alter the aforementioned conclusion. Accordingly, this court finds plaintiff's claims based on a failure to warn theory are preempted by federal law. As such, we do not address plaintiff's other arguments her claims based on a failure to warn survive a motion for summary judgment.

¶ 34 B. Voluntary Undertaking

¶ 35 Plaintiff also asserted negligence claims based on a voluntary undertaking theory. She contends the circuit court incorrectly identified the assumed duty of care alleged in her complaint and emphasizes her claims assert a duty to provide technical support. "Whether a duty exists is a question of law for the court to decide." *Bogenberger v. Pi Kappa Alpha Corp.*, 2018

IL 120951, ¶ 21, 104 N.E.3d 1110.

¶ 36 Citing *Luna v. Pizzas by Marchelloni*, 279 Ill. App. 3d 402, 404, 664 N.E.2d 1112, 1114 (1996), plaintiff notes a person can be liable for negligent performance of a voluntary undertaking. "Pursuant to the voluntary undertaking theory of liability, one who gratuitously renders services to another is subject to liability for bodily harm caused to the other by one's failure to exercise due care or 'such competence and skill as [one] possesses.' " (Internal quotation marks omitted.) *Luna*, 279 Ill. App. 3d at 404 (quoting *Cross v. Wells Fargo Alarm Services*, 82 Ill. 2d 313, 317, 412 N.E.2d 472, 474 (1980)). Illinois courts have adopted section 324(A) of the Restatement (Second) of Torts in analyzing voluntary undertaking claims. *Kennedy v. Medtronic, Inc.*, 366 Ill. App. 3d 298, 308, 851 N.E.2d 778, 786 (2006). That section provides, in pertinent part, the following:

> "One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if
>
> (a) his failure to exercise reasonable care increases the risk of such harm[.]"
>
> Restatement (Second) of Torts § 324A (1965).

" 'Under the voluntary undertaking theory of liability, the duty of care to be imposed on a defendant is limited to the extent of the undertaking.' " *Kennedy*, 366 Ill. App. 3d at 308 (quoting *Lange v. Fisher Real Estate Development Corp.*, 358 Ill. App. 3d 962, 973, 832 N.E.2d 274, 282 (2005)); *Bell v. Hutsell*, 2011 IL 110724, ¶ 12, 955 N.E.2d 1099. "The theory is narrowly construed." *Bell*, 2011 IL 110724, ¶ 12.

¶ 37 In support of her voluntary undertaking argument, plaintiff again cites the Indiana

Appellate Court's decision in *Malander*. There, the reviewing court found the defendant had not assumed a duty to make medical recommendations but, rather, had assumed a duty to make " 'technical' recommendations." *Malander*, 996 N.E.2d at 420-21. Having volunteered to provide technical support, the defendant assumed a duty to provide that support in a reasonable and prudent manner. *Malander*, 996 N.E.2d at 421. The reviewing court noted the defendant's "failure to exercise reasonable care in giving technical support would clearly increase the risk of harm to a patient." *Malander*, 996 N.E.2d at 421. The plaintiffs' supporting evidence showed the defendant's technician was present in the operating room and the physician talked on the telephone to additional technicians regarding "the short V-V intervals experienced by [the decedent]'s Lead." *Malander*, 996 N.E.2d at 421. The plaintiffs also provided supporting evidence the defendant's "technicians failed to follow the recommendations of its own internal memoranda regarding the short V-V intervals associated with this particular lead." *Malander*, 996 N.E.2d at 421. While the defendant did provide supporting evidence the small number of short V-V intervals associated with the decedent's Lead would not have been concerning, a genuine issue of material fact existed. *Malander*, 996 N.E.2d at 421.

¶ 38 The Medtronic Defendants assert *Malander* is distinguishable and this case is more like *Kennedy*, 366 Ill. App. 3d at 309, where the reviewing court affirmed the grant of summary judgment in favor of the defendant because the defendant did not owe a legal duty to the decedent that would support the plaintiff's negligence cause of action. There, the physician surgically implanted a pacemaker made by the defendant into the decedent at an outpatient facility. *Kennedy*, 366 Ill. App. 3d at 300. A clinical specialist for the defendant was present during the surgery to provide "technical support to ensure the lead parameters were correctly calibrated and the lead was functioning properly." *Kennedy*, 366 Ill. App. 3d at 301. After the surgery, the decedent

experienced health problems, and it was discovered the lead to the pacemaker had been placed in the left ventricle of the heart. *Kennedy,* 366 Ill. App. 3d at 301. The decedent died, and the administrator of the decedent's estate brought a negligence action against the defendant, asserting the defendant was negligent in selling the pacemaker to the physician and through its participation and assistance in the pacemaker implant surgery. *Kennedy,* 366 Ill. App. 3d at 301, 303. The circuit court granted summary judgment in the defendant's favor, and the plaintiff appealed. *Kennedy,* 366 Ill. App. 3d at 303.

¶ 39 On appeal, the plaintiff argued the defendant owed the decedent the following three duties: (1) to refrain from providing a pacemaker to the physician and from participating in the insertion of the pacemaker when the clinical technician knew the physician intended to proceed in an inadequate facility without qualified personnel present and without monitoring any of the decedent's vital signs; (2) to warn of the dangers inherent in proceeding with the surgery under the conditions present; and (3) to assist with the insertion in a reasonable manner once it voluntarily undertook to participate. *Kennedy,* 366 Ill. App. 3d at 303. As to the voluntary undertaking claim, the reviewing court rejected the plaintiff's claim the defendant voluntarily assumed a duty. *Kennedy,* 366 Ill. App. 3d at 308. It found the defendant's clinical specialist attended the decedent's surgery to provide technical support and ensure the lead parameters were correctly calibrated and the lead was functioning properly. *Kennedy,* 366 Ill. App. 3d at 308. It further found that limited role did not include the clinical specialist voluntarily assuming a duty for the placement of the lead into the correct ventricle of the decedent's heart. *Kennedy,* 366 Ill. App. 3d at 308. The reviewing court also rejected the plaintiff's contention the defendant voluntarily assumed a duty based simply upon a brief conversation between its clinical specialist and the plaintiff during which the clinical specialist allegedly reassured the plaintiff prior to her father's surgery. *Kennedy,* 366

Ill. App. 3d at 308.

¶ 40 1. *Whooley*

¶ 41 In her amended complaint, plaintiff asserted Whooley "undertook the duty to troubleshoot the Baclofen pump and catheter to verify the proper functioning of the device and catheter, including the consideration of the disclosure of Medtronic literature addressing emergency room procedures for Baclofen Withdrawal Syndrome." On appeal, plaintiff abandons the assertion Whooley undertook the duty to troubleshoot the catheter. Instead, in her appellant brief, plaintiff contends Whooley did not execute her duty to troubleshoot the pump in a reasonable and prudent manner because she incompletely communicated the results of her interrogation of the pump to Dr. Austin. Plaintiff contends Whooley did not inform Dr. Austin of the following: (1) the fact the interrogation did not find a problem did not rule out all potential issues stemming from the pump, (2) the interrogation did not test the "patency" of the catheter, and (3) catheters are a common source of complications with the device that could potentially cause baclofen withdrawal syndrome. Plaintiff argues Whooley had a far greater understanding of the limitations of the interrogation and the risks of baclofen withdrawal syndrome related to the pump than Dr. Austin. She notes Dr. Austin relied on her interrogation report in ruling out baclofen withdrawal as the likely cause of decedent's symptoms. The Medtronic Defendants disagree and contend Whooley accurately reported the results of the interrogation to Dr. Austin. They contend requiring Whooley to inform Dr. Austin of the aforementioned information about the interrogation constitutes intervening in decedent's treatment plan. Moreover, they assert plaintiff's arguments are not supported by Illinois law.

¶ 42 As stated, the duty of care imposed upon the defendant under a voluntary undertaking theory is limited to the extent of the undertaking and is narrowly construed. *Bell*, 2011

IL 110724, ¶ 12. Similar to the clinical specialist in *Kennedy*, the evidence before the circuit court on the summary judgment motion showed Whooley only voluntarily undertook a duty to determine whether the pump itself was functioning as intended by the medical team managing decedent's pump. No evidence indicated she undertook a duty to ensure decedent was actually receiving the baclofen in his spinal canal. We note plaintiff's suggestion Whooley had a duty to troubleshoot with Dr. Austin all possible issues with the pump's delivery of the baclofen based on Medtronic's internal documents was insufficiently argued in the appellant brief. Plaintiff did not cite to any legal authority, and the argument itself is brief and conclusory.

¶ 43 Whooley's deposition testimony demonstrates testing the integrity of the pump and the integrity of the catheter are two distinct and separate tests. Whooley explained an interrogation of the pump involved using an electronic device to read the pump to see how the pump was currently functioning and whether an alarm had been activated. During an interrogation, the pump itself was not accessed, and thus, the interrogation was noninvasive. A test of the catheter could be done "a number of ways," including a dye test, and it was the physician who chose which test was most appropriate for the patient.

¶ 44 In this case, the supporting evidence shows Whooley was only asked to interrogate decedent's pump. Dr. Jahangir, the on-call physician for the SIU Neurology team who was managing decedent's pump, recommended Dr. Austin have Medtronic interrogate the device. Whooley received a text message from a national answering service with the request to interrogate decedent's pump that day. Whooley called the telephone listed in the text, and Farley, decedent's emergency room nurse, stated a request had been made for "an interrogation." Whooley went to the hospital and interrogated decedent's pump. She also spoke with decedent's mother and looked at the pump's log. Whooley noted the log coincided with the timeline provided by decedent's

mother. Whooley further explained a nurse was able to access decedent's medical records, and Whooley confirmed the pump was programmed to be running the way the provider intended the pump to be running. Whooley then provided a pump printout to decedent's mother and Dr. Austin. She also explained to Dr. Austin the steps that she took with emergency room staff and the interrogation of the device. Whooley stated her role was specifically "to identify whether the pump itself, the computer that drives the delivery of the drug, that computer is intact and programmed correctly." Plaintiff acknowledges Whooley arguably met her duty of care in performing the interrogation.

¶ 45 However, plaintiff claims Whooley did not use reasonable care in reporting the interrogation findings because Whooley failed to communicate to Dr. Austin the significance and limitations of the interrogation's findings. Plaintiff cites no case law in support of her argument. Instead, plaintiff emphasizes Whooley's superior knowledge about the pump and possible problems with it compared to Dr. Austin. That argument overlooks the fact it was Dr. Austin who was the person responsible for decedent's care at the time of the interrogation and he was aware of his own limited knowledge about the pump. Dr. Austin could have asked Whooley more questions about the pump and the interrogation, or he could have talked to Dr. Jahangir, who had recommended the interrogation of the pump. As the Medtronic Defendants observe, to require Whooley to explain the limitations of the test and possible catheter issues would require a medical device sales representative with no medical training to volunteer theories about the cause of the patient's symptoms and thus intervene in the patient's treatment. In this case, besides baclofen withdrawal, Dr. Austin was considering other reasons for decedent's symptoms. Whooley had no way of knowing what information beyond the interrogation results Dr. Austin needed in making his clinical judgment. Thus, we disagree reasonable care includes informing the ordering physician

of additional possible issues with baclofen treatment or *sua sponte* educating the physician about the pump.

¶ 46 Additionally, we note this case is different from *Malander* where the defendant's employees gave information to the physician that was inconsistent with the defendant's internal memoranda. Here, plaintiff is asserting Whooley should have provided more information and not that she provided incorrect information.

¶ 47 In this case, plaintiff has failed to identify a genuine issue of material fact showing Whooley did not use reasonable care in exercising her assumed duty to interrogate decedent's pump. As such, summary judgment in Whooley's favor was proper as to the claims based on a theory of a voluntary undertaking.

¶ 48 2. *Ferrill*

¶ 49 On appeal, plaintiff asserts Ferrill undertook a duty to maintain and troubleshoot decedent's pump. She does not further elaborate on the duty and does not allege how Ferrill did not perform her duties in a reasonable manner to prevent harm to decedent. The Medtronic Defendants contend Ferrill was never involved in decedent's care and thus could not have owed decedent any of the alleged duties. Plaintiff did not reply to the Medtronic Defendants' argument. Accordingly, we find plaintiff failed to show Ferrill owed a duty to decedent and summary judgment in favor of Ferrill on the claims based on a voluntary undertaking theory was proper.

¶ 50 3. *Medtronic*

¶ 51 Plaintiff's claims against Medtronic were based on *respondeat superior* and, thus, entirely derivative. *Moy v. County of Cook*, 159 Ill. 2d 519, 524, 640 N.E.2d 926, 928 (1994). Since we have found the circuit court properly granted summary judgment in favor of Whooley and Ferrill, the court also properly granted summary judgment in favor of Medtronic.

¶ 52 III. CONCLUSION

¶ 53 For the reasons stated, we affirm the Sangamon County circuit court's judgment.

¶ 54 Affirmed.

No. 4-20-0490

Cite as:	*Cleeton v. SIU Healthcare, Inc.*, 2021 IL App (4th) 200490
Decision Under Review:	Appeal from the Circuit Court of Sangamon County, No. 19-L-32; the Hon. Raylene Grischow, Judge, presiding.
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