UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

WILLIAM BEAUMONT HOSPITAL and SOUTH OAKLAND ANESTHESIA ASSOCIATES, P.C.,

Plaintiffs,

v. Case No. 09-11941

MEDTRONIC, INC.,

Defendant.
_____/

OPINION AND ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION IN LIMINE AS MOOT

On June 12, 2009, Plaintiffs William Beaumont Hospital ("Beaumont") and South Oakland Anesthesia Associates, P.C. ("SOAA"), filed their first amended complaint. Plaintiffs seek contribution from Defendant Medtronic, Inc. ("Medtronic") under Mich. Comp. Laws § 600.2925a for amounts Plaintiffs paid to settle a tort claim arising out of the misuse of one of Defendant's medical procedure kits. Discovery concluded on July 8, 2010. On July 29, 2010, Defendant moved for summary judgment pursuant to Federal Rule of Civil Procedure 56. On August 19, 2010, Plaintiffs filed a response. On September 1, 2010, Defendant filed a reply. Having reviewed the briefs, the court concludes a hearing on this motion is unnecessary. *See* E.D. Mich. LR 7.1(e)(2). For the reasons stated below, the court will grant Defendant's motion.

I. BACKGROUND

On April 15, 2005, decedent Kathy Cober died of an overdose of morphine unintentionally administered through the catheter access port of her intrathecal pump

implant. The administering physician, Dr. Craig McCardell, was an anesthesiologist with SOAA. He was assisted by nurse Lori Cullen of Beaumont. Medtronic manufactured the implant and shipped it to Dr. Sikorsky in the Department of Anesthesiology at Beaumont. On May 28, 2008, SOAA and Beaumont agreed to settle a negligence suit by decedent's family to which Medtronic was not a party. Plaintiffs now seek contribution on the settlement amount, claiming Defendant was negligent in sending a Catheter Access Port Kit in a shipment it represented as containing Refill Kits.

Although the events causing the Catheter Access Port Kit to be shipped to Beaumont are disputed, Plaintiffs have presented sufficient evidence to create a genuine issue regarding whether an agent of Medtronic contacted Cullen several weeks before the accident and offered to send free samples of Refill Kits, with an understanding that only Refill Kits would be sent. However, all parties agree some communication occurred at that time and the kits were shipped to the hospital. Viewed in a light most favorable to the nonmoving parties, the undisputed evidence supports the following facts and inferences:

1. The shipment was addressed to Beaumont's Department of Anesthesiology, with attention to Dr. Sikorsky.
2. The shipment never reached Dr. Sikorsky.
3. The package contained two white boxes, labeled "Model 8551 Refill Kit." It also contained one blue box, labeled "Model 8540 Catheter Access Port Kit."
4. The box was received by Beaumont and directed to a nurse in the Department of Anesthesiology, who placed the contents in the drawer of a storage cabinet. The nurse who received the shipment left a note for Cullen indicating that the Refill

Kits had arrived. The nurse did not indicate in the note that there were different kits included, and Cullen did not examine the kits prior to use.

5. The Catheter Access Port Kit contained some sort of warning label cautioning against use in any refill procedure.

6. The Catheter Access Port Kit remained in the drawer until April 15, 2005, when Cullen retrieved it for use in the attempted refill procedure on the decedent's pump.

7. Cullen did not independently investigate whether it was a proper kit for the procedure, but relied on an a statement alleged to have been made by the Medtronic agent that only Refill Kits would be sent.

8. Cullen did not read the box, label, or warnings on the kit she selected from the drawer.

9. Cullen looked at the picture on the box and decided it contained all the necessary equipment.

10. Cullen presented the Catheter Access Port Kit to McCardell as a Refill Kit.

11. McCardell accepted it as a Refill Kit, and did not check the box, product, or instructions.

12. McCardell did not read the labels, but made a cursory inspection of the device itself prior to using the included template to access what he believed to be the reservoir port of the pump.

13. Newer pumps often have both a reservoir port, used for refills, and a catheter access port, used for tests. Reservoir ports are located in the center of

Medtronic pumps, with catheter access ports located at the periphery of the hockey puck-shaped devices.

14. McCardell knew at the time of the differences between catheter access ports and refill ports, as well as the presence of both on newer pump models.

15. McCardell stated he believed the pump to be an older model because of difficulty communicating wirelessly with the pump and the decedent's long history of chronic pain.

16. The decedent's original pump had been replaced with a newer unit in 2001.

17. Although McCardell had limited experience with the refill procedure, he followed the template because he assumed the reservoir ports were located at the periphery in older model pumps.

18. Prior to injecting morphine into the pump, McCardell attempted to empty the pump of its remaining supply. Because he had accessed the wrong port, he drew an unexpectedly large volume of spinal fluid, which he believed to be morphine from the pump.

In the suit by decedent's family against Plaintiffs, Defendant was not a party and did not engage in settlement negotiations. On May 20, 2008, Plaintiffs alerted Defendant to settlement negotiations and invited participation. Defendant contends this was insufficient to provide it with an opportunity to participate in the settlement process. Plaintiffs reached a settlement agreement with decedent's family on May 28, 2008, which was executed on June 25, 2008.

II. STANDARD

Under Federal Rule of Civil Procedure 56, summary judgment is proper when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "In deciding a motion for summary judgment, the court must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Sagan v. United States*, 342 F.3d 493, 497 (6th Cir. 2003). "Where the moving party has carried its burden of showing that the pleadings, depositions, answers to interrogatories, admissions and affidavits in the record, construed favorably to the non-moving party, do not raise a genuine issue of material fact for trial, entry of summary judgment is appropriate." *Gutierrez v. Lynch*, 826 F.2d 1534, 1536 (6th Cir. 1987) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986)).

The court does not weigh the evidence to determine the truth of the matter, but rather to determine if the evidence produced creates a genuine issue for trial. *Sagan*, 342 F.3d at 497 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). The moving party discharges its burden by "'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Horton v. Potter*, 369 F.3d 906, 909 (6th Cir. 2004) (citing *Celotex*, 477 U.S. at 325). The burden then shifts to the nonmoving party, who "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The non-moving party must put forth enough evidence to show that there exists "a genuine issue for trial." *Horton,* 369 F.3d at 909 (citing *Matsushita*, 475 U.S. at 587). Summary judgment is not appropriate

when "the evidence presents a sufficient disagreement to require submission to a jury." *Anderson*, 477 U.S. at 251-52.

The existence of a factual dispute alone does not, however, defeat a properly supported motion for summary judgment—the disputed factual issue must be material. *See id.* at 252 ("The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict – 'whether there is [evidence] upon which a jury can properly proceed to find a verdict for the party producing it, upon whom the *onus* of proof is imposed.'" (alteration in original) (citation omitted)). A fact is "material" for purposes of summary judgment when proof of that fact would establish or refute an essential element of the claim or a defense advanced by either party. *Kendall v. Hoover Co*., 751 F.2d 171, 174 (6th Cir. 1984) (citation omitted).

III. DISCUSSION

Michigan provides for an action in contribution "when 2 or more persons become jointly or severally liable in tort for the same injury to a person." Mich. Comp. Laws § 600.2925a(1). In order to obtain contribution from Defendant, Plaintiff must show that Defendant was negligent with respect to the decedent. Negligence under Michigan law is composed of four elements: 1) duty, 2) breach of duty, 3) causation, and 4) injury. *Bialick v. Megan Mary, Inc.*, 780 N.W.2d 599, 602 (Mich. App. 2009) (citing *Case v. Consumers Power Co.*, 615 N.W.2d 17 (Mich. 2000)). The first and last elements are not in question at this point. In Plaintiffs' amended complaint, they list three alleged facts on which to base Defendant's negligence: Defendant's representation that it was sending only refill kits, Defendant's inclusion within the shipment of a kit particularly ill-

suited for use as a refill kit, and Defendant's shipment of the kits to the Department of Anesthesia at Beaumont. (Pl. Am. Compl. ¶ 24.) Defendant moves for summary judgment on the basis that these facts show neither that Defendant breached a duty to the decedent nor that Defendant's breach was the proximate cause of the injury. Defendant also moves for summary judgment on the basis that it "was not given an opportunity to participate in the settlement negotiations" between Beaumont and Cober, as required by Mich. Comp. Laws § 600.2925a(3)(c). Because the court will grant the motion on other grounds, it need not reach this issue. The court must now decide whether the evidence presents a genuine issue of material fact as to whether Defendant breached a duty of care owed to the decedent that was a proximate cause of the decedent's injury.

A. Breach of Duty

Defendant first moves for summary judgment on the ground that Plaintiffs cannot establish that it breached a duty of care to the decedent. The alleged breach of duty lies in representing that all kits delivered would be suitable for refill procedures and in shipping a kit with minimal anesthesiological purpose to Beaumont's Department of Anesthesiology. The facts are disputed. Plaintiffs claim a representative from Medtronic called Cullen and offered to send "some Refill Kits." (Cullen Dep. 42:1-6.) This presents a question of fact for the jury because it is susceptible to multiple interpretations, depending on the context. One such interpretation would make it a declaration that Defendant would send only Refill Kits, while another interpretation would allow Defendant to send other kits with the Refill Kits. Similarly, the shipping address of the kits raises a genuine issue of fact. Although the kits were shipped to the

attention of Dr. Sikorsky, they were addressed to the Beaumont Department of Anesthesiology. Whether it was foreseeable that shipments addressed in such manner would be sent not to the individual but to the department is a question of fact.

Assuming Defendant owed a duty to the decedent to prevent foreseeable accidental misuse of its products by Plaintiffs, the determination of these facts in favor of Plaintiffs could support a finding that Defendant breached its duty. A breach occurs when a party does not exercise "reasonable care" under the circumstances. *Case v. Consumers Power Co.*, 615 N.W.2d 17, 18 (Mich. 2000). Reasonable care would include taking precautions against sending dangerous devices to persons who may mistakenly misuse them. Plaintiffs have presented evidence that a representative of Defendant conducted an investigation immediately following the incident, telling Cullen that the Catheter Access Port Kit should not have been delivered to the anesthesiology department. (Cullen Dep. 74.) From this statement and the danger of misidentification, it would be possible for a reasonable jury to conclude that the representation and shipment of the kits constituted a failure of due care under the circumstances. The facts are neither so unequivocal that this court can find no genuine issues nor so collateral that this court can find them immaterial to the determination of whether Defendant breached a duty of care. Therefore, summary judgment is inappropriate on these grounds.

B. Proximate Cause

Defendant also moves for summary judgment on the ground that Plaintiffs cannot establish proximate cause. The causation requirement in negligence comprises two distinct parts: causation in fact and proximate causation. *Skinner v. Square D Co.*, 516

N.W.2d 475, 479 (Mich. 1994) (citing *Moning v. Alfono*, 254 N.W.2d 759, 764 (Mich. 1977)). Causation in fact must be decided as a factual matter, determining whether the negligent action was a sine qua non of the injury. *Moning*, 254 N.W.2d at 765. As such, it is a question for the jury. Proximate cause analysis requires the determination of whether the results were a "natural and probable result of the negligent conduct." *O'Neal v. St. John Hosp. & Med. Ctr.*, No. 138180, 2010 WL 3037785 at *4 (Mich. July 31, 2010) (citations omitted). Where this question ultimately depends on facts in dispute, the determination must be given to the jury to find whether the facts are such that proximate cause exists. The issue of whether certain facts establish proximate cause, however, remains a question of law for the court. *Gillam v. Lloyd*, 432 N.W.2d 356, 364 (Mich. App. 1988) (citing *Moning*, 454 N.W.2d at 766). Therein lies the distinction between proximate and actual causation: the former is a question of law, while the latter is a question of fact. Causation in fact is not at issue in the instant motion.

The watchword of proximate cause is foreseeability. A cause in fact is also a proximate cause only if the risk of harm is a foreseeable result of the action. *Skinner*, 516 N.W.2d at 479; *Moning*, 254 N.W.2d at 765. Foreseeability, however, requires more than a mere possibility, supported by speculation as to any conceivable risk. An act is a proximate cause only if the result is "natural and probable." *O'Neal*, 2010 WL 3037785, at *4; *Kaiser v. Allen*, 746 N.W.2d 92, 95 (Mich. 2008) (citing *Shinholster v. Annapolis Hosp.*, 685 N.W.2d 275, 281 (Mich. 2004)). Although intervening acts may supercede the negligence of an actor, the earlier acts remain a proximate cause if the later negligent or even criminal acts are reasonably foreseeable. *Hickey v. Zezulka*,

487 N.W.2d 106, 118 (Mich. 1992) (citations omitted). A cause in fact is not a proximate cause, however, "if such remote cause did nothing more than furnish the condition or give rise to the occasion by which the injury was made possible" where "no danger existed in the condition, except because of the independent cause." *Fuller v. Hessler*, 197 N.W. 524, 525 (Mich. 1924); *see also Shinholster*, 685 N.W.2d at 282. An act which merely sets the stage for a wholly independent act of negligence remains nothing more than a cause in fact, insufficient to support a cause in negligence. Where two or more actors have produced causes in fact, "one actor's negligence will not be considered a proximate cause of the harm unless it was a substantial factor in producing the injury." *Brisboy v. Fibreboard Corp.*, 418 N.W.2d 650, 653 (Mich. 1988).

Even if Defendant's acts breached a duty of care to the decedent in some general sense, the sort of severe injury that occurred cannot be rationally said to be a "natural and probable" result of that nebulous breach. It would have been possible to speculate, ex ante, that such a result could occur, but "possible" ought not be read where "probable" properly belongs. Probable results would include the incurrence of additional shipping costs to replace the Catheter Access Port Kit with a Refill Kit or harm caused by delay upon the discovery that the item was not that which Beaumont expected to receive. At most, Defendant's action in sending the unexpected kit "furnished the condition" necessary for the subsequent negligence. A new, independent, and unlikely act of negligence on the part of Cullen or McCardell was needed for any injury to result. Defendant's ostensible negligence had come to rest without injury; it did not sit dormant, like a ticking bomb, waiting only for a victim. It had

been extinguished by the superceding gross negligence of failing to read even the label of the product about to be used in the presumably routine medical procedure.

Viewed in the light most favorable to Plaintiffs, the facts nonetheless evince reckless disregard for the potential for injury from using the wrong medical kit, as well as a willful blindness to the patently obvious. When the kits arrived at Beaumont, they were addressed to Dr. Sikorsky, but they were delivered directly to a nurse in the Beaumont Department of Anesthesia. Upon opening the shipping package, it should have been obvious that it was at least possible that the shipment contained two different types of kits. The shipment comprised two Refill Kits in white boxes and one Catheter Access Port Kit in a blue box, all properly labeled. This alone should have been enough to trigger some further inquiry if the nurse had expected only Refill Kits. Rather than investigate further, that nurse simply stored all three kits for further use. A cursory inspection would have revealed the different labeling, as well as the warnings that the Catheter Access Kit is contraindicated for all refill procedures. This nurse then left a note for Cullen, simply stating that the Refill Kits had arrived. Cullen relied solely on the equivocal representation of Defendant that it was sending only Refill Kits and the communication from the receiving nurse that the kits had been delivered. Cullen never verified the receipt of the kits, nor did she read the boxes. Instead, she opened the desk drawer, withdrew a box placed there by another nurse, looked intently at the picture on the cover, and decided the box contained all the necessary items. Based on this, Cullen selected the Catheter Access Port Kit for the refill procedure without ever once reading the label.

After Cullen had presented the kit to McCardell as a Refill Kit, McCardell used it without observing that it was a Catheter Access Port Kit. Although it is uncertain whether McCardell observed the kit box, he did examine the contents of the Catheter Access Port Kit. McCardell stated in his deposition that he knew of the difference between refill equipment and catheter access equipment in April 2005. He also knew at the time that modern pumps have two ports, one of which provides direct access to the catheter. Based on the decedent's medical record and difficulties communicating with the implant, however, McCardell concluded that the pump must have been an older model. Perhaps in reliance on the skill and diligence of Cullen, he simply assumed that the kit must be for an older model and that the older model had its refill port in a different location, which happened to coincide with the catheter port location of newer models. Rather than identifying the model, checking that the odd-looking template in the kit was compatible with the older model, or reading the labels indicating that it was a Catheter Access Port Kit, McCardell simply assumed that whatever kit he had before him must necessarily work for the procedure. Even when performing the procedure, McCardell ignored clear signs that would indicate he had the wrong port. Although the pump was nearly empty, he withdrew an unexpectedly large quantity of fluid before attempting to refill the pump. This should have indicated that the needle was not drawing from the pump reservoir, but some other source either within or without the pump. It was in fact drawing directly from the catheter through the catheter access port. At this point, the fatal overdose was inadvertently delivered.

None of the foregoing qualifies as foreseeable. It is neither natural nor probable that trained medical personnel would blindly use any kit within arm's reach. This

repeated and reckless disregard of the blindingly obvious cuts off any negligence on the part of Defendant in representing that it would ship only Refill Kits. In addition to being simply unforeseeable, the actions of Cullen and McCardell severed the causal chain and became superceding causes of the decedent's injuries. Although this court does not believe the courts of Michigan would go so far as to determine that failure to read warning labels constitutes a superceding cause in all cases, they have established that failure to heed clear warnings can be a superceding cause. *See Fleck v. Titan Tire Corp.*, 177 F.Supp.2d 605, 617-18 (E.D. Mich. 2001); *Coy v. Richard's Ind., Inc.*, 428 N.W.2d 734, 737 (Mich. App. 1988). In *Formella v. Ciba-Geigy Corp.*, the independent action of a physician in ignoring known risks and clear warning labels when prescribing a drug was a superceding cause of the patient's injuries, which relieved the manufacturer of liability from failing to warn the physician of the risks. 300 N.W.2d 356 (Mich. App. 1980). Although that was a products liability action, it is not at all clear that the procedural footing of the instant case does not mask what would otherwise be a products liability claim by the decedent against Medtronic. Medtronic's alleged liability in this case stems from putting into the stream of commerce a dangerous device with insufficient warnings or differentiation to allow a nurse and doctor to recognize its identity without reading the its label. In any event, the superceding cause doctrine is not limited to products liability. *See, e.g.*, *Heitsch v. Hampton*, 423 N.W.2d 297 (Mich. App. 1988) (wrongful death); *Hickey*, 487 N.W.2d 106 (liability based on 28 U.S.C. § 1983).

Although not binding authority, another case from Tennessee is directly on point and quite persuasive. In *Johnson v. Settle*, a medical center ordered heavily diluted

acetic acid, but the distributor sent nearly pure acetic acid. No. M1999-01237, Lo2001 WL 585093 (Tenn. App. June 1, 2001). The concentrated acid was used despite clear indications in packaging and labeling that it was not the expected product, resulting in severe burns to a patient. As in the instant case, delivering the wrong product was the basis of the alleged negligence, and in both cases the medical personnel failed to read the label or warnings on the products. The Tennessee appellate court granted judgment NOV because the unforeseeable intervening negligence of "open[ing] and pour[ing] from properly labeled bottle without checking the contents" was a superceding cause. *Id.* at *9. As in that case, it would offend all notions of reason and common sense to require a distributor to anticipate every possible careless misuse of dangerous products by sophisticated users. "Life will have to be made over, and human nature transformed, before prevision so extravagant can be accepted as the norm of conduct, the customary standard to which behavior must conform." *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 100 (N.Y. 1928).

The evidence that Defendant knew of the possibility of confusion between the Refill Kits and the Catheter Access Port Kits does not affect the ultimate determination of foreseeability in this case. Mistakes are to be expected as a natural concomitant of life. However, they are not the natural and probable result of all negligent acts. In fact, it appears from the record that the intervening actors would have disregarded virtually any warning, contraindication, label, or direction that could have been given. That the occasional misidentification had occurred in the past does not make total non-identification a foreseeable result. Such evidence merely moderates the extreme

attenuation of the causal connection between Defendant's misrepresentation and decedent's injury.

The facts before this court show that there is no genuine issue of material fact with respect to causation. Whether Defendant represented it would send only Refill Kits or breached a duty by sending a Catheter Access Port Kit is immaterial to the determination of proximate cause, as is the issue of whether the shipment should have been delivered to Dr. Sikorsky personally. The two individuals who directly used the kit admit they never read its clear label or warnings. Despite believing that different configurations of pump implants existed, they took no steps whatsoever to verify compatibility between the kit and the pump. Had Defendant sent a pacemaker replacement kit instead of a Catheter Access Port Kit, it would have been equally unforeseeable that Cullen and McCardell would have performed a pacemaker replacement. No reasonable jury could find the facts such that Defendant would be required to foresee that its clearly-labeled medical products would be identified by literate medical professionals by merely looking at the picture on the front of the boxes and guessing as to the contents. Therefore, the court finds that Defendant's actions, even if breaching a duty to decedent, were not the proximate cause of her injuries. There are no genuine issues of material fact, and Defendant is entitled to judgment as a matter of law.

IV. CONCLUSION

IT IS ORDERED that "Motion of Defendant Medtronic, Inc., for Summary Judgment" [Dkt. # 49] is GRANTED.

IT IS FURTHER ORDERED that "Plaintiffs' Motion in Limine to Exclude David Caraway, M.D., Ph.D., as an Expert Witness" [Dkt. # 48] is DENIED as moot.

S/Robert H. Cleland
ROBERT H. CLELAND
UNITED STATES DISTRICT JUDGE

Dated: October 8, 2010

I hereby certify that a copy of the foregoing document was mailed to counsel of record on this date, October 8, 2010, by electronic and/or ordinary mail.

S/Lisa G. Wagner
Case Manager and Deputy Clerk
(313) 234-5522