In the
Missouri Court of Appeals
Western District

JEFFREY ALLEN JOHNSON AND TAMMY ELAINE JOHNSON,	**WD73382 and WD73429**
Appellants-Respondents,	**OPINION FILED:**
v.	**March 6, 2012**
MEDTRONIC, INC.,	
Respondent-Appellant.	

Appeal from the Circuit Court of Clay County, Missouri
The Honorable Shane Terril Alexander, Judge

Before Alok Ahuja, P.J., Thomas H. Newton, and James Edward Welsh, JJ.

Jeffrey Allen and Tammy Elaine Johnson appeal the circuit court's grant of summary judgment in favor of Medtronic, Inc.,[1] in regard to the Johnsons' product liability claims for failure to warn and product defect. The Johnsons claimed that a defibrillator used on Jeffrey Johnson was unreasonably dangerous and in a defective condition because it automatically reverted to an asynchronous mode after each synchronized shock, permitted a user to give an asynchronous shock where a synchronized shock was medically indicated, and lacked any audible warning or other notice while using the defibrillator to alert the operator of the change

[1]Physio-Control, Inc., is a division of Medtronic, Inc., and was a named defendant. We collectively refer to Medtronic and Physio-Control as Medtronic.

from synchronized to asynchronous mode. They also claimed that Medtronic did not give adequate warning of this dangerous condition. The circuit court found that, as a matter of law, the instructions accompanying the defibrillator were adequate, that Medtronic's affirmative defense of the learned-intermediary doctrine applied to the failure to warn claim, and that the physician's use of the defibrillator in violation of the appropriate standard of care could not constitute a reasonably anticipated use by Medtronic. The Johnsons appeal, asserting that the circuit court erred in granting summary judgment because (1) genuine issues of material fact precluded summary judgment on their failure to warn claim, (2) the circuit court misapplied the law on the learned intermediary doctrine in regard to the failure to warn claim, and (3) genuine issues of material fact precluded summary judgment on their product defect claim. Medtronic also filed a cross-appeal asserting that the circuit court erred in failing to expand its basis for granting summary judgment because it failed to include that the Johnsons were unable to make a submissible case because (1) their only two liability experts should be excluded, (2) their usability study should be excluded, and (3) they could not establish causation. We affirm in part and reverse in part.

The evidence established that Jeffrey Johnson suffered from recurring atrial fibrillation, which is a heart rhythm disorder. On November 9, 2005, Jeffrey Johnson's wife, Tammy Johnson, took Jeffery Johnson to the emergency room at North Kansas City Hospital after Johnson experienced another episode of atrial fibrillation. At the emergency room, the nursing staff confirmed that Jeffrey Johnson was in atrial fibrillation. The staff contacted Northland Cardiology, which was the cardiology group of choice of Jeffrey Johnson for his condition. Dr. Steven Starr, the cardiologist that Jeffrey Johnson normally saw, was not available, but Dr. David M. Hahn was available.

Thereafter, Dr. Hahn arrived at the emergency room, confirmed that Jeffrey Johnson was in atrial fibrillation, and prepared to electrically cardiovert Jeffrey Johnson's heart to restore his heart beat to a normal rhythm. Electrical cardioversion involves the application of an electric shock to a patient's heart through the use of a defibrillator. Jeffrey Johnson had previously advised Dr. Starr and others at Northland Cardiology that he was supposed to undergo only biphasic cardioversion, which required the use of a biphasic defibrillator. At the emergency room, Jeffrey Johnson specifically confirmed with Dr. Hahn that a biphasic defibrillator would be used, and Dr. Hahn agreed that he knew that he should use a biphasic defibrillator and that he would do so. The specific device selected by Dr. Hahn for this procedure was the LifePak 9P defibrillator, which was manufactured by Medtronic. The LifePak 9P was a monophasic defibrillator.

The LifePak 9P defibrillator transmits shocks in either synchronous or asynchronous mode. The most basic function of the device is the delivery of a nonsynchronized shock in an emergency situation when a patient is suffering from cardiac arrest or *ventricular* fibrillation. The LifePak 9P is also used for non-emergency situations, such as electric cardioversion of *atrial* fibrillation. To cardiovert a patient suffering from *atrial* fibrillation, the standard medical protocol requires that the *synchronous* mode be selected on the defibrillator. If instead the *asynchronous* mode is selected while attempting cardioversion of atrial fibrillation, *ventricular* fibrillation can occur, which is much more serious and potentially more dangerous than atrial fibrillation. The default setting for the LifePak 9P is the asynchronous mode. Thus, for a synchronized shock to be given, the synchronous mode must be manually selected by the operator of the device for *each synchronized shock*. After each synchronized shock, the LifePak

9P automatically resets itself to the asynchronous mode, presumably to be ready for use in an emergency situation.

Further, the LifePak 9P had three levels of use instructions regarding synchronization of the LifePak 9P. First, an instruction manual was provided to users of the LifePak 9P defibrillator at North Kansas City Hospital and instructed the users how to operate the device and how to place the device in the synchronous mode. The instruction manual stated, "If synchronized cardioversion needs to be reattempted, press sync again, device automatically returns to the asynchronous mode after each synchronized discharge." Thus, the instructions in the instruction manual told the user that the defibrillator would reset to the asynchronous mode after each synchronized shock and that the device had to be reset to synchronous mode before attempting any subsequent synchronized shocks. Second, a label was displayed and affixed to the top of the machine itself, giving instructions for use regarding synchronization. The instructions specifically stated, "Push SYNC for each synchronized attempt."[2] Third, the LifePak 9P's display monitor allowed a user to determine whether or not the machine was in synchronous mode. An illuminated amber light on the SYNC button indicated when the machine was synchronized with the patient's heart rhythm. A green light reading “SYNC” displayed on the monitor whenever the LifePak 9P defibrillator was in the synchronous mode. Additionally, markers or carats appeared at the top on the "QRS complex" when the device was in synchronous mode. These indicators disappeared when the device was in asynchronous mode

[2]Though this instruction label had sections denominated “Danger” and “Warning,” the use instructions described in the text were not included under either of those headings. In addition, there was no language on the label stating that, unless the user pushed the SYNC button before each shock, the device would automatically return to the asynchronous mode.

(although the monitor did not affirmatively state that the device was prepared to deliver a nonsynchronized shock).

Prior to delivering the first shock from the LifePak 9P, Dr. Hahn selected the synchronous mode. Dr. Hahn then administered a synchronized shock to Jeffrey Johnson. This treatment was unsuccessful, however, and Jeffrey Johnson remained in a state of atrial fibrillation. At this point, Dr. Hahn again used the LifePak 9P in a second attempt to electrically cardiovert Jeffrey Johnson's heart beat. Dr. Hahn, however, did not select the synchronous mode on the LifePak 9P, and he made no effort to confirm that the LifePak 9P defibrillator was still in the synchronous mode before delivering the second shock (other than his erroneous assumption that the defibrillator was still in synchronous mode). Thus, because the LifePak 9P automatically resets itself to the asynchronous mode, a nonsynchronized shock was given to Jeffrey Johnson instead of a synchronized one. As a result, Johnson went into ventricular fibrillation, a serious, life-threatening condition. Dr. Hahn then applied 12 or more additional shocks to Jeffrey Johnson over the course of approximately 40 minutes in an effort to electrically cardiovert Johnson's heart.[3] Johnson remained in ventricular fibrillation after each of these subsequent shocks.

Finally, Dr. Hahn switched from the monophasic LifePak 9P defibrillator to a biphasic LifePak 12 defibrillator. Dr. Hahn applied one shock from the biphasic LifePak 12 defibrillator and successfully cardioverted Jeffrey Johnson's heart on the first shock.

Dr. Hahn admitted that he was aware that a patient with *atrial* fibrillation, who was stable and not under hemodynamic duress, should be given a synchronized shock and not a nonsynchronized shock. Further, he admitted that he had knowledge that some defibrillators

[3]It should be noted that each additional shock was nonsynchronized, which is appropriate in response to ventricular fibrillation.

possibly automatically reset to the asynchronous mode after being operated in the synchronous mode. Dr. Hahn said that he intended the second shock on Jeffrey Johnson be delivered as a synchronized shock and erroneously assumed that the defibrillator was still in synchronous mode, but that he did nothing further to confirm that the shock would be delivered in the synchronous mode. Dr. Hahn acknowledged that he had the physical capability of confirming whether the LifePak 9P was in the synchronous mode but that he did not confirm it "in the usual manners." Dr. Hahn said that, for all the shocks given after the initial shock, he did not know whether he was delivering a synchronized or nonsynchronized shock to Jeffrey Johnson. He admitted that "it was not a step in my mind to determine whether it was synchronized or nonsynchronized."

Dr. Hahn also admitted that he had never read the instruction manual on how to synchronize the LifePak 9P defibrillator and that he had never read the instructions affixed on the device itself. He admitted that, had he read those instructions, he would have understood them and that he could have followed them. Finally, Dr. Hahn acknowledged that, had he read these materials, he "presumably" would have followed the instructions and pushed the "SYNC" button before each synchronized attempt. He said that, had he followed the instructions for the LifePak 9P, it was "less likely that [Jeffrey Johnson's rhythm] would have degenerated to ventricular fibrillation."

Due to the extent of time that Jeffrey Johnson was in ventricular fibrillation, Jeffrey Johnson claimed that he suffered brain injury--specifically short term memory loss, a change in affect and mood, and an injury to his left arm as a result of compartment syndrome. Thereafter, Jeffrey Johnson and his wife filed suit against Medtronic asserting two products liability claims: product defect and failure to warn. In Count I, the Johnsons asserted that the LifePak 9P used to

cardiovert Jeffrey Johnson was in a defective condition and was unreasonably dangerous when put to a reasonably anticipated use. In Count II, the Johnsons asserted that Medtronic did not give adequate warning of the unreasonable danger that the LifePak 9P posed.

In particular, the Johnsons argued that, because the LifePak 9P automatically reverted to the asynchronous mode after each synchronized shock and required the user to then select the synchronous mode for each synchronized shock, the LifePak 9P suffered from a design flaw. Further they asserted that this flaw, coupled with the absence of any audible warning or affirmative indicator on the device's monitor during use of the defibrillator to alert the operator of this change in mode or the absence of some sort of lockout option whereby the operator could either lock the device in the synchronous mode or prevent the device from delivering a nonsynchronized shock when a heartbeat could be detected, caused the LifePak 9P to be in a "defective condition" and "unreasonably dangerous" when used by Dr. Hahn on Jeffrey Johnson.

Medtronic filed a motion for summary judgment on all claims, and the circuit court granted Medtronic's motion for summary judgment.[4] The circuit court found that the undisputed facts demonstrated that Dr. Hahn violated the applicable standard of care when he used the LifePak 9P on the second attempt to cardiovert Jeffrey Johnson's heart. The circuit court agreed with Medtronic that it was not required to manufacture and market a "fool-proof" device. The circuit court concluded that the use of the LifePak 9P by a trained medical practitioner in violation of the applicable standard of care could not constitute a "reasonably anticipated use" by Medtronic. Thus, the circuit court found that Medtronic successfully negated the "reasonably anticipated use" elements of both the product defect and failure to warn claims, and, therefore,

[4]Medtronic also filed two other motions for summary judgment, but the circuit court did not rule upon these motions.

Medtronic was entitled to judgment as a matter of law. The circuit court also found that Medtronic was entitled to summary judgment as a matter of law on the Johnsons' failure to warn claim based upon Medtronic's affirmative defense of the learned-intermediary doctrine. The circuit court found that, as a matter of law, the "instructions and warnings accompanying a medical device designed and provided solely for the use of trained medical personnel which are not read, followed, or relied upon by a licensed medical practitioner prior to that practitioner's use of the device cannot be inadequate, especially when viewed in combination with that practitioner's own independent knowledge of the characteristics of such devices." Jeffrey and Tammy Johnson appeal from the circuit court's grant of summary judgment in favor of Medtronic.

In their first point, the Johnsons assert that the circuit court erred in granting summary judgment on their failure to warn claim because genuine issues of disputed material fact precluded judgment as a matter of law. In particular the Johnsons contend that there was material evidence that Medtronic sold the LifePak 9P in the course of its business, that the LifePak 9P was unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, that Medtronic did not give adequate warning of the danger, that the LifePak 9P was used in a manner reasonably anticipated, and that the LifePak 9P's being sold without an adequate warning directly contributed to cause injury to Jeffrey Johnson. We disagree.

Our review of the circuit court's summary judgment is *de novo*. *ITT Commercial Fin. Corp. v. Mid-Am. Marine Supply Corp.*, 854 S.W.2d 371, 376 (Mo. banc 1993). "Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law." *Purcell v. Cape Girardeau Cnty. Comm'n*, 322 S.W.3d

522, 523 (Mo. banc 2010); Rule 74.04. "A defendant may establish a right to summary judgment by showing that the plaintiff is unable to produce sufficient evidence to establish one or more of the essential elements of the plaintiff's claim." *Hoffman v. Union Elec. Co.*, 176 S.W.3d 706, 707 (Mo. banc 2005). Further, summary judgment in the defendant's favor is appropriate "where there are no genuine disputes as to the existence of each of the facts necessary to support one of the defendant's properly pleaded affirmative defenses." *Purcell*, 322 S.W.3d at 523-24.

We must "sustain the trial court's award of summary judgment if the judgment can be sustained under any theory" supported by the record. *Rodgers v. Czamanske*, 862 S.W.2d 453, 458 (Mo. App. 1993) (citing *Zafft v. Eli Lilly and Co.*, 676 S.W.2d 241, 243 (Mo. banc 1984)). In reviewing the circuit court's judgment, we view the record in a light most favorable to the nonmoving party. *Lough v. Rolla Women's Clinic, Inc.*, 866 S.W.2d 851, 852 (Mo. banc 1993).

To prevail on their cause of action for strict liability failure to warn, the Johnsons had to establish: (1) Medtronic sold the LifePak 9P in the course of its business; (2) the LifePak 9P was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) Medtronic did not give adequate warning of the danger; (4) the LifePak 9P was used in a reasonably anticipated manner; and (5) Jeffrey Johnson was damaged as a direct result of the LifePak 9P's being sold without an adequate warning. *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. banc 2011).

Summary judgment was appropriate on the Johnsons' failure to warn claim because Jeffrey Johnson was not damaged as a result of the LifePak 9P's being sold without an adequate warning, at least as described by the Johnsons. The undisputed facts established that Dr. Hahn failed to read or in any way follow the instructions for the LifePak 9P, and the Johnsons have not contended that the manner in which the instructions were provided failed to effectively

communicate to users of the LifePak 9P. Instead, the Johnsons claim that, during use of the LifePak 9P, the defibrillator was not designed with features that would prevent misuse of the defibrillator.

Dr. Hahn admitted that he had never read the instruction manual on how to synchronize the LifePak 9P defibrillator and that he had never read the instructions affixed on the device itself. He admitted that, had he read those instructions, he would have understood them and that he could have followed them. Finally, Dr. Hahn acknowledged that, had he read the instructions and warnings, he "presumably" would have followed the instructions and pushed the "SYNC" button before each synchronized attempt. He said that, had he followed the instructions for the LifePak 9P, it was "less likely that [Jeffrey Johnson's rhythm] would have degenerated to ventricular fibrillation."

To prevail on their failure to warn claim, the Johnsons had to establish proximate cause. *Moore*, 332 S.W.3d at 762. To do this, they had to show that "'the warning would have altered the behavior of the individuals involved in the accident.'" *Id*. (quoting *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. banc 1992)). In this regard, Missouri supplies the presumption that a warning, if provided, will be read and heeded. *Id*. (citing *Arnold*, 834 S.W.2d at 194).

Dr. Hahn did not read either the instruction manual for, or instructional label on, the LifePak 9P.[5] Had Dr. Hahn read these instructions, he testified that he would have known to set the LifePak 9P to the synchronous mode before applying the second shock to Jeffrey Johnson. Indeed, a user who read the instructions would have known that the LifePak 9P reset to the

[5]We use the term "instructions" to refer to the relevant informational materials because there may be some question whether they--and particularly the label--constitute "warnings." *See Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 384-85 (Mo. banc 1986) ("there is a distinction between instructions and warnings. . . . Warnings signal danger while instructions serve principally to provide the user with information necessary to make proper and efficient use of the product.").

asynchronous mode after each synchronized shock and that the SYNC button would have to be pushed for each subsequent synchronized attempt. Moreover, Dr. Hahn acknowledged that he had the opportunity to read the label affixed to the LifePak 9P and the instruction manual but that he did not do so. He admitted that the label and the instructions in the manual adequately instructed him that the SYNC button had to be pushed before each synchronized attempt. Further, he admitted that, had he read those instructions, he would have understood them. Although the Johnsons generally complain that the LifePak 9P failed to effectively inform a user of his failure to press the SYNC button for each desired synchronized shock attempt, they make this argument by focusing on product use design defects, and not any complaint with the communication of the use instructions to users of the device. The adequacy of the instructions accompanying the LifePak 9P defibrillator in this case, therefore, made no difference in the outcome of Jeffrey Johnson's cardioversion because Dr. Hahn did not read those materials.

The circumstances in this case are similar to a failure to warn case from the Court of Appeals of Indiana. In *Peters v. Judd Drugs, Inc.*, 602 N.E.2d 162, 163 (Ind. App. 3 Dist. 1992), the plaintiff went to a hospital to be treated for urethritis. The plaintiff was supposed to be injected with silver nitrate for her condition. A nurse, however, mistakenly injected the plaintiff with potassium hydroxide, and the plaintiff was injured. *Id*. at 163. The nurse did not read the label on the potassium hydroxide before it was administered. *Id*. The label on the potassium hydroxide clearly stated that it was for "external use only." *Id*. The plaintiff claimed that the defendant was liable for her injuries, asserting that the warning label was inadequate. *Id*. at 165. The circuit court granted summary judgment, and the plaintiff appealed. *Id*. at 163. The Indiana Court of Appeals affirmed, concluding that the plaintiff could not recover based upon a theory that the warning, “For External Use Only,” was inadequate. *Id*. at 165. The court concluded:

"[T]he nurse did not read and misconstrue the label. Instead, the product was used without regard to the label and was used internally which was specifically warned against by the label. No genuine issue of material fact exists as to a strict liability cause of action." *Id.*[6]

The same principle applies here. Dr. Hahn did not read and misconstrue the instructions on use of the LifePak 9P in this case, and the Johnsons have not complained that the format or placement of the instructions impeded the communication of those instructions. With this backdrop, then, it is undisputed that Dr. Hahn used the LifePak 9P without regard to the instruction manual and the instruction label on the machine and, thus, Medtronic's alleged failure to warn or alleged inadequate warning was not the proximate cause of Jeffrey Johnson's injuries.

The Johnsons rely heavily upon *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371 (Mo. banc 1986), in support of their proposition that even though a product may be accompanied with instructions and warnings, a jury should always be allowed to determine whether "some better or different or greater warning should have been given[.]" In *Nesselrode*, the Missouri Supreme Court held that the determinative issue in a products liability case "is whether the information accompanying the product effectively communicates to the consumer or user the dangers that inhere in the product during normal use and the dangerous consequences that can or will result from misuse or abnormal use of the product." *Id.* at 382. According to the *Nesselrode* court, "the pivotal concerns in a failure to warn case litigated under a theory of strict tort liability

[6]Cases from other jurisdictions reach the same result. *See, e.g., Smith v. Sears Roebuck & Co.*, 232 Fed.Appx. 780, 784 (10th Cir. 2007) (Oklahoma law; expert testimony concerning inadequacy of warning in owner's manual for garage door opener properly excluded as irrelevant; "[w]here, as here, the undisputed evidence is that Ms. Smith never read the Owner's Manual, she cannot establish that the failure to warn caused the injury"); *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir 2004) (California law; "Motus acknowledges that Pfizer is obligated to warn doctors, not patients, of potential side-effects associated with its pharmaceutical products, and concedes that the doctor who prescribed Zoloft to her husband failed to read Pfizer's published warnings before prescribing the drug. Because the doctor testified that he did not read the warning label that accompanied Zoloft or rely on information provided by Pfizer's detail men before prescribing the drug to Mr. Motus, the adequacy of Pfizer's warnings is irrelevant to the disposition of this case.") (citation omitted)).

are: (1) whether the product is unreasonably dangerous when put to normal use without proper warnings and; (2) whether adequate warnings or any warnings at all were given." *Id*. at 384.

In *Nesselrode*, George Nesselrode died in an airplane crash. *Id*. at 373. The cause of the crash was determined to be the accidental reverse installation of two critical aircraft parts: the right and left elevator trim tab actuators. *Id*. at 374. These parts were visually identical. *Id*. The plaintiffs, Nesselrode's wife and his three daughters, sued the manufacturer of the parts under a theory of product liability for failure to warn, alleging that the actuators as manufactured and sold were defective in that they were not clearly labeled and were not accompanied with any warning regarding the consequences of reverse installation. *Id*. at 375. The evidence established that the maintenance manual did not contain any warnings concerning the possibility of reverse installation of the actuators and its consequences. *Id*. at 384. The actuators did, however, have identification numbers stamped on them "so as to comply with the FAA regulation requiring each element of the flight control system to have either '[fool] proof' design features or distinctive markings." *Id*. But, "the identification numbers stamped in ink on the actuators [had] no independent meaning without reference to [the manufacturer's] parts catalog." *Id*. The manufacturer's parts catalog "contained a warning that the catalog's sole function was to facilitate ordering parts and was not to be used in connection with the maintenance of the airplane." *Id*.

The *Nesselrode* court concluded that the plaintiffs "presented ample evidence to support a finding that [the manufacturer's] maintenance instructions did not constitute a warning and did not signal the danger that inhered in these actuators." *Id*. at 385. Accordingly the court held that it could not say "that as a matter of law plaintiffs failed to meet their burden of producing sufficient evidence showing that the actuators were unreasonably dangerous when used without knowledge of the hazardous propensities of the products' design features." *Id*.

Moreover, the manufacturer challenged the submissibility of the plaintiff's failure to warn case based upon the element of proximate cause. *Id*. The manufacturer relied heavily on the fact that the mechanics did not consult the maintenance manual when they installed the actuators. *Id*. The manufacturer argued that "the inclusion of 'additional warnings' in the maintenance manual would not have prevented the incorrect installation of the actuators" and that "the mechanics' failure to read the manual negates any connection between the absence of warnings and the cause of the fatal crash." *Id*. In response to this argument, the *Nesselrode* court stated:

> In making this argument, [the manufacturer] has omitted critical evidence adduced at trial which supports plaintiffs' position. Our review, however, does not permit us to do the same. Larry Douglas[, the airplane owner's maintenance inspector,] testified that he was familiar with the contents of the maintenance manual because he had cause to read it on prior occasions when called upon to replace worn actuators. Additionally, Al Graves, [the airplane owner's] Director of Maintenance, testified that he was unaware of any warnings in the maintenance manual or the presence of warnings in any other instructional literature published by [the manufacturer] which gave notice of the possibility of reverse installation. He testified further that had he known of any warnings concerning the actuators, he would have alerted his mechanics.
>
> We think plaintiffs' evidence would allow the jury to conclude that a warning was needed not only in the maintenance manual but also affixed to the actuators. Furthermore, Al Graves testified that he read [the manufacturer's] service bulletin and it too lacked a warning. [The mechanics] testified that they assumed any deviation from the industry standard would be noted by way of a caution or warning and if that were the case, they would have been made aware of any such warning and the dangers to be avoided. Furthermore, plaintiffs' evidence showed that the [airplane owner's] employees responsible for ordering parts were also without notice of the dangerous propensities of [the manufacturer's] actuators.
>
> In conclusion, we think the evidence was sufficient to allow a jury composed of men and women with reasonable minds to infer that had [the manufacturer] either affixed a warning to the actuators themselves, placed a warning in the maintenance manual or parts manual, or warned [the airplane owner] by way of a service bulletin, [the airplane owner] would have taken appropriate action to prevent the actuators from being reversely installed. In this respect, the evidence was sufficient to permit the jury to conclude that the instructions and directions found in [the manufacturer's] maintenance manual and

> the identification numbers stamped on the actuators did not provide adequate warning and that had adequate warnings been given, the accident would not have occurred. We find that plaintiffs did satisfy their burden of producing sufficient evidence on the element of proximate cause.

Id.

The present case is distinguishable from *Nesselrode*. Unlike the *Nesselrode* case, where the airplane's owner and maintenance supervisor had reviewed the product information provided by the manufacturer, the user of the defibrillator in this case, Dr. Hahn testified that he had never read the instruction manual on how to synchronize the LifePak 9P defibrillator and that he had never read the instructions affixed on the device itself. He admitted that, had he read those instructions, he would have understood them and that he could have followed them. Finally, the plaintiffs in *Nesselrode* suggested an additional *means* of providing a warning--labels affixed to the parts themselves--which the manufacturer had not attempted. Thus, *Nesselrode* is factually distinguishable from this case.

We acknowledge that in determining the adequacy of a warning, a court must consider "the placement of the warning, its language and how it may or may not impress the average user." *Brown v. Bay State Abrasives*, 821 S.W.2d 531, 533 (Mo. App. 1991). "In evaluating these factors, the dangerous nature of the product, the form in which it is used, the burden to be imposed by requiring warnings and the likelihood that the particular warning will be adequately communicated to those who will foreseeably use the product must also be considered." *Id.* "A warning, no matter how well stated or placed, is inadequate if it has no reasonable likelihood of reaching a foreseeable user and, thereby performing its intended function of risk reduction." *Id*. In this case, the end user, i.e. Dr. Hahn, admitted that he had the opportunity to read the label affixed to the LifePak 9P and the instruction manual but that he did not do so and that the label

and the instructions adequately communicated that the SYNC button had to be pushed before each synchronized attempt. Moreover, the Johnsons did not argue in opposition to summary judgment, and do not argue on appeal, that the label or manual should have been placed or formatted differently to increase the likelihood that Dr. Hahn would have actually read them. Instead, as we discuss below, the Johnsons argue that the LifePak 9P was defective in its design *despite* the instructional materials. While an argument that the manual or label could have been better placed or designed to reach a user might defeat Medtronic's causation argument, no such argument is made here.

The circuit court, therefore, did not err in granting summary judgment for Medtronic on the Johnsons' failure to warn claim. Medtronic established a right to summary judgment by showing that Medtronic's alleged failure to warn or alleged inadequate warning was not the proximate cause of Jeffrey Johnson's injuries.[7]

Finally, the Johnsons challenge the circuit court's granting summary judgment in favor of Medtronic on their product defect claim. The Johnsons contend that genuine issues of disputed material fact existed that precluded entering judgment as a matter of law. In particular, the Johnsons contend that there was material evidence that Medtronic sold the LifePak 9P in the course of its business, that the LifePak 9P was then in a defective condition and unreasonably dangerous when put to a reasonably anticipated use, that the LifePak 9P was used in a manner reasonably anticipated, and that the defective condition directly contributed to cause injury to

[7]Given our conclusion that summary judgment was proper because the Johnsons were not able to produce sufficient evidence to establish that Jeffrey Johnson was damaged as a result of the LifePak 9P's being sold without an adequate warning, we need not address the Johnsons' third point on appeal concerning whether the circuit court misapplied the learned intermediary doctrine to the failure to warn claim in this case.

Jeffrey Johnson. We agree that the circuit court erroneously disposed of the Johnsons' product defect claim by summary judgment.

The Johnsons contend that the LifePak 9P was defective and unreasonably dangerous because: (1) it did not have a forcing function, which "would require the user to override the machine when it senses a nonsynchronized shock is about to be given when a synchronized shock should be given"; (2) the screen on the LifePak 9P did not explicitly inform a user that the machine had reverted to asynchronous mode following a synchronized shock; and (3) there was no alarm or audible information provided to the doctor to alert the doctor to the fact that the device had reverted to asynchronous mode, despite the doctor's earlier selection of a synchronized shock.

To prevail on their cause of action for product defect, the Johnsons had to establish that: (1) Medtronic sold the LifePak 9P in the course of its business; (2) the LifePak 9P was then in a defective condition, unreasonably dangerous when put to a reasonably anticipated use; (3) the LifePak 9P was used in a manner reasonably anticipated; and (4) Jeffrey Johnson was damaged as a direct result of such defective condition as existed when the LifePak 9P was sold. *Strong v. American Cyanamid Co.*, 261 S.W.3d 493, 506 (Mo. App. 2007).

Although the Johnsons have themselves alleged that Dr. Hahn's use of the LifePak 9P in this case violated the standard of care to which he was subject, we nevertheless conclude that they have raised a genuine issue of material fact as to whether the LifePak 9P was then in a defective condition and unreasonably dangerous when put to a reasonably anticipated use and

whether Dr. Hahn's actions constituted a "reasonably anticipated use" of the device.[8] As *Nesselrode* makes clear, "[t]he concept of reasonably anticipated use . . . includes misuse and abnormal use which is objectively foreseeable." 707 S.W.2d at 381; *see also, e.g., Crump v. Versa Prods., Inc.*, 400 F.3d 1104, 1108 (8th Cir. 2005).

Here, the Johnson's presented evidence which could support a jury's finding that Dr. Hahn's use of the LifePak 9P was reasonably anticipated. The Johnsons presented evidence that, during field trials of the LifePak 9P, out of seven attempted synchronized cardioversions involving multiple shocks, one resulted in the delivery of a nonsynchronized shock. Further, out of 18 attempted synchronized cardiversions, two of them included non synchronized shocks. Whether these were intended or unintended nonsynchronized shocks are a matter of dispute between the parties. The Johnsons also presented evidence that Medtronic had received at least five complaints concerning unintended nonsynchronized shocks when machine operators were attempting a sychronized cardioversion. The documents memorializing these complaints include the statements that "[t]he physician indicated the operating mode is a hazard and should be redesigned to stay in synchronous mode," and that "the operator thought the device would stay in sync mode for the second shock." In another incident report, a Medtronic employee commented that "[a] well document[ed] risk of synced cardioversion is that the users may need to reset synch after each delivery of energy." The summary judgment record also contains an internal recommendation that "[w]hether or not sync mode automatically deactivates when energy is transferred should be a user-configurable option;" this recommendation, however, was not implemented until after 1994. Following this modification, five percent of devices returned to

[8]For the same reasons, we deny Medtronic's cross claim contending that the circuit court should have expanded its basis for granting summary judgment to include that the Johnsons were unable to make a submissible case on causation because Jeffrey Johnson would not have been injured had Dr. Hahn followed the standard of care.

Medtronic for servicing, approximately 1,500 machines out of 31,000 devices, had been user-configured to stay in synchronized mode following an initial synchronized shock.[9]

The Johnsons also presented evidence that the medical community was aware of the risk of user confusion concerning the features of particular defibrillators. The evidence indicates that defibrillators are not standardized in the United States and that health care professionals often use models of defibrillation equipment different from the equipment on which they were trained. Johnson also pointed to a paper published in 1986, which stated that "[i]t is common knowledge among technical staff and hospitals that the different cardioversion features of defibrillators are a cause of confusion among users and lead to errors of use." Further, the Johnsons presented deposition testimony from their expert indicating that a survey of defibrillator users showed that 52 percent of respondents "were unable to predict the actual operating mode of their instrument after an initial cardioversion effort."[10]

We recognize that Dr. Hahn's actions in this case were contrary to the instructions provided by Medtronic, both on a label on the defibrillator and in its instruction manual. However, the fact that a particular use of a product is contrary to the manufacturer's instructions does not, *per se*, establish that the use could not be anticipated. *See Chronister v. Bryco Arms*, 125 F.3d 624, 627 (8th Cir. 1997) (Missouri law; rejecting manufacturer's argument that "use of a product that contradicts that product's instructions or warnings is not a 'reasonably anticipated use,'" with the observation that "[i]t is basic products liability law that a manufacturer cannot

[9]All of these facts were gleaned from the parties' responses and exhibits attached to the various motions for summary judgment filed in this case.

[10]*See* n. 9, *supra*.

escape strict liability for a defective product that has been misused by the plaintiff, if that misuse is reasonably foreseeable").

The fact that we have rejected the Johnsons' failure to warn claim does not mandate a similar result as to the product defect claim. As the Missouri Supreme Court emphasized recently, "design defect and failure to warn theories constitute distinct theories aimed at protecting consumers from dangers that arise in different ways." *Moore,* 332 S.W.3d at 757.[11] Just as the evidence may support a jury finding that Dr. Hahn's improper use of the LifePak 9P, with its potentially life-threatening consequences, was reasonably anticipated, this same evidence would support the conclusion that the device was unreasonably dangerous despite the instructions Medtronic provided.

In other words, in certain instances, a manufacturer may be held liable where it chooses to warn of the danger (even admittedly adequately warn) rather than preclude the danger by design. Indeed, the Missouri Supreme Court has recognized that "design defect theories address the situation in which a design is itself inadequate, rendering the product unreasonably dangerous without regard to whether a warning is given--such as a lawn mower designed without a guard or deflector plate." *Id*. at 756. This is because, somewhere along intersecting lines of increasing dramatic warnings and the decreasing cost of precluding the danger by design, there must be a point where preclusion not only is preferred but required, lest a product be unreasonably dangerous. Needless to say, such a judgment would differ from product to product considering amongst other things the danger involved, the state of the art of the technology involved in both

[11] *See e.g. Palmer v. Hobart Corp.*, 849 S.W.2d 135, 141-42 (Mo. App. 1993) (jury's verdict in favor of manufacturer on a strict liability product defect claim was not inconsistent with the jury's verdict in favor of plaintiff on a strict liability failure to warn claim).

product function and danger preclusion, and the cost associated with both the product itself and the associated safety features.

Allowing the Johnsons to proceed on their product defect claim in this case becomes clearer if we consider a negligence claim as opposed to a strict liability design defect claim. Could a plaintiff maintain that a manufacturer failed to use ordinary care when it chose to warn instead of preclude the danger by design? The determination would be a battle of the experts as to the various components of that determination as to the risks involved and the social utility of the product, as well as the various "costs" of the design preclusion mechanisms (both in terms of money and in product performance). In this context, it is appropriate to recognize that a plaintiff not only has a cause of action but that such a determination is within the province of the finder of fact. This is no less so when a plaintiff decides to submit the same case under a theory of strict liability for a design defect. All of these same considerations would be involved in the determination of whether or not the product was defective and unreasonably dangerous because of the manufacturer's decision to warn of the danger as opposed to reduce or eliminate the danger by some design mechanism.

In this case, the Johnsons' expert testified that Medtronic unreasonably relied on its printed instructions to inform users of the proper means of operating the device. Instead of such passive materials, the Johnsons' expert opined that Medtronic should instead have provided active notification through explicit messages that the device had reverted to asynchronous mode on the defibrillator's monitor or through audible alarms, or by requiring users to manually override the device's default settings where the user sought to administer a nonsynchronized shock to a patient with an organized heart rhythm, following the administration of a synchronized shock. In light of this testimony, as well as the evidence concerning the reasonably

anticipated misuse of the LifePak 9P and the potentially fatal consequences of such misuse, it is a question of fact for the jury to decide as to whether or not a defibrillator sold without these safeguards constitutes a defective condition. *See Duke v. Gulf W. Mfg. Co.*, 660 S.W.2d 404, 415 (Mo. App. 1983). In these circumstances and in the context of a motion for summary judgment, we cannot conclude that Dr. Hahn's failure to review the available instructions necessarily defeated the Johnsons' design defect claim.

In its cross-appeal,[12] Medtronic argues that the circuit court's judgment can be sustained on the ground that the Johnsons' two liability experts should have been excluded under section 490.065, RSMo, because the experts lacked sufficient qualifications and relied on facts and data which were unreliable and on which experts in the field would not reasonably rely. Medtronic also argues that a "usability study" on which the experts relied should have been excluded.

Medtronic's cross-appeal arguments cannot sustain the circuit court's judgment at this juncture. Although it expressed "significant concerns" as to the admissibility of their testimony, the circuit court did not rule on Medtronic's motion to exclude the Johnsons' liability experts. The circuit court stated that, while it had been provided with "voluminous depositions" of the experts, it was "not going to make a ruling based on the deposition[s];" instead, the court concluded that "the fair way to go about it" would be "to give the plaintiff the opportunity to make an offer of proof outside the presence of the jury" through the witnesses' live testimony. Similarly, with respect to the usability study, the circuit court ruled that the Johnsons would be prohibited from referencing the study in *voir dire* or opening statement and that the court would

[12]Given that the circuit court's judgment was in Medtronic's favor and that Medtronic does not seek the modification or reversal of any portion of that judgment, the filing of a cross-appeal was "not technically necessary. [Medtronic], as the prevailing party, is entitled to advance any argument here in support of the judgment." *Coldwell Banker Residential Real Estate Servs., Inc. v. Mo. Real Estate Comm'n*, 712 S.W.2d 666, 668 n. 1 (Mo. banc 1986); *see also, e.g.*, *Holman v. Holman*, 228 S.W.3d 628, 633-34 (Mo. App. 2007); *Brockman v. Regency Fin. Corp.*, 124 S.W.3d 43, 50 (Mo. App. 2004).

further consider the issue in the context of an offer of proof. The court indicated that the offer of proof concerning the usability study would include examination of the degree to which the Johnsons' experts had relied on that study and the degree to which their reliance on the study impacted the admissibility of their opinions.

Medtronic does not argue that the circuit court abused its discretion by proceeding in this fashion. Given that the circuit court failed to make definitive rulings concerning the admissibility issues Medtronic raises and believed considerations of fairness required that the Johnsons be given an opportunity to present live testimony before a final ruling, it would be inappropriate for this court to address these fact-bound questions in the context of this appeal. These issues--as to which the circuit court expressed "significant concerns"--remain open to further litigation on remand.

We, therefore, affirm the circuit court's grant of summary judgment in favor of Medtronic in regard to the Johnsons' product liability claim for failure to warn. We reverse, however, the circuit court's grant of summary judgment in favor of Medtronic in regard to the Johnson's product liability claim for product defect and remand to the circuit court for further proceedings. We also deny Medtronic's cross-appeal.

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James Edward Welsh, Judge

All concur.