

**UNPUBLISHED**

**UNITED STATES COURT OF APPEALS**

**FOR THE FOURTH CIRCUIT**

HOPE LENEY MOYERS, A Minor, by  
and through her Mother and Next  
Friend, Kathy Sue Moyers,  
Plaintiff-Appellant,

and

KATHY SUE MOYERS, Individually;  
JEFFREY MOYERS, Individually,  
Plaintiffs,

v.

No. 98-2797

COROMETRICS MEDICAL SYSTEMS,  
INCORPORATED,  
Defendant-Appellee,

and

MARQUETTE ELECTRONICS,  
INCORPORATED; BRISTOL  
LABORATORIES, INCORPORATED;  
BRISTOL-MYERS-SQUIBB COMPANY,  
Defendants.

Appeal from the United States District Court  
for the Eastern District of Virginia at Richmond.  
Robert E. Payne, District Judge.  
(CA-97-648-3)

Argued: January 26, 2000

Decided: April 4, 2000

Before LUTTIG and WILLIAMS, Circuit Judges, and  
John T. COPENHAVER, Jr., United States District Judge for the  
Southern District of West Virginia, sitting by designation.

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Affirmed by unpublished per curiam opinion.

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## **COUNSEL**

**ARGUED:** Michael J. Miller, MILLER & ASSOCIATES, Alexandria, Virginia, for Appellant. Gary Joseph Spahn, MAYS & VALENTINE, L.L.P., Richmond, Virginia, for Appellee. **ON BRIEF:** Robert T. Hall, Holly Parkhurst Lear, HALL & SICKELS, P.C., Reston, Virginia, for Appellant. Dabney J. Carr, IV, MAYS & VALENTINE, L.L.P., Richmond, Virginia, for Appellee.

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Unpublished opinions are not binding precedent in this circuit. See Local Rule 36(c).

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## **OPINION**

### **PER CURIAM:**

Hope Lenee Moyers, a minor, and her parents, Kathy Sue Moyers and Jeffrey Moyers, (collectively, the Moyers) filed suit in the Circuit Court for the City of Richmond against Corometrics Medical Systems, Inc. (Corometrics), seeking recovery for severe neurological injuries Hope sustained at her birth that the Moyers alleged were caused by defects related to the audio alert function of the Corometrics Spectra 400 Extended Surveillance and Alert System. Corometrics removed the Moyers' suit to the United States District Court for the Eastern District of Virginia and, after substantial discovery, moved for summary judgment. By order and memorandum opinion, the district court granted summary judgment to Corometrics and dismissed the case with prejudice upon concluding that the Moyers failed to establish genuine issues of material fact on the elements of their claims for breach of implied warranty and negligence. The Moyers noted a timely appeal of this summary judgment order. Finding no error, we affirm.

## I.

Corometrics designed and manufactured the Spectra 400 Extended Surveillance and Alert System (Spectra 400 System or System), a medical device that aids physicians and nurses in monitoring the fetal heart rate (FHR) of multiple patients at a time. The Spectra 400 System consisted of a centrally located control unit, the Model 400 Control Unit, which acquired and stored data from the bedside fetal heart monitors of patients in labor, and three different types of displays of which the purchaser could buy some or all. In 1989, Winchester Medical Center (WMC) bought a System that consisted of the Model 400 Control Unit, the Model 415C Central Display Unit, and the Model 415R Remote Display Unit. The Model 415C Central Display Unit was a multi-function display located at the central nurses' station that provided a pictorial display of the FHR tracings made at bedside. The Model 415R Remote Display Unit was a limited-function display located in the physicians' lounge that also provided a view of the FHR tracings.

In addition to acquiring and storing data from the bedside fetal heart monitors, the Model 400 Control Unit contained software programs for the alert function of the System. These programs analyzed FHR data and uterine activity during labor and recognized several normal and abnormal FHR patterns. When particular parameters exceeded pre-set limits, the Spectra 400 System provided an audio alert that sounded at the Model 415C Central Display Unit. The System also provided a visual alert for these parameters on the "alert parameter screen" (APS) of the Model 415C Central Display Unit. The APS was activated, and hence visible, only if the user depressed a button to bring this screen into view on the monitor of the 415C Central Display Unit. Depicted on the APS were several parameters for which the Spectra 400 System was programmed to sound an alarm if the threshold limit for that parameter was exceeded, including baseline heart rate, FHR variability, decelerations, uterine contractions, and signal quality.

The APS also included the words "accelerations," "inc variability with UC," "overshoot," and "sinusoidal pattern." It is undisputed that the Spectra 400 System was not programmed to sound an audio alert for any of these four parameters. There was no warning on the

machine or the APS to alert users that these four parameters were inactive, although the right-hand column for these parameters was always blank, signifying their inactive status. In addition, the Spectra 400 System Operator's Manual indicated in two different places that the alert function for recognition of those four parameters would be a "future capability" of the machine. The Operator's Manual also clearly cautioned that the Spectra 400 System was not designed to replace observation and evaluation of the mother and fetus at regular intervals, and that the medical personnel using the machine should regularly assess the FHR tracing that is located at the patient's bedside. The same cautionary note also advised that "[t]he absence of an alert does not indicate fetal or maternal well-being" and that "[t]he alert system will not detect every possible abnormality and cannot detect abnormalities that have not been clinically recognized and described in the literature." (J.A. at 105.)

Robert Farrar, the Corometrics salesperson who marketed the Spectra 400 System to WMC, acknowledged that WMC purchased the System in part because of its alerting capability. In his in-services presentations given to the WMC staff following WMC's purchase of the Spectra 400 System, Farrar explained to the staff how to operate the System's surveillance and alert functions and explained the five active alert parameters. Farrar was not advised, when receiving instruction on how to conduct the in-service training, of what abnormalities the Spectra 400 System would not detect. At both the sales presentation and training sessions he gave, however, Farrar did not represent that the Spectra 400 System could detect or alert for sinusoidal rhythms or sinusoidal patterns. Moreover, at each in-service training session, Farrar used a chart that set forth the cautions from the Operator's Manual describing the System's limitations and read those cautions aloud.

Kathy Sue Moyers, Hope Moyers's mother, was admitted to WMC on August 27, 1991 at approximately 12:40 a.m. At that time, she was examined by Dr. John Willey, her treating obstetrician. Elizabeth Steinmetz, a labor and delivery nurse at WMC, was assigned to monitor and care for Mrs. Moyers. As part of that process, Steinmetz hooked up Mrs. Moyers to a fetal heart monitor that was connected to the Model 400 Control Unit. Steinmetz stayed in Mrs. Moyers's room from the time she began attending to Moyers at 12:45 a.m. until

between 1:18 a.m. and 1:20 a.m. At 1:18 a.m., Steinmetz administered the drug Stadol and left Mrs. Moyers's room one or two minutes later to care for another patient.

While Steinmetz was away from Mrs. Moyers's room, Mrs. Moyers developed a sinusoidal FHR pattern that began at 1:27 a.m. The FHR ranged from approximately 120 beats per minute down to approximately 60 beats per minute in repeating sine-like waves. As Steinmetz was returning to Mrs. Moyers's room, she met labor and delivery nurses Carol Moulton and Nancy Lauder milk at the central nurses' station. All three nurses observed what appeared to be a sinusoidal FHR pattern on the Model 415C Central Display Unit monitor. Because the pattern was not normal, Steinmetz and Lauder milk immediately proceeded to Mrs. Moyers's room, arriving at approximately 1:38 a.m., and Moulton called Dr. Willey. Moulton testified that she was positive that the alert on the Model 415C Central Display Unit sounded while she was talking on the phone with Dr. Willey, but was unable to identify what kind of problem prompted that alarm.

At approximately 1:42 a.m., Dr. Willey arrived at Mrs. Moyers's room in response to Moulton's call. Because Mrs. Moyers's FHR pattern was so unusual, Dr. Willey immediately applied an internal lead and reviewed Mrs. Moyers's FHR tracing. Dr. Willey thought that the FHR tracing indicated a sinusoidal pattern that had begun at 1:27 a.m. and that fluctuated between 60 and 120 beats per minute without dropping. Over the next few minutes, however, the FHR fell rather dramatically. According to Dr. Willey, if the FHR pattern had remained between 60 and 120, "we might have watched a little while," but when the baby's heart rate began to get lower, he believed that the baby was in trouble. (J.A. at 221.) At approximately 1:45 a.m., Dr. Willey ordered that an emergency cesarean section be performed. Dr. Willey could not, without speculating, state how long he would have waited to perform the cesarean section if the FHR had not started to diminish. Nor, without speculating, was he able to state whether he would have performed the cesarean section any earlier if he had been present in the room at 1:27 a.m. when the sinusoidal pattern developed.

At 1:54 a.m., when Mrs. Moyers was disconnected from the fetal heart monitor and taken to the operating room, the fetus had a heart

beat of approximately 60 beats per minute. Hope Moyers was delivered sixteen minutes later at 2:10 a.m. with no heartbeat and no respiration; resuscitation efforts were commenced. Approximately twelve to fifteen minutes after delivery, Hope registered a heartbeat. Unfortunately, Hope sustained severe and permanent neurological injuries.

None of the physicians or nurses who attended to Mrs. Moyers testified that they believed that the Spectra 400 System was capable of providing an audio alert for a sinusoidal FHR pattern or that they relied upon the System to provide such an alert. Steinmetz testified that she did not have any knowledge in 1991 as to whether a sinusoidal rhythm pattern would trigger an audio alarm on the Spectra 400 System. Steinmetz also testified that if she was at the central nurses' station and heard an alarm, she would "look up and notice it," but that she did not alter her patient care or surveillance practices in reliance upon the alarm component of the Spectra 400 System. (J.A. at 1066.) Steinmetz also could not recall whether she had read the Spectra 400 System Operator's Manual.<sup>1</sup> Steinmetz did testify that after Hope's delivery, she asked her co-workers if the alarm had gone off. Dr. Willey testified that he neither changed his practices, nor instructed nurses to do so, based upon the audio alert capacity of the Spectra 400 System. He also testified that he was not aware of any surveillance and alert system that alerted for a sinusoidal pattern and that he never relied upon any system at WMC to alert him or the nurses to a sinusoidal pattern. Like Steinmetz, Dr. Willey could not recall reading the Spectra 400 System Operator's Manual.

The Moyers subsequently brought the instant suit against Corometrics seeking recovery for the severe neurological injuries Hope sus-

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<sup>1</sup> Moulton, who was not attending Mrs. Moyers, testified similarly to Steinmetz. Moulton testified that she did not know whether a sinusoidal pattern would cause an alarm to sound and/or a signal to appear on the APS. Moulton also testified that she did not alter any practices because the System had an alarm feature, did not rely upon the System to alert her to all abnormalities, and was not instructed by anyone at the hospital to substitute the alarm for her professional care and surveillance of the patient. Moulton acknowledged that if an alarm went off, she would react to it. Moulton also could not recall whether she read the Spectra 400 System Operator's Manual.

tained at her birth that they alleged were caused by defects related to the audio alert function of the Spectra 400 System. **2** The Moyers' complaint set forth claims for (1) breach of express warranty by Corometrics; (2) breach of implied warranty of merchantability and fitness for a particular purpose by Corometrics; and (3) product liability/negligence based upon manufacturing and design defect and failure to warn. Corometrics removed the case to the United States District Court for the Eastern District of Virginia and filed a motion for summary judgment. In a decision issued from the bench on April 9, 1998, at the conclusion of a summary judgment hearing, the district court granted summary judgment to Corometrics on the ground that no reasonable jury could find that any defect, if there was a defect, in the Spectra 400 System proximately caused Hope's injuries. On April 10, 1998, the district court issued an order granting Corometrics's motion for summary judgment on all counts and dismissing the case with prejudice.

On April 20, 1998, the Moyers filed a motion to alter or amend judgment under Federal Rule of Civil Procedure 59(e). After holding a hearing, the district court granted the motion to alter or amend judgment for a mistake of fact, vacated its grant of summary judgment to Corometrics, and ordered the Moyers to submit a brief in opposition to Corometrics's motion for summary judgment. On July 10, 1998, the district court held a second summary judgment hearing. By order and memorandum opinion of November 12, 1998, the district court again granted summary judgment to Corometrics on all counts and dismissed the case with prejudice upon concluding that the Moyers failed to establish genuine issues of material fact as to their claims for breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, and negligence.**3** On December 10, 1998, the Moyers filed a timely notice of appeal.**4**

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**2** Bristol Laboratories, Inc. and Bristol-Myers Squibb Co. were also named defendants, but settled with the Moyers and are no longer parties to this case. Prior to this suit, the Moyers brought a malpractice suit against Steinmetz in state court, which resulted in a jury verdict in Steinmetz's favor.

**3** The Moyers did not challenge the district court's initial grant of summary judgment in connection with their claim for breach of express warranty.

**4** The Moyers did not appeal the district court's grant of summary judgment in connection with their claim for breach of implied warranty for a particular purpose.

## II.

On appeal, the Moyers argue that the district court erred in granting summary judgment to Corometrics because it failed to assume the credibility of their evidence or to give them the reasonable inferences to which they were entitled. The Moyers contend that they presented evidence from which a jury could find that the Spectra 400 System was defectively designed and/or accompanied by an inadequate warning under either a theory of breach of implied warranty of merchantability or a negligence theory and could find that these defects proximately caused Hope's injuries. In particular, they assert that the district court erred in holding that the testimony of their experts was insufficient to create a genuine issue of material fact with regard to their claim that the Spectra 400 System was defectively designed.<sup>5</sup>

Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the

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<sup>5</sup> The Moyers also argue on appeal that the district court erred in refusing to consider a negligence *per se* claim first raised in opposition to Corometrics's motion for summary judgment that asserted that the variances between the product cleared by the Food and Drug Administration and the product sold by Corometrics to WMC were evidence of alteration and misbranding in violation of the Food Drug and Cosmetics Act (FDCA). The record indicates that the Moyers' counsel conceded that a motion for leave to amend was required for the district court even to consider the FDCA-based negligence claim, and that rather than making such a motion, the Moyers' counsel voluntarily withdrew that claim. The docket sheet also does not indicate that the Moyers' counsel ever moved for leave to amend the complaint. Because the Moyers failed to raise the FDCA-based negligence claim in their complaint or in a motion for leave to amend, neither this claim nor the argument that the district court erred in refusing to allow the Moyers to amend their complaint is properly before this Court on appeal. See *Muth v. United States*, 1 F.3d 246, 250 (4th Cir. 1993) (noting that issues not raised below generally will not be considered on appeal unless refusing to consider them would be plain error or would result in a fundamental miscarriage of justice); *Mann v. Conlin*, 22 F.3d 100, 103 (6th Cir. 1994) (holding that the argument that the district court should have allowed the plaintiffs to amend their complaint was not properly before the court of appeals because the plaintiffs never requested leave to amend their complaint).

affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c)). Once a party properly makes a motion for summary judgment by demonstrating to the court that there is no genuine issue of material fact, the non-moving party must by affidavits or by "depositions, answers to interrogatories, and admissions on file," designate "specific facts showing that there is a genuine issue for trial." Id. at 324 (quoting Fed. R. Civ. P. 56(e)). Although "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor," Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986), in order to survive summary judgment, "[t]he mere existence of a scintilla of evidence in support of the [non movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-movant]," id. at 252. This Court reviews a grant of summary judgment de novo. See Higgins v. E.I. DuPont de Nemours & Co., 863 F.2d 1162, 1167 (4th Cir. 1988).

Under Virginia law, which controls resolution of this diversity action, a plaintiff may bring suit against a manufacturer or seller of a defective product under either a theory of breach of implied warranty of merchantability or a negligence theory. See Bly v. Otis Elevator Co., 713 F.2d 1040, 1042 (4th Cir. 1983). Under either theory, a plaintiff must show "(1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands." Logan v. Montgomery Ward & Co., 219 S.E.2d 685, 687 (Va. 1975). "A product is unreasonably dangerous if it is defective in assembly or manufacture, unreasonably dangerous in design, or unaccompanied by adequate warnings concerning its hazardous properties." Morgen Indus. v. Vaughan, 471 S.E.2d 489, 492 (Va. 1996). Although the duties imposed under the theories of negligence and implied warranty of merchantability vary slightly, **6** under both theo-

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**6** With regard to a cause of action asserting that a product is unreasonably dangerous because of its defective design, a theory of breach of implied warranty of merchantability focuses on the product and its attributes, while a negligence theory focuses on the defendant's conduct. See

ries, the plaintiff must prove that any breach of duty by the manufacturer or seller was the proximate cause of the plaintiff's injuries. See Butler v. Navistar Int'l Transp. Corp., 809 F. Supp. 1202, 1207 (W.D. Va. 1991).

The Moyers claim that, under both a theory of breach of implied warranty of merchantability and a negligence theory, the Spectra 400 System was unreasonably dangerous for the following reasons: (1) the Spectra 400 System was defectively designed because the words "sinusoidal pattern" appeared on the APS when the System indisputably lacked the capacity to alert for such a pattern, (2) the Spectra 400 System was defectively designed because Corometrics had the capability to install an alert detection to recognize a sinusoidal FHR pattern, but failed to do so when it sold the System to WMC in 1989, and (3) Corometrics inadequately warned the users of the Spectra 400 System that the alert function on the Model 415C Central Display Unit did not alert for the sinusoidal pattern.

We need not determine whether the Moyers established a genuine issue of material fact as to whether Corometrics breached a duty owed to the Moyers, because we conclude that the Moyers failed to establish a triable issue on whether any act or omission by Corometrics proximately caused Hope's injuries. The Supreme Court of Virginia has held that "[t]he proximate cause of an event is that act or omission which, in natural and continuous sequence, unbroken by an efficient intervening cause, produces the event, and without which that event would not have occurred." Banks v. City of Richmond, 348 S.E.2d

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Abbot v. American Cyanamid Co., 844 F.2d 1108, 1115-16 (4th Cir. 1988). With regard to a cause of action asserting that a product is unreasonably dangerous because it is accompanied by inadequate warnings, the most notable differences between a theory of breach of implied warranty and a negligence theory are that (1) a theory of implied warranty focuses on whether the inadequate warnings render the product unreasonably dangerous while a negligence theory looks at whether the manufacturer's conduct is unreasonable; and (2) under a negligence theory, the duty to warn is continuous and is not interrupted by manufacture or sale of the product. See Bly v. Otis Elevator Co., 713 F.2d 1040, 1045-46 (4th Cir. 1983).

280, 282 (Va. 1986) (internal quotation marks omitted). Although proximate cause is ordinarily a question of fact for the jury, it becomes a question of law for the court when reasonable minds could not disagree about the conclusion to be reached. See Phillips v. Southeast 4-H Educ. Ctr., 510 S.E.2d 458, 460 (Va. 1999). Evidence of proximate cause "must be sufficient to remove the case out of the realm of speculation and conjecture and into the realm of legitimate inference before submitting it to a jury for its determination." Id. at 461 (internal quotation marks omitted).

Essentially, the Moyers' argument on the issue of proximate causation is that if Steinmetz had not left Mrs. Moyers unattended, in reliance upon the Spectra 400 System's capability to alert for a sinusoidal pattern, Steinmetz would have alerted Dr. Willey of Mrs. Moyers's sinusoidal pattern sometime between 1:27 a.m., when the pattern developed, and 1:38 a.m., when she returned to Mrs. Moyers's room. Furthermore, the Moyers assert, had Dr. Willey been informed of the sinusoidal pattern earlier, he would have performed the cesarean section earlier, thus averting Hope's severe neurological injuries.

To survive summary judgment, the Moyers must establish a genuine issue of material fact for each link in this chain of causation. This the Moyers cannot do. First, the Moyers fail to establish a genuine issue of material fact as to whether Steinmetz or Dr. Willey acted in reliance upon the Spectra 400 System's capability to alert for a sinusoidal pattern. Both Steinmetz and Dr. Willey testified that they did not know whether the Spectra 400 System alerted for a sinusoidal pattern and that they did not alter their practices based upon the existence of an audio alert function. Moreover, neither Steinmetz nor Dr. Willey even recalled reading the Spectra 400 System Operator's Manual. Based upon this testimony, no reasonable factfinder could conclude that any defect in the design of the Spectra 400 System or the warnings accompanying it proximately caused the delay in Dr. Willey learning of Mrs. Moyers's condition.

In an attempt to create a triable issue, the Moyers contend that Steinmetz testified that she was "surprised" that the alarm did not sound at 1:27 a.m. when the pattern appeared, and that the district court should have drawn from this statement the inference that Steinmetz expected the System to alarm for the sinusoidal pattern and

relied upon it to do so. This argument misreads Steinmetz's testimony; she only testified that following Hope's delivery she asked her co-workers whether any of them had heard an alarm. The Moyers also assert that Steinmetz's testimony that if an alarm sounded she would "look up and notice it" and that she did not rely upon the audio alert function of the Spectra 400 System "a lot" leads to the permissible inference that she relied upon the System to some extent to alert her to abnormalities. (J.A. at 1066.) Contrary to the Moyers' argument, however, this portion of Steinmetz's testimony is a rather unremarkable statement that she would react if an audio alert went off; this statement is not at all inconsistent with her testimony that she did not alter her patient care or surveillance practices in reliance upon the alarm component of the Spectra 400 System. Finally, the Moyers argue that Steinmetz's testimony that she left Mrs. Moyers because Mrs. Moyers was being monitored and Steinmetz "didn't feel there was anything else necessary right then" leads to the reasonable inference that Steinmetz relied upon the Spectra 400 System to alert her for sinusoidal patterns. (J.A. at 1592.) This snippet of testimony does not even mention the alert function of the Spectra 400 System or sinusoidal patterns, and, therefore, also does not call into question Steinmetz's testimony that she did not alter her patient care or surveillance practices in reliance upon the alarm component of the System. Because the Moyers presented no evidence to remove the issue of reliance from the realm of speculation and conjecture and into the realm of legitimate inference, summary judgment is appropriate on this ground.<sup>7</sup>

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<sup>7</sup> The Moyers also argue that Moulton's reply of "No, not totally" to the question of whether she relied upon the System to alert her to all abnormalities leads to the clear inference that she relied upon the alert function of the System in part. (J.A. at 1609.) Because Mrs. Moyers was not Moulton's patient, and Moulton did not leave Mrs. Moyers unattended, the issue of Moulton's reliance upon the alert capability of the Spectra 400 System is immaterial. In any case, this reply is insufficient to contradict Moulton's unequivocal testimony that she did not alter any practices because the System had an alarm feature, did not rely upon the System to alert her to all abnormalities, and was not instructed by anyone at the hospital to substitute the alarm for her professional care and surveillance of the patient.

Moreover, even if the Moyers established a genuine issue of material fact as to reliance, they fail to establish a genuine issue of material fact as to whether Dr. Willey would have performed the cesarean section earlier if he had been called to Mrs. Moyers's room earlier. Dr. Willey testified that he could not, without speculating, state how long he would have waited to perform the cesarean section if the FHR had not started to diminish. He also testified that he could not state whether he would have performed the cesarean section any earlier if he had been present in the room at 1:27 a.m. when the sinusoidal pattern developed. Based upon Dr. Willey's testimony, no reasonable factfinder could conclude that any defect in the design of the Spectra 400 System or the warnings accompanying it proximately caused the delay in Hope's delivery.

In an attempt to create a triable issue, the Moyers presented the expert testimony of Dr. Lawrence Borow, an obstetrician and gynecologist. Dr. Borow testified that a reasonable obstetrician, if alerted promptly at 1:27 a.m. or 1:28 a.m. when this pattern emerged, "could" have delivered the baby sooner, and that had he been alerted to Mrs. Moyers's sinusoidal pattern at that time, he would have delivered the baby sooner. Whether the issue is what Dr. Willey would have done or what a reasonable obstetrician would have done, Dr. Borow did not specifically testify as to what an obstetrician in the exercise of reasonable care would or should have done. He only testified as to what he personally would have done or what a reasonable obstetrician could have done. Moreover, Corometrics's expert, Dr. James Christman, a Virginia board-certified obstetrician, testified that the standard of care would not have required the decision to proceed with a cesarean section until shortly after 1:42 a.m., when the FHR baseline clearly dropped below 120 beats per minute. As noted above, Dr. Willey could only speculate as to whether he might have performed the cesarean section earlier had he been in the room at 1:27 a.m. Because the Moyers presented no evidence to remove the issue of whether Dr. Willey would have performed the cesarean section earlier had he been informed of the sinusoidal pattern earlier from the realm of speculation and conjecture and into the realm of legitimate inference, summary judgment is appropriate on this ground as well.

III.

In sum, we conclude that no jury could reasonably find that any defect in the design of the Spectra 400 System or the warnings accompanying it proximately caused Hope Moyers's severe neurological injuries.<sup>8</sup> Because the Moyers failed to establish genuine issues of material fact as to proximate causation, we affirm the district court's order granting summary judgment to Corometrics on all counts and dismissing the case with prejudice.

AFFIRMED

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<sup>8</sup> By this disposition we need not determine whether the district court erred in determining that the testimony of the Moyers' expert witnesses was insufficient to create a genuine issue of material fact with regard to the Moyers' claim that the System was defectively designed.