DIANA MICHELE MILTON ET AL. *v.*
DOROTHY ROBINSON ET AL.*
(AC 32150)

Beach, Espinosa and Pellegrino, Js.

Argued May 25—officially released October 4, 2011

(Appeal from Superior Court, judicial district of Waterbury, Complex Litigation Docket, Stevens, J.)

Diana Michele Milton, pro se, and *Clive Milton*, pro se, the appellants (plaintiffs).

Joseph G. Blute, pro hac vice, with whom were *Yalonda T. Howze*, pro hac vice, and, on the brief, *Charlsa D. Broadus*, *James H. Rotondo* and *James E. Hennessey*, for the appellee (defendant Biogen Idec, Inc.).

Kevin M. Smith, with whom, on the brief, was *Robert J. Klee*, for the appellee (defendant Yale University School of Medicine et al.).

Opinion

BEACH, J. The plaintiffs, Diana Michele Milton and her husband, Clive Milton,[1] appeal from the summary judgment rendered by the trial court in favor of the defendants, Biogen Idec, Inc. (Biogen), Yale University School of Medicine (university) and Yale-New Haven Hospital (hospital).[2] On appeal, the plaintiff claims that the court (1) erroneously ordered a *Porter*[3] hearing regarding one of her expert witnesses, (2) abused its discretion by granting certain motions in limine in favor of the defendants, (3) erred by granting summary judgment in favor of the defendants and by denying her motion for summary judgment, (4) erroneously granted the university's motion to strike a count of her substitute complaint and (5) erroneously construed the counts of her complaint pertaining to the hospital and the university as sounding in medical malpractice rather than product liability.[4] We disagree and affirm the judgment of the trial court.

The following factual and procedural history is relevant to our resolution of the plaintiffs' appeal. In 1996, Biogen and the university entered into a clinical trial agreement in which the university agreed to conduct a phase III clinical study (study) investigating the efficacy of natalizumab, a Biogen product, for the treatment of relapsing-remitting multiple sclerosis. The agreement provided that the university was to conduct the study pursuant to a lengthy protocol developed by Biogen.[5] The protocol dictated that the study was to be randomized, double-blind and placebo-controlled. As such, the participants randomly were assigned to either a group receiving natalizumab or a group receiving a placebo. The placebo consisted of the excipients used in the study drug: saline solution, polysorbate 80 and water, but did not contain natalizumab, the active ingredient in the study drug. The study was double-blind in that neither the participants nor the personnel administering the study were informed of which participants were receiving natalizumab and which participants were receiving the placebo.

According to the plaintiff's deposition, she was diagnosed in 1997 with relapsing-remitting multiple sclerosis. Following her diagnosis, the plaintiff began consulting with Joseph Guarnaccia, a neurologist. Guarnaccia treated the plaintiff with various therapies that ultimately were unsuccessful and, as a result, she opted to cease all treatment. The plaintiff subsequently experienced trouble with her eyesight, which was caused by her multiple sclerosis. Having already attempted unsuccessful treatment regimens, Guarnaccia recommended to the plaintiff that she participate in the study at issue in this case.

In June, 2002, pursuant to Guarnaccia's recommendation, the plaintiff and Clive Milton consulted with Silva

Markovic, a physician at the university who was an investigator for the study. Markovic explained to the plaintiff the purpose and procedure of the study. Markovic also provided to the plaintiff an informed consent form, which described the study in detail, including its potential benefits and risks associated with the study.[6] After reading the informed consent form, the plaintiff and Clive Milton also discussed with Markovic the risks. In particular, they discussed the possibility that the plaintiff could suffer from rashes and allergic reactions. The plaintiff conceded that although she understood the disclosed risks associated with the study and was satisfied that such risks adequately were explained to her, she nonetheless voluntarily chose to participate in the study. She signed the informed consent form on June 11, 2002.[7]

As part of the screening process, the plaintiff also was required to complete a detailed medical history to determine whether she qualified to participate in the study. In her medical history, the plaintiff indicated that she suffered from various allergies but at the time was unaware of any allergy or sensitivity to polysorbate 80. Upon completing the medical history, the plaintiff was deemed qualified to participate in the study.

On July 9, 2002, the university administered to the plaintiff her first intravenous infusion pursuant to the study protocol.[8] The plaintiff claimed that following the infusion she experienced nausea and heart palpitations for approximately two or three hours. Clive Milton later telephoned the university to report the side effects from which the plaintiff suffered.

On August 6, 2002, the plaintiff received her second intravenous infusion. The plaintiff claimed that immediately after the infusion, she suffered from nausea and heart palpitations that lasted for a brief period of time. The plaintiff could not recall whether she formally reported these side effects; she, however, did discuss the side effects with the physician who had administered the infusion. The plaintiff conceded that she was not aware of any rashes or skin problems at this point in her treatment.

On September 9, 2002, the plaintiff received her third infusion. The plaintiff again claimed to have suffered from nausea and heart palpitations immediately following the infusion. Within twenty-four hours of the infusion, the plaintiff also began to experience a severe itching in her scalp. The itching extended down to the plaintiff's torso, at which time she noticed that her back was covered with "a big red rash . . . like I had a million mosquito bites." The plaintiff contacted the university and left a message informing it of the side effects from which she suffered. The university contacted the plaintiff approximately two days later and referred her to Julie Schaeffer, a dermatologist employed by the university. After conducting a biopsy, Schaeffer

informed the plaintiff that she likely was suffering from a drug related reaction. Thereafter, because the plaintiff's rash persisted, she decided, after consulting with university physicians, to withdraw from the study. The plaintiff subsequently was "unblinded," and it was revealed that she had been receiving infusions of the placebo rather than the study drug, natalizumab. The plaintiff contends that subsequent testing revealed that she was allergic to polysorbate 80.

The plaintiffs filed the operative complaint on January 29, 2008.[9] Counts one through six[10] of the complaint were directed against the university and the hospital and alleged, inter alia, that they (1) negligently conducted the study, (2) negligently failed to respond properly to the plaintiff's adverse reaction to the placebo and negligently failed to remove her from the study, (3) failed adequately to obtain her informed consent to participate in the study and (4) failed to provide medical treatment to the plaintiff. Counts seven through ten were directed against Biogen and alleged, inter alia, that Biogen (1) negligently failed to respond properly to her adverse reaction to the placebo and negligently failed to remove her from the study, (2) was negligent in using polysorbate 80 as a compound in the placebo, (3) negligently failed to conduct preliminary allergy testing as to the components contained in the study drug and the placebo, (4) breached its fiduciary relationship to the plaintiff and (5) deviated from its standard of care in developing the study protocol. The complaint also alleged that Clive Milton suffered both a loss of consortium and emotional distress as a result of the defendants' negligence.

On November 6, 2008, the plaintiff disclosed John Santilli, Jr., an allergist, as an expert witness concerning, inter alia, standard of care and causation. On May 1, 2009, the plaintiff disclosed Clive Milton as an expert witness concerning standard of care and causation. On May 13, 2009, the university and the hospital filed a joint motion for summary judgment, which the court denied on August 31, 2009. On May 15, 2009, Biogen filed a motion for summary judgment, which the court on September 2, 2009, granted only as to count seven of the complaint.

On August 5, 2009, the university and the hospital filed a motion in limine seeking to preclude Clive Milton from testifying as an expert, which the court granted. Also on August 5, 2009, the defendants filed several motions in limine seeking to preclude or to limit the testimony of Santilli. The court granted these motions in part and precluded Santilli from testifying as to some of the subject matters listed in the disclosure. The court also ordered a *Porter* hearing regarding some of the issues raised in the multiple motions in limine. On November 20, 2009, following the hearing, the court denied as moot the *Porter* motion but precluded Santilli

from testifying as an expert witness as to standard of care. Upon the court's ruling regarding the preclusion of Santilli's expert testimony, the defendants filed renewed motions for summary judgment, which the court granted. This appeal followed. Additional facts will be set forth as necessary.

I

The plaintiffs first claim that the court erroneously ordered a *Porter* hearing in order to determine the admissibility of Santilli's testimony. We disagree.

The following additional facts are relevant to our resolution of the plaintiffs' claim. On August 5, 2009, Biogen filed a motion in limine seeking to preclude Santilli from offering testimony pertaining to, inter alia, "any opinions on the adequacy of the clinical trial design," "the use of polysorbate 80 . . . in the . . . [s]tudy [d]rug placebo" and any opinions regarding any causal connection between polysorbate 80 and the plaintiff's skin rashes. Also on August 5, 2009, the university and the hospital filed three motions in limine seeking to preclude Santilli from offering testimony regarding causation and standard of care and to limit his testimony to the opinions he expressed during his deposition.

The court held a hearing on these motions on September 8, 2009. During the hearing, the court stated that it was "not confident that [it] could make the ruling on the basis of [Santilli's] deposition." The court ruled on parts of the motion but as to the other parts said that it was "inclined to hear . . . evidence [regarding Santilli's testimony] on the record . . . [a]nd evaluate the arguments and the motions which have been made in that context." The court scheduled a *Porter* hearing; the plaintiffs claim that the court erred in scheduling a hearing.[11]

The plaintiff's disclosure of Santilli as an expert witness stated that Santilli planned to offer, inter alia, the following opinions: (1) the study protocol developed by Biogen was defective because of the lack of allergen testing of the study drug components, (2) the plaintiff was allergic to polysorbate 80 prior to the study, (3) the infusion of the placebo caused the plaintiff's hypersensitivity to polysorbate 80, (4) the plaintiff should have been removed from the study after both the first and second placebo infusions, (5) the informed consent forms signed by the plaintiff were insufficient such that her consent was not fully informed, (6) the placebo contained a substance not intended for injectable use, (7) the university and the hospital breached their duty properly to review the study protocol and (8) the university improperly supervised the study.

We first set forth our relevant standard of review and legal principles that govern our analysis of the plaintiffs' claim. "[T]he trial court is vested with wide discretion

in determining the admissibility of evidence. . . . Because a trial court's ruling under *Porter* involves the admissibility of evidence, we review that ruling on appeal for an abuse of discretion." (Citation omitted; internal quotation marks omitted.) *State* v. *Sorabella*, 277 Conn. 155, 214, 891 A.2d 897, cert. denied, 549 U.S. 821, 127 S. Ct. 131, 166 L. Ed. 2d 36 (2006).

"In *State* v. *Porter*, [241 Conn. 57, 698 A.2d 739 (1997) (en banc), cert. denied, 523 U.S. 1058, 118 S. Ct. 1384, 140 L. Ed. 2d 645 (1998)], our Supreme Court adopted the test for determining the admissibility of scientific evidence set forth in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). In so doing, the court noted two threshold requirements to the admissibility of scientific evidence. First, that the subject of the testimony must be scientifically valid, meaning that it is scientific knowledge rooted in the methods and procedures of science . . . and is more than subjective belief or unsupported speculation. . . . This requirement establishes a standard of evidentiary reliability . . . as, [i]n a case involving scientific evidence, evidentiary reliability will be based upon scientific validity. . . . Second, the scientific evidence must fit the case in which it is presented. . . . In other words, proposed scientific testimony must be demonstrably relevant to the facts of the particular case in which it is offered, and not simply be valid in the abstract." (Citation omitted; internal quotation marks omitted.) *State* v. *Haughey*, 124 Conn. App. 58, 71, 3 A.3d 980, cert. denied, 299 Conn. 912, 10 A.3d 529 (2010).

Although the Supreme Court in *Porter* established the requirements for the admissibility of scientific evidence, it "did not define what constituted 'scientific evidence,' thereby allowing the courts to maintain some flexibility in applying the test. As a result, a court's initial inquiry should be whether the [evidence] at issue . . . is the type of evidence contemplated by *Porter*. . . . In *Porter*, our Supreme Court noted that 'some scientific principles have become so well established that an explicit . . . analysis [under *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, supra, 509 U.S. 579] is not necessary for admission of evidence thereunder. . . . Evidence derived from such principles would clearly withstand a *Daubert* analysis, and thus may be admitted simply on a showing of relevance.' " (Citations omitted; internal quotation marks omitted.) *State* v. *Legnani*, 109 Conn. App. 399, 419, 951 A.2d 674, cert. denied, 289 Conn. 940, 959 A.2d 1007 (2008).

The plaintiffs argue that because Santilli was disclosed properly and because he is a board certified allergist, it "was a manifest error [for] the . . . court to hold a *Porter* [hearing] for . . . Santilli when it was not expressly required as a matter of law." We disagree.

Even if Santilli was properly disclosed and was a board certified allergist, his proposed testimony was

not necessarily admissible simply upon a showing of relevance. The scientific principles informing his proposed testimony, which pertained to study protocols and allergic reactions to polysorbate 80, were not so obviously well established or universally recognized as reliable as to render erroneous the ordering of a reliability assessment pursuant to *Porter*. See *Maher* v. *Quest Diagnostics, Inc.*, 269 Conn. 154, 168 n.19, 847 A.2d 978 (2004) ("the standard articulated in *Porter* applies generally to scientific evidence, unless that scientific evidence is so well established that a threshold admissibility analysis is rendered unnecessary"); compare *State* v. *Hasan*, 205 Conn. 485, 534 A.2d 877 (1987) (podiatrist's testimony concerning probability that pair of sneakers would fit defendant's feet not scientific evidence because jury could employ common sense and independent judgment to view and evaluate evidence).

In order to conduct the reliability assessment under *Porter*, the court determined that a hearing was necessary and that it could not rule on the motions in limine based solely on Santilli's deposition. In doing so, the court acted within its discretion. Accordingly, we cannot say that the court erred by holding a *Porter* hearing to determine the admissibility of Santilli's testimony.[12]

II

The plaintiffs claim that the court abused its discretion by granting various motions in limine in favor of the defendants and thus precluding their disclosed expert witnesses from offering expert testimony. We are not persuaded.

We first set forth our relevant standard of review and legal principles that govern our analysis of the plaintiffs' claim. "The trial court's ruling on evidentiary matters will be overturned only upon a showing of a clear abuse of the court's discretion. . . . The trial court has wide discretion in ruling on the qualification of expert witnesses and the admissibility of their opinions. . . . The court's decision is not to be disturbed unless [its] discretion has been abused, or the error is clear and involves a misconception of the law. . . . Expert testimony should be admitted when: (1) the witness has a special skill or knowledge directly applicable to a matter in issue, (2) that skill or knowledge is not common to the average person, and (3) the testimony would be helpful to the court or jury in considering the issues. . . . It is well settled that [t]he true test of the admissibility of [expert] testimony is not whether the subject matter is common or uncommon, or whether many persons or few have some knowledge of the matter; but it is whether the witnesses offered as experts have any peculiar knowledge or experience, not common to the world, which renders their opinions founded on such knowledge or experience any aid to the court or the jury in determining the questions at issue. . . . Implicit in this standard is the requirement . . . that the expert's

knowledge or experience must be directly applicable to the matter specifically in issue." (Internal quotation marks omitted.) *Baranowski* v. *Safeco Ins. Co. of America*, 119 Conn. App. 85, 94–95, 986 A.2d 334 (2010).

A

The plaintiffs claim that the court abused its discretion by granting the motion in limine and thus precluding Clive Milton from testifying as an expert witness. We disagree.

The following additional facts are relevant to our resolution of the plaintiffs' claim. On May 1, 2009, the plaintiff disclosed Clive Milton as an expert witness. The disclosure stated that Clive Milton planned to offer, inter alia, the following opinions: (1) the known and anticipated risks of polysorbate 80; (2) the informed consent form signed by the plaintiff was insufficient, such that her consent was not fully informed; (3) the university and the hospital breached their duty to the plaintiff by failing to inform her of the risks of polysorbate 80; (4) the hospital permitted the submission of a defective clinical study protocol to the Food and Drug Administration (FDA); (5) the university improperly administered the drug to the plaintiff and (6) Biogen designed a product for use in a clinical study that was not intended for injectable use. On August 5, 2009, the university and the hospital filed a motion in limine seeking to preclude Clive Milton from testifying as an expert, which the court granted.

The plaintiffs claim that the court abused its discretion by precluding Clive Milton from testifying as an expert witness because he has "the appropriate training, education, skill or knowledge in [his particular field]." Specifically, the plaintiffs contend that "Clive Milton has researched multiple sclerosis and polysorbate for the past eleven and eight years, respectively, and the findings and opinions of that extensive research would be beneficial for the trier of fact to understand the material issues of fact."

This court previously has recognized that "[*e*]*xcept in malpractice cases*, it is not essential that an expert witness possess any particular credential, such as a license, in order to be qualified to testify, so long as his education or experience indicate that he has knowledge on a relevant subject significantly greater than that of persons lacking such education or experience." (Emphasis added.) *Conway* v. *American Excavating, Inc.*, 41 Conn. App. 437, 448–49, 676 A.2d 881 (1996). In the present case, there is no question that the plaintiffs' claim is grounded in medical malpractice and negligence in matters such as the design and implementation of clinical drug study protocols. Though Clive Milton may well have conscientiously educated himself in such matters, the preclusion of his testimony did not constitute an abuse of discretion, in light of his background

as an artist and film producer and lack of relevant training and experience.

B

The plaintiffs claim that the court abused its discretion by granting the defendants' various motions in limine regarding expert testimony by Santilli and thus precluding him from offering any expert testimony concerning standard of care. We disagree.

The following additional facts are relevant to our resolution of the plaintiffs' claim. As discussed previously, the plaintiff disclosed Santilli as an expert on November 6, 2008, and set forth the subject matter about which he intended to proffer expert testimony.[13] On January 7, 2009, the defendants conducted a deposition of Santilli and questioned him regarding his proposed expert opinions. Santilli offered the following testimony. He is an allergist with a special interest in mold-related allergies. Other than working with a mold therapy in the 1980s, he had not had any involvement with either pharmaceutical companies or biotechnology companies. He had neither designed nor acted as an investigator in a phase III clinical study. He had never designed a drug that contained polysorbate 80 as one of its components, nor had he produced any publications concerning polysorbate 80. In fact, Santilli conceded that, prior to this case, he had no knowledge in general about polysorbate 80. He further indicated that he was unfamiliar with the multitude of FDA standards and regulations that dictate the parameters of phase III clinical studies. Additionally, he admitted that he had not read the study protocol, which was the subject matter of his opinions.

The defendants then filed various motions in limine seeking to preclude Santilli from offering expert testimony. The court subsequently held a hearing, at which Santilli reiterated much of the same testimony from his deposition set forth previously. Santilli also provided the following additional testimony. As a result of not having read the study protocol, he did not know the concentration of polysorbate 80 contained within the placebo. Prior to rendering his opinion, he did not review Schaeffer's medical records documenting the plaintiff's rash. Also, he conceded that he was uncertain whether his opinion that the plaintiff should have been removed from the study following the appearance her rash was consistent with FDA standards.[14]

Following the hearing, the court granted the defendants' motions in limine and precluded Santilli from proffering expert testimony concerning standard of care. In its decision, the court noted that "Santilli is not a similar health care provider as compared with . . . treating neurologists [pursuant to General Statutes § 52-184c],[15] and he does not have sufficient training, experience and knowledge in the related filed of allergy

and immunology to provide expert testimony on the prevailing professional standard of care applicable to the medical malpractice claims involved in this case arising from a [p]hase III clinical trial of a drug for the treatment of multiple sclerosis." The court further reasoned that "[t]he evidence indicates that [Santilli] did not read and review the clinical trial protocol established for the study."

The court issued two separate memoranda of decision regarding Santilli's proposed testimony. One, granting the motion in limine of the university and the hospital, relied primarily on the fact that Santilli was not a similar health care provider pursuant to § 52-184c (c) nor did he have sufficient training, experience or knowledge to qualify under § 52-184c (d). The court, in light of the considerations previously mentioned, did not abuse its discretion.

The court issued another memorandum of decision granting Biogen's motion in limine. We note that the plaintiffs' claims against Biogen were not grounded specifically in medical malpractice. The court ruled that Biogen did not have the duty to determine whether the plaintiff should have been removed from the study in light of the learned intermediary doctrine.[16] The court also ruled, as an alternative ground, that Santilli was not qualified to testify as an expert regarding phase III clinical trials and related protocols.

We affirm specifically on the alternative ground. We conclude that the court did not abuse its discretion by precluding Santilli from offering expert testimony. Santilli conceded that he had little or no experience or involvement with phase III clinical trials, nor was he familiar with the relevant FDA standards and regulations that govern the nature and procedure of phase III clinical trials. Additionally, Santilli testified that, prior to the present case, he was completely unfamiliar with polysorbate 80. Moreover, Santilli conceded that he had not read the study protocol prior to forming his opinions, that he did not review the plaintiff's relevant medical records, nor was he aware of the concentration of polysorbate 80 contained within the placebo. The court did not abuse its discretion in deciding that Santilli lacked the requisite knowledge or experience to assist the jury in determining the pertinent matters in issue.[17]

III

The plaintiff also claims that the court erred by rendering summary judgment in favor of the defendants and denying her motion for summary judgment. We disagree.

We first set forth our well established standard of review of a trial court's ruling on a motion for summary judgment. "Practice Book § 17-49 provides that summary judgment shall be rendered forthwith if the pleadings, affidavits and any other proof submitted show that

there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. In deciding a motion for summary judgment, the trial court must view the evidence in the light most favorable to the nonmoving party. . . . The party moving for summary judgment has the burden of showing the absence of any genuine issue of material fact and that the party is, therefore, entitled to judgment as a matter of law. . . . Our review of the trial court's decision to grant [the defendant's] motion for summary judgment is plenary. . . .

"The party opposing a motion for summary judgment must present evidence that demonstrates the existence of some disputed factual issue. . . . The movant has the burden of showing the nonexistence of such issues but the evidence thus presented, if otherwise sufficient, is not rebutted by the bald statement that an issue of fact does exist. . . . To oppose a motion for summary judgment successfully, the nonmovant must recite specific facts . . . which contradict those stated in the movant's affidavits and documents. . . . The opposing party to a motion for summary judgment must substantiate its adverse claim by showing that there is a genuine issue of material fact together with the evidence disclosing the existence of such an issue." (Citation omitted; internal quotation marks omitted.) *Milliun* v. *New Milford Hospital*, 129 Conn. App. 81, 92–93, 20 A.3d 36 (2011).

A

The plaintiff claims that the court erred by granting summary judgment in favor of the defendants. We disagree.

The following additional facts are relevant to our review of the plaintiff's claim. After the court granted the defendants' motions in limine, precluding Clive Milton from testifying as an expert witness and Santilli from offering expert testimony as to standard of care, the defendants filed renewed motions for summary judgment. They argued that, because the plaintiff had been precluded from offering expert testimony as to the standard of care, she thus could not sustain her burden of proof on her medical malpractice claims as well as her claims against Biogen.[18] The court agreed, and stated that "summary judgment [as to the university and hospital] is warranted because as a matter of law expert testimony is required in order for the plaintiff to meet . . . [her] burden of proof, and the plaintiff . . . [has] not disclosed an expert witness competent to testify on the [issue] of liability . . . ." The court also summarily granted Biogen's motion following its rulings regarding the admissibility of expert testimony.

This court's decision in *Sullivan* v. *Yale-New Haven Hospital*, 64 Conn. App. 750, 785 A.2d 588 (2001), is dispositive of the plaintiff's claim as to the university

and hospital. The court in *Sullivan* stated that "[t]his court has approved the grant of a summary judgment in a medical malpractice case when, as in this case, it is evident that the plaintiff will be unable to produce at trial an expert witness to testify regarding the applicable standard of care. *Bourquin* v. *B. Braun Melsungen*, [40 Conn. App. 302, 314, 670 A.2d 1322, cert. denied, 237 Conn. 909, 675 A.2d 456 (1996)]; *Guzze* v. *New Britain General Hospital*, 16 Conn. App. 480, 485, 547 A.2d 944, cert. denied, 209 Conn. 823, 552 A.2d 430 (1988). It is well settled that the plaintiff cannot prevail [in a medical malpractice case] unless there [is] positive evidence of an expert nature from which the jury could reasonably conclude that the defendant was negligent, except where there is manifest such gross want of care or skill as to afford, of itself, an almost conclusive inference of negligence that the testimony of an expert is not necessary." (Internal quotation marks omitted.) *Sullivan* v. *Yale-New Haven Hospital*, supra, 766.

Here, the court granted the defendants' motions in limine and thus precluded Clive Milton from testifying as an expert witness and also precluded Santilli from proffering any testimony concerning standard of care. As these were the only two opinion witnesses the plaintiff had disclosed, she lacked the ability to present any expert testimony regarding the applicable standard of care. In a case such as the present one, which concerns complex details regarding the adequacy of a phase III clinical study and standards of care in designing experimental drugs for the treatment of relapsing-remitting multiple sclerosis, expert testimony is essential in order for the plaintiff to sustain her burden of proof. Accordingly, based on this court's decision in *Sullivan*, we conclude that the court did not err by granting summary judgment in favor of the university and hospital.[19] Similarly, the court did not abuse its discretion in determining that expert testimony was required to prove the claims against Biogen, in light of complex issues regarding protocols, warnings and causation.[20]

B

The plaintiff also claims that the court erred by denying her motion for summary judgment. We disagree.

The following additional facts are relevant to our review of the plaintiff's claim. On December 11, 2009, the plaintiff filed a motion for partial summary judgment as to liability with respect to her claims against the university and the hospital. The plaintiff argued that the doctrine of res ipsa loquitur established the negligence of the university and the hospital because, "as agents of Biogen, [they] controlled the [study drug] as dictated by the [c]linical [s]tudy [p]rotocol . . . ." The court subsequently denied the plaintiff's motion.

"The doctrine of res ipsa loquitur, literally the thing speaks for itself, permits a jury to infer negligence when

no direct evidence of negligence has been introduced. . . . The doctrine of res ipsa loquitur applies only when two prerequisites are satisfied. First, the situation, condition or apparatus causing the injury must be such that in the ordinary course of events no injury would have occurred unless someone had been negligent. Second, at the time of the injury, both inspection and operation must have been in the control of the party charged with neglect. . . . When both of these prerequisites are satisfied, a fact finder properly may conclude that it is more likely than not that the injury in question was caused by the defendant's negligence." (Internal quotation marks omitted.) *Boone* v. *William W. Backus Hospital*, 272 Conn. 551, 575–76, 864 A.2d 1 (2005).

Here, the plaintiff did not successfully establish a prima facie case of res ipsa loquitur because she was unable to satisfy the first prerequisite of the two element test. We already have determined that the court did not abuse its discretion by precluding Clive Milton and Santilli from offering expert testimony. Consequently, without the support of expert testimony, the plaintiff was unable to offer any evidence tending to show that the rash from which she suffered was of the nature that, in the ordinary course of events, would not have occurred in the absence of negligent conduct. Having failed to offer any evidence to that effect, we conclude that the court did not err by denying the plaintiff's motion for summary judgment.

IV

The plaintiffs claim that the court erroneously granted the university's motion to strike count seven of their October 15, 2007 substitute complaint.[21] We disagree.

The following additional facts are relevant to our resolution of the plaintiffs' claim. On October 15, 2007, the plaintiffs filed a substitute complaint. In count seven of the complaint, the plaintiffs alleged that the university's negligence in administering the study and its failure to provide treatment to the plaintiff harmed the plaintiff, which in turn caused Clive Milton to suffer emotional distress. On October 30, 2007, the university filed a motion to strike count seven of the complaint, arguing that the plaintiffs failed "to state a viable cause of action as a matter of law . . . because [the university] did not owe Clive Milton a duty of care to prevent emotional distress arising out of medical care rendered to his wife . . . ." The court subsequently granted the university's motion to strike.

We begin our analysis by setting forth our relevant standard of review. "In an appeal from a judgment granting a motion to strike, we operate in accordance with well established rules. . . . A motion to strike challenges the legal sufficiency of a pleading . . . and, consequently, requires no factual findings by the trial court.

As a result, our review of the [trial] court's ruling is plenary. . . . We take the facts to be those alleged in the complaint that has been stricken and we construe the complaint in the manner most favorable to sustaining its legal sufficiency. . . . [I]f facts provable in the complaint would support a cause of action, the motion to strike must be denied. . . . Thus, we assume the truth of both the specific factual allegations and any facts fairly provable thereunder. In doing so, moreover, we read the allegations broadly . . . rather than narrowly. . . . If facts provable in the complaint would support a cause of action, the motion to strike must be denied." (Citations omitted; internal quotation marks omitted.) *Sturm* v. *Harb Development, LLC*, 298 Conn. 124, 129–30, 2 A.3d 859 (2010).

Our Supreme Court's decision in *Maloney* v. *Conroy*, 208 Conn. 392, 545 A.2d 1059 (1988), is dispositive of this issue. In *Maloney*, the plaintiff initiated a medical malpractice action against two physicians and a hospital seeking to recover damages for severe emotional distress she alleged to have suffered as a result of the defendants' negligent medical treatment of her mother. Id., 393. The trial court granted the defendants' motions to strike the plaintiff's complaint and subsequently rendered a partial judgment against the plaintiff. Id. On appeal, our Supreme Court held "that a bystander to medical malpractice may not recover for emotional distress . . . ." Id.

In this case, count seven of the plaintiffs' October 15, 2007 complaint asserted a claim for emotional distress as a bystander to the university's alleged negligent medical treatment of the plaintiff. *Maloney* bars such a claim. Accordingly, we conclude that the court did not err by granting the university's motion to strike count seven of the plaintiffs' October 15, 2007 complaint.

V

The plaintiff claims that the court erroneously construed the counts of her complaint pertaining to the hospital and the university as sounding in medical malpractice rather than product liability. We are not persuaded.

The following additional facts are relevant to our resolution of the plaintiff's claim. The plaintiff filed a fourth amended complaint on March 14, 2006. In count two of that complaint, the plaintiff alleged that her injuries were caused by the university "pursuant to . . . General Statutes § 52-572m et seq."[22] The university subsequently filed a motion to strike this count of the plaintiff's complaint on the grounds that she was "alleging a claim for medical malpractice in addition to a products liability claim . . . [and] a malpractice claim cannot be brought when a products liability claim is asserted against a party in a single action . . . ."

The plaintiff subsequently filed an objection to the university's motion to strike, along with a memorandum of law in support thereof. In the memorandum, the plaintiff stated that her "cause of action against the [university] rests solely on malpractice and negligence . . . ." The plaintiff further stated that count two of the fourth amended complaint "does not assert or conclude that a claim for [p]roduct [l]iability is made, but . . . [rather asserts] a medical malpractice claim . . . ." The plaintiff then filed a fifth amended complaint that contained no mention of § 52-572m, nor did it contain any indication that the claims against either the university or the hospital were grounded in product liability.

Following the plaintiff's filing of her objection to the motion to strike and the filing of her fifth amended complaint, the court denied as moot the university's motion to strike count two of the plaintiff's fourth amended complaint. Thereafter, in July, 2010, the court rendered summary judgment in favor of the university and the hospital. In the judgment, the court stated that the plaintiff's "claims [against the university and the hospital] are based on medical malpractice and lack of informed consent." The plaintiff claims that this construction of her claims was erroneous.

It is well settled that "[t]he interpretation of pleadings is always a question of law for the court . . . ." (Internal quotation marks omitted.) *Embalmers' Supply Co.* v. *Giannitti*, 103 Conn. App. 20, 48, 929 A.2d 729, cert. denied, 284 Conn. 931, 934 A.2d 246 (2007). Therefore, "[o]ur review of the trial court's construction of the pleadings is plenary." (Internal quotation marks omitted.) *Florian* v. *Lenge*, 91 Conn. App. 268, 273, 880 A.2d 985 (2005).

We conclude that the court's interpretation of the plaintiff's claims against the university and the hospital as sounding in medical malpractice as opposed to product liability was not erroneous. Following the university's motion to strike, the plaintiff unequivocally stated that her claims against the university were grounded "solely on malpractice and negligence" and were not sounding in product liability. The plaintiff buttressed this assertion by failing to make any mention of or indication to product liability as to the university and the hospital when filing subsequent amended complaints, including the operative complaint. We do not conclude that the court erroneously construed the counts of the plaintiff's complaint pertaining to the hospital and the university as sounding in medical malpractice and not product liability.

The judgment is affirmed.

In this opinion the other judges concurred.

* We note that when they initially filed the case, the plaintiffs named as defendants Dorothy Robinson and Sarah Cohen, the agents for service of process for Yale University School of Medicine and Yale-New Haven Hospital. Thereafter, the trial court granted the plaintiffs' motion to amend the

summons to delete the agents named as defendants to name as the proper defendants Yale University School of Medicine and Yale-New Haven Hospital. The caption of this appeal, however, is consistent with the original title of this case.

[1] Hereafter in this opinion we refer to Diana Michele Milton as the plaintiff, to Clive Milton individually by name, and to both individuals collectively as the plaintiffs.

[2] Separate statements of issues and separate briefs were filed regarding the claims against the university and the hospital on the one hand and Biogen on the other. Because the issues against the defendants overlap to a marked degree, we will consider the issues as relating to both sets of defendants unless otherwise noted.

[3] *State* v. *Porter*, 241 Conn. 57, 698 A.2d 739 (1997) (en banc), cert. denied, 523 U.S. 1058, 118 S. Ct. 1384, 140 L. Ed. 2d 645 (1998).

[4] The plaintiffs' brief to this court mentions several other claimed errors. Many claims are conclusory and do not contain adequate legal support. In fact, during oral argument before this court, Clive Milton stated that the trial court committed twenty-two errors. We note that "such a multiplicity of issues can foreclose the appellant's opportunity to provide a fully reasoned discussion of the pivotal issues on appeal." *LeBlanc* v. *New England Raceway, LLC*, 116 Conn. App. 267, 280 n.4, 976 A.2d 750 (2009). Moreover, "[m]ultiplicity hints at lack of confidence in any one [issue] . . . [and] [m]ultiplying assignments of error will dilute and weaken a good case and will not save a bad one. . . . Most cases present only one, two, or three significant questions. . . . Usually . . . if you cannot win on a few major points, the others are not likely to help. . . . The effect of adding weak arguments will be to dilute the force of the stronger ones." (Internal quotation marks omitted.) *Southington* v. *Commercial Union Ins. Co.*, 71 Conn. App. 715, 740 n.14, 805 A.2d 76 (2002).

We have considered the remainder of the plaintiffs' claims not otherwise addressed in this opinion and conclude that they are without merit.

[5] In addition to providing the protocol, Biogen also provided to the university an "Investigator's Brochure," which contained detailed information regarding the known risks and benefits associated with natalizumab based on prior clinical experience.

[6] The plaintiff also was provided a copy of the protocol for the study.

[7] The plaintiff signed a second informed consent form on August 6, 2002. The second informed consent form contained most of the same information as the June 11, 2002 consent form, including the risks of suffering from allergic reactions and rashes.

[8] The protocol directed that each participant was to receive an intravenous infusion every four weeks for up to 116 weeks.

[9] The plaintiff served the original complaint in June, 2005.

[10] The complaint does not contain a fifth count.

[11] The *Porter* claims were never specifically resolved because the court ruled that Santilli was not properly qualified to offer expert opinions, as described previously, in any event.

[12] The decision to hold a hearing would also appear to be harmless in light of the court's decision to preclude Santilli's opinions in any event.

[13] See part I of this opinion.

[14] According to the plaintiff's deposition, removal from the study was not automatic but took place after discussions with her physicians and occurred more than one month after the rash appeared.

[15] General Statutes § 52-184c (d) provides: "Any health care provider may testify as an expert in any action if he: (1) Is a 'similar health care provider' pursuant to subsection (b) or (c) of this section; or (2) is not a similar health care provider pursuant to subsection (b) or (c) of this section but, to the satisfaction of the court, possesses sufficient training, experience and knowledge as a result of practice or teaching in a related field of medicine, so as to be able to provide such expert testimony as to the prevailing professional standard of care in a given field of medicine. Such training, experience or knowledge shall be as a result of the active involvement in the practice or teaching of medicine within the five-year period before the incident giving rise to the claim."

[16] "The learned intermediary doctrine is based on the principle that prescribing physicians act as learned intermediaries between a manufacturer and the consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment . . . [and as a result] adequate warnings to prescribing physicians obviate the need for manufacturers . . . to warn ultimate consumers

directly." (Internal quotation marks omitted.) *Hurley* v. *Heart Physicians, P.C.*, 298 Conn. 371, 380 n.8, 3 A.3d 892 (2010).

[17] The plaintiff also argues that, as a matter of law, Santilli was "guaranteed the right to testify and opine as to any issue contained in the medical record, including, but not limited to, causation, standard of care or any other related issue" pursuant to Practice Book § 13-4 (b) (2).

Practice Book § 13-4 (b) (2) provides in relevant part: "If the [expert] witness to be disclosed hereunder is a health care provider who rendered care or treatment to the plaintiff, and the opinions to be offered hereunder are based upon that provider's care or treatment, then the disclosure obligations under this section may be satisfied by disclosure to the parties of the medical records and reports of such care or treatment. A witness disclosed under this subsection shall be permitted to offer expert opinion testimony at trial as to any opinion as to which fair notice is given in the disclosed medical records or reports. . . ."

Even if we assume that Santilli was a health care provider who rendered care to the plaintiff, Practice Book § 13-4 (b) (2) does not confer a *right* to offer expert opinion testimony. Rather, this section merely sets forth the procedure a party may use to disclose opinions of health care providers who rendered treatment to the plaintiff. Accordingly, the plaintiff's argument has no merit. Further, the language of Practice Book § 13-4 (b) (2) was not in effect at the time the issue was decided in this case.

[18] Biogen also argued its position that it did not owe duties of patient care to the plaintiff in light of the learned intermediary doctrine.

[19] Additionally, we note that the court did not err by rendering summary judgment in favor of the defendants regarding Clive Milton's loss of consortium claims. As this court previously has noted, because it is a derivative cause of action, "loss of consortium "is dependent on the legal existence of the predicate action. . . . That is to say, if an adverse judgment bars the injured spouse's cause of action, any claim for loss of consortium necessarily fails as well." (Internal quotation marks omitted.) *Cavallaro* v. *Hospital of Saint Raphael*, 92 Conn. App. 59, 62 n.5, 882 A.2d 1254, cert. denied, 276 Conn. 926, 888 A.2d 93 (2005).

[20] Additionally, the evidence regarding the subject matter of the plaintiff's claims is "not the kind of evidence that readily may be understood and evaluated by a fact finder on the basis of common sense or independent powers of observation or comparison." *State* v. *Griffin*, 273 Conn. 266, 278, 869 A.2d 640 (2005). To the contrary, such evidence involves complex and intricate details regarding multiple FDA regulations that dictate the nature and guidelines of phase III clinical drug studies. Moreover, many of the opinions that Santilli sought to offer concern complicated scientific and medical information that is foreign to the average fact finder; for example, the composition of study drugs for the treatment of multiple sclerosis and how the components therein potentially are causally connected to various allergic reactions. Cf. *State* v. *Reid*, 254 Conn. 540, 547–48, 757 A.2d 482 (2000) (microscopic hair analysis not type of evidence subject to *Porter* hearing because it simply required jurors to use their own powers of observation and comparison).

[21] The plaintiff also claims that the court erroneously granted the hospital's motion to strike count two of her October 15, 2007 substitute complaint. The record reveals, however, that the court denied the hospital's motion to strike count two. Accordingly, because the plaintiff prevailed as to the motion to strike count two of her substitute complaint, there is no adverse ruling for us to review.

[22] General Statutes § 52-572m is the definition section of the Connecticut Product Liability Act.