[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 15-13979

D.C. Docket No. 2:13-cv-00733-KOB

BILLY RYAN LOONEY, etc., et al.,

Plaintiffs,

CHRISTIAN LEWIS,
By and through his parents, Bernita Lewis
and Earnest Thomas,
DRESHAN COLLINS,
By and through his mother, Sharrissa Cook,
JAYLEN MALONE,
By and through his mother, Nikida Sellers,

Plaintiffs - Appellants,

versus

SHEILA D. MOORE,
Director of the Office of the University of
Alabama Institutional Review Board,
FERDINAND URTHALER, M.D.,
Chairman of the University of Alabama
Institutional Review Board,
WALDEMAR A. CARLO, M.D.,
In his individual capacity,
MASIMO CORPORATION,

DR. JOHN CARPENTER,
in his individual capacity, et al,

Defendants - Appellees,

INDIVIDUAL MEMBERS OF THE UNIVERSITY
OF ALABAMA INSTITUTIONAL REVIEW
BOARD, THE, etc., et al.,

Defendants.

Appeal from the United States District Court
for the Northern District of Alabama

(July 6, 2017)

Before WILSON, and JULIE CARNES, Circuit Judges, and HALL,[*] District Judge.

JULIE CARNES, Circuit Judge:

CERTIFICATION FROM THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT TO THE SUPREME COURT OF ALABAMA PURSUANT TO ALABAMA RULE OF APPELLATE PROCEDURE 18.

TO THE SUPREME COURT OF ALABAMA AND ITS HONORABLE JUSTICES:

This appeal concerns an unsettled question of Alabama law that, in the interests of comity and consistency, we believe the Alabama Supreme Court to be

[*] The Honorable James Randal Hall, United States District Judge for the Southern District of Georgia, sitting by designation.

the appropriate court to answer. Through their parents, Plaintiffs DreShan Collins, Christian Lewis, and Jaylen Malone, brought claims against Defendants for harms allegedly visited on Plaintiffs when the latter were enrolled in a clinical study while being treated for health issues accompanying their premature births. Defendants fall into three groups: (1) Dr. Carlo, the physician who designed and ran the study; (2) Internal Review Board (IRB) physicians who approved the study and the informed consent materials; and (3) Masimo Corporation, which manufactured medical equipment used in the study.

Plaintiffs brought claims against the various Defendants for negligence, negligence per se, breach of fiduciary duty, products liability, and lack of informed consent. The district court granted summary judgment on all claims. Like the district court, we conclude that Plaintiffs have failed to establish that participation in the clinical study caused any injuries, which means that the negligence, negligence per se, breach of fiduciary duty, and products liability claims were properly dismissed.

The viability of the claim alleging lack of informed consent, however, is less clear. At issue is whether a plaintiff who claims that he did not give informed consent to medical treatment provided as part of a clinical study must show that he was injured as a result of that treatment. Alabama law has not addressed this particular question. Because its resolution will determine whether Plaintiffs' claim

may proceed and because there are "no clear controlling precedents" from the Alabama Supreme Court, we respectfully certify this question to the Alabama Supreme Court pursuant to Alabama Rule of Appellate Procedure 18.

I. BACKGROUND

The University of Alabama at Birmingham was the lead study site for a national clinical research trial known as the Surfactant, Positive Pressure, and Oxygenation Randomized Trial ("SUPPORT"). Designed by Dr. Carlo and approved by the IBR Defendants, the SUPPORT study was created to analyze the effects of differing oxygen saturation levels on premature infants. At the time of the study, it was nationally accepted (and neither party contests) that the recognized standard of care was to keep the oxygen saturation levels of low-birth-weight infants at between 85% and 95%. This standard notwithstanding, it was also known that a prolonged period of high oxygen saturation can result in oxygen toxicity which leads to an increased risk of "retinopathy of prematurity".[1] On the other hand, a prolonged period of low oxygen saturation can result in neuro-developmental impairment and death. Given the difficulties of calibrating the optimal oxygen range, the SUPPORT study sought to determine whether, within the accepted standard of care, there was a more precise range of oxygen saturation

[1] Retinopathy of prematurity is a disease that occurs in premature babies. It causes abnormal blood vessels to grow in the retina, and can lead to the retina detaching from the back of the eye, resulting in blindness.

that would better reduce the risk of exposing an infant to either too much or too little oxygen.

The SUPPORT study randomly divided eligible and enrolled premature infants into two groups. One group was to be kept at an oxygen saturation level between 85-89%, which is the low end of the standard-of-care range, while the other would be kept at an oxygen saturation level between 90-95%, which is the high end of that range. Further, to ensure double-blind data collection, the study would employ specialized oximeters (manufactured by Masimo) that would "mask" to an onlooker the true oxygen saturation levels of the infants. The oximeters would, however, signal an alarm whenever an infant's oxygen level strayed below 85% or above 95%.

Publishing the results of the study in the New England Journal of Medicine, the study authors concluded that infants in the high-oxygen group were more likely to be diagnosed with retinopathy while infants in the low-oxygen group were more likely to die. There was no statistically significant difference in the incidence of neuro-developmental impairments between the high and low groups.

To enroll in the study, Plaintiffs' guardians had to execute informed consent documents that were drafted and approved by Defendants. After the study's completion, however, the Department of Health and Human Services authored a

letter questioning whether these informed consent documents had properly disclosed all of the risks associated with enrollment in the SUPPORT study.

Plaintiffs filed the operative Fifth Amended Complaint in the United States District Court for the Northern District of Alabama asserting claims against Defendants for negligence, negligence per se, breach of fiduciary duty, products liability, and lack of informed consent. Plaintiffs allege that they suffered serious injuries as a result of their participation in the study. Specifically, Plaintiffs Lewis and Malone were assigned to the low-oxygen group, with prolonged periods of low oxygen saturation being associated with neuro-developmental impairment and death. Fortunately, neither infant died, but they did develop neurological issues. Plaintiff Collins was assigned to the high-oxygen group, with prolonged high-oxygen saturation being associated with retinopathy, which can lead to blindness. Plaintiff Collins did develop retinopathy, but fortunately he did not suffer permanent vision loss. Following discovery, Defendants moved for summary judgment asserting that, based on the undisputed material facts, Plaintiffs had failed to demonstrate that participation in the SUPPORT study had caused the injuries alleged in the Complaint. The district court agreed that Plaintiffs had failed to prove that their injuries were caused by participation in the SUPPORT study, as opposed to being a consequence of their premature births.

II. ANALYSIS

We agree that under applicable Alabama law and taking all inferences in the light most favorable to Plaintiffs, Plaintiffs have failed to show that enrollment in the SUPPORT study caused their injuries. What is not clear is whether the absence of an actual physical injury caused by the SUPPORT study dooms Plaintiffs' argument that Defendants are nonetheless liable because they failed to obtain Plaintiffs' informed consent to participate in that study. We first discuss the causation issue before turning to the question that we certify concerning the informed consent claim.[2]

A. Plaintiffs Have Presented Insufficient Evidence that the SUPPORT Study Caused Plaintiff's Alleged Injuries

The Alabama Supreme Court has made clear that, "to present a jury question, the plaintiff in a medical-malpractice action must adduce some evidence indicating that the alleged negligence (the breach of the appropriate standard of care) *probably* caused the injury. A mere possibility is insufficient."[3] *Cain v. Howorth*, 877 So. 2d 566, 576 (Ala. 2003) (quoting *Rivard v. Univ. of Alabama Health Servs. Found., P.C.*, 835 So. 2d 987, 988 (Ala. 2002)) (alterations omitted; emphasis in original); *see also Lyons v. Walker Reg'l Med. Ctr.*, 791 So. 2d 937,

[2] To be precise, this type of claim actually alleges a lack of informed consent. For ease of reference, however, we will often refer to this claim as an "informed consent claim."

[3] As discussed *infra*, the requirement that a plaintiff show that negligent medical treatment caused the injury is found in the Alabama Medical Liability Act, Ala. Code § 6-5-542(3).

942 (Ala. 2000); *Golden v. Stein*, 670 So. 2d 904, 907 (Ala. 1995). The district court concluded that Plaintiffs had failed to show that it was their participation in the SUPPORT study, as opposed to their premature births and consequent low birth-weight, that caused Plaintiffs' injuries. Defendants' three experts each recognized that the injuries suffered by Plaintiffs are consistent with those that extremely low birth-weight infants experience. In other words extreme prematurity, by itself, carries increased risks of the kinds of neuro-developmental and respiratory impairments claimed by the Plaintiffs. These experts opined that it is more likely than not that the Plaintiffs' injuries were caused by their prematurity and its related complications than by any participation in the SUPPORT study.

Indeed, Plaintiffs' own expert, Dr. Hermansen, refused to opine that Plaintiffs injuries were "probably" caused by participation in the SUPPORT study. Instead, he would say only that the study "significantly increased the risk" that the Plaintiffs would suffer these alleged injuries. Dr. Hermansen never testified that the SUPPORT study caused Plaintiffs' medical ailments, or even that the SUPPORT study *probably* caused the ailments; he opined only that the study "significantly increased the risk" that they would suffer from such ailments. In fact, in his subsequent deposition, Dr. Hersmansen could not identify any specific alternative care that the Plaintiffs should have, but did not receive, because of the

study, or any specific medical condition that called for a change in oxygen-saturation levels for any of the Plaintiffs.

An alleged "increased risk of harm" is not sufficient to survive summary judgment under Alabama law, which requires proof that the alleged negligence *probably* caused the injury. *Cain*, 877 So. 2d at 576. So strict is Alabama law on this point that Alabama courts have even rejected "medical monitoring" claims, in which plaintiffs allege that because prior medical procedures increased their risk of *future* harm, they were "injured" by the need, going forward, to self-monitor in order to detect future medical ailments. *See Hinton ex rel. Hinton v. Monsanto Co.*, 813 So. 2d 827, 829 (Ala. 2001) (plurality); *see also Houston Cty. Health Care Auth. v. Williams*, 961 So. 2d 795, 810–11 (Ala. 2006); *S. Bakeries, Inc. v. Knipp*, 852 So. 2d 712, 716–17 & n.7 (Ala. 2002). Admittedly, Plaintiffs do not allege that participation in the SUPPORT study exposed them to some future harm. Instead, they attempt to distinguish the above line of cases by describing their injury as being the increased risk of harm they faced *in the past*. But this argument only highlights the weakness of their position. Whether in the past or in the future, Plaintiffs can show, at most, only an increased risk of harm, not a probability that the alleged negligence actually caused any harm. *See Knipp*, 852 So. 2d at 716

("Alabama has long required a manifest, present injury before a plaintiff may recover in tort.").[4]

In short, Plaintiffs have not provided evidence that the SUPPORT study "probably" caused their injuries. For that reason, Plaintiffs' negligence, negligence per se, breach of fiduciary duty, and products liability claims are not viable under Alabama law, and the district court correctly dismissed them. What remains to be determined, however, is whether the absence of any medical injury caused by participation in the clinical study similarly means that the informed consent claim also fails.

B. Do Plaintiffs' Informed Consent Claims Require an Actual Medical Injury?

As noted, it is as clear as can be that a negligence action predicated on allegedly inadequate medical treatment requires the plaintiff to show that he was injured as a result of the particular treatment. As far as we can tell, however,

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[4] The cases cited by Plaintiffs—*Parker v. Collins*, *Waddell v. Jordan*, and *Murdoch v. Thomas*—do not save their claims, either. Collectively, these cases stand for the proposition that: "the issue of causation in a malpractice case may properly be submitted to the jury where there is evidence that prompt diagnosis and treatment would have placed the patient in a better position than she was in as a result of inferior medical care. It is not necessary to establish that prompt care could have prevented the injury or death of the patient; rather, the plaintiff must produce evidence to show that her condition was adversely affected by the alleged negligence." *Parker v. Collins*, 605 So. 2d 824, 827 (Ala. 1992) (citing *Waddell v. Jordan*, 302 So. 2d 74 (Ala. 1974) and *Murdoch v. Thomas*, 404 So. 2d 580 (Ala. 1981)).

But the problem for Plaintiffs is the absence of any evidence that their conditions were "adversely affected" by being placed in the SUPPORT study. Plaintiffs' expert testified that the SUPPORT study increased the *risk* that Plaintiffs' conditions had been adversely affected, but not that Plaintiffs' conditions *were* (or even *probably were*) adversely affected by the study.

Alabama law has yet to explicitly address the question whether proof of a medical injury is also required before a plaintiff can claim that his consent to a medical procedure was not informed. Specifically, if a plaintiff cannot prove that he suffered any injury as a result of a particular medical procedure, can he still potentially prevail if he shows that the doctor failed to obtain his informed consent to that procedure? In other words, is there a free-standing tort arising from a lack of informed consent, even if there is no injury resulting from the procedure at issue? Assuming that injury is required to sustain an informed consent claim arising out of medical treatment, does that rule still apply if the medical treatment is provided as part of a clinical study?

The answer to the above questions will depend on how an informed consent claim is characterized. If an informed consent claim is considered to be a type of medical malpractice claim, governed by the Alabama statute addressing such claims, then it is clear that a plaintiff must show the existence of an actual injury resulting from the procedure before he can raise a viable informed consent claim. If an informed consent claim is not classified as a malpractice type of claim—or if it exits the malpractice arena when the uninformed consent pertains to participation in a medical study administered as part of the medical treatment—then we must search for an answer in Alabama common law. And if, as Plaintiffs argue, an informed consent claim arising out of a medical study is neither a malpractice nor a

negligence claim, then we must identify precisely what type of claim it is and determine what Alabama law would prescribe as its elements.

Alabama law, however, does not expressly tell us whether such an informed consent claim is subject to the same requirements as a malpractice or negligence claim, nor does it speak to what the elements of such a claim would be if the claim finds no home in the malpractice/negligence camp. Given this uncertainty and the fact that the Alabama Supreme Court is the appropriate body to interpret Alabama law on this question, we certify that question to the Supreme Court in hopes that it will offer guidance. But first, we explain why we cannot figure out the answer on our own.

A medical malpractice claim under Alabama law requires proof of an actual injury. The Alabama Medical Liability Act (AMLA). Ala. Code § 6-5-542(3), "applies in any action for injury or damages or wrongful death, whether in contract or in tort, against a health care provider for breach of the standard of care." *Ex parte Vanderwall*, 201 So. 3d 525, 533 (Ala. 2015) (quotations and alterations omitted). The term "standard of care" is defined as "such reasonable care, skill, and diligence as other similarly situated health care providers in the same general line of practice, ordinarily have and exercise in like cases." Ala. Code § 6-5-542(2). As to proving a breach of that standard:

> A breach of the standard of care is the failure by a health care provider to comply with the standard of care, *which failure proximately causes*

> *personal injury or wrongful death. This definition applies to all actions* for injuries or damages or wrongful death whether in contract or tort and *whether based on intentional or unintentional conduct*."

Id. (emphasis added). In short, the text of the statute requires a "personal injury or wrongful death" before a medical malpractice action[5] can be viable.

Indeed, the Alabama Supreme Court has emphasized this requirement in its own interpretation of the AMLA. For example, plaintiffs in a putative class action sued a medical center based on the latter's action in potentially exposing the plaintiffs to fungal spores. The plaintiffs had suffered no physical injury but argued that the exposure to a potential harm was, by itself, the injury. Applying the AMLA, the Alabama Supreme Court disagreed, stating, "Under current Alabama caselaw, mere exposure to a hazardous substance resulting in no present manifestation of physical injury is not actionable under the AMLA where the exposure has increased only minimally the exposed person's chance of developing a serious physical disease and that person has suffered only mental anguish." *Houston Cty.*, 961 So. 2d at 810–11. As such, any plaintiffs who had not actually

[5] The AMLA only applies to claims against "a health care provider." Ala. Code § 6–5–548(a). The Alabama Supreme Court has explained: "Section 6–5–542, Ala. Code 1975 defines a 'health care provider' as '[a] medical practitioner, dental practitioner, medical institution, physician, dentist, hospital, or other health care provider as those terms are defined in Section 6–5–481.' Section 6–5–481(8) in turn defines 'other health care providers' as '[a]ny professional corporation or any person employed by physicians, dentists, or hospitals who are directly involved in the delivery of health care services.'" *Ex parte Vanderwall*, 201 So. 3d at 533.

suffered an infection or other adverse effects from the exposure had "not suffered a legal injury."[6] *Id*. at 811.

Thus, *Houston County* makes clear that claims governed by the AMLA require a showing of an actual physical injury. *See also Crutcher v. Williams*, 12 So. 3d 631, 648 (Ala. 2008) (holding that, under the AMLA, a plaintiff must prove that a delay in treatment "*proximately* and *probably* caused actual injury to the plaintiff"). The next question then is the extent to which the AMLA's requirement that an injury occur applies when a claim does not rest on negligent medical treatment, but instead on an assertion that in performing treatment to which the plaintiff had consented, the medical care provider conveyed inadequate warnings that thereby rendered the patient's consent to be uninformed.

On the one hand, there are indications from Alabama caselaw that the "injury" requirement of the AMLA applies to informed consent claims, just as it does to traditional medical malpractice claims based on negligent treatment. In *Houston County*, itself, the Alabama Supreme Court stated as a general matter that all of the claims in the case, *including* claims for lack of informed consent, were "governed by the Alabama Medical Liability Act" because they "allege a 'medical injury' arising in the context of their patient-hospital relationship as the basis for

[6] The Court did recognize, however, that those patients who had undertaken operations to remove the infected medical component because of the risk of infection "would have standing to bring an action." *Id*. at 812. Seemingly, the need for subsequent surgery to remedy or diminish the potential harm arising from the original surgery is deemed the injury.

each of their claims." *Houston Cty.*, 961 So. 2d at 810. Indeed, the Alabama Supreme Court has "consistently held that it is the substance of the action, rather than the form, that is the touchstone for determining whether an action is actually one alleging medical malpractice" and that "informed-consent claims brought against physicians and surgeons are governed by the AMLA." *Mock v. Allen*, 783 So. 2d 828, 832 (Ala. 2000), *abrogated on other grounds by Ex parte Vanderwall*, 201 So. 3d 525 (Ala. 2015); *see also Ex parte Mendel*, 942 So. 2d 829 (Ala. 2006) (analyzing the scope of plaintiff's allowable discovery for a lack of informed consent claim under the AMLA's discovery rules); *Collins v. Ashurst*, 821 So. 2d 173, 176 (Ala. 2001), *as modified on denial of reh'g* (Nov. 30, 2001) (noting that the AMLA "provides the applicable standard of care that governs all actions against health-care providers specified in the act"). Moreover, it arguably seems a bit incongruous that a patient subjected to negligent medical treatment is required to show that the treatment caused his injury, while a person whose only beef is that he was not fully informed of the risks of a procedure could prevail even if he suffered no injury at all.

On the other hand, in describing the elements necessary to prove an informed consent claim, Alabama law appears not to include as an element proof of an injury. In *Giles v. Brookwood Health Services, Inc.*, 5 So. 3d 533, 553–54

(Ala. 2008) and *Phelps v. Dempsey*, 656 So. 2d 377, 377 (Ala. 1995) the Alabama Supreme Court explained:

> The elements of a cause of action against a physician for failure to obtain informed consent are: (1) the physician's failure to inform the plaintiff of all material risks associated with the procedure, and (2) a showing that a reasonably prudent patient, with all the characteristics of the plaintiff and in the position of the plaintiff, would have declined the procedure had the patient been properly informed by the physician.

Giles, 5 So. 3d at 553–54 (quoting *Phelps*, 656 So. 2d at 377); *see also Ex parte Mendel*, 942 So. 2d at 832 (reciting this same standard). Noticeably missing is any requirement that the undisclosed risk actually materialize or that any injury actually occur.

But a conclusion that injury is not required for an informed consent claim, based on the absence of any mention of the need for injury in the above cases, is shaky because in each of these cases there clearly was an injury, and a serious one. So, there was no cause for the court to focus on the need for injury as an element of the claim, and instead the opinions explored the standards governing whether consent was informed. For example, in *Giles* the plaintiff argued that she had not been adequately informed that *either* of her ovaries might be removed in an operation when the physician removed the "wrong" ovary. *Giles*, 5 So. 3d at 533. Likewise, in *Phelps*, the plaintiff argued that he was not adequately apprised of the risk of post-operative wound infection when such an infection materialized—and

eventually required the amputation of a significant portion of the plaintiff's foot. *Phelps*, 656 So. 2d at 377. Finally, in *Mendel* the plaintiff argued that he was not adequately informed about his dentist's multiple suspensions and/or revocations after the dentist punctured the floor of the plaintiff's right maxillary sinus during an operation. *Mendel*, 942 So. 2d at 832.[7] Thus, in the above cases, the courts had no need to consider whether an injury of the type encompassed by the undisclosed risk had to be proved before a plaintiff could state an informed consent claim because a physical injury was present and the injury formed the basis of the plaintiffs' claims.[8]

Suffering from the same lack of persuasive punch is the case earlier cited in support of the notion that Alabama courts require proof of injury as part of an informed consent claim: *Houston County*. That case indicates generally that the AMLA, which requires proof of an injury, applies to an informed consent claim. But like *Phelps*, *Giles*, and *Mendel*, there was a physical injury in *Houston County*. Thus, the Alabama Supreme Court had no need to examine whether an informed

[7] Notably, however, *Mendel* did not decide whether such a theory would be actionable; it only ruled on the appropriate scope of discovery for such claims under the AMLA.

[8] The same is true of the two cases cited by *Phelps* following its articulation of the elements of a lack of informed consent claim. *See Fain v. Smith*, 479 So. 2d 1150 (Ala. 1985) (plaintiff injured by complications resulting from a pulmonary arteriogram); *Fore v. Brown*, 544 So. 2d 955 (Ala. 1989) (plaintiff suffered a perforation in his lower esophagus as the result of an esophagus dilation which was performed during an esophagogastroduodenoscopy).

consent claim lacking a physical injury should be analyzed differently, *vis a vis* the need for proof of an injury, than cases alleging simply negligent medical treatment.

In short, each party can point to Alabama caselaw in support of an argument favoring the party's respective position on the need to prove injury when asserting an informed consent claim. Defendants, however, have a ready analytic hook to support their argument that an injury is required: the AMLA and Alabama common law governing negligence actions, which Defendants argue govern this action. To bolster their argument that no injury is required, Plaintiffs thus need to be able to identify some analogous type of claim not requiring injury into which they can pigeonhole their own claim.

Plaintiffs have attempted to do so. They argue that an informed consent claim is akin to the tort claim of intentional battery, and that the latter requires no injury. *See Harper v. Winston Cty.*, 892 So. 2d 346, 353 (Ala. 2004) ("[A]n actual injury to the body is not a necessary element for an assault-and-battery claim"); *see also* Erin Sheley, *Rethinking Injury: The Case of Informed Consent*, 2015 B.Y.U. L. Rev. 63 (2015) ("The most critical pragmatic difference between the battery and negligence standards is that the latter, unlike the former, depends on the existence of the physical injury."). The Alabama Supreme Court has recognized that the AMLA does not apply when an actual battery has occurred. In *Ex parte Vanderwall*, the Alabama Supreme Court determined that AMLA did not govern

assault and battery claims against a physical therapist who had allegedly groped a patient's breasts and genitals during a treatment session. 201 So. 3d at 537–38, *reh'g denied* (Feb. 19, 2016). According to *Vanderwall*, the "the AMLA is not just concerned with who committed the alleged wrongful conduct or when and where that conduct occurred, but also with *whether the harm occurred because of the provision of medical services*." *Id*. at 537 (emphasis in original). But because "there was no therapeutic or medical reason for [defendant-doctor] to touch [plaintiff-patient's] breasts or her genitals in the course of treating her for back pain" then the "allegation of injury does not stem from the provision of medical services," and it is therefore not governed by the AMLA. *Id*. at 538.

Yet, for purposes of identifying an appropriate claim, there would be appear to be an obvious distinction between an intentional touching by a medical provider that was never consented to by the plaintiff (being groped) and a touching (via medical treatment) that the patient had agreed to, but did so without knowing all the pitfalls that the treatment might entail. In fact, Alabama law has distinguished between "lack of consent" (or no-consent) claims and "lack of informed consent" claims. In *Cain v. Howorth*, 877 So. 2d 566 (Ala. 2003), citing to a body of caselaw from other jurisdictions, the Alabama Supreme Court recognized that "[t]he law distinguishes between a total lack of consent for the contested act (battery) and the lack of informed consent (negligence)." *Id*. at 580–81 (internal

quotation marks omitted).[9] Because the plaintiff in *Cain* had only argued a "lack of consent" claim, rather than a "lack of informed consent" claim, the Alabama Supreme Court concluded that it did not need to decide whether the plaintiff could establish the latter claim under the facts of the case. *Id*. at 581. *See also Black v. Comer*, 38 So. 3d 16, 28 (Ala. 2009) (noting that *Cain* "distinguish[ed] between a claim of a lack of consent to the performance of a medical procedure and a claim of a 'lack of informed consent'").

In this case, Plaintiffs assert a lack of *informed* consent to their treatment, rather than the lack of *any* consent to these medical services. A determination that, under Alabama law, such claims sound in "negligence" rather than "battery," even when the medical treatment is part of a clinical study, presumably bolsters Defendants' argument that such claims require an actual injury arising from the allegedly breached duty.[10]

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[9] Many jurisdictions follow the rule that "a claim under the informed consent doctrine must be pled as a tort action for negligence, rather than as one for battery or assault." *Mole v. Jutton*, 846 A.2d 1035, 1042 (Md. 2004) (collecting cases); *see also* E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on A Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1 (2003) ("[I]nformed consent doctrine evolved away from battery during the 1960's and '70s when courts decided that, so long as the patient gave some sort of consent, the inadequacies of disclosure such as failing to mention a particular risk must be addressed as negligence."); Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J. L. & MED. 429, 438–39 (2006) ("The shift from battery to a negligence standard reflected judges' sentiments that a judgment of battery was inappropriate for the nature of the offense, as physicians did not intend to harm the patient, rather they failed to provide enough information.").

[10] Although Alabama law has apparently not yet squarely addressed whether an actual physical injury is required for an informed consent claim—whether the consent is given in a pure

In summary, Alabama law does not appear to have expressly decided whether physical injury is an element of an informed consent claim. Moreover, if injury is in fact an element of a typical informed consent claim when a physician has recommended treatment within the standard of care, does it makes a difference if the patient's uninformed consent was instead given for participation in a clinical study during which medical care providers deviated from the medical protocol they would ordinarily have followed had the patient not consented to participation in the study?

III. QUESTION TO BE CERTIFIED TO THE ALABAMA SUPREME COURT

"When substantial doubt exists about the answer to a material state law question upon which the case turns, a federal court should certify that question to

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treatment context or instead provided as part of a clinical study—other jurisdictions have. *See, e.g.*, *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972) ("No more than breach of any other legal duty does nonfulfillment of the physician's obligation to disclose alone establish liability to the patient. An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence. Occurrence of the risk must be harmful to the patient, for negligence unrelated to injury is nonactionable."); *Funke v. Fieldman*, 512 P.2d 539, 548 (Kan. 1973); *Downer v. Veilleux*, 322 A.2d 82, 92 (Me. 1974); *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979); *Hales v. Pittman*, 576 P.2d 493, 499 (Ariz. 1978); *Harnish v. Children's Hosp. Med. Ctr.*, 439 N.E.2d 240, 244 (Mass. 1982); *Reinhardt v. Colton*, 337 N.W.2d 88, 95–96 (Minn. 1983); *Hook v. Rothstein*, 316 S.E.2d 690, 704 (S.C. 1984); *Nickell v. Gonzalez*, 477 N.E.2d 1145, 1148 (Ohio 1985); *Smith v. Cotter*, 810 P.2d 1204, 1209 (Nev. 1991); *Bernard v. Block*, 575 N.Y.S.2d 506, 511 (N.Y. App. Div. 1991); *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 79-80 (N.J. 2002); *see also Cochran v. Wyeth, Inc.*, 3 A.3d 673, 680 (Pa. Super. Ct. 2010) ("[T]his Court is unable to locate any authority that has refused to adopt the proximate cause principle enunciated in *Canterbury* and *Downer*. In informed consent cases, it appears to be well-settled and without debate that the non-disclosed risk must manifest itself into actual injury in order for a plaintiff to establish proximate causation.").

the state supreme court in order to avoid making unnecessary state law guesses and to offer the state court the opportunity to explicate state law." *Mississippi Valley Title Ins. Co. v. Thompson*, 754 F.3d 1330, 1334 (11th Cir. 2014) ("Only a state supreme court can provide what we can be assured are 'correct' answers to state law questions, because a state's highest court is the one true and final arbiter of state law." (internal quotation marks omitted)). Because substantial doubt exists here about the answer to a material state law question, we respectfully certify the following question for a determination of state law:

> Must a patient whose particular medical treatment is dictated by the parameters of a clinical study, and who has not received adequate warnings of the risks of that particular protocol, prove that an injury actually resulted from the medical treatment in order to succeed on a claim that his consent to the procedure was not informed?

The phrasing of the above question should not restrict the Alabama Supreme Court's consideration of the issues presented in this appeal. In order to assist in its consideration of the issues, the entire records, along with the briefs of the parties, shall be transmitted to the Alabama Supreme Court. *Intervest Const. of Jax, Inc. v. Gen. Fid. Ins. Co.*, 662 F.3d 1328, 1333 (11th Cir. 2011).

QUESTION CERTIFIED.