**IN THE UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT COURT**
**SOUTHERN DIVISION**

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| **BILLY RYAN LOONEY, ET AL.,** | ) | |
| | ) | |
| **Plaintiffs,** | ) | |
| | ) | |
| **v.** | ) | **CIVIL ACTION NO.** |
| | ) | **2:13-CV-00733-KOB** |
| **SHEILA D MOORE, ET AL.,** | ) | |
| | ) | |
| **Defendants.** | ) | |

## MEMORANDUM OPINION

This matter comes before the court on "Motion to Dismiss the Third Amended Complaint on Behalf of the IRB Defendants"[1] (doc. 14), "Motion to Dismiss the Third Amended Complaint on Behalf of Dr. Waldemar A. Carlo" (doc. 15), and "Masimo Corporation's Motion to Dismiss Plaintiffs' Third Amended Complaint" (doc. 23). Plaintiffs[2] Breshan Collins, by and through his mother Sharrissa Cook; Christian Lewis, by and through his parents Bernita Lewis and Earnest Thomas; and Survonda Banks, as personal representative of Destiny Banks, bring this class action complaint against "Sheila D. Moore, Director of the University of Alabama Institutional Review Board, Ferdinand Urthaler, M.D., Chairman of the University of Alabama Institutional Review Board, the individual members of the University of Alabama Institutional Review Board, and Waldemar A. Carlo, M.D., all in their individual capacities, Masimo Corporation, ABC Health Care Providers #1-100, ABC Individuals #1-100, and XYZ Entitieds #1-10" (doc. 10, at 1). Plaintiffs allege that the Defendants injured the Plaintiffs during the Plaintiffs' participation in

[1] The term "IRB Defendants" is used by the parties and the court to refer to the individual members of the UAB Institutional Review Board ("IRB").

[2] Plaintiff Billy Ryan Looney was terminated from the case on June 21, 2013. (Doc. 10).

a clinical research study performed on infants born prematurely with extremely low birth weights at the University of Alabama, Birmingham. Three different Defendants or groups of Defendants filed motions to dismiss the Plaintiffs' class action complaint. For the following reasons, the court will GRANT the motions of the IRB Defendants and Dr. Carlo and GRANT IN PART and DENY IN PART Defendant Masimo's motion.

## I. FACTS

The Plaintiffs' most recent complaint, the "Third Amended Class Action Complaint and Jury Trial Demand," states the facts as follows. (Doc. 10).

### The Trial

Between 2004 and 2009, approximately 1,300 premature and/or low-birth-weight infants enrolled and participated in a multi-site, randomized human subject clinical trial called "the Surfactant, Positive Pressure, and Oxygenation Randomized Trial." Plaintiff Breshan Collins, Plaintiff Christian Lewis, and Destiny Banks, the now deceased daughter of Plaintiff Survonda Banks, enrolled in the Trial at the University of Alabama, Birmingham ("UAB") Hospital. Defendants Moore, Urthaler, and the individual members of the UAB Institutional Review Board (collectively the "IRB Defendants") oversaw the Trial and Defendant Carlo served as the principal investigator for the Trial.

The Trial had two aspects: (1) "exploring treatment with continuous positive airway pressure" ("CPAP Aspect"); and (2) "determining the appropriate levels of oxygen saturation in extremely low-birth-weight infants by comparing a lower versus a higher range of levels of oxygen saturation in such infants" ("Oxygen Aspect"). (Doc. 10, at ¶ 27). UAB served as the lead site on the Oxygen Aspect of the Trial, and Ms. Moore, Dr. Urthahler, the other IRB members,

and Dr. Carlo designed the protocol governing the Trial and drafted the informed consent document.

The Oxygen Aspect of the Trial sought to test the effects of various amounts of oxygen on infants' survival, neurological development, and likelihood of developing retinopathy of prematurity ("ROP"). The standard of care for infant oxygen levels is 85% to 95%, but according to the complaint, "it was not the standard of care for an infant to receive a random level between eighty-five and ninety-five percent, which would not be adjusted." (Doc. 10, at ¶ 52).

Each participant was randomly assigned to receive oxygen in either the "high"—91% to 95%—or "low"—85% to 89%—range; according to the informed consent form, study personnel assigned the infants to a range by "the flip of a coin." (Doc. 10, at ¶ 31). Once assigned to a range, each infant received an adjusted oxygen intake that kept the infant's blood oxygen saturation ($SpO_2$) within the assigned range. According to the complaint, the "amount of oxygen provided was not tailored to the infant's actual needs or the best medical interests of the infant." (Doc. 10, at ¶ 33).

**The Oximeter**

During the course of the Trial, doctors monitored the Plaintiffs and Infant Banks's blood oxygen saturation ($SpO_2$) using a pulse oximeter designed and manufactured by Defendant Masimo Corporation. Masimo's original oximeters were designed to display an infant's actual $SpO_2$ and to sound an alarm when the $SpO_2$ reached inappropriate levels. The Food and Drug Administration ("FDA") approved this design. According to the Trial protocol, Masimo altered the oximeters used for the Trial "so that the randomized range of $SpO_2$ (either 85%-89% or 91%-95%) will be indicated [on the display] by a range of 88%-92%. This is done by progressively

altering the offset as the alarm limits are approached . . . [so that the] target oxygen saturation (88-92%) of the display will be the same in both groups . . ." (Doc. 10, at ¶ 37). According to the complaint, "Masimo rigged the oximeter so that it would not reveal the actual oxygen level, and would not sound an alert when levels were too high or too low."

**The Trial Protocol and Informed Consent Document**

The Trial protocol document included a section entitled "Risks and Benefits," but the section failed to identify any risks associated with the infants' random assignment into the high and low ranges of the study. The Trial's model informed consent document described the risks of the study as follows:

> Participation in this study may involve some added risks or discomforts. Because all of the treatments proposed in this study are standard of care, there is no predictable increase in risk for your baby. Infants randomized to the CPAP group may, at some point in their care, require intubation and assisted ventilation (methods to help them breathe). If the attending physician deems this necessary, participation in the study will not affect this decision. Some unknown risks may be learned during the study. If these occur, you will be informed by the study personnel. The only other risk of this study is the risk to confidentiality. . . .

(Doc. 10, at ¶ 41).

**The OHRP Letter**

On March 7, 2013, the Office of Human Research Protection ("OHRP") sent a letter to the Vice President for Research & Economic Development at UAB concerning the Trial. The letter criticized the risk paragraph of the informed consent document, noting that it does not inform parents of the relationship between changing oxygen levels and the development of ROP, mortality, and "other forms of morbidity" and that it "does not identify any specific risk relating to randomizing infants to a high or low range of oxygen." (Doc. 10, at ¶ 43). The letter noted that

"the researchers had sufficient available information to know, before conducting the study, that participation might lead to differences in whether an infant survived, or developed blindness, in comparison to what might have happened to a child had that child not been enrolled in the study." (Doc. 10, at ¶ 44). The OHRP concluded: "[W]e determine that the informed consent document for this trial failed to adequately inform the parents of the reasonably foreseeable risks and discomforts of research participation." (Doc. 10, at ¶ 51).

**The Plaintiffs**

In their complaint, the Plaintiffs allege that "[a]t all relevant times, the Defendants were aware that infants who participated in the [Trial] would be placed at an increased risk of death . . . , blindness . . . , and lung disease and neurological damage . . . ." (Doc. 10, at ¶ 46). Furthermore, they allege that the "Plaintiffs' parents would not have enrolled the Plaintiffs had they been informed of the true risks, benefits, and nature of the [Trial]." (Doc. 10, at ¶ 54).

As a result of the Trial, Plaintiff Collins "suffers from severe and permanent developmental delays, PDA valve, and visual and Respiratory Issues, among other severe and permanent impairments"; Plaintiff Lewis "suffers from vision, hearing, and speech issues, among other severe and permanent impairments"; and Infant Banks passed away at twenty days of age. (Doc. 10, at ¶ 56).

**The Allegations**

The Plaintiffs bring this action as a class action, defining the class as "All individuals who participated in the human subject experiment called 'the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT)' at the University of Alabama and have as a result suffered injuries, damage, and/or death (and families of those individuals)." The Third Amended

Complaint alleges seven counts.

Count I alleges negligence against all Defendants except Masimo. Specifically, Plaintiffs allege that Ms. Moore, Dr. Urthaler, and the IRB Defendants, along with Dr. Carlo, individually and through their employees and agents, breached their obligations and duties and engaged in carelessness, negligence, gross negligence, recklessness, and willful and wanton conduct, causing Plaintiffs to sustain serious and debilitating personal injuries. The complaint lists seventeen particular ways in which the IRB Defendants and Dr. Carlo were negligent, including "[d]esigning and conducting an inherently unethical and flawed experiment," "[f]ailing to properly conduct the informed consent process," and "[f]ailing to properly and timely observe, discover, diagnose, treat, and care for [Plaintiffs'] condition." (Doc. 10, at ¶ 76).

Count II alleges negligence *per se* against all Defendants except Masimo. The Plaintiffs claim that the Code of Federal Regulations lays out certain requirements for human subject research and that the IRB Defendants and Dr. Carlo violated those regulations. Because Plaintiffs suffered harm as a direct and proximate result of Defendants' violations of the regulations, Plaintiffs claim the Defendants are negligent *per se*. The specific regulations that Plaintiffs claim the Defendants violated are 45 C.F.R. §§ 46.101, et seq., and 45 C.F.R. §§ 46.109, 111, 116.

Count III alleges lack of informed consent against all Defendants except Masimo. Count IV alleges breach of fiduciary duty against all Defendants except Masimo. Plaintiffs claim that Dr. Carlo and Defendants' agents (including medical personnel) had a physician-patient relationship with the Plaintiffs. Furthermore, they allege that the IRB Defendants and Dr. Carlo had a fiduciary duty to "disclose all information material to the decision to provide, withhold, or discontinue consent," and to "conduct an experiment with no risk to the infant Plaintiffs and

Class members, given their vulnerability." (Doc. 10, at ¶¶ 98-99). Plaintiffs claim that the Defendants breached these duties, that the Plaintiffs were injured as a direct and proximate result, and that the Defendants' conduct was malicious, willful, and wanton, justifying the imposition of punitive damages.

Count Five alleges products liability under the Alabama Extended Manufacturer's Liability Doctrine against Defendant Masimo only. Plaintiffs claim that the oximeter had a manufacturing defect because

> Masimo deviated from the FDA-approved design and rigged the oximeters so that (1) they would not display the actual oxygen saturation level in an infant's bloodstream (which had the effect of preventing physicians from knowing whether an infant was receiving appropriate oxygen); and (2) their alarms (which existed to prevent harm to the infants by alerting physicians to the fact that too much or too little oxygen was being received) would not be triggered.

(Doc. 10, at ¶ 109). According to the complaint, a safer, practical, alternative design was available in the original, FDA-approved design, and Masimo's actions were willful, wanton, and reckless, justifying the imposition of punitive damages.

Count VI alleges negligence against only Defendant Masimo. Specifically, Plaintiffs claim that "Masimo had a duty to the Plaintiffs to manufacture the oximeters in accordance with the FDA-approved design, and otherwise had a duty to the Plaintiffs to follow the FDA's requirements and act reasonably." (Doc. 10, at ¶ 123). Because Masimo breached this duty, the Plaintiffs suffered harm.

Finally, Count VII alleges wrongful death under Alabama law against all Defendants, claiming that as a result of the Defendants' conduct, Infant Banks and others similarly situated died.

## II. STANDARD OF REVIEW

The IRB Defendants and Dr. Carlo bring their motions pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Masimo brings its motion pursuant to Federal Rules of Civil Procedure 8 and 12.

Rule 12(b)(1) attacks come in two forms: facial attacks and factual attacks. *Lawrence v. Dunbar*, 919 F.2d 1525, 1528-29 (11th Cir. 1990). "Facial attacks on the complaint require the court merely to look and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction, and the allegations in this complaint are taken as true for the purposes of the motion." *Id*. at 1529 (internal quotations omitted). Factual attacks, however, "challenge the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such as testimony and affidavits, are considered." *Id*.

A Rule 12(b)(6) motion to dismiss attacks the legal sufficiency of the complaint. Generally, the Federal Rules of Civil Procedure require only that the complaint provide "'a short and plain statement of the claim' that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957) (quoting Fed. R. Civ. P. 8(a)). A plaintiff must provide the grounds of his entitlement, but Rule 8 generally does not require "detailed factual allegations." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley*, 355 U.S. at 47). It does, however, "demand[ ] more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal* 556 U.S. 662, 678 (2009). Pleadings that contain nothing more than "a formulaic recitation of the elements of a cause of action" do not meet Rule 8 standards nor do pleadings suffice that are based merely upon "labels or conclusions" or "naked assertions" without supporting factual allegations.

*Twombly*, 550 U.S. at 555, 557.

The Supreme Court explained that "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting and explaining its decision in *Twombly*, 550 U.S. at 570). To be plausible on its face, the claim must contain enough facts that "allow[ ] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Although "[t]he plausibility standard is not akin to a 'probability requirement,'" the complaint must demonstrate "more than a sheer possibility that a defendant has acted unlawfully." *Id.* "Where a complaint pleads facts that are merely consistent with a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

The Supreme Court has identified "two working principles" for the district court to use in applying the facial plausibility standard. The first principle is that, in evaluating motions to dismiss, the court must assume the veracity of *well-pleaded factual* allegations; however, the court does not have to accept as true legal conclusions even when "couched as [] factual allegation[s]" or "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal,* 556 U.S. at 678. The second principle is that "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 679. Thus, under one prong, the court determines the factual allegations that are well-pleaded and assumes their veracity, and then proceeds, under the second prong, to determine the claim's plausibility given the well-pleaded facts. That task is "context-specific" and, to survive the motion, the allegations must permit the court based on its "judicial experience and common sense. . . to infer more than

the mere possibility of misconduct." *Id.* If the court determines that well-pleaded facts, accepted as true, do not state a claim that is plausible, the claim must be dismissed. *Id.*

## III. DISCUSSION

### A. Fictitious Defendants

As a preliminary matter, the court notes that federal courts do not generally permit suits against fictitious parties. *See Richardson v. Johnson*, 598 F.3d 734, 738 (11th Cir. 2010) ("As a general matter, fictitious-party pleading is not permitted in federal court."). A limited exception exists when "the plaintiff's description of the defendant is so specific as to be at the very worst, surplusage." *Id*. (internal quotations omitted). In this case, the fictitious defendants are not specific and do not fall under the limited exception. As such, ABC Health Care Providers #1-100, ABC Individuals #1-100, and XYZ Entities #1-10 will be DISMISSED.

### B. The IRB Defendants' Motion to Dismiss

#### *i. Pleading requirements*

The IRB Defendants first argue that the complaint fails to meet basic federal pleading standards and should be dismissed. The Eleventh Circuit frowns on counts that do not set out which facts support specific causes of action, and has extensively explained the "unacceptable consequences" of shotgun pleadings. *See Davis v. Coca-Cola Bottling Co. Consol.*, 516 F.3d 955, 981-83 (11th Cir. 2008). The court finds merit in the IRB Defendants' argument that the complaint makes it "impossible to discern exactly what illegal conduct Plaintiffs are alleging for each particular cause of action." (Doc. 14, at 13-14). Rule 8 requires "'a short and plain statement of the claim' that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley*, 355 U.S. at 47 (quoting Fed. R. Civ. P. 8(a)).

Plaintiffs assert the claims in Counts I, II, III, and IV against "all Defendants except Masimo."[3] The court finds that this form of pleading is impermissible, particularly as to the allegations that relate specifically to treatment, diagnosis, and care; the claims challenge individual actions and decisions that cannot simply be imputed to a group without pleading some facts as to "who did what." The court finds that the complaint does not give the Defendants fair notice as to the claims and the grounds upon which they rest.

Furthermore, these allegations about treatment, diagnosis, and care are actually malpractice claims, which involve heightened pleading requirements under the Alabama Medical Liability Act ("AMLA"), as will be discussed in the context of Dr. Carlo's motion.[4] Under both the Rule 8(a) standard and the AMLA standard, Plaintiffs fail to sufficiently distinguish among the Defendants so as to put them on notice as to the claims against them.

As such, the court finds that Counts I, II, III, and IV are due to be DISMISSED as against the IRB Defendants. Because the Plaintiffs' previous amended complaints have not been at the direction of the court, the court will give Plaintiffs one more opportunity to adequately state their claims. (*See* Docs. 1, 8, 9, 10). The court will DISMISS these claims WITHOUT PREJUDICE, with leave to amend their complaint by February 5, 2014. The court notes that Plaintiff should take special care when re-pleading the specific, malpractice-type claims from the

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[3]Count VII is against *all* Defendants, but the court will address it later in the opinion, as the IRB Defendants incorporate Section III of Dr. Carlo's brief addressing Count VII.

[4]The IRB Defendants specifically incorporate Sections II of Dr. Carlo's motion to dismiss, which addresses the AMLA. Although the court's decision as to the IRB Defendants rests on the requirements of Rule 8(a), the court notes that to the extent it is alleged that the IRB Defendants are performing actions such as treatment and diagnosis, they should be considered health care providers under the Act.

complaint—namely, paragraph 76(h), (j), (k), and (l).

*ii. Sovereign Immunity*

The IRB Defendants briefly argue that "to the extent Plaintiffs are asserting claims against the IRB [as opposed to the IRB Defendants in their individual capacities], those claims are barred by sovereign immunity." (Doc. 14, at 14). The Plaintiffs do not address this argument in their response, but do emphasize that the IRB Defendants "have been sued in their individual capacities only." (Doc. 22, at 1). As such, the court will not address this argument, but notes that moving forward, Plaintiffs' complaint will be interpreted as being against the IRB Defendants *strictly in their individual capacities alone*.

*iii. State-Agent Immunity*

The IRB Defendants make several other immunity arguments, both of which are precluded by the courts conclusion that the complaint sufficiently alleges that the actions of the IRB Defendants were committed with malice. However, to forestall subsequent motions to dismiss on these grounds, the court addresses Defendants' arguments now and finds them unavailing.

The IRB Defendants argue that the claims against them should be dismissed because they are entitled to state-agent immunity. Both parties agree that the law applicable to state-agent immunity comes from the Supreme Court of Alabama's decision in *Ex parte Cranman*, 792 So. 2d 392 (Ala. 2000). The Court laid out the detailed "rule governing State-agent immunity" as follows:

> A State agent *shall* be immune from civil liability in his or her personal capacity when the conduct made the basis of the claim against the agent is based upon the agent's

(1) formulating plans, policies, or designs; or
(2) exercising his or her judgment in the administration of a department or agency of government, including, but not limited to, examples such as:
(a) making administrative adjudications;
(b) allocating resources;
(c) negotiating contracts;
(d) hiring, firing, transferring, assigning, or supervising personnel; or
(3) discharging duties imposed on a department or agency by statute, rule, or regulation, insofar as the statute, rule, or regulation prescribes the manner for performing the duties and the State agent performs the duties in that manner; or
(4) exercising judgment in the enforcement of the criminal laws of the State, including, but not limited to, law-enforcement officers' arresting or attempting to arrest persons; or
(5) exercising judgment in the discharge of duties imposed by statute, rule, or regulation in releasing prisoners, counseling or releasing persons of unsound mind, or educating students.

Notwithstanding anything to the contrary in the foregoing statement of the rule, a State agent *shall not* be immune from civil liability in his or her personal capacity
(1) when the Constitution or laws of the United States, or the Constitution of this State, or laws, rules, or regulations of this State enacted or promulgated for the purpose of regulating the activities of a governmental agency require otherwise; or
(2) when the State agent acts willfully, maliciously, fraudulently, in bad faith, beyond his or her authority, or under a mistaken interpretation of the law.

*Cranman*, 792 So. 2d at 405 (emphasis in original).

The IRB Defendants make a strong argument that the allegations against them fall under the first prong of the *Cranman* rule, which grants immunity for the formulation of "plans, policies, or designs." 792 So. 2d at 405. Had the rule stopped there, the court might have been inclined to find the IRB Defendants immune with respect to certain allegations, despite the Alabama Supreme Court's strong language cautioning against determining immunity at the motion to dismiss stage. *See Ex parte Ala. Dept. of Mental Health & Retardation*, 837 So. 2d 808, 813-14 (Ala. 2002) ("a motion to dismiss is typically not the appropriate vehicle by which to

assert qualified immunity or State-agent immunity and . . . normally the determination as to the existence of such a defense should be reserved until the summary-judgment stage, following appropriate discovery"). The rule, however, does not stop there.

The rule specifically states that a state agent *shall not* be immune when the State agent "acts willfully, maliciously, fraudulently, in bad faith, beyond his or her authority, or under a mistaken interpretation of the law." *Cranman*, 792 So. 2d at 405. Viewing the complaint in the light most favorable to the Plaintiffs, they allege that the IRB acted willfully and in bad faith by excluding known risks from the informed consent document. As such, this court will defer to the Alabama Supreme Court's warning in *Ex parte Alabama Department of Mental Health* and wait to decide this issue until the summary judgment stage when the parties have engaged in discovery and the court is better able to determine whether the IRB Defendants' conduct was willful or in bad faith.

*iv. Peer Review Immunity*

The IRB Defendants argue that they are entitled to peer review immunity under Alabama Code § 34-24-58, entitled "Decisions, opinions, etc., of utilization review committee privileged." That section extends privileged status to "[t]he decisions, opinions, actions and proceedings rendered" by "any committee of physicians or surgeons." ALA. CODE. § 34-24-58(a). The statute defines "committee" to include "one formed or appointed as a utilization review committee, or committee of similar purpose, to evaluate or review the diagnosis or treatment or the performance of medical services." ALA. CODE § 34-24-58(b).

Alabama courts have held that defendants attempting to invoke this privilege bear the burden of proving that they qualify for it. *See Ex parte St. Vincent's Hosp.*, 652 So. 2d 225, 230

(1994) (finding, in the context of a claim to privilege under § 34-24-58, that the "burden of proving that a privilege exists . . . is on [the defendant]"). In this case, although the court finds it plausible that Alabama courts could determine that the statute is applicable to institutional review boards at some time in the future, the IRB Defendants have not met their burden of proving the statute's applicability to them at this point.

On its face, the statute applies to "committee[s] of physicians or surgeons." ALA. CODE § 34-24-58(a). Based on the face of the complaint, the UAB IRB has at least one non-physician member: Ms. Sheila D. Moore. The court does not have enough facts at this stage of litigation to allow a thorough analysis of the IRB's make-up and functions. Although the IRB Defendants have offered one example of a case applying a similar peer review statute to the Alabama Board of Dental Examiners despite the membership of one dental hygienist, this one exception to another statute does not justify this court reading a significantly broader scope into § 34-24-58(a). *See Ex parte Mendel*, 942 So. 2d 829, 839 (Ala. 2006) (finding that Alabama Board of Dental Examiners qualified as a "committee" under § 6-5-333). The IRB Defendants' only example of a peer review statute applying directly to an IRB comes from another state; therefore, the precedent is not controlling in the consideration of Alabama's statute.

Additionally, the statute only grants privileged status where the decisions in question were "entered or acted upon in good faith and without malice and on the basis of facts reasonably known or reasonably believed to exist." ALA. CODE § 34-24-58(a). The complaint alleges that the IRB Defendants should have known about the risks to the infants in the Trial. Assuming it is true that the IRB Defendants knew of the risks, or reasonably believed the risks existed, the court can plausibly conclude that the actions of the IRB Defendants were committed with malice. Such a

conclusion is enough to preclude application of the statute *at this point*.

In sum, as to the IRB Defendants' motion to dismiss, the court will GRANT the motion, DISMISSING WITHOUT PREJUDICE Counts I, II, III, and IV. The court will address Count VII at a later point in the opinion.

**C. Dr. Carlo's Motion to Dismiss**

*i. Federal Employees Liability Reform and Tort Compensation Act*

Dr. Carlo argues that he is entitled to absolute immunity from the claims of negligent design of the trial because he qualifies as a federal employee; the Federal Employees Liability Reform and Tort Compensation Act ("FELRTCA") "extends this absolute immunity to government employees and agents by making the Federal Tort Claims Act ("FTCA") 'the exclusive remedy for individuals allegedly harmed by common law torts committed by Government employees acting within the scope of their employment." (Doc. 15, at 2) (quoting *Smith v. United States*, 877 F.2d 40, 42 (11th Cir. 1989)); 28 U.S.C. § 2679(b)(1). He submits that he is a federal employee because he meets the requirements of the Eleventh Circuit's "control test." That test says that an individual "is an employee of the Government if the Government controls and supervises the day-to-day activities of the alleged tortfeasor during the relevant time." (Doc. 15, at 3) (quoting *Bravo v. United States*, 532 F.3d 1154, 1159 (11th Cir. 2008)).

Dr. Carlo offers to the court several government websites that describe the Trial, Dr. Carlo's role in the trial, and the agencies associated with the Trial; he argues that these websites demonstrate that he qualifies as a federal employee under the control test. According to Dr. Carlo, the court is permitted to consider these websites for two reasons. First, the court can

consider them in its Rule 12(b)(6) analysis without converting the motion to dismiss into a motion for summary judgment by taking judicial notice of the websites as public records. (Doc. 15, at 4) (citing *Halmos v. Bomardier Aerospace Corp.*, 404 F. App'x 376, 377 (11th Cir. 2010)). Second, the court can consider them in its Rule 12(b)(1) analysis because the attack is factual, permitting the court to look at facts outside the pleadings. (Doc. 27, at 2) (citing *Lawrence v. Dunbar*, 919 F.2d 1525, 1529 (11th Cir. 1990)).

Even assuming, without deciding, that all of Dr. Carlo's legal arguments are true, the court finds that the information before it—including the facts alleged in the complaint *and* the websites—do not establish that Dr. Carlo is a federal employee entitled to the protection of the FELRTCA and the FTCA. Two of the three different websites put forth by Dr. Carlo simply describe the Neonatal Research Network and the Trial, without ever mentioning Dr. Carlo by name.[5] The third website is an article describing the Trial, which states: "The lead author of the article comparing oxygen saturation levels was Waldemar A. Carlo, of the University of Alabama at Birmingham."[6] The article continues to describe the study and quote Dr. Carlo's statement about the results. *Id*.

While these websites may establish government agency oversight of the Trial generally, they do not establish Dr. Carlo as a federal employee, even under a broad reading of the

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[5] *See* NICHD NEONATAL RESEARCH NETWORK, https://neonatal.rti.org/about/network.cfm (last visited December 10, 2013); RFA-HD-10-003, http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-10-003.html (last visited December 10, 2013).

[6] NATIONAL INSTITUTE OF HEALTH, NATIONAL HEART, LUNG AND BLOOD INSTITUTE, Higher Oxygen Levels Improve Preterm Survival, Increase Risk for Eye Condition (May 16, 2010, 1:00 PM) http://www.nhlbi.nih.gov/news/press-releases/2010/higher-oxygen-levels-improve-preterm-survival-increase-risk-for-eye-condition.html.

Defendant's proposed control test. The only specific mention of Dr. Carlo is as an author of the article on the study. In the very same paragraph the article states that another individual was the *NICHD* author of the paper, inversely indicating that Dr. Carlo was not in fact the author representing the agency. Even adding in the information on Dr. Carlo from the complaint—that he served as the principal investigator for the Trial—is not sufficient. Although the combination of the complaint and the website does potentially place him as a member of the Neonatal Research Network Steering Committee, which "has primary responsibility for the development and conduct of protocols and the preparation of publications," the website does not adequately explain the relationship of this committee to federal agency authority.[7]

Although Dr. Carlo's motion cites to various Federal Regulations and other aspects of the various websites that speak to the agencies' review and regulation of the Trial research and protocol, which likely have some effect on Dr. Carlo's participation in the Steering Committee, these connections are vague and tenuous and are not enough for the court to make a definitive finding that the government controls and supervises Dr. Carlo's day-to-day activities, or even that it necessarily has the authority to do so.

The decision to deny a motion to dismiss based on insufficient evidence to demonstrate entitlement to FTCA immunity is not unprecedented. Although the FTCA is usually invoked by the plaintiff as a basis for jurisdiction, requiring an immediate inquiry by the court into its applicability, the court finds that where the plaintiffs assert an independent basis for jurisdiction and a defendant invokes the FTCA as an affirmative defense, the defendant must put forth

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[7] NICHD NEONATAL RESEARCH NETWORK, https://neonatal.rti.org/about/network.cfm (last visited December 10, 2013).

sufficient evidence to establish his entitlement. *See Woodruff v. Covington*, 389 F.3d 1117, 1128 (10th Cir. 2004) (upholding the district court's denial of a defendant physician's motion to dismiss a negligence action against him where "these defendants have failed to demonstrate that they are entitled to FTCA immunity as 'federal employees'"). As such, the court will DENY Dr. Carlo's motion to dismiss the negligent design claims on the basis of his absolute immunity as a federal employee.

Dr. Carlo also argues that Plaintiffs' claims should be dismissed because they failed to exhaust their administrative remedies, as required under the FTCA. Because the court has already found that Dr. Carlo has failed to establish the applicability of the FTCA at this point, this aspect of Dr. Carlo's motion is also due to be DENIED.

*ii. Alabama Medical Liability Act*

Dr. Carlo's motion next argues that some of Plaintiffs' claims are actually medical malpractice claims and thus should be dismissed for failing to meet the heightened pleading standards of the Alabama Medical Liability Act ("AMLA"). The IRB Defendants also incorporate Dr. Carlo's argument.

Section 6-5-551 of the AMLA states:

> In any action for injury, damages, or wrongful death, whether in contract or in tort, against a health care provider for breach of the standard of care, whether resulting from acts or omissions in providing health care, or in the hiring, training, supervision, retention, or termination of care givers, the Alabama Medical Liability Act shall govern the parameters of discovery and all aspects of the action. The plaintiff shall include in the complaint filed in the action a detailed specification and factual description of each act and omission alleged by plaintiff to render the health care provider liable to plaintiff and shall include when feasible and ascertainable the date, time, and place of the act or acts.

ALA. CODE. § 6-5-551. Certain of Plaintiffs claims, though couched in other language, fall within

the parameters of this Act. Specifically, paragraph 76(h), (j), (k), and (l) are medical malpractice claims because they address the treatment, care, monitoring, observing, discovering, and diagnosis of the Plaintiffs and Infant Banks—all actions in tort for injury against Dr. Carlo, a health care provider, for breach of the standard of care.[8]

As AMLA claims, these allegations are subject to the heightened standard of pleading and must include "a detailed specification and factual description of each act and omission alleged." ALA. CODE § 6-5-551. This requirement is not tempered by the phrase "when feasible and ascertainable," as is the requirement that the plaintiff include the "date, time, and place of the act of acts." *Id*. Although Plaintiffs include a great deal of detail as to the design and risks of the Trial, the history of research on infant oxygenation, the function and design of the oximeter, and the OHRP critiques of the informed consent document, the Plaintiffs do not include any details or factual descriptions as to the actual treatment, care, and diagnosis of the named Plaintiffs and Infant Banks who were the actual participants in the Trial. Beyond the allegations that these infants were born in UAB Hospital in 2006 and briefly noting their impairments, the complaint does not describe when, how, or by whom the infants were treated and it does not include any other details that would be relevant to the treatment, care, monitoring, observing, discovering, and diagnosis of the infants.

In sum, the complaint does not meet the heightened pleading standard of § 6-5-551 for these claims; therefore, the allegations in paragraph 76(h), (j), (k), and (l) are due to be

[8] Even though the Plaintiffs have not used the term "medical malpractice" for their claims, the Alabama Supreme Court has found that the provisions of the AMLA extend beyond mere medical malpractice. *See Collins v. Ashurst*, 821 So. 2d 173, 176 (Ala. 2001) ("[W]e note that this Court has accepted other causes of action, distinct from medical malpractice, as being governed by the AMLA.").

DISMISSED WITHOUT PREJUDICE.

The informed consent claims, found in paragraph 76(e) and Count III, are also potentially medical malpractice claims under the AMLA. Every example of a claim for "lack of informed consent" that this court could identify from Alabama courts involved those courts treating the claim as a medical malpractice claim. *See, e.g., Houston County Health Care Authority v. Williams*, 961 So. 2d 795 (Ala. 2006); *Ex parte Mendel*, 942 So. 2d 829 (Ala. 2006); *Calin v. Howorth*, 877 So. 2d 566 (Ala. 2003); *Horton v. Shelby Medical Center*, 562 So. 2d 127 (Ala. 1989); *Tant v. Women's Clinic*, 382 So. 2d 1120 (Ala. 1980). None of these, cases, however, consider an informed consent claim in the context of a clinical trial or research study.

This court is not convinced that the two contexts for an informed consent claim are the same; the development of informed consent documents for a clinical trial is a much broader process that involves both the conversation between a doctor and his patient *and* the interplay between the trial managers and their legal department. Furthermore, even if this claim is not a medical malpractice claim, the way in which Plaintiffs have framed the allegations is also very similar to fraud, which necessitates a higher pleading standard under Rule 9(b). FED. R. CIV. PRO. 9(b). The court finds, however, that this case does not necessitate a decision on the nature of an informed consent claim in a clinical trial context, which is a matter of first impression in Alabama courts. Here, the court has already found that Plaintiffs' style of pleading is impermissible and that Plaintiffs must re-plead Counts I, II, III, and IV, stating the specific facts and Defendants for each claim. Because Dr. Carlo adopts and incorporates the arguments of the IRB Defendants, the court finds that Counts I, II, III, and IV are due to be DISMISSED WITHOUT PREJUDICE as to Dr. Carlo, as well. (Doc. 15, at 1 n.1). Plaintiffs have leave to

amend their complaint as to these counts by February 5, 2014.

*iii. Statute of Limitations for Wrongful Death Claim*

Dr. Carlo, along with all of the other Defendants, argue that Count VII—the wrongful death claim for Destiny Banks—is barred by the two-year statute of limitations. The Plaintiffs concede that this claim is barred, but request that Infant Banks's mother, Survonda Banks, be permitted to amend the complaint to assert a claim for parental loss of consortium. Defendants, in turn, argue that a parental loss of consortium claim is also barred.

The applicable statute of limitations to a loss of consortium claim is Alabama Code § 6-2-38 (*l*), which states: "All actions for any injury to the person or right of another not arising from contract and not specifically enumerated in this section must be brought within two years." *See Jones v. Phillips*, 553 So. 2d 106 (Ala. 1989) (addressing whether "the applicable two-year statute of limitations (Ala. Code 1975 § 6-2-38l) had run" on plaintiffs' claims for personal injuries and loss of consortium). This statute does not toll for infancy or incompetency. *See Emerson v. Southern Ry. Co.*, 404 So. 2d 576 (Ala. 1981) ("the derivative claim for loss of consortium of a spouse or parent is not subject to the tolling statute of the infant or incompetent"). Because the complaint states that Infant Banks died 20 days after her birth in 2006, the two-year statute of limitations has also run on any parental loss of consortium claim.

For these reasons, the court will GRANT all Defendants' motions IN PART as to the wrongful death claims Infant Banks's parents might plead by amendment and DISMISS Count VII of Plaintiffs' complaint. Plaintiff will be DENIED permission to amend the complaint to assert a claim for parental loss of consortium, as such a claim would be futile.

**D. Masimo Corporation's Motion to Dismiss**

*i. Preemption*

Masimo argues that Plaintiffs' claims against it are impliedly preempted by the FDA's medical device regulatory regime, as laid out in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001). Plaintiffs respond by arguing that Masimo reads *Buckman* too broadly and that their AEMLD and negligence claims are traditional state-law causes of action that are not impliedly preempted.

In *Buckman*, the Supreme Court found that the plaintiffs' state-law fraud-on-the-FDA claims were impliedly preempted by federal law. 531 U.S. at 348. It reached this conclusion by determining that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347 (internal quotations omitted). The Court continued to explain that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id*.

Masimo's theory is that because the Plaintiffs' claims "necessarily rest on the permissibility under the FDCA of the modifications Masimo made to the devices," they "would not exist in the absence of the FDCA, and are thus preempted." (Doc. 29, at 6). The court rejects this logic. Although the Plaintiffs use factual information about FDA standards and approval to support elements of their claim, the claims themselves are completely independent from the Federal Food, Drug, and Cosmetic Act and the Medical Device Amendments. If the FDA did not exist, Plaintiffs could still bring their AEMLD and negligence claims; they would simply be required to support them with different facts. Furthermore, the supporting cases cited by Masimo are not binding precedent in this circuit and, even if they were, do not broaden the reading of

*Buckman* to the extent advocated by Masimo. *See PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 922 (9th Cir. 2010) (finding that the FDCA preempted a Lanham Act claim that a "competitor violated the FDCA by misrepresenting that its product has received FDA clearance"); *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013) (finding that plaintiff's fraud by omission claim was impliedly preempted by the FDCA's enforcement scheme). The court will DENY the preemption arguments in Masimo's motion.

*ii. Alabama Extended Manufacturer's Liability Doctrine Claim*

Masimo argues that Plaintiffs fail to state a claim under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") because they do not adequately allege a defect or causation. To state a claim under the AEMLD, a plaintiff must show

> [1] that an injury was caused by one who sold a product in a defective condition that made the product unreasonably dangerous to the ultimate user or consumer; [2] that the seller was engaged in the business of selling such a product; and [3] that the product was expected to, and did, reach the user without substantial change in the condition in which it was sold.

*Tillman v. R.J. Reynolds Tobacco Co.*, 871 So. 2d 28, 31 (Ala. 2003) (quoting *Bell v. T.R. Miller Mill Co.*, 768 So. 2d 953, 957 (Ala. 2000)) (emphasis omitted).

Alabama courts have expounded on the "defect" element, explaining it as follows:

> In order to prove that a product is defective for purposes of the AEMLD, a plaintiff must prove that a safer, practical, alternative design was available to the manufacturer at the time it manufactured the product. The existence of a safer, practical alternative design must be proved by showing that:
>
> > (a) The plaintiff's injuries would have been eliminated or in some way reduced by use of the alternative design; and that
> >
> > (b) taking into consideration such factors as the intended use of the product, its styling, cost, and desirability, its safety aspects, the forseeability of the particular accident, the likelihood of injury, and the

> probable seriousness of the injury if that accident occurred, the obviousness of the defect, and the manufacturer's ability to eliminate the defect, the utility of the alternative design outweighed the utility of the design actually used.

*Garrie v. Summit Treestands, LLC*, 50 So. 3d 458, 465 (Ala. Civ. App. 2010) (quoting *Beech v. Outboard Marine Corp.*, 584 So. 2d 447, 450 (Ala. 1991)) (internal quotations omitted). Based on this statement of the elements of the claim, the court finds that the Plaintiffs' factual allegations proposing the FDA-approved oximeter design as a safer alternative to the oximeter used sufficiently state a claim for a defect.

Masimo cites *Interstate Eng'g, Inc. v. Burnette* to support its argument. 474 So. 2d 624 (Ala. 1985). Although the case describes one circumstance where a plaintiff met her burden of proof by establishing that certain heat detectors "were not fit for their intended purpose and were unreasonably dangerous," 474 So. 2d at 628, it by no means lays out a blanket definition of a manufacturing defect that requires, as Defendant Masimo argues, an "unintended flaw or abnormality." (Doc. 23 at 16). While the intended use of the product is one of several factors that could ultimately be considered in determining whether the Plaintiffs meet their burden of proof—or whether Defendants have established an affirmative defense—it is not a necessary *allegation* in determining whether Plaintiffs have adequately stated a claim.

Masimo fails to cite any cases under Alabama law to support its argument that Plaintiffs failed to properly allege the causation element of their AEMLD claim. Plaintiffs allege the facts surrounding the "defect" in the oximeter, as discussed above, and claim that the defect caused their injuries. This court is satisfied at the motion to dismiss phase.

*iii. Negligence Claim*

Masimo also argues that Plaintiffs fail to adequately allege negligence because they "do not plausibly allege that Masimo breached any duty to Plaintiffs." (Doc. 23 at 19). Masimo's argument, devoid of any case law, is even more conclusory than the complaint it attacks. The complaint, in addition to alleging facts about the design of the oximeter and safer alternatives, states: "Masimo had a duty to the Plaintiffs to manufacture the oximeters in accordance with the FDA-approved design, and otherwise had a duty to the Plaintiffs to follow the FDA's requirements and act reasonably. Masimo breached this duty . . . ." (Doc. 10, at ¶¶ 123-24). Such allegations are sufficient to state a claim.

## IV. CONCLUSION

For the reasons stated above, the IRB Defendants and Dr. Carlo's motions to dismiss are due to be GRANTED and Defendant Masimo's motion is due to be GRANTED IN PART and DENIED IN PART. The court will GRANT the motions of the IRB Defendants and Dr. Carlo and DISMISS Counts I, II, III, and IV WITHOUT PREJUDICE, with leave for Plaintiffs to amend the complaint by February 5, 2014. The court will GRANT the motions of all Defendants as to Count VII and DISMISS this count WITH PREJUDICE. The court will DENY Defendant Masimo's motion as to all other counts. The court will also DISMISS ABC Health Care Providers #1-100, ABC Individuals #1-100, and XYZ Entities #1-10. The court simultaneously will enter a separate Order to that effect.

DONE and ORDERED this 22nd day of January, 2014.

Karon O. Bowdre

KARON OWEN BOWDRE
CHIEF UNITED STATES DISTRICT JUDGE