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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

BILLY RYAN LOONEY, ET AL.,	]	
	]	
Plaintiffs,	]	
	]	
v.	]	
	]	**Case No.: 2:13-cv-00733-KOB**
SHEILA D MOORE, ET AL.,	]	
	]	
Defendants.	]	
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MEMORANDUM OPINION

This case involves a national clinical research trial known as the Surfactant, Positive Pressure, and Oxygenation Randomized Trial ("SUPPORT"). That research trial focused on the effects of oxygen saturation levels ("SpO2") in premature infants with extremely low-birth weights ("ELBW"). The infant Plaintiffs in this case, who participated in the SUPPORT study while receiving treatment at the University of Alabama-Birmingham Hospital, brought suit, by and through their parents, alleging that they suffered serious injuries as a result of participating in the study. (Doc. 48).

In their Fifth Amended Complaint, the Plaintiffs assert claims of negligence, negligence per se, and lack of informed consent against the individual members of the UAB Institutional

Review Board ("IRB Defendants"),[1] the board that approved the SUPPORT study at UAB. (Claims I-IX). The Plaintiffs also assert claims for negligence, breach of fiduciary duty, and lack of informed consent against Dr. Waldemar Carlo, who served as the principal investigator for the research trial and designed the trial's protocols. (Claims X-XII). Finally, the Plaintiffs assert claims for products liability and negligence against the Masimo Corporation, which manufactured modified pulse oximeters[2] that were used in the study. (Claims XIII-XIV).

All of the Defendants in the suit filed motions for summary judgment (doc. 65: Masimo, doc. 68: Dr. Carlo, & doc. 69: IRB Defendants), and the matter is now before the court on those motions. Also before the court are Dr. Carlo and the IRB Defendants' "Motion to Exclude or, in the Alternative, Limit the Testimony of Professor Robin Wilson and Dr. Marcus Hermansen" (doc. 70), and "Motion to Strike Exhibits C, H, I, K, L and M of Milstein's Declaration" (doc. 81). For the reasons discussed below, this court will grant all of the Defendants' motions for summary judgment. Additionally, because the Defendants are entitled to summary judgment regardless of the dispositions of the motions to strike, the court will deny those motions as moot.

I. Standard of Review

Summary judgment allows a trial court to decide cases when no genuine issues of material fact are present and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56. When a district court reviews a motion for summary judgment, it must determine two things: (1) whether any genuine issues of material fact exist; and if not, (2)

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[1] The following individual Defendants comprise the Institutional Review Board: Shelia D. Moore, Ferdinand Urthaler, Kenneth Pruitt, John Carpenter, Mary Hilliard, Richard Parker, William Blackerby, Marguerite Kinney, Marilyn Doss, Charles Boswell, and Denise Ball.

[2] Pulse oximeters are medical devices used for monitoring a patient's pulse and SpO2 levels.

whether the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c).

The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (quoting Fed. R. Civ. P. 56).

Once the moving party meets its burden of showing the district court that no genuine issues of material fact exist, the burden shifts to the non-moving party to produce sufficient favorable evidence "to demonstrate that there is indeed a material issue of fact that precludes summary judgment." *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir. 1991). "If the evidence [on which the nonmoving party relies] is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249–50 (1986).

In ruling on a motion for summary judgment, all evidence and inferences drawn from the underlying facts must be viewed in the light most favorable to the non-moving party. *See Graham v. State Farm Mut. Ins. Co.*, 193 F.3d 1274, 1282 (11th Cir. 1999). The evidence of the non-moving party "is to be believed and all justifiable inferences are to be drawn in [its] favor." *Anderson*, 477 U.S. at 255. "If reasonable minds could differ on the inferences arising from undisputed facts, then a court should deny summary judgment." *Allen v. Tyson Foods, Inc.*, 121 F.3d 642, 646 (11th Cir. 1997) (internal quotation marks and citations omitted). This standard exists because "the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150 (2000) (citation

and internal quotation marks omitted).

After both parties have addressed the motion for summary judgment, the court must grant the motion only if no genuine issues of material fact exist and if the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56.

II. Background

The SUPPORT trial was a national study participated in by more than twenty medical research centers through the United States, including UAB. The study involved two separate experiments. One experiment focused on the effect of different oxygen delivery methods. The other experiment, in which the Plaintiffs participated, focused on the effect of SpO2 levels on premature infants.

At the time of the trial, the nationally recognized standard of care for ELBW premature infants was to maintain SpO2 levels between 85% and 95%. Although the scientific community knew that extremely high SpO2 levels (above 96%) could lead to complications, including blindness caused by retinopathy of prematurity ("ROP"), and that extremely low levels (below 70%) could result in death or neurodevelopmental impairment, the effect of variations within the 85% to 95% range was unknown.

Dr. Carlo, the designer of the trial, created the SUPPORT study to "generate knowledge that could help physicians determine exactly how much oxygen to provide to extremely low birth weight infants to minimize ROP without contributing to undue increases in other problems (such as impaired brain development or even death)." (Doc. 48-1, at 5). To achieve that goal, Dr. Carlo divided the nationally accepted range of SpO2 levels into two separate ranges, a high range (between 90% and 95%) and a low range (between 85% and 90%). He then randomly divided

the enrolled infants between the two groups and tracked the infants' rates of death and ROP.

In monitoring premature infants' SpO2 levels, UAB typically uses a medical device known as a pulse oximeter. Pulse oximeters provide a digital reading of blood SpO2 levels and typically have alarms that sound if an infant's SpO2 levels fall outside of the 85% to 95% range accepted as the national standard of care. The SpO2 levels of infants enrolled in the SUPPORT study, however, were monitored using special pulse oximeters specifically modified by Masimo for the study. SUPPORT protocol required that both the research investigators and the treating health-care providers be "blinded" to whether each infant was in the low or high group. To satisfy this requirement, Masimo provided UAB with pulse oximeters that would mask the actual SpO2 levels of the infants by offsetting the values either up or down into a corresponding range of 88% to 92% saturation depending on whether the infant was in the high or low group. In other words, if an infant was in the low range group, with targeted values between 85% and 89%, the display on the pulse oximeter would be offset upwards to indicate that the infant was actually between 88% and 92%. Similarly, if an infant was in the high range group, with targeted values between 91% and 95%, the pulse oximeter would be offset downwards to indicate that the infant was actually between 88% and 92%. Because the pulse oximeters were offset, nurses and physicians could not know where an infant's saturation levels were within the 85% to 95% range. However, if the infant's saturation levels dropped below 85% or rose above 95%, an alarm would sound, and the pulse oximeter would unmask, displaying the infant's actual SpO2 level.

At the conclusion of the study, researchers compared the results of the high and low group to determine the effect of oxygen saturation levels on the rates of infant survival, neurological development, and development of ROP. The results of the study indicate that

infants assigned to the high oxygen group had higher rates of ROP than infants in the low oxygen group. Additionally, infants in the low oxygen group had statistically higher rates of death.

Before enrolling in the study, hospital personnel provided the parents of each premature infant with an informed-consent form. The form contained limited warnings about the possible risks of the study and identified possible skin breakdown at the oximeter site as the only increased risk of participation in the study. Each of the Plaintiffs' parents signed the informed-consent forms and allowed their infants to participate in the study.

After being enrolled, Plaintiffs Christian Lewis and Jaylen Malone were randomly assigned to the low oxygen group, and Plaintiff DreShan Collins was assigned to the high oxygen group. Although assigned to the low group, neither Christian Lewis nor Jaylen Malone died. They did, however, develop "neurological issues." DreShan Collins developed ROP but did not suffer permanent vision loss as a result.

In 2013, the Plaintiffs brought suit against the Defendants. In support of their claims, the Plaintiffs rely heavily on the testimony of Dr. Marcus Hermansen, a Pediatrician and Neonatologist. Dr. Hermansen offered numerous criticisms of the SUPPORT study's protocols and informed-consent form. He also opined that the Plaintiffs' participation in the study "significantly increased the risk they would suffer from the physical and other problems of the type or even more severe than they now experience." (Doc. 65-11, at 6–7).

II. Discussion

In their motions, the Defendants contend that they are entitled to summary judgment because the Plaintiffs failed to present sufficient evidence to create a genuine issue of material fact as to whether the SUPPORT study *caused* the Plaintiffs' injury. In other words, the

Defendants contend that because all of the Plaintiffs' claims against them arise out of the Plaintiffs' participation in SUPPORT, the Plaintiffs must prove, at a minimum, that the study caused them some injury. The Defendants are correct.

For any of the Plaintiffs' numerous claims to survive summary judgment, the Plaintiffs bear the burden of establishing causation. *See Univ. of Texas Southwestern Med. Ctr. v. Nassar*, —U.S.—, 133 S. Ct. 2517, 2524–25 (2013) (recognizing that causation "is a standard requirement of any tort claim"). To establish proximate cause under Alabama law, a plaintiff must establish that the defendant's acts or omissions "probably caused, rather than only possibly caused, the plaintiff's injury." *Breland ex rel. Breland v. Rich*, 69 So. 3d 803, 814–15 (Ala. 2011) (internal citation omitted).

To meet this burden, the Plaintiffs rely on the testimony of Dr. Hermansen, their sole expert to offer an opinion on causation. In his expert report, Dr. Hermansen made the following statement:

> *[P]articipation in the study resulted in increased risk of the adverse effects of too much or too little oxygen administration* – it was predictable that some infants would experience increased risk of ROP and blindness, while others would experience increased risk of death. The study's results with increased mortality (in the low saturation group) and increased ROP (in the high saturation group) should have been anticipated before the first infant was enrolled.
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> . . . .
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> To a reasonable degree of medical certainty the informed consent form and process did not meet applicable standards . . ., and *infants were placed at an increased risk of harm as the result of participation in the study . . . . Placing DreShan Collins, Christian Lewis, and Jaylen Malone in the study, where the oxygen saturation was randomized and thus the practitioners could not modify the saturation level depending on the needs of the patient, significantly increased the risk they would suffer from the physical and other problems of the type or even more severe than they now experience.*

(Doc. 65-11, at 6–7) (emphasis added).

According to the Plaintiffs, Dr. Hermansen's testimony is sufficient to create a jury questions as to whether their participation in the SUPPORT study caused both "the injuries they were put at risk of suffering" and the injuries they "actually suffered." (Doc. 73). The Plaintiffs are mistaken on both counts.

First, as to the injuries the Plaintiffs "were put at *risk* of suffering"—i.e. did not suffer—the Plaintiffs have neither a legal basis nor standing to assert claims based on these alleged "injuries."

Alabama courts have consistently declined to allow recovery for an increased risk of future harm. *See Hinton v. Monstanto Co.*, 813 So. 2d 827, 829–30 (Ala. 2001) (holding that "a cause of action based upon nothing more than an increased risk that an injury or an illness might one day occur would result in the courts of this State deciding cases based upon nothing more than speculation and conjecture"); *Pfizer, Inc. v. Farsian*, 682 So. 2d 405, 407 (Ala. 1996) ("Although the facts . . . indicate that the Bjork-Shiley heart valve has experienced problems with strut failures, [the plaintiff's] concern that his heart valve, which is presently functioning normally, could later malfunction is not an injury recognized by Alabama law.").

The Plaintiffs attempt to distinguish the numerous Alabama cases rejecting claims based on an increased risk of future harm by asserting that their claims are based upon an increased risk *past* harm. Within their response, the Plaintiffs provide the following explanation of their reasoning:

> The Plaintiffs allege that the Defendants' conduct caused the Plaintiffs to be at an actual, demonstrable increased risk of harm in the past. This the Plaintiffs and their

> experts can prove with virtually 100 percent certainty . . . .
>
> Indeed, in a situation where a defendant physician metaphorically played "Russian roulette" with an [sic] neonate, placing a neonate at a one in six chance (to use the "Russian roulette" analogy) of significant harm at the neonatal stage without any corresponding benefit to the neonate, and the neonate is lucky enough to avoid harm, the physician nevertheless placed the neonate at an actual increased risk of harm, as opposed to "nothing more than an increased risk that an injury or an illness might one day occur."
>
> The evidence more than supports a jury finding that, as a result of Dr. Carlo's conduct, the Plaintiffs were placed at an increased risk of harm. Indeed, though Christian Lewis and Jaylen Malone did not die as a result of being in the low arm of the study, they had a greater chance of dying than those in the high arm of the study, and those outside the study, and their parents were never informed of that fact. Similarly, though DreShan Collins' ROP thankfully did not ripen into blindness, he still had a greater chance of going blind than those in the low arm of the study, and those outside the study, and his parents were never informed of that fact. . . . The Plaintiffs' claims are not that they might be at a greater risk [of] developing injuries in the future, but that they were with almost 100 percent certainty placed at greater risk of developing injuries (death, developmental issues, CLD, ROP) in the past.

(Doc. 73, at 24–25).

This line of reasoning makes little sense and lacks basis in Alabama law. The key problem with asserting a claim for an increased risk of past harm is that the past harm *never actually occurred*. Alabama law, indeed every state's law, requires that a plaintiff suffer an injury to state a claim for relief. *See Hinton*, 813 So. 2d 827, 829 (Ala. 2001) ("For over two hundred years, one of the fundamental principles of tort law has been that a plaintiff cannot recover without proof of a physical injury."); *see In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016 (7th Cir. 2002) ("No injury, no tort, is an ingredient of every state's law."). The court has found no case law in any jurisdiction supporting the Plaintiffs' theory that an "increased risk of past harm" constitutes a legally cognizable injury, and the Plaintiffs have offered none.

The only cases Plaintiffs do offer in support of their theory are cases in which the

Alabama Supreme Court has allowed a plaintiff to avoid summary judgment by producing evidence that his condition "was adversely affected by the [physicians'] alleged negligence." *Parker v. Collins*, 605 So. 2d 824, 827 (Ala. 1992); *see Murdoch v. Thomas*, 404 So. 2d 580 (Ala. 1981); *Waddell v. Jordan*, 302 So. 2d 74 (Ala. 1974). All of those cases, however, are distinguishable because they involved claims based on injuries that the plaintiffs had *actually sustained*.

Not only do the Plaintiffs lack a legal basis for their "no injury" claims, but they also lack standing to assert such claims. To have Article III standing, a "plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks and citations omitted). The *risk* of a past injury that never materialized simply does not constitute a "concrete and particularized" injury necessary for standing. *See Pevsner v. Eastern Air Lines, Inc.*, 493 F.2d 916, 917–18 (5th Cir. 1974) ("A party who cannot show injury has no standing to sue."); *Griffin v. Dugger*, 823 F.2d 1479, 1482–83 (11th Cir. 1987) ("Under elementary principles of standing, a plaintiff must allege and show that he personally suffered injury. If he cannot show personal injury, then no [A]rticle III case or controversy exists, and a federal court is powerless to hear his grievance.").

In sum, the Plaintiffs' "increased risk of past harm" theory is unsupported by Alabama law and to allow such claims to move forward would violate Article III standing requirements. Accordingly, the court declines to recognize the Plaintiffs' "no injury" claims.

Although the Plaintiffs cannot assert claims based on an "increased risk of past harm" that did not materialize, the Plaintiffs may recover from the Defendants for actual injuries that

they suffered as long as they can present evidence that "the alleged negligence probably caused, rather than only possibly caused, [the Plaintiffs'] injury." *Miller v. Bailey*, 60 So. 3d 857, 862–63 (Ala. 2010). The Plaintiffs contend that DreShan Collins developed ROP and both Christian Lewis and Jaylen Malone developed "neurodevelopmental issues" because of their participation in the SUPPORT study.

In a bid to establish that their injuries were probably caused by the SUPPORT study, the Plaintiffs cite two pieces of evidence. First, the Plaintiffs contend that the injuries they suffered were *consistent* with the SpO2 levels at which they were maintained while participating in the SUPPORT study. Specifically, the Plaintiffs point out that DreShan Collins' high oxygen levels were consistent with the risk that he would develop ROP and that Christian Lewis and Jaylen Malone's low oxygen levels were consistent with the risk that they would develop "neurodevelopmental issues." Second, the Plaintiffs cite Dr. Hermansen's testimony that participation in the SUPPORT study "increased the risk [that the Plaintiffs] would suffer from the physical and other problems of the type or even more severe than they now experience." (Doc. 65-11, at 5–6).

Neither of those pieces of "evidence," however, are sufficient to create a jury question as to whether the SUPPORT study *probably* caused the Plaintiffs' injuries.

First, although each of the Plaintiffs' injuries are consistent with the SpO2 levels at which they were maintained while participating in the study, mere association of the injury and range does not establish causation. *See Ex parte Diversey Corp*, 742 So. 2d 1250, 1254 (Ala. 1999) ("Proof which goes no further than to show an injury could have occurred in an alleged way, does not warrant the conclusion that it did so occur, where from the same proof the injury can with

equal probability be attributed to some other cause."). As the old axiom goes, correlation does not equal causation. This statement is especially true in light of the Defendants' experts' unchallenged testimony that the Plaintiffs' extreme prematurity and the complications of their premature birth already put them at a very high risk of developing ROP or neurological issues. (*See* doc. 66-2, at 6; doc. 66-3, at 6). Given the multiple possible causes of the Plaintiffs' ROP and neurological issues, the fact that the Plaintiffs' injuries are *consistent* with the SpO2 levels at which they were maintained does not show that their injuries were *probably caused* by those SpO2 levels. *See Vesta Fire Ins. Corp. v. Milam & Co. Constr., Inc.*, 901 So. 2d 84, 101 (Ala. 2004) ("There may be two or more plausible explanations as to how an event happened or what produced it, yet, if the evidence is without selective application to any of them, they remain conjectures only.")

Second, Dr. Hermansen's testimony is insufficient to create a genuine dispute of material fact as to whether the SUPPORT study caused DreShan Collins' ROP, and Christian Lewis and Jaylen Malone's "neurodevelopmental issues." The strongest statement Dr. Hermansen offers as to causation is that the Plaintiffs' participation in SUPPORT "*increased the risk* [that the Plaintiffs] would suffer from the physical . . . problems . . . they now experience." (Doc. 65-11, at 5–6). Notably, Dr. Hermansen never identifies any specific illness or injury that he believes is related to the Plaintiffs' participation in SUPPORT. Nevertheless, even assuming that Dr. Hermansen testified that he believed the Plaintiffs' participation in SUPPORT increased the risk that they would suffer from ROP and neurological issues, that testimony would still be inadequate to establish causation. Dr. Hermansen's testimony that SUPPORT *increased the risk* of the Plaintiffs' injuries does not mean that SUPPORT– rather than the Plaintiffs' prematurity–

probably caused the Plaintiffs' injuries.

As stated above, the Plaintiffs' extremely premature births and the extensive complications with which they were each born already placed each of them at an exceptionally high risk of developing ROP or neurological issues. Given the numerous other possible causes of their injuries, the Plaintiffs must present expert testimony that their participation in the SUPPORT study "probably" caused their injuries. *See Breland ex rel. Breland v. Rich*, 69 So. 3d 803, 812–13 (Ala. 2011) (denying defendant's motion for summary judgment because the plaintiff's expert testified that, although the plaintiff's ROP could *possibly* have been caused by numerous other factors, the defendant's negligence *probably* caused the plaintiff to develop ROP); *Hill v. Fairfield Nursing and Rehabilitation Ctr., LLC*, 134 So. 3d 396, 406 (Ala. 2013) ("There must be more than the mere possibility that the negligence complained of caused the injury; rather, there must be evidence that the negligence complained of probably caused the injury.") (internal citation omitted). Dr. Hermansen, however, fails to offer such testimony; his opinion that SUPPORT "increased the risk" that the Plaintiffs would suffer their current injuries is tantamount to saying that the SUPPORT study "possibly" caused their injuries.

In their response, the Plaintiffs state that "[n]o expert can be asked to do the impossible, and prove a causal link between participation and [the Plaintiffs'] conditions with 100 percent certainty." (Doc. 73, at 28). The law does not require one-hundred percent certainty; instead, the law requires the Plaintiffs to prove that participation in the SUPPORT study *probably* caused the their conditions. *See Lyons v. Vaughan Reg'l Med. Ctr., LLC*, 23 So. 3d 23, 28–29 (Ala. 2009); *Groover v. Johnston*, 39 So. 3d 33, 40 (Ala. 2009). Dr. Hermansen's testimony simply does not express any opinion on the probability that participation in the study caused the Plaintiffs'

injuries.

In contrast, the Defendants' experts specifically offer opinions as to the probable cause of the Plaintiffs' ROP and neurological issues. Defendants' expert Dr. Brian Carter, a Professor of Pediatrics and practicing neonatologist, stated in an affidavit that he believed to a reasonable degree of medical certainty that "it is more likely than not that the injuries the Named-Plaintiffs complain of were caused by their prematurity and other complications that are unrelated to SUPPORT." (Doc. 66-2, at 5). Similarly, Dr. Richard Polin, a Professor of Pediatrics and the Director of Neonatology at New York Presbyterian Morgan Stanley Children's Hospital, stated that in his medical opinion "[t]he most likely cause of the Named-Plaintiffs' alleged conditions was their prematurity." (Doc. 66-3, at 5). Finally, Dr. Barbara Olson, a practicing pediatric neurologist, testified that "any neurologic injury allegedly suffered by the Named-Plaintiffs was a result of their extreme prematurity and other complications unrelated to SUPPORT." (Doc. 66-4, at 6).

Given the Defendants' experts' clear testimony that the Plaintiffs' injuries are not the result of their participation in the SUPPORT study, the Plaintiffs must present significant probative evidence to the contrary. *See Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 249–50 (1986). Dr. Hermansen's testimony fails to carry the Plaintiffs' burden. Accordingly, the Plaintiffs fail to create a genuine issue of material fact as to whether their participation in the SUPPORT study probably caused their injuries.

This reasoning applies not only to the Plaintiffs' negligence and negligence per se claims, but also to their informed consent, breach of fiduciary duty, and products liability claims. Regarding the latter three claims, the Plaintiffs also fail to establish injury and causation. As

discussed above, Plaintiffs' claims based on an increased risk of past harm fail because this risk is not a legally cognizable injury. Plaintiffs' claims based on the injuries actually suffered similarly fail because the Plaintiffs are unable to establish that a lack of informed consent, a breach of fiduciary duty, or a defectively designed oximeter probably caused the infant Plaintiffs' injuries. Consequently, the Defendants are entitled to summary judgment on all of the Plaintiffs' claims.

III. Conclusion

For the reasons discussed above, this court will **GRANT** the Defendants' motions for summary judgment as to all of the Plaintiffs' claims. (Docs. 65, 68, & 69). Additionally, because the dispositions of Dr. Carlo and the IRB Defendants' "Motion to Exclude or, in the Alternative, Limit the Testimony of Professor Robin Wilson and Dr. Marcus Hermansen" (doc. 70) and "Motion to Strike Exhibits C, H, I, K, L and M of Milstein's Declaration" (doc. 81) do not alter the outcomes of the motions for summary judgment, the court will **DENY** those motions as **MOOT**. The court will enter a separate final order with this opinion.

DONE and **ORDERED** this 13th day of August, 2015.

Karon O. Bowdre

KARON OWEN BOWDRE

CHIEF UNITED STATES DISTRICT JUDGE