IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO CIVIL ACTION NUMBERS:

Cisson, et al. v. C. R. Bard, Inc. 2:11-cv-00195

MEMORANDUM OPINION AND ORDER
(Plaintiffs' Motion for Clarification on the Court's Ruling on Bard's Failure to Test, and for a Ruling on Bard's Objections to Evidence that Bard Claims "Implies Bard had a Duty to Conduct Clinical Trials or Additional Testing)

Pending before the court is the Plaintiffs' Motion for Clarification on the Court's Ruling on Bard's Failure to Test, and for a Ruling on Bard's Objections to Evidence that Bard Claims "Implies Bard had a Duty to Conduct Clinical Trials or Additional Testing" [Docket 352].[1] Bard filed a response, and this motion is ripe for review. For the reasons discussed below, the plaintiffs' motion is **GRANTED**. My clarifications and rulings are set forth below.

I. Background

The instant motion implicates two evidentiary issues: evidence regarding Bard's failure to conduct testing and evidence related to the FDA 510(k) process. These issues were first raised in the parties' motions *in limine*, where the plaintiffs moved to exclude evidence related to the FDA 510(k) process and lack of enforcement and Bard moved to exclude evidence or argument that it owed or breached an independent duty to conduct additional testing or inspection. (*See* Pls.' Mot. in Limine No. 1 [Docket 265]; Def. Bard's Initial Mots. *in Limine* [Docket 268], at 14-

[1] This motion is hereinafter referred to as the Plaintiffs' Motion for Clarification.

16). I held that evidence related to the FDA 510(k) process and lack of enforcement should be excluded, but declined at the time to rule conclusively on the testing or inspection evidence, noting that "evidence regarding Bard's testing or inspection generally, or lack thereof, may be relevant to whether Bard 'knew or should have known' of the alleged dangers in the Avaulta products." (Mem. Op. & Order [Docket 302], at 6).

On Saturday, July 6, 2013, two days prior to trial, the parties informed the court of disagreements with regard to Bard's objections to the plaintiffs' deposition designations. I directed the parties to submit short briefs by the next morning, held a hearing, and ruled on the issue in the afternoon. The focus of the July 7, 2013, briefing and hearing was Bard's assertion that evidence regarding lack of clinical testing was "inextricably tied to the 510(k) process and FDA clearance." (Def. Bard's Br. in Supp. of its Objections to Pls.' Dep. Designations Related to the Lack of Clinical Trials [Docket 318], at 1). The plaintiffs focused on the issue of whether "Bard's testing (or failure to test) may bear on whether Bard 'knew or should have known' of the dangers of the Avaulta products." (Pls.' Resp. to Bard's Objection to Testing Evidence [Docket 347], at 1). The plaintiffs briefly argued that this evidence is "among the factors that bear on the reasonableness of a manufacturer's design decision" and that it would be unfair for Bard's witnesses to testify about testing and studies that were conducted while simultaneously excluding the plaintiffs from presenting evidence regarding testing and studies that were not conducted. (*Id.*). I ultimately ruled that:

> The Court is of the opinion that a mere failure to test does not show that Bard should have known and warned about certain unspecified and alleged defects or dangers. It does show and can only support such a proposition if there is evidence that it is more likely true than not that such testing would have revealed such unspecified defects or dangers.
>
> Therefore . . . I hold that the plaintiffs are first required to show that the testing . . . that they allege that Bard should have done would have revealed such defects or

> dangers before they can introduce lack of testing evidence *for the proposition that Bard should have known of certain unspecified defects or dangers.*

(Mots. Hr'g Tr. [Docket 319], at 30:14-31:4) (emphasis added). In sum, my ruling only went to the admissibility of the lack of testing evidence in connection with the plaintiffs' failure to warn claim.

II. The Plaintiffs' Motion for Clarification

In the instant motion, the plaintiffs present three arguments.[2] First, the plaintiffs offer evidence that they argue should satisfy my ruling requiring them to show that the testing that the plaintiffs allege Bard should have done would have revealed the defects or dangers that they allege Bard should have known and of which they should have warned. Second, the plaintiffs brief in full their assertion that evidence as to Bard's lack of testing is admissible for purposes of the risk-utility analysis under Georgia design defect law. Finally, the plaintiffs also brief in full their assertion that evidence as to Bard's lack of testing is admissible for the purpose of supporting their claim for punitive damages.

A. *The Plaintiffs' Failure to Warn Claim*

The plaintiffs argue that "[w]hile requiring Plaintiffs to prove what unperformed testing would have shown imposes an improper and onerous burden, the evidence in this case demonstrates what "[r]easonable, developed human skill and foresight" would have revealed if Bard had done the testing that Plaintiffs contend should have been done." (Pls.' Mot. for Clarification [Docket 352], at 10). Nonetheless, the plaintiffs' very motion states that "Bard . . .

[2] The plaintiffs briefly argue that my ruling was "based on the Court's interpretation that Plaintiffs were seeking to assert an independent claim for damages based on Bard's failure to test." (Pls.' Mot. for Clarification [Docket 352], at 7). This statement is incorrect; however, my ruling addressed evidence regarding Bard's failure to test with respect to only the plaintiffs' failure to warn claim. My ruling did not address this evidence with respect to the plaintiffs' design defect or punitive damages claims.

had a legal duty to warn of every danger or effective condition involving the Avaulta products that "reasonable, developed skill and foresight" *would have revealed*." (*Id.*) (emphasis added).

Bard frames my ruling as requiring the plaintiffs to lay a foundation by presenting evidence regarding "1) what results [a] study would have shown; 2) whether the results constituted information of a new risk or defect; and 3) whether the newly identified risk or defect is causally related to the injuries alleged." (Bard's Resp. [Docket 354], at 11). My prior ruling is hereby clarified to require all three of these elements to lay the foundation for the plaintiffs' evidence regarding Bard's failure to test in connection with the plaintiffs' failure to warn claims. First, without evidence as to what the study would have shown, the failure to test is merely speculative of what Bard "should have known." Second, if the results would not have shown a new risk or defect, the failure to test would not be relevant to what Bard "should have known."

After reviewing the evidence proffered by the plaintiffs, I **FIND** that such evidence is insufficient to lay the foundation for admitting evidence regarding Bard's lack of testing on the plaintiffs' failure to warn claim. The plaintiffs point to studies that Dr. James Ross, Bard's medical consultant, *proposed*. The plaintiffs argue that one study was *proposed* "to determine the cause, incidence and appropriate treatment of delayed healing and mucosal erosion." (Pls.' Mot. for Clarification [Docket 352], at 10). The plaintiffs argue that a second study was *proposed*, after the product was on the market, to "collect additional data validating the long-term safety and effectiveness of the Avaulta Plus, and was expressly intended to examine the onset date, resolution date, severity, seriousness, frequency, treatment and outcome of potential adverse events." (*Id.* at 11) (internal quotation marks removed) (emphasis removed).

The plaintiffs then conclude that "[i]f Bard had undertaken to perform the study *proposed* by its medical advisor, it *would have* learned these critically important facts." (*Id.* at 12)

(emphasis added). The plaintiffs reason that "Bard cannot dispute that these are facts that Bard would have learned had it conducted this proposed study because learning such facts was the very purpose of the study." (*Id.*). Additionally, the plaintiffs also argue that "actual clinical results" of Bard's products is evidence of what Bard would have learned from the studies proposed by Dr. Ross. (*Id.* at 13). Essentially, the plaintiffs reason that the studies Bard failed to conduct *would have* revealed adverse reactions because Dr. Ross *proposed* studies intending to study these reactions and because evidence shows that these reactions exist. The *proposed* studies and the evidence, however, do not answer the question of whether the studies, if actually conducted, *would have* revealed these adverse reactions.

Additionally, the plaintiffs argue that "Bard has the results of actual clinical studies done on the original Avaulta device (made by Sofradim), as well as more recent studies done on the Avaulta Plus and/or Avaulta Solo devices." (*Id.*). In support, the plaintiffs cite to six papers published between 2008 and 2013 involving studies conducted on various Avaulta products. However, the plaintiffs appear to offer these studies as standalone evidence. Statements contained in learned treatises, such as those at issue in these studies, only fall within the hearsay exception under Federal Rule of Evidence 803(18) if "the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination" and "the publication is established as a reliable authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice." Fed. R. Evid. 803(18). If both conditions are met, the statement is admissible and "may be read into evidence but not received as an exhibit." *Id.*

The plaintiffs provide no basis for how they intend to introduce these clinical studies at trial; they simply argue that "Bard cannot plausibly deny that the results of these recent studies

are relevant and reflective of what clinical studies would have revealed, had Bard not refused to conduct them." (Pls.' Mot. for Clarification [Docket 352], at 14). Furthermore, a review of these scientific studies reveals that they may not be entirely applicable to the instant matter. The product implanted in Ms. Cisson was the Avaulta Plus Posterior Biosynthetic Support System. (*See* Compl. [Docket 1], ¶ 8). The de Tayrac, Cervigni, and Vollebregt studies involved the original Avaulta product, the Culligan study involved the Avaulta Solo product, and the Thomin and Rudnick studies involved the Avaulta Plus Anterior product. To the extent that these products might be sufficiently similar to the Avaulta Plus Posterior product implanted in Ms. Cisson, such an opinion would be appropriately that of an expert witness.[3]

I **FIND** that the application of Federal Rule of Civil Procedure 26 to the plaintiffs' proffer of evidence make any ruling on admissibility premature. Nonetheless, I note again that, based on the arguments set forth in the plaintiffs' brief—and the lack of any expert opinions cited therein—it does not appear that the plaintiffs will be able to lay the foundation for the introduction of failure to test evidence for purposes of their failure to warn claim.

B. ***The Plaintiffs' Design Defect Claim***

The plaintiffs argue that "[e]vidence of Bard's inadequate testing, lack of clinical evidence, and refusal to conduct clinical studies as proposed by its medical advisor is directly relevant – indeed is essential – to Plaintiffs' design defect claim." (*Id.* at 14). Georgia has adopted a multi-factor risk-utility analysis for purposes of determining defect in both negligence and strict liability design defect claims, "in which the risks inherent in the product design are

[3] Bard also argues that the plaintiffs "cannot identify any previously unknown risk or danger that would have been identified by a Bard-conducted human clinical trial" and the plaintiffs "cannot show that Bard's failure to conduct a human clinical trial proximately caused the injuries they allegedly suffered." (Bard's Resp. [Docket 354], at 17). Under the current state of the proffer of evidence, I agree that the plaintiffs have not met their burden to lay a foundation for their failure to test evidence with respect to their failure to warn claim.

balanced against the utility of the designed product and the manufacturer's reasonableness in choosing the design." *Carmical v. Bell Helicopter Textron, Inc.*, 117 F.3d 490, 495 (11th Cir. 1997) (applying Georgia law). The concept of reasonableness in this analysis is based on

> whether the manufacturer acted reasonably in choosing a particular product design, given the probability and seriousness of the risk posed by the design, the usefulness of the product in that condition, and the burden on the manufacturer to take the necessary steps to eliminate the risk.

Banks v. ICI Americas, Inc., 450 S.E.2d 671, 673 (Ga. 1994). In other words, Bard had a duty to exercise reasonable care in choosing the design for the Avaulta product. While there is no *claim* for failure to test under Georgia law, under the risk-utility analysis for design defects, the duty to exercise reasonable care includes the duty to test the product. *See, e.g.*, *Lillebo v. Zimmer, Inc.*, No. 03-2919 (JRT/FLN), 2005 WL 388598, at *8 (D. Minn. 2005); *Nicklaus v. Hughes Tool Co.*, 417 F.2d 983, 986 (8th Cir. 1969); *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089-90 (5th Cir. 1973); *Dartez v. Fireboard Corp.*, 765 F.2d 456, 461 (5th Cir. 1985); *Nicholson v. Am. Safety Util. Corp.*, 476 S.E.2d 672, 676 (N.C. Ct. App. 1996); *Hensley v. Danek Med., Inc.*, 32 F. Supp. 2d 345, 351 (W.D.N.C. 1998); *see also* Restatement (Third) of Torts: Prod. Liab. § 2 cmt. m. (1998) ("Of course, a seller bears responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal.").

Bard ignores the plaintiffs' argument that a failure to test is directly relevant to the risk-utility analysis, focusing instead on the argument that a failure to test *claim* does not survive if the plaintiffs offer insufficient evidence of a product defect. (*See* Bard's Resp. [Docket 354], at 6). The cases cited by Bard are inapposite. Each of these cases involved a situation where a court analyzed the viability of a failure to test *claim*, and are irrelevant to the admissibility of failure to test evidence in the context of a design defect claim. *See, e.g.*, *Oddi v. Ford Motor Co.*, 234 F.3d

136, 144 (3d Cir. 2000) (viewing the plaintiffs' "negligent failure to test" claim as a separate claim and requiring evidence of a defect); *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 9 (S.C. 2010) (finding that where the plaintiffs failed to establish a product was defective and the strict liability claim based on this defect was dismissed, a negligence claim based on failure to test must also be dismissed); *Shires v. Celotex Corp.*, No. 85-7141, 1988 WL 1001970, at *2 (E.D. Pa. Mar. 30, 1988) (granting summary judgment on plaintiff's "negligent failure to test" claim, finding that any duty to test was subsumed within design defect claim); *West v. Broderick & Bascom Rope Co.*, 197 N.W.2d 202, 212-13 (Iowa 1972) (separate "negligent failure to test" charge was erroneously submitted to jury where no evidence was introduced that the product was defective); *McCroy v. Coastal Mart, Inc.*, 207 F. Supp. 2d 1265, 1279 (D. Kan. 2002) (Kansas law, discussing a negligence claim for failure to test and requiring proof of a defect to establish proximate cause).

None of these cases discuss evidence of a failure to test in the context of a risk-utility analysis, where the failure to test (analyzed in conjunction with all of the other factors in the risk-utility analysis) is itself evidence of whether Bard exercised reasonable care in choosing the product design. The risk-utility analysis merely goes to whether a defect exists that the manufacturer should be held liable for. Thus, even if Bard breached its duty under the risk-utility analysis, the plaintiffs must still establish that the defective product proximately caused their injuries. *See, e,g.*, *Boswell v. Overhead Door Corp.*, 664 S.E.2d 262, 263 (Ga. Ct. App. 2008) ("The plaintiff also has the burden of proving the causal connection between the alleged design or manufacturing defect and his injury.").

Accordingly, I **FIND** that the plaintiffs may present evidence of the lack of testing, lack of clinical evidence, and Bard's refusal to conduct clinical testing to support their design defect

claim. I further **FIND** that only evidence regarding pre-market studies is admissible for this purpose. Under Georgia law, a manufacturer of property is liable if "the property *when sold by the manufacturer* was not merchantable and reasonably suited to the use intended . . ." Ga. Stat. Ann. § 51-1-11(b)(1) (emphasis added).[4] If Bard breached its duty to test with respect to the plaintiffs' design defect claims, this breach occurred when Bard sold the Avaulta product. Evidence of studies that Bard failed to conduct post-market simply do not make it any more or less probable that Bard breached its duty to test at the time Bard sold the Avaulta product.

The difference between the plaintiffs' design defect and failure to warn claims merits discussion here. As stated above, and several times previously, Bard had a common law duty to test the Avaulta product prior to sale. The duty to test is subsumed within the plaintiffs' design defect and failure to warn claims. *See, e.g.*, *Lillebo*, 2005 WL 388598, at *8 (duty to test as part of risk-utility analysis); *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 793-94 (E.D. La. 2011) (duty to test as part of duty to warn). Under the plaintiffs' design defect claim, the issue of whether Bard conducted testing bears directly on whether Bard acted reasonably in choosing the design for the Avaulta product. In other words, the mere failure to test is evidence that Bard may have acted unreasonably under the risk-utility analysis. On the other hand, the mere failure to test, without more, is not evidence that Bard breached any duty to warn. Bard only has a duty to warn of any defects of which it had actual or constructive knowledge, and therefore, evidence that testing would have shown certain defects is a necessary prerequisite to establish that Bard had constructive knowledge of the defects.

[4] Failure to warn claims are an exception; the duty to warn of a danger may arise from a "manufacturer's post-sale knowledge acquired months, years, or even decades after the date of the first sale of the product." *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1218 (11th Cir. 1999) (applying Georgia law); *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994).

C. *The Plaintiffs' Punitive Damages Claim*

The plaintiffs argue that Bard's refusal to conduct Dr. Ross's proposed studies "is evidence of a conscious and deliberate choice of profits over patient safety," and "is *prima facie* evidence" of their punitive damages claim. (Pls.' Mot. for Clarification [Docket 352], at 19). As noted above, this is the first time that the plaintiffs have substantively argued the relevancy of this evidence to their punitive damages claim.

I **FIND** that the plaintiffs may present evidence of Bard's refusal to conduct clinical testing in order to support their punitive damages claim. In my June 4, 2013 Memorandum Opinion and Order on Bard's Partial Motion for Summary judgment on the Plaintiffs' Punitive Damages Claims, I stated:

> Bard cites to several cases to support its contention that a failure to test does not provide support for punitive damages. A review of these cases reveals that they simply find that a failure to test, *without more*, provides no support for an award of punitive damages. *See, e.g.*, *Mosser v. Fruehauf Corp.*, 940 F.2d 77, 86 (4th Cir. 1991) ("Factors relevant to the reasonableness of any failure to test . . . bear primarily on the question of negligence and provide no support for an award of punitive damages *in the absence of some evidence of conscious disregard of public safety*.") (emphasis added); *see id.* at 87 ("Many cases from other jurisdictions upholding punitive awards based in part on a failure to test involved aggravating circumstances including, significantly, the manufacturer's failure to act in the face of notice or knowledge of a defect.").

(Mem. Op. & Order [Docket 273], at 19 n.8); *see also Shurr v. A.R. Siegler, Inc.*, 70 F. Supp. 2d 900, 938-39 (E.D. Wis. 1999) (collecting cases and noting that where states upheld an award of punitive damages based on proof of inadequate or defective testing, such proof is "frequently in conjunction with knowledge of actual defects and failure to warn customers of known defects").

Under Georgia law, a "conscious indifference to consequences" is defined as "an intentional disregard of the rights of another, knowingly or willfully disregarding such rights." *Associated Health Sys., Inc. v. Jones*, 366 S.E.2d 147, 152 (Ga. Ct. App. 1988). As explained in

Mosser, "[t]here is a difference between a negligent failure to test and wanton disregard of danger." *Mosser*, 940 F.2d at 87.

The plaintiffs here have provided some evidence in this case that Bard had knowledge of certain defects. Knowledge of such defects, combined with evidence that Bard made a conscious decision to "repeatedly reject[] specific proposals for studies from its own medical advisor that the company needed to validate the safety of the Avaulta products through clinical studies," may show that Bard intentionally, knowingly, or willfully disregarded the plaintiffs' rights, and *may* therefore provide the "more" that is needed to support an award of punitive damages. (Pls.' Mot. for Clarification [Docket 352], at 19).

However, I **FIND** that evidence regarding Bard's refusal to conduct *post-market* testing will be excluded under Federal Rule of Evidence 403 *unless* the plaintiffs are able to lay a foundation for the admissibility of this evidence for the plaintiffs' failure to warn claim. If the plaintiffs are not able to lay a foundation for the admissibility of evidence regarding *post-market* testing, then any probative value that it might have to support the plaintiffs' punitive damages claim is substantially outweighed by the danger of confusing the issues and misleading the jury. Fed. R. Evid. 403.

Finally, I **FIND** that the parties are expressly prohibited from mentioning punitive damages in this matter. At the conclusion of the plaintiffs' case, I will make a determination as to whether the plaintiffs have offered sufficient evidence to present the question of punitive damages to the jury. If I find, at that time, that the question of punitive damages should go to the jury, the parties will be allowed to argue entitlement to punitive damages in their closing statements.

III. Admissible Evidence

After reviewing the plaintiffs' exhibits, and to assist the parties in preparation for trial, I **FIND** that Bard's objections to the plaintiffs' deposition designations in Exhibits 5-10 will be **OVERRULED** insofar as they involve Bard's lack of pre-market testing.[5] As discussed previously, evidence as to Bard's lack of post-market testing is inadmissible for the plaintiffs' design defect claim, and currently inadmissible for the plaintiffs' failure to warn and punitive damages claims. Any other *appropriate* objections will be taken up at trial. At the end of the evidence presented, if the plaintiffs have failed to lay the foundation for pre-market testing evidence for purposes of their failure to warn claim, I will instruct the jury that they may consider this evidence only for the purposes of the plaintiffs' design defect claim (and, subject to my findings above, the plaintiffs' punitive damages claim).

IV. Effect of my Rulings on the FDA 510(k) Evidence

I emphasize that despite my rulings above, evidence related to the FDA 510(k) process remains excluded. As I also explained at the motions hearing on July 7, 2013:

> [The] FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no . . . operative interaction with state tort laws.
>
> Whether the FDA 510(k) process required testing before [or after] marketing has nothing to do with whether Bard satisfied any other obligation under common law to conduct testing and then to do whatever it might have been required to do under law with the results of that testing.

(Mots. Hearing Tr. [Docket 319], at 31:15-31:23). This ruling is consistent with and supported by the Supreme Court's holdings in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and Bard's arguments do not convince me otherwise. In

[5] Exhibits 5 through 10 are "a list of Bard's asserted 'clinical study' objections, along with the corresponding highlighted deposition testimony and documents in question" for Bard witnesses John Deford, Daniel Delaney, Mark Downey, Jennifer Mercuri, Robert Orr, and James Ross. (Pls.' Mot. for Clarification [Docket 352], at 5).

both cases, the Supreme Court held that the FDA 510(k) process does not address safety and effectiveness and therefore did not preempt the plaintiffs' product liability claims, while the premarket approval process *does* address safety and effectiveness and therefore would preempt the plaintiffs' product liability claims, subject to other preemption requirements.[6]

This ruling is further consistent with Georgia law. As I explained in my July 1, 2013 Order regarding Bard's motion for reconsideration:

> Georgia law providing that the jury may consider compliance with federal regulations presumes that the regulations are applicable to the case. The Georgia Pattern Jury Instructions state that the jury "may consider proof of the manufacturer's compliance with federal or state *safety* standards . . ." Georgia Pattern Jury Instruction 62.670 (emphasis added). Similarly, the Restatement (Third) of Torts, Prod. Liab. § 4 states that "a product's compliance *with an applicable product safety statute or administrative regulation* is properly considered . . . ." (emphasis added). The comments to this section explain specifically that the phrase "safety statute or administrative regulation" is meant to encompass ones "that establish binding safety standards for the design and marketing of products." *Id.* § 4 cmt. a. Similarly, "the safety statute or administrative regulation must be such that compliance reduces the risk that caused the plaintiff's harm." *Id.* § 4 cmt. c.

(Order [Docket 309], at 3). In sum, Bard had a duty to test the Avaulta product as part of the risk-utility analysis assessing the reasonableness of its conduct independent of the FDA 510(k) process. The FDA 510(k) process is simply inapplicable and irrelevant to whether Bard acted reasonably in selecting the design of its product.

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[6] Bard has consistently argued that the Supreme Court has stated that the 510(k) process does go to safety and effectiveness, quoting from *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The sentence Bard focuses on states that:

> [T]he FDA simultaneously maintains the exhaustive PMA and the more limited § 510(k) processes in order to ensure both that medical devices are reasonably safe and effective and that, if the device qualifies under the § 510(k) exception, it is on the market within a relatively short period of time.

Id. at 349-50. Despite this statement, *Buckman* did not clearly overrule *Lohr* on the issue of whether the FDA 510(k) process addresses safety and effectiveness, and *Riegel* re-stated the holding in *Lohr* without any reference to *Buckman* or suggestion that *Buckman* overruled *Lohr* on this issue. In sum, the current state of Supreme Court precedent on the issue of whether the FDA 510(k) process addresses safety and effectiveness is very clear: it does not.

V. Conclusion

For the reasons discussed above, it is **ORDERED** that the Plaintiffs' Motion for Clarification [Docket 352] is **GRANTED** as discussed herein.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: July 23, 2013

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE