

**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
Queen, et al. v. C. R. Bard, Inc.	2:11-cv-00012
Rizzo, et al. v. C. R. Bard, Inc.	2:10-cv-01224
Jones v. C. R. Bard, Inc.	2:11-cv-00114

ORDER

(C. R. Bard, Inc.'s Motion for Clarification and Reconsideration)

Pending before the court is Defendant C. R. Bard, Inc.'s ("Bard") Motion for Clarification and Reconsideration of the Court's Order Granting Plaintiffs' Motion in Limine No. 1, or, Alternatively, Request for Certificate of Interlocutory Review [Docket 303].¹ The plaintiffs have responded, and the motion is ripe for review. For the reasons discussed below, Bard's motion is **GRANTED** insofar as it seeks reconsideration but **DENIED** otherwise.

After review, my rulings on evidence related to the 510(k) process and enforcement remain the same: all of the evidence related to the 510(k) process and enforcement is excluded under Federal Rules of Evidence 402 and 403. Bard's motion *in limine* No. 5 is clarified to be denied without prejudice, rather than simply denied. Finally, for reasons appearing to the court,

¹ Docket numbers cited herein refer to the documents in the *Cisson* case. Identical motions are also pending in *Queen* [Docket 307], *Rizzo* [Docket 336], and *Jones* [Docket 324], and this Memorandum Opinion and Order applies to those cases as well.

Bard's request for the court to certify the ruling for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) is **DENIED**.

I. Background

On June 27, 2013, I entered a Memorandum Opinion and Order in all four bellwether cases, which ruled on the parties' motions *in limine* and excluded all evidence related to the FDA 510(k) process and enforcement under Federal Rule of Evidence 403. Bard now seeks clarification and reconsideration, arguing that my Order "has unintended consequences that will radically and disproportionately affect the fairness of this trial." (Bard's Motion for Clarification & Reconsideration [Docket 303], at 1).

II. Discussion

Bard makes two primary arguments: (1) evidence of its compliance with federal regulations is "critical to" its defense against the plaintiffs' design defect and punitive damages claims; and (2) my Order conflicts with other rulings, creates an unfair playing field, and has practical implications for the trial of this matter. I will discuss these arguments in this order, as the discussion on the first issue directly relates to the second.

A. Evidence Regarding the FDA 510(k) Process and Enforcement

Bard argues that under the laws of many states, including Georgia, "Bard's compliance with federal regulations, including the 510(k) process, is prima facie evidence of the reasonableness of Bard's actions." (Bard's Mot. for Clarification & Reconsideration [Docket 303], at 8). For example, Georgia law identifies a variety of factors to be considered by the trier of fact in the "risk-utility" test to determine whether a product was defectively designed. *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 673-74 & n.6 (Ga. 1994). One such factor is the "manufacturer's proof of compliance with industry-wide practices, state of the art, or federal

regulations.” *Id.*; *see also Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 519 (Ga. 1997); *Duren v. Paccar, Inc.*, 549 S.E.2d 755, 757-58 (Ga. Ct. App. 2001) (identifying “compliance with federal standards or regulations” as one factor, among many, that the jury may consider in deciding the question of reasonableness).

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.

Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-49 (1996); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). There is ample case law discussing *Lohr* and finding that (1) the 510(k) process does not go to whether the product is safe and effective and (2) the 510(k) process does not impose any requirements on its own. *See, e.g., Martin v. Am. Med. Sys., Inc.*, 116 F.3d 102, 104 (4th Cir. 1997); *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 794 (8th Cir. 2001); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 747 n.6 (E.D. Pa. 2007); *Nicoll v. I-Flow, LLC*, No. 12-

1593, 2013 WL 2477032, at *3 (E.D. La. June 7, 2013); *Mack v. Stryker Corp.*, 893 F. Supp. 2d 976, 985 (D. Minn. 2012).² Because the FDA 510(k) process does not go to whether the Avaulta products are safe and effective and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues. My original ruling stands and evidence pertaining to the 510(k) process and enforcement is excluded.

B. Other FDA-Related Evidence

I now clarify my rulings regarding the scope of admissible FDA-related evidence. I first note that with respect to Bard's argument regarding Dr. David Kessler's testimony, my *Daubert* opinion expressly stated that "my rulings *not to exclude* expert opinions are not dispositive of their admissibility. In other words . . . they may still be excluded under Rule 403 or some other evidentiary rule." (Mem. Op. & Order [Docket 274], at 81). My ruling that evidence related to the FDA 510(k) process and enforcement is excluded under Rule 403 is thus entirely consistent with my prior ruling. Moreover, I emphasized in my rulings on the parties' motions *in limine* that for certain pieces of evidence, "a blanket exclusion . . . would be premature at this time." (Mem. Op. & Order [Docket 302], at 3). I therefore denied many of the parties' motions *in limine* without prejudice so that the parties could explicitly bring the issue up at a later point in time if appropriate. I made no findings that the additional FDA related evidence was "permitted" or "admissible." (Bard's Mot. for Clarification & Reconsideration [Docket 303], at 2). Bard's motions *in limine* No. 10, dealing with the FDA 522 order, and No. 14, dealing with adverse event reports, and medical device reports were expressly denied without prejudice. It appears

² In contrast, for example, two of the Georgia cases cited *supra* dealt specifically with safety standards. See *Duren*, 549 S.E.2d at 757-58; *Doyle*, 481 S.E.2d at 519.

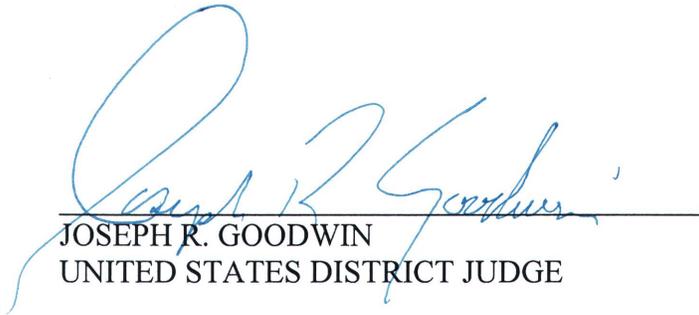
that, with regard to FDA-related evidence, only Bard's motion *in limine* No. 5 regarding the FDA's Public Health Notifications and Advisory Committee Meeting was fully denied. Accordingly, I clarify that Bard's motion *in limine* No. 5 is denied *without prejudice*.

III. Conclusion

For the reasons discussed above, it is **ORDERED** that Bard's motion for clarification and reconsideration (*Cisson* [Docket 303], *Queen* [Docket 307], *Rizzo* [Docket 336], *Jones* [Docket 324]) is **GRANTED** insofar as it seeks reconsideration but **DENIED** otherwise. After review, my rulings on evidence related to the 510(k) process and enforcement remain the same: all of the evidence related to the 510(k) process and enforcement are excluded under Federal Rules of Evidence 402 and 403. Bard's motion *in limine* No. 5 is clarified to be denied without prejudice, rather than simply denied. Finally, it is **ORDERED** that Bard's request for the court to certify the ruling for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) is **DENIED**.

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

ENTER: July 1, 2013



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE