UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE DISTRICT OF COLUMBIA, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW HAMPSHIRE, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, ex rel. WILLIAM ST. JOHN LACORTE,	CIVIL ACTION
VERSUS	NO. 11-1250
C.R. BARD, INC. and BARD ACCESS SYSTEMS, INC.	SECTION "N" (3)

ORDER AND REASONS

Presently before the Court is Defendants' "Motion to Dismiss the First Amended Complaint" (Rec. Doc. 60). For the reasons stated herein, **IT IS ORDERED** that the motion is **GRANTED IN PART** and **DENIED IN PART**.

As recounted in the Court's prior Order and Reasons (Rec. Doc. 40), Relator purports to allege claims under the False Claims Act, 31 U.S.C. §3729, *et seq.*, the anti-kickback provision of the Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. §1320a-7b, and various

states' false claims act statutes. In short, Relator asserts that Defendants fraudulently induced regulatory clearance of their medical devices. Thereafter, Relator contends, Defendants employed a fraudulent scheme to bring about the medically unnecessary prescription and implantation of these devices in violation of federal law. The Court's prior ruling identified various pleading deficiencies in Relator's original complaint warranting dismissal of his claims without prejudice to his right to cure those deficiencies by amendment.

Subsequent to the Court's prior ruling, Relator filed a voluminous amended complaint, consisting of approximately 500 paragraphs, and including 650 pages of attachments. See Rec. Doc. 45. The instant motion, again seeking dismissal pursuant to Rules 8, 9, and 12(b)(6) of the Federal Rules of Civil Procedure, followed. Having expended *numerous* hours carefully reviewing the parties' voluminous submissions and cited authorities, the Court, preferring to err on the side of caution, given that the present determination considers the allegations of Relator's complaint, rather than summary judgment submissions, declines to dismiss certain of Relator's claims at this stage of the proceeding.[1]

Specifically, Defendants' motion is denied relative to Relator's False Claims Act assertions[2] concerning alleged misrepresentations regarding whether the labels and instructions accompanying Defendants' reverse-taper PICC lines sufficiently notify health care providers using and prescribing Defendants' products that the maximum diameter of the proximal end of the PICC

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[1] The Court's original Order and Reasons (Rec. Doc. 40) recites the legal standards governing motions seeking relief under Rules 8, 9 and 12(b)(6), and the pertinent text of the False Claims Act. In the interest of brevity, given that the applicable legal principles do not appear to be disputed, the Court did not restate them herein.

[2] The pertinent claims are those asserted under 31 U.S.C. §3729(a)(1)(A) and (B).

line exceeds the French size reflected on the product label and the increased associated risks. The related claim that Defendants' ultrasound machines (marketed for use with Defendants' reverse-taper products) select catheters that are too large for patients' blood vessels, because of the reverse-taper design, likewise presently survives dismissal. Additionally, the motion to dismiss is denied relative to Defendants' alleged misrepresentations regarding factors determining the propriety of the various vascular access device for patients – particularly, the infusate characteristics of certain drugs and certain health conditions, including acute renal failure, liver transplants or liver disease, and prior thromboses – as well as any misrepresentations regarding the various devices' costs and other risk factors. Finally, the motion is denied relative to allegations that Defendants improperly instructed health care providers regarding proper creation and/or retention of patient medical records.

In denying Defendants' motion in these particular respects, the Court again emphasizes that the instant ruling certainly does not insulate Relator's claims from dismissal by means of a properly supported motion for summary judgment. Furthermore, as stated above, the motion to dismiss also is granted relative to several of Relator's claims based on his failure to rectify certain material deficiencies previously identified in the Court's prior Order and Reasons. Specifically, regarding Defendants' pre-market clearance notifications to the Food and Drug Administration ("FDA"), Relator's allegations remain insufficient to warrant a reasonable inference that pertinent FDA personnel, considering industry norms, were not adequately advised that the maximum diameter of the proximal end of the PICC line exceeds the French size reflected on the product label. This is particularly true given the information provided in Defendants' FDA submission describing the product design modification – that is, a reverse tapered section of the

catheter exhibiting a "gradual increase in diameter" such that it is "larger than the rest of the catheter tubing," – and noting a "slightly increased risk of mechanical phlebitis" because the reverse "tapered . . . segment of the catheter can be inserted into the vessel [.]"[3] The FDA submission also contains drawings, including a proposed labeling change, reflecting the increasing "reverse taper" section of the catheter and that at least part of it is to be (or may be) inserted into the patient's vessel.[4] To conclude otherwise would require the Court to assume that pertinent FDA personnel were not sufficiently knowledgeable to properly evaluate Defendants' pre-market clearance submissions and, if warranted, to require additional information regarding any areas of uncertainty concerning matters identified as posing a "new potential cause for failure."[5] Absent pertinent allegations supporting the validity of such an assumption, this the Court will not do.[6]

Except as stated above, Defendants' motion is likewise granted relative to Defendants' averred scheme to induce medically unnecessary use of their PICC's by means of training materials, product literature, and other marketing tools. As presented, the pertinent allegations of Relator's amended complaint do not allow the Court to reasonably infer the occurrence of unlawful conduct.

Finally, Relator's amended complaint fails to remedy the pleading deficiencies outlined in the Court's prior Order and Reasons relative to the False Claims Act conspiracy claim,

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[3] See Rec. Doc. 45-22, pp. 12-23.

[4] *Id.*, pp. 13-16 and 20.

[5] *Id.*, p. 23.

[6] Relator's amended complaint also does not allege any FDA recall of Defendants' reverse-taper designs (or other adverse regulatory action) since they were submitted for pre-clearance in 2001.

brought pursuant to 31 U.S.C. §3729(a)(1)(C), the anti-kickback provision of the Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. §1320a-7b, and the claims asserted under state law (except Count XIII, which is asserted under Louisiana law).[7] Accordingly, Defendants' motion also is granted relative to these claims.

New Orleans, Louisiana, this 29th day of September 2014.

KURT D. ENGELHARDT
United States District Judge

[7] The parties' submissions do not discuss the particulars of the purported Louisiana law claim. To the extent that the Louisiana provision is consistent with the federal statutes governing Relator's federal law claims, the Court's rulings regarding the federal claims likewise apply to the state law claim. To the extent that Defendants believe applicable legal principles otherwise warrant dismissal of the Louisiana law claim in its entirety, such relief must be sought by means of a separate, properly supported, motion.