

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

ROBERT STRINI and TERRY STRINI,

Plaintiffs,

v.

No. 05-CV-440
(GLS/DRH)

EDWARDS LIFESCIENCES CORPORATION;
EDWARDS LIFESCIENCES LLC; and
EDWARDS LIFESCIENCES (U.S.), INC.,

Defendants.

APPEARANCES:

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**DAVID R. HOMER
U.S. MAGISTRATE JUDGE**

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MEMORANDUM-DECISION AND ORDER

Presently pending are the motions of (1) plaintiffs Robert and Terry Strini ("Strinis")

and defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.), Inc. (collectively “Edwards”) to compel non-party St. Peter’s Hospital (“St. Peter’s”) to produce certain documents, and (2) St. Peter’s for a protective order precluding disclosure of such documents. Docket Nos. 66, 81. For the reasons which follow, the joint motion of the Strinis and Edwards is denied and St. Peter’s motion is granted.

I. Background

On April 9, 2002, Robert Strini underwent cardiac surgery at St. Peter’s in Albany, New York for replacement of an aortic valve. The surgery included replacement of Robert Strini’s defective valve with a bioprosthetic bovine valve (“valve”) manufactured by Edwards. Upon release from St. Peter’s, Robert Strini began to exhibit symptoms of infection. The symptoms persisted and in August 2002, Robert Strini was re-admitted to St. Peter’s. When tests indicated that the symptoms were caused by the valve, a second surgery was performed on August 9, 2002 and the valve was removed. The Strinis allege that as a result, Robert Strini suffered “an aneurysm, significant blood loss, and intraoperative strokes which left him confined to a nursing home” and “unable to walk.” Kunz Aff. (Docket No. 76(1)) at ¶ 3. Following removal, the valve was tested and found to be contaminated with mycobacterium appearing as vegetative growth on the valve.

During the times at issue in this case, St. Peter’s had in place a Patient Safety and Quality Improvement Committee formed pursuant to the mandates of state and federal laws. Coleman Aff. (Docket No. 81(3)) at ¶¶ 1, 7. There also existed within St. Peter’s an Infection Control Committee. *Id.* at ¶ 2. After the removal of the valve on August 9, 2002

and the discovery of the contamination, both committees conducted certain inquiries regarding the cause of the contamination and the procedures followed leading to its implantation in Robert Strini. Those inquiries did not lead to the generation of any formal reports. Id. at ¶ 9; see also Fuld Aff. (Docket No. 81(2)) at ¶ 6. The two committees did generate a total of four pages of records recording information received concerning the contaminated valve. Those four pages along with an affidavit of the record-keeper have been submitted to the Court for its ex parte, in camera review.¹ Those four pages constitute the documents at issue on these motions.²

II. Discussion

St. Peter's contends that the documents sought by the parties are protected from disclosure by N.Y. Pub. Health Law § 2805-m (McKinney 2002) and N.Y. Educ. Law § 6527(3) (McKinney Supp. 2006).

¹The Clerk is directed to file the affidavit and four pages of documents under seal.

²On April 25, 2006, Dr. Russell E. Newkirk testified that to his knowledge, reports concerning the contaminated valve had been prepared at St. Peter's by the hospital's Infection Control Committee and its Risk Management Committee. Novotny Letter (Docket No. 66) at 1. However, St. Peter's has submitted affidavits from the appropriate employees. See Fuld Aff.; Coleman Aff. They assert without qualification that Dr. Newkirk was mistaken and that the only documents regarding any investigation of the contaminated valve undertaken by St. Peter's is contained in the four pages submitted to the Court. Fuld Aff. at ¶¶ 5-7 (asserting that there is no Risk Management "Committee," there exists a Risk Management "Department," and the Risk Management Department prepared no report concerning the contaminated valve); Coleman Aff. at ¶¶ 8-10 (asserting that, contrary to Dr. Newkirk's testimony, the Infection Control Committee did not prepare any report as the result of any investigation of the contaminated valve). Accordingly, Dr. Newkirk's testimony that reports of investigation existed at St. Peter's was incorrect. The only documents regarding St. Peter's inquiries into the matter are contained in the four pages submitted to the Court ex parte and in camera.

New York law requires that each hospital maintain a quality assurance program to “review the services rendered in the hospital in order to improve the quality of medical, dental and podiatric care of patients. . . .” N.Y. Pub. Health Law § 2805-j (McKinney 2002); see also N.Y. Comp. Codes R. & Regs. tit. 10, § 405.6 (2006) (establishing Department of Health regulations to implement this mandate). Participation by a hospital in the Medicare program carries a similar federal requirement. See 42 C.F.R. § 482.21 (2006). Included within the quality assurance review function is the identification, prevention, and control of infection. See N.Y. Comp. Codes R. & Regs. tit. 10, § 405.6(b)(4). To encourage candor by those participating in the quality assurance program, state law has accorded such information a statutory protection in both N.Y. Pub. Health Law § 2805-m and N.Y. Educ. Law § 6527(3). Those provisions direct both the hospitals (§ 2805-m) and those individuals involved in the quality assurance programs (§ 6527(3)) to maintain the confidentiality of both documents and discussions within the purview of the program.³

In opposition to this contention, the parties argue that these statutory protections are inapplicable to the St. Peter’s documents here. The parties contend that these protections were created to protect hospitals’ quality assurance programs from disclosure and use in medical malpractice actions brought against hospitals and their physicians. Thus, the parties contend that because no claims have been brought against St. Peter’s or any of its

³The parties do not dispute that the statutory privileges created in the Public Health and Education laws govern the question of privilege raised by this motion. See Fed. R. Evid. 501 (“[I]n civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness . . . shall be determined in accordance with State law.”); see also Ryan v. Staten Island Univ. Hosp., No. 04-CV-2666 (ENV), 2006 WL 1025890, at *2 (E.D.N.Y. Apr. 13, 2006); Tartaglia v. Paul Revere Life Ins. Co., 948 F. Supp. 325, 326-27 (S.D.N.Y.1996).

physicians relating to their treatment of Robert Strini, the statutory protections are inapplicable to St. Peter's documents and do not protect them from disclosure.

For at least two reasons, the parties' contention must be rejected. First, the record is undisputed, and a review of the St. Peter's documents confirms, that those documents were prepared as part of St. Peter's quality assurance and infection control programs. Without more, then, the protections of the Public Health and Education Laws apply to the documents here. See Katherine F. v. State of New York, 94 N.Y.2d 200, 204-05 (1999) (holding that the Education Law protection applies to reports of sexual abuse consistent with its purpose "to promote the quality of care through self-review without fear of legal reprisal."); Logue v. Belez, 92 N.Y.2d 13, 17-18 (1998) (same as to Public Health Law); Crea v. Newfane Inter-Cmty. Mem. Hosp., 224 A.D.2d 976, 977 (4th Dep't 1996) ("There is no merit to the contention of plaintiff that, because her action is for breach of contract and does not concern the care and delivery of medical services, Public Health Law § 2805-m is inapplicable."). Thus, medical malpractice prevention is not the sole purpose of either statutory protection and the pendency or possibility of a medical malpractice claim is not a requirement for the applicability of either provision. Where, as here, a document was generated to insure and improve the quality of care to patients, that document is protected from compelled disclosure by the Public Health and Education Laws even in the absence of a formal claim of medical malpractice.

Second, even assuming that the existence of a pending or possible medical malpractice claim against the hospital or its physicians is required by these statutes, that requirement is satisfied here. Although the Strinis acknowledge that they can no longer bring a medical malpractice claim against St. Peter's or its physicians, see Pls. Mem. of Law

(Docket No. 76(6)) at 18, 21, Edwards may still pursue St. Peter's and its physicians for contribution and indemnity in the event of an adverse judgment. The fact that medical malpractice is not yet alleged in the action does not foreclose the possibility that such a claim could be made later as a result of what is disclosed in the St. Peter's documents or based on evidence from other sources. Moreover, the Strinis assert that their purpose for seeking the St. Peter's documents is "to rule out a possible [alternative] source of the contamination of the heart valve." Id. at 22. However stated, this very purpose raises issues of medical malpractice in the maintenance and implantation of the valve. For whatever reasons, both the Strinis and Edwards have opted not to assert any claims of medical malpractice directly against St. Peter's or its physicians to date. Nevertheless, although not yet explicitly contended by the parties, medical malpractice by St. Peter's and its physicians remains an issue both as to causation and as to contribution and indemnity. The present absence of a formal claim of medical malpractice cannot obviate this fact.

Therefore, both because an allegation of medical malpractice is not a prerequisite for invoking the protections of the Public Health and Education Laws and because, even if required, such allegations of medical malpractice are sufficiently present in this case, the parties' contentions that these statutory protections are inapplicable here must be rejected.

III. Conclusion

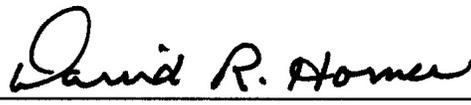
For the reasons stated above, it is hereby

ORDERED that the joint motion of the parties to compel St. Peter's to disclose certain documents (Docket No. 66) is **DENIED**, and St. Peter's motion for a protective order

precluding disclosure of such documents (Docket No. 81) is **GRANTED**.

IT IS SO ORDERED.

DATED: December 19, 2006
Albany, New York



United States Magistrate Judge