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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FIVE

POMONA VALLEY HOSPITAL MEDICAL CENTER, Petitioner, v. THE SUPERIOR COURT OF LOS ANGELES COUNTY, Respondent; APRIL CHRISTINE CABANA, Real Party in Interest.	No. B241684 (L.A. Super. Ct. No. BC465313)

ORIGINAL PROCEEDINGS; petition for writ of mandate. Michael P. Linfield, Judge. Writ granted.

Lewis, Brisbois, Bisgaard & Smith, L. Susan Snipes and Judith M. Tishkoff for Petitioner.

Baum, Hedlund, Aristei & Goldman, Ronald L.M. Goldman, Bijan Esfandiari and A. Ilyas Akbari for Real Party in Interest.

No appearance for Respondent.

Petitioner Pomona Valley Hospital Medical Center (the Hospital) contends the records of its institutional review board (IRB) are exempt from discovery under the protection of Evidence Code section 1157[1] for records of organized committees of medical staffs that have the responsibility of evaluation and improvement of the quality of care rendered in the Hospital. The Hospital seeks a writ of mandate directing respondent court to vacate its order compelling interrogatory responses and production of documents concerning information held solely by the Hospital's IRB. We hold the IRB is a medical staff committee whose records are exempt from discovery under section 1157. Therefore, we grant the petition.

BACKGROUND

Regulatory Scheme

In order to engage in biomedical research under federal law, a hospital must have an IRB to approve and provide continuing review of clinical investigations. An IRB is "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects." (21 C.F.R. § 56.102(g).) An IRB is also referred to under federal law as an "institutional review committee." (*Ibid.*)

In addition to approving and monitoring clinical investigations, the IRB's responsibilities include requiring documentation of informed consent from subjects (21 C.F.R. § 56.109(b), (c)) and maintaining certain records (21 C.F.R. § 56.115). The records must be retained for at least three years after the research has been completed and must be accessible for inspection and copying by the United States Food and Drug Administration (FDA). (21 C.F.R. § 56.115(b).) The FDA may refuse to consider an

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[1] All further statutory references are to the Evidence Code, unless otherwise stated.

application if the IRB or institution doesn't comply with the federal regulations. (21 C.F.R. §§ 56.115(c), 56.120, 56.121.)

An IRB must be composed of at least five members of varying backgrounds, including one member who is not affiliated with the hospital and one member whose primary concern is non-scientific. (21 C.F.R. § 56.107(a)-(d).) "In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice." (21 C.F.R. § 56.107(a).)

California law similarly requires that medical research projects must have "the prior approval of a broadly represented committee which shall assure maximum patient safety and understanding." (Cal. Code Regs., tit. 22, § 70708.)

Facts and Procedural History

The Hospital is a licensed acute care hospital with a governing body and an organized medical staff. The Hospital's bylaws define "medical staff or staff" as "the formal organization of all licensed physicians, dentists, and podiatrists who are privileged to attend patients in the Hospital." The bylaws establish several committees, including an IRB. The president of the medical staff is responsible for selecting IRB members pursuant to the bylaws. The membership must consist of physicians representatives of the board of directors, hospital administration, nursing administration, the director of pharmacy, and at least two lay persons from the community. The members of the IRB must be capable of judging the acceptability of clinical investigations with respect to institutional requirements, standards of professional practice, and community acceptance. The stated purpose of the IRB is to provide assurance to the medical staff, the governing board, and the community that the rights and welfare of patients involved in investigational studies are protected and patients are fully informed about the risks involved in the investigational study before they consent. The IRB is charged with

responsibility for the evaluation and approval of proposed investigational studies, as well as monitoring ongoing studies. It is the IRB's duty to require that each patient be adequately informed of the nature of the study and the possible side effects, risks and consequences of an investigational drug or device. It is also the IRB's duty to require that each patient sign an informed consent.

In September 2008, plaintiff and real party in interest April Cabana had a surgical procedure to correct back pain through the fusion of two vertebrae. According to the allegations of the complaint, Cabana's surgeon used a combination of two medical products during the surgery: a putty to promote bone growth and a bone void filler. The FDA had granted limited approvals for use of the putty and the filler individually, but not in combination. The putty is an investigational device that was granted a humanitarian device exemption by the FDA. Therefore, the Hospital's IRB was required to review and approve the use of the putty before Cabana's physician could use it. However, Cabana did not receive any consent form or information about the products that were used. The product migrated to other areas of her body and she experienced excessive bone growth that she attributes to the combined medical products. The bone growth required additional surgery in July 2009. Her surgeon used a different bone graft product during the second surgery in a manner that was not approved. Cabana has never recovered from the surgeries and continues to suffer from disabling pain.

Cabana filed a negligence complaint on July 13, 2001, against several defendants. On October 11, 2011, she filed an amendment to the complaint naming the Hospital as a Doe defendant. Cabana sought responses to interrogatories and production of documents from the Hospital concerning communications with the manufacturer of the putty and approval of the putty for use in treatment. The Hospital objected on the ground that any documents required to provide responses were possessed by the IRB and the IRB was a committee of the Hospital's organized medical staff. Therefore, the Hospital argued, the information was exempt from discovery under the protection of section 1157 for the records of an organized committee of medical staff or a peer review body having the responsibility of evaluation and improvement of the quality of care.

In April 2012, Cabana filed a motion to compel the Hospital to provide responses to the interrogatories and produce documents. Cabana asserted that the IRB is not medical staff as defined under section 1157, because federal law requires the IRB to include at least one person who is not a scientist and one person who is not affiliated with the Hospital. Cabana also argued that the IRB is not a peer review committee, because its function is not to review medical peers.

The Hospital opposed the motion on the ground that the language of section 1157 protected the records of both medical staff and peer review committees, and the IRB was a medical staff committee, even though it included community members who were not physicians. Cabana responded that the Hospital could not have any expectation of confidentiality as to the requested documents, because the documents had already been disclosed to unaffiliated third parties or were accessible by third parties. Cabana also argued that the Hospital's objection conflicted with California and federal laws mandating transparency and disclosure.

A hearing was held on May 15, 2012. The trial court concluded that the IRB was not a medical staff committee because the committee members included lay people. Therefore, the court found that section 1157 did not apply to IRBs. The court granted the motion to compel further responses and produce documents. The Hospital filed a petition for a writ of mandate seeking to compel the trial court to vacate its order.

DISCUSSION

Standard of Review

In general, we review the trial court's ruling on a motion to compel discovery for an abuse of discretion, because the trial court is vested with wide statutory discretion to manage discovery. (*John B. v. Superior Court* (2006) 38 Cal.4th 1177, 1186.) "In addition, if the trial court reached its decision after resolving conflicts in the evidence, or inferences that could be drawn from the evidence, we review those factual findings to

determine whether they are supported by substantial evidence. [Citation.]" (*County of Los Angeles v. Superior Court* (2006) 139 Cal.App.4th 8, 12.)

However, "where the propriety of a discovery order turns on statutory interpretation, an appellate court may determine the issue de novo as a question of law. [Citation.]" (*Britts v. Superior Court* (2006) 145 Cal.App.4th 1112, 1123.) "In construing a statute, a court's 'task is to ascertain the intent of the Legislature so as to effectuate the purpose of the enactment. [Citation.] We look first to the words of a statute, which are the most reliable indications of the Legislature's intent. [Citation.] We construe the words of a statute in context, and harmonize the various parts of an enactment by considering the provision at issue in the context of the statutory framework as a whole. [Citations.]' [Citation.] When statutory language is capable of more than one construction, courts must '"'give the provision a reasonable and commonsense interpretation consistent with the apparent purpose and intention of the lawmakers, practical rather than technical in nature, which upon application will result in wise policy rather than mischief or absurdity.'" [Citations.]' [Citation.]" (*Ibid.*)

Applicability of Section 1157

The Hospital contends that the proceedings and records of the IRB are subject to the protection of section 1157 for organized committees of medical staffs having the responsibility of evaluation and improvement of the quality of care rendered in the Hospital. We agree.

Section 1157, subdivision (a), states in pertinent part that "[n]either the proceedings nor the records of organized committees of medical . . . staffs in hospitals . . . having the responsibility of evaluation and improvement of the quality of care rendered in the hospital . . . shall be subject to discovery."[2]

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[2] Section 1157, subdivision (a) states: "Neither the proceedings nor the records of organized committees of medical, medical-dental, podiatric, registered dietitian, psychological, marriage and family therapist, licensed clinical social worker, professional

Section 1157 embodies the Legislature's belief that "external access to peer investigations conducted by staff committees stifles candor and inhibits objectivity" and that the quality of in-hospital medical practice is improved by insulating staff investigations with confidentiality. (*Matchett v. Superior Court* (1974) 40 Cal.App.3d 623, 629; cf. *County of Los Angeles v. Superior Court, supra,* 139 Cal.App.4th at p. 14 [the Legislature enacted section 1157.6 to provide county mental health professionals with the same immunities that protect hospital medical staffs serving on quality assurance committees].) "This confidentiality exacts a social cost because it impairs malpractice plaintiffs' access to evidence. In a damage suit for in-hospital malpractice against doctor or hospital or both, unavailability of recorded evidence of incompetence might seriously jeopardize or even prevent the plaintiff's recovery. Section 1157 represents a legislative choice between competing public concerns. It embraces the goal of medical staff candor at the cost of impairing plaintiffs' access to evidence." (*Matchett v. Superior Court, supra,* at p. 629, fn. omitted.)

Although membership on a "medical staff" may be restricted by statute to physicians and other licensed practitioners, this statutory requirement does not preclude the medical staff from organizing a committee which includes people other than licensed practitioners. (*Santa Rosa Memorial Hospital v. Superior Court* (1985) 174 Cal.App.3d 711, 718-719 (*Santa Rosa*).) The proceedings and records of the committee are

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clinical counselor, or veterinary staffs in hospitals, or of a peer review body, as defined in Section 805 of the Business and Professions Code, having the responsibility of evaluation and improvement of the quality of care rendered in the hospital, or for that peer review body, or medical or dental review or dental hygienist review or chiropractic review or podiatric review or registered dietitian review or veterinary review or acupuncturist review committees of local medical, dental, dental hygienist, podiatric, dietetic, veterinary, acupuncture, or chiropractic societies, marriage and family therapist, licensed clinical social worker, professional clinical counselor, or psychological review committees of state or local marriage and family therapist, state or local licensed clinical social worker, state or local licensed professional clinical counselor, or state or local psychological associations or societies having the responsibility of evaluation and improvement of the quality of care, shall be subject to discovery."

protected, even though the committee includes members who are not part of the medical staff. (*Ibid.*)

In *Santa Rosa*, the court considered whether the proceedings and records of an infection control committee were protected by section 1157, even though a majority of the committee members were not licensed practitioners. (*Santa Rosa, supra,* 174 Cal.App.3d at pp. 718-719.) The *Santa Rosa* court explained that "Section 1157, by its express terms, is in no way limited to medical staff committees composed solely, or primarily, of physicians. Nor, as a practical matter, are physicians the only health care professionals qualified to participate in the vital functions of such committees. Pursuant to the [h]ospital's medical staff bylaws, which are in accord with the standards of the [Joint Commission on Accreditation of Hospitals], the infection control committee is clearly a 'medical staff committee.' We reject the contention that the fact the committee is composed of a majority of personnel who are not physicians removes it for that reason alone from the ambit of section 1157." (*Ibid.*)

The facts of *Mt. Diablo Hospital Dist. v. Superior Court* (1986) 183 Cal.App.3d 30 (*Mt. Diablo*) are similar to the present case. The hospital in *Mt. Diablo* established a special medical staff committee to evaluate and approve standards for allowing physicians to use a particular drug in treatments at the hospital. (*Id.* at p. 33.) The *Mt. Diablo* court found that the protections of section 1157 were not limited to peer review of the past performance of human beings. (*Id.* at p. 34.) Section 1157 also protects the proceedings and records of a committee charged with reviewing the safety and efficacy of a medical product prior to allowing the use of the product by doctors in the hospital. (*Ibid.*) "The terms 'evaluation and improvement of the quality of care rendered in the hospital' cannot reasonably be construed to exclude consideration of standards for new physician treatments and drug care." (*Ibid.*, fn. omitted.)

The IRB in the present case evaluates the proposed use of experimental devices before physicians may use them at the Hospital, monitors the ongoing use of the devices, and ensures that patients are provided informed consent about use of the devices. The IRB's activities are necessary to evaluate and improve the quality of care rendered to

patients at the Hospital who are receiving experimental treatments. Section 1157 was enacted to protect the proceedings and records of medical staff committees, in order to encourage candor in their discussion and evaluation of medical treatments and patient care. The express language of section 1157 does not limit its protections to committees composed solely of licensed practitioners. The Legislature's goal to encourage candor and objectivity for committees performing these functions is not altered by the inclusion of lay people as committee members. The inclusion of lay people on the IRB who are not affiliated with a hospital is likely to increase objectivity, leading to increased patient protection and improved quality of care. The Hospital's inclusion of lay people who are not affiliated with the Hospital on the IRB as required by federal law does not void the protection of section 1157. Fundamentally, the IRB is a committee formed by the medical staff of the Hospital, whose membership is dictated by the Hospital's bylaws within the parameters of federal law, with the responsibility of evaluation and improvement of the quality of care rendered in the Hospital. The fact that certain IRB records are accessible by the FDA also does not negate the exemption of section 1157 as to discovery of those records in civil actions. Therefore, we conclude that the IRB is a committee of medical staff of the Hospital whose proceedings and records are exempt from discovery under section 1157.

The out-of-state federal authority which Cabana relies upon, *Konrady v. Oesterling* (1993) 149 F.R.D. 592 (*Konrady*), is readily distinguishable. In *Konrady,* a federal magistrate considered whether an IRB was a "review organization" under Minnesota's peer review statute. The statute defined a review organization as "[A] committee whose membership is limited to professional and administrative staff, except where otherwise provided for by state or federal law, and which is established by a hospital [or other specified entity] to gather and review information relating to the care and treatment of patients for the purposes of: [¶] (a) evaluating and improving the quality of health care rendered in the area or medical institution . . . ." (*Id.* at pp. 593-594, fn. omitted.) The court concluded that the IRB was not a review organization under Minnesota law, because it did not conduct "peer review." (*Id.* at p. 596.) Also, since the

FDA had the authority to disclose an adverse effect report upon request or its own initiative and the IRB had to provide access to certain information for FDA inspections, the IRB's communication was not made with an expectation of privacy. (*Id*. at p. 597.) However, the court also acknowledged that the voluntariness of the review was not a dispositive characteristic, because peer review was mandated by statute as well. (*Ibid*.) The *Konrady* court believed that the public interest in encouraging candor among professionals practicing health care did not apply to the activities of the IRB. (*Id*. at pp. 597-598.)

In contrast, California's protection is broader than Minnesota's peer review statute. The protection of section 1157 is not limited to peer review committees and peer review activities. The Minnesota statute does not contain any protection for medical staff committees in hospitals that have the responsibility of evaluation and improvement of the quality of care. In *Doe v. Illinois Masonic Medical Center* (1998) 297 Ill.App.3d 240 (*Doe*), the Illinois court similarly distinguished *Konrady*. The Illinois Medical Studies Act provides protection from discovery for the data of "'committees of licensed or accredited hospitals or their medical staffs, [including certain enumerated committees], used in the course of internal quality control or of medical study for the purpose of reducing morbidity or mortality . . . .' [Citation.]" (*Id*. at pp. 242-243.) The *Doe* court found that IRB records were protected under the Illinois statute. The *Doe* court noted, "Although we believe that peer review functions are probably an inherent and inextricable part of the IRB's review process, promoting peer review is not the *only* purpose of the Act." (*Id*. at p. 244, emphasis added.) The *Doe* court also found that both physician peer review programs and voluntary experimental research studies promote the goal of the Illinois statute "'to encourage candid and voluntary studies and programs used to improve hospital conditions and patient care or to reduce the rates of death and disease.' [Citation.]" (*Id*. at p. 245.)

At oral argument, Cabana asserted that some of her interrogatories or document requests are subject to discovery even if the IRB is a medical staff committee protected under section 1157. If Cabana has requested information that is not exempt, such as

"[i]nformation developed and obtained by hospital administrators or others which does not derive from an investigation into the quality of care or the evaluation thereof by a medical staff committee, and which does not disclose the investigative and evaluative activities of such a committee," that information is subject to discovery, regardless of whether it was later placed in the possession of the IRB. (See *Santa Rosa*, *supra*, 174 Cal.App.3d at p. 724.)

DISPOSITION

The petition for writ of mandate is granted. A peremptory writ shall issue directing respondent court to vacate its order of May 15, 2010, granting Cabana's motion to compel interrogatory responses and produce responsive documents. Costs are not awarded in this proceeding.

KRIEGLER, J.

We concur:

TURNER, P. J.

FERNS, J.*

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* Judge of the Los Angeles Superior Court assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.