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# IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA SECOND APPELLATE DISTRICT DIVISION TWO

KIMBERLY PICKETT,

B260878

Plaintiff and Appellant,

(Los Angeles County Super. Ct. No. BC529994)

v.

OLYMPIA MEDICAL CENTER,

Defendant and Respondent.

APPEAL from an order of the Superior Court of Los Angeles County. Terry A. Green, Judge. Reversed.

Baum Hedlund Aristei & Goldman, Ronald L.M. Goldman, Bijan Esfandiari, and Nicole K.H. Maldonado, for Plaintiff and Appellant.

Lewis Brisbois Bisgaard & Smith, Jeffry A. Miller, Brittany H. Bartold, Lee M. Thies, and John J. Weber for Defendant and Respondent.

Plaintiff and appellant Kimberly Pickett (Pickett) appeals from the order dismissing her negligence action against defendant and respondent Olympia Medical Center (Olympia) after the trial court sustained, without leave to amend, Olympia's demurrer to Pickett's second amended complaint (SAC). Olympia provided services and facilities for a surgery in which Pickett was allegedly injured.

The SAC states a claim for negligence against Olympia. We therefore reverse the order sustaining the demurrer and dismissing the action against Olympia.

# **BACKGROUND**

In December 2013, Pickett filed her original complaint. She later filed a first amended complaint alleging nine causes of action, one against Olympia. Following a successful demurrer by Olympia, where leave to amend was granted, Pickett filed her SAC.

The SAC alleges generally as follows: Pickett was a director of Medtronic, Inc. (Medtronic) when she sustained neck injuries at a work-related outing.

An MRI revealed disc compression in her cervical spine. A Medtronic co-worker recommended that she consult with Todd H. Lanman, M.D., a neurosurgeon in Beverly Hills. Unbeknownst to Pickett, Lanman was a prominent consultant for Medtronic, which paid him up to \$500,000 annually in fees and royalties.

Lanman examined Pickett and recommended cervical spine surgery using a Medtronic product called Infuse. Infuse consists of a bioengineered liquid bone graft (called rhBMP-2) that is intended to substitute for the patient's own bone when performing spinal fusion surgery, a surgical technique in which vertebrae are fused together so that motion no longer occurs between them. The Food and Drug Administration (FDA) has approved the use of Infuse in anterior lumbar fusion surgeries, where the Infuse is implanted in the lumbar spine in combination with a certain type of "cage," a hollow metal cylinder.

The FDA has not approved the use of Infuse in the cervical spine. Rather, in July 2008, the FDA issued a notification to "Healthcare Practitioner[s]" titled "Lifethreatening Complications Associated with Recombinant Human Bone Morphogenetic

Protein in Cervical Spine Fusion," noting reports of "life-threatening complications associated with" rhBMP, including Infuse, when used in the cervical spine. The notification stated that the FDA had received at least 38 reports of complications from the use of rhBMP in cervical spine fusion, including swelling of neck and throat tissue, compression of airway or neurological structures in the neck, and difficulty swallowing, breathing, or speaking. The notification further read: "Since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies."

Lanman did not disclose to Pickett his financial relationship with Medtronic or the FDA's concerns with the use of Infuse in the cervical spine. On June 25, 2012, Lanman performed Pickett's cervical spine surgery at Olympia. He implanted Infuse into her cervical spine, using a cage that was not approved for use with Infuse.

Following the surgery, Pickett experienced severe nerve pain radiating to her arms. A December 2012 scan revealed that she had developed Infuse-induced ectopic bone overgrowth in her cervical spine, which impinged nerves. Pickett met with various surgeons who told her that Infuse should not have been used in her cervical spine and that she needed revision surgery. Pickett had revision surgery in May 2013; the surgeon chiseled and drilled away some of the ectopic bone growth. Pickett continues to experience agonizing nerve pain, however, and may need further revision surgery.

Pickett's SAC alleges seven causes of action against Medtronic and two against Lanman. It alleges a single cause of action for negligence against Olympia. The SAC states that Olympia was negligent because: it permitted the off-label implantation of Infuse in Pickett's cervical spine despite the FDA's warning; it approved and allowed the off-label use of Infuse without any restrictions; and it participated in the preparation and implanting of the Infuse in Pickett's cervical spine. The SAC alleges that following the FDA's July 2008 notification, many hospitals and medical facilities in California and the United States, including another hospital where Lanman has privileges, implemented

policies and procedures prohibiting the off-label, cervical use of Infuse. The SAC further alleges that Lanman chose to perform Pickett's surgery at Olympia because the other hospital at which he had privileges would either have prohibited the use of Infuse in her cervical spine surgery or would have restricted such use or made it more difficult to use Infuse at its facility, whereas Olympia had no such prohibitions or restrictions. The SAC claims that Olympia was negligent in failing to implement any policies regarding the use of Infuse in the cervical spine and in allowing surgeons to implant Infuse in the cervical spine without first ensuring patients were enrolled in approved clinical trials. Further, Olympia failed to provide Pickett with appropriate consent forms warning of the FDA's concerns regarding Infuse.

Olympia filed a demurrer, arguing that it did not owe a duty to Pickett based on the SAC's allegations. The trial court sustained the demurrer without leave to amend and the action against Olympia was dismissed. Pickett timely appealed.

### **DISCUSSION**

#### I. Standard of review

We review the ruling sustaining the demurrer de novo, exercising independent judgment as to whether the complaint states a cause of action as a matter of law. (*Desai v. Farmers Ins. Exchange* (1996) 47 Cal.App.4th 1110, 1115 (*Desai*).) We give the complaint a reasonable interpretation, assuming that all properly pleaded material facts are true, but not assuming the truth of contentions, deductions, or conclusions of law. (*Aubry v. Tri-City Hospital Dist.* (1992) 2 Cal.4th 962, 967 (*Aubry*).)

A demurrer tests the legal sufficiency of the complaint. (*Hernandez v. City of Pomona* (1996) 49 Cal.App.4th 1492, 1497.) Accordingly, we are not concerned with the difficulties the plaintiff may have in proving the claims made in the complaint. (*Desai, supra*, 47 Cal.App.4th at p. 1115.) We are also unconcerned with the trial court's reasons for sustaining the demurrer, as it is the ruling, not the rationale, that is reviewable. (*Mendoza v. Town of Ross* (2005) 128 Cal.App.4th 625, 631; *Sackett v. Wyatt* (1973) 32 Cal.App.3d 592, 598, fn. 2.)

"The judgment must be affirmed 'if any one of the several grounds of demurrer is well taken. [Citations.]' [Citation.] However, it is error for a trial court to sustain a demurrer when the plaintiff has stated a cause of action under any possible legal theory. [Citation.] And it is an abuse of discretion to sustain a demurrer without leave to amend if the plaintiff shows there is a reasonable possibility any defect identified by the defendant can be cured by amendment. [Citation.]" (*Aubry, supra*, 2 Cal.4th at pp. 966-967.)

# II. Negligence and a hospital's duty of care

The elements of a negligence cause of action are ""(a) a *legal duty* to use due care; (b) a *breach* of such legal duty; [and] (c) the breach as the *proximate or legal cause* of the resulting injury." [Citation.]" (*Ladd v. County of San Mateo* (1996) 12 Cal.4th 913, 917-918.) "The existence and the scope of a duty of care in a given factual situation are issues of law for the court. [Citations.]" (*Walker v. Sonora Regional Medical Center* (2012) 202 Cal.App.4th 948, 958 (*Walker*).)

"[A] hospital has a duty of reasonable care to protect patients from harm [citation]." (*Elam v. College Park Hospital* (1982) 132 Cal.App.3d 332, 340 (*Elam*).) "The measure of duty of a hospital is to exercise that degree of care, skill and diligence used by hospitals generally in that community." (*Wood v. Samaritan Institution, Inc.* (1945) 26 Cal.2d 847, 851 (*Wood*); *Osborn v. Irwin Memorial Blood Bank* (1992) 5 Cal.App.4th 234, 285-286 (*Osborn*).) ""The extent and character of the care that a hospital owes its patients depends on the circumstances of each particular case . . . ." [Citation.]" (*Rice v. California Lutheran Hospital* (1945) 27 Cal.2d 296, 299.)

The scope of a hospital's duty of care to its patients was addressed by our Supreme Court in *Leung v. Verdugo Hills Hospital* (2012) 55 Cal.4th 291 (*Leung*). In that case, a newborn suffered irreversible brain damage soon after birth. The plaintiff newborn's mother repeatedly expressed concerns to the pediatrician and nurses regarding the baby's troubles with breastfeeding, yellowish eyes, chapped lips, and bruises on the head. She was told that the symptoms did not indicate an emergency, and to wait for the next scheduled appointment with the pediatrician. Before the next appointment, the

plaintiff developed kernicterus, resulting in severe brain damage. (*Id.* at p. 299.) In arguing that it was not liable for the plaintiff's injuries, the hospital averred that, because hospitals in general do not practice medicine, as a matter of public policy, its conduct could not be considered a legal cause of the plaintiff's injuries. (*Id.* at p. 309.) The Supreme Court disagreed, noting: ""Present-day hospitals, as their manner of operation plainly demonstrates, do far more than furnish facilities for treatment. They regularly employ on a salary basis a large staff of physicians, nurses and internes [sic], as well as administrative and manual workers, and they charge patients for medical care and treatment, collecting for such services, if necessary, by legal action. Certainly, the person who avails himself of 'hospital facilities' expects that the hospital will attempt to cure him, not that its nurses or other employees will act on their own responsibility."" (Id. at p. 310, quoting Mejia v. Community Hospital of San Bernardino (2002) 99 Cal. App. 4th 1448, 1453 (*Mejia*), and *Bing v. Thunig* (1957) 2 N.Y.2d 656.) The *Leung* court concluded: "Although hospitals do not practice medicine in the same sense as physicians, they do provide facilities and services in connection with the practice of medicine, and if they are negligent in doing so they can be held liable." (Leung, supra, at p. 310.) The court noted that the hospital had "implicitly recognized" that principle when it requested a jury instruction that stated: "A hospital must provide procedures, policies, facilities, supplies, and qualified personnel reasonably necessary for the treatment of its patients." (*Ibid*.)

Other cases in which courts have addressed a hospital's duty of care include *Meyer v. McNutt Hospital* (1916) 173 Cal. 156, in which a hospital was found to have breached its "duty of protection" to the plaintiff, who was burned while under the hospital's care, most likely by a hot water bottle placed near her bed. (*Id.* at pp.158-159.) In *Elam, supra*, 132 Cal.App.3d 332, the plaintiff alleged that she received negligent podiatric surgery at a hospital, and sought to hold both the surgeon and the hospital liable, arguing that the hospital had negligently failed to ensure that its staff physicians were competent. Finding that the plaintiff identified a cognizable duty of care, the court held that "a hospital is accountable for negligently screening the competency of its

medical staff to insure the adequacy of medical care rendered to patients at its facility." (*Id.* at p. 346.) In *Mejia, supra*, 99 Cal.App.4th 1448, the plaintiff entered an emergency room complaining of a hurt neck, was discharged by the emergency room physician after a radiologist determined that an X-ray showed no serious abnormalities, and awoke paralyzed; it was subsequently determined that her neck was actually broken. The plaintiff brought a lawsuit against various parties, including the hospital, claiming that the radiologist was an ostensible agent of the hospital. In reversing a nonsuit in favor of the hospital, the appellate court found that the issue of whether the radiologist was an ostensible agent could only be determined by the trier of fact. (*Id.* at pp. 1458-1459.)

The principles articulated in the foregoing cases are summarized in CACI No. 514, which defines a hospital's duty to its patients as follows: "A hospital is negligent if it does not use reasonable care toward its patients. A hospital must provide procedures, policies, facilities, supplies, and qualified personnel reasonably necessary for the treatment of its patients." (CACI No. 514; see *Leung, supra*, 55 Cal.4th at p. 310.)

# III. The SAC states a claim for negligence

The SAC alleges that the FDA issued a notice advising healthcare practitioners of life-threatening complications associated with the use of Infuse in the cervical spine and recommending against such use unless part of an approved clinical trial. The SAC further alleges that following the issuance of the FDA notice, other hospitals, including another hospital at which Lanman has privileges, implemented policies, procedures, and guidelines restricting the use of Infuse in the cervical spine by surgeons at their facilities. The SAC alleges that Olympia knew or should have known of the FDA notice, that Olympia failed to implement any guidelines, policies, or procedures regarding use of Infuse in the cervical spine, failed to inform Pickett of the FDA notice regarding use of Infuse in the cervical spine, and allowed Lanman to implant Infuse in Pickett's cervical spine without first determining whether she had been enrolled in an approved clinical trial. These allegations are sufficient to establish that Olympia breached a duty of care to Pickett.

Under California law, "a hospital has a duty of reasonable care to protect patients from harm [citation]." (*Elam, supra*, 132 Cal.App.3d at p. 340.) Those duties include providing "policies" and "procedures" that are "reasonably necessary" for the treatment of patients. (CACI No. 514; *Leung, supra*, 55 Cal.4th at p. 310.) The measure of a hospital's duty is the degree of care, skill, and diligence used by other hospitals in similar circumstances. (*Wood, supra*, 26 Cal.2d at p. 851; *Osborn, supra*, 5 Cal.App.4th at pp. 285-286.)

Olympia argues that the FDA notice imposed no duty on it to inform Pickett about the risks of using Infuse in the cervical spine or to implement policies and procedures governing such use and cites *Walker*, *supra*, 202 Cal.App.4th 948 as support for this argument. That case, however, is distinguishable.

At issue in *Walker* was whether a hospital that performed a cystic fibrosis screening test ordered by the plaintiff's doctor owed a duty to disclose the test results to the plaintiff. The plaintiff's doctor did not inform the plaintiff that she had tested positive for cystic fibrosis, and the plaintiff subsequently gave birth to a child who was diagnosed with cystic fibrosis. The court in Walker affirmed the summary judgment entered in the hospital's favor, concluding that to the extent the hospital was providing clinical laboratory services to perform a test ordered by the plaintiff's doctor, it owed a duty to send the laboratory results to the doctor only. The hospital had no affirmative duty to release the laboratory test results directly to the patient. (Walker, supra, 202 Cal.App.4th at p. 962.) The court based its decision on limitations imposed by both federal and California law restricting the persons to whom a laboratory may release a patient's test results to licensed medical professionals. The applicable statutes and regulations, the court in Walker reasoned, circumscribed the hospital's duty of care to transmit clinical laboratory test results to the physician who ordered the test. (*Id.* at pp. 961-962.) For that same reason, the court in Walker rejected the plaintiff's claim that the hospital had a duty to implement policies and procedures to ensure that she would be informed and counseled concerning the test results. (Id. at pp. 966-967.) The court further reasoned that imposing such a duty on the hospital might interfere in the physician-patient

relationship and would "create an onerous administrative burden on hospitals providing laboratory services." (*Ibid.*)

Here, unlike *Walker*, no federal or California law circumscribes Olympia's duty regarding the FDA notice. The procedural posture of the two cases also differs. *Walker* involved a motion for summary judgment, whereas the parties in the instant case are only in the pleading stage. Under the standard applicable here, we must assume that all properly pleaded material facts are true, and we do not consider any difficulties the plaintiff may have in proving the allegations made in the complaint. (*Aubry, supra*, 2 Cal.4th at p. 967; *Desai, supra*, 47 Cal.App.4th at p. 1115.)

The SAC alleges that Olympia breached a duty of care owed to Pickett, and that as a result of that breach of duty, Pickett sustained injuries and incurred damages. Pickett has alleged sufficient facts to state a negligence claim against Olympia. The trial court accordingly erred by sustaining the demurrer without leave to amend and dismissing the action against Olympia.

#### DISPOSITION

The order dismissing the action against Olympia Medical Center is reversed. Pickett is awarded her costs on appeal.

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|               | CHAVEZ | , J. |
|---------------|--------|------|
| I concur:     |        |      |
|               | J.     |      |
| ASHMANN-GERST |        |      |

I respectfully dissent.

Essentially, the allegations of the Second Amended Complaint (SAC) pertaining to Olympia Medical Center reveal little more than the fact that Olympia provided facilities and assistance for a surgery. Appellant Kimberly Pickett premises her negligence claim primarily on a theory that Olympia should have implemented policies prohibiting the use of Infuse in cervical spine surgery following the FDA's July 2008 notification.

The existence and scope of the duty of care are issues of law for the court to decide. (*Walker v. Sonora Regional Medical Center* (2012) 202 Cal.App.4th 948, 958.) CACI No. 514 (2016 ed.) provides, in part, that a hospital "must provide . . . policies . . . reasonably necessary for the treatment of its patients." (See also *Leung v. Verdugo Hills Hospital* (2012) 55 Cal.4th 291, 310.) "The measure of duty of a hospital is to exercise that degree of care, skill and diligence used by hospitals generally in that community . . . ." (*Rice v. California Lutheran Hospital* (1945) 27 Cal.2d 296, 299 (*Rice*); *Walker*, at p. 959, fn. 8.)

The SAC alleges that "a number of hospitals in California and nationally placed restrictions, prohibitions, limitations and/or safeguards against off-label cervical use of Infuse." Simply because "a number of hospitals" implemented such policies, however, does not mean that, by failing to implement such policies, Olympia fell below the "degree of care, skill and diligence used by hospitals" generally in Olympia's community. (See *Rice*, *supra*, 27 Cal.2d 296, 299.) It is possible that a dozen or even a hundred hospitals around the country have policies prohibiting Infuse in cervical spine surgery, but such a possibility does not lead to a legal conclusion that Olympia breached its duty of care by not having the policy. Instead, with no allegation that the standard of care within Olympia's community was to have a policy against Infuse, Pickett fails to effectively allege that Olympia breached its duty of care.

This is a pleading problem that possibly could have been cured by amendment. Pickett, though, has not properly requested amendment, and when asked at oral argument whether amendment would be helpful, Pickett's attorney responded that amendment was not needed and that the allegations were sufficient as pled.

Because I do not believe that Pickett has adequately alleged a negligence claim, I would affirm the trial court's order dismissing the action against Olympia.

|       | P.J |
|-------|-----|
| BOREN |     |