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IN THE STATE OF OREGON
MULTNOMAH COUNTY CIRCUIT COURT

02204

PETER ST. JOHN and **KARYN ST. JOHN** as Guardians of **SYDNEY ST. JOHN,**

Plaintiffs,

v.

KAISER PERMANENTE NORTHWEST, a California corporation; and **JOHN/JANE DOES 1 Through 3,** Oregon citizens,

Defendants.

Case No. 140202204

COMPLAINT

(NEGLIGENT SPOLIATION; DECLARATORY JUDGMENT)

DEMAND FOR JURY TRIAL

Plaintiffs allege:

1.

On behalf of their daughter, Sydney St. John, plaintiffs Peter and Karen St. John assert a claim of negligent spoliation against defendants Kaiser, John/Jane Doe 1 (circulating nurse P. Brynem), John/Jane Doe 2 (scrub nurse L.W.),[1] and John/Jane Doe 3 for failing to preserve a defective hearing device explanted from Sydney St. John's right ear, thus diminishing the settlement value of plaintiffs' product liability claim against the manufacturer.

[1] These two nurses signed their names to the "Surgical Implant Record and Charge Sheet" for the surgery on May 4, 2012, when the failed right hearing device was explanted. The nurses' signatures are partly illegible, so plaintiffs cannot adequately identify them. The document (009194 MD02 000022) is attached as Exhibit 01.

2.

Plaintiffs also seek declaratory judgment against defendant Kaiser to determine the validity of the lien it asserts on the settlement proceeds from the manufacturer. Defendant Kaiser substantially overstated the amount of the lien and refused to itemize or justify its expenses. In the alternative, plaintiffs seek an order from the Court forfeiting Kaiser's contractual claim to recover under the lien.

JURISDICTION AND PARTIES

3.

This Court has jurisdiction because plaintiffs are citizens of Oregon, and the Doe defendants are Oregon citizens.

4.

Venue is proper in Multnomah County because the defective hearing devices at issue were sold and implanted in this county, at Oregon Health & Science University in Portland.

The Plaintiffs

5.

Plaintiffs Peter St. John and Karyn St. John, and their daughter Sydney St. John, were at all relevant times residents and citizens of Tigard, Oregon.

6.

Plaintiffs are the legal guardians of their daughter Sydney St. John, who is three years old. Plaintiffs bring this action on Sydney's behalf.

Defendant Kaiser Permanente Northwest

7.

Defendant Kaiser Permanente Northwest ("Kaiser") provided the surgical services to Sydney St. John on February 17, 2012, and May 4, 2012, to replace the failed right and left cochlear implants. These services were provided at Kaiser's Sunnyside Hospital in Clackamas, Oregon.

8.

Defendant Kaiser provided healthcare benefits to Sydney St. John under a healthcare benefits plan which provides that Kaiser has a lien on the proceeds of any judgment or settlement the member obtains against a third party.

Defendants John/Jane Doe 1 through 3

9.

The John/Jane Doe ("Doe") defendants are employees of defendant Kaiser at Kaiser's Sunnyside Hospital. Doe defendant 1 (P. Brynem) was the circulating nurse and Doe defendant 2 (L.W.) was the scrub nurse on the day of Sydney St. John's May 4, 2012 surgery. Doe 3 supervised P. Brynem and L.W.

10.

Does 1 through 3 were responsible for the preservation, documentation and safekeeping of explanted medical devices at the facility, including the defective cochlear device removed from Sydney St. John's right ear on May 4, 2012.

FACTUAL BACKGROUND

11.

Sydney St. John was born in May 2010. She suffered from complete deafness as a result of a genetic hearing loss disorder.

12.

During the summer of 2010, Sydney was enrolled in an early intervention program and received a series of newborn hearing tests. In January 2011, Sydney underwent a cochlear implant evaluation at Oregon Health & Science University ("OHSU") in Portland. The results confirmed that Sydney was a candidate for bilateral cochlear implants.

13.

Cochlear implants are surgically implanted medical devices that provide a sense of sound to people who are either profoundly deaf or severely hard of hearing. The devices convert sound

into electrical energy that activates the auditory nerve, which sends the information to the brain where it is interpreted as sound.

14.

The Cochlear Nucleus CI500 implants at issue were manufactured by Cochlear Limited, an Australian corporation and were sold by its subsidiary Cochlear Americas (collectively referred to as "Cochlear Company"). The devices were approved by the Federal Food & Drug Administration (FDA).

15.

In 2011, Cochlear Companies learned that several of its hearing devices had malfunctioned, including the CI500 product line, due to manufacturing errors. A percentage of the devices had developed micro-cracks which allowed water molecules to enter the implants and caused them to fail. In October 2011, the FDA issued a recall of unimplanted Cochlear Nucleus C1512 devices. Cochlear Company issued a series of recall letters to its affected customers. The letters described the product, the problem, and actions to be taken by the customers. The letters instructed customers to examine their inventory and quarantine the affected devices. A recall response form was attached to the letters for customers to complete and return.

16.

In April 2011, when she was 11 months old, Sydney St. John underwent surgery at OHSU. Her surgeon implanted Cochlear Nucleus CI512 hearing devices in both ears.

17.

In December 2011, Sydney's left cochlear implant stopped working. Sydney underwent a second surgery on February 17, 2012 at Kaiser Sunnyside Hospital to replace the left implant.

18.

In March 2012, Sydney's right cochlear implant failed. She underwent a third surgery on May 4, 2012, to replace the right implant.

19.

Kaiser notified Cochlear Company that the left device was explanted due to loss of function. After physically inspecting and testing the explanted device, Cochlear Company concluded that the device's failure was consistent with the defect associated with the FDA recall. Kaiser did not retain the explanted right device. As a result, Cochlear Company was unable to determine whether it had malfunctioned and the cause of the failure.

20.

In September 2013, plaintiffs sent Cochlear Company a demand letter seeking compensation for the harm Sydney St. John suffered as a result of the defective implants and the multiple surgeries she was forced to undergo. Plaintiffs also contacted Kaiser to obtain a lien statement. Kaiser responded with a statement seeking $152,200. This amount included Sydney St. John's explant surgeries, at $72,050 each. Kaiser declined to provide an itemization of the surgeries.

21.

Plaintiffs believe Kaiser's lien includes reimbursement for the replacement cochlear devices, which cost $20,000 each. Cochlear provided the replacement implants to Kaiser free of charge.

22.

Cochlear Company offered to settle plaintiffs' claims for a confidential amount, but plaintiffs cannot agree to accept the offer unless they resolve Kaiser's lien. Plaintiffs have repeatedly contacted Kaiser to obtain itemization of the surgery and to negotiate a reduction of the amounts claimed under the lien, but Kaiser has not responded.

FIRST CLAIM FOR RELIEF

(Doe Defendants' and Kaiser Defendant's Liability for Negligent Spoliation of Explanted Cochlear Device)

23.

Plaintiffs reallege all previous paragraphs.

24.

Doe defendants are employees of defendant Kaiser at its Sunnyside facility. Their job responsibilities require them to follow Kaiser's protocols governing the documentation and preservation of medical devices that are explanted from surgery patients due to suspected defects.

25.

Cochlear Company asked defendant Kaiser to retain and preserve the explanted devices so they could physically inspect the devices and determine the existence and cause of any defect. Although Kaiser retained the explanted device that was removed from Sydney St. John's left ear on February 17, 2012 and provided it to Cochlear Company, Doe defendants misplaced or destroyed the cochlear device explanted from Sydney St. John's right ear on May 4, 2012. This prevented Cochlear Company from determining whether the right device failed due to the manufacturing defect that led to the FDA recall of the Cochlear Nucleus CI512 devices, or whether it failed for some other reason.

26.

Oregon health and safety regulations require defendant Kaiser and other hospitals to establish governing bodies to develop and review practices and procedures for their facilities. OAR 333-505-0005(2)(d). The governing body must make sure there are written policies to ensure quality assessment and performance guidelines to monitor the quality of patient care. OAR 333-505-0060(1). Oregon regulations also require Kaiser and other hospitals to develop procedures for its staff to follow in collecting and preserving specimens collected from medical procedures. OAR 333-520-0030(3)(c).

27.

As a "final distributor" of medical devices, defendant Kaiser must comply with FDA regulations requiring it to report any medical device failures to the manufacturer. 21 CFR § 821.1(c), § 821.3(h)(i). Specifically, defendant Kaiser is obligated to gather and provide the

manufacturer the lot, batch, model or serial number of the explanted device, the date the device was explanted and the date the device was returned to the distributor or otherwise disposed of. 21 CFR 821.30(a)(5).

28.

It is the standard of care in Oregon and elsewhere for hospitals to maintain detailed chain of custody records for explanted medical devices. For example, OHSU has a policy requiring "[c]areful identification, labeling, and storage" of specimens. Explanted medical devices require special documentation. The Swedish Medical Center in Seattle has a policy stated in bold print that its facilities must retain all medical devices that are explanted "due to an apparent failure of the device." In addition, the defective device must be reported to the manufacturer. Likewise, the Mercy Medical Center health system mandates that "Risk Management must retain medical devices removed due to apparent medical failure of the device."

29.

It was foreseeable to Kaiser and Doe defendants that preserving the implant and/or information identifying the device was necessary for Cochlear defendants and the FDA to ensure the effectiveness of patient notification and product recalls.

30.

Kaiser and Doe defendants knew or should have known that the Cochlear devices were expensive – each implant cost approximately $20,000 – and that Cochlear Company had a financial interest in retrieving its device to determine the cause of failure.

31.

Kaiser and Doe defendants knew or should have known that the defective explanted hearing device would be pivotal evidence in a product liability claim against Cochlear Company for manufacturing and selling a defective hearing device. Defendants should have foreseen that the loss of this explanted device would make it more difficult for the plaintiffs to prove that the device was defective. In addition, defendants should have foreseen that the loss of this explanted

device would either foreclose plaintiffs from recovering damages in a product liability case against Cochlear, or result in a diminution in value of the settlement of their claims.

32.

Based upon state and federal regulations and hospital standards, defendant Kaiser had a duty to develop policies to safeguard the cochlear implants removed from Sydney St. John's ears, maintain a detailed log of information specifically identifying the implants, and provide that information to Cochlear Company.

33.

Based on their education and training in compliance with regulatory and hospital safety standards, Doe defendants had a duty to follow Kaiser's policies, if such policies existed, to safeguard the cochlear device explanted from Sydney St. John's right ear so that Cochlear Company would have the opportunity to test the device and report their findings to the FDA.

34.

Upon information and belief, defendant Kaiser breached its duties of care in the following ways:

(a) Kaiser lacked adequate policies and procedures arising from state law and relevant standards of care to document the chain of custody of the cochlear implant removed from Sydney St. John's right ear, which resulted in Kaiser's and Doe defendants' misplacement or destruction of the device.

(c) If it did have such policies, Kaiser failed to properly instruct its employees to retain possession of the explanted device or to gather and provide Cochlear Company documentation of the lot, batch, model or serial number of the explanted device, the date the device was explanted and the date the device was returned to the distributor or otherwise disposed of, in violation of 21 CFR 821. As a result, Cochlear defendants could not verify that the cochlear implant removed from Sydney St. John's ear was among the devices subject to their recall notice.

35.

Upon information and belief, Doe defendants breached their duties of care in the following ways:

(a) Doe defendants did not follow Kaiser's chain of custody procedures governing the retention of the explanted medical device, causing them to misplace or destroy the cochlear implant.

(b) Doe defendants failed to retain possession of the explanted device or to gather and provide Cochlear Company documentation of the lot, batch, model or serial number of the explanted device, the date the device was explanted and the date the device was returned to the distributor or otherwise disposed of, in violation of 21 CFR 821. As a result, Cochlear Company could not verify that the cochlear implant removed from Sydney St. John's ear was among the devices subject to their recall notice.

36.

Although Cochlear agreed to settle with plaintiffs for design defect claims related to the device explanted from Sydney St. John's left ear, it would not agree to compensate plaintiffs for injuries to her right ear because, without physical evidence, plaintiffs could not prove that the missing cochlear device was defective.

37.

As a result, defendants' negligent spoliation of the explanted device has diminished the settlement value of plaintiffs' claims.

38.

Defendants' negligent spoliation of the explanted device caused plaintiffs damages in the amount of $100,000.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment For Equitable Relief to Determine Defendant Kaiser's Lien Reimbursement Rights)

39.

Plaintiffs reallege all previous paragraphs.

40.

Plaintiffs had family health insurance coverage through defendant Kaiser. Kaiser provided plaintiffs and its other insured "members" with the 2013-2014 Benefit Handbook, which is the insurance contract between the plaintiffs and defendant Kaiser. It contains a section entitled, "Injuries or Illnesses Alleged to be Caused by Third Parties," on pages 74-75. This section states in relevant part:

> Members must pay the Health Plan for covered services they receive for an injury or illness that is alleged to be caused by a third party's act or omission, except that you do not have to pay more than you receive from or on behalf of the third party. To the extent permitted by law, Kaiser has the option of becoming subrogated to all claims, causes of action, and other rights the Member may have against a third party . . . for monetary damages, compensation, or indemnification on account of the injury or illness allegedly caused by the third party. Health Plan will be so subrogated as of the time they mail or deliver a written notice of exercise of this option to you or your attorney, but Health Plan will be subrogated only to the extent of the total covered charges for the relevant services and supplies.
>
> To secure Health Plan's rights, Health Plan will have a lien on the proceeds of any judgment or settlement the Member obtains against a third party. The proceeds of any judgment or settlement that the Member obtains shall first be applied to satisfy Health Plan's lien regardless of whether the total amount of the recovery is less than the actual losses and damages the Member incurred.
>
> Members must make all reasonable efforts to pursue any claim they may have against a third party. Within 30 days after submitting or filing a claim or legal action against a third party, the Member must send written notice of the claim or legal action to Health Plan. . . .
>
> * * *
>
> . . . You must provide Kaiser written notice before you settle a claim, obtain a judgment or if it appears you will make a recovery of any kind. If you recover any amounts from any third party for relevant services already paid by Kaiser, you must repay Kaiser or place the funds in a specifically identifiable account and retain control over the recovered amounts to which Kaiser may assert a right.

41.

Pursuant to the contract provisions, plaintiffs notified Kaiser of the third party claim and requested lien reimbursement information. In response, Kaiser provided a Consolidated Statement of Benefits, which showed that the total benefits provided related to the third party case against Cochlear was $152,204.02. Of this total amount, one line stated:

2/17/2012	360 OPERATING ROOM SER	$72,053.00 (Provided Benefits)

Another line stated:

5/4/2012	360 FACILITY USE-OPERA	$72,053.00 (Provided Benefits)

42.

Kaiser provided no further detail of these charges.

43.

Plaintiffs' counsel requested an itemization of the operating charges for February 17, 2012 and May 4, 2012 because the lien amount of $152,204 raised the following concerns:

(a) The operating room charges appear to be significantly inflated. Cochlear's counsel informed plaintiffs' counsel that the usual and customary charges for the hearing device implant surgery is $18,000-$30,000, well below the $72,053 benefit amount that Kaiser billed for each procedure;

(b) Cochlear provided both the right and left replacement hearing devices free of charge to Kaiser, which would otherwise add about $40,000 to the cost of the procedures;

(c) During one of the surgeries, the doctor performed a procedure that was unrelated to the third party case against Cochlear (involving a drain). Charges related to that procedure should not be included in Kaiser's lien.

44.

Implicit in the parties' contract is the understanding that Kaiser's lien may include only those charges that are reasonable, that is, consistent with the usual and customary amounts charged to insurers and government payers. Accordingly, Kaiser has a duty to provide sufficient documentation and itemization of its lien amount to establish that the benefit amounts are

reasonable. Considering the questions raised by Kaiser's operating services charges, Kaiser has the burden to prove it has not included in its lien costs for devices that were provided by Cochlear free of charge.

45.

Furthermore, the contract provides that members are required to reimburse Kaiser only for "covered services they receive *for an injury or illness that is alleged to be caused* by a third party's act or omission . . . ." (emphasis added). Consequently, Kaiser has a duty to provide sufficient documentation and itemization of its lien amount to establish that the charges are related to the third party claims.

46.

Kaiser has refused to provide any further documentation or itemization of its lien amount, in particular, a breakdown of the operating room services on February 17, 2012 and May 4, 2012.

47.

Plaintiffs seek a declaratory judgment from this court ordering defendant Kaiser to provide documentation and itemization of its lien charges and to show:

(a) whether its charges are consistent with the usual and customary charges for these surgical procedures;

(b) whether its lien includes charges for the replaced hearing devices, which were provided free of charge; and

(c) whether the lien includes charges for procedures that were unrelated to the third party claims.

48.

Plaintiffs seek a declaratory judgment from this court to decide the proper amount of Kaiser's lien to be reimbursed from any proceeds of the plaintiffs' settlement with Cochlear Company.

49.

In the alternative, plaintiffs seek declaratory equitable relief from this court in the event the court finds that defendant Kaiser's negligent spoliation of the explanted hearing device caused plaintiffs to suffer a diminution in value of their damages.

50.

Defendant Kaiser is not entitled to enforce its lien if it has unclean hands. Kaiser has unclean hands for two reasons: it lost or destroyed the second (right) failed implant; and it made a false claim under the lien for the cost of both replacement cochlear implants even though Cochlear Company provided them to Kaiser free of charge.

51.

Accordingly, plaintiffs seek an order that defendant Kaiser's lien is null and void. Implicit in the contract between plaintiffs and Kaiser is the understanding that Kaiser will not interfere with plaintiffs' third party action in any way. To pay Kaiser its lien after it has diminished the value of the third party claims is contrary to both the letter and spirit of the contract, which requires:

> Members must make all reasonable efforts to pursue any claim they may have against a third party.

52.

The only reasonable reading of the contract is that if the members are required to "make all reasonable efforts to pursue the third party claim," Kaiser's Health Plan must make all reasonable efforts not to damage the case or interfere with it. In particular, the Health Plan must maintain and preserve critical evidence in its control. Defendant Kaiser failed to preserve the cochlear implant or the information necessary to confirm that the missing device was defective and subject to Cochlear Company's product recall. Defendant Kaiser did not hold up its part of the bargain and should therefore be ordered to forfeit its contractual claim to the lien.

JURY DEMAND

53.

Plaintiffs request trial by jury.

PRAYER FOR RELIEF

54.

Plaintiffs request judgment for all of the above stated causes of action against each of the defendants as follows:

(a) Economic and noneconomic damages against Kaiser and Doe defendants for the diminution in the value of their claims against Cochlear in the amount of $100,000;

(b) Declaratory judgment of the amount of defendant Kaiser's lien, or in the alternative, an order forfeiting Kaiser's contractual right to assert a lien; and

(b). Any further relief that this Court may deem just and proper.

Dated: Feb. 25, 2013.

WILLIAMS O'LEARY, L.L.C.

By: [signature]

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