NO. 26836

IN THE SUPREME COURT OF THE STATE OF HAWAI'I

NATTIE NACAPUY and ADOLFO NACAPUY, Plaintiffs-Appellants,

vs.

SAMUEL DACANAY, M.D.; CARDIOLOGY ASSOCIATES, INC., and ATSUSHI JIM TERAKUBO, M.D., Defendants-Appellees,

and

SCIMED LIFE SYSTEMS, INC.; BOSTON SCIENTIFIC CORPORATION, a Delaware corporation; BRETT BREDEN; LAKE REGION MANUFACTURING, INC.; JOHN DOES 1-10; JANE DOES 1-10; DOE CORPORATIONS 2-10; DOE PARTNERSHIPS 1-10; and DOE GOVERNMENTAL ENTITIES 1-10, Defendants.

(CIV. NOS. 01-1-1009 and 01-1-2080)

NATTIE SALES NACAPUY and ADOLFO RAMIREZ NACAPUY, Plaintiffs-Appellants,

vs.

CARDIOLOGY ASSOCIATES, INC.; SAMUEL DACANAY, M.D., and ATSUSHI JIM TERAKUBO, M.D., Defendants-Appellees,

and

ST. FRANCIS MEDICAL CENTER; JOHN DOES 1-10; JANE DOES 1-10; DOE CORPORATIONS 1-10; DOE PARTNERSHIPS 1-10; and DOE ENTITIES 1-10, Defendants,

and

ST. FRANCIS MEDICAL CENTER, Third-Party Plaintiff,

vs.

BOSTON SCIENTIFIC CORPORATION; SCIMED BUSINESS; SCIMED LIFE SYSTEMS, INC.; BOSTON SCIENTIFIC CORPORATION; JOHN DOES 1-50;

JANE DOES 1-50; DOE PARTNERSHIPS 1-50; DOE "NON-PROFIT" CORPORATIONS 1-50; and DOE CORPORATIONS 1-50, Third-Party Defendants.
(CIV. NO. 01-1-2080)

APPEALS FROM THE FIRST CIRCUIT COURT
(CIV. NOS. 01-1-1009 and 01-1-2080;)

MEMORANDUM OPINION

(By: Moon, C.J., Levinson, Nakayama, and Duffy, JJ., and Circuit Judge Town, in place of Acoba, J., recused)

Plaintiffs-Appellants, Nattie Nacapuy ("Mrs. Nacapuy") and Adolfo Nacapuy (collectively referred to as "the Nacapuys"), appeal from the first circuit court's[1] August 24, 2004 judgment in favor of all defendants, Cardiology Associates, Inc. ("Cardiology Associates"), Samuel Dacanay, M.D. ("Dr. Dacanay"), and Atsushi Jim Terakubo, M.D. ("Dr. Terakubo").

Two cases, which have been consolidated, arose after Mrs. Nacapuy underwent a percutaneous transluminal coronary angioplasty ("angioplasty") with stent procedure at St. Francis Medical Center that was followed by rapid restenosis and a bypass operation six weeks later. The Nacapuys' complaint against St. Francis Medical Center, Dr. Terakubo, and Dr. Dacanay asserted, inter alia, claims of negligence and lack of informed consent. This case was consolidated with a products liability case (Civil No. 01-1-1009) in which the Nacapuys filed a complaint against the manufacturer and distributors of a medical instrument that fractured during the angioplasty. The claims against the defendants of the products liability case and St. Francis Medical

[1] Following the reassignment of the case from Judge Dexter D. Del Rosario on June 4, 2004, the Honorable Bert I. Ayabe presided.

Center were dismissed by stipulation of the parties. The claims against Dr. Dacanay and Dr. Terakubo were resolved in their favor by summary judgment and jury verdict.

On appeal, the Nacapuys argue that: (1) the circuit court erred by granting Dr. Dacanay and Dr. Terakubo's motion for summary judgment on the issue of informed consent where (a) Dr. Dacanay retained control over Mrs. Nacapuy's procedure, (b) Mrs. Nacapuy would not have undergone the angioplasty with stent procedure if she was aware of its risks and the alternative bypass operation, and (c) Mrs. Nacapuy did not provide her informed consent for her reballooning procedure; (2) the circuit court erred by precluding any evidence on the issue of informed consent for the reballooning procedure against Dr. Dacanay based on its prior summary judgment ruling on informed consent, inasmuch as the Nacapuys had not previously claimed that Dr. Dacanay failed to obtain informed consent for the reballooning procedure; (3) the circuit court erred by precluding evidence of the Instruction Booklet of the Trooper Floppy Guide Wire ("package insert") where the Nacapuys offered it in conjunction with their expert witness, Dr. Stephen Hubbard ("Dr. Hubbard"), who was prepared to testify that it was relevant to the medical standard of care; (4) the circuit court erred by allowing Dr. Robert Chesne ("Dr. Chesne") to testify on a new opinion that he had not previously disclosed through discovery; (5) the circuit court erred by denying the Nacapuys' motion for partial summary judgment on the matter of res ipsa loquitur regarding Dr. Terakubo fracturing the guide wire during the angioplasty with

stent procedure because the three elements of this doctrine were met; and (6) the circuit court erred by denying the Nacapuys' jury instructions on negligence and thereby requiring expert testimony to establish the medical standard of care, even though the removal of the guide wire was within the jury's "common knowledge."

Based upon the following analysis, we vacate the circuit court's August 24, 2004 judgment and remand the case for a new trial.

I. BACKGROUND

A. Factual Background

1. Mrs. Nacapuy's medical history and Dr. Dacanay's recommendation for an angioplasty with stent procedure

On June 13, 2000, Mrs. Nacapuy, who was at the time, fifty-nine-years old with a several day history of chest pain, was recommended for admission to St. Francis Medical Center by her physician, Furtonato Elizaga, M.D., after her twelve-lead electrocardiogram (EKG) showed anterior ischemic changes. Mrs. Nacapuy was admitted to St. Francis Medical Center under the care of Dr. Dacanay.

On June 15, 2000, Dr. Dacanay performed several diagnostic tests on Mrs. Nacapuy including an angiogram,[2] a

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[2] Dr. Hubbard explained an angiogram as follows:

> "Angio" means blood vessel. "Gram" means picture so an angiogram is a picture of a blood vessel. These are called diagnostic angiograms. These pictures are taken inside to find out where blockages exist in the coronary arteries. They're done by putting a catheter into the artery and injecting dye in that catheter that does [sic] -- down the artery then shows up on X-ray and reveals where the blockages are.

medical imaging technique that takes x-rays of blood vessels. Mrs. Nacapuy's angiogram indicated "blockage in the left anterior descending artery" and "single-vessel coronary disease with high-grade proximal stenosis."

Dr. Dacanay believed that Mrs. Nacapuy was stable on medications but that she needed to undergo an angioplasty with stent procedure to unclog and open up her narrowed heart artery. "In a[n angioplasty with stent] procedure, a guide wire is advanced from the groin area to the left anterior descending artery, where the artery is narrowed or clogged by plaque and the stent is deployed with a balloon to open the narrowed artery."[3]

2. Dr. Terakubo performed the angioplasty with stent procedure

Because Dr. Dacanay was unavailable to perform the procedure and he believed that Mrs. Nacapuy required an

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[3] Dr. Terakubo explained the angioplasty with stent procedure as follows:

> A coronary stent is an artificial support device used to keep coronary arteries expanded, usually following a balloon angioplasty. A balloon angioplasty is used in patients with coronary artery disease; i.e., a narrowing or blockage of the blood vessels on the heart commonly caused by fat deposits resulting in a reduction of the oxygen supply to the heart muscle. In many cases, balloon angioplasty is unsuccessful and the vessel reoccludes [sic] after the procedure (restenosis). By forming a rigid support keeping the artery expanded, the stent can reduce restenosis and/or the need for coronary artery bypass graft ("CABG") surgery. The stent is commonly a stainless steel mesh tube. Since the stent will be placed inside an artery, the device comes in various sizes to match the size of the artery. In this case, the stent was manufactured in a collapsed condition around an uninflated balloon. The collapsed stent and balloon are delivered to the site of the blockage by inserting the stent balloon catheter onto a thin guide wire (like pushing a macaroni along a string) through a small tube. Once at the site, the balloon is pushed out of the guide catheter and is inflated with fluid pressure, opening up the stent and pressing it against the sides (intima) of the artery vessel.

angioplasty with stent procedure as soon as possible, he asked Dr. Terakubo to perform Mrs. Nacapuy's angioplasty with stent procedure on the following day, June 16, 2000. On the morning of June 16, 2000, Dr. Terakubo met with Mrs. Nacapuy and, according to Mrs. Nacapuy, Dr. Terakubo told her "I'm the expert. I will do your angioplasty." Mrs. Nacapuy claims that Dr. Terakubo did not further explain the procedure. However, Dr. Terakubo claims that during this meeting, he advised Mrs. Nacapuy of the attendant risks and complications associated with the procedure and of the treatment alternatives. It is undisputed that Mrs. Nacapuy signed a written informed consent for the angioplasty with stent procedure which included the following clause: "I recognize that, during the course of the operation, post operative care, medical treatment, anesthesia, or other procedure, unforeseen conditions may necessitate my above-named physician and his or her assistants, to perform such surgical or other procedures as are necessary to preserve my life or bodily functions."

At around 5:10 p.m. on June 16, 2000, Dr. Terakubo performed the angioplasty with stent procedure using the Boston Scientific Floppy guide wire and its new NIR Royal stent. Brandon Shibuya, a catheter technologist, Wes Ige, a technician, and nurse Karen Keala, R.N., assisted Dr. Terakubo. This was the first time Dr. Terakubo used the NIR Royal stent, however, he testified that it is "the next generation stent of the NIR stent," and that he used it because he is "very familiar with this particular brand and type of stent."

To begin the procedure, Dr. Terakubo made a small incision in the patient's right groin, using a femoral sheath (an approximately five inch plastic tube which allows access to the arteries) to maintain the opening at the artery and skin. He then inserted a guide catheter up to the left anterior descending artery, followed by the guide wire. While Dr. Terakubo advanced the catheter and wire to Mrs. Nacapuy's area of the blockage, he used the flouroscope, a tool that helped him see what was happening in her body to ensure that they moved in the right direction. After the guide wire and the guide catheter were in place, Dr. Terakubo pushed a balloon catheter over the guide wire until it reached the area of the artery to be repaired. Once at the site of the blockage, the deflated balloon was slowly inflated to compress plaque in the artery up against the sides and open up the artery. During the inflation of the stent and balloon, Dr. Terakubo took thirty-two pictures of the procedure. He thereafter deflated and withdrew the balloon.

As Dr. Terakubo subsequently withdrew the guide wire, he did not use a fluoroscope because "[i]t's standard procedures [sic] we don't look when we withdraw the wire." He testified that he felt "some resistance, very brief resistance, and it was just like going over the speed bump. By the time the hand move [sic], smooth actions, everything came out smoothly." He testified that he did not turn the fluoroscope on after he felt resistance in the pull because he

> pay[s] attention to little detail about the patient conditions. There's a monitor to monitor the blood pressures, heart rate. There was live E.K.G. The patient was right next to me. She was in sound condition. Patient was hemodynamically stable, is not [sic] complain about any chest discomfort. There's no E.K.G.

changes. I didn't have any issue that I suspect something was going on.

3. Complications of the angioplasty with stent procedure led to reballooning

Twenty minutes after Dr. Terakubo completed the angioplasty with stent procedure, while Brandon Shibuya was cleaning Mrs. Nacapuy's groin area, Brandon Shibuya noticed a wire sticking out of the femoral sheath. Brandon Shibuya immediately notified Dr. Terakubo, and after Dr. Terakubo took a picture of Mrs. Nacapuy's chest area with the fluoroscope, he discovered that there was a fragment of a wire in the artery.

Dr. Terakubo called in Dr. Dacanay, Dr. William Dang, Jr. (an owner of Cardiology Associates), and Dr. Carlos Moreno-Cabral (cardiac surgeon) to discuss the best treatment for Mrs. Nacapuy. Dr. Terakubo also contacted Brett Braden ("Braden"), the local representative for the maker of the stent and guide wire, Boston Scientific. According to Dr. Terakubo, Braden informed him that "sometimes the wire fractures in the angiogram procedures" and that Mrs. Nacapuy should be treated with coumadin, a blood thinner (anticoagulant) to prevent blood clotting.[4]

While Dr. Terakubo consulted with Dr. William Dang, Jr. and Braden, Dr. Dacanay performed an angiogram to determine if any obstructions needed to be corrected. After the doctors observed the pictures, they speculated that when Dr. Terakubo pulled the wire, he also pulled the stent. Dr. Terakubo also

[4] Mrs. Nacapuy testified that she continues to take Coumadin to prevent blood clotting.

concluded that a portion of the fractured guide wire was lost in Mrs. Nacapuy's circulatory system. The doctors decided that the best treatment would be to "reballoon" the distal portion of the stent ("reballooning procedure") -- rather than perform an emergency bypass to remove the fractured wire in the artery -- to correct the deformed stent and leave the portion of wire that was visible in the angiogram in place.[5]

During the reballooning procedure, Dr. Terakubo and Dr. Dacanay used a Choice guide wire, a stiffer and more slippery wire than the Scientific Floppy guide wire, because Dr. Terakubo had a lot of experience using that wire. Dr. Terakubo and Dr. Dacanay worked together to re-balloon the distorted distal end of the NIR Royal stent. In this procedure, part of the balloon extended beyond the distal edge of the stent and was inflated against the side of the vessel to ensure that the stent was fully compressed against the side of the artery.

After the procedure, Mrs. Nacapuy denied any chest discomfort and was transferred to ICU in stable condition. Dr. Terakubo and Dr. Dacanay met with Mrs. Nacapuy's family to explain the events that had occurred using the angioplasty with stent procedure. Mrs. Nacapuy was discharged from the hospital a week after her procedure, at which time, Dr. Dacanay believed that she was sufficiently "stable" to travel to the mainland for the purpose of a second opinion. Dr. Dacanay recommended that

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[5] The next day, on June 17, 2000, Dr. Dacanay performed a computed tomography (commonly referred to as "CAT Scan") to determine if there were any foreign bodies, including wires, in Mrs. Nacapuy's blood vessels. However, Dr. Dacanay did not find a wire.

Mrs. Nacapuy be orally anticoagulated and observed. However, following her discharge from St. Francis on June 23, 2004, Mrs. Nacapuy did not return to visit either Dr. Dacanay or Dr. Terakubo.

4. Mrs. Nacapuy underwent a bypass operation in California

Six weeks later, in August 2000, at Seton Memorial Hospital in San Francisco, California, Mrs. Nacapuy underwent open heart bypass surgery as a result of very rapid restenosis.[6] At trial, Dr. Kent Gershengorn testified that "from a medical probability standpoint the presentation of [Mrs. Nacapuy] with an acute event on August [10,] 2000, was most likely precipated by the presence of that wire trapped in the stent rather than just run-of-the-mill restenosis that we see." Dr. Hubbard testified that Dr. Dacanay performed beneath the applicable standard of care when he performed the second procedure without considering the potential damage it would cause the artery wall. Dr. Lee Guertler ("Dr. Guertler"), an expert witness called by Dr. Terakubo, testified that the "narrowing [of the blood vessel]

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[6] Dr. Chesne explained the concept of restenosis at trial:

> A. Well, you know what "stenosis" is, it means narrowing, and "restenosis" means that basically you took care of the narrowing and it's come back. Now, more specifically, when we deal with it when we've done intervention is because the restenosis comes back because of a number of things, either a scar has formed, whether there's overgrowth, whether there's a combination of overgrowth, or, in other words, you take a blood vessel, you expand the balloon in it, you cause an overly compensation or it's regrowing, or whether there's even some degree of clot in there or even new plaque forming. But when it reaches a certain amount of blockage, we have to deal with it.
>
> But almost any procedure we do has some degree of restenosis in it. It's degree that we're talking about. As soon as you deal with the blood vessel, there's a chance it has to heal, it has to scar and it has a chance to overreact, what we call "overgrowth."

occurred because people in a sincere attempt to repair an acute situation had created a balloon angioplasty partially in a 'protected environment,' . . . partially in a native blood vessel."

B. Procedural History

On March 29, 2001, the Nacapuys filed a complaint against Scimed Life Systems, Inc., Boston Scientific Corporation ("Boston Scientific"), Braden, Lake Region Manufacturing, Inc., (the manufacturer, maker, and representative of the stent and guide wire) in Civil No. 01-1-1009-03 ("01-1-1009"), alleging inter alia, that Mrs. Nacapuy "has been seriously and permanently injured as a result of the fracture of the catheter guide wire used in the coronary catherization because of the defendants' negligence, and manufacture and distribution of the catheter guide wire. On July 11, 2001, the Nacapuys filed a complaint against St. Francis Medical Center, Cardiology Associates, Dr. Dacanay, and Dr. Terakubo in Civil No. 01-1-2080-07 ("01-1-2080"), alleging, inter alia, (1) that the defendants were negligent in performing Mrs. Nacapuy's angioplasty with stent and reballooning procedure, (2) that defendants failed to obtain Mrs. Nacapuy's informed consent for the guide wire and stent procedure, in violation of Hawai'i Revised Statutes ("HRS") § 671-3; and (3) that defendants are liable for Mrs. Nacapuy's injury under the res ipsa loquitur doctrine. These cases were consolidated by stipulation on December 18, 2001.

The Nacapuys stipulated to dismiss their complaint against St. Francis Medical Center on October 23, 2003, and

against Scimed Life Systems, Inc., Boston Scientific Corporation, and Braden on November 26, 2003.

A jury trial commenced on July 6, 2004. Prior to and during the trial, the following issues, relevant to the Nacapuys' appeal, arose.

1. Dr. Dacanay's motion for summary judgment on the issue of informed consent

On October 6, 2003, Dr. Dacanay moved for summary judgment with respect to all claims alleged against him, including lack of informed consent. With respect to his claim that he failed to obtain informed consent from Mrs. Nacapuy, he argued (1) that when Dr. Terakubo obtained informed consent from Mrs. Nacapuy, it "br[oke] any chain of causation that would arguably make Dr. Dacanay responsible" and (2) that the Nacapuys' alleged damages do not arise from this informed consent claim. On November 26, 2003, the circuit court granted Dr. Dacanay's motion for summary judgment.

2. Dr. Terakubo's motion for summary judgment on the issue of informed consent

On October 9, 2003, Dr. Terakubo filed a motion for partial summary judgment on, inter alia, the issue of lack of informed consent, on the basis that Mrs. Nacapuy failed to establish the duty and causation elements of this test. He argued that he advised Mrs. Nacapuy of the risks and nature of the angioplasty with stent procedure and that Mrs. Nacapuy signed a written informed consent form. Furthermore, he argued that the Nacapuys had not proved causation, that a reasonable person with the patient's characteristics would not have consented to the

procedure had the patient been advised of the appropriate risk analysis. The circuit court granted Dr. Terakubo's motion for partial summary judgment on December 26, 2003.

3. Motion in limine to exclude expert testimony or evidence pertaining to the dismissed claims

On March 18, 2004, following the circuit court's order granting Dr. Dacanay's motion for summary judgment, the circuit court granted the Nacapuys' motion to file a first amended complaint against Dr. Dacanay and Dr. Terakubo. The Nacapuys filed their first amended complaint on March 23, 2004, claiming that Dr. Dacanay and Dr. Terakubo failed to obtain Mrs. Nacapuy's informed consent for the reballooning procedure:

> Defendants Drs. Dacanay and Terakubo failed to inform [Mrs. Nacapuy] of the risks of the second procedure to re-balloon the deformed stent, when they knew that the balloon would damage the blood vessel walls which were not protected by the stent. Defendants Drs. Dacanay and Terakubo failed to advise [Mrs. Nacapuy] of any alternatives and did not obtain her consent for the second procedure to re-balloon the stent.

On May 17, 2004, Dr. Dacanay filed a motion for summary judgment, asserting that the Nacapuys' first amended complaint alleging negligence and informed consent for the reballooning procedure does not "state any new claims against Dr. Dacanay, but instead puts a new spin on facts that were already known and claims that were already alleged -- and dismissed with prejudice -- against Dr. Dacanay."[7] The circuit court denied Dr. Dacanay's motion, ruling that there is a question of fact regarding whether

[7] Dr. Dacanay recognized that the first amended complaint, unlike the original complaint, alleged that Dr. Terakubo performed the reballooning procedure. However, he argued that the amendments are not based upon any new information discovered after summary judgment was granted in Dr. Dacanay's favor.

the re-ballooning of the stent caused any additional damage, without addressing Dr. Dacanay's argument against the informed consent claim.

On May 14, 2004, Dr. Dacanay filed a motion in limine to preclude expert testimony or evidence pertaining to the dismissed claims. He argued that the issue of informed consent has been thoroughly briefed and argued before the circuit court and that the court had already issued its definitive ruling dismissing that claim. On July 6, 2004, the circuit court granted Dr. Dacanay's motion in limine No. 4 to preclude expert testimony or evidence pertaining to dismissed claims.

4. Motion in limine to exclude the package insert instructing to manipulate the guide wire under fluoroscopy

On September 29, 2003, Dr. Terakubo and Cardiology Associates filed a motion in limine to preclude non-physicians from testifying as to the medical standard of care.[8] In their motion, which Dr. Dacanay joined on October 6, 2003, they argued against permitting evidence of the package insert which provides

[8] The Nacapuys contended that pursuant to Hawai'i Rules of Evidence ("HRE") 701, non-physicians may testify on their opinions in order to help determine facts in issue. They also argued that non-physicians of the manufacturer of the guide wire have witnessed "hundreds of [angioplasty] procedures[] to observe the interventional cardiologists and provide their advice and opinions as requested." The Nacapuys explained that the manufacturers and representatives of the product attend various seminars, schools, and go to hospitals to teach. Although they acknowledged that lay witnesses cannot testify on the medical standard of care, they contended that these non-physicians should "provide their opinions based on their own perceptions, background and knowledge about [angioplasty] procedures and use of guide wires."

the following relevant warnings[9]:

> When the guide wire is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the wire without observing the resultant tip response. Never advance the guide wire against resistance without first determining the reason for resistance under fluoroscopy. Excessive force against resistance may result in separation of the guide wire tip, damage to the catheter or vessel damage.

They contended that under Craft v. Peebles, 78 Hawai'i 287, 893 P.2d 138 (1995), a package insert may not establish a standard of care in a medical negligence action. They argued that because the package insert was not written by physicians, it would be prejudicial and confusing, and impermissible under HRE Rule 403.

At the June 29, 2004 hearing on this motion, the Nacapuys argued that the package insert should not be precluded as evidence:

> They're saying no witness should be able to testify that a doctor should read the book. In other words, he can throw it and trash it; and no witness should be able to say that he should read it as a standard of care.
>
> Your Honor, we're not offering any witness to say that the doctor should have read this book to establish the standard of care. We are offering the book to help the jury understand whether or not the doctor in his overall treatment of the patient

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[9] The package insert's Warnings/Adverse reactions states:

> SCIMED's Trooper and Patriot Guide Wires are designed and intended for one procedure only. Do not resterilize. Reuse can compromise the Guide Wire's performance characteristics and can cause infection, even if resterilized.
>
> Vessel trauma may result from the improper use of this device. Follow the enclosed directions carefully. When the guide wire is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the wire without observing the resultant tip response. Never advance the guide wire against resistance without first determining the reason for resistance under fluoroscopy. Excessive force against resistance may result in separation of the guide wire tip, damage to the catheter or vessel damage.
>
> Other potential adverse reactions which may result from the improper use of this device include, but are not limited to: Air embolism, hematoma at the puncture site, infection and perforation of the heart.

was negligence [sic] in any respect.

The circuit court orally granted the defendants' motion, stating that it "does not believe that the manufacture instructions should be allowed to determine the standard of care as indicated in the Craft v. Peebles case."

5. Dr. Chesne's opinion of Dr. Dacanay's treatment and care of Mrs. Nacapuy

At trial, Dr. Dacanay called Dr. Chesne as an expert witness. Dr. Chesne, who reviewed the records and depositions in the present case, opined that Dr. Dacanay met the standard of care with respect to his care and treatment of Mrs. Nacapuy:

> Q. Based upon your education and experience and based upon your review of the record in this case, do you have an opinion as to whether [Dr. Dacanay] met the standard of care with respect to his care and treatment of [Mrs. Nacapuy]?
> A. I do.

The Nacapuys' counsel immediately objected, and the following arguments were made at the bench:

> Mr. Ronald Au: May it please the Court, I deposed this gentleman in April of this year in Los Angeles and specifically I asked him if he had given all his opinions. All right? He gave specific opinions as to Doctor Terakubo, he was never asked and he never testified and he said those are all the opinions he has. He was never asked by [Dr.] Dacanay's counsel a question like that or anything close to it, Your Honor, and this Court has ruled that no new opinions.
>
> This is basic. I have the deposition here and if I'm in error, Mr. Cook, you show me what he said that he met the standard of care exactly for the reasons that you asked him just here. Show me.
>
> The Court: Mr. Cook?
>
> Mr. Cook: The deposition of Doctor Chesne is replete with his specific opinions regarding the propriety of Doctor Dacanay's care specifically with respect to the post-complication treatment. Mr. Au may not have asked him the broad question as to whether -- about the standard of care, but Doctor Chesne repeatedly testified about the details of Doctor Dacanay's treatment and said all of those aspects of his treatment were appropriate. I am entitled to ask the general question first and then get into the details.
>
> The Court: Mr. Nishimoto?
>
> Mr. Nishimoto: I have nothing to add.
>
> The Court: Okay.

> . . . .
>
> The Court: The Court's going to allow testimony to come in subject to corrections.

Dr. Chesne thereafter restated his opinion that Dr. Dacanay met the standard of care when treating Mrs. Nacapuy.

6. The Nacapuys' motion for judgment as a matter of law on the doctrine of res ipsa loquitur

On July 20, 2004, after all parties presented their witnesses, the Nacapuys orally renewed their motion for judgment as a matter of law on the doctrine of res ipsa loquitur. They had originally argued in their September 24, 2003 motion that this doctrine applies because (1) "a guide wire fracturing in a patient's coronary artery is an event that ordinarily does not occur unless someone has been negligent, [(2)] Defendants had exclusive control over the Trooper Floppy Guide Wire, and links Defendants with the probability that an accident was negligently caused," and (3) "[t]here is no evidence that the partially sedated patient, Ms. Nacapuy, did anything to have caused the guide wire to fracture." The circuit court denied the Nacapuys' motion for partial summary judgment regarding res ipsa loquitur on December 26, 2003.

During their renewed motion, the Nacapuys argued that "there is no explanation . . . for breaking the wire and the stent and deforming it other than potential negligence of the defendant." The defendants objected, incorporating their previous res ipsa loquitur arguments that this doctrine is inappropriate where expert medical testimony is required to establish the standard of care and the breach of that standard. Dr. Dacanay explained that "the common knowledge or experience of

men is not extensive enough to permit it to be said that the plaintiff's condition would not have existed except for negligence of the person to be charged."[10]

The circuit court orally denied the Nacapuys' motion for judgment as a matter of law on the doctrine of res ipsa loquitur.

7. Jury instructions of negligence or foreseeability

The Nacapuys claimed that Dr. Terakubo was negligent in fracturing the guide wire and requested jury instructions on ordinary negligence or foreseeability. These instructions provided:

> Court's Instruction 6.1
>
> Negligence is doing something which a reasonable person would not do, or failing to do something which a reasonable person would do. It is the failure to use that care which a reasonable person would use to avoid injury to himself, herself, or other people or damage the property.
>
> In deciding whether a person was negligent, you must consider what was done or not done under the circumstances as shown by the evidence in this case.
>
> Court's Instruction 6.2
>
> In determining whether a person was negligent, it may help to ask whether a reasonable person in the same situation would have foreseen or anticipated that injury or damage could result from that person's action or inaction. If such a result would be foreseeable by a reasonable person and if the conduct reasonably could be avoided then not to avoid would be negligence.

The defendants contended that the elements of medical negligence are covered in other jury instructions[11] and

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[10] After a hearing on this motion, the circuit court granted Dr. Dacanay's motion for summary judgment on November 26, 2003.

[11] The following instructions regarding medical malpractice were provided to the jury:

> Whenever an expert medical witness expresses an opinion, that opinion must be asked upon a reasonable medical probability. Plaintiffs in this case must show with reasonable medical

(continued...)

therefore, the standard negligence instructions are inappropriate. The court refused the Nacapuys' proposed instructions on negligence and foreseeability.

The jury returned its verdict on July 23, 2004 in favor of all defendants and the circuit court filed its final judgment on August 24, 2004. The Nacapuys filed a timely notice of appeal on September 21, 2004.

II. STANDARDS OF REVIEW

A. Summary Judgment

"We review the circuit court's grant or denial of summary judgment de novo." Willis v. Swain, 112 Hawai'i 184, 188,

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[11](...continued)
probability through expert testimony that Defendants were negligent and that such negligent conduct was a substantial factor in causing Plaintiff's injury.

To prove medical negligence, plaintiffs must prove all of the following elements:

(1) Defendants breached the applicable standard of care; and

(2) The breach of the standard of care was a legal cause of injury/damage to plaintiffs; and

(3) Plaintiffs sustained injury/damage.

In determining whether a physician was negligent, the physician's conduct should be considered in light of all the attendant circumstances at the time he acted. He should not be judged by the results of his treatment.

A medical doctor has a duty to possess and exercise that degree of knowledge, skill, care and diligence commonly possessed and exercised by other medical doctors in the same field and under similar conditions. This is known as the "standard of care." The failure to meet the standard of care constitutes a breach of the standard of care on the part of the doctor.

Plaintiffs are required to present testimony from an expert establishing the standard of care, that defendants breached this standard, and that defendants' breach was a legal cause of plaintiffs' injury/damages.

Where there is more than one recognized method of treatment, each of which conforms to the applicable standard of care, a physician does not breach the standard of care by utilizing one of these methods, provided such use conforms to the standard of care as defined by these instructions.

A physician is not an insurer of a patient's health. A physician is not negligent simply because of an unfortunate event if the physician conforms to the applicable standard of care.

145 P.3d 727, 731 (2006) (citing Hawai'i Cmty. Fed. Credit Union v. Keka, 94 Hawai'i 213, 221, 11 P.3d 1, 9 (2000)). The standard for granting a motion for summary judgment is settled:

> [S]ummary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. A fact is material if proof of that fact would have the effect of establishing or refuting one of the essential elements of a cause of action or defense asserted by the parties. The evidence must be viewed in the light most favorable to the non-moving party. In other words, we must view all of the evidence and the inferences drawn therefrom in the light most favorable to the party opposing the motion.

Id. (citing Keka, 94 Hawai'i at 221, 11 P.3d at 9) (some citations and internal quotation marks omitted).

B. Refusal To Modify Another Judge's Ruling

"Unless cogent reasons support the second court's action, any modification of a prior ruling of another court of equal and concurrent jurisdiction will be deemed an abuse of discretion." Wong v. City and County of Honolulu, 66 Haw. 389, 394, 665 P.2d 157, 162 (1983). We explained:

> A judge should generally be hesitant to modify, vacate or overrule a prior interlocutory order of another judge who sits in the same court. Judicial restraint in this situation stems from considerations of courtesy and comity in a court with multiple judges, where each judge has equal and concurrent jurisdiction.
>
> The normal hesitancy that a court would have in modifying its own prior rulings is even greater when a judge is asked to vacate the order of a brother or sister judge. The general rule which requires adherence to a prior interlocutory order of another judge of the same court thus commands even greater respect than the doctrine of "law of the case" which refers to the usual practice of courts to refuse to disturb all prior rulings in a particular case, including rulings made by the judge himself.

Id.

C. Admissibility of Evidence

> [D]ifferent standards of review must be applied to trial court decisions regarding the admissibility of evidence, depending on the requirements of the particular rule of evidence at issue.

> When application of a particular evidentiary rule can yield only one correct result, the proper standard for appellate review is the right/wrong standard. However, the traditional abuse of discretion standard should be applied in the case of those rules of evidence that require a "judgment call" on the part of the trial court.

State v. West, 95 Hawai'i 452, 456-57, 24 P.3d 648, 652-53 (2001) (quoting Kealoha v. County of Hawai'i, 74 Haw. 308, 319, 844 P.2d 670, 676 (1993)).

The standard of review for reviewing the exclusion of evidence under HRE 403 is the abuse of discretion standard. Ranches v. City and County of Honolulu, 115 Hawai'i 462, 468, 168 P.3d 592, 598 (2007) (citation omitted). Further, the circuit court has discretion as to whether expert testimony should be admitted, and its decision shall not be overturned unless there is a clear abuse of discretion. Estate of Klink ex rel. Klink v. State, 113 Hawai'i 332, 352, 152 P.3d 504, 542 (2007) (citation omitted).

It is well established that the circuit court abuses its discretion when

> it bases its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence. Office of Hawaiian Affairs v. State, 110 Hawai'i 338, 351, 133 P.3d 767, 780 (2006). Abuse of discretion occurs when "the trial court has clearly exceeded the bounds of reason or disregarded rules or principles of law or practice to the substantial detriment of a party litigant."

Ranches, 115 Hawai'i at 468, 168 P.3d at 598.

D. Motion for Judgment Notwithstanding the Verdict

A trial court's rulings on directed verdict or judgment notwithstanding the verdict ("JNOV") motions are reviewed de novo. Nelson v. Univ. of Hawai'i, 97 Hawai'i 376, 393, 38 P.3d 95, 112 (2001) (citing In re Estate of Herbert, 90 Hawai'i 443,

454, 979 P.2d 39, 50 (1999)).

> In deciding a motion for directed verdict or JNOV, the evidence and the inferences which may be fairly drawn therefrom must be considered in the light most favorable to the nonmoving party and either motion may be granted only where there can be but one reasonable conclusion as to the proper judgment.

Id. (citing Carr v. Strode, 79 Hawai'i 475, 486, 904 P.2d 489, 500 (1995)).

E. Jury Instructions

> When jury instructions or the omission thereof are at issue on appeal, the standard of review is whether, when read and considered as a whole, the instructions given are prejudicially insufficient, erroneous, inconsistent, or misleading. Erroneous instructions are presumptively harmful and are a ground for reversal unless it affirmatively appears from the record as a whole that the error was not prejudicial. [However, e]rror is not to be viewed in isolation and considered purely in the abstract. It must be examined in the light of the entire proceedings and given the effect which the whole record shows it to be entitled. In that context, the real question becomes whether there is a reasonable possibility that error might have contributed to conviction. If there is such a reasonable possibility in a criminal case, then the error is not harmless beyond a reasonable doubt, and the judgment of conviction on which it may have been based must be set aside.
>
> State v. Gonsalves, 108 Hawai'i 289, 292-93, 119 P.3d 597, 600-01 (2005).
>
> . . . .
>
> . . . [O]nce instructional error is demonstrated, we will vacate, without regard to whether timely objection was made, if there is a reasonable possibility that the error contributed to the defendant's conviction, i.e., that the erroneous jury instruction was not harmless beyond a reasonable doubt.

State v. Nichols, 111 Hawai'i 327, 334, 337, 141 P.3d 974, 981, 984 (2006).

III. DISCUSSION

A. The Circuit Court Erred By Granting Dr. Dacanay and Dr. Terakubo's Motion for Summary Judgment on the Issue of Informed Consent Where There Are Genuine Issues of Material Fact.

On appeal, the Nacapuys argue that the trial court

erred by granting Dr. Dacanay and Dr. Terakubo's motion for summary judgment "on the issue of informed consent in the initial [c]omplaint by disregarding the totality of the circumstances and jury question of causation." The Nacapuys argue that Dr. Dacanay and Dr. Terakubo owed Mrs. Nacapuy a duty to properly advise her of the "risks, complications, alternative treatments, and obtain her fully informed consent" for her angioplasty and reballooning procedures. The Nacapuys further contend that they presented sufficient evidence to survive summary judgment on the causation element of informed consent.

To establish a claim of negligent failure to obtain informed consent[12] under Hawai'i law, the plaintiff must

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[12] The ICA discussed the history and purpose of this tort in Bernard v. Char ["Bernard I"], 79 Hawai'i 371, 903 P.2d 676 (1995), as follows:

> About three decades ago, a medical negligence cause of action based on the doctrine of informed consent began to develop rapidly in this country. Under this theory of negligence, even a physician or surgeon who skillfully treats or operates on a patient may nevertheless be held liable for adverse consequences to the patient if: (1) the physician performs the treatment or operation without or beyond the scope of the patient's consent, or (2) the physician fails to inform the patient of the risks of a particular treatment or operation so that the patient can decide whether he or she is willing to undergo the treatment or operation.
>
> The informed consent doctrine is based on principles of individual autonomy, and specifically on the premise that every person has the right to determine what shall be done to his own body. Surgeons and other doctors are thus required to provide their patients with sufficient information to permit the patient himself to make an informed and intelligent decision on whether to submit to a proposed course of treatment or surgical procedure. Such a disclosure should include the nature of the pertinent ailment or condition, the risks of the proposed treatment or procedure, and the risks of any alternative methods of treatment, including the risks of failing to undergo any treatment at all.

Bernard I, 79 Hawai'i at 378, 903 P.2d at 683 (citing W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on the Law of Torts § 32, at 188 (5th ed.1984)).

demonstrate that:

> (1) the physician owed a duty to disclose the risk of one or more of the collateral injuries that the patient suffered; (2) the physician breached that duty; (3) the patient suffered injury; (4) the physician's breach of duty was a cause of the patient's injury in that (a) the physician's treatment was a substantial factor in bringing about the patient's injury and (b) a reasonable person in the plaintiff patient's position would not have consented to the treatment that led to the injuries had the plaintiff patient been properly informed; and (5) no other cause is a superseding cause of the patient's injury.

Barcai v. Betwee, 98 Hawai'i 470, 483-84, 50 P.3d 946, 959-60 (2002) (relying on Bernard v. Char ["Bernard II"], 79 Hawai'i 362, 371, 903 P.2d 667, 676 (1995) (footnote added)).

With respect to summary judgment, this court has previously declared that,

> [A] summary judgment motion challenges the very existence or legal sufficiency of the claim or defense to which it is addressed. In effect, the moving party takes the position that he or she is entitled to prevail because his or her opponent has no valid claim for relief or defense to the action. Accordingly, the moving party has the initial burden of identifying those portions of the record demonstrating the absence of a genuine issue of material fact. The moving party may discharge his or her burden by demonstrating that, if the case went to trial, there would be no competent evidence to support a judgment for his or her opponent. Cf. Celotex Corp. v. Catrett, 477 U.S. 317 . . . (1986) (a party moving for summary judgment under Federal Rules of Civil Procedure Rule 56 need not support his or her motion with affidavits or similar materials that negate his or her opponent's claims, but need only point out that there is an absence of evidence to support the opponent's claims). For if no evidence could be mustered to sustain the nonmoving party's position, a trial would be useless.

Exotics Hawaii-Kona, Inc. v. E.I. Du Pont De Nemours & Co., 116 Hawai'i 277, 301, 172 P.3d 1021, 1045 (2007) (quoting Young v. Planning Comm'n of the County of Kaua'i, 89 Hawai'i 400, 407, 974 P.2d 40, 47 (1999) (original brackets omitted). Summary judgment in favor of the defendant is proper when the plaintiff

> fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be no genuine issue as to any material fact, since a

> complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is entitled to judgment as a matter of law because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.

Id. at 302, 172 P.3d at 1046 (quoting Hall v. State, 7 Haw. App. 274, 284, 756 P.2d 1048, 1055 (1988)).

1. Dr. Terakubo's liability for failing to obtain Mrs. Nacapuy's informed consent for the angioplasty with stent procedure

a. Breach of duty

On appeal, the Nacapuys contend that Dr. Terakubo failed to advise Mrs. Nacapuy of the relevant risks associated with the angioplasty with stent procedure. Because this material fact is in dispute, there remains a genuine issue as to whether Dr. Terakubo breached his duty to advise Mrs. Nacapuy of the relevant risks associated with the angioplasty with stent procedure.

> The existence of a duty owed by the defendant to the plaintiff, that is, whether . . . such a relation exists between the parties that the community will impose a legal obligation upon one for the benefit of the other-or, more simply, whether the interest of the plaintiff which has suffered invasion was entitled legal protection at the hands of the defendant, is entirely a question of law.

Pulawa v. GTE Hawaiian Tel, 112 Hawai'i 3, 11-12, 143 P.3d 1205, 1213-14 (2006) (quoting Knodle v. Waikiki Gateway Hotel, Inc., 69 Haw. 376, 385, 742 P.2d 377, 383 (1987)).

The physician is required to disclose to his patient the:

> (1) condition being treated; (2) nature and character of the proposed treatment or surgical procedure; (3) anticipated results; (4) recognized possible alternative forms of treatment; and (5) recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, as well as the recognized possible alternative forms of treatment,

including non-treatment.
Barcai, 98 Hawai'i at 483, 50 P.3d at 959 (citing HRS § 671-3). Under Hawaii's "patient oriented standard," a "physician [is required] to disclose 'what a reasonable patient needs to hear from his or her physician in order to make an informed and intelligent decision regarding treatment." Id. at 484, 50 P.3d at 960 (quoting Carr v. Strode, 79 Hawai'i 475, 484, 904 P.2d 489, 498 (1995)). Because this standard is patient-focused, "a patient is not required to produce any expert medical testimony regarding what other reasonable [physicians] would have disclosed under the same or similar circumstances."[13] Carr, 79 Hawai'i at 484, 904 P.2d at 498 (quoting Bernard I, 79 Hawai'i at 382, 903 P.2d at 687).

As stated supra, Dr. Terakubo claims that on June 16, 2000, he advised Mrs. Nacapuy of the attendant risks and complications associated with the procedure and of the treatment

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[13] In adopting this patient-oriented standard, we reasoned that it

> better respects the patient's right of self-determination and affixes the focus of the inquiry regarding the standard of disclosure on the motivating force and purpose of the doctrine of informed consent-aiding the individual patient in making an important decision regarding medical care. It also protects against the pitfalls of proof associated with the physician-oriented standard discussed in Canterbury [v. Spence, 464 F.2d 772, reh'g denied, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972)].

Carr, 79 Hawai'i at 485, 904 P.2d at 499. A professional standard, in contrast,

> is at odds with the patient's prerogative to decide on projected therapy himself [or herself]. That prerogative, we have said, is at the very foundation of the duty to disclose, and both the patient's right to know and the physician's correlative obligation to tell . . . are diluted to the extent that its compass is dictated by the medical profession.

Id. (quoting Canterbury, 464 F.2d at 786).

alternatives.[14] However, according to Mrs. Nacapuy, Dr. Terakubo did not explain the procedure, but merely introduced himself and told her, "'I'm the expert. I will do your angioplasty.'" Moreover, although Mrs. Nacapuy gave Dr. Terakubo written consent to perform the procedure on her, "a consent form is no substitute for a physicians's affirmative duty to inform his or her patient." Ditto v. McCurdy, 86 Hawai'i 93, 120, 947 P.2d 961, 988 (App. 1997). Further, although Mrs. Nacapuy admitted that she read the Informed Consent form prior to signing it, Mrs. Nacapuy also stated at her deposition that she did not understand what she was signing:

> Q: Did the nurse explain to you what you were signing?
> A: Well, I was worried because they rush me to sign things, and she was saying like don't worry because everything is standard in this hospital. That's why everything is typewritten

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[14] At his deposition on 3/29/02, Dr. Terakubo stated:

> A: I told her about risk and benefit of the procedures.
> Q: What were the risks? What did you tell her?
> A: I went over with her what I'm going to do. I tell her the procedures. And I told her about the possible potential complications.
> Q: What are the complications you told her?
> A: Aside from the explanation in the procedures, I told her about bleeding complications, infections, kidney damage because of the contrast dye.
> Q: Kidney what?
> A: Kidney dysfunction because of the contrast dye used. I told her about possibility she may have irregular heart rhythm, stroke, heart attack or death or requiring emergent open heart surgery.
> . . . .
> Q: Did you tell her there's a possible risk of coronary damage?
> A: Yes, I have.
> Q: What did you tell her about coronary damage?
> A: I told her that the angioplasty -- I explain the procedure about the angioplasty, how we open the blocked area of the heart artery and how we use the stent to scaffold the arteries. But despite those means, if the artery keeps collapsing, any kind of vascular damages, she may require emergent open heart surgery as a last resort to save her life.

> so you don't have to worry. These are all standard, she said, so I relied on that word.
>
> . . . .
>
> Q: Did she express anything else?
>
> A: No. I just sign.
>
> . . . .
>
> Q: Again, let me clarify. When you mentioned that things had not been fully explained, were you talking about this document had not been fully explained or the procedure had not been fully explained?
>
> A: This document is not fully explained because I didn't understand fully, you know, but she [nurse] said it's all typewritten, and it's a standard procedure so just sign it. And then Dr. Terakubo didn't explain how he going to do it. He just say we'll do angioplasty. We will put balloon in you vessel or something.
>
> Q: When did he tell you this?
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> A: The time he met me. No, that was Dr. Dacanay. I'm sorry, I get mixed up. The word that Dr. Terakubo say, I am Dr. Terakubo. I'm the expert. I will do your angioplasty.

Because of these disparate accounts, there is a genuine issue of material fact regarding whether Dr. Terakubo advised Mrs. Nacapuy of the attendant risks and complications associated with the procedure and of the treatment alternatives.

b. causation

Alternatively, Dr. Terakubo argues that the circuit court properly awarded summary judgment in his favor on the issue of informed consent because the Nacapuys did not establish causation -- that a reasonable person in Mrs. Nacapuy's position would not have consented to the treatment that led to the injuries had Mrs. Nacapuy been properly informed. Dr. Terakubo argues that Mrs. Nacapuy's claim that she would have chosen some other alternative to treatment does not establish the causation element.

In an informed consent claim, causation is "to be judged by an objective standard, that is, whether a reasonable person in the plaintiff-patient's position would have consented

to the treatment that led to his or her injuries had the plaintiff-patient been properly informed of the risk of the injury that befell him or her." Bernard II, 79 Hawai'i at 371, 903 P.2d at 676 (emphasis added). In Bernard II, we discussed three causation standards -- the "objective standard," the "subjective standard," and the "modified objective standard,"[15] -- overruled the ICA-crafted "modified objective standard," and adopted the objective standard in line with the majority of courts for three main reasons. Id. at 366-371, 903 P.2d at 671-676.

First, we observed that the subjective plaintiff/patient standard is criticized because it is impossible to ascertain what the plaintiff would have done knowing the risks and alternatives:

> As with the standards for disclosure, there are different approaches to the criterion for causality. One point of view emphasizes the unfairness to practitioners involved in gauging what might have happened by what patients say they would have done had the risk information been disclosed. The patient-plaintiffs are thus placed in a unique position and allowed to state in court that, after all is said and done, in retrospect they would not have agreed to treatment. Patients cannot divorce their re-created decision process from hindsight. The same difficulty will trouble triers of fact. No one can be really certain that a

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[15] The ICA endorsed the modified objective standard in Leyson v. Steuermann, 5 Haw. App. 504, 705 P.2d 37 (1985), overruled on other grounds by Bernard II, 79 Hawai'i at 371, 903 P.2d at 676. Under the ICA's modified objective approach,

> a plaintiff seeking to establish causation is not required to testify that he or she would have foregone treatment if disclosure of the risks had been made. However, in order to avoid a directed verdict against him or her, the plaintiff must adduce evidence to support a finding that the plaintiff, acting rationally and reasonably, would have withheld consent to a proposed course of treatment or surgery if properly advised of the risks.

Bernard I, 79 Hawai'i at 384, 903 P.2d at 689 (citing W. Page Keeton, D. Dobbs, R. Keeton & D. Owen, Prosser and Keeton on the Law of Torts § 32, at 192 (5th ed. 1984)).

> patient would have withheld consent at the time if he or she had known the undisclosed facts. Moreover, if the patient should die as a result of the procedure, reliance upon such a test of causality as this would probably preclude recovery altogether.

Id. at 368, 903 P.2d at 673. (quoting F. Rozovsky, Consent to Treatment, § 1.13.4, 62-63 (1984)). Second, we ruled that the objective standard is consistent with the general negligence action which "measures the conduct of the person in question against that of a 'reasonable person in like circumstances.'" Id. at 369, 903 P.2d at 674. Finally, we noted that because this standard considers the patient's position, it properly takes into account the patient's individual fears and beliefs. Id. at 369-70, 903 P.2d at 674-75.

Thus, as previously stated, the causation standard is "whether a reasonable person in the plaintiff-patient's position would have consented to the treatment that led to his or her injuries had the plaintiff-patient been properly informed of the risk of the injury that befell him or her." Bernard II, 79 Hawai'i at 371, 903 P.2d at 676. Under this standard,

> the physician is less subject to a disgruntled patient's obvious bias in testifying in hindsight or disillusionment following unsuccessful treatment. Furthermore, because no deference is given to the credibility of the particular plaintiff, the plaintiff is not required to affirmatively testify that he would have foregone treatment if he had been informed of the material risks.

Id. (citations omitted). If the plaintiff does testify, however, "[h]is [or her] testimony, albeit hindsight, is material and relevant and entitled to be considered by the jury. It simply is not conclusive of the causation issue." Id. at 370 n. 5, 903 P.2d at 675 n. 5 (quoting Fain v. Smith, 479 So.2d 1150, 1155 (Ala. 1985)).

In order to grant Dr. Terakubo summary judgment on this issue, we must find that as a matter of law, a reasonable person in the plaintiff-patient's position would have consented to the treatment that led to his or her injuries had the plaintiff-patient been properly informed of the risk of the injury that befell him or her. According to the evidence adduced at trial, a majority of people prefer to undergo angioplasty over the alternative bypass operation.[16] Dr. Hubbard also explained that the risk of operative mortality from bypass surgery is slightly higher than the risk of operative mortality from an angioplasty, "between a one percent and a half a percent." However, this statistic does not necessarily indicate that the minority of people who choose bypass surgery, knowing the risks, are as a matter of law, unreasonable. In fact, Dr. Hubbard expressed that "[t]here are a lot of people, perhaps not the majority of people, but a substantial number of people [who,] when you put the chances to them," favor undergoing a bypass operation because it

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[16] Dr. Hubbard also testified that

> as between a angioplasty stent procedure and a bypass, (a) there is a greater risk of mortality with bypass, (b) there is greater pain and suffering with bypass, (c) it is 'harder to go through' a bypass, (d) 'nationwide more and more angioplasties are done and fewer and fewer bypasses are done,' (e) he is an 'enthusiast' of angioplasty, (f) the majority of people would have chosen angioplasty over bypass, and (g) if given the choice, he himself would have recommended angioplasty over bypass.

Dr. Hubbard explained that a patient may choose an angioplasty "because you're trading off a procedure that can be done -- you know, if all goes well, you could be in and out of the hospital on the same day or the next day and you're home and back to normal, no residual disability after an angioplasty, whereas, if you have surgery, you have to go through healing the wounds of your surgery. It's harder to go through it."

is more lasting.[17] Dr. Hubbard explains the risk of angioplasty procedures to patients as follows:

> "Look, if I do this angioplasty, there's a [fifteen] percent chance in the next three to four months we are going to be doing this all over again, and you may end up getting bypass surgery anyway, or you could get a single vessel artery graft, you have a very high likelihood this thing is going to last you for [fifteen] years, very durable graft, but you're going to have to go through some pain and suffering for a couple of weeks to get there, but then you're going to be less likely to come back."
>
> Say it's somebody that wants to go to the Amazon and doesn't want to deal with me anymore. I've seriously -- I've found a number of people who will elect to have bypass surgery when that's an option even if it's, you know, something that's technically amenable to angioplasty.

He observed that "[t]here are people who are willing to take a chance and go for the thing that's not painful, as painful, usually, or people who just, you know, want the best most solid, stable solution they can possibly get." Thus, Dr. Hubbard informs the patient of the risks and alternatives to the angioplasty with stent procedure to allow him or her to make an informed medical decision.

Based on Dr. Hubbard's testimony that a "substantial" amount of people choose to undergo bypass operations, we cannot conclude that, as a matter of law, a reasonable person in Mrs. Nacapuy's position would have consented to the treatment that led

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[17] Dr. Hubbard further explained that various people will choose a bypass surgery over angioplasty:

> Overall, the survival rates are pretty similar. There's no obvious advantage in terms of whether you're likely to be alive in one year or five years between having a bypass, a single vessel bypass, and a single vessel angioplasty. I'm not even sure that study's been done but I assume the survival rates are going to be excellent in both cases, so that's what I would -- that's how I would put it to the patient, and I would say essentially you get a more durable result with surgery, and you go through less pain and suffering getting it done when you have an angioplasty, and people have different priorities.

to her injuries had she been properly informed of the risk of the injury that befell her. Hence, we conclude that the circuit court erred in granting summary judgment in favor of Dr. Terakubo regarding Dr. Terakubo's liability for informed consent for the angioplasty with stent procedure.

2. Dr. Dacanay's duty to obtain Mrs. Nacapuy's informed consent for the angioplasty with stent procedure

The Nacapuys also contend that Dr. Dacanay owed Mrs. Nacapuy a duty to advise her of the risks, complications, and alternative treatments, and obtain her fully informed consent for her angioplasty procedure. However, Dr. Dacanay, relying on O'Neal v. Hammer, 87 Hawai'i 183, 953 P.2d 561 (1998), maintains that he was not under the duty to warn Mrs. Nacapuy of the risks of the procedure.

In O'Neal, this court addressed whether "a physician who refers his patient to another physician for some special treatment and participates in a combined plan of treatment has a duty to disclose the risks connected with the special treatment." O'Neal, 87 Hawai'i at 187, 953 P.2d at 565. We recognized that most jurisdictions hold that a referring physician does not have the duty to obtain a patient's informed consent, but nevertheless, we adopted a "degree of control" standard for determining whether a referring physician has a duty to obtain informed consent:

> Where the referring physician neither performs the procedure nor retains control over the patient's treatment, that physician does not have a duty to obtain informed consent. On the other hand, where a physician orders a specific procedure or otherwise retains control over the treatment of the patient, the physician is subject to a duty to obtain informed consent.

Id. at 187, 953 P.2d at 565 (citing Prooth v. Wallsh, 432 N.Y.S.2d 663 (N.Y. Sup. Ct. 1980), Nisenholtz v. Mount Sinai Hospital, 483 N.Y.S.2d 568 (N.Y. Sup. Ct. 1984), Kashkin v. Mount Sinai Medical Center, 538 N.Y.S.2d 686 (N.Y. Sup. Ct. 1989)). Under this standard, as the New York County Supreme Court held in Nisenholtz, a referring doctor who merely proposed further treatment did not have a duty to obtain the patient's informed consent. Id. at 188, 953 P.2d at 566 (citing Kashkin, 538 N.Y.S.2d at 688). However, a physician who formally orders and arranges the procedure -- and where the operating physician's role "was merely to perform the procedure" -- has a duty to obtain the patient's informed consent. Id.; Kashkin, 538 N.Y.S.2d at 688. Under the "degree of control" standard, in O'Neal, we determined that the circuit court erred in granting the defendant-physician's motion for directed verdict even where he did not perform the surgery, because the defendant-physician coordinated all phases of the treatment and initiated the irrevocable step in the treatment which required the surgery at issue. O'Neal, 87 Hawai'i at 189, 953 P.2d at 567.

In the instant case, although Dr. Dacanay did not perform the angioplasty with stent procedure, he recommended, and it was eventually decided, that Mrs. Nacapuy would undergo this procedure. Dr. Dacanay then asked Dr. Terakubo to perform Mrs. Nacapuy's angioplasty with stent procedure. Thus, Dr. Dacanay, like the defendant-physicians in O'Neal, Kashkin, and Prooth, retained sufficient control over Mrs. Nacapuy's procedure to require him to inform her of the risks and alternatives to the

angioplasty with stent procedure.

Dr. Dacanay correctly points out that we also declared in O'Neal that "this duty may be discharged if another physician procures an informed consent from the patient prior to surgery, thereby breaking the chain of causation leading to the referring physician." Id. at 189, 953 P.2d at 567 (citing Shkolnik v. Hospital For Joint Diseases, 211 A.D.2d 347, 627 N.Y.S.2d 353 ([N.Y. App. Div.] 1995) (holding that plaintiff must prove that the referring doctor's failure to obtain informed consent was a legal cause of plaintiff's injury)). Thus, Dr. Dacanay asserts that because Dr. Terakubo obtained Mrs. Nacapuy's informed consent for the angioplasty with stent procedure, "the chain of causation that would arguably make Dr. Dacanay responsible for obtaining her consent for that procedure" is broken. However, because there remains a genuine issue as to whether Dr. Terakubo advised Mrs. Nacapuy of the relevant risks associated with the angioplasty with stent procedure, this exception does not entitle Dr. Dacanay to summary judgment on this issue. Thus, viewing the evidence in the light most favorable to Mrs. Nacapuy, we hold that the circuit court erred in granting Dr. Dacanay's motion for summary judgment where he maintained sufficient control over Mrs. Nacapuy's procedure and it is unclear whether Dr. Terakubo obtained Mrs. Nacapuy's informed consent.

3. Dr. Dacanay and Dr. Terakubo's duty to obtain Mrs. Nacapuy's informed consent for the second angioplasty with stent procedure

The Nacapuys also argue on appeal that the circuit court erred by granting summary judgment on the issue of informed

consent because Dr. Dacanay and Dr. Terakubo had a duty to advise Mrs. Nacapuy of the risks, complications, and alternatives of the reballooning procedure. In light of the conflicting testimony regarding Mrs. Nacapuy's state of consciousness and the emergency nature of the situation, we agree.

Indeed, there is a genuine issue of material fact as to whether Mrs. Nacapuy was conscious of the situation during her angioplasty with stent procedure. Mrs. Nacapuy argues that she was only partially sedated during the angioplasty with stent procedure. Upon completion of the angioplasty with stent procedure, she "heard [Dr.] Terakubo say[,] 'We have succeeded.' When she heard him say that, she opened her eyes to look at the fluoroscope screen but it was not turned on. Within seconds, she felt a tug and screamed, 'Ouch!'" Mrs. Nacapuy also testified that she was "still partially up" during the reballooning procedure:

> Q. Alright, then we heard about Dr. Terakubo re-ballooning the stent. Now, you were still partially up, is that right?
> A. Yes, I am partially up.
> Q. Did you know what he was -- why he was doing this, any idea? You have any idea why he was doing this?
> A. No.
> Q. Not at all.
> A. No.
> . . . .
> Q. So he didn't tell you that the stent had deformed and that he was trying to straighten it out again before he did it?
> A. Nobody was saying anything.
> Q. He was just doing it?
> A. Yes, yes.

Nurse Karen Keala, who administered drugs to sedate her and monitored her during the procedure, confirmed that Mrs. Nacapuy was sleepy but arousable.

In contrast, Dr. Terakubo disputes that Mrs. Nacapuy

screamed when the guide wire fractured and argues that there are no nerve endings inside an artery to initiate such a pain response. He further points out that Nurse Karen Keala testified that she did not recall any such outburst from Mrs. Nacapuy. Dr. Terakubo and Dr. Dacanay argue that they could not have adequately informed Mrs. Nacapuy of the complications and the plan to perform the reballooning procedure when she was partially sedated and that "it would have been inappropriate to delay the reballooning procedure until the sedation from the initial procedure had worn off and Mrs. Nacapuy was in a position to provide informed consent for the ballooning."

There is also a genuine issue as to whether the "[d]efendants were dealing with an emergent complication that required them to act promptly to obtain the best result possible for their patient." It is well established that a physician clearly has no duty of disclosure of even material risks in the event of emergency situations. Leyson, 5 Haw. App. at 513-14, 705 P.2d at 45.[18]

According to the defendants, Mrs. Nacapuy "had a good flow vessel but [she] had a foreign body sitting where it

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[18] Leyson declared that the informed consent doctrine does not apply in certain situations:

> The informed consent doctrine is circumscribed by a variety of limitations, and the physician is not required to disclose risks that are unexpected or immaterial, by whatever standard, nor even material risks where disclosure is precluded by an emergency situation, by the patient's incapacity, by the patient's waiver of his right to receive the information, or where disclosure would be harmful to the patient, which gives the doctor a "therapeutic privilege" to withhold the information. Nor, of course, need the doctor disclose risks that are commonly understood, obvious, or already known to the patient.

Leyson, 5 Haw. App. at 513-14, 705 P.2d at 45.

shouldn't be sitting and the question is what do you do about that." Dr. Chesne, an expert witness called by Dr. Dacanay agreed, testifying that, "at that point in time . . . a decision had to be made. There were multiple things that could have been done."

However, Mrs. Nacapuy's expert witness, Dr. Hubbard, disagreed. Dr. Hubbard testified that under the circumstances, Dr. Dacanay and Dr. Terakubo had a duty to obtain Mrs. Nacapuy's informed consent prior to performing the reballooning procedure:

> When a patient - when complications have occurred in the middle of angioplasty and the patient is frightened, the patient is - knows that something is going on, that for at the very least for the patient's peace of mind they need to have as complete information as possible as to what's going on.
> . . . .
> They need to be participants as much as possible in the decision making, if they have an option, and I think that it's neglectful towards the patient to go on for hours with all of this happening without explaining what's happening.

Inasmuch as the parties present conflicting evidence as to Mrs. Nacapuy's level of consciousness and the emergency nature of the reballooning procedure, the defendants did not meet their burden under summary judgment to show the absence of any genuine issue of material fact as to whether Mrs. Nacapuy would have been able to give her informed consent for the reballooning procedure. The circuit court erred by granting the defendants summary judgment on this issue.

Accordingly, we vacate the circuit court's orders granting summary judgment in favor of Dr. Terakubo and Dr. Dacanay and against the Nacapuys and remand for further proceedings to determine whether Dr. Terakubo and Dr. Dacanay are liable for failing to obtain Mrs. Nacapuy's informed consent for

the angioplasty with stent procedure and reballooning procedure.

B. The Circuit Court Erred By Granting Dr. Dacanay's Motion in Limine No. 4 Precluding Evidence on the Issue of Informed Consent.

The Nacapuys argue on appeal that the circuit court erred by granting Dr. Dacanay's motion in limine No. 4 to preclude evidence on the issue of informed consent based on its prior summary judgment rulings by another judge[19] because "the prior summary judgment ruling applied only to the initial complaint," and "had no prospective effect" on the new and different claims in their first amended complaint. They further contend that "there were 'cogent reasons' for the court to allow evidence on the new allegation of failure to obtain informed consent for the [reballooning] procedure."

As previously stated, it is well established that "[a] judge should generally be hesitant to modify, vacate, or overrule a prior interlocutory order of another judge who sits in the same court." Wong, 66 Haw. at 394, 665 P.2d at 162. Under the "law of the case" doctrine, "[u]nless cogent reasons support the second court's action, any modification of a prior ruling of another court of equal and concurrent jurisdiction will be deemed an abuse of discretion." Id. However, inasmuch as the Nacapuys argue that this doctrine is inapplicable because they first claimed that Dr. Dacanay failed to obtain Mrs. Nacapuy's informed consent in their first amended complaint filed March 23, 2004, we shall start by discussing the Nacapuys' arguments made prior to

[19] Judge Dexter D. Del Rosario presided over the first summary judgment ruling. However, as stated supra, the case was reassigned to Judge Bert I. Ayabe on June 4, 2004.

the circuit court's November 26, 2003 summary judgment ruling.

Prior to the circuit court's November 26, 2003 summary judgment ruling, the Nacapuys did not explicitly claim that Dr. Dacanay failed to obtain Mrs. Nacapuy's informed consent for the reballooning procedure. In the Nacapuys' October 15, 2003 memorandum in opposition to Dr. Dacanay's motion for partial summary judgment, the Nacapuys quoted Dr. Hubbard's deposition, see supra, in which he opined that Dr. Dacanay had a duty to obtain her informed consent for the reballooning procedure. They also argued that Dr. Dacanay was Mrs. Nacapuy's attending physician throughout her procedure and assisted Dr. Terakubo when the fractured guide wire was discovered, thus owing Mrs. Nacapuy a duty to obtain her informed consent to perform the angioplasty with stent procedure. Although the Nacapuys had sufficient information also to argue that Dr. Dacanay had a duty to obtain her informed consent for the reballooning procedure, they apparently did not assert this claim prior to the circuit court's summary judgment ruling in favor of Dr. Dacanay. Therefore, because the prior summary judgment ruling in favor of Dr. Dacanay did not address Dr. Dacanay's duty to obtain Mrs. Nacapuy's informed consent for the reballooning procedure, the circuit court erred by precluding evidence on this issue based on the "law of the case" doctrine.

Moreover, as we have concluded supra, there remains a genuine issue of material fact as to whether Dr. Dacanay owed Mrs. Nacapuy a duty to obtain her informed consent for the reballooning procedure. Thus, we reverse the circuit court's

order granting Dr. Dacanay's motion in limine No. 4 to preclude evidence on the issue of informed consent for the reballooning procedure.

C. The Circuit Court Erroneously Misinterpreted Craft In Excluding Evidence of the Package Insert Where the Nacapuys Offered This Evidence In Conjunction With Expert Witnesses.

The Nacapuys argue on appeal that the circuit court abused its discretion by precluding evidence of the package insert when, pursuant to Craft, it was offered "in conjunction with Dr. Hubbard's expert testimony that [Dr.] Terakubo failed to meet the 'medical standard of care.'" As a result of this ruling, Dr. Terakubo was precluded from testifying that he had never read the package insert cautioning that the guide wire should be moved under fluoroscopy at all times. However, the defendants argue that this evidence was properly excluded because package inserts may not set medical standards of care and this evidence was prejudicial and irrelevant.

This court discussed the effect of package inserts in medical malpractice claims in Craft. Craft, 78 Hawai'i at 298-301, 893 P.2d at 149-152. In Craft, the trial court granted the defendant's motion for partial summary judgment where Craft, the plaintiff, submitted evidence that the defendant violated express warnings in the package insert but did not provide expert medical testimony regarding the standard of care. Id. at 298, 893 P.2d at 149. We explained that

> [m]edical malpractice plaintiffs have traditionally been required to produce expert medical testimony to prove the applicable standard of medical care and the breach of that standard, and have often encountered practical problems in procuring such testimony, such as the reluctance of physicians to testify against their colleagues. As a result, the issue of whether a drug

> manufacturer's recommendations concerning the use of its drug in the package insert and the parallel entry in the Physician's Desk Reference may be used as an alternative or a supplement to expert medical testimony in proving the standard of care in connection with a physician's prescription and administration of a drug can be crucial.

Id. at 299, 893 P.2d at 150 (quoting Annotation, Medical Malpractice: Drug Manufacturer's Package Insert Recommendations as Evidence of Standard of Care, 82 A.L.R.4th 166, 172-73 (1990)). Craft pointed to several jurisdictions that adopted the rule that the package insert that provides proper instructions itself constitutes prima facie evidence of the standard of care. Id. at 299-300, 893 P.2d at 150-51. However, we recognized that the contrary view considers a package insert alongside expert testimony but does not deem it conclusive of the standard of care. Id. at 299, 893 P.2d at 150 (citing Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 154 Cal. App. 2d 560, 317 P.2d 170 (1957); Ramon v. Farr, 770 P.2d 131 (Utah 1989). See Salgo, 154 Cal. App. 2d at 576, 317 P.2d at 180 (the defendants, contesting the introduction of drug package inserts, argued that "drug manufacturer's recommendations are always conservative and are quickly outdated, that they expect and the custom is that after a material has been available for a period of time, physicians using it rely primarily on their own experience and the published literature of colleagues concerning its use in actual practice"). We observed other criticisms of package inserts as evidence:

> "[A] medical background is necessary to comprehend insert terminology and to recognize the limitations of the information presented." [See Comment, Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits, 44 U.Chi.L.Rev. 398, 425 (1977).] "Unlike experts on the stand, inserts cannot aid the jury by answering hypothetical questions concerning their

> application to a particular case." Id. Additionally, the drug company supplying the inserts has conflicting motives: to sell the drug, to avoid tort liability for failure to warn, and to give basic information to physicians. Id. at 424.

Id. at 300 n.17, 893 P.2d at 151 n.17. In light of this criticism, we held that package inserts "may be considered by the fact finder along with expert testimony, but may not alone define the standard of care." Id. at 300, 893 P.2d at 151. Because Craft relied exclusively on the package insert and did not offer expert testimony, we affirmed the trial court's granting of partial summary judgment in favor of the defendant. Id. at 301, 893 P.2d at 152.

The defendants argued before the circuit court, and the circuit court agreed, that pursuant to Craft, relevant medical standards of care can only be set by persons within the medical community, and thus, the package insert is impermissible. Though this statement of law is true, the Nacapuys did not argue that the package insert sets the medical standard of care -- rather, they sought to admit it to supplement the testimony of Dr. Hubbard as to the medical standard of care. Our holding in Craft does not preclude the circuit court from admitting the package insert to support the Nacapuys' argument that the medical standard of care is to use the fluoroscope. On appeal, Dr. Terakubo attempts to limit Craft's holding to summary judgment rulings, but Craft's discussion regarding the relevance of package inserts and its ruling that package inserts may be considered by the fact finder is certainly applicable where the defendants moved to exclude the package insert. Therefore, the circuit court erred in its exclusion of the package insert

inasmuch as its ruling was exclusively based on an erroneous interpretation of Craft.

Alternatively, the defendants argue that the circuit court properly precluded the package insert from evidence because it was written by manufacturers and thus, is irrelevant and prejudicial. However, as stated supra, in Craft, we held that package inserts written by manufacturers may be considered alongside expert testimony. Craft, 78 Hawai'i at 300, 893 P.2d at 151. See also Salgo, 154 Cal. App.2d 560, 317 P.2d 170 (1957) (ruling the same even though the court acknowledged that manufacturer's recommendations are quickly outdated and that the physicians may rely on their own experiences); Ramon v. Farr, 770 P.2d 131, 135-36 (Utah 1989) (ruling the same and recognizing that package inserts are not designed to establish a standard of medical practice but for multiple purposes -- advertising for the manufacturer, regulation by the government, and information for the doctor -- whereas the standard is based on a physician's training, experience and skill as related to the needs of the patient). Thus, we established in Craft that a package insert is not precluded as evidence merely because it is not written by medical professionals.

Dr. Terakubo argues that the Nacapuys' own expert witness, Dr. Hubbard, who testified that Dr. Terakubo acted beneath the medical standard of care when he withdrew the guide wire without using the fluoroscope, opined that the package insert instructions were "incomplete." Dr. Hubbard also declared that it would have been beneath the standard of medical care not

to read the package insert unless "Dr. Terakubo was familiar with the use of the [guide wire]." However, Dr. Hubbard's criticism of the package insert was that "[t]he instructions were essentially the same as they had been for a long time before the invention of stents," even though stents, "net-like structure[s] that can catch [] guidewire[s]," "are an additional hazard to entrapment of guidewires." Even assuming that the package insert did not fully explain the risks of the guide wire, its instructions and warnings are nevertheless relevant to the applicable medical standard of care.

We cannot conclude that the exclusion of this evidence was harmless. See HRS § 641-2;[20] Hawai'i Rules of Civil Procedure ("HRCP") Rule 61.[21] We have provided that "[e]ven an erroneous exclusion of relevant evidence does not necessarily call for reversal of the trial court, if no prejudice results. And where essentially the same evidence is given by other witnesses or other means, the trial court's exclusion of relevant evidence constitutes harmless error." Wakabayashi v. Hertz Corp., 66 Haw. 265, 272, 660 P.2d 1309, 1314 (1983) (citations omitted) (finding

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[20] HRS § 641-2 (Supp. 2004) states in pertinent part, "No judgment, order, or decree shall be reversed, amended, or modified for any error or defect, unless the court is of the opinion that it has injuriously affected the substantial rights of the appellant."

[21] HRCP Rule 61 provides:

> No error in either the admission or the exclusion of evidence and no error or defect in any ruling or order or in anything done or omitted by the court or by any of the parties is ground for granting a new trial or for setting aside a verdict or for vacating, modifying, or otherwise disturbing a judgment or order, unless refusal to take such action appears to the court inconsistent with substantial justice. The court at every stage of the proceeding must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.

that the defendant was not prejudiced and thus, the trial court did not commit reversible error where it admitted evidence that was previously excluded even where the defendant was "denied the opportunity of presenting this proof in an effective manner"). See Kekua v. Kaiser Found. Hosp., 61 Haw. 208, 601 P.2d 364 (1979) (ruling that the circuit court's error in excluding testimony from a witness is harmless error because another witness provided the "almost identical testimony" and the excluded testimony would not have affected the judgment). In the instant case, however, the excluded package insert evidence was not the "same evidence [] given by other witnesses or other means." Although Dr. Hubbard testified that Dr. Terakubo should have removed the guide wire under fluoroscope,[22] he was a different source than the package insert, which was written by the manufacturer of the guide wire prior to the incident and provided with the distribution of the guide wire. Moreover, the

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[22] Dr. Hubbard reasoned that this standard was not met because

> . . . the average physician doing interventional cardiology with his degree of training would do the procedure of removing the guide wire under fluoroscope and would thereby have not caused this complication.

He further testified as follows:

> Q. What would the difference have been if he had used fluoroscope?
> A. I believe that he would have seen that the guide wire got stuck on the stent, he would have been able to advance the guide wire or otherwise free it from the stent rather than continuing to pull on it until it actually deformed the stent and broke the guide wire.
> . . . .
> Q. What is the standard of care in withdrawing a guide wire where you feel resistance?
> A. It's to ascertain what the cause of the resistance is, to stop pulling, do a fluoroscope, and find out what the problem is before going any further.

defendants questioned Dr. Hubbard's credibility as a "professional" expert witness.[23] Dr. Guertler, despite testifying that Dr. Terakubo's removal of the wire met the standard of care, also testified that he would have used the fluoroscope in this case as that would have been "careful and prudent." Inasmuch as the circuit court's exclusion of the packet insert evidence was not harmless, we vacate the circuit court's August 24, 2004 judgment and remand the case for a new trial.

D. The Circuit Court Did Not Abuse Its Discretion By Allowing Dr. Chesne to Testify That Dr. Dacanay Met His Standard of Care Inasmuch As He Stated This Opinion During His Deposition.

Next, the Nacapuys argue that the circuit court abused its discretion by allowing Dr. Chesne to present a new opinion at trial that was not provided in discovery or deposition -- his opinion that Dr. Dacanay met the standard of care. They argue that this "surprise testimony" was prejudicial because their expert witness, Dr. Hubbard, was thereafter unavailable to rebut

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[23] Dr. Terakubo's closing argument stated in pertinent part as follows:

> [Dr.] Hubbard has not practiced as an interventional cardiologist since 1999. [Dr.] Hubbard has not practiced as an interventionalist cardiologist because he takes a medication that causes him cognitive impairment. "Cognitive" we all know refers to thinking.
>
> Doctor Hubbard is of the mind that although he is cognitively disabled from practicing as an interventional cardiologist he is not disabled from going to courtrooms all over the country and criticizing physicians who practice in an area, interventional cardiology, which he has not practiced in years and in fact is disabled from practicing in.
>
> [Dr.] Hubbard is a professional witness, [Dr.] Hubbard advertises his availability as an expert witness. He has his own website. He subscribes to services that connect lawyers who are looking for experts with experts who are looking for lawyers. He caters to the plaintiff's bar. [Dr.] Hubbard works for lawyers that sue doctors.

Dr. Chesne's testimony.

The defendants, however, point out that during Dr. Chesne's deposition taken on April 26, 2004, he opined that all doctors, including Dr. Dacanay, met the standard of care:

> Q. Are you saying the treatment of Ms. Nacapuy by Dr. Gershengorn was beneath the standard of medical care?
> A. Absolutely not.
> Q. How about Dr. Zapolanski?
> A. Absolutely not.
> Q. So --
> A. I don't think anybody in this case treated Ms. Nacapuy beneath community standards.
> Q. That includes every doctor who saw her?
> A. Absolutely.

The record indicates that Dr. Chesne previously discussed his opinion that all doctors, including Dr. Dacanay, met the medical standard of care in the reballooning procedure during his deposition. Therefore, the circuit court did not abuse its discretion by allowing Dr. Chesne to present this same opinion at trial.

E. The Circuit Court Did Not Err By Denying the Nacapuys' Motion for Judgment as a Matter of Law on Res Ipsa Loquitur Because The Fracturing of the Guide Wire May Have Occurred In the Absence of Negligence.

The Nacapuys argue on appeal that the circuit court erred by denying their motion for judgment as a matter of law on the doctrine of res ipsa loquitur where the res ipsa loquitur elements were met. They argue that there is sufficient circumstantial evidence present to employ the doctrine of res ipsa loquitur, thereby allowing them to present the case to the jury.

It is well established that

> [t]he doctrine of res ipsa loquitur provides that whenever a thing that produced an injury is shown to have been under the control

> and management of the defendant and the occurrence is such as in the ordinary course of events does not happen if due care has been exercised, the fact of the injury itself will be deemed to afford sufficient evidence to support a recovery in the absence of any explanation by the defendant tending to show that the injury was not due to his want of care. Under the res ipsa loquitur theory, then, the fact of the casualty and the attendant circumstances may themselves furnish all the proof of negligence that the injured person is able to offer or that it is necessary to offer without further proof of the defendant's duty and of his negligence to perform it.

Carlos v. MTL, Inc., 77 Hawai'i 269, 277, 883 P.2d 691, 699 (App. 1994) (quoting Turner v. Willis, 59 Haw. 319, 324-25, 582 P.2d 710, 714 (1978)) (internal quotations and ellipses omitted)). A plaintiff must establish the following three elements to invoke the res ipsa loquitur doctrine:

> 1. The event must be one which ordinarily does not occur in the absence of someone's negligence.
> 2. It must be caused by an agency or instrumentality within the exclusive control of the defendant.
> 3. It must not have been due to any voluntary action or contribution on the part of the plaintiff.

Id. at 278-79, 883 P.2d at 699-700 (quoting Medina v. Figuered, 3 Haw. App. 186, 188, 647 P.2d 292, 294 (1982) (citing Prosser, Law of Torts § 39 at 214 (1978))). The Nacapuys claim that the three res ipsa loquitur elements are met: (1) "the fracturing of the guide wire would not ordinarily occur in the absence of some negligence," (2) "In the first [angioplasty] procedure [Dr.] Terakubo had exclusive control over the guide wire during its withdrawal, and [(3)] [there was] no evidence that Ms. Nacapuy did anything which contributed to the guide wire fracturing." However, in light of the fact that there was contradicting testimony from various expert witnesses as to whether Dr. Terakubo was negligent, we disagree.

The Nacapuys assert that "the fracturing of the guide

wire would not ordinarily occur in the absence of some negligence" because the guide wire was not defective and yet, it broke when Dr. Terakubo withdrew it. However, as Dr. Terakubo argues, a complication in itself "does not mean the attending physician was negligent." See Sung Wha Kim Lyu v. Shinn, 40 Haw. 198, 1953 WL 7556, at *3 (1953) ("The gravamen of this case is negligence, and negligence cannot be inferred from the fact alone that the patient died. The Maxim 'res ipsa loquitur,' has no application to a case of this character. Negligence is not to be presumed; it must be proved [] and the plaintiffs were required to assume the burden of proving the negligence charged and that [] death resulted proximately from such negligence."). At trial, Dr. Guertler testified that the complication was not due to the negligence of Dr. Terakubo and explained that Dr. Terakubo was not negligent in removing the guide wire by "holding [the guide catheter] in place and pulling [the guide wire] out in one block." He reasoned that Mrs. Nacapuy had a very straight and "very large blood vessel, no narrowing left, a buttress of what you and I can think of as chicken wire in place that's firmly opposed to the artery wall. There's no reason in any interventionalist's mind to think that you would not be able to directly withdraw that entire system." Dr. Guertler opined that withdrawing the wire was not negligent even though Dr. Terakubo felt a "slight hesitation":

> A. . . . [W]hen Dr. Terakubo started pulling something -- the system back, what he described was a slight hesitation. He described it as a speed bump. That slight hesitation, or speed bump if you will, represented a change in the resistance or a change in the sensation of the guide wire and the catheter and guide system. And that was immediately released so he felt something, then immediately changed and he had normal perception.

> This is not something that you -- it's sort of a multi-sense thing; you can feel the vibration and feel the resistance and you can tell how hard things are to pull.
>
> On the basis of the fact that it was minimal and the fact that it was immediately released, he continued to withdraw. During the period of withdrawal he did not feel anything different, according to him, and it wasn't until he got called back into the room that he appreciated that there was a technical problem.
>
> . . . .
>
> Q. Now, do you have an opinion as to whether [Dr.] Terakubo breached the standard of care or was negligent in this case when, upon feeling the resistance, he did not stop and turn on the fluoroscope to check what was going on?
>
> . . . .
>
> A. I do.
>
> Q. And what was your opinion?
>
> A. No, he was not. You're -- the system that you're working in is about three or four feet north of where you went in so, for example, he was in the groin and working up here in the chest. You can imagine that in people there are twists and turns in the blood vessel.
>
> As people get older, they have calcium buildup, they may have obesity, they may have problems from previous surgical intervention. So it's very, very, very common to have periods of time where you feel a little tugging, little changes, little glitches in the system. That is all part and parcel of what you feel and that's part of your training.
>
> . . . .
>
> [W]hen you have a person who says I've done many of these before, what I felt was a transient hesitation and, furthermore, after the hesitation there was no change in the way things felt, I don't think it's unreasonable not to stop and look.

He further opined that removing the guide wire without the use of the fluoroscope would not have changed the outcome of the procedure. Inasmuch as "one reasonable conclusion" cannot be drawn from the record as to whether the fracturing of the guide wire would not ordinarily occur in the absence of some negligence, the circuit court properly denied the Nacapuys' motion for judgment as a matter of law on the res ipsa loquitur doctrine.

F. The Circuit Court Did Not Err By Refusing to Instruct the Jury On Negligence Because the "Common Knowledge" Exception to the Medical Standard of Care Is Inapplicable In Determining Whether Dr. Terakubo Negligently Withdrew the Guide Wire In the Angioplasty with Stent Procedure.

The Nacapuys argue that the circuit court erred by refusing to instruct the jury on negligence where Dr. Terakubo fractured the guide wire when withdrawing it from Mrs. Nacapuy's coronary artery. Under a general negligence claim, because the appropriate standard of care would be within the jury's "common knowledge," expert witness testimony would not be required to establish a medical standard of care. We have recognized that a medical standard of care (and also, expert testimony), is not required in certain situations:

> It is well settled that in medical malpractice actions, the question of negligence must be decided by reference to relevant medical standards of care for which the plaintiff carries the burden of proving through expert medical testimony. Nishi v. Hartwell, 52 Haw. 188, 195, 473 P.2d 116, 121 (1970) (citations omitted). The standard of care to which a doctor has failed to adhere must be established by expert testimony because "a jury generally lacks the 'requisite special knowledge, technical training, and background to be able to determine the applicable standard without the assistance of an expert.'" Rosenberg v. Cahill, 99 N.J. 318, 325, 492 A.2d 371, 374 (1985) (citations omitted). There are, however, exceptions to the rule.
>
> The "common knowledge" exception, which is similar to the doctrine of res ipsa loquitur, provides that certain medical situations present routine or non-complex matters wherein a lay person is capable of supplanting the applicable standard of care from his or her "common knowledge" or ordinary experience. See id.; see also Medina v. Figuered, 3 Haw. App. 186, 188, 647 P.2d 292, 294 (1982).

Craft, 78 Hawai'i at 298, 893 P.2d at 149. We stated that the common knowledge exception applies in cases where:

> There are "some medical and surgical errors on which any layman is competent to pass judgment and conclude from common experience that such things do not happen if there has been proper skill and care. When an operation leaves a sponge in the patient's interior, or removes or injures an inappropriate part of his anatomy, or when a tooth is

> dropped down his windpipe or he suffers a serious burn from a hot water bottle, or when instruments are not sterilized, the thing speaks for itself without the aid of any expert's advice."
>
> Medina, 3 Haw. App. at 188, 647 P.2d at 294 (quoting W.P. Keeton, D. Dobbs, R. Keeton, D. Owen, Prosser and Keeton on the Law of Torts, § 39 at 227-28 (4th ed. 1978) (footnotes omitted)).

Id. Under these applicable circumstances, the case is an ordinary negligence case rather than a medical malpractice case, "thus obviating the necessity of expert testimony to establish the applicable standard of care. This exception, however, is rare in application." Id. (citations omitted).

The facts in the present case are unambiguously distinguishable to the examples we previously quoted from Craft, see supra, in which expert testimony is not needed to inform a jury of the medical standards of care. The Nacapuys state that Dr. Terakubo was negligent because he did not stop pulling the guide wire even though he felt slight resistence. However, as explained supra, even among the expert witnesses, there was disagreement as to whether Dr. Terakubo met the reasonable standard of care.[24] According to Dr. Hubbard, because the standard of care in that situation is "to ascertain what the cause of the resistance is, to stop pulling, do a fluoroscope, and find out what the problem is before going any further," he failed to meet the standard of care. However, other expert witnesses testified that a physician must exercise "reasonable care" when withdrawing the guide wire. Thus, where even expert witnesses disagreed, lay jurors, drawing purely on their own

[24] Dr. Chesne testified that withdrawing a guide wire without the use of a fluoroscope is judged by a standard of reasonableness in arguing that a physician must exercise "reasonable care" when withdrawing the guide wire. All of the expert witnesses agreed that the "withdrawal of the guide wire must be done carefully."

backgrounds and experiences, cannot determine what is unreasonable when withdrawing the guide wire. The jury needed the experts' "requisite special knowledge, technical training, and background to be able to determine the applicable standard" in determining whether Dr. Terakubo breached his standard of care,[25] and the circuit court did not err by ruling that expert testimony was required and rejecting the ordinary negligence instruction.

The Nacapuys compare the present facts to those in Runnells v. Rogers, 596 S.W.2d 87 (Tenn. 1980), in which the Supreme Court of Tennessee held that expert testimony was not required where the defendant physician attempted to but was unable to remove a wire imbedded in his foot during an accident. Runnells, 596 S.W. 2d at 88-91. The defendant observed the plaintiff's foot worsen over several weeks and yet, failed to remedy the situation by removing the wire. Id. at 88-89. The Runnells court reasoned that removing the wire was "within the common knowledge of laymen . . . . Even a barefoot boy knows that when his foot is infested by a sticker, splinter, thorn, pin or other foreign object, it must be removed. Most assuredly this lies within the ken of a layman." Id. at 90. It concluded that under the common knowledge exception, expert testimony was not required as to whether the defendant should have removed the wire from the plaintiff's foot. Id. at 90.

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[25] For the same reason, Dr. Hubbard's testimony that Dr. Terakubo's standard of care was based on what "the average physician doing interventional cardiology with his degree of training would do [when performing] the procedure of removing the guide wire under fluoroscope," further supports the proposition that the medical standard of care, requiring expert testimony, applies.

Runnells presents far different facts than the instant case. Here, the parties dispute the method by which Dr. Terakubo removed the guide wire. The Nacapuys' argument that "the withdrawal of the guide wire without fluoroscopy by Terakubo did not involve a complicated medical procedure" disregards not only the contrasting expert testimony as to whether Dr. Terakubo negligently removed the guide wire, but also, the technicality of the angioplasty with stent procedure. Understanding this procedure "includ[es] selection of the guide wire and stent, angling of the tip of the guide wire, pre-inflation of the balloon to compress the plaque and open the artery, inflation of the balloon to the proper atmospheric pressure to ensure good opposition of the stent to the intima of the artery, discretionary use of fluoroscopy in order to minimize the radiation exposure, and the method of withdrawal of the guide catheter, guide wire, and balloon wire, among other things."

Inasmuch as the appropriate standard of care of removing the guide wire in an angioplasty with stent procedure is not within the common knowledge of a jury, the "common knowledge" exception does not apply, and the circuit court properly refused the Nacapuys' proposed instructions on negligence and foreseeability.

IV. CONCLUSION

Based upon the foregoing analysis, we hold that: (1) the circuit court erred by granting Dr. Dacanay and Dr. Terakubo's motion for summary judgment on the issue of informed consent inasmuch as there are genuine issues of material fact

regarding whether (a) Dr. Terakubo informed Mrs. Nacapuy of the risks and alternatives to the angioplasty with stent procedure and obtained her informed consent, (b) a reasonable person in Mrs. Nacapuy's position would have consented to the angioplasty with stent procedure that led to Mrs. Nacapuy's injuries had Mrs. Nacapuy been properly informed of the risks, (c) Dr. Dacanay had a duty to warn Mrs. Nacapuy of the risks of the angioplasty with stent procedure where he retained a degree of control over Mrs. Nacapuy's procedure, and (d) Mrs. Nacapuy was able to give her informed consent for the reballooning procedure; (2) the circuit court erred by granting Dr. Dacanay's motion in limine no. 4 precluding evidence on the issue of informed consent for the reballooning procedure because there remains a genuine issue as to whether he had a duty to obtain her informed consent for the reballooning procedure; (3) the circuit court erroneously excluded evidence of the package insert where the Nacapuys intended to argue that it supported expert testimony, but did not set the applicable medical standard of care; (4) the circuit court did not abuse its discretion by allowing Dr. Chesne to testify that Dr. Dacanay met his standard of care inasmuch as he stated this opinion during his deposition; (5) the circuit court did not err by denying the Nacapuys' motion for judgment as a matter of law on res ipsa loquitur because the fracturing of the guide wire may have occurred in the absence of someone's negligence; and (6) the circuit court did not err by refusing to instruct the jury on negligence because the "common knowledge" exception, which excuses expert testimony, does not apply in

determining whether Dr. Terakubo negligently withdrew the guide wire in the angioplasty with stent procedure.

Accordingly, we vacate the circuit court's August 24, 2004 judgment and remand the case for a new trial.

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