IN THE SUPREME COURT OF THE STATE OF HAWAIʻI

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CUC THI NGO, ANGELO NGUYEN, ANTHONY NGUYEN, AN VAN NGUYEN, and LEO YOUNG, ESQ., in his capacity as Personal Representative of the Estate of Jennifer Giao Nguyen, Deceased,
Petitioners/Plaintiffs-Appellants,

vs.

THE QUEEN'S MEDICAL CENTER, a Hawaiʻi Domestic Nonprofit Corporation; THINH T. NGUYEN, M.D.; THE EMERGENCY GROUP, INC., a Hawaiʻi Domestic Professional Corporation,
Respondents/Defendants-Appellees.

SCWC-30172

CERTIORARI TO THE INTERMEDIATE COURT OF APPEALS
(ICA NO. 30172; CIV. NO. 07-1-0268)

August 31, 2015

RECKTENWALD, C.J., NAKAYAMA, McKENNA, AND POLLACK, JJ., AND CIRCUIT JUDGE AYABE, ASSIGNED BY REASON OF VACANCY

OPINION OF THE COURT BY McKENNA, J.

I. Introduction

This case arises from the death of a nine-year-old minor child ("Minor") from cardiac arrest caused by hypovolemic shock, a condition that results when "severe blood and fluid loss make the heart unable to pump enough blood" through the

body. Ngo v. Queen's Med. Ctr., No. 30172, at 5 (App. Dec. 30, 2013) (mem.). Petitioners/Plaintiffs-Appellants are Minor's parents ("Parents"), brothers, and the personal representative of Minor's Estate (collectively "Plaintiffs"). Plaintiffs claim, inter alia, that Respondents/Defendants-Appellees the Queen's Medical Center ("QMC"),[1] Dr. Thinh T. Nguyen (hereinafter "Defendant"), and The Emergency Group, Inc. (collectively, "Defendants") failed to provide information required under the informed consent doctrine before treating Minor for nausea and vomiting with the anti-emetic medication Reglan.[2] Plaintiffs assert that Reglan led to Minor's hypovolemic shock because it increased the motility of Minor's stomach and small intestines, or, in other words, increased Minor's diarrhea. It is undisputed that Defendant did not give Plaintiffs any information about Reglan or its risks and side effects, and did not provide any information regarding alternative treatments.

The Circuit Court of the First Circuit ("circuit court") granted judgment as a matter of law ("JMOL") in favor of Defendants on the informed consent claim.[3] The Intermediate

[1] QMC is not a party in the appellate proceedings as the sole issue on appeal is Defendant's alleged failure to obtain Plaintiffs' informed consent; thus, issues concerning QMC will not be discussed except where relevant.

[2] Anti-emetic medications help to prevent nausea and vomiting.

[3] The Honorable Glenn J. Kim presided.

Court of Appeals ("ICA") affirmed the circuit court's decision on appeal, concluding that Plaintiffs failed to meet their evidentiary burden regarding the "materiality of the risk of harm" that resulted from Defendant's treatment of Minor with Reglan.

At issue in this appeal is the extent of a plaintiff's burden of presenting expert medical evidence regarding the "materiality of the risk of harm" that occurred in order to support a prima facie case for a physician's negligent failure to obtain informed consent.[4]

Hawaiʻi law on the doctrine of informed consent has evolved significantly in the past three decades. The doctrine originated in the common law, and was largely codified in 1976 in Hawaiʻi Revised Statutes ("HRS") § 671-3, which has since been amended several times. Some common law precepts, however, still govern. For example, we have held that "expert testimony will ordinarily be required to establish the 'materiality' of the

[4] Plaintiffs present the following questions on certiorari:

1. Whether it was error to exclude or discount evidence of information contained in a drug's package insert or [Physicians' Desk Reference] entry, in combination with expert testimony as to the significance of that information, on a claim of informed consent.

2. Whether a physician's admitted failure to disclose the information required by [Hawaiʻi Revised Statutes ("HRS") §§] 671-3(b)(1) through (6), when coupled with evidence of the materiality of such failure, precludes a finding of informed consent.

risks, i.e., 'the nature of risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of particular risks, and the nature of available alternatives to treatment[]'" ("expert testimony requirements"). Ray v. Kapiolani Med. Specialists, 125 Hawaiʻi 253, 262, 259 P.3d 569, 578 (2011) (citations omitted). "The standard of disclosure of material risks prior to treatment, however, . . . is capable of determination under the patient-oriented standard without reference to prevailing medical standards or medical judgment . . . ." Carr v. Strode, 79 Hawaiʻi 475, 485 n.6, 904 P.2d 489, 499 n.6 (1995).

In this case, Plaintiffs' experts testified on the risks of Reglan generally, and also explained the significance of the information in the manufacturer's insert. Moreover, pursuant to Craft v. Peebles, 78 Hawaiʻi 287, 893 P.2d 138 (1995), although a manufacturer's insert cannot, on its own, satisfy a plaintiff's burden of producing expert testimony to establish the materiality of a risk, it can constitute evidence that a fact finder may consider along with expert testimony on the issue. We hold, therefore, that Plaintiffs presented sufficient expert medical evidence to advance their informed consent claim to the jury.

In addition, Plaintiffs' complaint clearly alleged that Defendant treated Minor "without obtaining the informed

consent of Plaintiff[.]" The informed consent doctrine includes a physician's duty to disclose "recognized alternative treatments or procedures" and "intended and anticipated results of the proposed treatment or procedure[.]" Relevant evidence of alternative treatments and the use of Reglan in children was adduced. Therefore, the ICA erred in concluding that Plaintiffs waived the issue of Defendant's failure to inform them of all statutorily mandated information.

Accordingly, we vacate in part (1) the ICA's February 11, 2014 Judgment on Appeal as to Plaintiffs' informed consent claims; and (2) the circuit court's July 28, 2009 Final Judgment as well as its order granting Defendants' motion for JMOL as to Plaintiffs' informed consent claims, and remand the case to the circuit court for further proceedings consistent with this opinion.

II. Background

A. Facts

On Friday, February 13, 2004, Minor's Parents and two brothers took nine-year-old Minor to the QMC emergency room ("ER") to be treated for diarrhea and vomiting, which she had been experiencing since the previous night.[5] Defendant treated Minor at the QMC ER, where he performed a variety of tests,

[5] Parents are not fluent in English, but their children are fluent. Minor's brother Anthony Nguyen served as an interpreter for Defendant and Parents while Minor was in the hospital.

which revealed an elevated heart rate, mild to moderate dehydration, and a possible infection.

Defendant diagnosed Minor with viral gastroenteritis, an infection of the stomach. He ordered intravenous ("IV") fluid of normal saline and ten milligrams of Reglan through an IV line. Upon discharge, Minor was given a prescription for ten milligrams of Reglan tablets to take as needed for nausea, and instructed to follow up with her primary physician in three to four days.

Minor continued to suffer from diarrhea and vomiting after returning home. Minor's mother testified that she gave Minor Reglan tablets every six hours as directed.[6] One of Minor's brothers called QMC three times -- on Friday night, Saturday morning, and Saturday night -- concerning Minor's continued symptoms. Each time, QMC staff told him to let the medicine work, and to follow up with Minor's primary physician on Monday. The family testified that Minor's symptoms remained the same throughout the weekend.

At 3:00 a.m. on Sunday morning, Minor told her Parents that she was having trouble breathing. At 7:00 a.m., Minor became unconscious and an ambulance was called to take her to

[6] Plaintiffs' expert testimony focused mainly on the IV administration of Reglan because whether any Reglan tablets actually entered Minor's system was disputed.

the hospital, where she died of cardiac arrest caused by hypovolemic shock.

B. Circuit Court Proceedings

On February 12, 2007, Plaintiffs filed a complaint in circuit court against Defendants, alleging medical negligence and negligent failure to obtain informed consent.

1. The Trial

a. Testimony of Defendant

At trial, Plaintiffs called Defendant as an adverse witness. The following exchange took place regarding Defendant's failure to provide pretreatment disclosures:

> Q. When you prescribed and caused the intravenous dosage of Reglan to be given, before doing so, did you ever tell the parents of any risks involved with Reglan?
>
> A. No.
>
> Q. After the IV was in process, did you ever tell the parents of any risks associated with Reglan?
>
> A. No[.]
>
> . . .
>
> Q. When you wrote out the prescription, . . . before the parents left the hospital, did you at any time give them any warnings of any kind about the drug Reglan?
>
> A. No.

Defendant testified that he did not inform Parents of the manufacturer's position on the safety and effectiveness of Reglan in pediatric patients. He contended that the manufacturer's warning meant that the safety and effectiveness of Reglan in pediatric patients had not been established to standards set by the United States Food and Drug Administration

("FDA"); however, he testified that "[his] training and experience has made this drug a safe medication." Defendant also testified that he prescribed Reglan to pediatric patients as "an off-label use[,]" and that he prescribed the dosage based on Minor's weight, which was approximately 150 lbs.

Defendant testified that he knew diarrhea was a side effect of Reglan. He further testified that he did not attempt to treat Minor's diarrhea other than by ordering IV fluids to hydrate her.

In addition, Defendant testified that at the time he administered Reglan to Minor, he knew that an alternative drug without Reglan's side effects was "out there but [he] didn't use it" because "it wasn't available to [him] to use." Plaintiffs' counsel clarified that the alternative drug was Zofran. Plaintiffs' counsel also introduced into evidence a list of drugs approved by the FDA in 1991, which included Zofran. Defendant further testified that he knew of the existence of an alternative anti-emetic medication approved by the FDA to treat pediatric patients for nausea, Phenergan; however, he contended that it was a "worse drug[.]"

b. Reglan Manufacturer's Package Insert

During Defendant's testimony, a printout of the FDA version of the Reglan manufacturer's package insert in effect at

the time ("manufacturer's insert") was entered into evidence over objection.[7]

The manufacturer's insert states, in relevant part, as follows:

> CONTRAINDICATIONS
> [Reglan] should not be used whenever stimulation of gastrointestinal motility might be dangerous, e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction or perforation.
>
> . . . .
>
> Pediatric Use
> Safety and effectiveness in pediatric patients have not been established (see OVERDOSAGE).
>
> . . . .
>
> The safety profile of [Reglan] in adults cannot be extrapolated to pediatric patients.
>
> . . . .
>
> ADVERSE REACTIONS
> In general, the incidence of adverse reactions correlates with the dose and duration of [Reglan] administration. The following reactions have been reported, although in most instances, data do not permit an estimate of frequency:
>
> . . . .
>
> Gastrointestinal
> Nausea and bowel disturbances, primarily diarrhea.

c. Testimony of Dr. Gary Leroy Towle ("Dr. Towle")

Plaintiffs called Dr. Towle to testify as an expert on the standard of care and the material risks of Reglan. Dr. Towle testified that "Reglan is not recommended for use in children except for very specific circumstances" not present in

[7] Defendant testified that although he had not read the version of the manufacturer's insert admitted at trial, he had known of the information it contained at the time he administered Reglan to Minor. In addition, another expert, Dr. Gary Leroy Towle, explained that the version admitted at trial was substantially similar to the Physicians' Desk Reference or manufacturer's package insert for Reglan.

this case. Interpreting the manufacturer's insert, Dr. Towle testified that the manufacturer could not say Reglan was safe to treat pediatric patients, but was not saying it was unsafe either. Rather, Reglan's safety in pediatric patients was undetermined.

Dr. Towle testified that "one of the ways Reglan works is that it gets the pylorus, or the sphincter between the stomach and small intestines, to relax and open up and allow the contents of the stomach to pass through to the small intestine." He stated that "[t]he problem with Reglan is it increases the motility of the stomach and small intestine. In other words, it gets it going, it gets things flowing through it." Dr. Towle also testified that the contraindications section in the Reglan insert states that Reglan should not be used whenever stimulation of gastrointestinal motility might be dangerous. Dr. Towle stated that in Minor's case, although Reglan did not directly cause diarrhea in and of itself, "if you're emptying the stomach and you're dumping things into the small intestine, it kind of gets the intestines going and diarrhea is one of the more common side effects with Reglan."

Dr. Towle testified that he would have started with other anti-emetics, such as Phenergan and Zofran, which the FDA has specifically approved to treat pediatric patients, and which were safer for use in children with nausea and vomiting. He

testified that one of the more common side effects of Reglan was increased diarrhea, and while Zofran or other "anti-emetics theoretically can increase diarrhea[,] Reglan is more likely to" have this effect. Dr. Towle also testified that Zofran was an "excellent anti-emetic. It's used in chemotherapy patients, in cancer patients, and also for people with gastroenteritis. It works very well. It has a relatively low side effect profile. It's very popular and it could be the most popular one now replacing even Tigan and Phenergan."

Dr. Towle stated, however, that he could not testify to a reasonable degree of medical probability that Reglan increased Minor's nausea and diarrhea, nor that it had any side effects that were of consequence to Minor. Dr. Towle also stated that he could not say whether Defendant should have warned Parents about any risks because "[i]t's like asking what's the dose of some medicine you're not supposed to give. I can't answer that."

d. Testimony of Dr. James Gallup ("Dr. Gallup")

Plaintiffs also called Dr. Gallup to testify as an expert on the cause of Minor's death. With respect to any effect Reglan may have had on Minor's system, Dr. Gallup opined that "it did what Reglan is noted well to do and that is stimulate the contraction of smooth muscle, particularly in the intestine and the stomach to a lesser extent." Dr. Gallup

testified that Reglan relaxes the "sphincter so that any fluid in the stomach can easily get transported down through the small intestine into the large intestine." He further testified that Zofran does not do this and "works almost exactly in the opposite direction."

Dr. Gallup opined that Reglan moderately increased Minor's diarrhea, which significantly increased her dehydration. He further opined that the increase in dehydration was a substantial factor leading to Minor's hypovolemic shock because the dehydration "quite significantly hastened the loss of workable fluid . . . into the intestinal tract and loss from the body ultimately." As to Minor's cause of death, he opined that Minor "died from cardiac arrest as a result of hypovolemic shock[.]" He further opined that Reglan was a substantial factor in causing Minor's death.

On redirect, Dr. Gallup clarified that Reglan "may have increased the volume [of diarrhea, but] may not have increased the frequency."

e. Motion for Judgment as a Matter of Law

At the close of Plaintiffs' case in chief, Defendants moved for JMOL on the issue of informed consent, arguing that Plaintiffs' experts failed to opine on the materiality of the risks of Reglan to meet Plaintiffs' burden of adducing expert

medical testimony. Plaintiffs cross-moved for JMOL,[8] contending that the testimony of Drs. Towle and Gallup in combination with the manufacturer's insert constituted "competent expert evidence" of the risks.

The circuit court agreed with Defendants, and stated:

> [T]he issue essentially is there's not a legally cognizable informed consent claim in this case. . . .
>
> In the Court's view, not only is there no expert testimony, as is required[,] . . . the parents . . . were never asked whether if they had been informed of certain things they would have given permission, etc., etc., [sic] which are all elements of informed consent.[9]
>
> . . . [W]hat we've got here is a case of medical negligence, period. Informed consent may sound like -- may sound viable sort of in some sort of common sensible view, well, he should have told the parents about Reglan and what it could cause, etc. But . . . in the Court's view there

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[8] Hawaiʻi Rules of Civil Procedure (HRCP) Rule 50(a) (2000) provides:

> (1) If during a trial by jury a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the court may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue.
>
> (2) Motions for judgment as a matter of law may be made at any time before submission of the case to the jury. Such a motion shall specify the judgment sought and the law and the facts on which the moving party is entitled to the judgment.

HRCP Rule 50(a) (emphasis added). Although Plaintiffs cross-moved for JMOL, the circuit court would not have been able to grant the motion at that time because Defendants had not presented any evidence, and thus, had not "been fully heard" on the informed consent claims.

[9] We note that the circuit court erred in concluding that Plaintiffs failed to establish an element of informed consent by not specifically testifying that they would have withheld consent if properly informed of the risks. We address this error in note 16 in Part IV.B, infra.

> simply is no legally cognizable claim for informed consent on the facts of this case.
>
> And you add that to -- and in a sense that's why there was no expert testimony on materiality because it's simply not an informed consent case.

The circuit court granted JMOL in Defendants' favor on the issue of informed consent, concluding that, even viewing the evidence and inferences therefrom in the light most favorable to Plaintiffs, a reasonable jury could not find in their favor. On July 28, 2009, the circuit court subsequently entered its Final Judgment.

2. Plaintiffs' Renewed Motion

On August 10, 2009, Plaintiffs filed a "Renewed Motion to Amend the Complaint to Conform to the Evidence and Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, Motion for New Trial" ("Renewed Motion"). Plaintiffs argued, inter alia, that JMOL on the informed consent claim should have been entered in their favor because Defendant failed to provide statutorily mandated information pursuant to HRS § 671-3(b) (Supp. 2008)[10] about (1) recognized alternative treatments and/or

[10] HRS § 671-3 (Supp. 2008) provides, in relevant part:

> (b) The following information shall be supplied to the patient or the patient's guardian or legal surrogate prior to obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure:
>
> (1) The condition to be treated;
>
> (2) A description of the proposed treatment or procedure;
>
> (3) The intended and anticipated results of the proposed treatment or procedure;

(continued . . .)

medications, and (2) recognized material risks of serious complications or mortality associated with the proposed treatment or procedure.

The circuit court denied Plaintiffs' Renewed Motion at an October 14, 2009 hearing, and entered its order the following day.

On November 13, 2009, Plaintiffs appealed the July 28, 2009 Final Judgment and October 15, 2009 order denying their Renewed Motion to the ICA.

C. Appeal to the ICA

On appeal, the ICA affirmed the circuit court's grant of JMOL in Defendant's favor, concluding that Plaintiffs' "expert testimony presented at trial [did] not sufficiently establish the 'materiality of the risk of harm' imposed by [Defendant's] administration of ten milligrams of Reglan to [Minor]." Ngo, mem. op. at 15. In particular, the ICA

(. . . continued)

(4) The recognized alternative treatments or procedures, including the option of not providing these treatments or procedures;

(5) The recognized material risks of serious complications or mortality associated with:

(A) The proposed treatment or procedure;

(B) The recognized alternative treatments or procedures; and

(C) Not undergoing any treatment or procedure; and

(6) The recognized benefits of the recognized alternative treatments or procedures.

concluded that "expert testimony was not adduced to establish the 'probabilities of therapeutic success' or 'the frequency of the occurrence of particular risks' and therefore Plaintiffs failed to carry their evidentiary burden." Ngo, mem. op. at 16 (citing Carr, 79 Hawaiʻi at 486, 904 P.2d at 500).

With respect to Plaintiffs' evidence at trial, the ICA concluded that Dr. Towle's testimony that he could not opine on whether the risks should have been explained to "[P]arents because Reglan 'should not have been given [to Minor] no matter what in these circumstances[]'" "did not sufficiently elaborate on the probabilities that Reglan treatment would be successful[.]" Id. The ICA further concluded that Dr. Towle's testimony "that Reglan posed a greater risk of gastric motility, i.e., diarrhea, than other anti-emetics" did not establish the frequency of occurrence nor significance of that risk. Ngo, mem. op. at 17.

Addressing Plaintiffs' argument that Defendant's testimony in conjunction with the manufacturer's warning established the materiality of the risk, the ICA concluded that "the manufacturer's warning, in and of itself, does not establish the materiality of risk of harm with respect to Reglan, because it does not constitute 'expert testimony' and does not permit a legitimate inference regarding the materiality

of the risk."[11] Ngo, mem. op. at 19 (citing Craft, 78 Hawai'i at 306, 893 P.2d at 157).

Finally, the ICA held that Plaintiffs waived their claim that Defendant "failed to provide statutorily mandated information to [Minor's] parents other than the risks of Reglan . . . [b]ecause Plaintiffs failed to raise this argument to the circuit court[.]" Ngo, mem. op. at 22.

III. Standard of Review

"A trial court's ruling on a motion for judgment as a matter of law is reviewed de novo." Ray, 125 Hawai'i at 261, 259 P.3d at 577 (emphasis omitted) (citations omitted). Hawai'i appellate courts apply the same standard as the trial court. Miyamoto v. Lum, 104 Hawai'i 1, 7, 84 P.3d 509, 515 (2004) (citation omitted). Trial courts apply the following standard:

> A motion for judgment as a matter of law may be granted only when after disregarding conflicting evidence, giving to the non-moving party's evidence all the value to which it is legally entitled, and indulging every legitimate inference which may be drawn from the evidence in the non-moving party's favor, it can be said that there is no evidence to support a jury verdict in his or her favor.

Ray, 125 Hawai'i at 261, 259 P.3d at 577 (brackets omitted) (quoting Miyamoto, 104 Hawai'i at 7, 84 P.3d at 515).

[11] The ICA explained that its holding "that no legitimate inference about the materiality of risks . . . can be drawn from the Reglan manufacturer's warning is consistent with case law in other jurisdictions, which hold that testimony that a treatment may or may not be safe does not establish risks pertinent to an informed consent issue." Ngo, mem. op. at 20 (citations omitted).

IV. Discussion

Hawaii's informed consent doctrine is generally based on the policy judgment that "every human being of adult years and sound mind has a right to determine what shall be done with his or her own body[.]" Leyson v. Steuermann, 5 Haw. App. 504, 513, 705 P.2d 37, 44 (1985) (brackets and citation omitted), overruled on other grounds by Bernard v. Char, 79 Hawaiʻi 362, 903 P.2d 667 (1995) (hereinafter "Bernard II"). "Physicians have an obligation to obtain the informed consent of their patients before administering diagnostic and treatment procedures." Barcai v. Betwee, 98 Hawaiʻi 470, 483, 50 P.3d 946, 959 (2002) (citing Carr, 79 Hawaiʻi at 479, 904 P.2d at 493). It is "well-settled that a physician owes a duty to a patient to disclose sufficient information about a proposed course of treatment or surgical procedure so that the patient can make an informed and intelligent decision about whether to submit to the treatment or surgical procedure[.]" Bernard v. Char, 79 Hawaiʻi 371, 380, 903 P.2d 676, 685 (App. 1995), aff'd, 79 Hawaiʻi 362, 903 P.2d 667 (hereinafter "Bernard I").

Before the informed consent doctrine was codified in HRS § 671-3, Hawaiʻi courts recognized the common law doctrine of informed consent. See Nishi v. Hartwell, 52 Haw. 188, 191, 473 P.2d 116, 119 (1970), overruled by Carr, 79 Hawaiʻi 475, 904 P.2d

489. The expert testimony requirements originated in the common law. See, e.g., Mroczkowski v. Straub Clinic & Hosp., Inc., 6 Haw. App. 563, 567, 732 P.2d 1255, 1258 (1987) (trial court granted directed verdict based on patient's failure to introduce expert testimony as to specific risks of harm defendant was required to disclose); Bernard I, 79 Hawaiʻi at 383, 903 P.2d at 688 (adopting expert testimony requirements in dental malpractice case founded on the common law doctrine of informed consent). When the doctrine was codified, Hawaiʻi courts continued to utilize elements of the common law doctrine to analyze and interpret the statutory requirements. See Leyson, 5 Haw. App. at 516, 705 P.2d at 46, overruled on other grounds by Bernard II, 79 Hawaiʻi 362, 903 P.2d 667 (noting that it was not clear from the language or history of HRS chapter 671 whether the legislative intent was to supplant Nishi's general standards of required disclosures). As the interplay between the common law and the statute has not always been clear, we review the development of the doctrine of informed consent.

A. An Overview of Informed Consent in Hawaiʻi

1. The Common Law Doctrine of Informed Consent

The common law doctrine of informed consent was first recognized as a subset of medical negligence actions. In Nishi, this court explained that the common law doctrine of informed consent imposed upon a physician "a duty to disclose to his

patient all relevant information concerning a proposed treatment, including the collateral hazards attendant thereto, so that the patient's consent to the treatment would be an intelligent one based on complete information." 52 Haw. at 191, 473 P.2d at 119 (citation omitted), overruled by Carr, 79 Hawaiʻi 475, 904 P.2d 489.

In determining the question of a physician's liability for nondisclosure, the Nishi court noted that "courts generally follow the rule applicable to medical malpractice actions predicated on alleged negligence in treatment which requires the question of negligence to be decided by reference to relevant medical standards and imposes on the plaintiff the burden of proving the applicable standard by expert medical testimony." 52 Haw. at 195, 473 P.2d at 121. The Nishi court then held that the "plaintiffs did not adduce any expert medical testimony to establish a medical standard from which the jury could find that defendants deviated from their duty . . . ." 52 Haw. at 196, 473 P.2d at 121. Rather, the "defendants, by their testimonies, established the medical standard applicable to this case. The medical standard so established was that [of] a competent and responsible medical practitioner . . . ." 52 Haw. at 196-97, 473 P.2d at 121.

In 1976, the informed consent doctrine was codified in HRS § 671-3.[12] HRS § 671-3 (1976 Repl.) "directed the board of medical examiners (board) to specifically itemize the probable risks and effects of each specific treatment or surgical procedure." Mroczkowski, 6 Haw. App. at 567, 732 P.2d at 1258. The resulting itemizations were to be prima facie evidence of the information a physician was required to disclose to a patient in order to obtain informed consent. Id. (explaining

[12] HRS § 671-3 (1976 Repl.) stated:

> (a) In any action for medical tort based on an incident that occurred after January 1, 1977, based on the rendering of professional service without informed consent, evidence may be introduced that the health care provider complied with standards established by the board of medical examiners governing the information required to be given by or at the direction of the health care provider to a patient, or the patient's guardian in the case of a patient who is not competent to give informed consent.
>
> (b) The board of medical examiners shall, insofar as practicable, establish reasonable standards of medical practice, applicable to specific treatment and surgical procedures, for the substantive content of the information required to be given and the manner in which it is given and in which consent is received in order to constitute informed consent from a patient or a patient's guardian. The standards shall include provisions which are designed to reasonably inform and to be understandable by a patient or a patient's guardian of the probable risks and effects of the proposed treatment or surgical procedure, and of the probable risks of not receiving the proposed treatment or surgical procedure. The standards established by the board shall be prima facie evidence of the standards of care required but may be rebutted by either party.
>
> (c) Nothing in this section shall require informed consent from a patient or a patient's guardian when emergency treatment or emergency surgical procedure is rendered by a health care provider and the obtaining of consent is not reasonably feasible under the circumstances without adversely affecting the condition of the patient's health.

that the board's standards were "admissible as evidence of the required specific standards of care only if the board's specific standards [we]re designed to reasonably inform the patient of, inter alia, the recognized serious possible risks and complications of each specific treatment or surgical procedure"). The board, however, did not fulfill the statutory mandate because there were too many medical and surgical procedures to provide such an itemization. 6 Haw. App. at 567, 732 P.2d at 1259.

In Leyson, 5 Haw. App. 504, 705 P.2d 37, overruled by Bernard II, 79 Hawaiʻi 362, 903 P.2d 667, the ICA first recognized the emerging confusion in the informed consent doctrine. First, the ICA opined that that there appeared to be a conflict in Nishi regarding the scope of a physician's duty. The ICA explained that "Nishi initially describe[d] the [informed consent] doctrine as a precise and definite duty[,]" 5 Haw. App. at 513, 705 P.2d at 44, on the part of the physician to disclose "all relevant information concerning a proposed treatment, including the collateral hazards attendant thereto, so that the patient's consent to the treatment would be an intelligent one based on complete information[,]" 5 Haw. App. at 512, 705 P.2d at 44 (quoting Nishi, 52 Haw. at 191, 473 P.2d at 119), "but then it alternatively describe[d] the doctrine as a duty to comply with relevant medical standards[]" by requiring

plaintiffs to prove the applicable medical standard of disclosure. 5 Haw. App. at 513, 705 P.2d at 44. Second, the ICA noted that the duty to inform had been codified in HRS § 671-3; however, it was "not clear from the language or history of chapter 671 whether the legislature's intent was to supplant Nishi's ambiguously defined duty of disclosure." 5 Haw. App. at 516, 705 P.2d at 46. The ICA also noted that under the common law, a "physician [was] not required to disclose risks that are unexpected or immaterial, by whatever standard, nor . . . risks that are commonly understood, obvious, or already known to the patient." 5 Haw. App. at 513-14, 705 P.2d at 45 (footnote omitted) (quoting W. Page Keeton, Dan B. Dobbs, Robert E. Keeton, and David G. Owen, Prosser and Keeton on The Law of Torts, § 32 at 192 (5th ed. 1984)).

The ICA then set out five material elements for the tort of a physician's negligent failure to disclose risks of harm prior to treatment, which this court adopted in Bernard II, 79 Hawaiʻi 362, 903 P.2d 670. The five elements are as follows:

> (1) [the physician] owed a duty to disclose to [the patient] the risk of one or more of the collateral injuries that [the patient] suffered; (2) [the physician] breached [his or her] duty; (3) [the patient] suffered injury; and (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) [the patient], acting rationally and reasonably, would not have undergone the treatment had he [or she] been informed of the risk of the harm that in fact occurred; and (5) no other cause is a superseding cause.

Bernard II, 79 Hawai'i at 365, 903 P.2d at 670 (alterations in original) (quoting Leyson, 5 Haw. App. at 516-17, 705 P.2d at 47); see also Barcai, 98 Hawai'i at 483-84, 50 P.3d at 959-60 (reaffirming the five elements required to establish a claim of negligent failure to obtain informed consent under Hawai'i law).

HRS § 671-3 was amended in 1983,[13] and provided that the applicable general standard of information a physician was required to disclose, among other things, was "all recognized

[13] HRS § 671-3 (Supp. 1983) provided:

> (a) The board of medical examiners, insofar as practicable, shall establish standards for health care providers to follow in giving information to a patient, or to a patient's guardian if the patient is not competent to give an informed consent, to insure that the patient's consent to treatment is an informed consent. The standards may include the substantive content of the information to be given, the manner in which the information is to be given by the health care provider and the manner in which consent is to be given by the patient or the patient's guardian.
>
> (b) If the standards established by the board of medical examiners include provisions which are designed to reasonably inform a patient, or a patient's guardian, of:
>
> (1) The condition being treated;
>
> (2) The nature and character of the proposed treatment or surgical procedure;
>
> (3) The anticipated results;
>
> (4) The recognized possible alternative forms of treatment; and
>
> (5) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, and in the recognized possible alternative forms of treatment, including non-treatment,
>
> then the standards shall be admissible as evidence of the standard of care required of the health care providers.

serious possible risks of harm and complications that the physician knew of or should have known[.]" Mroczkowski, 6 Haw. App. at 567, 732 P.2d at 1258; see also Keomaka v. Zakaib, 8 Haw. App. 518, 525, 811 P.2d 478, 483, cert. denied, 72 Haw. 618, 841 P.2d 1075 (1991) (holding that a physician owes a duty to disclose items set forth in HRS § 671-3(b), "including the 'recognized serious possible risks' and the 'recognized possible alternative forms of treatment[]'").

2. The Patient-Oriented Standard of Disclosure and Expert Testimony Requirements

Nishi and HRS § 671-3 left unresolved the question of the standard applicable to the tort of a physician's negligent failure to obtain informed consent, as well as the role of expert testimony in establishing a prima facie case of negligent failure to obtain informed consent. In Carr, 79 Hawaiʻi 475, 904 P.2d 489, this court addressed these issues.

This court first expressly adopted the "patient-oriented standard" to govern whether a physician owes a duty to disclose a particular piece of information to a patient prior to treatment, overruling Nishi to the extent that it required a plaintiff to prove the applicable standard of disclosure of material risks prior to treatment by expert medical testimony. 79 Hawaiʻi at 485, 904 P.2d at 499. Recognizing that (1) Nishi was decided without the benefit of the seminal decision on the

patient-oriented standard of disclosure, Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); (2) the informed consent doctrine had been codified; and (3) the growing nationwide trend favored the patient-oriented standard, this court held that the dispositive inquiry regarding a physician's duty of disclosure in an informed consent case was no longer "what the physician believes his or her patient needs to hear in order for the patient to make an informed and intelligent decision[.]" 79 Hawaiʻi at 486, 904 P.2d at 500. Rather, "the focus should be on what a reasonable person objectively needs to hear from his or her physician to allow the patient to make an informed and intelligent decision regarding proposed medical treatment." Id. This court therefore held, "a plaintiff is not required to prove the standard of disclosure required for informed consent with medical expert evidence[.]" 79 Hawaiʻi at 487, 904 P.2d at 501.

In a footnote, this court differentiated between the standard of care and the standard of disclosure of material risks prior to treatment with respect to the necessity of expert testimony as follows:

> It is clear that the standard of care for a claim based on allegedly negligent medical treatment must be established by reference to prevailing standards of conduct in the applicable medical community and must be so proved by expert medical 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." The

> standard of disclosure of material risks prior to treatment, however, as we have discussed above, is capable of determination under the patient-oriented standard without reference to prevailing medical standards or medical judgment, although such evidence may, subject to a Hawaiʻi Rule of Evidence 403 balancing, be relevant and admissible.

79 Hawaiʻi at 485 n.6, 904 P.2d at 499 n.6 (internal citation omitted) (quoting Craft, 78 Hawaiʻi at 298, 893 P.2d at 149).

Next, citing to the ICA's decision in Bernard I, however, this court cautioned "that our adoption of the patient-oriented standard does not relieve plaintiffs of their burden to provide expert medical testimony[,]" 79 Hawaiʻi at 486, 904 P.2d at 500 (citing Bernard I, 79 Hawaiʻi at 383, 903 P.2d at 688), "to establish the 'materiality' and/or the magnitude of the risk of harm that in fact occurs." 79 Hawaiʻi at 486 n.7, 904 P.2d at 500 n.7. This court held that "a plaintiff maintains the burden of adducing expert medical testimony to establish 'the nature of risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of particular risks, and the nature of available alternatives to treatment.'" 79 Hawaiʻi at 486, 904 P.2d at 500 (quoting Bernard I, 79 Hawaiʻi at 383, 903 P.2d at 688). See also Barcai, 98 Hawaiʻi at 484, 50 P.3d at 960; Ray, 125 Hawaiʻi at 268, 259 P.3d at 584.

In further support of the conclusion in Carr that expert testimony is required in informed consent cases, this

court cited the United States Court of Appeals for the District of Columbia's decision in Canterbury, 464 F.2d 772. This seminal decision explained why expert testimony is critical in informed consent cases:

> Experts are ordinarily indispensable to identify and elucidate for the factfinder the risks of therapy and the consequences of leaving existing maladies untreated. They are normally needed on issues as to the cause of any injury or disability suffered by the patient . . . . Save for relative[ly] infrequent instances where questions of this type are resolvable wholly within the realm of ordinary human knowledge and experience, the need for the expert is clear.

464 F.2d at 791-92, quoted in Carr, 79 Hawaiʻi at 486, 904 P.2d at 500.

In Barcai, this court reaffirmed our holdings concerning the "materiality" of the risk in informed consent cases. This court explained that "expert testimony will ordinarily be required" to establish the first aspect of "materiality" -- "the 'materiality' of the risks, i.e., 'nature of risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of particular risks, and the nature of available alternatives to treatment.'"[14] 98 Hawaiʻi at 484, 50 P.3d at 960 (emphasis added)

[14] We note that expert testimony is not required in all situations. As stated infra, expert testimony is not required to determine what a reasonable patient needs to hear in order to make an informed decision regarding proposed medical treatment. In addition, expert testimony is ordinarily, but not universally required to rebut a defendant physician's justification of nondisclosure on the basis of the therapeutic privilege exception. Barcai, 98 Hawaiʻi at 486, 50 P.3d at 962 ("[W]here [a] defendant physician justifies nondisclosure on the basis of the therapeutic privilege (continued . . .)

(quoting Carr, 79 Hawaiʻi at 486, 904 P.2d at 500 (citing Bernard I, 79 Hawaiʻi at 383, 903 P.2d at 688)). This court then explained that, "[b]ecause lay jurors do not normally possess such information, it must be made available to them by an expert[,]" so that the jury can make a factual determination regarding the second aspect of "materiality" -- the materiality of the medical information to a patient's decision, i.e., "whether a reasonable person would have wanted to consider the purportedly withheld information before consenting to the treatment." Id. (citing 79 Hawaiʻi at 486, 904 P.2d at 500).

(. . . continued)
exception, expert testimony may be required to refute the contention."). The therapeutic privilege exception "recognizes that, under some circumstances, disclosure of certain risks would not be in the patient's best medical interests." Carr, 79 Hawaiʻi at 480, 904 P.2d at 494. With regard to the necessity of expert testimony to rebut the therapeutic privilege exception, this court has stated:

> If the jury could evaluate the defendant physician's testimony without specialized expert knowledge, no such expert testimony is needed and the jury should be instructed on the informed consent issue. . . . It is only when the particular facts associated with the physician's rationale for withholding disclosure involve "medical facts" that expert testimony will be required to rebut the claim and allow the jury to consider an informed consent claim.

98 Hawaiʻi at 486 n.10, 50 P.3d at 962 n.10.

Barcai further stated that "all of the Hawaiʻi cases cited since Nishi-- and [] Canterbury, as well-- . . . repeatedly discuss the exception in the context of explicating 'limits' to the patient oriented standard, thereby suggesting that Hawaiʻi appellate courts have intended this exception to remain applicable." 98 Hawaiʻi at 485 n.9, 961 n.9 (citations omitted). We discuss the exception as illustrative of the necessity of expert testimony in informed consent cases. We do not address the continued viability of the therapeutic privilege exception under the current iteration of HRS § 671-3(b), as that issue is not before us.

The second aspect of materiality does not require expert testimony, although, as recognized by footnote 6 from Carr quoted above, expert testimony can also be helpful.

Following Barcai, HRS § 671-3 was amended in 2003 (effective January 1, 2004) to integrate advances to legal and medical standards regarding the materiality of the risk of harm. See 2003 Haw. Sess. Laws Act 114, § 2 at 221-222; see also S. Stand. Comm. Rep. No. 1228, in 2003 Senate Journal, at 1547. HRS § 671-3 (Supp. 2003)[15] mandated disclosure of specific

[15] HRS § 671-3 (Supp. 2003) provided, in relevant part:

> (a) The board of medical examiners may establish standards for health care providers to follow in giving information to a patient, or to a patient's guardian or legal surrogate if the patient lacks the capacity to give an informed consent, to ensure that the patient's consent to treatment is an informed consent. The standards shall be consistent with subsection (b) and may include:
>
> (1) The substantive content of the information to be given;
>
> (2) The manner in which the information is to be given by the health care provider; and
>
> (3) The manner in which consent is to be given by the patient or the patient's guardian or legal surrogate.
>
> (b) The following information shall be supplied to the patient or the patient's guardian or legal surrogate prior to obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure:
>
> (1) The condition to be treated;
>
> (2) A description of the proposed treatment or procedure;
>
> (3) The intended and anticipated results of the proposed treatment or procedure;

(continued . . .)

information, in particular, "recognized material risks of serious complications or mortality[,]" as opposed to general standards of medical practice established by the board, and maintained the patient-oriented standard from Carr. See S. Stand. Comm. Rep. No. 1228, in 2003 Senate Journal, at 1547; see also H.B. 651, H.D. 2, 22d Leg., Reg. Sess. (2003) (prior version of bill that became the 2003 act amending HRS § 671-3(b) contemplated switching to a physician-oriented standard).

In Ray, this court "interpreted HRS § 671-3(b) as supplying the standard for a physician's duty to disclose information to the patient." 125 Hawaiʻi at 266, 259 P.3d at 582. Under HRS § 671-3(b) (Supp. 2008), a physician's duty to inform encompasses four separate duties: (1) the general duty to supply information about a proposed medical treatment or procedure embodied by HRS § 671-3(b)(1)-(3); (2) the duty to

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(. . . continued)

(4) The recognized alternative treatments or procedures, including the option of not providing these treatments or procedures; and

(5) The recognized material risks of serious complications or mortality associated with:

(A) The proposed treatment or procedure

(B) The recognized alternative treatments or procedures; and

(C) Not undergoing any treatment or procedure; and

(6) The recognized benefits of the recognized alternative treatments or procedures.

inform the patient of recognized alternative treatments or procedures, including the option of not providing these treatments or procedures, as provided in HRS § 671-3(b)(4); (3) the duty to warn of material risks as provided in HRS § 671-3(b)(5); and (4) the duty to inform patients of the recognized benefits of any recognized alternative treatments or procedures as provided in HRS § 671-3(b)(6).

Under HRS § 671-3(b)(5)(A), Plaintiffs' main claim, a physician is required to inform patients of "recognized material risks of serious complications or mortality associated with . . . [t]he proposed treatment or procedure[.]" Thus, at trial, a plaintiff alleging a violation of this subsection bears the burden of presenting expert medical evidence to establish prima facie that the risk of harm to which the plaintiff was subjected is a "recognized material risk[] of serious complications or mortality associated with . . . [t]he proposed treatment or procedure[.]" Cf. Ray, 125 Hawaiʻi at 268, 259 P.3d at 584 (holding that a "plaintiff will need to show that the medical community recognizes the different dosage as an alternative treatment" in an HRS § 671-3(b)(4) claim). "[E]xpert 'testimony is not conclusive and like any testimony, the jury may accept or reject it.'" 125 Hawaiʻi at 262, 259 P.3d at 578 (quoting Bachran v. Morishige, 52 Haw. 61, 67, 469 P.2d 808, 812 (1970)).

Once a plaintiff adduces expert testimony establishing prima facie that the risk of harm that occurred is a "recognized material risk[] of serious complication or mortality[,]" whether the physician was required to supply that information to the patient prior to obtaining consent is a question for the factfinder that does not require expert testimony, although, as noted in the quotation from Carr, supra (citing Craft), expert testimony can also be relevant and admissible. See 79 Hawaiʻi at 485 n.6, 904 P.2d at 499 n.6 (citation omitted). In other words, the jury, applying the patient-oriented standard, decides "what a reasonable person objectively needs to hear from his or her physician to allow the patient to make an informed and intelligent decision regarding proposed medical treatment." Ray, 125 Hawaiʻi at 267, 259 P.3d at 583 (quoting Carr, 79 Hawaiʻi at 486, 904 P.2d at 500) (quotation marks omitted).

B. The Circuit Court Erred in Granting JMOL Because Reglan's Package Insert Combined With Expert Testimony Sufficiently Established the Materiality of the Risk of Reglan

Plaintiffs argue that the ICA erred in concluding that they failed to establish the materiality of the risk by expert testimony, and in affirming the circuit court's grant of JMOL in Defendants' favor on that basis. Plaintiffs assert that the manufacturer's warning, in combination with expert testimony as to the significance of that information, sufficiently established the materiality of the risk of harm to which Minor

was subjected when Defendant administered Reglan to Minor. We agree.

"Claims for negligent failure to obtain informed consent typically arise when a plaintiff patient alleges that the defendant physician failed to warn the patient of a particular risk associated with the procedure and the particular risk ultimately occurred." Barcai, 98 Hawaiʻi at 483, 50 P.3d at 959.

> To establish a claim of negligent failure to obtain informed consent under Hawaiʻi law, the plaintiff must 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.

98 Hawaiʻi at 483-84, 50 P.3d at 959-60 (citation omitted).[16] The first prong of this common law formulation of the tort is

[16] Although not raised by the parties nor on appeal, we note that in granting JMOL in Defendant's favor on the informed consent claim, the circuit court stated, "the parents . . . were never asked whether if they had been informed of certain things they would have given permission[.]" Plaintiffs' subjective view is, however, unnecessary. We have held,

> the question of part (b) causation in an action based on the doctrine of informed consent 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 Hawaiʻi at 371, 903 P.2d at 676. Thus, in this case, a determination of proximate causation depends upon whether there was sufficient evidence for a jury to find that, had Plaintiffs been advised of

(continued . . .)

subject to appropriate modification based on the specific provisions of HRS § 671-3(b) alleged to have been violated; in other words, the first prong is now "the physician violated a duty of disclosure under HRS § 671-3(b)." In proving the elements of an informed consent claim alleging an HRS § 671-3(b)(5)(A) violation, a plaintiff must present expert testimony to establish prima facie that the risk of harm to which the plaintiff was subjected is an undisclosed "recognized material risk[] of serious complications or mortality associated with . . . [t]he proposed treatment or procedure[.]" Although not explicitly required by HRS § 671-3(b)(5), expert testimony is typically necessary to establish the medical information statutorily required to be disclosed.

In this case, the ICA misconstrued Craft, 78 Hawaiʻi 287, 893 P.2d 138, when it concluded that the manufacturer's insert "does not constitute 'expert testimony' and does not permit a legitimate inference regarding the materiality of the risk." Ngo, mem. op. at 19 (citing 78 Hawaiʻi at 306, 893 P.2d at 157). In Craft, we affirmed the trial court's reading of a jury instruction "that a plaintiff who brings 'an action based on informed consent must establish the applicable standard of

(. . . continued)
the risks of Reglan, they would not have consented to its use to treat Minor. Plaintiffs need not testify as to what they subjectively would have done if properly informed of the risks.

care through expert medical testimony and manufacturer's package inserts do not, by themselves, set the standard of care which is applicable to a physician on the issue of informed consent.'" 78 Hawaiʻi at 306, 893 P.2d at 157 (brackets omitted). Thus, Craft recognized the view that "a drug manufacturer's package insert merely constitutes evidence to be considered along with the expert's testimony[,]" but does not supplant expert testimony. 78 Hawaiʻi at 299, 893 P.2d at 150 (discussing the conflicting views of package inserts). Therefore, under Craft, although information contained in a manufacturer's insert cannot, on its own, satisfy a plaintiff's burden of production in an informed consent case, it can constitute evidence that the jury or fact finder may consider along with the requisite expert testimony.

In the instant case, while the manufacturer's insert did not establish the materiality of the risk of increased diarrhea by itself, Plaintiffs adduced expert testimony regarding the significance of the information in the manufacturer's insert. Plaintiffs' expert testimony, in conjunction with the manufacturer's insert, established prima facie that Defendant failed to supply Plaintiffs with "recognized material risks of serious complications or mortality associated with" Reglan, as required by HRS § 671-3(b)(5)(A). Applying the standard applicable to a motion for JMOL, it cannot

be said that there was no evidence to support a jury verdict in Plaintiffs' favor on their informed consent claim. Ray, 125 Hawaiʻi at 261, 259 P.3d at 577 (brackets omitted) (quoting Miyamoto, 104 Hawaiʻi at 7, 84 P.3d at 515). Therefore, Plaintiffs' informed consent claim should have been presented to the jury.

The ICA erred in concluding that "expert testimony was not adduced to establish the 'probabilities of therapeutic success' or 'the frequency of the occurrence of particular risks' and therefore Plaintiffs failed to carry their evidentiary burden." Ngo, mem. op. at 16 (citing Carr, 79 Hawaiʻi at 486, 904 P.2d at 500). The "probabilities of therapeutic success" is not part of an informed consent claim based on an alleged HRS § 671-3(b)(5)(A) violation, but is information required to be provided under HRS § 671-3(b)(3), the "intended and anticipated results of the proposed treatment or procedure[.]" With respect to the risks that must be disclosed under HRS § 671-3(b)(5)(A), at trial, Plaintiffs' expert medical evidence established that increased diarrhea is a risk associated with Reglan. Defendant expressly admitted that he knew diarrhea was a side effect of Reglan. With respect to adverse gastrointestinal reactions, the manufacturer's insert listed: "nausea and bowel disturbances, primarily diarrhea[.]" Plaintiffs' expert, Dr. Towle, testified that "one of the ways

Reglan works is that it gets the pylorus, or the sphincter between the stomach and small intestines, to relax and open up and allow the contents of the stomach to pass through to the small intestine." Dr. Towle further stated that in Minor's case, although Reglan did not directly affect the lower intestine and cause diarrhea in and of itself, "if you're emptying the stomach and you're dumping things into the small intestine, it kind of gets the intestines going and diarrhea is one of the more common side effects with Reglan." Moreover, Dr. Towle pointed out that the contraindications section in the manufacturer's insert states that Reglan should not be used whenever stimulation of gastrointestinal motility might be dangerous. He further testified that Reglan "should not have been given no matter what in the circumstances of this case." Finally, Dr. Towle testified that Reglan is more likely to increase diarrhea than Zofran or other anti-emetics. Therefore, Plaintiffs' expert medical evidence established increased diarrhea as a common side effect of Reglan.

Plaintiffs' other expert witness, Dr. Gallup testified that, in his opinion, Reglan moderately increased the amount of fluid excreted out of Minor's system through diarrhea, thereby significantly increasing her dehydration. He further testified that this increase in dehydration was a substantial factor in leading to her hypovolemic shock.

Although diarrhea is not a serious complication that generally results in death, in the instant case, the evidence established that Minor was moderately dehydrated and losing fluid through both vomiting and diarrhea. Plaintiffs' expert testimony and the manufacturer's insert established increased diarrhea as a risk associated with Reglan, and that Reglan should not be used when stimulation of gastrointestinal motility might be dangerous. Therefore, Plaintiffs presented expert evidence that Minor might not be able to tolerate increased diarrhea. In short, Plaintiffs did adduce expert testimony establishing the "probabilities of therapeutic success" and "the frequency of the occurrence of particular risks" under the former common law formulation of the duties. More importantly, however, Plaintiffs adduced expert testimony regarding a violation of Defendant's current statutory duty under HRS § 671-3(b)(5)(A).

Accordingly, the ICA erred in concluding that Plaintiffs' "expert testimony presented at trial [did] not sufficiently establish the 'materiality of the risk of harm' imposed by [Defendant's] administration of ten milligrams of Reglan to [Minor]." Ngo, mem. op. at 15.

C. The ICA Erred in Concluding that Plaintiffs Waived Their Claim that Defendant Failed to Provide Other Statutorily Mandated Information

Plaintiffs also contend that the ICA erred in ruling that they waived their argument that Defendant failed to provide all statutorily required disclosures, including information about "alternative treatments or medications, the risks of Reglan and alternative treatments, or the alternative of no treatment, or the benefits of Reglan and its alternatives, including the alternative of no treatment."

Plaintiffs assert that they in fact raised the nondisclosure issue. Plaintiffs specifically alleged in their complaint that Defendant treated Minor "without obtaining the informed consent of Plaintiff," and "failed to adequately inform Plaintiffs of the nature of the treatment and risks thereof[.]" Although Plaintiffs' complaint omitted the specific statutory provisions, Plaintiffs' allegation that Defendant treated Minor "without obtaining the informed consent of Plaintiff[]" clearly implicated a physician's duty of disclosure, which includes the duties enumerated in HRS § 671-3(b).

We recently ruled on the scope of a physician's duty under HRS § 671-3(b)(4) in Ray, 125 Hawaiʻi 253, 259 P.3d 569. The plaintiffs in Ray adduced evidence in support of their contention that recognized alternative dosing regimens of the same treatment had a lower risk of the harm the patient

ultimately suffered. 125 Hawaiʻi at 267, 259 P.3d at 583. The defendants moved for JMOL on the issue of informed consent because it was undisputed that defendants informed the patient of the risk of injury that occurred. 125 Hawaiʻi at 265, 259 P.3d at 581. This court held that the circuit court properly denied the defendant's motion because "an alternative dosage can constitute a 'recognized alternative treatment' within the meaning of HRS § 671-3(b)(4)." 125 Hawaiʻi at 267, 259 P.3d at 583. This court further held, "[i]f a reasonable patient would need to hear the information to make an informed decision, the physician is required to disclose that information." Id.

In the instant case, Plaintiffs similarly adduced evidence of recognized alternative treatments to Reglan. Plaintiffs' counsel elicited testimony from Defendant indicating that, at the time he administered Reglan to Minor, he knew of the existence of alternative anti-emetic medications, including Zofran, which did not have Reglan's side effects, and Phenergan, which was specifically approved by the FDA to treat nausea in pediatric patients. Dr. Towle testified that safer alternatives to Reglan existed, including Zofran, which had been approved for use in pediatric patients, had a lower risk of causing diarrhea, and could be the most "popular" anti-emetic. In addition, Dr. Gallup testified that while Reglan relaxes the "sphincter so that any fluid in the stomach can easily get transported down

through the small intestine into the large intestine," does not do this and in fact, "works almost exactly in the opposite direction." Thus, at trial, Plaintiffs raised the issue of Defendant's failure to inform them of recognized alternative treatments pursuant to HRS § 671-3(b)(4).

Moreover, although expert evidence of the "probabilities of therapeutic success" was not required as part of Plaintiffs' HRS § 671-3(b)(5)(A) claim, as discussed in Part IV.B, supra, a physician's failure to provide such information implicates a claim based on a violation of HRS § 671-3(b)(3), which requires disclosure of the "intended and anticipated results of the proposed treatment or procedure[.]"

In this case, Defendant admitted that he did not inform Plaintiffs that the manufacturer's insert stated that "[s]afety and effectiveness in pediatric patients have not been established (see overdosage)." See (Reglan insert). The manufacturer's insert also stated that "[t]he safety profile of [Reglan] in adults cannot be extrapolated to pediatric patients." Dr. Towle testified that the manufacturer's statement meant that the safety and effectiveness of Reglan in pediatric patients was undetermined. In addition, Dr. Towle testified that "Reglan is not recommended for use in children except for very specific circumstances" not present in this

case. Despite these warnings, Defendant prescribed Reglan based on Minor's weight of 150 lbs.

Accordingly, the ICA erred in concluding that Plaintiffs waived these additional informed consent claims.

V. Conclusion

Based on the evidence adduced at trial, the circuit court erred in granting JMOL in favor of Defendants on Plaintiffs' informed consent claims. Because the court did so at the end of Plaintiffs' case, however, the defense may not have been fully heard on the informed consent claims. Although we answer Plaintiffs' first question on certiorari in the affirmative and rule that Plaintiffs presented sufficient evidence to have the jury consider their informed consent claims, we decline to answer the second question.[17] Accordingly, we vacate in part (1) the ICA's February 11, 2014 Judgment on Appeal as to Plaintiffs' informed consent claims; and (2) the circuit court's July 28, 2009 Final Judgment as well as its order granting Defendants' motion for JMOL as to Plaintiffs'

[17] See supra notes 4 (questions on certiorari) and 8 (regarding HRCP Rule 50, which governs JMOLs).

informed consent claims and its award of costs, and remand the case to the circuit court for further proceedings consistent with this opinion.

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