IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR NEW CASTLE COUNTY

Lashanda Spencer as Administratrix of the Estate of Muriel Stewart, and Lashanda Spencer Individually, Plaintiff, v. John Goodill, M.D., Defendant.	))))))))))))))	C.A. No. 08C-06-183 RRC

Submitted: November 23, 2009
Decided: December 4, 2009

Upon Plaintiff's Motion in Limine Regarding Proximate Causation in an Informed Consent Action.
DENIED.

MEMORANDUM OPINION

Kenneth M. Roseman, Esquire, Kenneth M. Roseman, P.A., Wilmington, Delaware, Attorney for Plaintiff

Bradley J. Goewert, Esquire and Lorenza A. Wolhar, Esquire, Marshall Dennehey Warner Coleman & Goggin, Wilmington, Delaware, Attorneys for Defendant

COOCH, J.

I. INTRODUCTION

Plaintiff's Motion in Limine arises out of an informed consent claim brought pursuant to 18 *Del. C.* § 6852 by Plaintiff, Lashanda Spencer, on behalf of Muriel Stewart, her mother ("Decedent"). Plaintiff has alleged that by Defendant not having provided "informed consent" to Plaintiff's decedent prior to a bronchoscopy,[1] Defendant committed medical negligence that ultimately caused Decedent's death.[2] Plaintiff has also brought a Wrongful Death action pursuant to 10 *Del. C.* § 3724. At the pretrial conference on November 2, 2009, Plaintiff withdrew her prior allegations of negligence concerning the medical procedure itself performed by Defendant, leaving only the claim of lack of "informed consent" for trial.

Plaintiff's motion raises two interrelated issues.[3] The first issue is whether an action based on lack of informed consent requires, as a matter of proximate causation, proof that the patient would not have undergone the medical procedure, at the time consent was given, had proper medical information been provided by the health care provider, despite no explicit

[1] Proposed jury instruction submitted by Defendant on November 13, 2009.
[2] This survival action is brought pursuant to 10 *Del. C.* § 3704.
[3] The issues that are the subject of this motion were raised for the first time by the Plaintiff in the pretrial stipulation filed on October 30, 2009 at Paragraph 4 ("Issues any party contends remains to be litigated"). The Court has decided to treat Plaintiff's motion as a motion in limine to be decided before trial.

requirement of proximate causation in Delaware's Informed Consent Statute.

The second issue, assuming the Court concludes (as it has) that a claimant in an informed consent action must prove, as a matter of proximate causation, that the medical procedure would not have taken place if the claimant had been properly informed of the risks, is whether a claimant must prove that a hypothetical "reasonable patient" in similar circumstances to the claimant would have decided against undergoing the medical procedure (the "objective standard"), or whether the particular claimant in an informed consent action would have decided against the procedure if that particular claimant had been properly informed (the "subjective standard").

This Court now holds that, in an action brought pursuant to the Informed Consent Statute, a claimant must prove that that patient would not have undergone the medical procedure if properly informed. It is not enough, as Plaintiff argues, that, under the Informed Consent Statute, all that is needed to succeed on an informed consent claim, insofar as proximate causation is required, is a showing that the patient was not properly informed of the risks and that the medical procedure caused the injuries or death.

Additionally, this Court holds that in proving proximate causation, Delaware follows the objective standard. In this case, Plaintiff must prove that a hypothetical "reasonable person" in similar circumstances to Decedent would not have consented to the bronchoscopy if properly informed of the risks.

For all the following reasons, Plaintiff's motion in limine is **DENIED**.

II. FACTS

This case stems from the alleged failure of a health care provider to have provided Plaintiff's decedent "informed consent" prior to a medical operation. Plaintiff alleges that on or about July 17, 2007, Defendant provided "negligent medical treatment" to Muriel Stewart, Plaintiff's mother, by failing to have adequately informed her of the risks involved in a bronchoscopy.[4] Plaintiff alleges that Decedent needed this information to have made an informed decision, and that Defendant should be held liable in not providing the necessary information. Plaintiff has also brought a wrongful death claim on her own behalf alleging that the death

[4] Defendant denies this allegation and asserts that Decedent was properly informed of the risks.

of her mother caused her to suffer "mental anguish."[5] The facts pertinent to this motion are not in dispute; the motion raises only questions of law.

Both parties have submitted proposed jury instructions based on the Informed Consent Statute that frame the issue. Plaintiff has requested that the Court give Superior Court Pattern Civil Jury Instruction § 7.2A ("Informed Consent"), which states:

> [Lashanda Spencer] alleges that [Dr. Goodill] committed medical negligence by failing to obtain [Muriel Stewart's] informed consent to perform a [bronchoscopy]. "Informed consent" is a patient's consent to a procedure after the healthcare provider has explained both the nature of the proposed procedure or treatment and the risks and alternatives that a reasonable patient would want to know in deciding whether to undergo the procedure or treatment. The explanation must be reasonably understandable to a general lay audience.
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> You may consider whether the doctor supplied information to the extent customarily given to patients by other healthcare providers in the same or similar field of medicine at the time of the [bronchoscopy]. The doctor doesn't have to advise of hazards that are:
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> (1) inherent in a treatment, and
>
> (2) are generally known to people of ordinary intelligence and awareness in a position similar to that of [Muriel Stewart].
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> To prevail on this claim, [Lashanda Spencer] must prove by a preponderance of the evidence:
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> (1) that before the procedure, [Dr. Goodill] failed to tell [Muriel Stewart] about certain risks of the procedure or alternatives to it; and

[5] This Court previously held that Plaintiff may proceed on her claim of "mental anguish" absent a showing of physical injury. *See Spencer v. Goodill*, 2009 WL 3823217 (Del. Super.).

> (2) that a reasonable patient would have considered this information to be important in deciding whether to have the procedure; and
>
> (3) that [Muriel Stewart] has suffered injury as a proximate result of the procedure.[6]

Defendant has submitted an alternative proposed jury instruction, which differs from Plaintiff's jury instruction only in that Defendant's jury instruction additionally requires the jury to find "that a reasonably prudent patient would have declined to undergo the procedure if [that reasonably prudent patient] had known the risks."

III. CONTENTIONS OF THE PARTIES

A. The "Causation" Issue

Plaintiff argues that the Informed Consent Statute does not require a plaintiff to prove "causation" in that the Informed Consent Statute "does not require the instant plaintiff to prove that the decedent would not have undergone the fatal medical procedure if she had been informed of the risks of that procedure."[7] Plaintiff asserts that the General Assembly did not specifically include this "causation" element in the Informed Consent Statute and that requiring a plaintiff to prove the "additional" element of the above "causation" would "engraft an additional element of proof that

[6] Del. P.J.I Civ. § 7.2A (2000).
[7] Pl. Op. Br. at 1.

was not included by the legislature."[8] Plaintiff argues that proximate causation is shown if the claimant is injured or died as a result of a medical procedure about which the claimant was not properly informed.

In response, Defendant argues that Delaware's Informed Consent statute is based on the common law tort of negligence and that causation is not an "additional" element but is an "essential element in any negligence action [including medical negligence]."[9] Therefore, Defendant argues that Plaintiff must prove:

> "but for" defendant's negligent act, the injury would not have occurred. In the context of an alleged violation of informed consent: but for the physician's failure to advise of the risk of surgery, plaintiff would not have undergone the surgery. Conversely stated, if the plaintiff would have undergone the procedure if adequately informed, causation can not be proven.[10]

B. Objective or Subjective Standard for Causation

The Court, after initial briefing on this motion was completed, proposed an additional question to the parties:

> Assuming only hypothetically that the Court were to agree with Defendant's position that, as to causation, Plaintiff must prove that the decedent would not have had the surgical procedure, does a subjective standard (what would the decedent have done) or an objective standard (what would a reasonable patient have done) apply?

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[8] *Id.* at 2.
[9] Def. Op. Br. at 5.
[10] *Id.* at 6.

In response, Defendant argues that Delaware follows an objective standard on causation insofar as the jury must determine whether "a reasonably prudent patient would not have undergone the procedure."[11] Defendant asserts that "focusing on what a reasonable, prudent person in a similar circumstance would have done in the plaintiff's position having been informed of all the risks . . . [is a flexible standard] and allows consideration of plaintiff's particular facts and circumstances to be considered as it is based upon what a reasonable prudent person in a similar circumstance would do."[12]

In response, Plaintiff argues, again, that the General Assembly did not intend to add a "causation" requirement to the Informed Consent Statute. Plaintiff asserts that, because the "causation" element does not appear in the statute, "it is impossible to determine whether the legislature intended the issue to be decided by the application of a subjective or objective standard."[13] She asserts that Delaware's Informed Consent Statute does not require any showing that a decedent would have "decided differently" if properly informed of the risks.

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[11] Def. Letter Memo at 1
[12] *Id.* at 5.
[13] Pl. Letter Memo at 1.

IV. DISCUSSION

A. The "Causation" Issue

The first issue before the Court is whether an action based on lack of informed consent requires, as a matter of proximate causation, proof that the patient would not have undergone the medical procedure, at the time consent was given, had proper medical information been provided by the health care provider, despite no explicit requirement of proximate causation in Delaware's Informed Consent Statute.

1. The Tort of Informed Consent is Based on Negligence

The tort of informed consent is grounded on the sound principle that every individual should have a basic right to determine what is done to his or her own body.[14] Many states, including Delaware, have adopted

[14] *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891) (holding that in a case involving a surgical examination "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."); *Kulak v. City of New York*, 88 F.3d 63, 74 (2d Cir. 1996) (holding that ""[i]t is a firmly established principle of the common law of New York that every individual 'of adult years and sound mind has a right to determine what shall be done with his own body' and to control the course of his medical treatment.") (citing *Rivers v. Katz*, 495 N.E.2d 337, 341 (N.Y. 1986)); *Trombley v. Starr-Wood Cardiac Group*, PC, 3 P.3d 916, 924 (Alaska 2000) ("The informed consent claim is based on the principle that every human being of adult years and sound mind has a right to determine what shall be done to his or her own body.") (citing *Korman v. Mallin*, 858 P.2d 1145, 1149 (Alaska 1993)); *Stamford Hosp. v. Vega*, 674 A.2d 821, 831 (Conn. 1996) ("The right to refuse medical treatment is a right rooted in this nation's fundamental legal tradition of self-determination.") (citing *McConnell v. Beverly Enterprises-Connecticut, Inc.*, 553 A.2d 596 (Conn. 1989)).

statutes creating a statutory tort action based on a lack of informed consent,[15] but there is a split in the law of other jurisdictions on whether this cause of action is based on the tort of negligence or the tort of battery.[16]

The Delaware Informed Consent Statute is found under the "Medical Negligence" chapter of the Delaware Insurance Code and provides:

> (a) No recovery of damages based upon a lack of informed consent shall be allowed in any action for medical negligence unless:
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> (1) The injury alleged involved a nonemergency treatment, procedure or surgery; and
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> (2) The injured party proved by a preponderance of evidence that the health care provider did not supply information regarding such treatment, procedure or surgery to the extent customarily given to patients, or other persons authorized to give consent for patients by other licensed health care providers in the same or similar field of medicine as the defendant.
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> (b) In any action for medical negligence, in addition to other defenses provided by law, it shall be a defense to any allegation that such health care provider treated, examined or otherwise rendered professional care to an injured party without his or her informed consent that:
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> (1) A person of ordinary intelligence and awareness in a position similar to that of the injured party could reasonably be expected to appreciate and

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[15] The category of claims based solely on informed consent is narrow. "Egregious medical conduct can usually be remedied in a malpractice case in which an informed consent claim would be superfluous." *See* Aaron D. Twerski & Neil B. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. Ill. L. Rev. 607, 645 (1998).

[16] *Compare Acuna v. Turkish*, 930 A.2d 416, 425 (N.J. 2007) (holding that an action based on the informed consent doctrine is based on a "firmly established principle of negligence"), *with Fitzpatrick v. Natter*, 961 A.2d 1229, 1242 n. 13 (Pa. 2008) ("An informed consent action . . . [in Pennsylvania] sounds in battery rather than in negligence."); *see also* 1 Dan B. Dobbs, The Law of Torts 654 (2001).

> comprehend hazards inherent in such treatment;
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> (2) The injured party assured the health care provider he or she would undergo the treatment regardless of the risk involved or that he or she did not want to be given the information or any part thereof to which he or she could otherwise be entitled; or
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> (3) It was reasonable for the health care provider to limit the extent of his or her disclosures of the risks of the treatment, procedure or surgery to the injured party because further disclosure could be expected to affect, adversely and substantially, the injured party's condition, or the outcome of the treatment, procedure or surgery.[17]

"Informed Consent" has the following statutory definition:

> "Informed consent" means the consent of a patient to the performance of health care services by a health care provider given after the health care provider has informed the patient, to an extent reasonably comprehensible to general lay understanding, of the nature of the proposed procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis.[18]

Several Delaware cases have held that informed consent is a negligence-based claim. In *Valentine v. Mark*, this Court held that the Informed Consent Statute "specifically references informed consent as a subset of medical negligence, saying, '[n]o recovery of damages based upon a lack of informed consent shall be allowed in any action for medical negligence unless' certain conditions are met."[19] Similarly, in *Brzoska v. Olsen*, the Delaware Supreme Court held that an action based on the

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[17] 18 *Del. C.* § 6852.
[18] 18 *Del. C.* § 6801(6).
[19] *Valentine v. Mark*, 2004 WL 2419131, at *3 (Del. Super.).

Informed Consent Statute "should be pleaded in negligence-not battery."[20] Finally, in *Patten v. Freedman*, a case granting summary judgment for Defendant because there was no evidence that the defendant's negligence was the proximate cause of injury to the plaintiff, this Court explicitly stated that:

> an action for malpractice based on lack of informed consent is a negligence action. In a negligence action, a plaintiff must show that a negligent act by the defendant proximately caused an injury to the plaintiff.[21]

Most actions based on negligence, as opposed to battery, require a separate showing of causation as a prerequisite to recovery.[22]

Both *Brzoska* and *Patten* held that Delaware follows a negligence theory when interpreting a cause of action based on informed consent. This is consistent with how many other jurisdictions have interpreted a tort claim based on lack of informed consent. As one authority has noted:

> Thus under the view currently prevailing, the patient who consents to an operation on his right toe has a battery action if the surgeon operates on

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[20] *Brzoska v. Olsen*, 668 A.2d 1355, 1366 (Del. 1995) ("If a health care provider violates his or her duty of care in obtaining the consent of the patient by failing to disclose all relevant information (risks) that a reasonable person would deem significant in making a decision to have the procedure, the action should be pleaded in negligence-not battery."); *see Patten v. Freedman*, 1989 WL 64116, at * 3 (Del. Super.) (stating that "an action for malpractice based on lack of informed consent is a negligence action."); *Guinan v. A.I. DuPont Hospital for Children*, 597 F.Supp.2d 517, 526 (E.D.Pa. 2009) (stating that an informed consent action in Delaware "sounds in negligence").

[21] *Patten*, 1989 WL 64116, at * 3.

[22] 1 Dan B. Dobbs, The Law of Torts 269 (2001) (stating that causation is required as part of a prima facie case for negligence).

> the left toe instead. But the patient who consents to an operation on his right toe without being informed that the operation entails a serious risk that he will lose his leg must make out a claim for negligent nondisclosure.[23]

In the present case, Decedent has alleged a tort claim based on the lack of informed consent. According to both *Brzoska* and *Patten*, and similar to the "view currently prevailing," the instant action, brought pursuant to the Informed Consent statute, is a negligence-based action.

Thus, under Delaware's Informed Consent Statute, a health care provider has a duty to:

> supply information regarding [medical treatment] to the extent customarily given to patients, or other persons authorized to give consent for patients by other licensed health care providers in the same or similar field of medicine as the defendant.[24]

It follows that the health care provider breaches that duty by not supplying the patient with the proper information to make an informed decision about undergoing a medical procedure.

2. Proximate Causation is Required in an Informed Consent Action

A plaintiff must also establish "proximate cause" as a prerequisite to recovery pursuant to the Informed Consent Statute.[25] Delaware's definition of proximate cause is well established: "[t]he defendant's

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[23] *Id.* at 654.
[24] 18 *Del. C.* § 6852
[25] *Patten*, 1989 WL 64116, at * 3.

conduct is a cause of the event if the event would not have occurred but for that conduct; conversely, the defendant's conduct is not a cause of the event, if the event would have occurred without it."[26] Similarly, Superior Court Pattern Civil Jury Instruction § 21.1 ("Proximate Cause") states:

> Proximate cause is a cause that directly produces the harm, and but for which the harm would not have occurred. A proximate cause brings about, or helps to bring about, the [injury], and it must have been necessary to the result.[27]

As explained below, Plaintiff must prove that "the event would not have occurred but for [the failure to disclose proper information]."[28] Stated another way, a plaintiff must prove that she would have "decided differently"[29] if properly informed; or otherwise there is no casual connection between the failure to disclose and the injury. "The patient [] has no complaint if [s]he would have submitted to the [medical procedure] notwithstanding awareness that the risk was one of its perils."[30]

a. Delaware Courts Have Addressed this Issue

At least two Delaware Superior Court cases have recognized at least implicitly that a patient must prove that the patient would have decided against the medical procedure if properly informed of the risks prior to the

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[26] *Culver v. Bennett*, 588 A.2d 1094, 1097 (Del. 1991) (citing W. Keeton, *Prosser and Keeton on The Law of Torts* 263 (5th ed. 1984)).
[27] Del. P.J.I Civ. § 21.8 (2000).
[28] *Culver*, 588 A.2d at 1097.
[29] The term used by both parties in the briefing.
[30] *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972).

procedure. Thus, in *Kocher v. Capodanno*, this Court granted defendant's and third-party defendant's motions for a new trial because of an excessive jury verdict, but ultimately found no underlying legal error.[31] In *Kocher*, defendant and third-party defendant argued that the Court erred in not awarding a directed verdict during trial when the plaintiff did not directly testify that she would have decided against the medical procedure if properly informed.[32] Plaintiff had testified that "if the risks of the surgery had been explained . . . she would have gotten a second opinion."[33] The Court, finding no legal error, stated that "[a]n element of [informed consent] is that a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of material facts relating to the treatment."[34] *Kocher* stated that a plaintiff must establish that that plaintiff would not have undergone the medical procedure if properly informed of the risks.[35]

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[31] *Kocher v. Capodanno*, 1990 WL 127823, at * 1 (Del. Super.).
[32] *Id.*
[33] *Id.* at *2.
[34] *Id.*
[35] Plaintiff asserts that *Kocher* supports her contention because "the trial judge allowed the informed consent claim to go to the jury even though the plaintiff did not testify that she would have rejected the proposed procedure if informed consent had been given." Pl. Op. Br. at 4. However, the plaintiff in *Kocher* did testify that she would have declined the procedure because she would have gotten a second opinion. *Kocher*, 1990 WL 127823, at * 1. All that is required under the Informed Consent Statute in this case is that Plaintiff demonstrate that her decedent would have decided against the procedure at the time consent was given. *Kocher* supports this proposition because Plaintiff in

Additionally in *Bello v. Ikeda*, this Court, in a bench ruling, granted a defendant's request for a jury instruction that instructed the jury, as a requirement of proximate causation, that the plaintiff, if properly informed of the risks, would have declined the medical procedure.[36] The *Bello* Court compared informed consent with a failure-to-warn claim.[37] *Bello* held that, similar to a failure-to-warn claim, a plaintiff bringing an Informed Consent Claim has the burden of proving that "if he were warned, he would have or she would have acted differently."[38]

However, in contrast to *Kocher* and *Bello*, this Court has at least once held that a plaintiff need not establish as a matter of proximate causation that the claimant would have decided against the medical procedure if properly informed of the risks.[39] Thus, in *Koch v. Cardiology Consultants, P.A.*, a case analyzing the Informed Consent Statute in connection with a claim stemming from death allegedly caused by a side effect to prescription drugs, the Court held that "Plaintiffs need not affirmatively establish that [Plaintiff's decedent] would have refused to

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that case stated that she would have declined consent when it was given in favor of getting a second opinion.

[36] C.A. No. 06C-02-266, at 6 (Bench Ruling) (Jul. 7, 2008) (granting the defendant's request for a proximate causation instruction).

[37] *Id.*

[38] *Id.*

[39] *Koch v. Cardiology Consultants, P.A.*, C.A. No. 05C-10-176, slip op. (Jun. 16, 2008).

take the medication prescribed if she had been given the full information."[40] Thus, *Koch* did not require Plaintiff to prove that the patient would have decided against the procedure if properly informed.

Plaintiff has asked this Court to "adopt" the holding in *Koch*.[41] However, *Koch* only briefly analyzed any causation requirements of the Informed Consent Statute. Moreover, *Koch* relied on *Moore v. Fan,* a case that this Court finds inapposite.[42] *Koch* did examine the statutory language of the Informed Consent Statute, but did not cite any of the cases or secondary authority used by this Court to determine that informed consent is a negligence-based claim with a concomitant requirement that a patient would have declined the medical procedure if properly informed.

Although this Court recognizes the importance of *stare decisis*, which holds "when a point has been once settled by decision it forms a precedent which is not afterwards to be departed from or lightly overruled or set aside[,]"[43] this Court declines to follow *Koch*,[44] and finds both

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[40] *Id.* at 7.
[41] Pl. Op. Br. at 1.
[42] *Moore* denied Plaintiff's motion for a new trial based on an allegedly "defective" jury verdict. *Moore* ultimately held that Superior Court Pattern Jury Instruction § 7.2A was appropriate to instruct the jury (and the verdict form submitted to the jury was legally accurate based on the instruction), but *Moore* did not discuss what the jury instruction meant by "proximate cause." *Moore v. Fan*, 2004 WL 2914318 (Del. Super.).
[43] *Stenta v. General Motors Corp.*, 2009 WL 1509299, at * 8 (Del. Super.) (citing *Oscar George, Inc. v. Potts,* 115 A.2d 479, 481 (Del.1955)).

Kocher and the bench ruling in *Bello* (insofar as it relates to causation) more persuasive.

b. A Requirement of this Proximate Causation is Consistent with the Law of Other Jurisdictions

Requiring Plaintiff to prove that she would have decided against the medical procedure if properly informed of the risks is consistent with the approach taken by many jurisdictions in negligence claims based on a lack of informed consent.[45] According to Dobbs:

> the shift to negligence theory [from a battery theory] meant that the plaintiff would be required to prove five things: (1) nondisclosure of the required information; (2) actual damage such as loss of a leg; (3) resulting from the risks of which the patient was not informed; (4) cause in fact, which is to say that the plaintiff would have rejected the medical treatment if she had known the risk; and (5) that reasonable persons, if properly informed, would have rejected the proposed treatment.[46]

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[44] Defendant has advised the Court that "[t]his holding in *Koch* was on appeal to the Delaware Supreme Court, C.A. No. 354, 2008 (Del. 2008), was briefed by the parties (including an amicus curiae brief by the Delaware Medical Society), and went as far as oral argument, but the appeal was withdrawn before this challenged issue was decided by the Delaware Supreme Court." Def. Op. Br. at n. 2.

[45] *Wagner v. Georgetown Univ. Med. Ctr.*, 768 A.2d 546, 561 (D.C. 2001) (holding that "[a] causal connection exists when, but only when, disclosure of significant risks incidental to treatment would have resulted in a decision against it.") (citing *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972)); *Kenny v. Wepman*, 753 A.2d 924, 926 (R.I. 2000) (holding that a patient must prove that "if he or she had been informed of the material risks and alternative methods of treatment, he or she would not have consented to the procedure."); *Harnish v. Children's Hosp. Med. Ctr.*, 439 N.E.2d 240, 244 (Mass. 1982) ("At trial, the plaintiff must also show that had the proper information been provided neither he nor a reasonable person in similar circumstances would have undergone the procedure.").

[46] 1 Dan B. Dobbs, The Law of Torts 654 (2001) (citations omitted); The requirements for an informed consent claim stated in American Jurisprudence are similar to those set forth in Dobbs. American Jurisprudence states that a plaintiff must prove: "(1) that the physician owed a duty to disclose the risk; (2) that the physician breached duty; (3) that the patient suffered an injury; (4) that the physician's breach of the duty to disclose was the proximate cause of the injury." 61 Am. Jur. 2d *Physicians, Surgeons, etc.* § 153

Many courts of other jurisdictions analyzing the proximate cause element of negligence-based informed consent actions have required a plaintiff to "demonstrate that a reasonable person knowing of the risk would not have consented to the treatment, and that the undisclosed risk actually occurred, causing harm to the patient."[47] This approach is consistent with Delaware's definition of proximate cause.[48]

c. The "Informed Consent" Superior Court Pattern Jury Instruction also does not Eliminate the Requirement of Proximate Cause to Establish that, "but for" the Negligent Act, the Injury or Death would not have Occurred

Despite Plaintiff's assertion that "causation" was not included by the General Assembly in the Informed Consent Statute, this Court, by this ruling, is not "engrafting" an additional element onto the Informed Consent

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(2004) (citing *Phelps v. Dempsey*, 656 So. 2d 377 (Ala. 1995); *Natanson v. Kline*, 354 P.2d 670 (Kan. 1960)).

[47] 61 Am. Jur. 2d *Physicians, Surgeons, etc*. § 183 (2004); *see also Canesi ex rel. Canesi v. Wilson*, 730 A.2d 805, 813 (N.J. 1999) (holding that a "plaintiff must prove not only that a reasonably prudent patient in her position, if apprised of all material risks, would have elected a different course of treatment or care . . . and that the undisclosed risk actually materialized and that it was medically caused by the treatment."); *K.A.C. v. Benson*, 527 N.W.2d 553, 561 (Minn. 1995) ("To prevail on a claim for negligent nondisclosure plaintiff must demonstrate that a reasonable person knowing of the risk would not have consented to treatment, and that the undisclosed risk actually materialized in harm.").

[48] This approach is inconsistent with informed consent in Pennsylvania, a state whose law Plaintiff uses to support her position. Despite Plaintiff's assertion that Pennsylvania law is persuasive, Pennsylvania has adopted a battery theory of informed consent. *Fitzpatrick v. Natter*, 961 A.2d 1229, 1242 n. 13 (Pa. 2008) ("An informed consent action . . . [in Pennsylvania] sounds in battery rather than in negligence."). This is opposed to Delaware's Informed Consent Statute, which is based on negligence.

Statute not intended by the General Assembly because Plaintiff is required to prove a cause of action based on negligence, an element of which is causation.

Although Plaintiff is correct that the Informed Consent Statute does not explicitly set forth a requirement of proximate cause, *Patten*, among other cases, nevertheless has held that showing proximate cause is necessary.[49] Moreover, Superior Court Pattern Jury Instruction § 7.2A ("Informed Consent") has specifically adopted a requirement of proximate cause (although not making clear what was meant by that requirement).[50]

Plaintiff makes the good point that this Court should follow Superior Court Pattern Jury Instruction § 7.2A ("Informed Consent") because that jury instruction, in existence and used for many years, does not explicitly state that a claimant must show that the claimant would not have undergone the medical procedure if properly informed of the risks. Superior Court Pattern Jury Instruction § 7.2A ("Informed Consent") does contain the element of "proximate cause" which states: "(3) that [the patient] has suffered injury as a proximate result of the procedure."[51] Plaintiff argues that the needed proximate causation is shown if the

[49] *Patten*, 1989 WL 64116, at * 3.
[50] Del. P.J.I Civ. § 7.2A (2000)
[51] *Id.*

claimant is injured or died as a result of a medical procedure about which the claimant was not properly informed.

However, the pattern jury instruction does not give clear guidance as to what Plaintiff must prove to establish the element of proximate cause. This Court will utilize Defendant's proffered proximate cause instruction in its Informed Consent jury instruction to clarify the proximate cause requirement discussed *supra*.

d. Summary

As one court has stated: "[t]he very purpose of the disclosure rule is to protect the patient against consequences which, if known, he would have avoided by forgoing the treatment."[52] One commentator has suggested that:

> [i]f causation were conclusively presumed, patients with unfortunate medical outcomes would be able to recover damages for the harm resulting from those outcomes each and every time the doctor failed to disclose material information, even though the outcome followed a procedure that was reasonably recommended and reasonably performed."[53]

Notably, in the instant case, Plaintiff does not contend that the bronchoscopy was not "reasonably recommended and reasonably performed."

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[52] *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972).
[53] Aaron D. Twerski & Neil B. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. Ill. L. Rev. 607, 645 (1998).

This Court holds that the requirement of "proximate cause" in an Informed Consent action requires that Plaintiff must prove the causal connection by proving by a preponderance of the evidence that "that a reasonably prudent patient would have declined to undergo the procedure if [that reasonably prudent patient] had known the risks."[54]

B. Objective or Subjective Standard

Having held that Plaintiff must prove "causation" under the Informed Consent Statute in that Plaintiff must prove by a preponderance of the evidence that Decedent would have decided against undergoing the bronchoscopy if properly informed of the risks of that procedure, the Court must now decide whether the law requires Plaintiff to prove that a hypothetical "reasonable patient" would have in fact decided differently (the "objective standard") or whether this particular patient, Muriel Stewart, would have, herself, decided differently (the "subjective standard").

This Court agrees with the observation of numerous cases from other jurisdictions and from secondary authorities that "[t]he majority rule on causation [in informed consent cases] asks whether a reasonable person would have consented to the proposed treatment had he or she been

[54] Def. Proposed Jury Ins.

informed of the attendant risks."[55] "The objective test focuses on what the attitudes and actions of the reasonable person in the position of the patient would have been rather than on what the attitudes and actions of the particular patient of the litigation actually were."[56]

The seminal and oft-cited case addressing the issue of whether to apply the objective or subjective standard to an informed consent claim is the 1972 case of *Canterbury v. Spence* decided by the United States Court of Appeals for the District of Columbia. In *Canterbury*, the court rejected the subjective standard, stating that:

> [the subjective standard] places the physician in jeopardy of the patient's hindsight and bitterness. It places the factfinder in the position of deciding whether a speculative answer to a hypothetical question is to be credited. It calls for a subjective determination solely on testimony of a patient-witness shadowed by the occurrence of the undisclosed risk.[57]

Canterbury held that the objective standard is more appropriate for a claim based on informed consent. *Canterbury* further held:

> Better it is, we believe, to resolve the causality issue on an objective basis: in terms of what a prudent person in the patient's position would have decided if suitably informed of all perils bearing significance. If adequate disclosure could reasonably be expected to have caused that person to

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[55] Samuel Oddi, *Reverse Informed Consent: The Unreasonably Dangerous Patient*, 46 Vand. L. Rev. 1417, 1428 (1993); *see Schreiber v. Physicians Ins. Co. of Wis.*, 588 N.W.2d 26, 33 (Wis. 1999) (holding that "this court has agreed with the majority of American jurisdictions in employing what is known as the 'objective test.'"); *Aronson v. Harriman*, 901 S.W.2d 832, 841 (Ark. 1995) (holding that the objective test is the majority rule).

[56] *Schreiber*, 588 N.W.2d at 33.

[57] *Canterbury*, 464 F.2d at 790-91.

> decline the treatment because of the revelation of the kind of risk or danger that resulted in harm, causation is shown, but otherwise not. The patient's testimony is relevant on that score of course but it would not threaten to dominate the findings. And since that testimony would probably be appraised congruently with the factfinder's belief in its reasonableness, the case for a wholly objective standard for passing on causation is strengthened. Such a standard would in any event ease the fact-finding process and better assure the truth as its product.[58]

Although the objective standard is the majority rule, at least two jurisdictions apply the subjective standard.[59] In *Scott v. Bradford*, the Oklahoma Supreme Court noted that "[a]lthough the Canterbury rule is probably that of the majority, its "reasonable man" approach has been criticized by some commentators as backtracking on its own theory of self-determination."[60] *Scott* held:

> To the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient's right of self-determination is [i]rrevocably lost. This basic right to know and decide is the reason for the full-disclosure rule. Accordingly, we decline to jeopardize this right by the imposition of the "reasonable man" standard.[61]

However, at least two Delaware cases have indirectly addressed the issue of whether Delaware follows the objective or subjective standard in an informed consent claim. In *Patten*, the Delaware Superior Court held

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[58] *Id.* at 791 (citations omitted).
[59] Peter H. Schuck, *Rethinking Informed Consent*, 103 Yale L.J. 899, 919 (1994) (citing Oklahoma and Oregon as jurisdictions that apply the subjective standard).
[60] *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1980) (citing Seidelson, Medical Malpractice: Informed Consent Cases in "Full-Disclosure" Jurisdictions, 14 Duq. L. Rev. 309 (1976); Katz, Informed Consent A Fairy Tale? Laws Vision, 39 U. Pitt. L. Rev. 137 (1977)).
[61] *Id.*

that "a plaintiff must show that a negligent act by the defendant proximately caused an injury to the plaintiff."[62] *Patten* cited with approval *Largey v. Rothman,* a New Jersey case addressing whether proximate cause must be shown by application of an objective standard. Notably, *Largey* elected to use the objective standard and held that "[u]nder the "prudent patient" standard 'causation must also be shown: *i.e.,* that the prudent person in the patient's position would have decided differently if adequately informed.'"[63] Additionally, the *Kocher* Court expressly stated that "[a]n element of [informed consent] is that a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of material facts relating to the treatment."[64]

This Court holds that the objective standard, endorsed by most jurisdictions that have considered the issue, is the appropriate standard on which to instruct the jury as to the causation element of an informed consent claim.[65] The objective standard is fair to both patients and health care providers. As one secondary authority has observed:

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[62] *Patten*, 1989 WL 64116, at *3.
[63] *Largey v. Rothman*, 540 A.2d 504, 510 (N.J. 1988) (citing *Perna v. Pirozzi*, 457 A.2d 431 (N.J. 1983) and *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972)).
[64] *Kocher*, 1990 WL 127823, at * 2.
[65] Although the bench ruling in *Bello v. Ikeda* stated that the court would follow an objective standard regarding causation. The jury instruction that was ultimately approved, for reasons not clear from the record, applied a subjective standard. The approved jury instruction stated:

> 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 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. Some courts, nonetheless, recognize such a causality standard.
>
> The great preponderance of jurisdictions follow[] the 'reasonable person' standard of causality, which is perceived as a much more fair standard to both plaintiffs and defendants. This standard is based on what a reasonable person in the patient's position would have done had risk information been disclosed. What a reasonable person would agree to depends in large measure on the facts and surrounding circumstances of an individual case. The standard reflects the view that obtaining consent must be accomplished on a case-by-case basis, taking into account the peculiar needs and concerns of each patient.[66]

The objective standard recognizes that "the patient's hindsight testimony as to what [s]he would have hypothetically done, though relevant, is not determinative of the issue."[67] The objective standard allows a jury to consider other relevant evidence outside of the credibility

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> To prevail on this claim, plaintiffs must prove by a preponderance of the evidence: . . .
> (3) that Ms. Bello would have declined to undergo the procedure if she had known the risks and alternative . . .

Bello v. Ikeda C.A. No. 06C-02-266, at 6 (Bench Ruling).

[66] F. Rozovsky, *Consent to Treatment,* § 1.13.4, "Causation in Negligent Consent" 62-63 (1984).

[67] *Sard v. Hardy*, 379 A.2d 1014, 1025 (Md. 1977).

of a patient's testimony.[68] The jury may consider factors such as the patient's "medical condition, age, risk factors, etc. . . ."[69] to come to a determination of whether a reasonable person in the decedent's condition would have undergone the medical treatment.

Plaintiff argues that "[a]ll the cases cited by the defendant involve jurisdictions in which informed consent claims arise from the common law or have adopted statutes that expressly impose the 'decided differently' requirement."[70] Even though Plaintiff may be correct insofar as some other state statutes have explicitly adopted a "decided differently" requirement, cases from those jurisdictions are otherwise helpful in analyzing Delaware's own causation requirement because Delaware's law, much like the law of other states, is based on negligence.

This Court holds that Plaintiff must prove that a reasonable patient in the position of Decedent, Muriel Stewart, would have "decided differently" if properly informed of the risks of the bronchoscopy.

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[68] *Scaria v. St. Paul Fire & Marine Ins. Co.*, 227 N.W.2d 647, 654 (Wis. 1975) (stating that "[the subjective standard] ties the factual conclusion on causation simply to the assessment of the patient's credibility . . .").

[69] *Backlund v. Univ. of Wash.*, 975 P.2d 950, 959 (Wash. 1999).

[70] Pl. Letter Memo at n. 1.

V. CONCLUSION

For all the reasons stated above, Plaintiff's motion in limine **DENIED**.

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Richard R. Cooch

oc: Prothonotary