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Marc D. Ginsberg The John Marshall Law School (Chicago)

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INFORMED CONSENT: NO LONGER JUST WHAT THE DOCTOR ORDERED? REVISITED

Marc D. Ginsberg*

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ABSTRACT

The law of informed consent in medicine has evolved from the original doctrine which required the physician's disclosure of the risks, benefits, and complications of (and alternatives to) a proposed procedure or treatment. The doctrine now implicates the disclosure of matters personal to the physician. Questions regarding the breadth of the doctrine in other respects have developed as well. This paper represents the author's second examination of the unconventional aspects of the law of informed consent.

I. INTRODUCTION

Several years ago, I authored what I intended as a comprehensive paper on the "unconventional" aspects of informed consent, largely focusing on matters more personal to the "disclosing" physician.¹ Since that time, other authors have commented on these matters.² As the law of informed consent has developed, courts have recently considered different informed consent issues unrelated to the typical required disclosure. In light of these decisions, I have concluded that it is time to revisit the unconventional and other selected topics of informed consent.

II. A DISCLOSURE DOCTRINE

At the outset, it should be noted, medicine and law have conflicting opinions about the gist of informed consent. I have written "that medicine views informed consent as a communicative process with patient

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^{1.} Marc D. Ginsberg, Informed Consent: No Longer Just What the Doctor Ordered? The "Contributions" of Medical Associations and Courts to a More Patient Friendly Doctrine, 15 MICH. ST. J. MED. & L. 17 (2010).

^{2.} See, e.g., Nadia N. Sawicki, Modernizing Informed Consent: Expanding the Boundaries of Materiality, 2016 U. ILL. L. REV. 821 (2016); Samuel D. Hodge, Jr. et al., Must Physicians Disclose an Alcohol or Substance Abuse Problem when Requesting a Patient Sign an Informed Consent Document? 91 N.D. L. REV. 309 (2015).

involvement."³ The law of informed consent largely recognizes consent as a disclosure doctrine; the best evidence of which is the well-known *Canterbury v. Spence*, footnote 36:⁴

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We discard the thought that the patient should ask for information before the physician is required to disclose. Caveat emptor is not the norm for the consumer of medical services. Duty to disclose is more than a call to speak merely on the patient's request, or merely to answer the patient's questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision. The patient may be ignorant, confused, overawed by the physician or frightened by the hospital, or even ashamed to inquire. Perhaps relatively few patients could in any event identify the relevant questions in the absence of prior explanation by the physician. Physicians and hospitals have patients of widely divergent socio-economic backgrounds, and a rule which presumes a degree of sophistication which many members of society lack is likely to breed gross inequities.⁵

The distinction between the medical and legal models of informed consent is significant. For example, if a patient is involved in a conversation with a physician about a proposed procedure or treatment and asks the physician for information which the physician misrepresents, the patient may have a misrepresentation claim, not an informed consent claim.⁶ However, a physician's failure to make a required disclosure yields an informed consent claim.

III. INFORMED CONSENT—MYTH OR REALITY?

Before navigating the boundaries of informed consent, I should confess my concern that true informed consent is a fiction. While I have previously written on this topic,⁷ I am certainly not a pioneer in this area. Informed consent has been explored and subjected to legal and medical

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^{3.} Marc D. Ginsberg, Beyond Canterbury: Can Medicine and Law Agree About Informed Consent? And Does it Matter?, 45 J. L. MED. & ETHICS 106, 108 (2017) (citing Christine Grady, Enduring and Emerging Challenges of Informed Consent, 372 NEW ENG. J. MED. 855, 856 (2015)). See also Charles G. Kels, Liability for Medical Battery in the Military Health System, 179 MIL. MED. 1, 1 (2014) ("[T]he doctrine of informed consent generally requires discussion.").

^{4.} Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972). *But see* Shinal v. Toms, 162 A.3d 429 (Pa. 2017) (recognizing informed consent as a dialogue).

^{5.} Canterbury, 464 F.2d at 783 n.36 (citations omitted).

^{6.} See Duffy v. Flagg, 905 A.2d 15, 23 (Conn. 2006). But see Willis v. Bender, 596 F.3d 1244, 1260 (10th Cir. 2010) (predicting that "the Wyoming Supreme Court would allow an informed consent claim where a physician lies to a patent as to physician-specific information in direct response to a patient's questions concerning the same in the course of obtaining the patient's consent and the questions seek concrete verifiable facts." (emphasis omitted)).

^{7.} Ginsberg, *supra* note 1.

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scholarship for quite some time.⁸ My point is that a patient's time with a physician is brief;⁹ the general literacy rate in the United States is not particularly impressive;¹⁰ the health literacy rate is lower yet;¹¹ and many patients prefer not to participate in the healthcare decision-making.¹² These facts redirect the physician-patient relationship to medical paternalism, the first target of the law of informed consent. My skepticism aside, informed consent is an important and developing constituent of medical-legal jurisprudence. These developments merit scrutiny and the remainder of this paper focuses on these topics.

IV. THE NATURE OF THE INFORMED CONSENT CLAIM

A. Informed Consent vs. Medical Battery

It is difficult to imagine that 60 years have passed from what is believed to be the first reported informed consent judicial opinion.¹³ Since that holding, courts are required to explain the distinction between claims sounding in medical battery and claims in informed consent. For example, battery is an intentional tort.¹⁴ Medical battery occurs when a patient receives unauthorized, unconsented treatment.¹⁵ In contrast, an informed consent claim arises when a physician fails to properly disclose information to a patient that consented to treatment.¹⁶

*Lounsbury v. Capel*¹⁷ is a classic medical battery case. Lounsbury, a construction worker, sustained a work related "compression fracture to one of the vertebrae in his back."¹⁸ A treating physician opined that

13. Salgo v. Leland Stanford Jr. Univ. Bd. of Trs., 317 P.2d 170 (Cal. Ct. App. 1957).

^{8.} See, e.g., Jay Katz, Informed Consent – Must it Remain a Fairy Tale?, 10 J. CONTEMP. HEALTH L. & POL'Y 69 (1994); Kenneth Boyd, The Impossibility of Informed Consent?, 41 J. MED. ETHICS 44 (2015).

^{9.} See Donna R. Rhoades et al., Speaking and Interruptions During Primary Care Office Visits, 33 FAM. MED. 528, 531 (2001).

^{10.} See U.S. DEP'T OF EDUC., ADULT LITERACY IN AMERICA – A FIRST LOOK AT THE FINDINGS OF THE NATIONAL ADULT LITERACY SURVEY, at xvi (2002).

^{11.} See Xuewei Chen et al., Blending Health Literacy with an English as a Second Language Curriculum: A Systematic Literature Review, 20 J. HEALTH COMM. 101, 101 (2015).

^{12.} Wendy Levinson et al., Not All Patients Want to Participate In Decision Making, 20 J. GEN. INTERNAL MED. 531, 533 (2005).

^{14.} DAN B. DOBBS, THE LAW OF TORTS 52-53 (2000).

^{15.} BARRY R. FURROW ET AL., HEALTH LAW 121 (3rd ed. 2015).

^{16.} See, e.g., Blanchard v. Kellum, 975 S.W.2d 522, 524 (Tenn. 1998) (discussing unauthorized dental extractions as a battery claim).

^{17. 836} P.2d 188 (Utah Ct. App. 1992).

^{18.} *Id.* at 189. For an excellent discussion of vertebral compression fractures, see Daniela Alexandru & William So, *Evaluation and Management of Vertebral Compression Fractures*, 16 PERMANENTE J. 46 (2012); Am. Ass'n. Neurological Surgeons, *Vertebral Compression Fracture*, http://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Vertebral-Compression-

Lounsbury suffered "a herniated disc which was impinging on Lounsbury's nerves and causing him pain."¹⁹ His doctor suggested surgery but Lounsbury desired a second opinion, resulting in a referral to the defendant, Dr. Capel.

The opinion of the Utah Court of Appeals reveals that Lounsbury twice refused to consent to surgery as he had not been advised of the results of a pre-operative myelogram²⁰ and desired to speak with the surgeon preoperatively. Apparently, Dr. Capel coerced Lounsbury's wife to consent for him while he was unconscious. "She assumed that [her husband] had talked to Dr. Capel and had agreed to the surgery following review of the myelogram."²¹

Lounsbury commenced a lawsuit for civil battery against Dr. Capel. The trial court incorrectly concluded that Utah's informed consent statute governed Lounsbury's claim against Dr. Capel for failure to obtain informed consent.²²The trial court also stated Lounsbury could not establish the requisite elements of the claim²³ and entered Judgment against Dr. Capel.

On appeal, the court of appeals noted the difference between informed consent and battery claims.²⁴ The court of appeals importantly stated:

It appears well settled that the battery theory remains applicable where a medical treatment or procedure is completely unauthorized. . . . [W]e find nothing in case law or secondary sources to suggest that the doctrine of informed consent has displaced the common law remedy of battery in cases of *no* consent.²⁵

The court of appeals held that Lounsbury had a viable medical battery

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Fractures [https://perma.cc/TQQ8-AEXG] ("VCFs occur when the bony block or vertebral body in the spine collapses, which can lead to severe pain, deformity and loss of height.").

^{19.} Lounsbury, 836 P.2d at 189.

^{20.} *Id.* at 190. "A myelogram is a diagnostic imaging procedure done by a radiologist. It was a contrast dye and X-rays or computed tomography (CT) to look for problems in the spinal canal." *Myelogram*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/healthlibrary/test_procedures/neurological/myelogram_92,P07670 [https://perma.cc/4Y53-4SU8]; *See also* K. Lindblom, *Technique and Results in Myelography and Disc Puncture*, 34 ACTA RADIOLOGICA 321 (1950); Christop Ozdoba et al., *Myelography in the Age of MRI: Why We Do It and How We Do It*, 2011 RADIOLOGY RES. & PRAC. 1 (2011).

^{21.} Lounsbury, 836 P.2d at 190.

^{22.} Id. at 191 (citing Utah Code Ann. § 78-14-5(1) (1987)) (containing the elements of an informed consent claim).

^{23.} *Lounsbury*, 836 P.2d at 191-92. The trial court also concluded that Lounsbury's wife had effectively consented for him and this consent constituted an "absolute defense" to the claim. *Id.* at 192.

^{24.} Id.

^{25.} Id. at 193-94.

claim. Thus, the trial court's judgment in favor of Dr. Capel was reversed and remanded for further proceedings.²⁶

Despite the seemingly clear distinction between medical battery and informed consent claims, the distinction needs to be clearer to courts and counsel representing medical negligence claimants. Courts of last resort have recently been required to re-educate counsel about the distinction.²⁷ Therefore, a battery claim involving a patient's consent to surgical procedure—allegedly performed incorrectly on the patient—implicated medical negligence, not battery,²⁸ and an alleged failure to inform a patient of all risks of a consented-to surgical procedure is, similarly, not a battery.²⁹

B. Misrepresentation vs. Informed Consent

Assume that during a physician's typical informed consent disclosure, the patient interrupts to inquire of the physician's experience or credentials. In response to the patient's inquiry, the physician knowingly provides false information to the patient. Will the physician's misrepresentation provide the predicate for an informed consent claim?

Not surprisingly, there is no consensus answer to this question. Fraudulent misrepresentation claims commonly do not involve personal injuries,³⁰ yet an action sounding in fraud under this factual scenario has been endorsed.³¹

In 2001, the Supreme Court of Pennsylvania held that a physician's misrepresentation of his surgical experience "in response to a specific question posed by [a patient]"³² did not yield an informed consent claim but instead a claim for misrepresentation.³³ The court took the position that "information personal to the physician, whether solicited by the patient or not, is irrelevant to the doctrine of informed consent"³⁴ and stated "that the doctrine of informed consent is not the legal panacea for

^{26.} Id. at 199.

^{27.} See Mayr v. Osborne, 795 S.E.2d 731 (Va. 2017); White v. Beeks, 469 S.W.3d 517 (Tenn. 2015); Humboldt Gen. Hosp. v. Sixth Jud. Dist. Ct., 376 P.3d 167 (Nev. 2016).

^{28.} Mayr, 795 S.E.2d at 731.

^{29.} White, 469 S.W.3d at 517.

^{30.} See Laura Barke, When What You Don't Know Can Hurt You: Third Party Liability for Fraudulent Misrepresentation in Non-Commercial Settings After Doe v. Dilling, 888 N.E.2d 24 (III. 2008), 34 S. ILL. U. L. J. 201, 203 (2009).

^{31.} Heyward H. Bouknight, III, Between the Scalpel and the Lie: Comparing Theories of Physician Accountability for Misrepresentations of Experience and Competence, 60 WASH. & LEE L. REV. 1515, 1553 (2003).

^{32.} Duttry v. Patterson, 771 A.2d 1255, 1258 (Pa. 2001).

^{33.} Id. at 1259.

^{34.} Id.

all damages arising out of any type of malfeasance by a physician."35

In 2002, the Supreme Court of New Jersey held that a physician's misrepresentation of his credentials as a board certified physician in response to a specific inquiry (by the patient's wife) would not support a fraud claim, but would support an informed consent claim.³⁶ The court emphasized that the "misrepresented or exaggerated physician experience would have to significantly increase a risk of a procedure in order for it to affect the judgment of a reasonably prudent patient in an informed consent case."³⁷

The United States Court of Appeals, Tenth Circuit weighed in on this topic in *Willis v. Bender.*³⁸ In *Willis*, a patient sued a general surgeon for medical negligence as he allegedly perforated the patient's small bowel during a laparoscopic gallbladder removal.³⁹ During the meeting in which the patient's history was taken and surgical options were discussed, the patient:

asked Bender about his experience and track record with the laparoscopic procedure, whether he had ever been sued and whether he had ever had any problems with his medical license. Bender told [the patient] he had never been sued, never had any problems with his medical license and his success rate with the laparoscopic procedure was "99.9% right on the mark."⁴⁰

Postoperatively, the patient learned that her surgeon provided her false information about prior lawsuits filed against him. He "had in fact been sued several times, including by a family of a patient who had died after undergoing a laparoscopic cholecystectomy performed by Bender in 2001."⁴¹ Essentially, this case focused on the issue of whether a physician may lie to a patient "and then use that false information to secure a patient's consent."⁴²

The court of appeals noted that the medical negligence claim was based on diversity jurisdiction. Therefore, the informed consent issue must be resolved pursuant to Wyoming law and the court "must attempt

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^{35.} Id.

^{36.} Howard v. Univ. of Med. & Dentistry, 800 A.2d 73, 85-86 (N.J. 2002).

^{37.} Id. at 85.

^{38. 596} F.3d 1244 (10th Cir. 2010).

^{39.} This surgical procedural complication is reported in the medical literature and is thought to occur rarely. *See* Jay T. Bishoff et al., *Laparoscopic Bowel Injury: Incidence and Clinical Presentation*, 161 J. UROLOGY 887, 888 (1999); Ikennah L. Browne & Elijah Dixon, *Delayed Jejunal Perforation After Laparoscopic Cholecystectomy*, 2 J. SURG. CASE REP. 1 (2016).

^{40.} Willis, 596 F.3d at 1247 (citation omitted).

^{41.} Id. at 1248.

^{42.} Id. at 1249-50.

to predict how the Wyoming Supreme Court would resolve the issue."43 In examining the Wyoming law of informed consent, the court of appeals identified Wyoming's professional model of the doctrine, requiring a physician "to disclose only such risks that a reasonable practitioner of like training would have disclosed in the same or similar circumstances."44 Wyoming law permitted an informed consent claim to be based on a misrepresentation of the risks of treatment,⁴⁵ but the court of appeals identified a split of authority on the issue of whether a physician "had a duty to truthfully answer... physician specific questions."46 After reviewing available authority from other jurisdictions, the court of appeals predicted that the Wyoming Supreme Court would recognize an informed consent claim because the defendant-physician's "alleged misrepresentations to [Plaintiff] in response to her direct questions allegedly induced her to consent to the surgery and its risks."47 The misrepresentations must be in response to "questions seek[ing] concrete verifiable facts, not the doctor's subjective opinion or judgment as to the quality of his performance or abilities."48

Is the distinction between an informed consent claim based on a negligent non-disclosure and one based on a fraudulent misrepresentation an irrelevant difference? Certainly, a court could simply pronounce that all material non-disclosures and misrepresentations, whether or not responding to patient inquiries, will provide the predicate for an informed consent claim. It should be remembered that classic fraudulent misrepresentation claims do not require the establishment of a professional standard of care and the use of expert witnesses. Therefore, when analyzing an informed consent claim a court should consider the physician's disclosure to the patient, whether or not the patient inquires of the physician. This type of analysis eliminates the problem of having to expand the doctrine to include the subject matter of the patient's inquiry; inquiries typically not covered by the doctrine—physician specific, personal information.

C. Free Standing Informed Consent Claim—Is A Predicate Tortious

^{43.} Id. at 1254.

^{44.} *Id. See also* Ryan Childers et al., *Informed Consent and the Surgeon*, 208 J. AM. C. SURGEONS 627, 629 (2009) (explaining the basic difference between the professional and reasonable patient standard models).

^{45.} Willis, 596 F.3d at 1255.

^{46.} Id. at 1256.

^{47.} Id. at 1258.

^{48.} Id. at 1260.

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Injury Required?

It is well understood that:

Causation is established in an informed consent case if the plaintiff can prove a link between the failure of a doctor to disclose and the patient's injury—first that the risk not disclosed in fact materialized, and second, that a patient would have declined treatment if he had received full information about that risk.⁴⁹

Nevertheless, recently, the United States Court of Appeals, Eleventh Circuit, in *Looney v. Moore*,⁵⁰ addressed an informed consent claim without evidence of an injury.

Looney involved claims arising from a "national clinical research trial . . . created to analyze the effects of differing oxygen saturation levels on premature infants."⁵¹ The University of Alabama, Birmingham held the trial. Plaintiffs, the research trial participants, claimed "that they suffered serious injuries as a result of their participation in the study."⁵² Their claims, including lack of informed consent, were filed in a federal court in Alabama. The defendants successfully moved for summary judgment,⁵³ urging "that Plaintiffs had failed to prove that their injuries were caused by participation in the . . . study, as opposed to being a consequence of their premature births."⁵⁴

On appeal, the court of appeals framed the free-standing informed consent claim as follows:

As far as we can tell, however, Alabama law has yet to explicitly address the question whether proof of a medical injury is also required before a plaintiff can claim that his consent to a medical procedure was not informed. Specifically, if a plaintiff cannot prove that he suffered any injury as a result of a particular medical procedure, can he still potentially prevail if he shows that the doctor failed to obtain his informed consent to that procedure? In other words, is there a freestanding tort arising from a lack of informed consent, even if there is no injury resulting from the procedure at issue?⁵⁵

The court of appeals certified the case to the Alabama Supreme Court for guidance insofar as "Alabama law . . . does not expressly tell us whether such an informed consent claim is subject to the same requirements as a

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^{49.} FURROW ET AL., supra note 15, at 139.

^{50. 861} F.3d 1303 (11th Cir. 2017).

^{51.} Id. at 1306.

^{52.} Id. at 1307.

^{53.} FED R. CIV. P. 56.

^{54.} Looney, 861 F.3d at 1307.

^{55.} Id. at 1309.

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malpractice or negligence claim, nor does it speak to what the elements of such a claim would be if the claim finds no home in the malpractice/negligence camp."⁵⁶ The court of appeals looked to inconsistencies in Alabama law as well as the law of other jurisdictions in concluding that Alabama law was unsettled.

The following question was, therefore, certified to the Alabama Supreme Court:

Must a patient whose particular medical treatment is dictated by the parameters of a clinical study, and who has not received adequate warnings of the risks of that particular protocol, prove that an injury actually resulted from the medical treatment in order to succeed on a claim that his consent to the procedure was not informed?⁵⁷

The court of appeals noted the certified question should be limited to treatment in the context of a clinical study. The court of appeals may have hoped that the Alabama Supreme Court, in answering the question, would generally clarify Alabama's law of informed consent. Regrettably, on September 7, 2017, the Supreme Court of Alabama issued an order "declin[ing] to answer the certified question."⁵⁸

V. TO DISCLOSE OR NOT TO DISCLOSE

A. The Uninsured Physician

Physicians are consumers of professional liability insurance.⁵⁹ As with other liability insurance coverage, medical malpractice insurance carries "the virtue[s] of spreading the risk of loss among many to make it possible for the individual to bear the economic burden of adversity."⁶⁰ In addition to having to provide financial protection against potentially successful medical negligence claims,⁶¹ physicians may also be required to demonstrate evidence of professional liability coverage as a condition of obtaining hospital staff privileges.⁶² Thus, obtaining professional

^{56.} Id.

^{57.} Id. at 1314.

^{58.} Lewis v. Moore, No. 1160893, 2017 Ala. LEXIS 149 (Ala. Sept. 7, 2017).

^{59.} See Jonathan Thomas, *The Effect of Medical Malpractice*, 19 ANNALS HEALTH L. ADVANCE DIRECTIVE 306, 311 (2010).

^{60.} Melvin M. Belli, *The Social Value of Liability Insurance*, 13 HASTINGS L.J. 169, 169 (1961).

^{61.} Anupam B. Jena et al., *Malpractice Risk According to Physician Specialty*, 365 NEW ENG. J. MED. 629 (2011).

^{62.} See Brian M. Peters & Wendy Cherner Maneval., Medical Staff Membership Criteria: A Credentialing Minefield, 5 MED. STAFF COUNSELOR 1, fn. 4 (1991); HEALTH CARE LITIGATION AND RISK MANAGEMENT ANSWER BOOK 2015 306 (David S. Greenberg & Brian D. Schneider eds., 2015);

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liability insurance is a cost of doing business.

However, not all physicians opt for professional liability insurance coverage. It has been reported that physicians who are uninsured choose this path because of the high cost of insurance in an effort to limit their potential exposure to professional liability.⁶³ The phenomenon of an uninsured physician in Florida has received great attention in legal scholarship.⁶⁴ In Florida, by virtue of a state statute,⁶⁵ "physicians who opt to 'go bare' must display a sign in their office including a recognition that they have elected not to carry medical malpractice liability insurance."⁶⁶

Should a physician have an obligation to disclose the lack of professional liability insurance coverage to a patient in order to satisfy the law of informed consent? In 2015, the Supreme Court of New Jersey considered this question in *Jarrell v. Kaul.*⁶⁷ New Jersey requires practicing physicians to have professional liability insurance coverage.⁶⁸ The plaintiff Jarrell suffered from chronic back pain.⁶⁹ In 2005, Dr. Kaul, a referral from Jarrell's chiropractor,⁷⁰ "performed a spinal fusion⁷¹ procedure at a surgical center"⁷² after Dr. Kaul "diagnosed Jarrell with a

64. Stephanie Hauser, *The Default in Florida's Tort Reform: How Bankruptcy Affects the Meaning of Financial Responsibility*, 65 U. MIAMI L. REV. 233 (2010).

- 66. Hauser, supra note 64, at 242.
- 67. 123 A.3d 1022 (N.J. 2015).
- 68. N.J. STAT. ANN. § 45:9-19.17a. (2004).

69. For an excellent discussion of chronic back pain, see Richard A. Deyo et al., *Overtreating Chronic Back Pain: Time to Back Off?*, 22 J. AM. BD. FAM. MED. 62 (2009) (noting that back pain is the most common of musculoskeletal pain complaints). *See also* Gunnar B J Andersson, *Epidemiological Features of Chronic Low-Back Pain*, 354 LANCET 581 (1999) (noting the high frequency of chronic back pain in the population).

70. "Chiropractic training focuses on the spine and emphasizes a particular therapeutic technique—spinal manipulation... Chiropractors generally believe that most back pain is caused by anatomic derangements in the spine, such as vertebral subluxations, that can be identified on a spinal radiograph and effectively treated using spinal manipulation." Daniel C. Cherkin & Frederick A. MacCornack, *Patient Evaluations of Low Back Pain Care from Family Physicians and Chiropractors*, 150 W. J. MED. 351, 354-55 (1989).

 See Stephen J. Lipson, Spinal-Fusion Surgery—Advances and Concerns, 350 N. ENG. J. MED. 643 (2004).

72. Jarrell, 123 A.3d at 1024.

Sara Rosenbaum & Marilynn Sager, Unlocking the Hospital Doors: Medical Staff Membership and Physicians Who Serve the Poor, 9 YALE L. & POL'Y REV. 46, 56 (1991) (discussing "adequate liability insurance" as a criteria for staff privileges). See also Kelly v. St. Vincent Hosp., 692 P.2d 1350 (N.M. Ct. App. 1984) (finding hospital has rational basis to require on-staff physicians to maintain professional liability insurance).

^{63.} Allen Kachalia et al., *Physician Responses to the Malpractice Crisis: From Defense to Offense*, 33 J.L. MED. & ETHICS 416 (2005).

^{65.} FLA. STAT. ANN. § 458.320 (West 2014).

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herniated lumbar disc,⁷³ lumbar radiculopathy,⁷⁴ and discogenic back pain^{75,*76} Postoperatively, Jarrell experienced worsening pain and other complications.⁷⁷ Jarrell's friend referred him to a neurosurgeon. After evaluating Jarrell, the neurosurgeon "concluded that Dr. Kaul improperly placed some screws that pinched a nerve causing the pain and drop foot."⁷⁸ The neurosurgeon performed a reparative procedure, but postoperatively, Jarrell continued to have pain and limited physical activity.⁷⁹

Jarrell and his wife brought a multi-count claim against Dr. Kaul and the surgical center where Dr. Kaul served as Medical Director.⁸⁰ Among the claims Jarrell filed, one was for lack of informed consent, urging that Dr. Kaul "knew that he was uninsured at the time he obtained Jarrell's consent to perform surgery,"⁸¹ and that Dr. Kaul should have disclosed his uninsured status to Jarrell as it "would have been significant in [Jarrell's] decision making."⁸² Dr. Kaul argued "that a physician's duty to obtain informed consent from a patient prior to undertaking medical treatment is limited to the risks associated with the treatment, not whether a patient may have a source to pay a monetary judgment in the event the physician negligently discharges his professional duties."⁸³

The New Jersey Supreme Court discussed the origin of the doctrine of informed consent, by referring to an eighteenth century English opinion.⁸⁴ The court stated, "there is reliable evidence that medical

^{73.} See Jo Jordan et al., *Herniated Lumbar Disc*, 2011 BMJ CLINICAL EVIDENCE 1118 (2011) ("Herniated lumbar disc is a displacement of the disc material... beyond the intervertebral disc space.").

^{74.} See Andrew J. Schoenfeld & Bradley K. Weiner, *Treatment of Lumbar Disc Herniation: Evidence-Based Practice*, 3 INT'L J. GEN. MED. 209, 209 (2010) ("The more treatable condition of lumbar radiculopathy . . . arises when extruded disc material contacts, or exerts pressure, on the thecal sac or lumbar nerve roots."). *See also* Stephen E. Abram, *Pain Mechanism in Lumbar Radiculopathy*, 67 ANESTHESIA & ANALGESIA 1135 (1988).

^{75. &}quot;Discogenic low back pain is non-radicular and occurs in the absence of spinal deformity, instability and signs of neural tension. It arises from the disc itself and the mechanism of its production is uncertain." B. Peng et al., *The Pathogenesis of Discogenic Low Back Pain*, 87 J. BONE & JOINT SURGERY 62, 62 (2005); Sohail K. Mizra et al., *One-Year Outcomes of Surgical Versus Non-Surgical Treatments for Discogenic Back Pain: A Community-Based Prospective Cohort Study*, 13 SPINE J. 1421 (2013).

^{76.} Jarrell, 123 A.3d at 1025.

^{77.} Id.

^{78.} Id.

^{79.} Id.

^{80.} Id.

^{81.} *Id.* at 1031.

^{82.} Id.

^{83.} *Id.* at 1032.

^{84.} Id. (citing Slater v. Baker & Stapleton, 95 Eng. Rep. 860 (KB 1767)).

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informed consent dates back to ancient times."⁸⁵ Furthermore, after noting that the doctrine contemplates "a disclosure of the risks associated with the recommended procedure and alternative procedures or therapies;"⁸⁶ the court concluded that the disclosure of "whether [a physician] maintains medical malpractice liability insurance, . . . is . . . 'not a perfect fit' with our informed consent jurisprudence."⁸⁷ The court noted that a physician's lack of professional liability insurance does not necessarily derive from the physician's lack of skill.⁸⁸ However, they did not address the issue of whether an uninsured physician is more or less likely to practice medicine carefully. Accordingly, the court decided that a financial loss sustained by a patient "is not the injury that the informed consent doctrine ever contemplated."⁸⁹

The dissenting/concurring opinion clearly tethers the defendantphysician's financial insecurity to his competence (incompetence),⁹⁰ and referred to the case facts as "present[ing] the quintessential case of lack of informed consent."⁹¹ Without any citation to authority, the dissent/concurrence further states:

A patient has a right to know whether a physician performing a procedure is in a financially responsible position in the event that the patient suffers injuries due to medical malpractice. A reasonable patient would consider a physician's lack of insurance a material factor in making a decision whether to have spinal surgery. That is so because an uninsured physician provides no financial safety net for a patient who is harmed by the physician. Lack of insurance also may suggest that the carrier considered the physician incompetent to perform the procedure.⁹²

Neither the majority nor dissenting/concurring opinions address the actual risk of the uninsured physician. Is this physician more likely to be careful and avoid mistakes due to the possibility of personal, uninsured liability? Or is the uninsured physician more likely to practice carelessly, or with reckless abandon, on the assumption that the lack of professional

^{85.} Ginsberg, supra note 1, at 19 (citing P. Dalla-Vorgio et al, Is Consent in Medicine a Concept only of Modern Times?, 27 J. MED. ETHICS 59, 59-61 (2001); Constantinos Trompoukis & John Lascaratos, Surgical Operation During the Ottoman Period. Informed Consent According to Documents of the Ottoman Archives of Crete, 10 T. KLIN. J. MED. ETHICS, L. & HIST. 163, 163-67 (2002).

^{86.} Jarrell, 123 A.3d at 1033.

^{87.} Id. at 1034.

^{88.} Id. at 1035.

^{89.} Id.

^{90.} Id. at 1040.

^{91.} Id.

^{92.} Id. at 1042.

liability insurance somehow provides a level of comfort?⁹³ It has been urged that there is a risk when addressing an uninsured physician who is a co-defendant with an insured physician in medical negligence litigation. The theory is the plaintiff's counsel will attempt to influence the uninsured co-defendant "to criticize the insured co-defendant physician in deposition or at trial. Refusing to do so subjects the bare physician to aggressive action by the plaintiff's attorney and the potential for financial ruin."⁹⁴

*Jarrell v. Kaul*⁹⁵ may not be as cutting edge of an informed consent opinion as much as it is an outlier. The facts of this case involve a boardcertified anesthesiologist who performed a procedure typically performed by a neurosurgeon or orthopedic surgeon in a non-hospital setting. Hospitals routinely require evidence of medical liability coverage as a condition of staff privileges. As an informed consent case, however, the scope of the disclosure cannot be without boundaries. A patient may be interested to know that the procedure to which the patient is about to submit may be negligently performed, yet this is not a disclosable risk.⁹⁶ Undoubtedly, other unconventional "risks" could be imagined. The "risk" of the uninsured physician is fairly considered outside the bounds of informed consent, although a debate on this topic is not without merit.⁹⁷

B. Abortion

It is an understatement that abortion is a controversial and politically charged topic in the United States. This paper is not the forum in which to address divisive and quite significant legal issues on that topic.⁹⁸ However, interesting jurisprudence exists relating to the required physician disclosure in connection with a first trimester abortion.⁹⁹ Specifically, the issue is whether the physician is obligated to advise the patient that a first trimester abortion is a procedure which kills an alleged

^{93.} It has been suggested that "[b]y insulating doctor from risks, insurance can also reduce physicians' incentive to exercise due care." Charles Silver et al., *Policy Limits, Payouts, and Blood Money: Medical Malpractice Settlements in the Shadow of Insurance*, 5 U.C. IRVINE L. REV. 559, 561 (2015) (no citation to authority supporting the authors' statement).

^{94.} Cliff Rapp, Risky Business: Practicing with Uninsured Physicians, www.sfc-acs.org/fpic/risky_bus.pdf [https://perma.cc/HBM3-3QUP].

^{95. 123} A.3d at 1022.

^{96.} See Ginsberg, supra note 1, at 62.

^{97.} Even insured physicians risk "excess" verdicts. See Silver et al., supra note 93, at 567.

^{98.} See Maya Manian., The Irrational Woman: Informed Consent and Abortion Decision-Making, 16 DUKE J. GENDER L. & POL'Y 223 (2009); Robert Post, Informed Consent to Abortion: A First Amendment Analysis of Compelled Physical Speech, 2007 U. ILL. L. REV. 939 (2007).

^{99.} First trimester pregnancies have been defined as "gestations at 12 weeks from the last menstrual period or less." Richard John Lyus et al., *First Trimester Procedural Abortion in Family Medicine*, 22 J. AM. BD. FAM. MED. 169 (2009).

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human being.100

In *Doe v. Planned Parenthood*,¹⁰¹ a nineteen-year old woman, approximately 12 weeks pregnant, obtained counseling from Planned Parenthood (PP). The operative facts are as follows:

[She] asked a PP counselor whether an abortion would terminate the life of a human being in the biological sense. The counselor replied in the negative. The plaintiff told the counselor that she had been informed by a pregnancy help center that an abortion terminates the life of a human being. The counselor replied that pregnancy help centers often deliberately misrepresent the facts to prospective mothers. The counselor assured her that an abortion did not terminate the life of a human being. Given this assurance, the plaintiff decided to have an abortion that same day.¹⁰²

Two years following the abortion, Plaintiff filed suit "individually and on behalf of her aborted fetus . . . against the clinic, its doctors, and its nursing/counseling staff,"¹⁰³ claiming that "the defendant had a duty to inform her that an abortion 'procedure would terminate the life of a second patient, a living human being as a matter of biological fact."¹⁰⁴ Plaintiff claimed that "but for the defendants' failure to fully inform her of the direct and collateral consequences of an abortion, she would not have terminated her pregnancy."¹⁰⁵ The court dismissed the complaint, holding that there was "no duty to inform a patient . . . that an abortion terminates the life of a human being in the biological sense as a matter of law."¹⁰⁶

The appellate court referred to the Illinois common law of informed consent¹⁰⁷ and to New Jersey jurisprudence¹⁰⁸ in concluding that "[n]o court, regardless of where it sits, has found a *common law duty* requiring doctors to tell their pregnant patients that aborting an embryo, or fetus, is

^{100.} Doe v. Planned Parenthood, 956 N.E.2d 564 (Ill. 2011); Acuna v. Turkish, 930 A.2d 416 (N.J. 2007).

^{101. 956} N.E.2d at 564.

^{102.} Id. at 567.

^{103.} Id.

^{104.} *Id.* Plaintiff also claimed that "the defendants had duty to inform her there is a greater risk of death, depression, suicide and breast cancer in women who undergo an abortion than in those who give birth." As to this issue, see John M. Thorp et al., *Long-Term Physical and Psychological Health Consequences of Induced Abortion: A Review of the Evidence*, 72 LINACRE Q. 44 (2005); David C. Reardon et al., *Deaths Associated with Abortion Compared to Childbirth—A Review of New and Old Data and the Medical and Legal Implications*, 20 J. CONTEMP. HEALTH L. & POL'Y 279 (2004).

^{105.} Planned Parenthood, 956 N.E.2d at 568.

^{106.} Id. Of course, whether a fetus is a human being is the subject of debate. See Soroush Dabbagh, Fetus as Human Being: Where is the Cut-off Point?, 2 J. MED. ETHICS & HIST. MED. 1 (2009).

^{107.} Planned Parenthood, 956 N.E.2d at 568.

^{108.} Acuna v. Turkish, 930 A.2d 416 (N.J. 2007).

procedure."¹¹¹ Previously, the Supreme Court of New Jersey, in *Acuna v. Turkish*,¹¹² considered a similar claim, very different than the facts in *Doe*.¹¹³ Here, the informed consent claim alleged "that Dr. Turkish breached a duty owed to [Plaintiff] by failing to inform her of 'the scientific and medical fact that [her six-to eight-week-old embryo] was a complete, separate, unique and irreplaceable human being' and that an abortion would result in 'killing an existing human being."¹¹⁴

Plaintiff's obstetrician-gynecologist (ob-gyn), Dr. Turkish, had previously delivered one of her children.¹¹⁵ Plaintiff's medical history included a kidney problem which allegedly threatened her life unless she had an abortion.¹¹⁶ Plaintiff alleged that Dr. Turkish recommended she have an abortion because of her condition, which Dr. Turkish denied. He "claimed that Plaintiff introduced the subject of abortion as an option."¹¹⁷ In any event, Plaintiff later executed a consent for the abortion. "On the form, plaintiff acknowledged that defendant 'explained all of the risks and complications to [her]."¹¹⁸ Dr. Turkish then "performed a vacuum aspiration,¹¹⁹ which ended the pregnancy."¹²⁰

Subsequently, another doctor diagnosed Plaintiff with an incomplete abortion, which he treated.¹²¹ A nurse's explanation of what occurred led Plaintiff to believe "'that [there] was a baby and not just blood' inside of

^{109.} Planned Parenthood, 956 N.E.2d at 572.

^{110.} Acuna, 930 A.2d at 416.

^{111.} Planned Parenthood, 956 N.E.2d at 573. There is medical scholarship reporting the complications of abortion. See E. Hakim-Elahi et al., Complications of First-Trimester Abortion: A Report of 170,000 Cases, 76 OBSTETRICS & GYNECOLOGY 129 (1990).

^{112. 930} A.2d at 416.

^{113.} Planned Parenthood, 956 N.E.2d at 564.

^{114.} Acuna, 930 A.2d at 418.

^{115.} Id. at 419.

^{116.} Id.

^{117.} Id.

^{118.} Id.

^{119. &}quot;Manual vacuum aspiration (MVA) is a technique of suction curettage for first-trimester abortion that has been performed for many years. It is performed using a handheld syringe attached to a uterine catheter. It has been used internationally for many years and has been shown to be safe and effective for early abortion, menstrual extraction, and completing incomplete abortions." John M. Westfall et al., *Manual Vacuum Aspiration for First-Trimester Abortion*, 7 ARCH. FAM. MED. 559, 559 (1998).

^{120.} Acuna, 930 A.2d at 419.

^{121.} Id.

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her."¹²² Plaintiff's research caused her to conclude "that the abortion procedures killed a 'human being."¹²³

Plaintiff filed a claim "primarily focused on the theory of lack of informed consent."¹²⁴ Essentially, Plaintiff claimed that Dr. Turkish did not disclose, among other things, that "abortion involved 'actually killing an existing human being."¹²⁵ A lengthy procedural history ensued, with the following findings of the trial judge:

- By demanding that a physician advise a pregnant woman that her non-viable embryo "is in all material respects equivalent to a person born and alive," plaintiff would require that the doctor convey "a value judgment not a medical fact."¹²⁶
- [Q]uestions of when life begins and whether a woman should terminate a pregnancy "involved moral, philosophical, and religious questions."¹²⁷
- "[T]hose trained in the respective disciplines of medicine, philosophy, and theology" have failed to reach a consensus about when life begins.¹²⁸
- The law has left the question of whether to abort or go to term with a non-viable embryo . . . "for each woman to decide for herself."¹²⁹
- [A] physician is not required to advise a woman that her non-viable embryo "is a living human being" to obtain her informed consent for an abortion.¹³⁰

The state supreme court, after a lengthy discussion of the law of informed consent, concluded that New Jersey's common law did not contemplate the duty to disclose urged by the plaintiff.¹³¹ The court's decision is consistent with the informed consent policy of limiting the required disclosure to medical facts directly related to the proposed procedure or treatment.

C. Detail of a Medical Procedure

Consider this frequent scenario: a patient consults a general surgeon for a commonly performed surgical procedure—hernia repair, appendectomy, or gallbladder removal. The informed consent disclosure

^{122.} Id.

^{123.} Acuna, 930 A.2d at 420.

^{124.} *Id.*

^{125.} Id.

^{126.} *Id.* at 422.

^{127.} Id.

^{128.} Id. (quoting Roe v. Wade, 410 U.S. 113, 159 (1973)).

^{129.} *Id.*

^{130.} *Id.*131. *Acuna*, 930 A.2d at 428.

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requires the surgeon to advise the patient of the recommended procedure, but in how much detail? Medical literature is replete with the actual procedural detail of the hernia repair,¹³² appendectomy,¹³³ and cholecystectomy,¹³⁴ but it is simply unreasonable for the surgeon to expect that the patient seek this much detail and have the ability to comprehend it. This puts the surgeon in a difficult situation. It has been urged that the law of informed consent has "made it plain that it is not appropriate to surrender the degree of detail to the sole judgment of the medical profession itself."¹³⁵ Yet, an equally cogent and realistic position is that "[t]he real limits of patient . . . comprehension suggest[s] that it is unreasonable to seek *consent* for every detail of a proposed treatment."¹³⁶ What, then, is the obligation of the physician when explaining a medical procedure to a patient?

Oregon, pursuant to statute, has given physicians, in part, a reasonably clear path to the disclosure. Oregon's informed consent statute provides as follows:

ORS § 677.097

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Procedure to obtain informed consent of patient

(1) In order to obtain the informed consent of a patient, a physician or physician assistant shall explain the following:

(a) In general terms the procedure or treatment to be undertaken;

(b) That there may be alternative procedures or methods of treatment, if any; and

(c) That there are risks, if any, to the procedure or treatment.

(2) After giving the explanation specified in subsection (1) of this section, the physician or physician assistant shall ask the patient if the patient wants a more detailed explanation. If the patient requests further explanation, the physician or physician assistant shall disclose in substantial detail the procedure, the viable alternatives and the material risks unless to do so would be materially detrimental to the patient. In determining that further explanation would be materially detrimental the physician or physician assistant shall give due consideration to the standards of practice of reasonable medical or podiatric practitioners in the same or a similar community under the same or similar

^{132.} B. Ramshaw et al., *Laparoscopic Inguinal Hernia Repair*, 15 SURGICAL ENDOSCOPY. 50 (2001).

^{133.} Carol E. H. Scott-Conner et al., *Laparoscopic Appendectomy – Initial Experience in a Teaching Program*, 215 ANNS. SURGERY 660 (1992).

^{134.} Walter Reynolds, Jr., *The First Laparoscopic Cholecystectomy*, 5 J. SOC. LAPAROENDOSCOPIC SURGEONS 89 (2001); Bruce D. Schirmer et al., *Laparoscopic Cholecystectomy* – *Treatment of Choice for Symptomatic Cholelithiasis*, 213 ANNS. SURGERY 665 (1991).

M.D. Kirby, Informed Consent: What Does it Mean?, 9 J. MED. ETHICS 69, 73 (1983).

^{136.} O. O'Neill, Some Limits of Informed Consent, 29 J. MED. ETHICS 4, 6 (2003).

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circumstances.137

Pursuant to the statute, the procedure shall be explained in general terms.¹³⁸ The statutory requirement then extends beyond the *disclosure doctrine* for the character of informed consent requires the physician to inquire of the patient if the patient desires additional detail. If the patient opts for more detail, the Oregon informed consent process involves much more of a communication or conversation than contemplated by the classic informed consent doctrine. The Court of Appeals of Oregon in 1990 described the informed consent process.¹³⁹ More recently, the Superior Court of Connecticut subscripted to a less detailed description of a surgical procedure when it stated that, "a requirement under the nature of procedure element of the informed consent cases that a doctor describe a surgical procedure in great detail would place an impossible burden on surgeons and make it difficult for reviewing courts to develop guidelines to implement application of this nature of procedure element."¹⁴⁰

Certainly, the amount and depth of detail to be disclosed by the physician is not determinable by a formulaic application. A "general" description of a proposed procedure or treatment seems realistic in terms of time constraints and patient literacy.

D. Non-Physician Participation in Surgical Procedure

Quite recently, the Supreme Court of Oklahoma considered what is, hopefully, an aberrant factual scenario in *Hurley v. Kirk.*¹⁴¹ Here, a surgeon allowed a non-physician to perform a portion of a total laparoscopic hysterectomy.¹⁴² The patient consented to the procedure but the surgeon never informed the patient that the person who would assist in surgery had credentials as an EMT, surgical technician, LPN, and first assistant,¹⁴³ but *not* as a physician. During the procedure, the patient suffered various injuries and required corrective surgery.¹⁴⁴

The trial court resolved Plaintiff's claim by summary judgment in

^{137.} Procedure to Obtain Informed Consent of Patient, Or. Rev. Stat. § 677.097 (2017).

^{138.} Id.

^{139.} See Wenger v. Oregon Urology Clinic, 796 P.2d 376, 377 (Or. Ct. App. 1990).

^{140.} Ranciato v. Schwarts, No. NNHCV116023107S, 2014 WL 7497403, at *31 (Conn. Super. Ct. Nov. 26, 2014).

^{141. 398} P.3d 7 (Okla. 2017).

^{142.} This procedure is well explained in Jon I. Einarsson & Yoko Suzuki, *Total Laparoscopic Hysterectomy: 10 Steps Toward a Successful Procedure*, 2 REVS. OBSTETRICS & GYNECOLOGY 57 (2009).

^{143.} Kirk, 398 P.3d at 9.

^{144.} Id.

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favor of the defendants and the appellate court affirmed.¹⁴⁵ The state supreme court referred to its informed consent jurisprudence in its holding and held that the defendant surgeon owed a duty to the patient to disclose the anticipated participation of a non-physician in the surgical procedure. Specifically, the court stated:

Today, this Court reemphasizes that the scope of a physician's communications must be measured by his/her patient's need to know enough information to enable the patient to make an informed and intelligent choice. In other words, full disclosure of all material risks incident to treatment must be made. As such, no physician has carte blanche to delegate any or all tasks to a non-doctor. To hold otherwise, would obliterate a patient's freedom of choice and reinstate the paternalistic approach to medicine The scope of the duty to inform is broad enough to include a physician's duty to inform the patient "who" will be performing significant portions of the procedure or surgical tasks.¹⁴⁶

The opinion in *Hurley*,¹⁴⁷ in light of its facts, is quite reasonable. The non-physician in the surgical procedure increased the patient's risk of surgical injury due to his participation. Accordingly, the patient was entitled to know of this participant in advance of surgery and choose a different surgeon.

E. Physician Personal Life and Personal Decisions

Is a physician obligated to disclose to a patient that the physician is allegedly having an affair with the patient's wife? In 2012, the Court of Appeals of Georgia answered. No.¹⁴⁸ In *Witcher v. McGauley*,¹⁴⁹ both spouses were patients of the defendant-physician. Prior to the discovery of the alleged affair, the defendant treated the husband-spouse "for complaints including depression and anxiety."¹⁵⁰ The defendant-physician diagnosed husband-spouse "with Attention Deficit Disorder (ADD), which necessitated prescribing medication."¹⁵¹ The husband-spouse had advised the defendant-physician "that he thought 'something was not clicking right at home," which was causing him to have an inability to focus on his work."¹⁵² His medical negligence and breach of

^{145.} Id. at 7.

^{146.} *Id.* at 10-11.

^{147.} *Id.* at 7.

^{148.} Witcher v. McGauley, 730 S.E.2d 56 (Ga. Ct. App. 2012).

^{149.} *Id*.

^{150.} *Id.* at 58.

^{151.} *Id.* 152. *Id.*

fiduciary duty claims against the defendant-physician were based in part on the alleged affair and resulting damages—divorce, the need to seek psychiatric care, loss of employment, "mental and physical distress, humiliation, and anguish."¹⁵³ The court noted that the defendant-physician "had no duty to disclose to his patient personal life factors, such as an affair, that might adversely affect his professional performance."¹⁵⁴

In *Hooks v. Humphries*,¹⁵⁵ the Court of Appeals of Georgia considered an informed consent claim arising from a birth injury. During Plaintiff's pre-natal care, her ob-gyn advised her "that he no longer delivered babies, that his medical treatment would be limited to her prenatal care, and that he would refer her to another obstetrician for delivery of the baby."¹⁵⁶ When Plaintiff returned to see the defendant, he advised Plaintiff "that her pregnancy was considered high risk based on her age, her history of smoking, of complications in prior pregnancies, and of failing to comply with doctor's instructions."¹⁵⁷ Her ob-gyn referred Plaintiff that she may have gestational diabetes.¹⁵⁹

The defendant ceased to provide care to Plaintiff. Other physicians cared for the Plaintiff and, ultimately, she gave birth to a large baby, which, "[d]uring the delivery . . . sustained a shoulder dystocia,¹⁶⁰ Erb's palsy,¹⁶¹ and meconium aspiration syndrome^{162,*163}

Plaintiff commenced a medical negligence lawsuit against the defendant, which resulted in a defense verdict at trial.¹⁶⁴ The trial court previously granted summary judgment in favor of the defendant in

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^{153.} Id.

^{154.} *Id.* at 63. For scholarship regarding sexual relationships between physicians and patients, see Scott M. Puglise, Note, *Calling Dr. Love: The Physician-Patient Sexual Relationship as Grounds for Medical Malpractice – Society Pays While the Doctor and Patient Play*, 14 J. L. & HEALTH 321 (1999-2000).

^{155. 692} S.E.2d 845 (Ga. Ct. App. 2010).

^{156.} Id. at 847.

^{157.} Id.

^{158.} Id.

^{159.} *Id. See also*, Am. Diabetes Ass'n, *Gestational Diabetes Mellitus*, 27 DIABETES CARE S 88 (2004) (defining gestational diabetes as any degree of glucose intolerance with onset or first recognition during pregnancy).

^{160.} See Robert B. Gherman et al., Shoulder Dystocia: The Unpreventable Obstetric Emergency with Empiric Management Guidelines, 195 AM. J. OBSTETRICS & GYNECOLOGY 657 (2006).

^{161.} See Michael Chater et al., Erb's Palsy – Who is to Blame and What Will Happen?, 9 PAEDIATR CHILD HEALTH 556 (2004).

^{162.} See Robert Bacsik, Meconium Aspiration Syndrome, 24 PEDIATRIC CLINICS N. AM. 463 (1977).

^{163.} Hooks, 692 S.E.2d at 847.

^{164.} Id. at 846.

connection with a breach of fiduciary duty claim.¹⁶⁵ The essence of that claim was the defendant's failure "to disclose to [Plaintiff] the reasons he no longer delivered babies."¹⁶⁶ Apparently, Plaintiff's counsel approached the topic during the defendant's deposition, when he "testified that he no longer practiced in labor and delivery for 'mostly personal and some political reasons."¹⁶⁷

The court of appeals easily disposed of Plaintiff's claim regarding the non-disclosure. It held that a "physician has no duty to voluntarily disclose negative information¹⁶⁸ about his personal life to patients . . . even if the patient indicates that the information would have [been] useful in determining whether to seek treatment elsewhere."¹⁶⁹ Additionally, the court of appeals indicated that the disclosure of personal matters was not included in "the specific categories of information set forth in Georgia's informed consent statute."¹⁷⁰

Plaintiff's claim in *Hooks* surely defies logic. Once Plaintiff's physician advised her of the factors complicating her pregnancy, including gestational diabetes, a referral to a maternal-fetal medicine specialist¹⁷¹ was realistic. The defendant-physician very likely would not have undertaken the delivery even if he had not opted to no longer deliver babies. The non-disclosure did not increase any risk to the patient. Thus, her claim was without merit.

F. Physician Health History

Physicians are patients, too,¹⁷² and, therefore, are entitled to health information privacy.¹⁷³ However, a physician's health history could create risk to patients, particularly if the physician's health is compromised and might impact the ability to provide quality care. Is the physician under an obligation to disclose this disease or disability to the patient in order to obtain the patient's informed consent? Recent jurisprudence speaks to this

^{165.} *Id*.

^{166.} Id. at 848.

^{167.} Id.

^{168.} It is not at all clear what was "negative" about an ob-gyn's decision to no longer deliver babies.

^{169.} *Hooks*, 692 S.E.2d at 848.

^{170.} Id. Referring to OCGA § 31-9-6.1(a).

^{171. &}quot;Maternal fetal medicine (MFM) physicians are high risk pregnancy experts, specializing in the un-routine." Society for Maternal-Fetal Medicine, *What is a MFM?*, https://www.smfm.org/members [https://perma.cc/J23A-ZQ6G].

^{172.} See Amy Domeyer-Klenske & Marcy Rosenbaum, When Doctor Becomes Patient: Challenges and Strategies in Caring for Physician-Patients, 44 FAM. MED. 471 (2012).

^{173.} See Lawrence O. Gostin, National Health Information Privacy: Regulations Under the Health Insurance Portability and Accountability Act, 285 JAMA 3015 (2001) (discussing the importance of patient information privacy).

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In *Robert v. Marx*,¹⁷⁵ the Court of Appeal of Louisiana considered whether a urologist had a duty to disclose his elective eye surgery which occurred eight days before he performed Plaintiff's vasectomy. The defendant-physician had suffered a retinal detachment¹⁷⁶ which he had successfully surgically repaired.¹⁷⁷ His vision had improved as of the date of Plaintiff's surgery, during which the defendant-physician "utilize[d] a magnifying loupe."¹⁷⁸

Plaintiff experienced significant postoperative complications requiring follow-up medical and surgical care.¹⁷⁹ Plaintiff filed a medical negligence claim based on the lack of informed consent. The trial court entered summary judgment in favor of the defendant-physician.

On appeal, the court referred to the Louisiana informed consent statute¹⁸⁰ noting that "a doctor's duty of disclosure to a patient includes only those risks that are material."¹⁸¹ The court then noted the following significant, "undisputed facts":¹⁸² Plaintiff's postoperative "complications were known and material risks that might have been expected from the surgery";¹⁸³ Plaintiff "was advised of [a postoperative] risk and consented to the surgery";¹⁸⁴ and the defendant-physician "was released by his doctor to perform acts in his medical practice."¹⁸⁵ The court's comments suggest that the informed consent disclosure was appropriate and the defendant-physician's prior eye condition and surgery did not constitute a risk to the patient.

Finally, the court made an important distinction between a classic medical negligence claim and an informed consent claim pertaining to the case facts as follows: "[A] physician's inability to perform surgery because of his impaired physical condition is not a matter concerning informed consent of the patient but negligence of the physician."¹⁸⁶ This

186. *Id.* at 467.

^{174.} See also Sarah Haston, Note, Impaired Physicians and the Scope of Informed Consent: Balancing Patient Safety with Physician Privacy, 41 FLA. ST. L. REV. 1125 (2014).

^{175. 109} So. 3d 462 (La. Ct. App. 2013).

^{176.} See John Lane et al., Retinal Detachment: Imaging and Surgical Treatments and Complications, 23 RADIOGRAPHICS 983 (2003); Ray F. Gariano et al., Evaluation and Management of Suspected Retinal Detachment, 69 AM. FAM. PHYSICIAN 1691 (2004).

^{177.} Marx, 109 So. 3d at 464.

^{178.} Id.

^{179.} Id. at 463-464.

^{180.} LA. Rev. Stat. § 40:1299.40.

^{181.} Marx, 109 So. 3d at 466.

^{182.} Id.

^{183.} Id.

^{184.} *Id*.

^{185.} Id.

suggests that a physician is simply not obligated to disclose personal health information to obtain a patient's informed consent, even if the physician's health would pose a risk to the patient. Presumably, a patient injured as a result of medical negligence caused by the physician's impaired health will learn of the impairment during the pre-trial discovery process. Of course, this provides little, if any, consolation to a patient who might well have opted for a different physician.

Another recent examination of an informed consent claim involving the defendant-physician's health occurred in *Rice v. Brakel.*¹⁸⁷ This case involved a spinal surgery performed by a physician with an apparent prescription pain medication dependency.¹⁸⁸ The patient came across this information while researching 'the Board of Medical Examiners' website to check the disciplinary history of a doctor licensed in the state."¹⁸⁹ This research also revealed that the defendant-physician "had been reprimanded by the board and placed on probation for five years."¹⁹⁰

Plaintiff filed a claim for medical battery, medical malpractice and negligent supervision. The trial court entered summary judgment on behalf of the defendant-physician. On appeal, the court discussed all of these theories. Insofar as the alleged failure of the defendant-physician to disclose his alleged drug dependence and disciplinary history is concerned, the court stated that "[Plaintiff] has an available cause of action for any damages caused by [defendant's] failure to disclose, because the duty to disclose relevant risks already exists under the informed consent theory of medical malpractice."¹⁹¹ Nevertheless, the court also found that Plaintiff had not introduced any evidence to prove "that he would have declined the treatment had [defendant's] status been disclosed"¹⁹² or that the non-disclosure proximately caused any injury.¹⁹³

The Court of Appeals of Georgia in *Williams v. Booker* addressed a surgeon's alcohol addiction.¹⁹⁴ Here, the court reviewed the denial of defendants' motions for summary judgment pertaining to this addiction. The defendant-physician had performed a laparoscopic gallbladder removal¹⁹⁵ for Plaintiff. Postoperatively, it appeared that the Plaintiff had

195. See Jeffrey B. Comitalo, Laparoscopic Cholecystectomy and Newer Techniques of Gallbladder Removal, 16 J. SOC'Y. LAPAROENDOSCOPIC SURGEONS 406, 406-07 (2012) (explaining the surgical technique).

^{187. 310} P.3d 16 (Ariz. Ct. App. 2013).

^{188.} *Id.* at 18.

^{189.} *Id*.

^{190.} Id.

^{191.} Id. at 20.

^{192.} Id. at 22 (citation omitted).

^{193.} Id.

^{194. 712} S.E.2d 617 (Ga. Ct. App. 2011).

suffered an intraoperative bile duct injury.¹⁹⁶ Plaintiff commenced a hospital and medical negligence claim, alleging, among other things, "that [defendant] was addicted to alcohol and that his alcoholism impaired his ability to perform surgery"¹⁹⁷ and "that the hospital was aware of [defendant's] alcohol addiction and violated a duty to disclose [his] alcohol addiction to her."¹⁹⁸ The physician-defendant admitted that he was an alcoholic.¹⁹⁹

The court addressed the relevance of defendant's addiction, stating that "[i]n medical malpractice suits, evidence of a physicians' alcohol or drug use or addiction is relevant and admissible only when there is evidence from which the jury may infer that the physician was under the influence of alcohol or drugs at the time of the allegedly negligent treatment."²⁰⁰ Of course, the relevance analysis did not address the issue of disclosure to obtain informed consent.

As to the informed consent claim against the hospital, the court noted that Plaintiff provided no authority to support his claim that the hospital had a duty to inform the patient of a physician's alcoholism. The court cited to Georgia jurisprudence holding "that a physician has no duty to inform a patient of his use and dependence upon the illegal drug cocaine."²⁰¹ Therefore, there was "no basis for [Plaintiff's] failure-to-disclose claim."²⁰² Such a claim could not be prosecuted against the physician or hospital.

Informed consent claims concerning physician health implicate sensitive and controversial matters. The most reasonable approach would support a required disclosure if the physician's health condition creates a realistic risk to the patient which would not exist in the absence of that condition.

G. Physician's Relationship with Medical Product Manufacturer and Financial Interest in Treatment Procedure

In *Shapira v. Christiana Care Health Services, Inc.*²⁰³, the Supreme Court of Delaware considered the appeal from a verdict in favor of the defense in a medical negligence claim involving a thoracic surgeon who

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^{196.} Booker, 712 S.E.2s at 619.

^{197.} Id.

^{198.} Id.

^{199.} Id.

^{200.} Id. at 620.

^{201.} *Id.* at 621 (*citing* Albany Urology Clinic v. Cleveland, 272 Ga. 296, 296-297, 528 S.E.2d 777 (2000)).

^{202.} Id. at 622.

^{203. 99} A.3d 217 (Del. 2014).

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had a financial interest in a product which was used to treat the plaintiff. Plaintiff "fell from a ladder and suffered multiple non-displaced rib fractures, among other injuries."²⁰⁴ Plaintiff was hospitalized and attended to by defendant, a thoracic surgeon, who performed a pain management procedure (called an On-Q procedure) where the surgeon inserted a catheter over Plaintiff's ribs through which pain medication was delivered.²⁰⁵ The use of the catheter in this procedure was not FDA approved, constituting "an 'off-label' use of the

... catheter."²⁰⁶

In advance of the procedure, the surgeon would have discussed it with the patient, including its purpose, "aims, risks and alternatives."²⁰⁷ The patient consented to the procedure. However, the surgeon did not disclose his "independent interest in the . . . procedure."²⁰⁸ The court explained the surgeon's "interest" in great detail, as follows.

In 2007, Shapira entered into a contract with the On-Q's manufacturer, I-Flow Corporation, under which Shapira became a member of I-Flow's speaker's bureau. I-Flow paid Shapira to give presentations to other physicians about the On-Q procedure, and Shapira created a promotional pamphlet about the procedure. Also in 2007, Shapira created a database at Christiana Hospital to collect information about his patients' responses to the On-Q procedure. Around that time, the number of patients on whom Shapira performed the On-Q procedure began to increase significantly. In 2009, Shapira requested and received approval from CCHS's Institutional Review Board ("IRB") to study the effectiveness of the On-Q procedure using the patient data he was collecting. By mid-2009, Shapira had labeled himself, in addition to a thoracic surgeon, an "interventional pain management physician" based on his frequent performance of the On-Q procedure at Christiana Hospital.²⁰⁹

Additionally, and significantly, the surgeon only discussed oral and intravenous pain medication as an alternative and did not discuss epidural anesthesia as an option.²¹⁰

Post-procedure, the patient suffered complications and required

^{204.} Id. at 219.

^{205.} Id.

^{206.} Id.

^{207.} Id.

^{208.} Id. at 220.

^{209.} Id.

^{210.} Id. See Manoj K. Karmakar, & Anthony M.-H. Ho, Acute Pain Management of Patients with Multiple Fractured Ribs, 54 J. TRAUMA 615, 616 (2003) (noting multiple approaches to pain management of fractured ribs, including the epidural approach, which the defendant, Dr. Shapira, did not discuss with the patient).

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additional surgical procedures.²¹¹ Plaintiff brought a medical negligence action against the physician including a claim for informed consent. The jury returned a verdict for the plaintiff.²¹²

The state supreme court characterized the informed consent claim as implicating a conflict of interest, specifically, that the physician-defendant failed "to disclose significant personal conflicts of interest regarding the On-Q procedure, including his business relationship with I-Flow."²¹³ The court referred to Delaware's informed consent statute which defined informed consent as follows:

[T]he 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.²¹⁴

The statute would have required the defendant-physician to present the Plaintiff with an alternative method of pain management, which he did not do. Thus the defendant-physician violated the standard of care.²¹⁵

As to the surgeon's financial connection to the pain management procedure he performed, the court found his connection created a conflict of interest such that he performed a procedure which benefitted him, "not because it was the most appropriate procedure."²¹⁶ Furthermore, "the conflict created a risk that [he] did not disclose or consider all reasonable alternatives."²¹⁷ The surgeon had the incentive to "play down the risks of the . . . procedure and play up the problems with alternative treatments."²¹⁸ Therefore, the non-disclosure increased the risk to the patient receiving the procedure which might have been avoided had the patient known of another option.

Shapira is a current example of the issues considered by the California Supreme Court in *Moore v. Regents of the University of California.*²¹⁹ It is clear that a physician is obligated to disclose any

^{211.} Shapira, 99 A.3d at 220.

^{212.} Id.

^{213.} Id. at 221.

^{214.} Id. (quoting Del. Code Ann. tit. 18, § 6801 (Lexis Advance through 81 Del. Laws, ch. 425)).

^{215.} Shapira, 99 A.3d at 221.

^{216.} Id. at 222.

^{217.} Id.

^{218.} Id.

^{219. 793} P.2d 479 (Cal. 1990).

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financial interest related to a proposed treatment beyond just the compensation the physician charges for the medical services rendered. The financial conflict places a patient at risk of unnecessary medical care or of more dangerous treatment than necessary.

H. Off Label Use of Surgical Device

In *Seavey v. Globus Medical*,²²⁰ the court considered various motions for summary judgment in product liability and lack of informed consent claims relating to the use of a surgical fixation device.²²¹ The surgeon's use of the device was "off-label"—a use not approved by the FDA. The surgeon did not disclose the off-label use of the device to the patient when obtaining the patient's consent for the surgical procedure.

Typically, non-disclosure of an off-label use of a medical device does not violate the doctrine of informed consent.²²² The *Seavey* trial judge recognized this principle when he stated:

[W]hen a surgeon uses a medical device in an "off-label" manner, a failure to disclose that information to the patient is, alone, insufficient to support a claim that the physician failed to meet the applicable disclosure standard... "the FDA regulatory status 'do[es] not speak directly to the medical issues surrounding a particular surgery." This is the case because the FDA's "concern is to regulate the marketing and labelling of medical devices, not to intrude upon the practice of medicine or redefine the doctrine of informed consent." Doctors may "use medical devices for off-label purposes that are not FDA approved, provided that the FDA has approved the device for some other purpose."²²³

The court also confirmed that New Jersey law was consistent with this principle.²²⁴

The court, however, did not pronounce a *per se* rule regarding the non-disclosure of the FDA regulatory status of a surgical device. It is possible that FDA regulatory status could recognize a risk to a patient through an off-label use. If so, that status must be disclosed by the physician in order to obtain the patient's informed consent.²²⁵ In addition, in order to prove the materiality of that risk, the patient must produce

^{220.} Seavy v. Globus Medical Inc., No. 11-2240, 2014 WL 1876957 (D.N.J. 2014).

^{221.} See Dilip K. Sengupta & Harry N. Herkowitz, *Pedicle Screw-Based Posterior Dynamic Stabilization: Literature Review*, 2012 ADVANCES ORTHOPEDICS. 1, 4 (2012) (referring to a transition device which may well have been the subject of the lawsuit).

^{222.} See J.M. Beck & E.D. Azari, FDA, Off Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 FOOD & DRUG L. J. 71, 76 (1998).

^{223.} Seavy, No. 11-22402014, 2014 WL 1876957 at *13 (citations omitted).

^{224.} Id. at *14.

^{225.} Id. at *15.

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expert testimony.²²⁶ Plaintiff did not produce that testimony.

I. Differential Diagnosis—Proper Diagnosis

Not long ago, I authored a detailed paper on informed consent and the differential diagnosis.²²⁷ The paper examined the experiences of various jurisdictions and urged that physicians cannot be expected to disclose the entire differential diagnosis and treatment options (including risks, benefits and complications) for discarded diagnoses.²²⁸ It also urged that a doctrine of informed consent which required the disclosure of the differential diagnosis could yield unnecessary medical procedures and pose danger to patients.²²⁹ The failure of a physician to arrive at a correct diagnosis should yield a medical negligence claim, not an informed consent claim.²³⁰

J. Physician Experience

Are patients better served by receiving treatment from more experienced rather than less experienced physicians? It has been reported that "[e]xperience is strongly related to better outcomes in surgery and obstetrics, but studies examining association between physician experience and quality of care for medical patients have reported mixed results."²³¹ If physician experience is related to outcome, does inexperience or less experience constitute a material risk to a patient which the physician is obligated to disclose? In other words, is a physician required to disclose to a patient that a more experienced physician is available and preferable?

In 2017, the Court of Appeals of Iowa, in *Andersen v. Khanna*,²³² held that no "Iowa court has explicitly considered whether the doctor's inexperience is a material risk or factor that falls within the duty to disclose."²³³ The court referred to the Iowa informed consent statute²³⁴ and stated that it "is silent as to any physician-specific information that

^{226.} Id. at *16.

^{227.} Marc D. Ginsberg, Informed Consent and the Differential Diagnosis: How the Law Can Overestimate Patient Autonomy and Compromise Health Care, 60 WAYNE L. REV. 349 (2014).

^{228.} Id.

^{229.} Id.

^{230.} See Pagani v. Weiss, Nos. 1279 EDA 2013, 1442 EDA 2013, 2014 WL 10965858 (Sup. Ct. Pa. March 27, 2014).

^{231.} Findlay A. McAlister et al., *Physician experience and outcomes among patients admitted to general internal medicine teaching wards*, 187 CMAJ 1041 (2015).

^{232.} No. 14-1682, 2017 WL 363221 (Iowa Ct. App. 2017).

^{233.} Id. at 10.

^{234.} Iowa Code § 147.137(1) (2018).

must be disclosed to meet the informed-consent requirements."²³⁵ Therefore, under Iowa law, the defendant's alleged inexperience (as a cardiac surgeon) could not support an informed consent claim.

The court of appeals decision was, however, short-lived. In 2018, on further review by the Supreme Court of Iowa, the *Andersen* decision was vacated.²³⁶ The state supreme court focused on the fact that the defendant-physician did not have any experience or training in performing the particular Bentall procedure²³⁷ used on Andersen.²³⁸ Insofar as Iowa had adopted a reasonable patient model of informed consent,²³⁹ the Supreme Court held that a physician's personal characteristics, including experience, can be material to a patient's decision to undertake treatment.²⁴⁰ The Supreme Court's specific holding is as follows:

Accordingly, we hold a physician's experience or training with the proposed treatment can be information material to the decision of a reasonable person in the patient's position to or not to undergo the proposed treatment. Whether such information is material will depend on the facts and circumstances of each case and will be for the jury to decide, unless as a matter of law no reasonable person in the patient's position would find such information material.²⁴¹

Of course, the position taken by the Iowa Supreme Court potentially places many Iowa physicians in peril. There is always a more experienced physician. How much (or little) experience is material to a reasonable patient? How will less experienced physicians gain experience if they must routinely disclose their experience and, presumably, the identities of more experienced physicians?

In 2015, the Superior Court of New Jersey, Appellate Division, in *Lynch v. Pressman*²⁴² came to the same conclusion. Here, the defendant-physician, an orthopedic surgeon (not a hand surgeon) "performed endoscopic carpal tunnel release (CTR) surgery²⁴³ on Plaintiff's dominant

^{235.} Khanna, No. 14-1682, 2017 WL 363221 at 10.

^{236.} Andersen v. Khanna, 913 N.W.2d 526, 542 (Iowa 2018).

^{237.} The Bentall procedure refers to "[a] technique for complete replacement of the aortic valve and ascending aorta in cases of aneurysm of the ascending aorta with aortic valve ectasia." Hugh Bentall & Antony De Bono, *A Technique for Complete Replacement of the Ascending Aorta*, 23 THORAX 338 (1968). *See also* Christian D. Etz et al., *The Bentall Procedure: Is it the Gold Standard? A Series of 597 Consecutive Cases*, 140 J. THORACIC & CARDIOV. SURG. 564 (2010).

^{238.} *Khanna*, 913 N.W.2d at 530.

^{239.} Id. at 537.

^{240.} Id.

^{241.} Id. at 542.

^{242.} No. L-1650-10, 2015 WL 1237190 (N.J. Super. Ct. App. Div. Mar. 4, 2015).

^{243. &}quot;Carpal tunnel syndrome . . . is the most common compression neuropathy of the upper extremity." James C.Y. Chow & Michael E. Hantes, *Endoscopic Carpal Tunnel Release: Thirteen*

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right hand,"²⁴⁴ resulting in complications.²⁴⁵ This resulted in additional hand surgery, during which "defendant discovered that he had severed Plaintiff's common digital nerve²⁴⁶ in the previous endoscopic procedure, and performed microscopic repair on the nerve."²⁴⁷ Postoperatively, the complications remained.

Plaintiff's complaint, including an informed consent claim, alleged "that defendant never informed her that his experience with performing endoscopic CTR surgery consisted of less than ten percent of all surgical procedures that he routinely performed."²⁴⁸ Plaintiff claimed that if she was aware of defendant's inexperience and the surgical risks she would not have consented.²⁴⁹

The informed consent claim went to trial and resulted in a jury verdict for the defendant. On appeal, the appellate court affirmed. The surgeon's "non-disclosure" was not a misrepresentation of his credentials.²⁵⁰ The surgeon did not, under New Jersey law, have an obligation to disclose his surgical experience to obtain the patient's informed consent.

K. Sophisticated Care Facility

A question related to the prior section: Does the doctrine of informed consent require a physician to disclose to the patient the option of seeking treatment at a facility which can provide more sophisticated care? In *Torres v. Carrese*,²⁵¹ the Appellate Court of Connecticut held that this disclosure is not required.

In *Torres*,²⁵² Plaintiff, an obstetrical patient, sued obstetriciangynecologists after delivering a child via cesarean hysterectomy. The delivery became complicated by a placental condition (placental percreta) in addition to bleeding. Thus, the plaintiff-patient required a hysterectomy

252. Id.

Years' Experience with the Chow Technique, 27 J. HAND SURGERY 1011, 1011 (2002) (also explaining the endoscopic surgical technique).

^{244.} Pressman, 2015 WL 1237190, at *1.

^{245.} Id. See Raymond W. Tse et al., Early major complications of endoscopic carpal tunnel release: A review of 1200 cases, 11 CAN. J. PLAST. SURG. 131 (2003) (a clinical review of complications resulting from endoscopic carpel tunnel release).

^{246.} See Nitin J. Engineer et al., Variations in the Anatomy of the Third Common Digital Nerve and Landmarks to Avoid Injury to the Third Common Digital Nerve With Carpal Tunnel Release, 8 OPEN ACCESS J. PLAST. SURG. 465, 466 (2008) (explaining that "the common digital nerve of the third web space was the most frequently injured digital nerve").

^{247.} Pressman, 2015 WL 1237190, at *1.

^{248.} Id.

^{249.} Id.

^{250.} *Id.* at *6.

^{251. 90} A.3d 256 (Conn. App. Ct. 2014).

and urologic treatment.²⁵³ The trial court granted summary judgment to the defendants on Plaintiff's informed consent claim, which alleged that the defendant should have disclosed "that the cesarean hysterectomy could perhaps be more safely performed at another health care facility."²⁵⁴ The appellate court affirmed, stating:

None of our courts have addressed a claim closely analogous to the plaintiff's—that is, whether a physician has an obligation to inform his or her patient that a procedure may be better performed at another health care facility. We hold that on the facts presented in this case, [defendant] had no such obligation... The procedure itself does not necessarily extend to the place where the procedure is to be performed; in the circumstances of this case, the alleged fact that the facility was not a tertiary facility was not, as a matter of law, a material risk.²⁵⁵

The appellate court, however, did not preempt possible informed consent claims, based on different facts, founded on the non-disclosure of alternative treatment venues.²⁵⁶ The difficulty here is the notion that a less sophisticated treatment facility (and its personnel) may constitute a material risk to a patient. For example, is a community-based physician required to disclose that a patient would be better served at a university teaching facility? The point is that there is almost *always*, a "better" facility based on reputation, prestige, credentials of staff physicians, and available training programs. It is simply not possible for every patient to be referred to a more sophisticated facility. Instead, the failure of a physician to make an appropriate referral may constitute medical negligence. Yet "failure" does not fit well with an informed consent claim.

L. Disciplinary History

It is well known that disciplinary action against a physician by a state medical licensing board rarely relates to quality of care issues.²⁵⁷ When disciplinary action does result from poor medical care, is the disciplined

^{253.} Id. at 260-61. See also, Robert Washecka & Amanda Behling, Urologic Complications of Placenta Percreta Invading the Urinary Bladder: A case Report and Review of the Literature, 61 HAW. MED. J. 66 (2002) (explaining placenta percreta and placenta accrete).

^{254.} Carrese, 90 A.3d at 270.

^{255.} Id. at 277.

^{256.} Id., n.36.

^{257.} See Nadia N. Sawicki, Character, Competence, and the Principles of Medical Discipline, 13 J. HEALTH CARE L. & POL'Y 285 (2010) (an analysis of the disciplinary functions of state medical licensing boards). But see James Morrison & Peter Wickersham, Physicians Disciplined by a State Medical Board, 279 JAMA 1889 (1998) (reporting on a substantial number of disciplinary matters relating to "negligence or incompetence.").

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physician obligated to disclose this disciplinary history to obtain a patient's informed consent? Does this disciplinary action create a risk to patients? A recent trial court opinion speaks to this issue.

In *McBreairty v. Body Cosmetica*,²⁵⁸ the trial court considered a motion to strike an informed consent claim focusing on a plastic surgeon's alleged failure to disclose "that his medical license in New York had been subject to discipline, and that his medical license was on probation in Connecticut at the time of the initial consultation [with the patient]."²⁵⁹ Plaintiff also alleged the surgeon's non-disclosure of required retraining, surgical monitoring, consent orders as to his Connecticut medical license, and various "complaints lodged against him over the years for reasons relating to patient safety and/or his skills as a plastic surgeon."²⁶⁰ Plaintiff also alleged that the defendant failed to inform her of the risks and complications of breast augmentation surgery.²⁶¹

The court reviewed the Connecticut law of informed consent, referring to the *Duffy v. Flagg*²⁶² factors, including "the risks and hazards of the procedure,"²⁶³ and stated that Plaintiff's "allegations certainly contain provider specific information which a jury could conclude would be 'material to a reasonable patient' so as to trigger a duty to disclose."²⁶⁴ Accordingly, Plaintiff "set forth a viable cause of action for informed consent."²⁶⁵

M. Qualifications of Treatment Personnel

Patients who seek surgical care at teaching institutions must accept that residents under the supervision of attending physicians will participate in surgery. The Supreme Court in New York recently emphasized this point in *Collado v. New York City Health & Hosp.*²⁶⁶ Here, an attending surgeon and a resident, supervised by the attending performed an eye surgery on a patient.²⁶⁷ Surgical complications occurred. Allegedly the patient was non-compliant with the surgeon's medication recommendations. The patient then had subsequent unsuccessful surgical procedures and lost her vision in one eye.²⁶⁸

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265. Id. at *4.

^{258.} No. CV156027857S, 2016 WL 5798785 (Conn. Super. Ct. Sept. 2, 2016).

^{259.} Id at *1.

^{260.} Id.

^{261.} Id.

^{262. 905} A.2d 15 (Conn. 2006).

^{263.} Id. at 20.

^{264.} McBreairty, 2016 WL 5798785, at *3.

^{266. 11} N.Y.S.3d 466 (N.Y. Sup. Ct. 2015).

^{267.} Id. at 466.

^{268.} Id. at 467.

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The court noted that by seeking treatment at the hospital, "[Plaintiff] 'consented to the customs and practices of that hospital,' which in hospitals with residency programs means residents performing supervised surgeries."²⁶⁹ Furthermore, the court held that "[t]here is no requirement in the context of informed consent to disclose the 'qualifications of personnel providing . . . treatment."²⁷⁰

N. Cost of Treatment

Currently, there are no reported judicial opinions on the topic of financial informed consent— the required disclosure to the patient of the cost of recommended treatment. However, this topic has not escaped scrutiny in medical and legal scholarship.²⁷¹ It has been urged that physicians have an ethical duty to engage patients in discussion of the cost of treatment²⁷² because financial informed consent is a component of patient autonomy.²⁷³ Various explanations have been advanced for why medical providers do not typically obtain a patient's financial informed consent:

- [P]hysicians typically lack accurate information about the cost of treatment.²⁷⁴
- Long-standing professional norms prevent discussion of fees before a physician cares for the sick.²⁷⁵
- Enormous accounting complexity causes both providers and patients to lack the capacity to negotiate and assent to a bill.²⁷⁶

These explanations aside, treatment decisions require physicianpatient information exchange, as recently articulated by the Eleventh Circuit Court of Appeals in *Silva v. Baptist Health South Florida*:²⁷⁷

There can be no question that the exchange of information between

^{269.} Id. at 470 (citations omitted).

^{270.} Id. at 472 (citation omitted).

^{271.} See Sawicki, supra note 2; see also Christopher Robertson, Should Patient Responsibility For Costs Change the Doctor-Patient Relationship?, 50 WAKE FOREST L. REV. 363 (2015); see also Barak D. Richman et al., Overbilling and Informed Financial Consent – A Contractual Solution, 367 N. ENGL. J. MED. 396 (2012); see also Alicia Hall, Financial Side Effect: Why Patients Should Be Informed of Costs, 44 HASTINGS CTR. REPORT 41 (2014); Cf. Timothy A. Caulfield & Diana E. Ginn, The High Price of Full Disclosure: Informed Consent and Cost Containment in Health Care, 22 Man. L.J. 328 (1994) (Canadian health care).

^{272.} Sawicki, supra note 2, at 849.

^{273.} Id.

^{274.} Id. at 849-50.

^{275.} Richman et al., supra note 271.

^{276.} Id.

^{277. 856} F.3d 824 (11th Cir. 2017). (Thanks to Prof. Thaddeus Pope of Mitchell/Hamline Law School for bringing this opinion to my attention).

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doctor and patient is part-and-parcel of healthcare services. Thus, regardless of whether a patient ultimately receives the correct diagnosis or medically acceptable treatment, that patient has been denied the equal opportunity *to participate* in healthcare services whenever he or she cannot communicate medically relevant information effectively with medical staff.²⁷⁸

The concept of financial informed consent is consistent with this principle.²⁷⁹

VI. DELEGABILITY OF DISCLOSURE

In a recent opinion, which profoundly impacts the Pennsylvania law of informed consent, the Supreme Court of Pennsylvania held that a physician may not delegate the duty to obtain a patient's informed consent to a surgical procedure.²⁸⁰ *Shinal v. Toms* concerned a medical negligence action arising from a neurosurgical procedure to remove "a recurrent non-malignant tumor from the pituitary region of [Plaintiff's] brain."²⁸¹ Various surgical options were available,²⁸² involving total or less than total removal.

The Plaintiff decided to have surgery but, following a meeting with the defendant, "the surgical approach had not yet been determined."²⁸³ During that meeting, the defendant-physician reviewed "the alternatives, risks, and benefits of total versus subtotal resection."²⁸⁴ Thereafter, Plaintiff had a telephone conversation and a meeting with the defendant-physician's physician assistant (PA).²⁸⁵ During these interactions, there

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Published by IdeaExchange@UAkron, 2019

^{278.} Id. at 834.

^{279.} The Appellate Court of Illinois recently decided *Turner v. Orthopedic & Shoulder Center*, *S.C.* involving a patient claim for consumer fraud and intentional infliction of emotional distress "premised on defendant's charging her more for medical services than the amounts that defendant had agreed to charge, in its contract with Plaintiff's health insurer." 82 N.E.3d 801, 802 (Ill. App. Ct. 2017). The court suggested that Plaintiff was a third-party beneficiary of the provider agreement between the health care provider and plaintiff's insurer. *Id.* at 808. If so, insured patients may be able to claim that they are entitled to know the cost of treatment to be paid by insurer to provider—perhaps only a "half-step" short of financial informed consent.

^{280.} Shinal v. Toms, 162 A.3d 429 (Pa. 2017).

^{281.} Id. at 433.

^{282.} See William F. Chandler & Ariel L. Barkan, Treatment of Pituitary Tumors: A Surgical Perspective, 37 ENDOCRINOL. METAB. CLIN. N. AM. 51 (2008); See also Gregory A. Kaltsas et al., Clinical Review: Diagnosis and Management of Pituitary Carcinomas, 90 J. CLIN. ENDOCRINOL METAB. 3089 (2005).

^{283.} Shinal, 162 A.3d at 434.

^{284.} Id.

^{285. &}quot;PAs are licensed health professionals, certified by a national examination process, who practice medicine with physician supervision." Roderick S. Hooker & Linda E. Berlin, *Trends in The Supply Of Physician Assistants and Nurse Practitioners in The United States*, 21 HEALTH AFFAIRS 174 (2002).

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were discussions about surgery, radiation, and the surgical incision. "The physician assistant obtained [Plaintiff's] medical history, conducted a physical, and provided [Plaintiff] with information relating to the surgery. [Plaintiff] signed an informed consent form."²⁸⁶

The defendant-physician performed "an open craniotomy total resection of the brain tumor" and "perforated [Plaintiff's] carotid artery, which resulted in hemorrhage, stroke, brain injury, and partial blindness."²⁸⁷ A medical negligence lawsuit ensued, "alleging that [the defendant-physician] failed to obtain [Plaintiff's] informed consent for . . . surgery"²⁸⁸ by "[failing] to explain the risks of surgery to [Plaintiff] or to offer her the lower risk surgical alternative of subtotal resection of the benign tumor, followed by radiation."²⁸⁹ On appeal, the state supreme court focused on the Pennsylvania informed consent statute²⁹⁰ and the defendant-physician's position, "that, while it is the physician's duty to obtain the patient's informed consent, the physician is not required to supply all of the information personally."²⁹¹ The Pennsylvania informed consent statute, in relevant part, provides as follows:

(a) **Duty of physicians**. Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

(1) Performing surgery, including the related administration of anes thesia.

(b) Description of procedure. Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide.²⁹²

The text of the statute clearly notes that the duty to obtain informed consent is owed by the physician— the statute is silent on the issue of delegability of the duty. Nevertheless, the state supreme court emphasized "that the duty to obtain informed consent belongs solely to the physician

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^{286.} *Shinal*, 162 A.3d at 434.

^{287.} Id.

^{288.} Id.

^{289.} Id. at 435.

^{290. 40} P.S. § 1303.504.504.

^{291.} Shinal, 162 A.3d at 452.

^{292. 40} P.S. § 1303.504.

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and that it is non-delegable."²⁹³ Furthermore, the court, in recognizing informed consent as more than a disclosure doctrine, stated:

[W]e hold that a physician cannot rely upon a subordinate to disclose the information required to obtain informed consent. Without direct dialogue and a two-way exchange between the physician and patient, the physician cannot be confident that the patient comprehends the risks, benefits, likelihood of success and alternatives.²⁹⁴ Were the law to permit physicians to delegate the provision of critical information to staff, it would undermine patient autonomy and bodily integrity by depriving the patient of the opportunity to engage in a dialogue with his or her chosen health care provider. A regime that would countenance delegation of the informed consent process would undermine the primacy of the physician-patient relationship. Only by personally satisfying the duty of disclosure may the physician ensure that consent truly is informed.²⁹⁵

Of course, the Pennsylvania informed consent statute, even if presumably requiring the non-delegable disclosure by the physician, simply does not suggest an informed consent dialogue, discussion, or conversation. The court in *Shinal* has engrafted that process on to the statute by judicial interpretation and stated, "[i]nformed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent."²⁹⁶

It will be interesting to determine if the *Shinal* opinion influences other courts to adopt its interpretation of the doctrine of informed consent, expanding it beyond a disclosure doctrine. How a court is able to analyze the communication process and patient understanding remains to be seen.

VII. REFERRING PHYSICIAN AND INFORMED CONSENT

On appeal from a denial of a physician's motion for summary judgment, a New York state appellate court recently pronounced that a referring physician may be subject to an informed consent claim.²⁹⁷ In *Odoardi v. Abramson*,²⁹⁸ plaintiff brought a medical negligence action arising from laser eye surgery. The appellant-physician urged "that he

^{293.} Shinal, 162 A.3d at 453.

^{294.} Id.

^{295.} Id.

^{296.} Id.

^{297.} Odoardi v. Abramson, 42 N.Y.S.3d 1 (N.Y. App. Div. 2016).

^{298.} Id.

cannot be liable on a claim for lack of informed consent because he was merely a referring physician."²⁹⁹ This argument failed on appeal as "unpersuasive in light of the evidence that he comanaged plaintiff's care and that the Lasik surgeon specifically relied upon Dr. Liberatore's examination to clear Plaintiff for the surgery."³⁰⁰

The brief opinion in *Odoardi* provides no specific analysis as to how a non-operating physician would obtain informed consent for a procedure he did not perform. Of concern would be the possibility of inconsistent disclosures by multiple physicians and patient confusion.

VIII. AN EVIDENTIARY ISSUE: ADMISSIBILITY OF THE INFORMED CONSENT DISCLOSURE IN A NON-INFORMED CONSENT MEDICAL NEGLIGENCE CLAIM

Quite recently, courts have considered an interesting evidentiary issue. Are the details of an informed consent disclosure relevant in a non-informed consent medical negligence claim? Evidence of this disclosure might be offered by plaintiff or defendant-physician if relevant to establishing compliance with or deviation from the standard of care. Keep in mind that relevance as defined by the Federal Rules of Evidence (and similar state rules) reflects a rather low bar to hurdle. Federal Rule of Evidence 401 provides that "[e]vidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."³⁰¹ "Essentially, Rule 401 requires that there be a logical relationship between the evidence sought to be introduced and a 'fact... of consequence' in the case."³⁰²

It may, therefore, be reasonable to propose a logical connection between the information disclosed by the physician and the physician's recognition of the standard of care. The informed consent disclosure suggests that the physician is capable (or incapable) of understanding the treatment or procedure which has been recommended.

The FRE 401 inquiry does not end the analysis because not all relevant evidence is admissible, pursuant to Federal Rule of Evidence 403, which provides that "[t]he court may exclude relevant evidence if its

^{299.} *Id.* Presumably, the appellant-physician was not the surgeon; however, he is an ophthalmologist. About Dr. Benjamin Liberatore, https://health.usnews.com/doctors/benjamin-liberatore-68161 (last visited 12/13/17); St. John's Riverside Hospital, https://doctors.riversidehealth.org/details/423/benjamin-liberato [https://perma.cc/HX7Y-5E9M].

^{300.} Odoardi, 42 N.Y.S. at 1.

^{301.} FED. R. EVID. 401.

^{302.} Martin A. Schwartz et al., *Trial Evidence 2011: Advocacy, Analysis, & Illustrations*, 28 TOURO L. REV. 1, 2 (2012).

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probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."³⁰³ A trial court may have concern that evidence of informed consent in a non-informed consent medical negligence trial might suggest to the jury that the plaintiff's awareness of risks and complications of a procedure or treatment indicates that the plaintiff consented to negligent treatment.³⁰⁴ Under these circumstances, relevant evidence (the informed consent disclosure) is legitimately excluded from evidence pursuant to FRE 403.³⁰⁵

Two very recent decisions worthy of comment are *Ehrlich v*. *Sorokin*³⁰⁶ and *Wilson v*. *Patel*.³⁰⁷ In *Ehrlich*, Plaintiff filed a medical negligence action, without an informed consent claim, following complications from a colonoscopy.³⁰⁸ At trial, over Plaintiff's objections, the trial court held that the informed consent disclosure was relevant to the standard of care.³⁰⁹ Additionally, "the trial judge allowed the jury to review Plaintiff's informed consent documents as part of its deliberation."³¹⁰ The jury returned a defense verdict.

On appeal, the appellate court noted that New Jersey case law had not yet addressed "the admissibility of informed consent evidence where the plaintiff has only asserted a claim of negligent treatment."³¹¹ After reviewing the case law of various jurisdictions, the appellate court concluded that the informed consent evidence was inadmissible, and its admission was reversible error.³¹² The appellate court essentially based its determination on a relevance analysis, including the danger that admissibility may lead the jury to believe that the patient's consent to the procedure implies consent to an injury.³¹³

*Wilson*³¹⁴ involved a medical negligence claim following complications of esophageal dilation, requiring reparative thoracic surgery. Plaintiff claimed that the defendant-physician performed an unnecessary procedure—Plaintiff neither claimed lack of informed

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^{303.} FED. R. EVID. 403.

^{304.} See Brady v. Urbas, 111 A.3d 1155, 1162 (Pa. 2015).

^{305.} FED. R. EVID. 403.

^{306. 165} A.3d 812 (N.J. Super. Ct. App. Div. 2017).

^{307. 517} S.W.3d 520 (Sup. Ct. Mo. 2017).

^{308.} See Theodore R. Levin et al., Complications of Colonoscopy in an Integrated Health Care Delivery System, 147 ANN. INTERN. MED. 212 (2007).

^{309.} *Ehrlich*, 165 A.3d at 816.

^{310.} Id. at 817.

^{311.} Id. at 818.

^{312.} Id. at 819.

^{313.} Id. at 820.

^{314. 517} S.W.3d 520 (Sup. Ct. Mo. 2017).

consent nor did the defendant-physician raise an affirmative defense based on informed consent.³¹⁵ Defendant's counsel referred to informed consent during opening statement, cross-examined Plaintiff on this topic and referred to informed consent during defendant's direct examination.³¹⁶ The judge provided the jury a consent form to examine during deliberations and the jury returned a defense verdict.³¹⁷

On appeal, the Supreme Court of Missouri identified the informed consent evidentiary issue as one of first impression.³¹⁸ After reviewing decisions from other jurisdictions³¹⁹ the court stated that it "joins the chorus of other state supreme courts and holds that evidence of alleged informed consent is irrelevant and can only mislead the jury in a medical malpractice case based on negligent performance of care and treatment."³²⁰

In Brady v. Urbas, 321 the Supreme Court of Pennsylvania considered this issue in a podiatry negligence case, not including an informed consent claim. The defendant-podiatrist performed four surgical procedures, obtaining Plaintiff's consent for each. Plaintiff alleged negligence in the last three procedures. At trial, Plaintiff moved in limine to exclude evidence of her surgical consents, based on relevance and prejudice. The judge denied the motion. The defendant-podiatrist had urged that the evidence was relevant to Plaintiff's "credibility as a witness and to her state of mind at the time of the surgeries." After a jury verdict for the defendant-podiatrist and a reversal on appeal, the Supreme Court of Pennsylvania affirmed, noting that "the fact that a patient may have agreed to a procedure in light of the known risks does not make it more or less probable that the physician was negligent in either considering the patient an appropriate candidate for the operation or in performing it in the postconsent timeframe."³²² This, of course, is a relevance analysis pertaining to the podiatrist's conduct.

The Court of Appeals of Nebraska considered the same issue in *Hillyer v. Midwest Gastrointestinal Associates*.³²³ Here, Plaintiff alleged that her colon was perforated during a colonoscopy performed by the

^{315.} Id. at 522.

^{316.} Id.

^{317.} Id. at 523.

^{318.} Id. at 524.

^{319.} Id. at 524-25.

^{320.} Id. at 526.

^{321. 111} A.3d 1155, 1162 (Pa. 2015).

^{322.} Id. at 1162.

^{323. 883} N.W.2d 404 (Neb. Ct. App. 2016).

defendant.³²⁴ Additional serious complications resulted.³²⁵ At trial, the court admitted evidence of the defendant's "discussions with [Plaintiff] and other patients regarding risks and complications associated with colonoscopies."³²⁶ The defendant "was allowed to testify that with every patient, he goes through the list of complications and risks for the procedure, including perforations and the potential need for surgery."³²⁷ Although the court of appeals did not adopt a *per se* rule of inadmissibility after reviewing the law of other jurisdictions, it did "hold, as a matter of first impression, that evidence of risk-of-procedure or risk-of-surgery discussions with the patient is generally irrelevant and unfairly prejudicial where the plaintiff alleges only negligence, and not lack of informed consent."³²⁸ Therefore, the court of appeals holding implicates both the logical connection of the evidence to medical negligence and the potential prejudice to Plaintiff even if the evidence is relevant.

It is likely that the "substance" of the informed consent disclosure (discussion) can be admissible to prove the defendant-physician's knowledge or ignorance of the standard of care if the litigants simply are prohibited by the trial court from linking the proposed medical treatment/procedure, risks, and complications to the patient's consent in a non-informed consent case. In this fashion, the focus is on the physician's awareness of the applicable standard of care and the jury will not be inclined to believe that the patient "consented" to the alleged medical negligence.³²⁹

IX. CONCLUSION

The intent of this paper is to explore the landscape of the unconventional aspects of informed consent, focusing primarily on the physician's duty to disclose. The law of informed consent has continued to develop since *Canterbury v. Spence*,³³⁰ implicating issues certainly not contemplated more than forty-five years ago. I suspect the doctrine may continue to expand and yield scholarship on topics not previously examined in depth.

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^{324.} Id. at 407.

^{325.} Id.

^{326.} Id.

^{327.} Id. at 408.

^{328.} Id. at 412.

^{329.} For other judicial opinions adopting this approach, see Baird v. Owczarek, 93 A.3d 1222 (Del. 2014); Warren v. Imperia, 287 P.3d 1128 (Or. Ct. App. 2012); Schwartz v. Johnson, 49 A.3d 359 (Md. Ct. Spec. App. 2012); Hayes v. Camel, 927 A.2d 880 (Conn. 2007); Wright v. Kaye, 593 S.E.2d 307 (Va. 2004).

^{330.} Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

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In a sense, informed consent is a legal doctrine which intrudes on the practice of medicine. The case law discussed in this paper imposes disclosure requirements on physicians by courts—courts which, typically, are not students of medicine.³³¹ The results (overbreadth of the doctrine) are potentially disastrous for physicians and patients, as occurred some years ago in Wisconsin.³³²

As the examination of informed consent continues, so should the analysis of whether true informed consent is possible or desired by most patients. For an accurate analysis, courts must be mindful of both medicine and the law.

^{331.} Of course, the court may interpret informed consent statutes, promulgated by legislators who, typically, are not students of medicine.

^{332.} See Ginsberg, supra note 227.