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THE MYSTERIOUS SURVIVAL OF THE POLICY AGAINST INFORMED CONSENT LIABILITY FOR HOSPITALS

*Robert Gatter**

INTRODUCTION

The last year has seen something old and something new concerning hospitals, informed consent, and the law. At least four appellate courts in 2005 have reiterated the old rule that hospitals generally do not have a duty to obtain the informed consent of their patients prior to treatment.¹ In each case, the court's opinion offers little anal-

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1 See *Foster v. Traul*, 120 P.3d 278, 281–82 (Idaho 2005) (affirming dismissal of claims that a hospital's nurse negligently failed to assure that the informed consent had been obtained prior to treatment and that hospital had an independent duty to obtain informed consent, where the plaintiff failed to produce any evidence of the nursing standard of care with respect to informed consent, and where the statute provides that doctors have a duty to obtain informed consent and that hospitals may perform ministerial informed consent tasks without practicing medicine); *Mohsan v. Roule-Graham*, 907 So. 2d 804, 806 (La. Ct. App. 2005) (dismissing claim that the hospital, through its nurses, failed to document the patient's consent to a hysterectomy affirmed by state intermediate appellate court where precedent existed holding that hospitals do not have a duty to obtain informed consent); *Daniels v. Durham County Hosp. Corp.*, 615 S.E.2d 60, 64–65 (N.C. Ct. App. 2005) (dismissing claim against a hospital for nurse's failure to obtain informed consent affirmed by state intermediate appellate court where precedent existed holding that hospitals do not have a duty to obtain informed consent, where the state supreme court opinion on point had no precedential value because that court had been evenly split on whether hospitals have a duty to obtain informed consent, and where the plaintiff failed to produce evidence that hospital policy required nurses to obtain informed consent).

Less clear is the ruling in *Bailey v. Owens*, 793 N.Y.S.2d 40 (App. Div. 2005), where an intermediate state appellate court affirmed summary judgment for a hospital on

ysis of the public policy underlying its ruling, and instead each does little more than cite to precedent or a statute in support of its conclusion.² Prior case law, however, reveals underlying assumptions that only doctors have the expertise necessary to lead patients through the informed consent process and that hospitals merely assist physicians in carrying out the ministerial tasks related to that process.³

At the same time—and in stark contrast to the law's assumptions—hospitals made news by implementing systems that direct the process by which their physicians seek the informed consent of patients to hospital-based treatments. In particular, hospitals have installed multimedia platforms designed to walk patients and doctors through the process of explaining patients' treatment options, disclosing the risks and benefits of those options, recording patients' consent or refusal of treatments, and incorporating the record of informed consent into patients' medical charts. For example, in April 2005, it

an informed consent claim. The rule was based on both the hospital's producing a form signed by the patient authorizing the allegedly unauthorized treatment and the patient's failure to produce evidence that the hospital knew or should have known that informed consent was lacking. Because the opinion focuses on the breach element of the claim, and because it skips the element of duty in its analysis, it could be interpreted to suggest that the hospital had an informed consent duty. This interpretation is undercut, however, by the court's citation of *Cirella v. Cent. Gen. Hosp.*, 630 N.Y.S.2d 93, 94 (App. Div. 1995) (citing *Porandon v. Karp*, 490 N.Y.S.2d 904 (App. Div. 1985)), where the Supreme Court Appellate Division held that, under the state's informed consent statute, hospitals do not have a duty to obtain informed consent. Thus, *Bailey* is best interpreted as a case holding that hospitals do not have a duty to obtain their patients' informed consent and, even if such a duty existed, the plaintiff failed to produce evidence tending to establish any breach.

Also noteworthy is *Gotlin v. Lederman*, 367 F. Supp. 2d 349 (E.D.N.Y. 2005), which, in the course of recognizing that hospitals can under narrow circumstances be vicariously liable for the failure of their affiliated physicians to obtain a patient's informed consent, reiterated the principle that hospitals do not owe a direct duty to patients to obtain their informed consent. *Id.* at 361–62. Here, a federal district court, applying New York's informed consent law, denied a motion to dismiss an informed consent claim against a hospital. The complaint alleged that several doctors at the hospital, who were acting as the hospital's agents, made false marketing claims about a cancer treatment offered at the hospital in the hopes of attracting cancer patients from outside of the United States. *Id.* at 352–53. In denying the motion, the court ruled that New York's informed consent statute applies only to physicians. *Id.* at 362. Nonetheless, the court noted that hospitals can be held vicariously liable for treatment provided by their physicians without informed consent if an agency relationship can be established. *Id.* It then reasoned that dismissal of the plaintiffs' complaint for failure to state a cognizable claim is inappropriate because the complaint alleges that an agency relationship existed between the doctors and the defendant hospital. *Id.*

² See *supra* note 1.

³ See *infra* notes 31–45 and accompanying text.

was reported that the U.S. Department of Veterans Affairs was completing its installation of an automated informed consent application known as iMedConsent in each of its 162 medical centers nationwide so as to improve the quality of treatment disclosures and prevent the loss of paper consent forms.⁴ The VA is not alone. According to a July 2005 KPMG health care industry analysis, hospitals across the country are piloting similar multimedia informed consent aids, including HCA, which operates 190 U.S. hospitals.⁵

Thus, while hospitals have embarked on a plan to exert unprecedented control of the informed consent process, courts remain true to established law, which presumes that control over—and, consequently, responsibility for—informed consent should reside exclusively with physicians.⁶ Given the conflict, one would assume that a change in the law is simply a matter of time.⁷

This Article argues, however, that a change in the law's policy against imposing informed consent duties on hospitals based on the new role that hospitals are poised to play in the informed consent process is unlikely. Instead, it claims that, if the history of this nearly forty-year-old policy is any indication, it will survive these changes in the clinical practice of informed consent just as it has routinely sur-

4 See Beckie Kelly Schuerenberg, *Consent App Gets OK from VA Center*, HEALTH DATA MGMT., Mar. 2005, <http://www.healthdatamanagement.com/html/current/PastIssueStory.cfm?ArticleID=10742&issuedate=2005-04-01>.

5 See Richard Merli, *Managing the Malpractice Storm Online*, KPMG HEALTH CARE INSIDER, July 14, 2005, http://www.kpmginsiders.com/display_analysis.asp?cs_id=136915.

6 Hospitals are not the only institutional health care providers to interject themselves into the informed consent process. There is evidence that managed care organizations are becoming similarly involved. See Healthwise, Online Information Solutions, http://www.healthwise.org/p_online_cont.aspx#top (last visited Feb. 8, 2005) (reporting that eight of the nation's top ten managed care organizations use Healthwise databases to provide information to their members); see also Frances H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, 31 IND. L. REV. 1019, 1040 (1998) (comparing the involvement of managed care organizations in informed consent with the involvement of hospitals). Nonetheless, this Article is limited to the consideration of hospitals because there is a significant history of informed consent claims against hospitals while very few such claims have been brought against managed care organizations.

7 Professor Fran Miller predicted in a 1998 article that, as hospitals continue to take an ever greater role in educating patients about their conditions and treatment options, it is only a matter of time before the law recognizes that the standard of care for hospitals in the informed consent arena has changed. See Miller, *supra* note 6, at 1040; see also Shelley S. Fraser, Note, *Hospital Liability: Drawing a Fine Line with Informed Consent in Today's Evolving Health Care Arena*, 1 IND. HEALTH L. REV. 253, 277 (2004) (concluding that the time may have arrived when the law will begin to hold hospitals accountable for their role in the informed consent process).

vived so many similar changes before. It has persisted despite a steady expansion of the institutionalization of informed consent. It has also survived the discovery that physicians generally fail to communicate treatment information in ways that enable patients to understand that information. Additionally, the policy has remained intact even as courts have diminished the role of medical expertise in informed consent law, and even as federal regulations impose a duty on hospitals to oversee informed consent related to any human subjects research they house. Furthermore, the policy has outlasted a historic expansion of hospital liability for treatment injuries based on both vicarious and direct corporate liability doctrines.

The staying power of the law's policy is remarkable in part because it has bucked so many of these trends, and in part because the policy has done so without changing its underlying rationale. Mysteriously, courts continue to claim that informed consent is a process driven primarily by medical expertise and, consequently, that hospitals are incapable of overseeing it despite the fact that these claims are contradicted by current policy and practices concerning both informed consent and health care quality assurance. Indeed, this Article challenges each of the law's claims and finds them to be outdated and unpersuasive. Given that the law's policy against imposing informed consent duties on hospitals has survived nonetheless, this Article concludes that some other rationale must be at work and that this rationale has yet to be articulated.

As a result of this analysis, this Article not only proposes a redistribution of informed consent responsibilities among physicians and hospitals, it also predicts that the law will not adopt such a redistribution unless the reasons for the law's existing policy are more clearly articulated and accounted for. This Article then takes on this task, hypothesizing that the law's policy reflects a misguided effort by courts to preserve the trustworthiness of medicine and the medical profession. The trust hypothesis is tested against clues offered by courts about why the policy against imposing informed consent duties on hospitals is worth preserving. Additionally, it is bolstered by other sources confirming the perception that the doctor-patient relationship is fiduciary in nature and, more importantly, that the informed consent process is fundamental to sustaining that trust relationship. Finally, this Article provides a complete picture of medical trust based upon recent analysis of the phenomenon and demonstrates that the law best preserves medical trust by recognizing that hospitals and physicians are cofiduciaries that enter into a treatment relationship with a hospital patient. This, in turn, supports the view that a policy of making the informed consent process the exclusive turf of physicians is

erroneous and that redistributing responsibilities between these confiduciaries is a better strategy.

This Article begins in Part I with an analysis of the case law addressing informed consent claims against hospitals and the policy against imposing informed consent duties on hospitals established therein. Part II then tracks the policy's survival despite several conflicting clinical and legal trends, and it concludes with a set of proposed institutional informed consent duties. These institutional duties include (1) a duty to require that physicians on staff obtain the informed consent of their patients prior to any treatments provided at the hospital, (2) a duty to assure that no treatment is provided in the hospital without prior verification that the patient has provided an informed consent to the proposed treatment, (3) a duty for hospitals to include in their quality assurance programs the monitoring of informed consent practices, (4) a duty to assure that any treatment information disseminated by hospitals directly to patients is accurate, complete, understandable, and equally accessible to all similarly situated patients, and (5) a duty to assure that any individuals assigned by a hospital to assist informed patients in the decisionmaking process are qualified to provide such assistance and that they are reasonably available to patients when needed. Finally, Part III presents the trust hypothesis to both account for the policy's persistence and argue for its reform.

I. THE LAW'S POLICY AGAINST IMPOSING INFORMED CONSENT DUTIES ON HOSPITALS

While physicians have a legally enforceable duty to obtain the informed consent of their patients prior to treatment, hospitals generally do not. As demonstrated below, courts almost universally refuse to impose duties on hospitals to disclose treatment information to their patients or to verify that hospital patients received treatment information from their treating physicians. In some jurisdictions, courts even refuse to recognize a hospital's duty to assure that patients have consented to treatment, regardless of whether consent is sufficiently informed. In virtually every case, courts refuse to impose such duties out of deference to physicians' expertise and for the purpose of preserving the sanctity of the doctor-patient relationship. Although the law recognizes circumstances in which a hospital can be liable in an informed consent claim—such as where the hospital employs the breaching physician or where the breach concerned participation in medical research housed by the hospital—these circumstances are so narrowly tailored that they are unlikely to affect how hospitals provide

treatment information to patients in the vast majority of daily patient encounters. Moreover, the recent trend among courts appears to favor strict adherence to the traditional policy of protecting against hospital intrusion into the informed consent process. All of this is described in detail below following a brief overview of the informed consent doctrine.

A. *Informed Consent Law: A Short Primer*

Informed consent is a legal doctrine that enables individuals injured as a result of unauthorized medical treatments to receive compensation from the treating physician.⁸ It does so by imposing two related duties on physicians.⁹ First, it obligates physicians to disclose

8 See generally JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 41–164 (2d ed. 2001); RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 25–39, 114–50 (1986); JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 48–84 (2002). For a brief overview of informed consent law, see Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 *LOV. U. CHI. L.J.* 557, 561–67 (2000).

9 The distinction between the two duties can be difficult to detect in case law, but it is most often revealed in the subtleties of the language courts use to describe the informed consent doctrine. See, e.g., *Collins v. Am. Home Prods. Corp.*, No. Civ.A. 3:01CV979LN, 2001 WL 34073167, at *7 (S.D. Miss. June 21, 2001) (referring to the duty to warn patients about treatment risks and the duty to obtain consent to treatment as “twin duties”); *Van Sice v. Sentany*, 595 N.E.2d 264, 267 (Ind. Ct. App. 1992) (referring to the informed consent doctrine as containing “duties to disclose information and obtain informed consent”); *Hannemann v. Boyson*, 698 N.W.2d 714, 728 (Wis. 2005) (referring to the state’s informed consent doctrine as imposing duties to “disclose [information] and obtain [consent]”). The distinction courts draw between claims for unauthorized treatment and claims for insufficiently informed consents to treatment more clearly reveal that the doctrine imposes duties to both inform patients of treatment information and perform only treatments that are authorized by patients. See, e.g., *Blanchard v. Kellum*, 975 S.W.2d 522, 524 (Tenn. 1998) (distinguishing between “cases in which a doctor performs an unauthorized procedure” and cases in which “the patient claims that the doctor failed to inform the patient of any or all the risks inherent in the procedure”); *Bundrick v. Stewart*, 114 P.3d 1204, 1208 (Wash. Ct. App. 2005) (distinguishing between a claim for a physician’s failure to obtain consent at all and a claim for a physician’s failure to disclose treatment information). Similarly, pattern jury instructions indicate a distinction between a physician’s obligation to obtain consent and her obligation to provide information to her patients on which they can make an intelligent choice about whether or not to consent to proposed treatments. Compare, e.g., *CIVIL COMM. ON CAL. JURY INSTRUCTIONS, CALIFORNIA JURY INSTRUCTIONS—CIVIL (BAJI) § 6.10* (2005) [hereinafter *BAJI*] (providing that “a physician has a duty to obtain the consent of a patient before treating or operating on the patient”), with *id.* § 6.11 (providing that “a physician has a duty to disclose to the patient all material information to enable the patient to make an informed decision regarding the proposed operation or treatment”); *MINN. DIST. JUDGES ASS’N COMM. ON JURY INSTRUCTIONS GUIDES—CIVIL (CIVJIG) § 80.22* (identify-

information to their patients that is material to the treatment decisions their patients will make.¹⁰ Second, the doctrine requires a physician to abstain from treating a patient until the patient has consented to the treatment.¹¹ Thus, a physician can be held liable under the doctrine if she fails to obtain her patient's consent,¹² or if she obtains her patient's consent but does so without first providing the patient with adequate treatment information.¹³

If a patient is treated without her consent, treatment is unauthorized, and the informed consent claim generally takes the form of a battery cause of action.¹⁴ Such "no-consent" cases are rare. Far more

ing the duty of a physician to obtain a patient's consent prior to treatment), *with id.* § 80.25 (identifying the duty of physicians to disclose treatment information to patients); 1B COMM. ON PATTERN JURY INSTRUCTIONS ASS'N OF SUPREME COURT JUSTICES, NEW YORK PATTERN JURY INSTRUCTION—CIVIL § 2:150A (3d ed. 2006), *with* 2 COMM. ON PATTERN JURY INSTRUCTIONS ASS'N OF SUPREME COURT JUSTICES, NEW YORK PATTERN JURY INSTRUCTION—CIVIL § 3.3 (2d ed. 2006). Finally, secondary sources acknowledge that informed consent doctrine imposes two related duties. *See, e.g.*, Paula Walter, *The Doctrine of Informed Consent: A Tale of Two Cultures and Two Legal Traditions*, 14 ISSUES L. & MED. 357, 366–67 (1999) (identifying the two duties).

10 *See* BAJI, *supra* note 9, § 6.11 (providing that "[a] physician has a duty to disclose to the patient all material information to enable the patient to make an informed decision regarding the proposed operation or treatment" and indicating that this instruction should be combined with instruction 6.10).

11 *See* BAJI, *supra* note 9, § 6.10 (stating that "[a] physician has a duty to obtain the consent of a patient before treating or operating on the patient").

12 *See, e.g.*, *Duncan v. Scottsdale Med. Imaging, Ltd.*, 70 P.3d 435 (Ariz. 2003) (recognizing patient's informed consent claim against health care provider for allegedly administering a pain medication other than one of the two medications authorized by the patient).

13 *See, e.g.*, *Scaria v. St. Paul Fire & Marine Ins. Co.*, 227 N.W.2d 647 (Wis. 1975) (concerning patient, who was paralyzed as a result of test in which contrast dye was injected into his arteries through a catheter, claiming a lack of informed consent because the physician failed to disclose the risk of paralysis associated with the procedure at the time the patient consented).

14 *See* *Mole v. Jutton*, 846 A.2d 1035, 1045–48 (Md. 2004) (rejecting argument of plaintiff that she was entitled to bring her informed consent claim on a battery theory and holding that the battery version of an informed consent claim applies only where treatment was provided without any consent or when the treatment exceeded the bounds of the patient's consent).

In "no-consent" cases, the compensable harm includes not only any negative consequences of treatment, but also the treatment itself, and this is true even if the treatment is a technical success. *See, e.g.*, *Harvey v. Strickland*, 566 S.E.2d 529, 536 n.4 (S.C. 2002) (rejecting physician's argument that proof of the patient's receiving blood products that the patient had expressly refused was insufficient to establish a legally cognizable injury in a battery-based informed consent claim). Causation tends to be uncontroversial, so long as the claimed harm to the patient is the sort that would result from the kind of treatment received. *See* *Montgomery v. Bazaz-Sehgal*, 798 A.2d 742, 750–51 (Pa. 2002) (identifying, in the course of addressing the need for

common is the informed consent claim alleging that a physician has breached the duty to disclose adequate treatment information to patients prior to obtaining the consent of the patient to treatment. In those cases, the plaintiff has consented to treatment, but she claims that her physician failed to provide her with sufficient information on which to base her treatment decision and that she was harmed as a result.¹⁵

Unlike claims alleging completely unauthorized treatment, claims based on a breach of the physician's duty to disclose generally sound in negligence.¹⁶ They require physicians to disclose "material" treatment information to patients.¹⁷ Although the law in every state imposes such a duty, states are divided about how best to define its scope, with roughly half requiring physicians to disclose information that a reasonable person would consider significant to the treatment decision at hand,¹⁸ and the other jurisdictions directing doctors to disclose information that a reasonably prudent physician would dis-

expert testimony as to causation in a battery-based claim for total lack of consent, that plaintiff need only establish that the claimed injuries arose from the unauthorized medical treatment).

15 Most often, plaintiffs claim that their physicians failed to disclose a risk of harm associated with the authorized procedure. *See, e.g., Scaria*, 227 N.W.2d at 650 (discussing failure to disclose risk of paralysis from catheterization). Claims can also be based on a failure of the physician to disclose other kinds of treatment information, such as the patient's prognosis, *see, e.g., Martin v. Richards*, 531 N.W.2d 70, 73 (Wis. 1995) (alleging failure to disclose that head injuries could result in an intracranial bleed), or alternative treatment to the one proposed by the physician, *see, e.g., id.* (alleging failure to disclose option of an immediate CT scan to diagnose severity of head injuries).

16 *See* BERG ET AL., *supra* note 8, at 134–36. Pennsylvania law is a notable exception. In that jurisdiction, all claims for the failure to obtain informed consent sound in battery whether based on a breach of the duty to obtain consent or a breach of the duty to disclose treatment information. The Pennsylvania Supreme Court, when reviewing the decision of an intermediate court of appeals, stated,

The Superior Court also erred in further distinguishing informed consent from medical battery premised upon the alleged applicability of negligence principles in informed consent cases. . . . No such distinction exists in our jurisprudence. *Lack of consent for surgery involves the same general concept without regard to whether consent was uninformed or completely lacking. The result is the same—the patient is subjected to a surgical procedure to which he did not consent.*

Montgomery, 798 A.2d at 749 (emphasis added) (citation omitted). The battery basis of informed consent claims in Pennsylvania has been retained in the codified version of the claim. *See* 40 PA. CONS. STAT. ANN. § 1303.504 (West Supp. 2005); *Kremp v. Yavorek*, No. 99 CV 3759, 2002 WL 31730629 (Pa. Ct. Com. Pl. May 24, 2002) (interpreting the almost identical predecessor to the current statute).

17 *See, e.g., Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cir. 1972).

18 *See* Gatter, *supra* note 8, at 563 & n.40.

close in the same or similar circumstances.¹⁹ The split among the jurisdictions is largely explained by a difference of opinion about whether or not the identification of treatment information to disclose is a matter of medical expertise.²⁰

A plaintiff who establishes a breach of the duty to disclose material treatment information must also prove that the inadequate disclosure caused her to consent to treatment.²¹ This requires the plaintiff to prove that a reasonable person with the information that was wrongfully withheld from the patient would have refused the treatment that allegedly harmed the plaintiff.²² Additionally, the plaintiff must establish that the treatment to which she consented was a substantial factor in causing the claimed injuries.²³ Where the claim concerns a failure to disclose an alternative treatment, the plaintiff must establish that she would have avoided the claimed injury had she received the alternative treatment.²⁴ Where the claim concerns a failure to disclose a treatment risk, the plaintiff must establish that the undisclosed risk actually materialized in her case.²⁵

In summary, informed consent law compensates individuals for injuries resulting from unauthorized medical treatments under a battery theory. Additionally, it permits a patient to recover damages for injuries resulting from a bad treatment outcome that would likely have been avoided had the patient been informed of all reasonable treatment options or injuries resulting from an undisclosed risk of treatment that the patient would not have voluntarily assumed had it been made known.

19 See, e.g., *Fain v. Smith*, 479 So. 2d 1150, 1152 (Ala. 1985).

20 See BERG ET AL., *supra* note 8, at 46–51; see also *Woolley v. Henderson*, 418 A.2d 1123, 1131 (Me. 1980) (rejecting the reasonable person standard and adopting the prudent physician standard for disclosure and reasoning that the law avoids “placing good medical practice in jeopardy” and that it must work to keep “[t]he physician’s attention . . . focused on the best interests of his patient and not on what a lay jury, unschooled in medicine, may, after the fact, conclude he should have disclosed”); KATZ, *supra* note 8, at 81 (quoting a Wisconsin Supreme Court justice who wrote that while “[c]hildren play at the game of being a doctor, . . . judges and juries ought not to”). Katz sees claims of medical expertise used to justify legal rules, such as the use of the prudent physician disclosure standard over the reasonable person standard, as part of a larger political struggle of the medical profession to maintain its authority and to prevent lay interference in matters of medicine. See *id.* at 30–47.

21 See BERG ET AL., *supra* note 8, at 138–40.

22 See, e.g., *Bernard v. Char*, 903 P.2d 667, 676 (Haw. 1995).

23 See BERG ET AL., *supra* note 8, at 137–38.

24 See Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 329 n.225 (1999).

25 See *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972); *McMahon v. Finlayson*, 632 N.E.2d 410, 412 (Mass. App. Ct. 1994).

The history of informed consent law is one largely of disappointed expectations. In part, this is because the legal doctrine is founded upon,²⁶ and repeatedly judged against,²⁷ a set of ethical aspirations that are difficult for the law to satisfy in practice. For example,

26 Historically speaking, the legal doctrine preceded and inspired the ethical doctrine. See FADEN & BEAUCHAMP, *supra* note 8, at 91–98. In fact, the leading history on informed consent claims that “[i]nformed consent is a creature originally of law and later snatched from the courts by interdisciplinary interests and spearheaded by . . . [philosophical] ethics.” *Id.* at 92.

This is not to say that informed consent law is not affected by ethics. Judges ruling on informed consent cases prior to development of the ethical doctrine in the late 1970s refer to broad notions of self-determination and autonomy in an apparent effort to establish an ethical foundation for the legal rules they apply. See, e.g., *Canterbury*, 464 F.2d at 780 (identifying the right to bodily integrity as “[t]he root premise . . . fundamental in American jurisprudence”); *Pratt v. Davis*, 118 Ill. App. 161 (1905) (proclaiming the right to bodily integrity as “the first and greatest right” of free citizens, which is universally accepted among free governments); *Natanson v. Kline*, 350 P.2d 1093, 1104 (Kan. 1960) (“Anglo-American law starts with the premise of thorough-going self-determination.”); *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914) (announcing that each person has “the right to determine what shall be done with his own body”), *abrogated by* *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957). Moreover, the law has attempted to account for advances in the ethical doctrine beginning in the 1980s. For example, case law exists that expressly refers to the ethical doctrine. See, e.g., *Haley v. United States*, 739 F.2d 1502, 1506–07 (10th Cir. 1984) (quoting a passage from JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 92 (1984), to justify the application of a disclosure rule to the facts of the case); *Arato v. Avedon*, 858 P.2d 598, 605–06 (Cal. 1993) (referring to the debate concerning the gap between the aspirations of the doctrine and its practical implementation); *In re Farrell*, 529 A.2d 404, 418 (N.J. 1987) (O’Hern, J., concurring) (referring to the concept of “shared decisionmaking” as proposed by the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research to help resolve a case involving a refusal of life-sustaining medical treatment). Additionally, legal academics routinely use the ethical aspirations of informed consent as a basis from which to critique the legal doctrine and propose changes to it. See BERG ET AL., *supra* note 8, at 146–61 (reviewing scholarly criticism of informed consent law).

27 See, e.g., FADEN & BEAUCHAMP, *supra* note 8, at 274–87 (distinguishing between informed consent as an ethical doctrine that requires autonomous authorization of medical treatment and informed consent as a set of institutional rules—including legal rules—designed to determine if consent to treatment is valid, and recognizing that, while legal rules fail to satisfy the ethical doctrine, they should nonetheless be modeled after the ethical doctrine); KATZ, *supra* note 8, at 48–84 (contrasting the holdings in informed consent cases, which construed the rights of patients narrowly and the discretion of physicians broadly, with the proclamations of courts in those cases that informed consent law protects patient self-determination); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 903–04 (1994) (identifying the common practice among informed consent “idealists” to criticize the legal doctrine of informed consent based on its failure to achieve the goals of the ethical doctrine). Katz concludes that “[j]udges toyed briefly with the idea of patients’ right to self-determination and largely cast it aside.” KATZ, *supra* note 8, at 82.

underlying the informed consent are ethical principles demanding that medicine respect patient autonomy and pursue shared decision-making between a doctor and patient.²⁸ Shared decisionmaking imagines that a doctor and a patient work in tandem to help the patient arrive at an autonomous decision, with the doctor acting as the medical expert and the patient acting as expert as to her values and preferences. Despite requiring that physicians provide treatment information to patients, informed consent law falls short of realizing shared decisionmaking because it does not require physicians to assure that patients understand the information that is provided to them²⁹ or to help patients identify and apply their own values to the treatment information provided. Consequently, it is possible for a physician to merely warn patients about treatment risks in order to comply with the law and yet fall far short of the shared decisionmaking ideal.

B. The Policy Against Imposing a Duty for Hospitals To Disclose Treatment Information

The distinction between cases involving duty to disclose treatment information and cases involving the duty to obtain consent prior to treatment, discussed above, remains important in informed consent cases brought against hospitals. Other ancillary duties arise in each of these kinds of cases as well. For example, cases alleging a breach of the duty to obtain patient authorization may also allege that a hospital has a duty to document patient consent and a duty to identify and resolve any discrepancies between treatments being provided and treatments authorized in the consent documents. Cases involving inadequately informed consent, on the other hand, may also address the duty of the hospital to require the physician to provide treatment information and a duty to assure that the physician has done so.

While courts have often disregarded the difference between cases alleging inadequately informed consent and cases alleging a complete absence of consent, these distinctions provide a useful structure for categorizing cases and analyzing them as a whole.³⁰ Thus, the analysis

28 See FADEN & BEAUCHAMP, *supra* note 8, at 3–20, 91–101; KATZ, *supra* note 8, at 48–84.

29 See, e.g., *Canterbury*, 464 F.2d at 780 n.15 (explaining that the law treats physician's disclosure as a proxy for patient's understanding).

30 There are cases in which this distinction is difficult to discern. For example, *Campbell v. Pitt County Memorial Hospital, Inc.*, 352 S.E.2d 902 (N.C. Ct. App.), *aff'd*, 362 S.E.2d 273 (N.C. 1987), involved an alleged duty to assure that a patient's attending physician obtained the patient's informed consent to treatment. Under the facts of the case, the patient complained that she had not received information about her

below will begin with cases addressing the claimed duty of hospitals to disclose treatment information and the related duty to assure that a patient's physician has provided such information. It will then move to a discussion of the duty of hospitals to prevent treatment in the absence of consent and the related duty of documenting consent and resolving discrepancies between the consent documentation and actual treatment.

Ironically, the history of the law's policy against imposing on hospitals a duty to disclose treatment information or a duty to assure that the patient's physician has made such disclosures begins with a case upholding such a duty. In 1966 an intermediate New York appellate court in *Fiorentino v. Wenger*³¹ upheld a verdict against a hospital based on the hospital's failure to assure that treatment information had been disclosed to the plaintiff.³² In that case, a fourteen-year-old boy suffering from a curvature of the spine died from complications of experimental spinal surgery.³³ The surgery involved attaching a jack to the spine with screws, and it had been developed by the surgeon in this case as an alternative to spinal fusion, which was the standard treatment at the time. He was the only surgeon in the country employing the procedure, and he had performed it thirty-five times previously with mixed results. In five cases, complications developed, including one case resulting in paralysis and death. The surgeon began referring patients to the defendant-hospital when another hospital prohibited him from performing the spinal-jack procedure in its facilities. The defendant-hospital knew about the nature of the surgery, its novelty, the prior complications patients had experienced

treatment alternatives or about their respective risks and benefits (which suggests a breach of the duty to disclose); yet, she had not been asked to consent at all to the treatment (which suggests a breach of the duty not to treat patients without their permission). In such a case, courts must be clear whether a duty to assure that informed consent was obtained means a duty to assure that the patient has authorized treatment whether or not she has received sufficient treatment information, or a duty to assure that the patient received sufficient treatment information prior to her consent, or both. In *Campbell* the duty to assure that a patient's informed consent has been obtained appears to include a duty to assure that sufficient disclosures have been made by the attending physician to the patient. See *id.* at 907-08. For a more detailed description of *Campbell*, see *infra* notes 70-78 and accompanying text.

31 272 N.Y.S.2d 557 (App. Div. 1966) (mem.), *rev'd*, 227 N.E.2d 296 (N.Y. 1967).

32 Although *Fiorentino* was the first appellate court decision to address the duty of hospitals with respect to the disclosures made in the process of informed consent, it is not the first to address hospital liability for nonconsensual medical treatment.

33 The factual summary is an amalgamation of those described in each of the appellate court decisions in the case. See cases cited *supra* note 31.

from the procedure, and that the surgeon no longer performed the procedure at another area hospital.

The boy's mother sued both the surgeon and the hospital in which the surgery was performed, claiming that neither had sufficiently informed her about the surgery so that she could make an informed decision about whether to consent to it for her son. She claimed that she was not told the risks of and alternatives to the surgery, including that the procedure was experimental and that it carried a risk of death. A jury returned a verdict in her favor against both the surgeon and the hospital.

On appeal, the court affirmed the verdict without any analysis or citation to authority. The only clue to its reasoning is one concluding sentence. After holding that the physician had a duty to disclose to the plaintiff "that the procedure he proposed was novel and unorthodox and that there were risks incident to or possible in its use," the court wrote:

We are . . . of the opinion that, knowing the nature of the proposed operation, the history of its utilization by the defendant physician, and the fact that it had not been recognized by the medical profession in the community, or in the nation, as an accepted method for the correction of scoliosis, the defendant Hospital was obligated to ascertain that the physician had made such a disclosure before permitting the operation to take place.³⁴

Thus, the court imposed on the hospital not a duty to disclose treatment information to the patient, but rather a duty of oversight to assure that the surgeon had fulfilled his disclosure obligations.

A dissenter on the panel argued that, when an independently contracted physician has obtained consent, a hospital should not have a duty "to go behind such consent to ascertain whether . . . an informed consent had been given. . . . Indeed, discussion by the Hospital of the matter of consent might have constituted an invasion of the confidential relationship existing between the patient and his doctor."³⁵ This was a precursor of reasoning that would be applied in this case and in many others.

The highest appellate court in New York reversed *Fiorentino* in 1967, holding that, as a matter of law, hospitals do not have an obligation to confirm that its physicians have obtained the informed consent of their patients to hospital-based treatments.³⁶ The court's holding was based on the need to keep doctor-patient relationships free from

34 *Fiorentino*, 272 N.Y.S.2d at 559.

35 *Id.* (Rabin, J., dissenting).

36 227 N.E.2d 296.

interference by those unqualified to make professional medical judgments.

[I]t would not be just for a court, having the benefit of hindsight, to impose liability on a hospital for its failure to intervene in the independent physician-patient relationship. That relationship is always one of great delicacy. And it is perhaps the most delicate matter, often with fluctuating indications, from time to time with the same patient, whether a physician should advise the patient (or his family), more or less, about a proposed procedure, the gruesome details, and the available alternatives. Such a decision is particularly one calling for the exercise of medical judgment. In the exercise of that discretion, involving as it does grave risks to the patient, a third party should not ordinarily meddle.³⁷

Since 1967, courts in nearly forty cases spread over twenty-two different jurisdictions have held that hospitals do not have a duty to disclose treatment information to their patients or to assure that patients' physicians do so, ruling instead that the duty of disclosure applies only to physicians.³⁸ These decisions have come at a steady

37 *Id.* at 300 (citation omitted).

38 See *Keyser v. St. Mary's Hosp.*, 662 F. Supp. 191 (D. Idaho 1987); *Wells v. Storey*, 792 So. 2d 1034 (Ala. 1999); *Ward v. Lutheran Hosp. & Homes Soc'y of Am.*, 963 P.2d 1031 (Alaska 1998); *Krane v. St. Anthony Hosp. Sys.*, 738 P.2d 75 (Colo. Ct. App. 1987); *Petriello v. Kalman*, 576 A.2d 474 (Conn. 1990); *Doe v. Stamford Hosp.*, No. FA 970160804S, 1998 WL 182411 (Conn. Super. Ct. Apr. 8, 1998); *Parr v. Palmyra Park Hosp.*, 228 S.E.2d 596 (Ga. Ct. App. 1976); *Foster v. Traul*, No. 30052, 2005 WL 1692955 (Idaho Sept. 12, 2005); *Winters v. Podzamsky*, 621 N.E.2d 72 (Ill. App. Ct. 1993); *Pickle v. Curns*, 435 N.E.2d 877 (Ill. App. Ct. 1982); *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355 (Iowa 1987); *Lincoln v. Gupta*, 370 N.W.2d 312 (Mich. Ct. App. 1985); *Baltzell v. Baptist Med. Ctr.*, 718 S.W.2d 140 (Mo. Ct. App. 1986); *Ackerman v. Lerwick*, 676 S.W.2d 318 (Mo. Ct. App. 1984); *Roberson v. Menorah Med. Ctr.*, 588 S.W.2d 134 (Mo. Ct. App. 1979); *Giese v. Stice*, 567 N.W.2d 156 (Neb. 1997); *Cooper v. Curry*, 589 P.2d 201 (N.M. Ct. App. 1978); *DeSena ex rel. DeSena v. NYU Med. Ctr.*, 773 N.Y.S.2d 836 (App. Div. 2003); *Cox v. Haworth*, 283 S.E.2d 392 (N.C. Ct. App. 1981); *Long v. Jaszczak*, 688 N.W.2d 173 (N.D. 2004); *Kershaw v. Reichert*, 445 N.W.2d 16 (N.D. 1989); *Grandillo v. Montesclaros*, 739 N.E.2d 863 (Ohio Ct. App. 2000); *Goss v. Okla. Blood Inst.*, 856 P.2d 998 (Okla. Civ. App. 1990); *Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. Ct. 1995); *Krout v. Martin*, 50 Pa. D. & C.3d 472 (Pa. Ct. Com. Pl. 1989); *George v. Ayoub*, 50 Pa. D. & C.3d 322 (Pa. Ct. Com. Pl. 1988); *Gross v. Hoyt*, 1 Pa. D. & C.4th 490 (Pa. Ct. Com. Pl. 1988); *Margotta v. Lancaster Gen. Hosp.*, 47 Pa. D. & C.3d 300 (Pa. Ct. Com. Pl. 1987); *Hurley v. Won*, 9 Pa. D. & C.3d 796 (Pa. Ct. Com. Pl. 1979); *Bryant v. HCA Health Servs. of N. Tenn., Inc.*, 15 S.W.3d 804 (Tenn. 2000); *Boney v. Mother Frances Hosp.*, 880 S.W.2d 140 (Tex. App. 1994); *Ritter v. Delaney*, 790 S.W.2d 29 (Tex. App. 1990); *Nevauex v. Park Place Hosp.*, 656 S.W.2d 923 (Tex. App. 1983); *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815 (Wash. 1990); *Alexander v. Gonser*, 711 P.2d 347 (Wash.

pace of one or two each year,³⁹ and they have been highly consistent in their reasoning. Most often, courts describe informed consent as a delicate process in which the physician's intimate familiarity with each patient joins the doctor's expert knowledge about treatments and his or her professional sense of how to inform without alarming each patient.⁴⁰ Thus, they see it as a uniquely professional process that culminates in a conversation between doctor and patient that is tailored to the particular needs of each patient in terms of both the substantive disclosures and the method of communication.⁴¹ Hospitals, they say, are ill-suited to participate in such a professional process because they lack the expertise, the knowledge of the patient, and the professional judgment to manage the task of communicating sensitive information to vulnerable patients. Consider for example, this passage written by the Superior Court of Pennsylvania in a 1995 opinion:

It is the surgeon and not the hospital who has the education, training and experience necessary to advise each patient of risks associated with the proposed surgery. Likewise, by virtue of his relationship with the patient, the physician is in the best position to know the patient's medical history and to evaluate and explain the risks of a particular operation in light of the particular medical history. Appellants' attempt to impose upon a hospital the duty not only to "ensure" that physicians obtain informed consent but also to draft the "substantive information to be disclosed," ignores these unique aspects of the physician-patient relationship.⁴²

According to this view, requiring hospitals to participate or oversee the disclosure process would do more harm than good by disrupting the doctor-patient relationship at one of its most fragile

Ct. App. 1985); *Scaria v. St. Paul Fire & Marine Ins. Co.*, 227 N.W.2d 647 (Wis. 1975); *Staudt v. Froedtert Mem'l Lutheran Hosp.*, 580 N.W.2d 361 (Wis. Ct. App. 1998).

39 No cases were reported after 1967 until 1975, but from 1975 through 1979, there were five reported cases. During the period from 1980 through 1989, fifteen cases were reported. From 1990 through 1999, thirteen cases were reported. And another five cases have been reported from 2000 through 2005.

40 See, e.g., *Wells*, 792 So. 2d at 1038-39; *Ward*, 963 P.2d at 1039-40; *Krane*, 738 P.2d at 77; *Roberson*, 588 S.W.2d at 137; *Giese*, 567 N.W.2d at 163; *Howell*, 785 P.2d at 822; *Alexander*, 711 P.2d at 351.

41 See *Cross v. Trapp*, 294 S.E.2d 446, 459 (W. Va. 1982) ("The process of consenting to medical treatment, especially surgery, is an ongoing process in many cases. Discussion between the physician and his or her patient concerning proposed treatment may very well continue between the time the patient first walks into the physician's office and the time of surgery or other treatment.").

42 *Kelly*, 664 A.2d at 151.

moments.⁴³ While most courts are motivated to protect patients from intrusions into their confidential communications with their physicians by institutions unqualified to practice medicine, some also appear to be protecting the professional turf of physicians by emphasizing the impropriety of questioning medical authority.⁴⁴ As one judge put it, a duty to oversee the informed consent process is a “disturbing duty of going behind a treating physician’s back.”⁴⁵

Despite concern for the meddlesome intrusions of unskilled hospitals into the delicate process by which treatment information is disclosed to hospital patients, courts have acknowledged two unique circumstances in which a hospital can be held liable for breach of a duty to disclose. Yet, both are readily distinguishable from the bulk of unsuccessful claims of inadequate disclosure against hospitals. Consequently, they have not undermined the general rule against imposing disclosure duties on hospitals, and they are unlikely to affect hospital behavior with respect to information disclosure.

First, a hospital can be held vicariously liable when one of its affiliated physicians breaches the duty to disclose treatment information to a patient prior to hospital-based treatment, but only if the hospital employs the physician or otherwise controls the physician’s conduct within the hospital as if it employed the physician.⁴⁶ This exception is

43 See, e.g., *Pauscher*, 408 N.W.2d at 362 (stating that the process of information disclosure “lie[s] at the heart of the doctor-patient relationship” and therefore hospitals should not intervene); *Roberson*, 588 S.W.2d at 137 (“[T]he presentation to the patient of risks involved in prospective surgery cannot but call for some very nice judgments.”); *Alexander*, 711 P.2d at 351 (imposing a duty on hospitals to intervene in the process of disclosure would be more disruptive than beneficial); *Cross*, 294 S.E.2d at 459 (concluding informed consent is an ongoing process that takes place over multiple encounters between doctor and patient, which would only be disrupted if hospitals were involved).

44 See, e.g., *Petriello v. Kalman*, 576 A.2d 474, 479 (Conn. 1990) (expressing disbelief that a hospital, by adopting a rule that prohibited treatment in the absence of a signed consent form, could have intended a nurse to “countermand the judgment” of the attending physician that consent had been obtained despite the existence of an unsigned consent form).

45 *Campbell v. Pitt County Mem’l Hosp., Inc.*, 352 S.E.2d 902, 914 (N.C. Ct. App.) (Orr, J., dissenting in part), *aff’d*, 362 S.E.2d 273 (N.C. 1987).

46 See *Gotlin v. Ledermen*, 367 F. Supp. 2d 349, 362–64 (E.D.N.Y. 2005) (overturning dismissal of informed consent claim against hospital where the complaint alleged vicarious liability for breach of the duty of disclosure by physicians alleged to be the employees or agents of the hospital); *Burnet v. Spokane Ambulance*, 772 P.2d 1027, 1031 (Wash. Ct. App. 1989) (holding a hospital can be vicariously liable for its physician’s breach of the duty of disclosure, but only where it is established that the physician was employed by the hospital); see also *Valcin v. Pub. Health Trust*, 473 So. 2d 1297 (Fla. Dist. Ct. App. 1984) (addressing the informed consent claim against public hospital on its merits where the doctor was employed by the hospital). *But see*

a straight forward application of the respondeat superior doctrine.⁴⁷ Despite being widely recognized, however, the exception is rarely applicable because physicians are generally not employed by the hospitals in which they practice. Instead, most physicians have independent contractor relationships with the hospitals in which they practice based on their holding nonexclusive privileges to treat patients in those hospitals. Courts have ruled that this is an insufficient basis on which to claim that the hospital controls the physician's conduct with respect to informed consent disclosures.⁴⁸ Given that hospitals generally do not employ the physicians who practice in their facilities, this exception is unlikely to affect whether and how hospitals participate in the informed consent process.

Moreover, one appellate court has ruled that hospitals cannot be held vicariously liable for even its employed physician's breach of the duty to disclose treatment information, suggesting that the vicarious liability exception could be in jeopardy. In *Valles v. Albert Einstein Medical Center*,⁴⁹ the Pennsylvania Supreme Court reviewed a claim of vicarious liability against a hospital for the failure of an allegedly employed physician to disclose treatment information to a patient. A lower court had granted summary judgment to the hospital, and the plaintiff on appeal argued that hospitals are subject to vicarious liability for the failure of their employed physicians to obtain informed consent, and that a question of fact existed about whether the defendant-hospital actually employed the physician in this case, which question precluded summary judgment. The Pennsylvania Supreme Court was skeptical that there was sufficient evidence in the record to raise a question of fact about whether the physician was an employee or an independent contractor of the hospital.⁵⁰ Rather than rule on this basis, however, the court held that the hospital was entitled to judgment as a matter of law.⁵¹ It reasoned that hospitals simply lack the ability to control the disclosure practices of physicians and, without such control, cannot be subject to vicarious liability.

In our view, a medical facility cannot maintain control over . . . [informed consent practices within] the physician-patient relation-

Valles v. Albert Einstein Med. Ctr., 805 A.2d 1232, 1239 (Pa. 2002) (holding that hospitals cannot be vicariously liable for the failure of even their employed physicians to obtain informed consent because hospitals cannot control the process by which physicians obtain informed consent).

47 See, e.g., *Gotlin*, 367 F. Supp. 2d at 362.

48 See, e.g., *Newell v. Trident Med. Ctr.*, 597 S.E.2d 776 (S.C. 2004).

49 805 A.2d 1232.

50 See *id.* at 1238-39.

51 See *id.* at 1239.

ship. . . . Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to interject an element of a hospital's control into this highly individualized and dynamic relationship. . . . Thus, we hold that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.⁵²

To date, there is no indication that courts in other jurisdictions are persuaded by *Valles*.⁵³ Courts in each of two cases on point, which were decided after *Valles*, recognized that a hospital can be vicariously liable for the failure of a physician employed by the hospital to obtain the informed consent of a hospital patient, and each did so without distinguishing (or even citing) *Valles*.⁵⁴ Thus, Pennsylvania's refusal to recognize the vicarious liability exception may be nothing more than an outlier as compared to the law in other jurisdictions. On the other hand, because the ruling in *Valles* is based on the premise that hospitals are incapable of controlling the disclosure practices of its physicians—a proposition almost universally accepted in the case law—we may not yet know the persuasive impact of *Valles* in other jurisdictions. Thus, the vicarious liability exception has a narrow reach, and, depending on reaction to *Valles* outside of Pennsylvania, it may become extinct.

A second exception applies to hospitals housing clinical research on humans. Courts have held that a hospital, when acting as a research institution, owes a duty directly to the human subjects of such research to assure that such subject receives specific information concerning the research and its risks prior to consenting to participate in

52 *Id.* at 1239. Oddly, the court went so far as to say that, when a physician employed by a hospital fails to provide adequate disclosures as part of obtaining a patient's informed consent to a hospital-based procedure, the physician is acting outside the scope of employment. *See id.*

53 A federal court applying Pennsylvania law relied on *Valles* to dismiss a vicarious liability claim against a hospital based on the alleged failure of physicians employed by the hospital to obtain the plaintiff's informed consent to a blood transfusion. *See Calfee v. City Ave. Hosp.*, No. Civ.A. 02-1085, 2003 WL 21197311 (E.D. Pa. May 21, 2003).

54 *See Gotlin v. Lederman*, 367 F. Supp. 2d 349 (E.D.N.Y. 2005) (dismissing vicarious liability claims against hospital for failure of a physician to obtain informed consent is inappropriate where complaint alleges an employment or other agency relationship); *Newell v. Trident Med. Ctr.*, 597 S.E.2d 776 (S.C. 2004) (dismissing vicarious liability claims against hospital for failure of a nonemployed physician to obtain a patient's informed consent is appropriate because plaintiff cannot make out a sufficient agency relationship).

the study.⁵⁵ Federal law regulates medical research on humans,⁵⁶ and it imposes informed consent duties directly on hospitals that permit such research to be conducted within their facilities.⁵⁷ When performing in its capacity as a research institution, a hospital must establish an institutional review board (IRB), and no research on human subjects may be conducted within the hospital unless it is approved by the IRB.⁵⁸ Authorization of proposed clinical research is conditioned upon the IRB's assurance that researchers will obtain the informed consent of each research subject prior to enrolling each subject in the study, that researchers will disclose specific information concerning the study, its risks and benefits, and its alternatives as part of the informed consent process, and that informed consent will be documented on a written form approved by the IRB.⁵⁹

Several courts have ruled that these regulations, and the procedures adopted by hospitals to comply with them, impose a duty on hospitals to assure that anyone participating in research within the hospital has received proper disclosures concerning the research and its risks. The first of these was *Fritter v. Iolab Corp.*,⁶⁰ in which a hospital patient consented to and received intraocular lens implants without having first been informed that the lenses were experimental, that he was participating in study of their safety and effectiveness, or that the procedure carried with it both known and unknown risks. The procedure damaged the patient's vision, and he sued the hospital in which the procedure was performed, claiming failure to obtain informed consent.⁶¹ A trial court granted the hospital's motion for judgment notwithstanding the verdict in favor of the plaintiff, and the plaintiff appealed.⁶² On appeal, the Superior Court of Pennsylvania reversed the trial court, holding that the hospital had a duty to assure that the patient had received the disclosures required by federal law concern-

55 See *Lenahan v. Univ. of Chi.*, 808 N.E.2d 1078 (Ill. App. Ct. 2004); *Kus v. Sherman Hosp.*, 644 N.E.2d 1214 (Ill. App. Ct. 1995); *Baird v. Am. Med. Optics*, 693 A.2d 904 (N.J. Super. Ct. App. Div. 1997); *Fritter v. Iolab Corp.*, 607 A.2d 1111 (Pa. Super. Ct. 1992). But see *Kershaw v. Reichert*, 445 N.W.2d 16, 17 (N.D. 1989) (holding informed consent claim against hospital by a research subject injured in the course of participating in a clinical study was properly dismissed because federal research regulations do not grant a private right of action).

56 See generally 21 C.F.R. pt. 50 (2005); 45 C.F.R. pt. 46 (2005).

57 See 45 C.F.R. §§ 46.111(a)(4)–(5), 46.116.

58 See *id.* § 46.109.

59 See *id.* § 46.111(a)(4)–(5).

60 607 A.2d 1111 (Pa. Super. Ct. 1992).

61 *Id.* at 1111–12.

62 *Fritter v. Iolab Corp.*, No. 2306, 1990 WL 902457 (Pa. Ct. Com. Pl. Oct. 19, 1990), *rev'd*, 607 A.2d 1111.

ing the research.⁶³ The court reasoned that the hospital voluntarily assumed a duty to assure that informed consent to research was obtained when the hospital permitted the research to be conducted in its facility, which triggered the application of federal research regulations.⁶⁴ In further support of its conclusion, the court also pointed to the hospital's adoption of policies and procedures designed to prevent research from being conducted on anyone prior to obtaining informed consent.⁶⁵ Finally, it distinguished earlier Pennsylvania case law that had refused to impose disclosure duties on hospitals, indicating that none of those cases involved federally regulated research on humans.⁶⁶

While other courts have followed the precedent set by *Friter*, they have also been careful to do so only in the narrow circumstance where federal research regulations apply. For example, courts have refused to interpret *Friter* as holding that hospitals adopting policies and procedures concerning the disclosure of treatment information assume a duty to oversee such disclosures.⁶⁷ Similarly, courts have refused to apply the logic of *Friter* where treatments are novel, but not provided as part of a clinical study,⁶⁸ or where devices are used for purposes other than those for which they have received approval from the Food and Drug Administration.⁶⁹ Thus, the cases holding that hospitals can be held liable for failing to assure the disclosure of research risks are based on the factual distinction between research and treatment in hospitals and on the fact that federal law has superseded state law only

63 See 607 A.2d at 1114.

64 See *id.* (citing to FDA regulations and testimony of two doctors practicing at the hospital, including the chair of the hospital's IRB).

65 See *id.* (noting that the operating room nurse was obligated by hospital policy to stop any procedure involving the experimental lenses unless the consent form approved by the IRB was in the patient's chart and signed by the patient).

66 See *id.* at 1113.

67 This is most evident from an examination of Pennsylvania cases following *Friter*. In *Boyd v. Somerset Hospital*, 24 Pa. D. & C.4th 564 (Pa. Ct. Com. Pl. 1993), a Pennsylvania trial court reversed summary judgment for a hospital on an informed consent claim unrelated to human subjects research. It argued that *Friter* recognized that hospitals could assume a duty to oversee the process of informed consent, and that this holding can apply outside the context of human subjects research. *Id.* at 574. Later, the court that had decided *Friter* clarified its holding, saying that the case applied only where the claim involved participation in federally regulated human research. See *Valles v. Albert Einstein Med. Ctr.*, 758 A.2d 1238, 1243 (Pa. Super. Ct. 2000), *aff'd*, 805 A.2d 1232 (Pa. 2002).

68 See *Bryant v. HCA Health Serv. of N. Tenn., Inc.*, 15 S.W.3d 804 (Tenn. 2000) (noting the patient was not enrolled in clinical study).

69 See *id.*; *Staudt v. Froedtert Mem'l Lutheran Hosp.*, 580 N.W.2d 361 (Wis. Ct. App. 1998).

in the case of research. Accordingly, the research exception, like the vicarious liability exception, is narrow and, despite analogies that can be drawn between institutional oversight of both hospital-based research and hospital-based treatment, the exception has not been applied outside the context of federally regulated research.

Since 1967, only two courts have broken from the traditional policy that the law does not impose on hospitals a duty of disclosure or a duty to assure physician disclosures. Yet, neither has had, or is likely to have, much effect on the traditional policy nationwide.

In 1987, a divided panel of the Court of Appeals of North Carolina ruled that a hospital has a duty to take reasonable steps to assure that physicians practicing in the hospital obtain the informed consent of a hospital patient prior to treatment.⁷⁰ In *Campbell v. Pitt County Memorial Hospital, Inc.*,⁷¹ the plaintiffs were parents of a child injured at birth allegedly as a result of the hospital's failure to inform the parents prior to a vaginal delivery that the child was in a breech position, that there was a choice between delivering the child vaginally or by cesarean section, and about the relative risks of each method of delivery given the child's position *in utero*.⁷² A jury had awarded a verdict for the parents and the hospital appealed, arguing that the law does not impose a duty on hospitals to obtain the informed consent of patients.⁷³ The court of appeals held that the doctrine of corporate negligence requires hospitals "to make a reasonable effort to monitor and oversee the treatment which is prescribed and administered by physicians practicing at the facility" and that this could encompass a duty to assure that the informed consent of a hospital patient has been obtained prior to treatment.⁷⁴ Additionally, it held that there was sufficient evidence on the record to support the jury's determination that such a duty existed in this case and was breached.⁷⁵ Specifically, the court pointed to evidence establishing that the standard of care for nurses is to assure that patients have received an explanation from their doctors about the nature, alternatives, and risks of pro-

70 See *Campbell v. Pitt County Mem'l Hosp., Inc.*, 352 S.E.2d 902, 906-08 (N.C. Ct. App.), *aff'd*, 362 S.E.2d 273 (N.C. 1987). Each member of a three-judge panel on the Court of Appeals of North Carolina filed opinions in the case. The informed consent holding is based upon the "majority" opinion by Judge Wells and the concurring opinion of Judge Becton.

71 352 S.E.2d 902.

72 *Id.* at 903-04.

73 *Id.* at 904.

74 *Id.* at 907 (quoting *Bost v. Riley*, 262 S.E.2d 391 (N.C. Ct. App. 1980)).

75 See *id.* at 907-08.

posed procedures prior to treatment.⁷⁶ Moreover, it identified evidence showing that the defendant hospital adopted a policy requiring labor and delivery nurses to present patients with consent forms and to obtain patients' signatures on those forms prior to treatment.⁷⁷ One judge dissented, arguing that the corporate negligence doctrine was not intended to force hospital personnel to intervene into the doctor-patient relationship and therefore that there can be no duty on the hospital with respect to informed consent.⁷⁸

Campbell has had little effect in North Carolina or elsewhere. Many courts have faced the issue addressed in *Campbell* since 1987,⁷⁹ and yet only one court outside of North Carolina has cited *Campbell*,⁸⁰ and none have followed its lead. There are several reasons for this. First, the decision has been stripped of its precedential value.⁸¹ The North Carolina Supreme Court reviewed *Campbell* but was evenly divided about whether to affirm or overrule the court of appeals.⁸² In the absence of a decisive vote by the supreme court, *Campbell* was allowed to stand, but it could not be cited as binding precedent.⁸³ For this reason, the Court of Appeals of North Carolina refused to rely on *Campbell* when it again addressed the issue of hospital liability for informed consent in 2005, turning instead to a case that pre-dated *Campbell*, which had held that hospitals do not have any duties with respect to informed consent.⁸⁴ Second, *Campbell* may be limited by the fact that the hospital had a policy specifically requiring labor and delivery nurses to secure each patient's signature on a consent form, which the North Carolina Court of Appeals distinguished from a hospital policy requiring that *someone*—but not necessarily a nurse—obtain the informed consent of patients prior to delivery.⁸⁵ Third, the

76 See *id.*

77 See *id.*

78 See *id.* at 912–13 (Orr, J., dissenting in part).

79 See cases cited *supra* note 38.

80 See *Johnson v. Sears, Roebuck & Co.*, 832 P.2d 797, 799, 800 (N.M. Ct. App. 1992).

81 While courts outside of North Carolina could cite to *Campbell* as persuasive authority, they are less likely to do so given that the case has lost its precedential value in its own jurisdiction. See, e.g., *id.* at 800 (refusing to rely on *Campbell* in part because of its having been stripped of its precedential value).

82 See *Campbell v. Pitt County Mem'l Hosp., Inc.*, 362 S.E.2d 273, 276 (N.C. 1987).

83 See *id.*; *Daniels v. Durham County Hosp. Corp.*, 615 S.E.2d 60, 64 (N.C. Ct. App. 2005).

84 See *Daniels*, 615 S.E.2d at 64–65 (relying on *Cox v. Haworth*, 283 S.E.2d 392 (N.C. Ct. App. 1981)).

85 See *id.* at 64.

corporate negligence doctrine in health care, which is the theoretical foundation of *Campbell*, has been rejected or ignored by most courts as a basis for imposing informed consent duties on hospitals, a phenomenon addressed in greater detail in Part II.C of this Article.

Sherwood-Armour v. Danbury Hospital,⁸⁶ is the second of two cases holding that a hospital has a duty to disclose treatment information to its patients. Like *Campbell*, it has limited precedential value in its own jurisdiction, and it rests on a questionable theoretical foundation, which likely undermines its persuasiveness in other jurisdictions.

In *Sherwood-Armour* a plaintiff alleged that she became infected with HIV when she was transfused with blood supplied by the defendant-hospital. She claimed that the hospital had a duty to warn her of the risks of receiving a blood transfusion or to inform her of the option to receive blood that had been tested and confirmed to be HIV-free.⁸⁷ Initially, judgment had been entered for the hospital on the grounds that the statute of limitations had expired;⁸⁸ however, that ruling was reversed by the Connecticut Supreme Court, and the case was remanded. In its opinion, the supreme court had opined that a hospital may be liable for failing to inform its patient of the risks associated with a transfusion of blood supplied by the hospital.⁸⁹ It did so without addressing an earlier case in which the supreme court ruled that hospitals do not have a duty to disclose treatment information to their patients.⁹⁰ This left the trial court stuck between two binding and apparently conflicting precedents when, on remand, the hospital again moved for summary judgment, this time arguing that Connecticut law does not impose a duty of disclosure on hospitals.⁹¹ The court, in an effort to honor both precedents, attempted to craft a narrow exception to the rule that hospitals do not have a duty to disclose treatment information.⁹² It held that a hospital has a duty to warn of defects in the products it supplies to its patients when it knows of those defects and yet cannot correct them, which, the court said, is distinguishable from a duty to inform patients generally of risks associ-

86 35 Conn. L. Rptr. 659 (Super. Ct. 2003).

87 *Id.* at 659.

88 *Sherwood v. Danbury Hosp.*, No. CV 960324786S, 1998 WL 867248 (Conn. Sup. Ct. Dec. 2, 1998), *aff'd in part, rev'd in part*, 746 A.2d 730 (Conn. 2000), *remanded to* 35 Conn. L. Rptr. 659.

89 746 A.2d at 737.

90 *See* *Petriello v. Kalman*, 576 A.2d 474 (Conn. 1990).

91 *Sherwood-Armour*, 35 Conn. L. Rptr. at 659.

92 The court described its effort as one to "reconcile" the two binding precedents, rather than to craft an exception, but it later admitted that its ruling erodes the policy against imposing informed consent duties on hospitals. *Id.* at 660 & 662 n.4. Thus, I interpret the court's effort as creating as narrow an exception as possible.

ated with treatment services rendered in the hospital.⁹³ Thus, according to the court, a hospital supplies its patient with a defective product when it provides that patient with blood it knows has not been tested for HIV.⁹⁴ In essence, the court held that a rule against imposing informed consent duties on hospitals should not be read to abrogate standard principles of product liability. The court then denied the hospital's motion for summary judgment, holding that a question of fact exists about whether tested blood was available to the hospital at the time of the transfusion.⁹⁵

Sherwood-Armour was decided in 2003, and there has been little time during which to examine its persuasiveness.⁹⁶ Nonetheless, there are two reasons to predict that it will have little effect on informed consent policy. First, it is a trial court decision and thus is not binding on any other court in Connecticut. Second, it is based on product liability principles, which courts have been reluctant to apply to hospitals because they have not considered hospitals to be like other manufacturers, distributors, or retailers that introduce products into the marketplace.⁹⁷

In summary, the rule against imposing disclosure duties on hospitals persists based on an underlying goal of preventing third parties from intruding into the delicate relationship between doctor and patient. While exceptions exist, they are of narrow application.

C. *The Uncertain Duty of Hospitals To Prevent Unauthorized Treatment of Patients*

Courts have been somewhat less reluctant to recognize a duty for hospitals to protect their patients from nonconsensual treatment than they have been to impose disclosure duties. Since 1982, at least nine cases have ruled on the issue of whether hospitals have a duty to assure that a patient has provided consent prior to treatment.⁹⁸ Three

93 See *id.* at 660–61.

94 See *id.*

95 *Id.* at 661.

96 None of the eight cases decided in 2004 or 2005 have cited to *Sherwood-Armour*. See *Gotlin v. Lederman*, 367 F. Supp. 2d 349 (E.D.N.Y. 2005); *Foster v. Traul*, 120 P.3d 278 (Idaho 2005); *Lenahan v. Univ. of Chi.*, 808 N.E.2d 1078 (Ill. App. Ct. 2004); *Mohsan v. Roule-Graham*, 907 So. 2d 804 (La. Ct. App. 2005); *Bailey v. Owens*, 793 N.Y.S.2d 40 (App. Div. 2005); *Daniels v. Durham County Hosp. Corp.*, 615 S.E.2d 60 (N.C. Ct. App. 2005); *Long v. Jaszczak*, 688 N.W.2d 173 (N.D. 2004); *Newell v. Trident Med. Ctr.*, 597 S.E.2d 776 (S.C. 2004).

97 See BARRY R. FURROW ET AL., *HEALTH LAW* 356–66 (5th ed. 2004).

98 All but one of these cases were decided in 1992 or later. See *Marsh v. Crawford Long Hosp. of Emory Univ.*, 444 S.E.2d 357 (Ga. Ct. App. 1994); *Auler v. Van Natta*,

of these cases have held that such a duty exists.⁹⁹ In each of these three cases, patients claimed that the defendant-hospitals failed to protect them from receiving surgical procedures to which they did not consent.¹⁰⁰ The court in each case recognized that while only physicians have a duty to obtain patients' informed consent, hospitals have a duty to reasonably protect their patients from nonconsensual treat-

686 N.E.2d 172 (Ind. Ct. App. 1997); *Mohsan v. Roule-Graham*, 907 So. 2d 804 (La. Ct. App. 2005); *Kelley v. Kitahama*, 675 So. 2d 1181 (La. Ct. App. 1996); *Johnson v. Sears, Roebuck & Co.*, 832 P.2d 797 (N.M. Ct. App. 1992); *Urban v. Spohn Hosp.*, 869 S.W.2d 450 (Tex. App. 1993); *Cross v. Trapp*, 294 S.E.2d 446 (W. Va. 1982); *Montalvo v. Borkovec*, 647 N.W.2d 413 (Wis. Ct. App. 2002); *Mathias v. St. Catherine's Hosp., Inc.*, 569 N.W.2d 330 (Wis. Ct. App. 1997).

Another four courts addressed the issue in dicta. Of these, two suggested that hospitals have a duty to assure that the patient has authorized the scheduled treatment, implicitly recognizing a distinction between a duty to assure disclosures and a duty to assure authorization of the scheduled procedure. *See Winters v. Podzamsky*, 621 N.E.2d 72, 76 (Ill. App. Ct. 1993); *Krout v. Martin*, 50 Pa. D. & C.3d 472, 476-77 (Pa. Ct. Com. Pl. 1989). The other two stated that no such duty exists. *Petriello v. Kulman*, 576 A.2d 474, 478-79 (Conn. 1990); *Boney v. Mother Frances Hosp.*, 880 S.W.2d 140, 143 (Tex. App. 1994). None of them provided any explanation.

Additionally, one state statute distinguishes between the medical task of providing disclosures to patients and the ministerial task of documenting consent. *See IDAHO CODE ANN.* § 39-4306 (2005) (repealed 2005) (ministerial task of recording consent is not the practice of medicine).

Interestingly, *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (N.Y. 1914), *abrogated by Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957), is one of the earliest no consent claims pursued against a hospital. Despite being heralded for vindicating the right of patients to be free of unwanted medical treatment, the *Schloendorff* court refused to impose a duty on the defendant-hospital to prevent the nonconsensual treatment of one of its patients. The case involved a patient who received extensive surgery despite having consented only to an exploratory procedure. *Id.* at 93. She sued the hospital for medical battery. While the court refused to apply the charitable immunity doctrine to the claim, it nonetheless held that the hospital could not be held liable because the physicians who allegedly treated her were not subject to the hospital's control and because the nurse who knew that the patient had consented only to exploratory surgery was not present at the surgery and thus did not have reason to know that the physicians would exceed the bounds of the patient's consent. *Id.* at 93-95.

99 *See Marsh*, 444 S.E.2d 357; *Urban*, 869 S.W.2d 450; *Mathias*, 569 N.W.2d 330; *see also* *Douglass v. Florence Gen. Hosp.*, 259 S.E.2d 117 (S.C. 1979) (suggesting that such a duty exists in the course of addressing whether the case should be dismissed on the basis of the charitable immunity doctrine).

100 *See Marsh*, 444 S.E.2d 357 (discussing a patient who had consented to abdominal liposuction and complains she received a more invasive and scarring procedure without her consent); *Urban*, 869 S.W.2d 450 (reviewing plaintiff's contention that, while anesthetized for other consensual surgery, she received a hemorrhoidectomy she had specifically refused); *Mathias*, 569 N.W.2d 330 (involving a plaintiff who alleged that she was sterilized without her consent while still anesthetized following childbirth).

ment, which includes identifying and reporting to patients' physicians any discrepancies between scheduled procedures and procedures for which consent has been obtained.¹⁰¹ This, they held, arises not from the informed consent doctrine but from simple negligence principles as applied to hospitals.¹⁰²

Consider, for example, the ruling in *Urban v. Spohn Hospital*¹⁰³ where the patient, while anesthetized for other consensual surgical procedures, received a hemorrhoidectomy that she had specifically refused several times in conversations with more than one hospital nurse. Despite their awareness of the patient's refusals, and their knowledge that the patient was scheduled for a hemorrhoidectomy, none of the hospital's nurses notified the patient's physician or any hospital supervisor that the patient had refused one of the procedures that she was scheduled to receive. The patient sued the hospital, claiming that it acted negligently in failing to assure that she received only those treatments to which she had consented.¹⁰⁴ The trial court granted summary judgment for the hospital on the theory that, under Texas law, hospitals do not owe patients any duty with respect to informed consent.¹⁰⁵ The Texas Court of Appeals reversed, holding that the law does not prohibit imposing a duty on hospitals concerning informed consent, and it remanded the case for further factual proceedings.¹⁰⁶ In so ruling, the court distinguished precedent that refused to impose on hospitals a duty to obtain informed consent.¹⁰⁷ It did so by differentiating between a claim of failure to obtain informed consent and a claim of simple negligence. It wrote:

101 See *Marsh*, 444 S.E.2d at 358 (reversing grant of summary judgment for hospital based on the existence of a duty); *Urban*, 869 S.W.2d at 452–53 (reversing summary judgment for the hospital and remanding the case for further proceedings based on existence of duty); *Mathias*, 569 N.W.2d at 335 (recognizing the duty in the course of holding that the hospital satisfied its duty when its nurse discovered and reported to the patient's attending physician that there was no signed consent form for the procedure the physician was planning to perform).

102 See *Marsh*, 444 S.E.2d at 358 (holding that the duty arises from the general duty of hospitals to exercise reasonable care in protecting their patients, and that responsibility for breach of this duty does not transfer to the attending physician where the breach resulted from conduct of a hospital's nurse in the course of carrying out administrative tasks); *Urban*, 869 S.W.2d at 452–53 (holding that the duty arises from ordinary negligence principles applicable to the hospital); *Mathias*, 569 N.W.2d at 334–35 (considering whether a duty arises under a "theory of foreseeability" and not under an informed consent theory).

103 869 S.W.2d 450.

104 *Id.* at 451–52.

105 See *id.* at 452.

106 See *id.* at 452–53.

107 See *id.* (distinguishing *Ritter v. Delaney*, 790 S.W.2d 29 (Tex. App. 1990)).

[The patient's] pleadings stated a cause of action for negligence on the part of the hospital *apart from the alleged failure to obtain consent*. We cannot say as a matter of law that merely because the physician is ultimately responsible for obtaining consent for medical procedures, that a hospital is therefore totally insulated from liability for all acts relating to such procedures.¹⁰⁸

The court went on to decide that negligence principles may impose a duty on the hospital, through its nurses, to reasonably assure that patients are not provided with treatments to which they have not consented.¹⁰⁹

In contrast, the common thread running through the cases in which courts refused to impose on hospitals a duty to protect patients from nonconsensual treatment¹¹⁰ is that no distinction is made between the duty to disclose treatment information and the duty to obtain consent prior to treatment.¹¹¹ In *Cross v. Trapp*,¹¹² for example, the patient claimed that a hospital failed to prevent a surgeon from providing a procedure that went beyond the scope of the patient's consent.¹¹³ The West Virginia Supreme Court ruled that the hospital had no duty to "obtain consent" because such a duty would force hospitals to disrupt ongoing conversations between doctors and patients about treatments.¹¹⁴ The court's reasoning indicates that it may have misunderstood the duty at issue. By attempting to protect the conversations through which doctors disclose treatment information prior to seeking a patient's consent, the court signaled that it perceived the relevant issue to be whether hospitals had a duty to intervene in the disclosure process. Thus, it did not address whether the hospital had a duty to assure that, after the disclosure process is complete the patient has actually agreed to receive the treatment about to be provided. Such a duty would not interfere with the disclosure process.

108 *Id.* at 453 (emphasis added).

109 *See id.* ("Nor can we say that ordinary prudence would not require some inquiry by a nurse into the correctness of performing a surgical procedure over the direct, unambiguous, verbal objection of the patient.").

110 The duty to protect hospital patients from nonconsensual treatments is also referred to as a duty for hospitals to document consent and a duty to assure that physicians obtain consent prior to treatment.

111 *See* *Auler v. Van Natta*, 686 N.E.2d 172 (Ind. Ct. App. 1997); *Mohsan v. Roule-Graham*, 907 So. 2d 804 (La. Ct. App. 2005); *Kelley v. Kitahama*, 675 So. 2d 1181 (La. Ct. App. 1996); *Johnson v. Sears, Roebuck & Co.*, 832 P.2d 797 (N.M. Ct. App. 1992); *Cross v. Trapp*, 294 S.E.2d 446 (W. Va. 1982); *Montalvo v. Borkovec*, 647 N.W.2d 413 (Wis. Ct. App. 2002).

112 294 S.E.2d 446.

113 *Id.* at 449.

114 *See id.* at 472.

At times, courts have been distracted by a claimed distinction between a hospital's "obtaining" informed consent and "assuring" that a physician has obtained informed consent. This has led some courts to focus on whether there is an institutional responsibility to assure that adequate disclosures have been made, rather than the relevant question of whether there is an institutional responsibility to assure that patients have authorized treatment at all. For example, in *Johnson v. Sears, Roebuck & Co.*,¹¹⁵ a patient claimed that he received a blood transfusion without his authorization, and he sued the hospital, claiming that it had breached a duty to protect him from nonconsensual treatments within its facility.¹¹⁶ A trial court dismissed the claim on the grounds that, as a matter of law, hospitals do not have informed consent duties.¹¹⁷ The New Mexico Court of Appeals affirmed.¹¹⁸ Despite facing a claim of no consent, the court based its holding on reasons that apply to claims that a hospital has failed to provide sufficient treatment information.¹¹⁹ It reasoned that hospitals lack the expertise to determine the patient's condition, the treatment options, and the risks and benefits of those options, all of which are necessary for sufficient disclosure.¹²⁰ Nonetheless, the court acknowledged that the plaintiff claimed a separate duty for hospitals to assure that a patient's consent has been obtained prior to treatment.¹²¹ Yet, this did not cure the court's confusion. Instead, the court interpreted the duty as one requiring hospitals to assure not only that consent exists, but also that it was sufficiently informed. This is apparent from the court's rationale for rejecting the claimed duty. It reasoned that if a hospital does not have a duty to disclose treatment information to patients, then it should not have a duty to ensure that someone else has done so. It wrote that "there would be little reason to impose a duty to ensure that someone else had obtained consent if there was no corresponding duty to advise the patient of relevant, relative risks and benefits or otherwise obtain an informed consent upon determining that he or she had not yet given one."¹²²

With so few cases addressing the issue of whether hospitals have a duty to protect their patients from nonconsensual treatment, and with such apparent confusion among courts about the difference between

115 832 P.2d 797.

116 *Id.* at 797.

117 *Id.* at 798.

118 *Id.* at 797.

119 *Id.* at 799.

120 *See id.*

121 *Id.*

122 *Id.*

that duty and the duty of disclosure, it is difficult to identify a trend that helps to predict the likelihood that courts will recognize such a duty in the future. On the one hand, it is likely that, over time, the flawed logic of earlier decisions will be identified and corrected by courts facing the same issue in the future. This could mean that courts will be more willing to recognize the duty once they discover that it can be reconciled with precedents refusing to impose a duty on hospitals to assure the sufficiency of treatment disclosures. On the other hand, the most recent court to address the question of whether a hospital has a duty to protect its patients from nonconsensual treatments rejected it outright with no analysis, suggesting an unwillingness to examine flaws in earlier decisions.¹²³

In summary, hospitals are virtually immune from liability related to claims for treatment based on insufficiently informed consent and claims for treatment without any consent. For nearly forty years, courts have consistently rejected arguments that hospitals have a duty to provide patients with treatment information sufficient to enable informed decisionmaking or to assure that patients' physicians do so, recognizing only narrow exceptions in the case of federally regulated human subjects research and in cases where the hospital employs the physician whose disclosures were deficient. Courts in a few jurisdictions have recognized a more limited duty for hospitals to assure that patients have consented to the treatments they are scheduled to receive, without regard to how well informed those consents were. Yet, the majority of courts addressing the existence of even this more limited duty have rejected it. Throughout this forty-year period, the prevailing rationale has been that the process of disclosure and consent is both complex and delicate, requiring medical expertise and communication skills that only a physician possesses. According to this logic, the law should not impose a duty on hospitals to become involved in the informed consent process because hospitals are not competent to do so and would only cause harm by meddling in it.

The remainder of this Article challenges the wisdom of the law's policy against imposing informed consent duties on hospitals. It identifies the fallacies on which the policy is based as well as the degree to which the policy is out of step with the clinical reality of hospital involvement in informed consent. In so doing, this Article also identifies the value of hospital participation in informed consent and proposes institutional informed consent duties designed to harness that value in a manner that also promotes accountability.

123 See *Mohsan v. Roule-Graham*, 907 So. 2d 804 (La. Ct. App. 2005).

At the same time, the current policy against imposing informed consent duties on hospitals has survived four decades of intense scrutiny, and it has done so despite changes in both informed consent law and the general legal responsibility of hospitals to safeguard their patients. Thus, this Article predicts that any proposal to recognize institutional informed consent duties will fail unless there is a better understanding of why the policy has survived. This Article then takes on the task of both identifying a reason for the policy's survival and accounting for that reason as part of the project to reform the law's policy.

II. THE POLICY'S MYSTERIOUS PERSISTENCE

The law's policy against imposing informed consent duties on hospitals is unsustainable because it is founded on several fallacies. It presumes that hospitals have not yet inserted themselves into the informed consent process, that the process is uniquely tailored to meet the individual needs of each patient, and that every aspect of the process requires medical expertise and delicate professional judgment that cannot be standardized. As discussed below, these assumptions are simply wrong, and they have been wrong for quite some time. As a result, the law has failed to encourage institutional behavior that could improve the efficiency and quality of informed consent, and it has permitted hospitals to intervene in the informed consent process without sufficient accountability.

Accordingly, this portion of this Article proposes institutional informed consent duties designed to redistribute responsibility for the informed consent process. These institutional duties include (1) a duty to require that physicians on staff obtain the informed consent of their patients prior to any treatments provided at the hospital, (2) a duty to assure that no treatment is provided in the hospital without prior verification that the patient has provided an informed consent to the proposed treatment, (3) a duty for hospitals to include in their quality assurance programs the monitoring of informed consent practices and outcomes, (4) a duty to assure that any treatment information disseminated by hospitals to patients is accurate, complete, understandable, and equally accessible to all similarly situated hospital patients, and (5) a duty to assure that any hospital employees assisting patients in the post-disclosure, decisionmaking process are qualified to provide such assistance and that they are reasonably available to patients when needed.

A. *The Policy's Persistence Despite the Role of Hospitals in the Informed Consent Process*

One of the fallacies on which the law bases its determination that hospitals are not subject to informed consent liability is its assessment that hospitals are not involved in the informed consent process. Despite the fact that hospitals are responsible for coordinating complex medical treatment for their patients, the law regards hospitals as merely the facility in which medical decisionmaking takes place between a doctor and a patient. For example, in *Cox v. Haworth*,¹²⁴ the North Carolina Court of Appeals found that the exclusive role of the hospital in which a patient was injured from contrast dye injected into him by his physician was to "provide facilities and support personnel" to the patient's attending physician.¹²⁵ Accordingly, it ruled that the hospital had no duties related to the patient's allegedly receiving treatment without his informed consent.¹²⁶ Remarkably, the *Cox* court's determination about the nonexistent role of hospitals in the informed consent process appears irreconcilable with its observation only paragraphs before that the role of modern hospitals has expanded. Quoting an opinion adopted by the court only one year earlier, it wrote, "[p]rior to modern times, a hospital undertook, 'only to furnish room, food, facilities for operation, and attendants' In contrast, today's hospitals regulate their medical staffs to a much greater degree and play a much more active role in furnishing patients medical treatment.'"¹²⁷ Despite recognizing the expanded role of hospitals, the court did not address whether the record contained information about the role actually played by the defendant-hospital with respect to informed consent in the plaintiff's case. It simply presumed that informed consent was excluded from the modernization of hospital functions.¹²⁸

Despite the law's view that hospitals are not and shall not be part of the informed consent process, they are deeply involved. Moreover,

124 283 S.E.2d 392 (N.C. Ct. App. 1981).

125 *Id.* at 395.

126 *Id.* at 395-96.

127 *Id.* at 395 (quoting *Bost v. Riley*, 262 S.E.2d 391, 395 (N.C. Ct. App. 1980)).

128 *Id.* As a technical matter the court examined the newly adopted doctrine of direct corporate liability for hospitals and found that overseeing the informed consent process was not among the enumerated duties listed in support of corporate liability doctrine when it was adopted. *See id.* Thus, it refused to apply that doctrine. *See id.* It did not reach the larger policy question about why the court was unwilling to interpret a duty to assure informed consent as another example of hospitals' more expansive role that justifies the general corporate duty of hospitals to safeguard patients.

as demonstrated below, the role of hospitals in informed consent has expanded consistently since the early 1970s.

Virtually every hospital in the country has policies and procedures to assure that the informed consent of their patients is obtained prior to treatment. In part, this is because the nation's private accrediting organization for hospitals, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), requires such policies as a condition of accreditation.¹²⁹ That hospitals adopt informed consent policies and procedures in informed consent case law also is consistent with references to those policies and procedures.¹³⁰ Similarly, hospitals routinely develop their own consent forms that physicians practicing in those hospitals use for the purpose of recording consent.¹³¹ The forms often contain a hospital's name or logo and may even recite the hospital's policy to require evidence of informed consent prior to treatment.¹³² There is even evidence that as long as twenty years ago, hospitals were purchasing pre-fabricated, informed consent forms from outside vendors. For example, a 1984 opinion of the Missouri Court of Appeals refers to an expert witness who "operates a business which produces and sells consent forms to hospitals."¹³³

Even when faced with such facts, however, courts generally are not persuaded that any informed consent duty can be imposed on hospitals. For example, in *Petriello v. Kalman*,¹³⁴ a physician operated on a patient even after the physician and a nurse had discovered pre-operatively that the then sedated patient had yet to sign the hospital's informed consent form.¹³⁵ Moreover, he did so in direct violation of a hospital policy that forbids sedation or treatment unless the form has

129 See JOINT COMM'N FOR THE ACCREDITATION OF HEALTHCARE ORGS., 2003 COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS TX 5.2-5.2.2 (2003) [hereinafter JOINT COMM'N].

130 See, e.g., *Petriello v. Kalman*, 576 A.2d 474 (Conn. 1990); *Butler v. S. Fulton Med. Ctr., Inc.*, 452 S.E.2d 768 (Ga. Ct. App. 1994); *Daniels v. Durham County Hosp. Corp.*, 615 S.E.2d 60, 64 (N.C. Ct. App. 2005); *Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. Ct. 1995).

131 See, e.g., *Roberson v. Menorah Med. Ctr.*, 588 S.W.2d 134, 137 (Mo. Ct. App. 1979) (detailing a hospital's administrative adoption and distribution of consent forms); see also M. Bottrell et al., *Hospital Informed Consent for Procedure Forms: Facilitating Quality Patient-Physician Interaction*, 135 ARCHIVES SURGERY 26 (2000) (containing a study that gathered consent forms from 157 hospitals).

132 See, e.g., *Auler v. Van Natta*, 686 N.E.2d 172, 173 (Ind. Ct. App. 1997).

133 *Ackerman v. Lerwick*, 676 S.W.2d 318, 321 (Mo. Ct. App. 1984).

134 576 A.2d 474.

135 *Id.* at 476.

been executed.¹³⁶ After holding that the law does not generally impose informed consent duties on hospitals, the court ruled that the existence and violation of the hospital's informed consent policy, while relevant to the existence of an informed consent duty, was insufficient to establish the duty.¹³⁷ The Connecticut Supreme Court reasoned that, by adopting the policy, the hospital merely "'sought to increase the likelihood that *doctors* would warn patients.'"¹³⁸ Other courts in other jurisdictions have ruled similarly.¹³⁹

The law's effort to explain away these practices is weak. First, courts fail to acknowledge that hospitals first adopted informed consent policies in the early 1970s to appease frustrated health care consumers, not physicians.¹⁴⁰ On the heels of the civil and welfare rights movements, consumers in the late 1960s and early 1970s employed the strategies of political activism (e.g., sit-ins, picket lines, and protest rallies) against hospitals in major U.S. cities and at meetings of the JCAHO.¹⁴¹ They protested, among other things, the failure of hospitals to protect patients from being treated without their consent and to assure that patients receive sufficient and understandable treatment information so as to make informed treatment decisions.¹⁴² Consumers succeeded in forcing JCAHO and the American Hospital Association to endorse specific rights for hospital patients, including the right to refuse treatment and the right to receive understandable treatment information.¹⁴³ This is the genesis of JCAHO's historical and current accreditation requirements concerning informed consent. Thus, the claim that hospitals' informed consent policies and forms are directed at the hospitals' physicians and not their patients is undercut by material evidence that these policies and forms were originally created to protect consumers in informed consent process. In short, those policies and forms are evidence of a public policy for hospitals to intervene in the doctor-patient relationship, especially in matters related to informed consent.

136 *Id.*

137 *Id.* at 479.

138 *Id.* (quoting *Mele v. Sherman Hosp.*, 838 F.2d 923, 925 (7th Cir. 1988)).

139 See, e.g., *Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. Ct. 1995); *Newell v. Trident Med. Ctr.*, 597 S.E.2d 776 (S.C. 2004).

140 See FADEN & BEAUCHAMP, *supra* note 8, at 93–95; Robert Gatter, *Faith, Confidence, and Health Care: Fostering Trust in Medicine Through Law*, 39 WAKE FOREST L. REV. 395, 423–24 (2004).

141 See Gatter, *supra* note 140, at 423–24.

142 See *id.*

143 See FADEN & BEAUCHAMP, *supra* note 8, at 93–95.

Beyond policies and forms, hospitals also assign employees to participate in the informed consent process, and their responsibilities have expanded over time. Nurses, in particular, have been assigned the task of providing patients with consent forms, obtaining their signatures on those forms, placing signed forms into patients' charts, and confirming that evidence of consent exists prior to performing scheduled procedures.¹⁴⁴ Yet, the standard of care for nurses with respect to informed consent appears to have moved beyond simply recording evidence of consent. It now includes assuring that physicians have provided treatment information to patients prior to consent. In *Campbell v. Pitt County Memorial Hospital, Inc.*,¹⁴⁵ for example, testimony was taken from an expert about the nursing standard of care for informed consent: "Explaining the risk of alternative procedures would be the responsibility of the physician[;] [a]ssuring that the patient has had an explanation would be the responsibility of the nurse."¹⁴⁶ Additionally, the Code of Ethics of the American Nurses' Association has been interpreted to require that nurses answer patients' questions concerning their treatments and otherwise assure that patients understand the treatment decisions they make.¹⁴⁷ Moreover, a recent examination of the burdens of medical decisionmaking on modern patients, published in the *New York Times*, reveals that hospitals employ "patient advocates" to help patients make sense of treatment information they receive and to provide guidance as patients make difficult treatment choices.¹⁴⁸ Thus, hospital employees participate not only in the ministerial tasks of informed consent, but also in the process of providing understandable treatment information and aiding each patient to make medical decisions based on that information.

Again, despite indisputable evidence that hospital employees are increasingly involved in the informed consent process the law has not altered its policy against enforcing informed consent duties on hospitals. Some courts have ruled that the "borrowed servant" doctrine shields a hospital from liability for its nurses' mistakes in the informed

144 See, e.g., *id.*; see also *Krout v. Martin*, 50 Pa. D. & C.3d 472, 473 (Pa. Ct. Com. Pl. 1989) (containing example of consent forms administered by a nurse).

145 352 S.E.2d 902 (N.C. Ct. App.), *aff'd*, 362 S.E.2d 273 (N.C. 1987).

146 *Id.* at 908 (alterations in original).

147 See Susanne A. Quallich, *The Practice of Informed Consent*, 17 DERMATOLOGY NURSING 49, 51 (2005).

148 See Jan Hoffman, *Getting Help: Patients Turn to Advocates, Support Groups and E-mail, Too*, N.Y. TIMES, Aug. 14, 2005, at A19.

consent process.¹⁴⁹ In *Ritter v. Delaney*,¹⁵⁰ for example, a plaintiff attempted to argue that the treating physician was an agent of the defendant-hospital and, as evidence of the agency relationship, pointed to the hospital's having provided the physician with a nurse employed by the hospital to provide assistance in obtaining a patient's consent to treatment.¹⁵¹ The court's response suggests that the hospital insulates itself from liability for a nurse's role in the informed consent doctrine where the nurse is a hospital servant "borrowed" by a physician. It wrote:

We fail to see how the hospital relinquishing control of the nurse to Dr. Manning would impose any duty upon the hospital to obtain the informed consent of the patient.

We also fail to see how Dr. Manning ordering the nurse to have the patient sign a hospital permit to operate amounts to the appellee hospital taking on a *non-delegable duty from the physician*, thereby imposing a duty upon the hospital to obtain the informed consent of the patient¹⁵²

Other courts have reasoned that nurses are not physicians and thus lack the medical expertise that justifies the law's imposing an informed consent duty.¹⁵³

The weakness of the law's reasoning is apparent. Courts fail to account for evidence that an independent standard of care exists for nurses with respect to informed consent, which includes assuring that the patient has spoken to the treating physician about treatment risks and alternatives, that the patient understands the information that has been provided, and that the patient consents to treatment.¹⁵⁴ This standard of care is evidenced both by the actual practices of nurses and by nursing experts.¹⁵⁵

149 *But see* *Butler v. S. Fulton Med. Ctr., Inc.*, 452 S.E.2d 768, 772 (Ga. Ct. App. 1994) (holding that a nurse performing ministerial task of recording a patient's consent on a form is not a "borrowed servant"); *Marsh v. Crawford Long Hosp. of Emory Univ.*, 444 S.E.2d 357, 358 (Ga. Ct. App. 1994) (same); *see also* IDAHO CODE ANN. § 39-4306 (2005) (repealed 2005) (stating that the ministerial work of recording informed consent is not the practice of medicine).

150 790 S.W.2d 29 (Tex. App. 1990).

151 *See id.* at 32.

152 *Id.*

153 *See, e.g., Wells v. Storey*, 792 So. 2d 1034, 1039 (Ala. 1999). *But see supra* Part I.C (describing cases in which courts have imposed a duty on hospitals, through their nurses, to identify and report any discrepancies between the procedure to which the patient has consented and the scheduled procedure).

154 *See supra* notes 144–48 and accompanying text.

155 *See supra* notes 144–48 and accompanying text.

The evidence of hospital involvement in the informed consent process discussed to this point has appeared in case law. Yet, there is substantially more evidence that the law has not yet been forced to account for.

Hospitals have become direct suppliers of treatment information to patients through actual and virtual patient libraries. Many stock and staff “resource centers,” providing patients with books, videos, audio tapes, and access to online materials designed to educate them about their conditions and treatment options.¹⁵⁶ More recently, brick-and-mortar patient libraries have given way to virtual ones. Some hospitals develop, through their medical staffs, disease-specific information for patients as well as “decision aids” designed to assist patients sort through treatment information so as to reach personalized decisions,¹⁵⁷ which are then posted online.¹⁵⁸ Other hospitals pay for access to large commercial databases designed to provide the same kinds of information and assistance. Healthwise is an example of one such database, and it boasts having contracts with “hundreds of hospitals” to provide online health information to patients.¹⁵⁹

To this point, hospitals have been depicted as having interjected themselves into the informed consent process by enforcing policies and procedures, by providing consent forms, by employing personnel to assure that informed consent has been obtained and is sufficiently recorded, and by supplying supplemental treatment information to patients. Because of newly developed, computerized informed consent platforms, however, such piecemeal involvement is already giving way to a new paradigm in which hospitals are the comprehensive managers of the informed consent process.

156 See Miller, *supra* note 6, at 1036–37.

157 A decision aid is a tool to assist an individual identify his treatment preferences based on his goals and degree of risk aversion. Thus, decision aids are different from brochures and other media that provide disease and treatment information to patients. Rather than informing a patient’s treatment choice, a decision aid helps patients make choices in the face of medical uncertainty. For more information on decision aids, see generally John Billings, *Promoting the Dissemination of Decision Aids: An Odyssey in a Dysfunctional Health Care Financing System*, HEALTH AFF., Oct. 7, 2004, at 129, available at <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.var.128v1>; Annette M. O’Connor et al., *Modifying Unwarranted Variations in Health Care: Shared Decision Making Using Patient Decision Aids*, HEALTH AFF., Oct. 7, 2004, at 63, available at <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.var.63v1>.

158 For example, see the “decision guides” adopted and disseminated by the Mayo Clinic, available at <http://mayoclinic.com/health/TreatmentDecisionIndex/TreatmentDecisionIndex>.

159 See Healthwise, *supra* note 6.

Several businesses have produced and are selling to hospitals electronic informed consent applications.¹⁶⁰ Each application attempts to provide patients with information about their particular conditions and their proposed medical treatments using understandable language and a medium which patients can refer back to at a later time. For example, iMedConsent provides online treatment information in written form, which can be viewed electronically or printed on paper.¹⁶¹ Another product—Emmi—is a narrated slide show combining graphics and written text, which can be accessed repeatedly online or printed.¹⁶² These products provide information at a deliberate pace so that patients can better absorb it. So, for example, the Emmi presentation on c-section takes about thirty minutes to view.¹⁶³ Furthermore, the information provided by each application is designed to satisfy disclosure duties. Each addresses the risks associated with a proposed procedure as well as risks and benefits of the alternative treatments. Each also documents a general consent to a procedure and an acknowledgment of each of its associated risks. For example, iMedConsent generates online consent forms that include a list of the specific risks, and it then records an electronic patient signature.¹⁶⁴ Emmi, on the other hand, prompts patients to acknowledge the explanation of risks one by one with a mouse click, and each acknowledgment is separately recorded and stored electronically.¹⁶⁵ Finally, none of the applications are designed to replace one-on-one consultation between patient and physician. Rather, each is designed to educate

160 See, e.g., Dialog Medical, iMedConsent, <http://www.dialogmedical.com> (last visited Feb. 8, 2006) (marketing the iMedConsent application); PrivaComp, PrivaSure, <http://www.privacomp.com/privasure.htm> (last visited Feb. 4, 2006) (marketing PrivaSure informed consent system); Rightfield Solutions, Product Demo, <http://rightfield.net/demo.shtml> (last visited Feb. 8, 2006) (marketing the expectation management medical information (Emmi) system); VisionTree, Healthcare Online, <http://www.visiontree.com/index.cfm/fuseaction/products.healthcare> (last visited Feb. 8, 2006) (marketing VisionTree Healthcare Online).

161 See Dialog Medical, iMedConsent Enterprise, <http://www.dialogmedical.com/enterprise.htm#> (follow “Sample Documents” hyperlink at the bottom of the page) (last visited Feb. 4, 2006).

162 See Rightfield Solutions, *supra* note 160 (providing several procedure-specific demonstrations).

163 See *id.* (follow “C-section” hyperlink under “Product Demo”). While the demonstration lasts about five minutes, it is clear from a sample screen recording aspects of the patient’s interaction with the application that the entire presentation is quite lengthy.

164 See Dialog Medical, *supra* note 161 (follow “Sample Documents” hyperlink at the bottom of the page).

165 See Rightfield Solutions, *supra* note 160 (follow any one of several hyperlinks for procedure-specific demonstrations).

patients concentrating on the basics of a proposed treatment, which allows doctors to focus on the unique informational needs of a particular patient.

Recent news suggests that these automated, electronic informed consent applications have piqued the interest of hospitals. As mentioned in the introduction to this Article, the Veterans Affairs has completed its installation of iMedConsent at each of its 162 medical centers.¹⁶⁶ Additionally, in July 2005, the makers of VisionTree Healthcare announced that the product was being piloted by a cancer center in Maryland, and that the system "has been successfully implemented at sites around the country in the fields of oncology for [gynecology], breast and prostate cancer, as well as neurosurgery, spine surgery, cardiology and orthopedics . . . includ[ing at] UCLA Medical Center, Saint Luke's Hospital Kansas City, Vantage Oncology and Baylor College of Medicine."¹⁶⁷ Similarly, a flagship medical center in a New York chain of hospitals, as well as a seventeen-hospital system associated with the University of Pittsburgh Medical Center are piloting the Emmi system.¹⁶⁸ Moreover, an industry analysis by KPMG confirms a trend among hospitals to employ online, automated informed consent applications as a way of managing both liability risks and patients' expectations.¹⁶⁹

To be clear, the role of a hospital in the informed consent process changes fundamentally when it employs one of the automated informed consent policies and processes described above. No longer does the hospital merely encourage or even assure that physicians have obtained informed consent prior to treatment. Instead, the hospital manages the entire process of disclosing standard treatment information and securing consent, leaving their physicians in control of answering remaining patient questions and otherwise addressing informational needs of particular patients that deviate from the norm.

This new managerial role for hospitals is even more apparent from the role hospitals may play in assisting patients to process treatment information and to arrive at a treatment decision that reflects each patient's preferences.¹⁷⁰ Dartmouth-Hitchcock Medical Center,

166 See *supra* note 4 and accompanying text.

167 See Press Release, VisionTree, Holy Cross Hospital Implements VisionTree Healthcare To Help Patients Make Informed Treatment Decisions (July 18, 2005), available at <http://www.visiontree.com/index.cfm/fuseaction/newsevents.healthcare>.

168 See Merli, *supra* note 5.

169 See *id.*

170 In addition to the example described here, see *supra* note 148 and accompanying text for a description of hospitals' use of patient advocates as medical decision-making counselors.

for example, has a Center for Shared Decision Making, which employs personal counselors to help patients sort through treatment information and make decisions that reflect their preferences.¹⁷¹ The Center is staffed by nurse-counselors and overseen by a member of the hospital's medical staff.¹⁷² It also houses brochures and videos commonly associated with a hospital's patient resource center.¹⁷³

A managerial role for hospitals in the informed consent process, while a relatively new concept in the evolving relationship between hospitals and the patients they treat, is not new in the relationship between hospitals and human subjects who participate in medical research. As noted earlier, federal law since the 1970s has required institutions in which human subjects research is conducted to oversee the entire process by which individuals (often patients) consent to participate in such research, which includes approving substantive disclosures made to potential research subjects and the form on which those disclosures are made and on which consent is recorded.¹⁷⁴ Accordingly, there is precedent—both clinical precedent and legal precedent—for substantial institutional oversight of the informed consent process.

Thus, the law's policy against imposing informed consent duties on hospitals is based on an antiquated view that hospitals are merely the facilities in which medical decisionmaking takes place at the sole direction of independent physicians. Not only is this view inconsistent with clinical reality, but it also leads to an irresponsible policy of permitting hospitals to participate in the informed consent process without any legal accountability. Thus, we are left to hope that market forces are sufficient to assure that the potential social value of institutional oversight of informed consent is, in fact, realized.

While the expanding role of hospitals in the informed consent process is evidence of how antiquated the law's policy is, it is also evidence of the policy's staying power. In other words, the policy has proven resistant to change based on evolving clinical practices. Accordingly, while it may be difficult to imagine how the policy can sur-

171 See Dartmouth-Hitchcock Med. Ctr., Center for Shared Decisions Making [hereinafter Dartmouth-Hitchcock, About], http://www.dhmc.org/webpage.cfm?site_id=2&org_id=108&gsec_id=0&sec_id=0&item_id=2486 (last visited Feb. 4, 2006). The Center is closely associated with organizations that research and develop decision aids. See Dartmouth-Hitchcock Med. Ctr., Our Staff [hereinafter Dartmouth-Hitchcock, Our Staff], http://www.dhmc.org/webpage.cfm?site_id=2&org_id=108&morg_id=0&sec_id=0&gsec_id=13223&item_id=13223 (last visted Feb. 4, 2006).

172 See Dartmouth-Hitchcock, Our Staff, *supra* note 171.

173 See Dartmouth-Hitchcock, About, *supra* note 171.

174 See *supra* notes 55–59 and accompanying text.

vive the most recent trend among hospitals to implement automated informed consent applications, the policy's lasting power despite such changes in the past suggests otherwise. This is all the more apparent given that the policy, in addition to surviving changes in clinical practice, has also weathered substantial changes in the law's conception of medical expertise and institutional liability. This is explored next.

B. The Policy's Persistence Despite the Law's Rethinking Expertise and Standardization in Informed Consent

At the foundation of the law's policy against imposing informed consent duties on hospitals is the erroneous claim that managing the informed consent process requires a physician's knowledge and skills and, thus, that the law should protect the process against interference by those outside of the medical profession, including hospitals.¹⁷⁵ The claim can be broken down into two parts. First is the claim of technical, medical expertise. According to this claim, only a physician can provide the necessary disclosures to patients because only physicians have the expert ability to determine and explain a patient's diagnosis, prognosis, and treatment options, as well as the risks and benefits of those options.¹⁷⁶ Likewise, only the treating physician has access to a patient's medical history and other information about the patient's condition, which is needed to determine what treatment information may be uniquely important to that patient.¹⁷⁷

In contrast, the second claim concerns skills for making difficult judgments about whether and, if so, how to disclose sensitive treatment information to patients. As the Missouri Court of Appeals put it in *Roberson v. Menorah Medical Center*,¹⁷⁸ "[t]he presentation to the patient of risks involved in prospective surgery cannot but call for some very nice judgments. . . . [T]he patient may have his apprehensions unnecessarily and unduly heightened if risks are unwisely presented, leading him to an imprudent choice. Risks must be placed in perspec-

¹⁷⁵ See *supra* notes 36–45 and accompanying text.

¹⁷⁶ See, e.g., *Kelly v. Methodist Hosp.*, 664 A.2d 148, 151 (Pa. Super. Ct. 1995). The court found:

It is the surgeon and not the hospital who has the education, training and experience necessary to advise each patient of risks associated with the proposed surgery. Likewise, by virtue of his relationship with the patient, the physician is in the best position to know the patient's medical history and to evaluate and explain the risks of a particular operation in light of the particular medical history.

Id.

¹⁷⁷ See *id.*

¹⁷⁸ 588 S.W.2d 134 (Mo. Ct. App. 1979).

tive.”¹⁷⁹ Similarly, the court in *Fiorentino* called these judgments “the most delicate matter” of the physician-patient relationship,¹⁸⁰ and many courts have employed that language since.¹⁸¹

Thus, while the first claim is about technical expertise, the second concerns the art of patient communication. Despite this distinction, however, courts generally lump the two claims together in the course of ruling that hospitals lack the expertise to participate in the informed consent process.¹⁸²

While the informed consent process certainly depends on expert knowledge about patients’ conditions, their treatment options, and the risks and benefits of those options, case law has overblown its importance, failing to observe boundaries to medical expertise in informed consent. This is most obvious in the case law’s failure to recognize that physicians, while expert at identifying treatment disclosures, are not necessarily expert communicators.

Since the 1970s researchers have studied the quality of communication between doctor and patient, and their work has revealed that physicians employ communication methods that undercut the likelihood that patients will understand what they are told.¹⁸³ For exam-

179 *Id.* at 137.

180 *Fiorentino v. Wenger*, 227 N.E.2d 296, 300 (N.Y. 1967).

181 *See, e.g., Campbell v. Pitt County Mem’l Hosp., Inc.*, 352 S.E.2d 902, 914 (N.C. Ct. App.), *aff’d*, 362 S.E.2d 273 (N.C. 1987); *Alexander v. Gonser*, 711 P.2d 347, 351 (Wash. Ct. App. 1985); *Mathias v. St. Catherine’s Hosp., Inc.*, 569 N.W.2d 330, 333 (Wis. Ct. App. 1997).

182 For example, consider the complete passage from *Roberson*:

The presentation to the patient of risks involved in prospective surgery cannot but call for some very nice judgments. On the one hand the patient is entitled to such information as he needs to make an intelligent decision and to give an informed intelligent consent. And yet the patient may have his apprehensions unnecessarily and unduly heightened if risks are unwisely presented, leading him to an imprudent choice. Risks must be placed in perspective. The one dealing with the patient at this point must have knowledge of the patient—his temperament, his intelligence, his mental condition and his physical condition. He must also have a knowledge of the surgery itself—its risks, whether imminent or remote, and whether it is pressing, deferrable or optional. He must know the availability of conservative methods of treatment, if any, and their promises for success as compared to the surgery. All these factors must be placed in the equation. The physician alone is equipped to make the delicate judgments called for.

Roberson, 588 S.W.2d at 137; *see also Kelly*, 664 A.2d at 151 (referring to an informed consent claim against the hospital as “not only improvident but unworkable as well” because it turns on hospitals’ exercising skills they do not possess).

183 Indeed, by the mid-1980s, most of the observations that follow concerning the shortcomings of doctor-patient communication and their effect on the informed consent process were apparent from the empirical work completed as of that date. *See*

ple, physicians tend to use technical medical terms, which patients do not understand.¹⁸⁴ Additionally, even on nontechnical matters, they commonly employ language at a graduate-school level of complexity, which again most patients are ill-equipped to comprehend.¹⁸⁵ Furthermore, physician-patient communications often reinforce a power imbalance between the two parties and thereby discourages patients from asking questions. For example, physicians control the interactions by asking close-ended questions, interrupting patient answers and redirecting conversation.¹⁸⁶ Likewise, physician-patient interactions tend to be relatively short, serving the physician's interest in clinical efficiency.¹⁸⁷ Moreover, doctor-patient communication takes place at a time when patients are feeling ill or simply anxious. In such a communicative environment, it is unlikely that patients will remember or understand information provided to them.¹⁸⁸

Finally, the problem of "framing bias" in doctor-patient communication has been apparent since the early 1980s.¹⁸⁹ Whether done intentionally or unintentionally, physicians affect the treatment choices patients make by the way they present treatment information to patients.¹⁹⁰ For example, individuals are significantly more likely to consent to a proposed surgical procedure if statistics concerning prior

FADEN & BEAUCHAMP, *supra* note 8, at 316–29 (summarizing data and its implications).

184 See Robert Gatter, *Unnecessary Adversaries at the End of Life: Mediating End-of-Life Treatment Disputes To Prevent Erosion of Physician-Patient Relationships*, 79 B.U. L. REV. 1091, 1114 n.105 (1999) (citing Vera M. Henzl, *Linguistic Means of Social Distancing in Physician-Patient Communication*, in DOCTOR-PATIENT INTERACTION 78, 86–87 (Walburga Von Raffler-Engel ed., 1989)); see also FADEN & BEAUCHAMP, *supra* note 8, at 316–19 (recognizing that, even when technical terms are avoided or defined, conceptual differences remain because of differences in background and training).

185 See BERG ET AL., *supra* note 8, at 196–97 (citing empirical evaluations of language used in informed consent forms); see also Gatter, *supra* note 184, at 1114 n.105 (same).

186 See M. Kim Marvel et al., *Soliciting the Patient's Agenda: Have We Improved?*, 281 JAMA 283 (1999); see also Gatter, *supra* note 184, at 1114 n.104 (citing NANCY AINSWORTH-VAUGHN, CLAIMING POWER IN DOCTOR-PATIENT TALK 68–71, 89 (1998); ALEXANDRA DUNDAS TODD, INTIMATE ADVERSARIES 82–90 (1989); CANDACE WEST, ROUTINE COMPLICATIONS: TROUBLES WITH TALK BETWEEN DOCTORS AND PATIENTS 51–96 (1984)).

187 See David Mechanic et al., *Are Patients' Office Visits with Physicians Getting Shorter?*, 344 NEW ENG. J. MED. 198 (2001) (finding that, on average, physicians spent twenty minutes with each patient, which represented an increase of about two minutes as compared to just ten years earlier); see also Fraser, *supra* note 7, at 267–68.

188 See FADEN & BEAUCHAMP, *supra* note 8, at 323–26 (examining the effects of stress and illness on comprehension in the informed consent process).

189 See *id.* at 319 n.47, 320 n.48 (citing to studies published in 1981 and 1982).

190 See *id.* at 319–20.

patients' outcomes are presented in terms of a survival rate rather than a mortality rate.¹⁹¹ This, in turn, creates an opportunity for a physician's bias about a medical treatment decision to interfere with the patient's understanding of her treatment options and with her ability to make an autonomous choice.

Thus, empirical evidence has demonstrated for more than twenty years that physicians are not experts at communicating treatment information to their patients in ways that promote understanding. This may explain why a recent review of empirical studies concluded that using a third-party educator may be the best method for improving comprehension of information provided during the informed consent process.¹⁹² Nonetheless, the law continues to impose duties of disclosure only on physicians on the theory that they are best equipped to explain treatment risks to patients.¹⁹³

Not only has the law's policy against imposing informed consent duties on hospitals endured despite evidence undercutting its assumption that physicians are expert communicators, it has also survived the realization that informed consent disclosures can be standardized and thus does not depend on an in-person deployment of technical, medical expertise. Case law presumes that a physician is needed to custom tailor treatment disclosures to each patient based upon the physician's expert assessment of the patient's unique informational needs. In early cases, courts claimed that physicians needed to determine what treatment information to withhold from their patients based on the physician's clinical evaluation of the patient's emotional and physical condition.¹⁹⁴ For example, the *Fiorentino* court, in support of its finding that only physicians are qualified to disclose treatment information, reasoned that a physician's expertise is needed to assess "fluctuating indications" of a patient's ability to cope with such infor-

191 See Katrina Armstrong et al., *Effects of Framing as Gain Versus Loss in Understanding and Hypothetical Treatment Choices: Survival and Mortality Curves*, 22 MED. DECISION MAKING 76 (2002). Interestingly, Faden and Beauchamp describe a nearly identical study published in 1982, which reached the same conclusion. See FADEN & BEAUCHAMP, *supra* note 8, at 319–20 (citing Barbara McNeil et al., *On the Elicitation of Preferences for Alternative Therapies*, 306 NEW ENG. J. MED. 1259 (1982)).

192 See James Flory & Ezekiel Emanuel, *Interventions To Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review*, 292 JAMA 1593 (2004) (reviewing results of many empirical studies testing various methods for improving comprehension of information provided to potential research subjects as part of the process of informed consent for participation in clinical research).

193 See, e.g., *Kelly v. Methodist Hosp.*, 664 A.2d 148, 151 (Pa. Super. Ct. 1995).

194 See *Roberson v. Menorah Med. Ctr.*, 588 S.W.2d 134, 137 (Mo. Ct. App. 1979) (claiming that physicians must determine whether to withhold information based on the physician's assessment of the patient's physical condition and "temperment").

mation.¹⁹⁵ Additionally, the court found not only that each patient requires a separate assessment, but also that any one patient's ability to cope with treatment information can change and thus must be reassessed from time to time.¹⁹⁶ More recent cases, on the other hand, imagine that physicians add detail to their disclosures based upon the particular medical circumstances of each patient. The Pennsylvania Superior Court in *Kelly v. Methodist Hospital*,¹⁹⁷ for example, found that physicians individualize their disclosures "in light of the [patient's] particular medical history," and it contrasts this with the perception that hospitals would make disclosures "in laundry-list fashion."¹⁹⁸ Given the presumption that the content of a treatment disclosure turns in part on a physician's expert assessment of each patient's fluctuating medical and emotional conditions, courts perceive the disclosure process should not be subject to institutional standardization because it is too "dynamic" and "individualized."¹⁹⁹

This perception, however, has been proven wrong. Certainly, a physician's expertise is often required to address a patient's particular concerns or unique informational needs. Yet, the need for expert, custom-tailored disclosures is not so great as to make standardized disclosures impossible or imprudent. Indeed, the case law's implied claim that standardization is bad public policy ignores the fact that principles of fairness and efficiency temper goals of protecting patients and their autonomy through the informed consent doctrine. At its inception and throughout its early development, the informed consent doctrine was almost purely patient-centered, with public policy debates focused on how best to balance the protection of patients' well-being with protection of patients' autonomy.²⁰⁰ During the 1970s, informed consent became defined by the goal of promoting patient autonomy.²⁰¹ Shortly thereafter, critical commentary focused on an apparent gap that was witnessed between the informed consent doctrine as conceived and the informed consent doctrine as it was employed in the law and in medical practice, culminating in the mid-1980s with the publication of *The Silent World of Doctor and Patient* by

195 See *Fiorentino v. Wenger*, 227 N.E.2d 296, 300 (N.Y. 1967).

196 See *id.*

197 664 A.2d 148.

198 *Id.* at 151.

199 See *Valles v. Albert Einstein Med. Ctr.*, 805 A.2d 1232, 1239 (Pa. 2002) ("Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to interject an element of a hospital's control into this highly individualized and dynamic relationship.").

200 See FADEN & BEAUCHAMP, *supra* note 8, at 25-40.

201 See *id.* at 40-42.

Jay Katz²⁰² and *A History and Theory of Informed Consent* by Ruth R. Faden and Tom L. Beauchamp.²⁰³ As the doctrine matured, however, other public policy concerns received their due. For example, the law recognized that, out of fairness, physicians should not be burdened with the responsibility of meeting every informational need of each individual patient and assuring that each patient actually understood the treatment information provided to her. Instead, physicians were responsible for disclosing only material information, with patients bearing the burden to both pursue any additional information and to make sense of the information that was provided.²⁰⁴ Furthermore, commentators recognized the costs associated with an uncompromising commitment to patient autonomy, and calls to eliminate the gap between rhetoric and reality of informed consent are now qualified by concerns for promoting clinically efficient medical decisionmaking.²⁰⁵

Thus, the law's policy against imposing informed consent duties on hospitals on the grounds that public policy demands such a high degree of expert individualization of patient disclosures as to eliminate standardized disclosure is directly at odds with current state of public policy about informed consent. Somehow, evolving thought about the goals and limits of the informed consent doctrine has bypassed this segment of informed consent law.

Beyond its claim that standardized disclosures are a bad idea, the law also erroneously claims that such standardization is in fact impossible.²⁰⁶ Reality, however, disproves this claim as well. Certainly, the availability of new, online informed consent applications that disclose standard treatment options and their risks and benefits based on pa-

202 See KATZ, *supra* note 8.

203 See FADEN & BEAUCHAMP, *supra* note 8.

204 See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 786–88 (D.C. Cir. 1972).

205 Peter H. Schuck's article, *Rethinking Informed Consent*, was highly influential. It persuasively identified and criticized how informed consent commentary had stagnated because commentators speak exclusively from the perspective of either a proponent of patient autonomy or a proponent of clinical efficiency. Schuck, *supra* note 27, at 902–05. I borrowed Schuck's theme in my own writing on informed consent, arguing that we cannot ignore the "trade-off between the benefit of greater autonomy and the clinical costs of achieving it" and concluding that, "[j]ust as it makes no sense to achieve greater clinical efficiency through eliminating the rights of patients to consent to treatments, it makes no sense to achieve fully autonomous medical decision-making by bankrupting the health care delivery system." Gatter, *supra* note 8, at 588.

206 See, e.g., *Kelly v. Methodist Hosp.*, 664 A.2d 148, 151 (Pa. Super. Ct. 1995) ("[W]e are unable to conceive of how a hospital could draft, in laundry-list fashion, 'the substantive information to be disclosed' for each surgery as it relates to each patient. Thus, the approach suggested by appellants would prove not only imprudent but unworkable as well." (quoting *Shaw v. Kirschbaum*, 653 A.2d 12, 15 (Pa. Super. Ct. 1994))).

tients' medical conditions is evidence that standardization is possible.²⁰⁷ Yet, standardized informed consent disclosures have a longer history, and, ironically, the law is instrumental in that history. First, federal regulations adopted in the early 1970s obligated research institutions, including hospitals, to form institutional review boards and assure that they oversee all aspects of human subjects research going on in their facilities, including, in particular, the substantive disclosures that prospective research subjects were to receive as part of the informed consent process.²⁰⁸ Thus, for more than thirty years IRBs have scrutinized consent forms that list specific risks and benefits of participation in proposed medical experiments, which, if approved, are distributed to prospective research subjects in a uniform manner. While such standardized disclosures are not the exclusive source of information for prospective research subjects about the risks of participation in a clinical study, they are an essential component of assuring that disclosures are adequate and uniformly delivered. Second, states routinely supplement general informed consent standards by mandating the disclosure of particular risk information associated with specific procedures.²⁰⁹ In fact, laws in at least two states attempt to codify treatment-specific, standardized, informed consent disclosures for every known procedure. The legislatures in Texas and Louisiana have established medical disclosure panels and charged them with the responsibility of identifying all medical procedures for which risk disclosures are necessary and, for each of those procedures, creating a standard set of disclosures.²¹⁰ These procedure-specific, disclosure lists are then publicized, and a physician is presumed to have satisfied her obligation to provide adequate disclosures to a patient concerning a proposed procedure if she delivers to the patient the relevant stan-

207 See *supra* notes 159–73 and accompanying text.

208 See *supra* notes 55–59 and accompanying text.

209 See, e.g., ARK. CODE ANN. § 17-95-108(a)(3) (Supp. 2005) (requiring that physicians disclose “vitamin deficiency and malnutrition” as a risk of gastric bypass surgery); CAL. HEALTH & SAFETY CODE § 1645 (West 1990 & Supp. 2006) (requiring physicians to disclose to surgical patients their options of receiving transfusions of autologous blood or directed or nondirected homologous blood from volunteers together with the risks and benefits of each blood source, and to do so “by means of a standardized written summary” developed by the state’s health department); *id.* § 1690 (West 1990) (requiring physicians to disclose to all patients for whom a hysterectomy has been proposed that the procedure will render the patient sterile and that the procedure is irreversible).

210 See LA. REV. STAT. ANN. § 40:1299.40E (2001 & Supp. 2005); TEX. CIV. PRAC. & REM. CODE ANN. §§ 74.102–.103 (Vernon Supp. 2005).

dardized list of disclosures.²¹¹ Finally, despite its stated goal of providing patients with treatment information that is necessary for patients in their specific circumstances to make informed treatment choices, the law generally permits physicians to formulate disclosures based on their patients' medical conditions or proposed treatments without regard to other attributes that might make that patient unique.²¹² As I have described elsewhere, state laws obligate physicians to disclose "material" treatment information, but they permit physicians to identify "material" information based solely on either the patient's diagnosis or the treatment that has been proposed to the patient.²¹³ Accordingly, physicians may ignore all nonmedical attributes of their patients in formulating their disclosures without fear of liability. In this way, the common law too permits standardized disclosures based on medical conditions and treatments.

Although there is room for debate about how best to combine standardized and individualized disclosure in informed consent, there can be no doubt that standardization is possible and that it should play a role in informed consent processes designed to both adequately and efficiently enable patients to make informed treatment choices. Furthermore, standardization in informed consent changes the way physician expertise is deployed in the informed consent process. It is used to develop standard disclosures and to identify the clinical circumstances in which those disclosures may be used. Consequently, there is less need to have a physician on hand in every clinical encounter where disclosures will be made.

To this point, we have examined how the legitimate role for medical expertise in the informed consent process has been diminished by the realization that physicians, despite their expert knowledge about treatments and their risks, are not necessarily expert communicators of treatment information, and how it has been further diminished by a concern for clinical efficiency in informed consent and, with it, greater legitimacy for standardization practices in the disclosure of treatment information. The role for medical expertise has been diminished further still by the law's well-documented shift away from identifying treatment information that must be disclosed based on a professional standard of care.²¹⁴ The law first recognized a duty of

211 See LA. REV. STAT. ANN. § 40:1299.40E; TEX. CIV. PRAC. & REM. CODE ANN. § 74.105.

212 See generally Gatter, *supra* note 8, at 567–74.

213 See *id.* at 567–68.

214 For histories of informed consent law, see BERG ET AL., *supra* note 8, at 41–52; FADEN & BEAUCHAMP, *supra* note 8, at 114–50; KATZ, *supra* note 8, at 1–29.

disclosure associated with a duty to obtain consent in the late 1950s,²¹⁵ and shortly thereafter it was established that a claimed breach of the duty of disclosure would be treated as a professional negligence claim.²¹⁶ Consequently, the scope of the duty to disclose is based on a medical standard of care: a physician must disclose to patients information about a proposed treatment as would a reasonably prudent physician under the same or similar circumstances.²¹⁷ Thus, the professional standard for disclosure applied in informed consent cases generally in 1967 when *Fiorentino* refused to recognize an informed consent duty applicable to a hospital, reasoning that the law should not impose such a duty except on those with medical expertise.²¹⁸ The standard by which the law defines the duty to disclose began to change, however, in 1972 with the decision in *Canterbury v. Spence*,²¹⁹ which employed a reasonable-person, rather than a reasonable-physician, standard of disclosure.²²⁰ It held that a physician must disclose to a patient treatment information that a reasonable person, in what the physician knows or should know to be the patient's position, would consider material to her treatment decision.²²¹ Although the reasonable-person standard has not completely replaced the reasonable-physician standard, it has been adopted by approximately half of all U.S. jurisdictions.²²² That standard rejects the claim that the classification of treatment information as either material or immaterial is a matter of medical expertise. Thus, it further diminishes the role for physician expertise in the disclosure process. Rather than directing physicians to make disclosures based on the customs of their medical colleagues, the reasonable-person standard instructs physicians to be guided by what reasonable lay persons would want to know. Accordingly, medical expertise may be used legitimately to identify a patient's condition, the viable options for treating that condition, the risks and benefits of each of those options, and the various probabilities that those risks and benefits arise. The next step, however, of determining

215 See *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Ct. App. 1957).

216 See *Natanson v. Kline*, 350 P.2d 1093 (Kan.), *clarified by* 354 P.2d 670 (Kan. 1960); see also FADEN & BEAUCHAMP, *supra* note 8, at 132 (arguing that courts addressing claims of inadequate disclosure after *Natanson* generally adopted the professional negligence model).

217 See *Natanson*, 350 P.2d at 1106.

218 See *supra* notes 36–37 and accompanying text.

219 464 F.2d 772 (D.C. Cir. 1972).

220 See *id.* at 787.

221 See *id.*

222 See Gatter, *supra* note 8, at 563–67; see also FURROW ET AL., *supra* note 97, at 356–66.

which of these expertly assembled pieces of information will be disclosed to the patient is not a matter of expertise according to the reasonable-person standard.

The vast majority of cases addressing whether hospitals can be held liable for breaches of the informed consent doctrine were decided after 1972,²²³ and thus after the reasonable-person standard for disclosure had been introduced as a minority viewpoint. Consequently, some were decided in jurisdictions employing the reasonable-person standard while others were decided in jurisdictions using the reasonable-physician standard. Yet, there does not appear to be a correlation between the standard of disclosure used in a particular jurisdiction and the outcome of case alleging that a hospital has breached an informed consent duty. In other words, despite a shift in policy over the last thirty years away from complete deference to medical expertise about what treatment information is and is not relevant to treatment decisions, the law's policy against imposing informed consent duties on hospitals has remained constant as has its underlying rationale that only physicians have the expertise necessary to justify the law's recognition of informed consent duties.

A common theme has emerged from the analysis to this point. The law's policy against imposing informed consent duties on hospitals is a survivor. It has persisted in spite of substantial shifts in informed consent policy and practice, even when some of those shifts have occurred within the law itself. This theme continues as a shift in the law's perception of hospitals and their legal responsibility for safeguarding their patients is examined.

C. The Policy's Persistence Despite the Rise of Corporate Negligence in Health Care

The law's policy against imposing informed consent duties on hospitals has also survived the rise of direct institutional liability in health care, and this is perhaps the best evidence of the policy's staying power. The corporate negligence doctrine, which imposes a general duty on hospitals to safeguard their patients, appears on its face to apply to the issue of institutional informed consent. As described in detail below, this is evidenced by the fact that several courts considering claims of institutional informed consent liability have expressly addressed the doctrine in their rulings. Nonetheless, they have refused to recognize institutional informed consent duties arising from the doctrine. Thus, as demonstrated below, the law appears to have

²²³ See *supra* notes 1, 67 (listing cases holding that hospitals have informed consent duties).

made a deliberate policy choice to shield the informed consent process from institutional liability principles that apply to all other aspects of the hospital-patient relationship.

The corporate negligence doctrine was first recognized in the mid-1960s,²²⁴ and it both took shape and took hold during the 1980s and early 1990s.²²⁵ It recognizes that a hospital owes each of its patients a duty "to ensure the patient's safety and well-being while at the hospital,"²²⁶ and it includes a duty to maintain safe and adequate facilities, to permit only qualified physicians to practice within the institution, to oversee those who practice within the hospital, and to implement policies and procedures designed to ensure quality care for hospital patients.²²⁷ The doctrine was a substantial change from earlier law because it recognized that hospitals owe duties directly to their patients. Thus, patients were no longer obligated to rely solely on a claim of vicarious liability to receive compensation for a treatment injury from a hospital.²²⁸

On its face, the doctrine supports imposing informed consent duties on hospitals. As a general matter, a patient's safety is undermined when she is at risk for receiving unauthorized treatments or for suffering a treatment's side effects about which she was unaware at the time of treatment. In other words, a failure to obtain informed consent is not only a matter of personal indignity, it is also a matter of diminished safety and poor quality care.²²⁹ Furthermore, two of the particu-

224 See, e.g., *Darling v. Charleston Cmty. Mem'l Hosp.*, 211 N.E.2d 253, 258 (Ill. 1965) (holding sufficient evidence existed to support a factual determination that a hospital owed and breached a duty to implement a system for identifying and responding to inadequate treatment of a patient by a physician permitted to practice within the hospital).

225 See, e.g., *Bost v. Riley*, 262 S.E.2d 391, 396 (N.C. Ct. App. 1980) (recognizing a hospital's duty to its patients to monitor and oversee treatment provided by physicians permitted to practice within the institution); *Thompson v. Nason Hosp.*, 591 A.2d 703, 707 (Pa. 1991) (hospital owes each patient a duty "to ensure the patient's safety and well-being while at the hospital"); see also Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 385-94 (1994) (tracing the evolution of the corporate negligence doctrine following the fall of charitable immunity for hospitals and a period of reliance on agency liability, and reporting that, as of 1994, twenty-one states had adopted the corporate negligence doctrine).

226 *Thompson*, 591 A.2d at 707.

227 See *id.*

228 See *id.* at 706-07 (summarizing the history of hospital liability from charitable immunity to vicarious liability and then to corporate negligence).

229 While the informed consent doctrine is traditionally known for its vindication of the right to self-determination among patients, see, e.g., Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340,

lar duties recognized under the direct institutional liability principle encompass a role for hospitals in assuring that patients have provided informed consent prior to treatment.²³⁰ The doctrine imposes a duty for hospitals to “oversee all persons who practice medicine within its walls as to patient care,”²³¹ which would include physicians when they use their professional skills to identify and communicate medical conditions, treatment options, and the risks and benefits of those options for their patients while in the hospital. Additionally, there is “a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients,”²³² which would include the obligation of hospitals to implement policies and procedures designed to assure that patients are not being exposed to treatment risks they did not knowledgeably assume or to treatments they did not authorize.

The applicability of direct institutional liability principles to the issue of hospital liability for informed consent failures goes deeper than the language of the liability rules, however. It originates in the policy underlying those principles.

Ultimately, it is the need for hospitals to coordinate complex medical care that justifies the law’s imposing on hospitals a duty to safeguard patients. In the second half of the twentieth century, hospitals evolved from being merely the *places* where complex care took place to being the *systems* that managed that complexity.²³³ Modern hospitals maintain various kinds of facilities and services designed to

347 (1974), it has been adopted as a doctrine that promotes patient safety and health care quality as well, see THE LEAPFROG GROUP, HOSPITAL QUALITY AND SAFETY SURVEY 46 (2005), <https://leapfrog.medstat.com/pdf/final.pdf> (describing informed consent as “an additional layer of protection [that] decrease[s] the potential for medical errors”); see also INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 196 (Linda T. Kohn et al. eds., 2000) (identifying the informed patient as a “major unused resource in most hospitals, clinics, and practices” who—armed with an informed understanding of his medications—can “intercept the rare but predictable error” related to medications); JOINT COMM’N, *supra* note 129, 5.2–5.3 (making the implementation of informed consent policies and procedures a requirement of hospital accreditation).

230 See, e.g., *Tuttle v. Silver*, 21 Pa. D. & C.4th 271 (Pa. Ct. Com. Pl. 1993) (holding that the corporate negligence duties to oversee those who practice within a hospital and to implement policies and procedures to ensure quality of care provide a foundation for imposing informed consent duties on hospitals), *abrogated by Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. Ct. 1995).

231 *Thompson*, 591 A.2d at 707.

232 *Id.*

233 Rosemary Stevens, in her history of twentieth-century U.S. hospitals, traces this change to the 1930s when medical care became more technological and thus more hospital-based. Because of the growth in technological complexity of care, the hospital took on an independent institutional life, changing from the individual physician’s

centralize the care of acutely ill patients, including operating rooms, intensive care units, radiological services, laboratory services, and pharmacies. Likewise, they bring together highly skilled personnel at all levels of expertise (e.g., physicians, nurses, and technicians) across a variety of generalized, specialized, and sub-specialized fields of medicine. Most importantly, hospitals implement systems to coordinate personnel and resources for the purposes of providing complete and high quality medical care to each of their patients. As one court put it, "[t]he corporate hospital of today has assumed the role of a comprehensive health center with responsibility for arranging and coordinating the total health care of its patients."²³⁴

By imposing direct institutional duties on hospitals to safeguard their patients, the law acknowledges that the quality of medical care in hospitals is significantly affected by the degree of institutional oversight and coordination employed at hospitals, and that the task of oversight and coordination is best placed on hospitals as managers. As Professors Abraham and Weiler describe it, medical care is increasingly provided through "teams" of personnel, which increases the risk of a bad medical outcome as a result of "failures of communication" among team members, and the law must account for this by imposing liability on those best situated to organize and equip those teams.²³⁵ "[T]he hospital," they conclude, "occupies an ideal strategic position within the health care system from which to accomplish this crucial quality assurance mission."²³⁶

Thus, the value that hospitals bring to the process of informed consent is their ability to improve quality through systemic organization. Hospitals can improve the process by contributing capital, human resources, and institutional procedures for the purposes of (1) identifying standard disclosures; (2) assuring that disclosures are accurate, thorough, understandable, and continuously available to patients for repeat learning; (3) recording and confirming informed consent; (4) providing greater access to personnel for assistance throughout the decisionmaking process; and (5) continuously identifying and cor-

"workshop" to "a technological system in its own right." ROSEMARY STEVENS, IN *SICKNESS AND IN WEALTH* 172-81 (rev. ed., Johns Hopkins Univ. Press 1999) (1979).

234 *Thompson*, 591 A.2d at 706.

235 See Abraham & Weiler, *supra* note 225, at 413 (arguing for the law to move from the current system of permitting claims of individual physician malpractice and claims of corporate negligence against hospitals to a system of comprehensive enterprise liability).

236 *Id.*; see also INST. OF MED., *supra* note 229, at 69-201 (concluding that medical errors are most commonly a result of system failures and that improving safety begins with improving the way health care systems are organized and overseen).

recting deficiencies in institutional informed consent practices. All of this decreases the risk that treatments are provided without informed consent.

Hospital coordination of informed consent is also likely to improve the efficiency of health care delivery in two ways. First, by assuring that patients receive accurate, thorough, understandable, and repeatedly accessible treatment information, hospitals increase the likelihood that patients select a treatment option that serves their treatment goals and minimizes their personal risk of harm.²³⁷ Second, hospitals can assure that informed consent tasks are delegated across a spectrum of institutional mechanisms and personnel in a manner that provides sufficient expertise at all stages of the process without unnecessarily burdening personnel at any level of expertise. This would relieve physicians of the responsibility of orchestrating informed consent, and it would assure that the clinical time physicians spend on informed consent is driven by a real need for their expertise. Such efficiencies may improve health care quality as well because well informed patients tend to comply more completely with treatment plans and experience better treatment outcomes than other patients,²³⁸ and because relief from overburdened clinical time likely decreases the risk of medical error.

Given the clear alignment of institutional liability principles, policy favoring improved systemic management of complex health care, and the value hospitals can add by managing the informed consent process, one would assume that courts could not avoid imposing informed consent duties on hospitals when confronted with these arguments. But this is not the case. The vast majority of courts addressing whether the corporate negligence doctrine provides a basis for imposing informed consent duties on hospitals have held that it does not.²³⁹ Meanwhile, almost every case ruling that informed consent duties ap-

237 See Gatter, *supra* note 8, at 590–91 (describing an increased likelihood of patients receiving optimal treatments—i.e., treatments that are likely to satisfy their goals, as an efficient result).

238 See *id.* at 591 & n.177; see also Laura A. Siminoff et al., *The Promise of Empirical Research in the Study of Informed Consent Theory and Practice*, 16 HEALTHCARE ETHICS COMMITTEE F. 53, 56 (2004).

239 See, e.g., *Petriello v. Kalman*, 576 A.2d 474 (Conn. 1990); *Johnson v. Sears, Roebuck & Co.*, 832 P.2d 797 (N.M. Ct. App. 1992); *Cooper v. Curry*, 589 P.2d 201 (N.M. Ct. App. 1978); *Cox v. Haworth*, 283 S.E.2d 392 (N.C. Ct. App. 1981); *Tucker v. Cmty. Med. Ctr.*, 833 A.2d 217 (Pa. Super. Ct. 2003); *Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super. Ct. 1995); *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815 (Wash. 1990). But see *Magana v. Elie*, 439 N.E.2d 1319 (Ill. App. Ct. 1982).

ply to hospitals based on the doctrine has been overturned or otherwise stripped of its precedential value.²⁴⁰

Furthermore, the facial applicability of direct institutional liability principles appears to have had little effect on the law's thinking. The reasoning courts employ to reject informed consent duties for hospitals in the face of the corporate negligence doctrine is the same as that used prior to the rise of that doctrine, namely that informed consent requires expertise and professionalism that only physicians possess and that imposing informed consent duties on hospitals would disrupt the doctor-patient relationship at one of its most delicate moments.²⁴¹ Other courts have held that the doctrine does not apply because none of the specific duties commonly associated with the doctrine (e.g., the duty to select and retain only qualified physicians) address informed consent.²⁴² Thus, they avoid the doctrine altogether by ignoring the broad principle of safeguarding hospital patients that gave rise to the more specific duties on which those courts focus their attention.

The fact that courts have considered and rejected the application of the corporate negligence doctrine in institutional informed consent claims demonstrates that the persistence of the law's policy against imposing informed consent duties on hospitals is deliberate. Before they were forced to address the doctrine, courts generally had not had to account for the broad legal and clinical trends identified above. At most, courts were faced with only sporadic arguments concerning a hospital informed consent form or policy or a nurse recording consent.²⁴³ Moreover, they had not (and still have not) faced a case in which the defendant-hospital exercised the kind of managerial control over the informed consent process that is becoming the norm. Without more, one might speculate that the policy's survival has simply been an accident of history. But the law's determination that the corporate negligence doctrine does not encompass informed consent undercuts that interpretation and, instead, indicates that the law in-

240 See *Campbell v. Pitt County Mem'l Hosp., Inc.*, 352 S.E.2d 902 (N.C. Ct. App.), *aff'd*, 362 S.E.2d 273, 276 (N.C. 1987); see also *Tuttle v. Silver*, 21 Pa. D. & C.4th 271 (Pa. Ct. Com. Pl. 1993), *abrogated by Kelly*, 664 A.2d 148; *Campana v. Robert Packer Hosp.*, 12 Pa. D. & C. 4th 343 (Pa. Ct. Com. Pl. 1991), *abrogated by Kelly*, 664 A.2d 148. But see *Magana*, 439 N.E.2d 1319.

241 See *Sears, Roebuck & Co.*, 832 P.2d at 798-800; *Campbell*, 352 S.E.2d at 912-14 (Orr, J., dissenting in part); *Kelly*, 664 A.2d at 149-51.

242 See, e.g., *Cox*, 283 S.E.2d at 394-95.

243 See *supra* notes 140-43 and accompanying text (concerning courts efforts to account for hospitals' informed consent policies, procedures, and forms); *supra* notes 143-148 and accompanying text (describing the courts' efforts to account for hospitals' use of nurses in the informed consent process).

tends to preserve its policy against imposing informed consent duties on hospitals.

All of this, in turn, suggests that the policy against imposing informed consent duties on hospitals will survive new and future trends as well. Consider, for example, the current trend to improve health care quality. Following a 2000 report on medical error by the Institute of Medicine,²⁴⁴ public attention has turned to improving health care quality by improving the organizational systems in which health care is delivered. Nonetheless, since 2001 eight courts in seven different states have ruled against imposing informed consent duties against hospitals.²⁴⁵ This includes two cases in Pennsylvania decided after a legislative overhaul of that state's medical liability system,²⁴⁶ which included new requirements for hospitals to implement quality improvement programs specifically designed to identify and correct failures of institutional systems that result in harm to patients and a new state authority designed to enforce those requirements.²⁴⁷

Thus, the survival of the law's policy does *not* appear to be another example of law unintentionally lagging behind social or technological advances. Accordingly, one cannot assume that a change in the policy is simply a matter of time.²⁴⁸ Instead, proponents of change must account for the law's deliberate choice to exempt hospitals from liability related to informed consent when hospitals are held generally responsible for safeguarding their patients. This is the task taken on below in Part III. First, however, new institutional informed consent duties are proposed.

D. Proposed Institutional Informed Consent Duties

The false logic on which the law's policy rests and the clinical and legal trends that the policy has survived not only indicate a need for reform, they also suggest the nature of that reform. As described be-

244 See INST. OF MED., *supra* note 229.

245 See *Foster v. Traul*, 120 P.3d 278 (Idaho 2005); *Mohsan v. Roule-Graham*, 907 So. 2d 804 (La. Ct. App. 2005); *DeSena ex rel. DeSena v. NYU Med. Ctr.*, 773 N.Y.S.2d 836 (App. Div. 2003); *Daniels v. Durham County Hosp. Corp.*, 615 S.E.2d 60 (N.C. Ct. App. 2005); *Long v. Jaszczak*, 688 N.W.2d 173 (N.D. 2004); *Valles v. Albert Einstein Med. Ctr.*, 805 A.2d 1232 (Pa. 2002); *Tucker v. Cmty. Med. Ctr.*, 833 A.2d 217 (Pa. Super. Ct. 2003); *Newell v. Trident Med. Ctr.*, 597 S.E.2d 776 (S.C. 2004).

246 See *Valles*, 805 A.2d 1232; *Tucker*, 833 A.2d 217.

247 See Medical Care Availability and Reduction of Error Act (MCARE), 2002 Pa. Laws 154 (codified at 40 PA. CONS. STAT. ANN. §§ 1303.101–.910 (Supp. 2005)). For the provisions relating to hospital quality improvement programs, see 40 PA. CONS. STAT. ANN. §§ 1303.301–314 (Supp. 2005).

248 See, e.g., *Miller*, *supra* note 6.

low, the law should enforce against hospitals a series of duties, referred to collectively as institutional informed consent duties.

The duties are not designed to remove physicians from the informed consent process, but rather to redistribute informed consent responsibilities that the law has traditionally allocated to physicians alone. Moreover, the redistribution reflected in the institutional informed consent duties proposed here is based on the premise that the physician is expert at the initial task of identifying a patient's medical condition, the viable treatment options for that condition, and the risks and benefits of each of those options. Likewise, it is premised on the fact that physicians, despite their medical expertise, are not expert at communicating treatment information and that their clinical time may not be best spent engaged in the depth and breadth of communication necessary to facilitate comprehension. Accordingly, the duties are designed to shift to hospitals informed consent responsibilities that do not depend upon medical expertise, and, in this way, they are intended to complement the legitimate use of medical expertise in informed consent.

First, a duty should be imposed on hospitals to require that physicians on staff obtain the informed consent of their patients prior to any treatments provided at the hospital, and that each hospital implements procedures to ensure that its physicians abide by this requirement. For example, hospitals should keep track of instances in which it appears that treatment was provided without consent or without adequately informed consent, and this information must be made part of quality review and credentialing functions of hospitals. Such a system would enable hospitals to identify and take corrective action with respect to physicians whose informed consent practices appear to repeatedly fall below the standard of care.

Second, the law should recognize a duty for hospitals to assure that no treatment is provided in the hospital without prior verification that the patient has provided an informed consent to the proposed treatment. At a minimum, this would require hospitals to assure that consent to a proposed procedure is recorded in a manner that can be reviewed, that such record of consent is verified immediately prior to treatment, and that treatments will not proceed unless a record of the patient's consent can be verified. In addition, the duty should be interpreted to require hospitals to verify that certain categories of information were provided to the patient, including the patient's medical condition, the viable options for treating that condition, and the risks and benefits of each treatment option. This would likely mean that hospitals would be forced to require physicians to make a written record of the disclosures that were made to each patient. Furthermore,

to the extent that treatment disclosures are standardized or otherwise established, then the hospital should be required to assure that at least the standard disclosures were made. This duty should not be interpreted, however, to require hospitals to assure that all disclosures required by law were made because there will be cases in which no standard set of disclosures exists and in which additional disclosures beyond those contained in a standard disclosure may be required because of peculiar medical circumstances of the patient.

Third, the law should impose on hospitals a duty to include in their quality assurance programs the monitoring of informed consent practices and outcomes. Such a duty would improve the likelihood that hospitals identify and correct systemic flaws in their informed consent programs.

Fourth, where hospitals disseminate treatment information directly to patients, they have a duty to assure that the information is accurate, complete, understandable, and equally accessible to all similarly situated hospital patients. This duty includes a duty to maintain equipment used in the informed consent process in reasonable working order. The duty assures that hospitals are directly responsible to patients for flaws in any information disclosure system implemented by a hospital, and it applies whether the hospital designed the system itself or acquired it from an outside vendor.

Finally, where hospitals employ personnel to assist patients in the decisionmaking process, they should have a duty to assure that those individuals are qualified to provide medical decisionmaking assistance and that those employees are scheduled by the hospitals such that there is reasonable access to such help regardless of the time of day.

Each of these duties is derived from actual clinical practice by hospitals with respect to informed consent, and each is designed to protect the patient's interest in receiving only those treatments the patient has authorized in a knowledgeable way. Moreover, they each have a foundation in the corporate negligence doctrine because they are designed to safeguard patients and improve the quality of care. Nonetheless, there is little reason to believe that the law will impose institutional informed consent duties outlined here despite their solid foundation in clinical practice and law. Instead, nearly forty years of experience indicates that the law's policy against imposing informed consent duties on hospitals is unlikely to be reversed notwithstanding clear evidence of hospital involvement in the informed consent process or well established institutional liability principles. Thus, unless the mysterious survival of this policy can be accounted for, the law appears unlikely to adopt any proposed set of institutional informed consent duties.

III. DO ASSUMPTIONS ABOUT TRUST AND INFORMED CONSENT RESOLVE THE MYSTERY?

The question remains: how has the law's policy against imposing informed consent duties on hospitals survived? It is argued here that unarticulated and erroneous assumptions by the law about trust in medicine and its relationship to informed consent may be the answer to this question. Perhaps the policy rests on the idea that the law must not undermine trust in physicians and that protecting the informed consent process as a function purely of the doctor-patient relationship is key in that effort. As described below, such a view would be consistent with claims about the importance of trust in medicine and descriptions of informed consent as a fiduciary doctrine. Additionally, it would account for not only the policy's survival, but also the reasons courts give for refusing to impose informed consent duties on hospitals. Moreover, it would identify a strategy for reform. Our growing knowledge of trust in medicine indicates that trust operates across the many players in modern health care delivery, including physicians, hospitals, and health insurers, and that it is implicated in all aspects of health care delivery. Accordingly, as concluded below, the fundamental problem with the law's policy against imposing informed consent duties on hospitals is that it has an inappropriately narrow view of trust in medicine, one that fails to account for the role of hospitals and the informed consent process in creating a trustworthy system for care. This, in turn, bolsters the proposal to adopt the institutional duties described above because they redistribute informed consent responsibilities in a manner that promotes trust in the systems through which patients receive care.

A. *Making the Case for an Unarticulated Goal of Preserving Medical Trust*

Trust is characterized by the vulnerability of one to the discretionary care of another; trust occurs when one believes that someone to whom she has consigned her interests will protect and serve those interests.²⁴⁹ Trust in medicine, then, results when a patient, already

249 See Robert Gatter, *Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327, 358 (2003); Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 474 (2002) [hereinafter Hall, *Law, Medicine, and Trust*] (describing trust as having "an optimistic attitude towards one's vulnerability" while in the care of another).

For additional literature relating to trust in modern medicine, see Bradford H. Gray, *Trust and Trustworthy Care in the Managed Care Era*, HEALTH AFF., Jan.-Feb. 1997, at 37; Mark A. Hall, *Arrow on Trust*, 26 J. HEALTH POL. POL'Y & L. 1131 (2001) [herein-

vulnerable as a result of an illness or injury, chooses to make herself more vulnerable by placing her health interests in the hands of health professionals and health care institutions in the belief that they will help her achieve improved health.

Trust has long been recognized as playing an integral role in medicine, but a renewed interest in medical trust has deepened our understanding of it.²⁵⁰ Most important to the inquiry here is that trust in medicine includes different objects of trust. In other words, trust in medicine is not merely a function of trust in physicians. Instead, there are several objects of trust in medicine, including hospitals.²⁵¹ Additionally, there are different kinds of trust: interpersonal trust, which generally is based on personal experience, and systemic trust, which is based on perceptions of institutions and structures designed to support those institutions.²⁵² Thus, a patient could trust her

after Hall, Arrow]; Hall, *Law, Medicine, and Trust*, *supra*; David Mechanic, *Changing Medical Organization and the Erosion of Trust*, 74 MILBANK Q. 171 (1996) [hereinafter Mechanic, *Changing Medical Organization*]; David Mechanic, *The Functions and Limitations of Trust in the Provision of Medical Care*, 23 J. HEALTH POL. POL'Y & L. 661 (1998) [hereinafter Mechanic, *The Functions and Limitations of Trust in the Provision of Medical Care*]; David Mechanic & Mark Schlesinger, *The Impact of Managed Care on Patients' Trust in Medical Care and Their Physicians*, 275 JAMA 1693 (1996); David Mechanic, *Public Trust and Initiatives for New Health Care Partnerships*, 76 MILBANK Q. 281 (1998); Stephen D. Pearson & Lisa H. Raeke, *Patients Trust in Physicians: Many Theories, Few Measures, and Little Data*, 15 J. GEN. INTERNAL MED. 509 (2000).

For empirical studies relating to trust in medicine, see Lynda A. Anderson & Robert F. Dedrick, *Development of the Trust in Physician Scale: A Measure To Assess Interpersonal Trust in Patient-Physician Relationships*, 67 PSYCHOL. REP. 1091 (1990); Mark A. Hall et al., *Measuring Patients' Trust in Their Primary Care Providers*, 59 MED. CARE RES. & REV. 293 (2002); Mark A. Hall et al., *Trust in the Medical Profession: Conceptual and Measurement Issues*, 37 HEALTH SERV. RES. 1419 (2002) [hereinafter Hall et al., *Trust in the Medical Profession*]; Audiey C. Kao et al., *Patients' Trust in Their Physicians: Effects of Choice, Continuity, and Payment Method*, 13 J. GEN. INTERNAL MED. 681 (1998) [hereinafter Kao et al., *Patients' Trust*]; Audiey C. Kao et al., *The Relationship Between Method of Physician Payment and Patient Trust*, 280 JAMA 1708 (1998); David H. Thom et al., *Further Validation and Reliability Testing of the Trust in Physician Scale*, 37 MED. CARE 510 (1999); Beiyao Zheng et al., *Development of a Scale To Measure Patients' Trust in Health Insurers*, 37 HEALTH SERV. RES. 187 (2002).

250 See Gatter, *supra* note 140, at 398–405 (identifying and explaining an emerging medical trust movement and conclusions that have resulted from empirical study of trust in medicine).

251 See Mark A. Hall et al., *Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter?*, 79 MILBANK Q. 613, 619–20 (2001); Thomas A. LaVeist et al., *Attitudes About Racism, Medical Mistrust, and Satisfaction with Care Among African American and White Cardiac Patients*, 57 MED. CARE RES. & REV. 146 (2000).

252 See Hall et al., *supra* note 251, at 619–20. The interpersonal/systemic trust distinction commonly overlaps with distinctions among the objects of trust, with interpersonal trust directed at particular hospitals or physicians and systemic trust directed

local hospital because of a personal experience (interpersonal trust) or because of what she has learned about the operating structure of that hospital (systemic trust) or because she trusts all hospitals that share certain characteristics such as accreditation or integration into a chain of hospitals (systemic trust again).

Furthermore, there is a halo effect associated with medical trust, such that trust in one object (e.g., a hospital) can generate trust in a second, related object (e.g., a physician on staff at the trusted hospital).²⁵³ This can happen when interpersonal trust in one object is extended to a second object, but it may also result from a transfer of systemic trust. For example, a patient who does not have any personal experience with a hospital might trust that hospital because, based on its location and its portrayal in the media, she perceives it to be committed to caring for an underserved population. She then might trust a physician practicing in that hospital solely because of the physician's association with the hospital she trusts. In that case, trust in the hospital is systemic in nature because it arises from information other than personal experience, and the halo effect operates to extend that systemic trust to include physicians practicing in the hospital. Thus, while the objects and sources of trust in medicine are subject to conceptual categorization, the halo effect demonstrates that medical trust operates across categorical boundaries in practice, as trust in one object generates trust in another.²⁵⁴

The substantive elements of medical trust and their effect upon each other also demonstrate that, despite its many shapes and forms, medical trust must be regarded as a singular phenomenon. Trust in medicine is comprised of several identifiable elements, including "fidelity, competence, honesty, and confidentiality."²⁵⁵ Yet, researchers have found that change in any one of these dimensions of medical trust creates a similar change in each of the other dimensions such that, in practice, medical trust operates as one, "unidimensional construct."²⁵⁶

In addition to learning more about what medical trust is, renewed interest in medical trust has confirmed our sense of how trust

at broader categories such as the medical profession or hospitals in general. *See id.* Thus, it is possible for a patient to trust her local hospital (interpersonal trust) while distrusting hospitals in general (systemic (dis)trust).

²⁵³ *See id.* at 620.

²⁵⁴ Although trust is used to explain this point, the same is true of distrust as well.

²⁵⁵ Hall, *Law, Medicine, and Trust*, *supra* note 249, at 476.

²⁵⁶ *See* Hall et al., *supra* note 251, at 623–24.

affects patient behavior.²⁵⁷ Studies confirm that trust among patients positively correlates with seeking needed medical care. In other words, the more trust a patient places in medicine, the more likely the patient is to obtain care when it is needed, and the less trusting a patient, the more likely the patient is to postpone seeking care. Likewise, the more trusting a patient, the more likely the patient is to comply with a treatment plan and, thus, the more likely the patient is to experience a positive clinical outcome.²⁵⁸ There is also speculation that medical trust triggers the placebo effect and other mechanisms of healing that cannot be explained scientifically.²⁵⁹ Furthermore, medical trust has economic value as well. Trusting patients are less likely to question their physicians' medical judgments by seeking second opinions, and they are less likely to enter into disputes with care providers when a bad outcome occurs.²⁶⁰ Additionally, trusting patients are also likely to recommend their hospital or physician to another.²⁶¹

Thus, medical trust has substantial instrumental value in that it encourages medically responsible behavior in the face of illness or injury, and it does so in ways that minimize the economic costs of treatment.²⁶² As I have written elsewhere, a trusting patient "is a dream patient—a satisfied, repeat customer who follows doctors' orders, does not visit competitors or raise a fuss about treatment received, and even drums up new business from time to time."²⁶³ Additionally, some say that medical trust has intrinsic value. For example, Professor Mark A. Hall writes that medical trust is a core value of any treatment relationship because it enables patients to cope with the vulnerability created by a health crisis and the assault on a patient's sense of self that can otherwise occur.²⁶⁴ I interpret claims about the intrinsic value of medical trust as indications of the extraordinary degree of

257 See *id.* at 629; see also Mechanic, *The Functions and Limitations of Trust in the Provision of Medical Care*, *supra* note 249.

258 See Hall et al., *Trust in the Medical Profession*, *supra* note 249, at 1432–33; Thom et al., *supra* note 249, at 514.

259 See Hall, *Law, Medicine, and Trust*, *supra* note 249, at 479–81.

260 See Hall et al., *Trust in the Medical Profession*, *supra* note 249, at 1433.

261 See Kao et al., *Patients' Trust*, *supra* note 249, at 684 tbl.4 (the duration of patient-physician relationships tend to be longer among patients with high physician trust scores when compared to patients with comparatively lower physician trust scores).

262 See Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 965 (1963), *reprinted in* 26 J. HEALTH POL. POL'Y & L. 851, 875 (2001) (noting that trust reduces transaction costs in medicine); see also Hall, *Arrow*, *supra* note 249, at 1133–34.

263 Gatter, *supra* note 140, at 401.

264 Hall, *Law, Medicine, and Trust*, *supra* note 249, at 477–78.

importance we as a society attach to the medical trust as a coping mechanism. In other words, we so highly value what medical trust can do for us during a medical crisis that we perceive medical trust as not just a means to an end, but as an end unto itself.²⁶⁵

In the end, one can picture medical trust as a phenomenon omnipresent throughout our health care delivery system, flowing seamlessly among various treatment relationships and enabling a given patient to form a single attitude toward all parts of an institutionally coordinated team of professionals and resources that comprise the system on which the patient relies for her medical care, while at the same time encouraging patient behaviors that effectively and efficiently promote health. With this picture in mind, a viable explanation for why the law has refused to impose informed consent duties on hospitals begins to take shape.

Courts, relying on an intuitive sense of medical trust and its value, conclude that rules of law should be consistent with the preservation of medical trust. This conclusion is particularly likely when courts rule on informed consent claims against physicians because the informed consent doctrine arises from fiduciary principles.²⁶⁶ Courts reason that patients are vulnerable in the medical decisionmaking process because they do not have the information they need to make good decisions and because they lack the ability to find and understand that information. Thus, they depend on their physicians for information and explanations. Indeed, patients are so dependent on their physicians that courts conceive of the doctor-patient relationship as a trust relationship.²⁶⁷ This, in turn, leads courts to use fiduciary principles to regulate the doctor-patient relationship, including disclosure principles that have resulted in the disclosure duties integral to informed consent law. In fact, Professor Hall has identified this logic in two classic informed consent cases and concluded that informed consent law is a quintessential example of law developed from a premise of trust.²⁶⁸ In short, informed consent law is a trust-based doctrine, and so it is logical that courts would work to interpret informed consent law so as to preserve medical trust.

Informed consent law's foundation in a trust designed to address the informational vulnerability of patients also helps to explain why courts have applied disclosure duties exclusively to physicians. Early cases concerning the duty of physicians to disclose treatment informa-

265 See Gatter, *supra* note 140, at 444-45.

266 See Hall, *Law, Medicine, and Trust*, *supra* note 249, at 489-91.

267 See *id.*

268 See *id.*

tion to their patients are concerned with a particular kind of vulnerability, namely, the risk that patients cannot make autonomous treatment decisions because they lack expert knowledge about their medical conditions and treatment options.²⁶⁹ Thus, the disclosure duties arise from a trust relationship defined by the physician's possessing and the patient's lacking expert medical knowledge. Given this, it is understandable that courts might fear that informed consent law would lose its foundation in trust if it did not assure that treatment information was provided directly from the expert physician to the vulnerable patient. From this perspective, any interference with the delivery of treatment information by physician to patient by one who does not have the medical expertise of a physician risks slowing or diverting the flow of information and, as a result, undermining the ability of the expert physician to address the patient's informational vulnerability. This, in turn, offers a plausible explanation for why courts that refuse to impose informed consent duties on hospitals have consistently returned to the premise that only physicians have the expertise to inform patients and that the process of disclosure must be protected from nonexperts.²⁷⁰ Similarly, this may explain why those courts consistently refer to hospital involvement in the informed consent process as "interfering"²⁷¹ and "meddlesome."²⁷²

Courts may also have concluded that informed consent should be the exclusive turf of physicians based on intuitive notions about the intrinsic value of medical trust inherent in the doctor-patient relationship. In *Cooper v. Curry*,²⁷³ the New Mexico Supreme Court refused to impose informed consent duties on a hospital because it would undermine the "fiduciary relationship" between doctor and patient.²⁷⁴ More subtly, the Iowa Supreme Court ruled similarly, referring to the informed consent process as lying "at the heart of the doctor-patient

269 *See id.*

270 *See supra* Part I.B.

271 *See, e.g.,* *Sherwood-Armour v. Danbury Hosp.*, 35 Conn. L. Rptr. 659, 660 (Super. Ct. 2003); *Ackerman v. Lerwick*, 676 S.W.2d 318, 321 (Mo. Ct. App. 1984); *Giese v. Stice*, 567 N.W.2d 156, 164 (Neb. 1997); *Cooper v. Curry*, 589 P.2d 201, 204 (N.M. Ct. App. 1978); *Bryant v. HCA Health Servs. of N. Tenn., Inc.*, 15 S.W.3d 804, 809 (Tenn. 2000).

272 *See, e.g.,* *Ward v. Lutheran Hosps. & Homes Soc'y of Am., Inc.*, 963 P.2d 1031, 1039 (Alaska 1998); *Fiorentino v. Wegner*, 227 N.E.2d 296, 300 (N.Y. 1967); *Campbell v. Pitt County Mem'l Hosp., Inc.*, 352 S.E.2d 902, 914 (Ct. App.), *aff'd*, 362 S.E.2d 273 (N.C. 1987); *Alexander v. Gonser*, 711 P.2d 347, 351 (Wash. Ct. App. 1985); *Mathias v. St. Catherine's Hosp., Inc.*, 569 N.W.2d 330, 333 (Wis. Ct. App. 1997).

273 589 P.2d 201.

274 *Id.* at 204.

relationship.”²⁷⁵ Claims that the informed consent doctrine is at the core of a fiduciary doctor-patient relationship, like claims that trust is the primary value of all treatment relationships,²⁷⁶ lead to the conclusion that the law must guard against intrusions into the doctor-patient relationship so as to avoid disrupting the fragile processes through which medical trust is developed and maintained. Indeed, the fragility of trust is a central lesson from the modern analysis of medical trust. Trust is perceived as an unstable, psychological state that is irreparably damaged if it is perceived to have been breached.²⁷⁷ Accordingly, references of courts rejecting informed consent claims against hospitals to the informed consent process as the most “delicate” matter in the “delicate” doctor-patient relationship,²⁷⁸ may reflect the law’s perception that, if it were to require hospitals to participate in the disclosure process, it would be inviting a bull into the china shop of medical trust. Indeed, this may also explain why courts have refused to impose not only disclosure duties on hospitals, but also duties to assure that physicians have obtained a patient’s informed consent prior to treatment.²⁷⁹ Some courts have reasoned that imposing a duty to assure consent will put the law on a slippery slope toward imposing a duty to disclose.²⁸⁰ This could reflect the perception that, given the fragility of trust in medicine, the best policy is to keep hospitals completely out of the informed consent process so as not to take any risk of an erosion of trust.²⁸¹

Finally, the trust hypothesis provides a plausible explanation for why the law’s policy against imposing informed consent duties on hospitals has survived despite the clinical reality that hospitals are deeply involved in the informed consent process. First, given the extraordi-

275 *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 362 (Iowa 1987).

276 *See* Hall, *Law, Medicine, and Trust*, *supra* note 249, at 477.

277 *See* Gatter, *supra* note 140, at 402–03; Hall et al., *supra* note 251, at 618; Mechanic, *Changing Medical Organization*, *supra* note 249, at 173 (“[T]rust is particularly fragile because negative events are more visible, they carry greater psychological weight, they are perceived as more credible, and they inhibit the kinds of experience needed to overcome distrust.”).

278 *See, e.g., Fiorentino v. Wegner*, 227 N.E.2d 296, 300 (N.Y. 1967) (describing the doctor-patient relationship as one of “great delicacy” and referring to the informed consent process as the most “delicate” matter within that relationship).

279 *See supra* Part I.C.

280 *See, e.g., Campbell v. Pitt County Mem’l Hosp., Inc.*, 352 S.E.2d 902, 911 (N.C. Ct. App.) (Becton, J., concurring in part and dissenting in part), *aff’d*, 362 S.E.2d 273 (N.C. 1987).

281 *See* Gatter, *supra* 140, at 402–03 (claiming that, if one conceives of medical trust as fragile and beyond repair if broken, then this leads to a regulatory strategy of avoiding breaches of trust).

nary value that trust appears to bring to health care delivery and the perception that informed consent uniquely embodies the process by which medical trust is preserved, courts may conclude that preserving trust outweighs the need to hold hospitals accountable for their involvement in the informed consent process. They might rationalize that, by holding physicians exclusively accountable, it gives an incentive to physicians—the presumptive facilitators of medical trust—to police the intrusiveness of hospitals' participation in informed consent. Alternatively, given the presumptive fragility of medical trust, the law may have elected to ignore incremental increases in hospital involvement rather than acknowledge and require hospital involvement, which would (so it is feared) disrupt the delicate process by which medical trust is maintained.

The more challenging question is how the medical trust hypothesis explains the policy's persistence despite the rise of the corporate negligence doctrine in health care. The doctrine has been interpreted to require hospitals to oversee the competence of those who practice medicine within the hospital and to assure the quality of care provided in the hospital.²⁸² Thus, the law forces hospitals to oversee matters of medical expertise even though hospitals lack medical expertise themselves. If the law requires hospital oversight of medical expertise generally, then why not in the specific case of expertise related to the informed consent process? Moreover, it has been established that medical trust includes trust in the competence of providers.²⁸³ Thus, by requiring hospitals to oversee the competence of providers practicing medicine within their institutions, it is already requiring hospitals to tread on the delicate turf of medical trust. Again, if so, then why not in the case of competence in the informed consent process?

The answer turns on a distinction that can be drawn between the relationship of trust to medical malpractice law, on the one hand, and the relationship of trust to informed consent law, on the other hand. While both medical malpractice law and informed consent law can be justified under a principle of promoting trust in medicine, the law has explicitly regarded the informed consent doctrine as having its foundation in trust principles.²⁸⁴ For example, although informed consent law is enforced through negligence and battery constructs, courts commonly refer to it as a doctrine arising from fiduciary characteris-

282 See *supra* notes 229–32 and accompanying text.

283 See Hall et al., *supra* note 251, at 621–22.

284 See Hall, *Law, Medicine, and Trust*, *supra* note 249, at 489–94 (contrasting the relationships of trust to informed consent law and medical malpractice law).

tics of the doctor-patient relationship.²⁸⁵ In comparison, it is difficult to find any court that refers to medical malpractice claims as having their foundation in fiduciary principles. Thus, it is plausible to say that a physician's duty to obtain a patient's informed consent to treatment goes beyond obligations of due care that are owed in the course of providing that treatment.²⁸⁶ Accordingly, it is at least minimally rational for courts to rule that the corporate negligence doctrine obligates hospitals to implement systems designed to assure that their physicians practice with due care, but not systems designed to assure that their physicians act in accordance with fiduciary obligations that go beyond obligations of due care.

B. Medical Trust as a Basis for Reforming the Law's Policy

If it is true that the law's policy against imposing informed consent duties on hospitals has survived because of an unarticulated goal to preserve trust in medicine by declaring the informed consent process to be the exclusive domain of physicians and protecting it from interference by hospitals, then that unarticulated goal also provides a basis for reforming the law's policy to recognize the institutional informed consent duties outlined above. In short, by refusing to impose any informed consent duties on hospitals, informed consent law has lost touch with its own fiduciary foundation. Unless the law enforces informed consent duties against hospitals, it will erode trust in medicine.

The law's critical mistake is failing to recognize that physicians are no longer the only kind of health care provider who enters into a fiduciary relationship with hospital patients. As hospitals have taken on responsibilities to organize the delivery of health care to their patients, they enter into fiduciary relationships with each of their patients as well, which are defined by the hospital's obligation to protect

285 See *id.* at 489–91 (analyzing language used in *Cobbs v. Grant* and *Canterbury v. Spence*); see also *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1069 (S.D. Fla. 2003) (the informed consent doctrine “grew out of a treating physician's fiduciary duty to disclose” treatment information to patients); *Moore v. Regents*, 793 P.2d 479, 483 (Cal. 1990) (referring to the duty of disclosure as a physician's “fiduciary duty”); *Howard v. Univ. of Med. & Dentistry*, 800 A.2d 73, 78 (N.J. 2002) (“[The] patient-centered view of informed consent stresses . . . the fiduciary relationship between a doctor and his or her patients.”); *Keogan v. Holy Family Hosp.*, 622 P.2d 1246, 1252 (Wash. 1980) (referring to the physician's duty to obtain informed consent as a “fiduciary” duty).

286 See *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972) (“The patient's reliance upon the physician is a trust of the kind which traditionally has exacted obligations beyond those associated with arms-length transactions.”).

the well-being of patients under their care.²⁸⁷ In fact, given that hospital-based treatment for a particular patient is often provided by several physicians and many nurses and technicians, and that it is coordinated through various labs and departments, it is best to conceive of the patient's having entered into one relationship with the hospital and attending physician as cofiduciaries, who together are responsible for the coordinated care of the patient.²⁸⁸

The role of the hospital as a fiduciary certainly finds support in the general duty imposed by the corporate negligence doctrine for hospitals to take reasonable measures to safeguard their patients. As described above, the corporate negligence doctrine arises out of the law's recognition that hospitals play a vital role in assuring the quality of hospital care through its staffing of the hospital and its policies and procedures for organizing its resources for the purpose of executing a particular treatment plan.²⁸⁹ This role for hospitals directly implicates the competence and fidelity components of medical trust.²⁹⁰ By assuring that its facilities are properly maintained and equipped, that they are adequately staffed with personnel whose qualifications to practice medicine have been verified, and that measures are in place to coordinate the various aspects of treatment so as to prevent substandard care at any time during a patient's population, the hospital is improving the system's competence to provide quality care. In so doing, the hospital is also placing above other considerations the patient's interest in receiving complex medical care in a safe and effective manner.

Moreover, the hospital's fiduciary role is apparent in its management of the informed consent process in particular. By expressly requiring that patients provide informed consent prior to any hospital-based treatment, by providing consent forms and implementing procedures for their use, and by assigning hospital employees to confirm that there is evidence of informed consent prior to treatment, hospitals serve the patients' interests in understanding their treatment options and having their treatment preferences honored. Furthermore, hospitals are taking seriously the interest of patients in not only receiving treatment information, but also in receiving information in a manner that is likely to result in understanding, and in receiving assistance

287 See *Cooper v. Curry*, 589 P.2d 201, 207 (N.M. Ct. App. 1978) (Sutin, J., dissenting) ("A fiduciary relationship exists between hospital-patient and physician-patient.").

288 See Frank A. Chervenak & Laurence B. McCullough, *Physicians and Hospital Managers as Cofiduciaries of Patients: Rhetoric or Reality?*, 48 J. HEALTHCARE MGMT. 172, 176 (2003).

289 See *supra* notes 229–32 and accompanying text.

290 See *supra* note 252 and accompanying text.

to sort through that information so as to arrive at decisions that reflect patients' unique values. This is evident in the fact that hospitals are piloting automated informed consent applications designed to provide patients with a thorough presentation of standard information related to their treatment options at a pace and employing language that will improve comprehension. Additionally, it is demonstrated by hospitals assigning employees to help guide patients through the decisionmaking process after all treatment information is in hand.

Indeed, the steadily increasing role of hospitals in the informed consent process indicates the degree to which patients remained vulnerable in the medical decisionmaking process when only physicians were attempting to meet their decisionmaking needs. Often, patients who received complex treatment information in a meeting with a busy physician were left to make treatment choices without being fully aware of the nature and consequences of their decisions and without any safeguard against being overwhelmed by the information provided or by the decision itself. Physicians simply do not have the time to assure that each patient understands the treatment information provided or to guide them through the task of sorting treatment information and identifying their own preferences for the purposes of making an autonomous decision. Thus, patients have an unmet need for help to understand treatment information and make autonomous choices even after treatment information has been disclosed. Accordingly, the syllogism that gave rise to the fiduciary obligation of physicians to disclose treatment information to patients also gives rise to a fiduciary obligation of hospitals, as coordinators of care, to further assist patients in the medical decisionmaking process.²⁹¹

In this way, the goal of preserving medical trust accounts for the core reason why courts refuse to impose informed consent duties on hospitals. If the trust hypothesis is correct, courts are concerned that, by requiring hospitals to interfere in the informed consent process, it will fail to enable physicians to address the vulnerability of patients in the medical decisionmaking process. Given that patients remain vulnerable in the absence of additional decisionmaking assistance, however, and that hospitals are in a better position than physicians to

291 See Hall, *Law, Medicine, and Trust*, *supra* note 249, at 477–78 (stating that patients are dependent on their health care provider for assistance in understanding their treatment choices so that patients can decide for themselves what course of treatment to undertake, and this dependence creates a vulnerability that is characteristic of trust relationships in which the entrusted party is obligated to assist the entrusting party in ways that go beyond due care, and so health care providers should be obligated to assist patients to understand their treatment choices in ways consistent with a fiduciary relationship).

provide that additional assistance, the goal of preserving trust in medicine is best served by imposing informed consent duties on hospitals.

The trust hypothesis also accounts for any claimed distinction between the application of the corporate negligence doctrine to a breach of negligence standards and its application to a breach of fiduciary standards. As discussed above, a viable argument exists that hospitals are obligated to implement systems to prevent medical negligence among their physicians, but that this does not include obligations to oversee physicians' compliance with fiduciary obligations that exceed the requirements of due care. The argument is unpersuasive, however, if the law is attempting to preserve trust in medicine. As argued above, whether preventing harms that would be compensated under principles of negligence or fiduciary principles, hospitals assist in the project of preserving trust in medicine when they participate in the coordination of all aspects of a patient's care, including the process of informed consent.

The touchstone of preserving medical trust also places in perspective the law's concern for expertise in the informed consent process. Undoubtedly, physicians are experts in identifying patients' medical conditions, the options for treating those conditions, and the risks and benefits of each of those options. Thus, while hospitals can improve the competence of the informed consent process by contributing expertise in the communication of treatment information, expertise in aiding patients to process treatment information, and expertise in confirming that the informed consent process is complete prior to treatment, they cannot and should not replace physicians as medical experts. Indeed, to do so would undermine the competence of the informed consent process and thus be inconsistent with the goal of preserving trust in medicine. Instead, the goal of preserving trust leads to a coordinated distribution of expertise so as to improve the overall competence of the informed consent process.

Finally, preserving trust in hospital-based informed consent processes requires a measure of accountability.²⁹² As described above, it is unclear whether the increasing role that hospitals play in managing the informed consent process sufficiently serves the interests of patients. There is a risk that a hospital will manage its informed consent process in ways that serve its own interests to increase the likelihood that physicians will refer patients to the hospital, to free-up clinical time for physicians to provide additional fee-generating proce-

292 See Gatter, *supra* note 249, at 361–63 (explaining how a trustworthy medical system requires a legally accountable medical system).

dures, to improve the public image of the hospital, or to increase its patient satisfaction scores. Yet, there is no guarantee that serving these interests also adequately protect patients' interests. Thus, the responsibility of the law is to impose institutional informed consent duties that will provide hospitals with the incentive to assure that equipment and staff involved in the informed consent process are well coordinated so that patients are not injured by defects in the system. Such duties contribute to the preservation of medical trust by promoting the legal accountability of hospitals with respect to informed consent, which increases the opportunity for "systematic" medical trust to develop.²⁹³

CONCLUSION

The law's policy against imposing informed consent duties on hospitals is a mysterious exception to the modern trend in law of holding hospitals responsible for safeguarding the patients they serve and the law's more limited view on the importance of medical expertise in the informed consent process. The oddity of this policy is magnified by the clinical realities that cut against it. Clinical experience indicates that doctors have limited time to provide treatment information to patients at all, let alone in ways that are likely to promote understanding. Additionally, hospitals have increasingly involved themselves in the informed consent process, at first, through the implementation of policies, procedures, and forms, and then through the use of employees to record and confirm consent and through the direct dissemination of treatment information to patients. Today, hospitals are preparing to manage the informed consent process thoroughly through the use of automated informed consent applications and live counselors.

Throughout all of this change, the law's policy has remained unchanged. It has insisted that only physicians have the expertise and professionalism to conduct the informed consent process, and that hospitals will undermine that process and the doctor-patient relationship by getting involved. It has held this position despite recognizing that hospitals participate at least to some degree in the informed consent process, and it has not budged even in the face of the corporate negligence doctrine that imposes a duty on hospitals to safeguard their patients and oversee the quality of care provided to them.

Hospitals can add value to the medical decisionmaking process by assuring that patients receive standard treatment information deliv-

293 For a description of systematic trust in medicine, see *supra* notes 250-55 and the accompanying text.

ered in an understandable manner, that they can communicate with their physicians about particular questions and unique informational needs, that patients have access to individuals who can help them process treatment information and make treatment decisions that reflect their preferences, and that patients have in fact completed the informed consent process before treatments are provided. Thus, the law should impose institutional informed consent duties on hospitals as proposed in this Article so as to redistribute informed consent responsibilities more reasonably among physicians and hospitals.

Given the persistence of the law's policy against imposing informed consent duties on hospitals, however, it is unclear whether any reform proposal can succeed. The thesis of this Article has been that an unarticulated rationale has driven courts to maintain the policy against institutional informed consent duties despite its apparent inconsistency with clinical and legal trends. I have argued that a misguided effort to preserve trust in medicine may be at work. If this is true, then a full understanding of medical trust and its application to the informed consent process should cause courts to reconsider the policy and impose institutional informed consent duties that would not only encourage hospitals to improve the quality of informed consent, but also assure that those improvements serve the interests of patients.

