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## Eliminating Liability for Lack of Informed Consent to Medical Treatment

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## ELIMINATING LIABILITY FOR LACK OF INFORMED CONSENT TO MEDICAL TREATMENT

*Valerie Gutmann Koch* \*

### ABSTRACT

*The legal doctrine of informed consent, which imposes tort liability for failure to disclose the risks, benefits, and alternatives of a proposed medical intervention, is often criticized for emphasizing ritual over relationships, contributing to the deterioration of the doctor-patient relationship by encouraging the practice of defensive medicine. This article considers a rather radical response to the allegations that the tort of lack of informed consent does not serve the lofty goal of protecting patient self-determination by ensuring that treatment decisions are voluntary and informed, namely the elimination of liability for failure to provide informed consent to medical treatment. In doing so, this article evaluates the rationale and procedure for abolishing a common law private right of action for lack of informed consent, as well as potential alternatives to tort liability for failure of informed consent to medical treatment. The article concludes that the time has not come for a wholesale elimination of the private right of action for lack of informed consent to treatment. Abolishing liability for lack of informed consent in treatment would not only eliminate the deterrent effect for potential bad actors, but would also remove recourse for those who have suffered harm due to a failure of informed consent.*

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## TABLE OF CONTENTS

INTRODUCTION .....	1213
I. THE LEGAL DOCTRINE OF INFORMED CONSENT TO MEDICAL TREATMENT .....	1214
II. ARGUMENTS FOR ELIMINATING LEGAL LIABILITY FOR LACK OF INFORMED CONSENT .....	1219
A. <i>The Doctrine of Informed Consent Shields Physicians from         Liability, Rather than Promoting Patient Autonomy</i> .....	1219
B. <i>Imposition of Legal Liability for Failure of Informed Consent         Results in a Substitution of Form for Process</i> .....	1224
C. <i>The Legal Doctrine of Informed Consent Is Impractical in         Application</i> .....	1227
1. Due to Competing Materiality Standards, the Legal Doctrine of Informed Consent Is Unpredictably Enforced ....	1228
2. The Objective Causation and Injury Requirements Undermine the Principle of Patient Autonomy .....	1230
D. <i>The Legal Doctrine of Informed Consent Is Not as Historically         Entrenched as It Seems</i> .....	1231
III. CONSIDERING SOLUTIONS .....	1232
A. <i>Eliminating Legal Liability for Informed Consent</i> .....	1233
B. <i>Alternatives to Legal Liability for Informed Consent</i> .....	1234
1. A Return to the “Old Days” .....	1234
2. Creation of a New Tort .....	1235
3. Establishment of a Fiduciary Duty of Care .....	1237
4. Self-Regulation .....	1238
CONCLUSION .....	1239

## INTRODUCTION

Less than a century ago, courts sought to ensure patients' autonomous medical decision making by affirming a private right of action for failure of informed consent. The tort of lack of informed consent is intended to compensate, or make whole, the patient who is harmed by her doctor due to a failure to disclose the risks, benefits, and alternatives to a proposed intervention. Although it is a new cause of action by historical accounts, this tort is now firmly entrenched in precedent or codified by state statute.

However, despite the legal doctrine's emphasis on the primacy of autonomous, voluntary, and informed decision making, courts and scholars quickly began recognizing the deficiencies in relying on the informed consent doctrine to realize its goals.<sup>1</sup> Thus, this article considers a rather radical response to the inadequacies of the legal doctrine of informed consent: the elimination of liability for failure to provide informed consent to medical treatment. This proposed response would transform and overturn a complex and historically entrenched area of law—one upon which much of medical practice is based.

Relying on the theoretical constructs in which other common law tort claims have been contracted or eliminated, this article evaluates the rationale and procedure for abolishing a common law private right of action. Eliminating legal liability for informed consent to treatment may reduce the doctrinal ambiguity concerning claims for informed consent. It is commonly argued that the informed consent process in the medical context has been co-opted by the legal community in an effort to protect health care providers from liability, and that it contributes to the deterioration of the doctor-patient relationship.

Part I introduces historical context to the reasoning behind the establishment of the tort of lack of informed consent to treatment. Part II then analyzes the various justifications for eliminating the legal doctrine, while Part III presents potential alternatives to civil liability for lack of informed consent to medical treatment.

This article concludes that, despite concerns, the time has not come for a wholesale elimination of the private right of action for lack of informed consent to treatment. Abolishing liability for lack

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1. *See infra* Part I.

of informed consent to treatment would not only eliminate the deterrent effect for potential bad actors, but it would also remove recourse for those who have suffered harm due to a failure of informed consent.

## I. THE LEGAL DOCTRINE OF INFORMED CONSENT TO MEDICAL TREATMENT

Of the three key principles underlying medical ethics—beneficence, respect for persons, and justice<sup>2</sup>—the practice of medicine appeared to give particular weight to just one until the middle of the twentieth century: beneficence.<sup>3</sup> The doctor's decisions were driven by the ethical principle of nonmaleficence—the foundational value often claimed to have been enunciated in the Hippocratic Oath, which required him to “above all, do no harm” to the patient.<sup>4</sup> Doctors knew best, and often made decisions for their patients without any input from those patients—or even without informing them of what they were doing.<sup>5</sup> Thus, until the middle of the twentieth century, the medical profession was “viewed as a typical example of a patriarchal system.”<sup>6</sup>

Courts relied upon the traditional intentional tort of battery to resolve cases involving failure to obtain consent in the treatment setting.<sup>7</sup> Patients alleged unauthorized physical contact; in other words, patients had to prove that the provided medical intervention was without their consent, rather than treatment they would

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2. JAMES F. CHILDRESS & TOM L. BEAUCHAMP, *PRINCIPLES OF BIOMEDICAL ETHICS* 13 (7th ed. 2013).

3. *Id.*

4. Cedric M. Smith, *Origin and Uses of Primum non Nocere—Above All, Do No Harm!*, 45 *J. CLINICAL PHARMACOLOGY* 371, 373, 375 (2005).

5. Holly Fernandez Lynch has explained that:

For most of the history of medicine, patients followed the advice of their physicians without a dialogue regarding alternatives, risks and benefits, or the patient's goals. The doctor was the expert and the patient bore the dependent, vulnerable sick role. Physicians introduced only those treatment options they deemed appropriate, which, of course, left very little room for conflicts, especially in an era when patients had almost no access to medical information on their own.

HOLLY FERNANDEZ LYNCH, *CONFLICTS OF CONSCIENCE IN HEALTH CARE: AN INSTITUTIONAL COMPROMISE* 21 (2008).

6. Felicity Goodyear-Smith & Stephen Buetow, *Power Issues in the Doctor-Patient Relationship*, 9 *HEALTH CARE ANALYSIS* 449, 450–51 (2001).

7. Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 *YALE L.J.* 219, 223–24, 229 (1985).

not have consented to if they had more complete information.<sup>8</sup> Importantly, the tort of battery does not protect choices that do not involve physical touching.<sup>9</sup>

Less than a century ago, courts began affirming a private right of action for failure of informed consent,<sup>10</sup> with the understanding that respect for persons is achieved by respecting individual self-determination and autonomous decision making.<sup>11</sup> The doctrine of medical informed consent evolved from the theory that individuals have the right to make health care decisions to further their own health and welfare.<sup>12</sup> The legal doctrine of informed consent therefore endeavors to dispose of the paternalistic “doctor knows best” approach to medicine.<sup>13</sup> It developed via the common law—or judge-made law—under the rubric of negligence law, beginning in the 1950s.<sup>14</sup> As citizens asserted their rights in myriad aspects of American life in the 1960s and 1970s, patients also claimed increasing self-determination in their medical decision making, thereby shifting the emphasis from nonmaleficence to the ethical principle of respect for persons and, accordingly, autonomy.<sup>15</sup>

Patients asserted their autonomy by taking those who failed to disclose the risks, benefits, and alternatives of a proposed medical

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8. *Id.* at 224–26. For example, if a patient consented to an amputation of the left leg and the surgeon amputated the right leg by mistake, there was no consent and the surgeon has committed a battery on the patient. Similarly, if a patient specifically told a surgeon not to excise the tumor if one were found during exploratory surgery, a surgeon who did remove the tumor committed a battery.

9. *Id.* at 229–30.

10. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 783 (D.C. Cir. 1972); *Cobbs v. Grant*, 502 P.2d 1, 8 (Cal. 1972).

11. *Canterbury*, 464 F.2d at 780; *Cobbs*, 502 P.2d at 9–10.

12. See Shultz, *supra* note 7, at 219–22.

13. Ryan Childers et al., *Informed Consent and the Surgeon*, 208 J. AM. C. SURGEONS 627, 627 (2009).

14. The term “informed consent”—and with it, a proposed duty to disclose—first appeared in 1957 in the California case, *Salgo v. Leland Stanford Jr. University Board of Trustees*, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) (holding that physicians had a duty to disclose all facts that were necessary for the patient to make an intelligent health care decision); see also Anthony P. Szczygiel, *Beyond Informed Consent*, OHIO N.U. L. REV. 171, 197 (1994) (discussing how *Salgo* was the first reported medical malpractice case to use “informed consent”).

15. Valerie Gutmann Koch, *A Private Right of Action for Informed Consent in Research*, 45 SETON HALL L. REV. 173, 179 (2015). This shift away from medical paternalism and toward patient-driven medicine has been described as “[t]he historical transition from the regime of ‘doctor is right’ to ‘patient has rights.’” See Sheldon F. Kurtz, *The Law of Informed Consent: From “Doctor Is Right” to “Patient Has Rights,”* 50 SYRACUSE L. REV. 1243, 1243, 1245 (2000).

intervention to court.<sup>16</sup> Thus, those decades witnessed a proliferation of litigation in which patients claimed that their physicians had an ethical obligation to disclose the nature and risks of an intervention before providing it.<sup>17</sup> In recognizing the autonomy of patients, many courts decided that battery was not an appropriate cause of action for cases involving interventions that were performed with the patient's *consent* but without adequate disclosure of the risks, benefits, and alternatives to the agreed-upon intervention.<sup>18</sup>

Under a cause of action for failure to provide informed consent, failure to disclose the risks of a proposed medical intervention or therapy "may allow an individual to recover for harm arising from nondisclosure of information material to the individual's decision to agree to the intervention."<sup>19</sup> In other words, under a claim for lack of informed consent, a patient may recover when she consented to the intervention itself but disclosure of the risks was insufficient.<sup>20</sup> "Today, all United States jurisdictions have adopted some form of the doctrine of informed consent either by statutory enactment or judicial decision."<sup>21</sup> In general, jurisdictions where the doctrine of informed consent has been introduced by common law decision have more extensive requirements concerning patient information and participation.<sup>22</sup>

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16. See Kurtz, *supra* note 15, at 1247.

17. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 778 (D.C. Cir. 1972); *Cobbs v. Grant*, 502 P.2d 1, 5 (Cal. 1972).

18. Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 319 (2002).

19. Koch, *supra* note 15, at 180.

20. *Id.*

21. *Id.*

22. *Id.* at 180 n.25. Most informed consent statutes were enacted after 1975 in response to the rise in medical malpractice litigation. See *id.* They bear indications of state Medical Society lobbying and often state that a signed consent is at least prima facie evidence of an adequately informed consent. E.g., FLA. STAT. § 766.103 (2018) ("A consent which is evidenced in writing and meets the requirements of subsection (3) shall, if validly signed by the patient or another authorized person, raise a rebuttable presumption of a valid consent."); GA. CODE ANN. § 31-9-6.1 (2012) ("If a consent to a diagnostic or surgical procedure is required to be obtained under this Code section and such consent discloses in general terms the information required in subsection (a) of this Code section, is duly evidenced in writing, and is signed by the patient or other person or persons authorized to consent pursuant to the terms of this chapter, then such consent shall be rebuttably presumed to be a valid consent."); IND. CODE § 34-18-12-2 (1999); LA. STAT. ANN. § 40:1299.40 (2004); ME. STAT. tit. 24, § 2905 (2013) ("A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized persons, shall be presumed to be a valid consent. This presumption, however, may be subject to rebuttal

Until the early 1970s, in resolving cases involving failure to provide informed consent, most courts followed the “community standard” of disclosure: requiring disclosure only of what physicians wished the patient to know.<sup>23</sup> Consent was generally legally adequate as long as the patient had notice of the nature and scope of the proposed medical intervention: what the physician proposed and its probable result.<sup>24</sup> When challenged in court, experts testified as to the appropriate extent of disclosure based on professional standards.<sup>25</sup>

This paternalistic standard has been gradually replaced in a number of jurisdictions by a standard requiring disclosure of what the patient needs to know—thereby imposing a more affirmative duty on the physician.<sup>26</sup> This shift was demonstrated by the seminal 1972 cases, *Canterbury v. Spence*<sup>27</sup> and *Cobbs v. Grant*,<sup>28</sup> which addressed the question of the legal adequacy of a patient’s consent to medical treatment. These cases changed the prevailing rules for

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only upon proof that such consent was obtained through fraud, deception or misrepresentation of material fact.”); NEV. REV. STAT. § 41A.110 (2017); N.C. GEN. STAT. § 90-21.13 (2018) (“A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained by fraud, deception, or misrepresentation of a material fact.”); OHIO REV. CODE ANN. § 2317.54 (West 2018) (“Written consent to a surgical or medical procedure or course of procedures shall, to the extent that it fulfills all the requirements in divisions (A), (B), and (C) of this section, be presumed to be valid and effective . . . .”); UTAH CODE ANN. § 78B-3-406 (West 2009); WASH. REV. CODE § 7.70.060 (2012); see also Alan J. Weisbard, *Informed Consent: The Law’s Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749, 752 n.10 (1986).

23. See, e.g., *Cobbs v. Grant*, 502 P.2d 1, 10 (Cal. 1972).

24. See Jay Katz, *Informed Consent—a Fairy Tale? Law’s Vision*, 39 U. PITT. L. REV. 137, 146, 152 (1977).

25. See *id.* at 154.

26. See *id.* at 147–48.

27. 464 F.2d 772 (D.C. Cir. 1972). The Court of Appeals for the D.C. Circuit addressed the case of a nineteen-year-old patient with chronic back pain who underwent a laminectomy, which had an estimated one percent risk of paralysis. *Id.* at 776, 778. The physician requested phone and then written consent from the patient’s mother, but did not tell the patient of the risk, due to the concern that it might discourage him from undergoing surgery. *Id.* At trial, the physician argued that he ought to be able to withhold information if it might deter the patient from accepting beneficial therapy, frighten the patient, delay convalescence, or impose a negative placebo effect. *Id.* at 778. When paralysis occurred, the patient sued. *Id.*

28. In *Cobbs*, the Supreme Court of California focused on the relative information disparity between the doctor and patient, stating, “[T]he patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process, thus raising an obligation in the doctor that transcends arms-length transactions.” *Cobbs*, 502 P.2d at 9. In other words, patients need to know the risks because they bear them.



the duty to disclose, holding that the decision to accept or reject therapy is a personal decision and not a medical decision to be made by a doctor.<sup>29</sup> Thus, under this newer standard, doctors have a duty to disclose all information that is material to a reasoned decision by the patient to accept or reject the offered intervention.<sup>30</sup> Whether the information is “material” is determined by what a “reasonably prudent” person would deem material, including the degree and incidence of the risk of the proposed intervention, the available alternatives to the intervention, and the risks and benefits of no treatment at all.<sup>31</sup>

Today, half of American jurisdictions accept the core point that a patient’s need for information in order to effectuate self-determination requires a standard of disclosure established by law (the “reasonable patient” standard) rather than the community standard.<sup>32</sup> The community standard is one in which the scope of the doctor’s duty to provide information is based on the custom of physicians practicing in the same or in a similar community using medical expert testimony.<sup>33</sup> A claim of lack of informed consent requires the same elements required to establish a traditional negligence claim: (1) a duty of care owed by the defendant to use reasonable care to prevent harm to the plaintiff, (2) breach of that duty, (3) harm or injury to the plaintiff, and (4) a causal link between the injury and the breach of duty.<sup>34</sup> Importantly, almost every state applies an objective standard for proving causation, whereby the “patient must show that a reasonably prudent person in the patient’s medical condition would not have chosen the procedure had he been fully informed.”<sup>35</sup> Moreover, in order to recover

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29. See Katz, *supra* note 24, at 154–55.

30. See *Canterbury*, 464 F.2d at 786–87; *Cobbs*, 502 P.2d at 11.

31. *Canterbury*, 464 F.2d at 784, 787–88.

32. See Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 430 (2006).

33. See generally Charles L. Sprung & Bruce J. Winick, *Informed Consent in Theory and Practice: Legal and Medical Perspectives on the Informed Consent Doctrine and a Proposed Reconceptualization*, 17 CRITICAL CARE MED. 1346, 1347–48 (1989) (discussing the two standards that define a physician’s duty to disclose). It has been argued that this standard encourages “disengaged monologues” on the part of the physician. Katz, *supra* note 24, at 146–47.

34. See JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 132–34 (2d ed. 2001).

35. Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, 697 (2012).

for failure to provide informed consent, it must be proven that the patient experienced actual (usually physical) injury.<sup>36</sup>

## II. ARGUMENTS FOR ELIMINATING LEGAL LIABILITY FOR LACK OF INFORMED CONSENT

Since its establishment, the tort of informed consent has been analyzed, and often critiqued, for its effectiveness and usefulness.<sup>37</sup> Despite the fact that the legal doctrine of informed consent is one of the most widely accepted efforts to encapsulate ethical principles in law, studies have consistently shown that the results of efforts to increase patient understanding and self-determination are disappointing.<sup>38</sup> Thus, the question must be raised: if legal liability for failure to ensure voluntary, informed, medical decision making is ineffective in achieving its goals, or, in fact, hinders achievement of those goals, why not eliminate the tort of lack of informed consent? This part will explore the various justifications for doing so.

### A. *The Doctrine of Informed Consent Shields Physicians from Liability, Rather than Promoting Patient Autonomy*

Since the establishment of the tort of lack of informed consent, it has been accused of being both needlessly adversarial and backward-looking, resulting in the process of obtaining informed consent to treatment becoming a defensive endeavor.<sup>39</sup> Instead of focusing on informing patients and ensuring patient self-determination—the principles upon which *Canterbury* and other decisions were presumably based—the practice of obtaining informed consent to treatment may be centered on protecting health care providers from litigation.<sup>40</sup> In other words, it is argued that the informed consent process in the medical context has been co-opted by the legal community in an effort to protect health care providers from liability, and it no longer serves the lofty goal of ensuring a robust process to protect patients' decision making by

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36. Weisbard, *supra* note 22, at 753–54.

37. *See id.* at 751.

38. Daniel E. Hall et al., *Informed Consent for Clinical Treatment*, 184 CANADIAN MED. ASS'N J. 533, 536 & nn.50–54 (2012).

39. *See* Weisbard, *supra* note 22, at 751.

40. *See id.* at 759, 762–63.

guaranteeing that treatment decisions are voluntary and informed.<sup>41</sup>

This argument is not new. Dr. Jay Katz distinguished between “the *legal* doctrine [of informed consent], as promulgated by judges, and the *idea* of informed consent, based on a commitment to individual self-determination.”<sup>42</sup> Relying in part on Dr. Katz’s work, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research conducted a study of informed consent, culminating in its 1982 report, *Making Health Care Decisions*.<sup>43</sup> The report recognized the deep disconnect between the legal doctrine of informed consent and the presumed goals of the informed consent process.<sup>44</sup> In condemning the increasing legalism of discussion on informed consent, the Commission recognized that the law cannot be “the primary means of bringing about needed changes in attitudes and practices.”<sup>45</sup> The Commission therefore concluded that although informed consent is “essentially an ethical imperative,”<sup>46</sup> actual patient consent bears little resemblance to legal doctrines and descriptions of informed consent.<sup>47</sup> The implication was that, without greater communication between patient and physician, the definition of informed consent would become a doctrine shaped retrospectively by judicial decisions.<sup>48</sup>

The Commission determined that the imposition of legal liability for medical informed consent resulted in the overprovisioning of information for the purpose of avoiding liability,<sup>49</sup> and advocated that “[e]thically valid consent is a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be

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41. *See id.* at 762–63.

42. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT*, at xliii (Johns Hopkins Univ. Press 2002) (1984).

43. PRESIDENT’S COMM’N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMEDICAL & BEHAVIORAL RESEARCH, *MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP* 10 (1982) [hereinafter PRESIDENT’S COMM’N], [https://repository.library.georgetown.edu/bitstream/handle/10822/559354/making\\_health\\_care\\_decisions.pdf?sequence=1&isAllowed=y](https://repository.library.georgetown.edu/bitstream/handle/10822/559354/making_health_care_decisions.pdf?sequence=1&isAllowed=y) [<https://perma.cc/BU59-EL4L>].

44. *See id.* at 29, 31.

45. *Id.*

46. *Id.* at 2.

47. *Id.* at 2, 16–18, 29.

48. *Id.* at 29.

49. *Id.* at 71–72; *see also* Kurtz, *supra* note 15, at 1245. Moreover, as opposed to increasing patient understanding, the doctrine leads to disengaged monologues by physicians. Katz, *supra* note 24, at 139–40.

equated with reciting the contents of a form that details the risks of particular treatments.”<sup>50</sup>

Concerns persist over the legal doctrine of informed consent’s ability to increase patient understanding and ensure voluntary medical decision making. Although the modern understanding of the doctrine seeks to dispose of the paternalistic “doctor knows best” approach to patient management and give patients the right to individual self-determination,<sup>51</sup> scholars such as Alexander Capron argue that informed consent has become “a charade, a symbolic but contentless formality.”<sup>52</sup> William Sage opines, “Because of technical complexity, patient vulnerability, and the power of physicians to persuade, it is unclear whether informed consent represents true empowerment or merely the illusion of self-determination.”<sup>53</sup> He continues, “[D]isclosure made defensively to gain protection from liability tends to be overly detailed and legalistic, based more on what has survived scrutiny in the past than on what would be useful to recipients.”<sup>54</sup> Similarly, Kayte Spector-Bagdady and colleagues express concern about the influence that the threat of liability has on the standard of care, concluding that the “[c]linicians’ fear of litigation is a challenge to [the] ethical paradigm” underlying the “complex balance between the principles of beneficence and autonomy.”<sup>55</sup> They recognize that “[c]linicians reasonably want to protect themselves against claims of liability, but whether there is an ethical way to do so is unclear.”<sup>56</sup>

Others have studied the apparent disconnect between the doctrine of informed consent in theory and the application of informed consent in practice. Peter Schuck surveyed empirical studies and concluded that “most physician-patient discussions appear to be rather perfunctory and reinforce physician control.”<sup>57</sup> He observed

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50. PRESIDENT’S COMM’N, *supra* note 43, at 2.

51. *Id.* at 17, 36.

52. Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 367 (1974).

53. William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1705 n.8 (1999).

54. *Id.* at 1824.

55. Kayte Spector-Bagdady et al., *Stemming the Standard-of-Care Sprawl: Clinical Self-Interest and the Case of Electronic Fetal Monitoring*, HASTINGS CTR. REP., Nov.–Dec. 2017, at 16, 16.

56. *Id.* at 19.

57. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 932–33 (1994).

that physicians avoid interactive, open-ended dialogue and concluded that “informed consent law in action is often ritualistic, formalistic, and hollow.”<sup>58</sup> In 1988, Cathy Jones spent six months as an observer in a 900-bed medical center and determined that

the informed consent procedures that most of them used, while sometimes meeting the letter of the informed consent doctrine, rarely met what should be its spirit, *i.e.*, providing adequate information and attempting to ensure that patients understand the information so they can make knowing and voluntary decisions about medical care.<sup>59</sup>

She concluded that under the status quo, “[p]atients are not protected; physicians are burdened with requirements that mean little; the law and society’s principles concerning individual autonomy and decisionmaking are effectuated in name only.”<sup>60</sup>

It is often argued that because the legal doctrine of medical informed consent sets the floor for ethical behavior, physicians may only disclose the minimum that the law requires.<sup>61</sup> The threat of liability may lead physicians to overfocus on avoiding it, resulting in the neglect of the process of medical informed consent to facilitate discussion and understanding.<sup>62</sup> John Lantos has observed that the focus on legal compliance, rather than ensuring medical self-determination for patients, may be demonstrated by the fact that more articles on informed consent are cross-referenced under “risk-management” than under “patient autonomy” or “ethics.”<sup>63</sup>

By emphasizing ritual over relationships, the imposition of legal liability on the informed consent process may, therefore, contribute to the deterioration of the doctor-patient relationship. As Peter Angelos, a surgeon at the University of Chicago, has explained, in the surgical context, “[t]he informed consent process today . . . may . . . not adequately acknowledge the importance of trust in the surgeon that surgical informed consent requires.”<sup>64</sup>

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58. *Id.* at 933–34.

59. Cathy J. Jones, *Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy*, 47 WASH. & LEE L. REV. 379, 397–98 (1990).

60. *Id.* at 427.

61. Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J.L. ETHICS & PUB. POL’Y 245, 273–75 (2000).

62. *Id.* at 273–74.

63. John Lantos, *Informed Consent: The Whole Truth for Patients?*, 72 CANCER 2811, 2813 (1993).

64. Kinga B. Skowron & Peter Angelos, *Surgical Informed Consent Revisited: Time to Revise the Routine?*, 41 WORLD J. SURGERY 1, 2 (2017).

Thus, to facilitate patient autonomous decision making, the informed consent process must enable a genuine human relationship. However, Thomas Szasz and Marc Hollender point out that “the concept of a relationship is a novel one in medicine.”<sup>65</sup> Physicians are trained to categorize “things” and “functions” instead of joint participations that human relationships require.<sup>66</sup> Furthermore, legal liability imposes claims of fault and incompetence on physicians and can therefore create an antagonistic relationship between physicians and patients, in opposition to the dialogue that the doctrine of informed consent is intended to foster.<sup>67</sup>

Further, defenders of the legal doctrine of informed consent claim that the threat of legal liability for failure to provide informed consent serves as a deterrent for potential bad actors.<sup>68</sup> Those who seek to avoid the process of informed consent might be incentivized to engage in the process of disclosing the risks, benefits, and alternatives of proposed treatments in order to avoid liability. However, studies have demonstrated that liability may not have the deterrent effect it is intended to have.<sup>69</sup> For example, one study recently concluded that “the risk of litigation didn’t translate into better outcomes.”<sup>70</sup>

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65. Thomas S. Szasz & Marc Hollender, *The Basic Models of the Doctor-Patient Relationship*, in *MORAL PROBLEMS IN MEDICINE* 64, 64 (Sam Gorovitz et al. eds., 1976).

66. Karene M. Boos & Eric J. Boos, *At the Intersection of Law and Morality: A Descriptive Sociology of the Effectiveness of Informed Consent Law*, 5 *J.L. & SOC’Y* 457, 471 (2004).

67. *Id.* at 471–72.

68. See Lisa Rapaport, *Stronger Malpractice Laws May Not Prevent Surgical Complications*, *REUTERS* (Jan. 27, 2017, 10:31 AM), <https://www.reuters.com/article/us-health-surgery-malpractice-laws/stronger-malpractice-laws-may-not-prevent-surgical-complications-idUSKBN15B1NM> [<https://perma.cc/7RYD-5LDB>] (stating that medical malpractice laws that make it easier for a patient to sue a doctor create protections necessary to improve care).

69. *Id.*; see Christina A. Minami et al., *Association Between State Medical Malpractice Environment and Postoperative Outcomes in the United States*, 224 *J. AM. C. SURGEONS* 310, 311 (2017) (“Higher risk malpractice environments were not consistently associated with a lower likelihood of surgical postoperative complications, bringing into question the ability of malpractice lawsuits to promote health care quality.”).

70. Rapaport, *supra* note 68.

B. *Imposition of Legal Liability for Failure of Informed Consent Results in a Substitution of Form for Process*

The informed consent form is intended to be approached as an instrument to enhance patient understanding of the proposed intervention.<sup>71</sup> However, critics of the legal doctrine of informed consent point to the inadequacies of and overreliance on consent forms in medical practice, due to physicians' focus on avoiding legal liability.<sup>72</sup> Informed consent forms often provide legally mandated information without regard to the usefulness of these forms in increasing patients' level of comprehension and understanding.<sup>73</sup> Thus, it has been recognized that, "[u]nfortunately, the consent form has at times replaced the process it was intended to substantiate."<sup>74</sup>

In reality, it is argued that the imposition of legal liability for failure to obtain informed consent has done little to encourage dialogue between physicians and patients. A study by Clarence H. Braddock and colleagues directly observed over 1000 patient encounters with primary care physicians and surgeons and studied over 3500 clinical decisions of varying degrees of complexity.<sup>75</sup> The researchers found that only nine percent of the observed decisions met the criteria for informed decision making.<sup>76</sup> Out of the approx-

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71. Victor Ali, Note, *Consent Forms as Part of the Informed Consent Process: Moving Away from "Medical Miranda,"* 54 HASTINGS L.J. 1575, 1591 (2003).

72. *Id.* at 1576-77.

Despite its critical importance to the provision of safe, high-quality, patient-centered health care, the process of informed consent in clinical practice is frequently inadequate, and prior research has demonstrated that patient comprehension of the key elements of clinical informed consent is often poor. Physicians receive little training in how to conduct informed consent discussions. Misunderstandings about consent requirements and goals, differing legal standards for informed consent disclosure, and the time pressures and competing demands of clinical medicine may also hinder the informed consent process. Many consent forms do not contain the key elements of informed consent or are written in a language too complex for many patients to understand. Patients who do not speak English or have limited literacy are at increased risk for poor comprehension.

Yael Y. Schenker et al., *Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: A Systematic Review,* 31 MED. DECISION MAKING 151, 152 (2011).

73. See Schenker et al., *supra* note 72, at 152.

74. Sprung & Winick, *supra* note 33, at 1348.

75. Clarence H. Braddock III et al., *Informed Decision Making in Outpatient Practice: Time to Get Back to Basics,* 282 JAMA 2313, 2313 (1999).

76. *Id.* The criteria include:

imately 3500 clinical decisions, less than one percent of intermediate and complex medical decisions were completely informed.<sup>77</sup> The results demonstrate that there are serious deficiencies in the level of information provided to patients, and the imposition of legal liability may not be effective in ensuring appropriate disclosures.<sup>78</sup>

In another example, a study found that few cancer patients read informed consent forms carefully, even when consenting to chemotherapy, radiation therapy, or surgery one day before treatment.<sup>79</sup> In fact, in a study of 200 patients who had signed informed consent forms, nearly eighty percent viewed the forms as legal protection for the physician.<sup>80</sup> The authors concluded that because patients view consent forms as a means for physicians to shield themselves from legal liability, patients are less likely to utilize the forms to enhance their understanding of proposed medical interventions.<sup>81</sup> As a result, legal liability presents a barrier to trust between patients and physicians.<sup>82</sup>

It is widely understood that, in order to include all legally mandated information, informed consent forms are often overlong and unintelligible, such that the average patient would be unable to fully understand the potential risks and benefits of the proposed intervention.<sup>83</sup> Informed consent documents have been analogized to “clickwrap agreements for computer software,” such that their

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(1) the patient’s role in decision making, (2) the nature of the decision, (3) alternatives, (4) pros (benefits) and cons (risks) of the alternatives, (5) uncertainties associated with the decision, (6) an assessment of the patient’s understanding of the decision, and (7) an exploration of the patient’s preferences. These criteria represent a synthesis of the bioethics literature and professional consensus on important elements of informed decision making.

*Id.* at 2315.

77. *Id.* at 2313.

78. *Id.*

79. See Barrie R. Cassileth et al., *Informed Consent—Why Are Its Goals Imperfectly Realized?*, 302 NEW ENG. J. MED. 896, 897 (1980).

80. *Id.* at 898–99.

81. See *id.* at 899.

82. *Id.*

83. See Jorge L. Contreras, *Genetic Property*, 105 GEO. L.J. 1, 29 (2016); Barbara A. Koenig, *Have We Asked Too Much of Consent?*, HASTINGS CTR. REP., July–Aug. 2014, at 33, 33; see also Leanne Stunkel et al., *Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form*, IRB, July–Aug. 2010, at 1, 7 (assessing informed consent forms in the research context and concluding that “too much attention is spent on the details of consent forms, possibly as a result of legal liability issues” and that “[t]ime spent revising the small details and specific wording of informed consent documents does not appear to impact comprehension”).



length and complexity result in the fact that “all but the most sophisticated readers have difficulty understanding it.”<sup>84</sup> In overproviding the risks and other information in an effort to meet legal disclosure requirements, informed consent forms may be poorly drafted, unreadable, overly complicated, and inundated with detail.<sup>85</sup> They may, therefore, render an understanding of the risks and benefits of a proposed intervention near impossible.

Alan Meisel and Mark Kuczewski posit that, in the view of some physicians, consent forms function as “medical Miranda warn[ing[s],” which diminish some patients’ reliance on consent forms for medical disclosures and decision making.<sup>86</sup> Physicians wrongly believe that a patient’s signature satisfies the legal requirement of informed consent, in the same way law enforcement agents only need to advise suspects of their constitutional rights to avoid lawsuits. Thus, the question of whether someone “*consent[ed]* the patient” is heard frequently in the medical setting, implying that “consent’ is something that is done to the patient, not something that the patient does.”<sup>87</sup> In turn, the threat of legal liability for failure to ensure voluntary, informed consent has covered the physician-patient relationship with “bureaucratic red tape.”<sup>88</sup> Thus, the legal doctrine of informed consent may contribute to diminishing patient understanding, replacing the process of physician-patient dialogue with the ritual signing of a form that patients may not even trust or understand.

Taking it a step further, overreliance on *form* rather than *process* may also allow enterprising health care providers to impose their own treatment preferences on patients at the expense of a patient’s autonomous decision making.<sup>89</sup> In other words, the legal doctrine of informed consent may be used to co-opt the goal of facilitating autonomous informed decision making. For example, it may be argued that those physicians who would approach the doctor-patient interaction from a paternalistic perspective may rely on the ritual required by the legal doctrine of informed consent to

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84. Contreras, *supra* note 83, at 29.

85. See Michael K. Paasche-Orlow et al., *Readability Standards for Informed-Consent Forms as Compared with Actual Readability*, 348 NEW ENG. J. MED. 721, 722 (2003). Almost half of American adults read at or below the eighth-grade level. *Id.* at 725.

86. Alan Meisel & Mark Kuczewski, *Legal and Ethical Myths About Informed Consent*, 156 ARCHIVES INTERNAL MED. 2521, 2522 (1996); Ali, *supra* note 71, at 1578.

87. Scott, *supra* note 61, at 274.

88. *Id.*

89. See *id.* at 274–75.

avoid engaging in the process of shared decision making. These physicians could “capitalize on the interrelationship between the law’s focus on disclosure and the patient’s inability to understand,” thereby satisfying the law’s disclosure requirements but doing so by utilizing complicated and technical wording in order to make patients consent to the physician’s judgment.<sup>90</sup> Alternatively, in the absence of a robust informed consent process, the informed consent form could present information in a manner “such that the patient will choose the alternative the physician thinks best regardless of what the patient might choose to do” if her decision was truly autonomous and informed.<sup>91</sup>

### C. *The Legal Doctrine of Informed Consent Is Impractical in Application*

It may also be argued that the legal doctrine of informed consent does not serve the realities of the clinical setting.<sup>92</sup> As Robin Fretwell Wilson observes, “For most patients, there is a gaping gulf between [patients’] desire to participate in choices about their care and what actually transpires.”<sup>93</sup> This is because the law is notoriously vague and shifting,<sup>94</sup> and physicians are not provided with specific guidance about how to comply.<sup>95</sup> Moreover, the nature of medical interventions does not allow informed consent at every step. Charles Sprung and Bruce Winick argue,

Rather than being a simple, one-time, discrete deliberation concerning a procedure with risks, benefits, and alternatives, [medical care] is a complex, evolving pursuit of a diagnosis and proper treatment regimen. . . . Medical realities preclude informed consent at every step of a patient’s work-up. Such a requirement would destroy the trust and reliance patients place in their physicians. Because of the complexities of medical logic and practice, a set of alternatives from which the patient can choose is rarely presented. Physicians may behave as

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90. Kurtz, *supra* note 15, at 1254.

91. Jones, *supra* note 59, at 402.

92. See, e.g., Hall et al., *supra* note 38, at 535–36 (“Research suggests that physicians rarely meet even minimal standards of disclosure for the purposes of obtaining informed consent. For example, Braddock and colleagues looked at 1057 physician-patient encounters involving 59 primary care physicians and 65 general or orthopedic surgeons. Only 9% of the 2553 clinical decisions made during these encounters met the criteria for completely informed decision-making.”).

93. Robin Fretwell Wilson, *The Promise of Informed Consent*, in THE OXFORD HANDBOOK OF U.S. HEALTHCARE LAW 213, 214 (I. Glenn Cohen et al. eds., 2017).

94. See Weisbard, *supra* note 22, at 752–53.

95. See Meisel & Kuczewski, *supra* note 86, at 2521.

they do because of their awareness, confirmed by studies that patients usually are not interested in, nor do they believe they are capable of, playing the role assigned to them by law.<sup>96</sup>

The required elements of an informed consent claim may, in fact, hinder the ability to ensure that patients are able to make informed, voluntary medical decisions. Many argue that the law's onerous legal requirements necessitate overdisclosure rather than comprehension and trust in the doctor-patient relationship.<sup>97</sup> It is argued that "[l]ike warning labels generally, 'overdisclosure' makes it difficult for patients to distinguish meaningful risks from trivial ones," resulting in less comprehension.<sup>98</sup> Further, the dueling materiality standards—and consequently, the inconsistent application of the doctrine—and the objective causation and injury requirements may serve to actually undermine patient autonomy.<sup>99</sup>

#### 1. Due to Competing Materiality Standards, the Legal Doctrine of Informed Consent Is Unpredictably Enforced

While the threat of legal liability may lead physicians to provide more information to patients and give greater deference to patients' preferences, the jurisdictional split regarding the materiality standards that govern the physician's duty to disclose may lead to a lack of uniformity in the ability to enforce the legal doctrine of informed consent.<sup>100</sup> Thus, the competing materiality standards—the physician-based standard and the patient-based standard—may result in unpredictability in one's ability to recover for a failure to obtain informed consent.<sup>101</sup>

In the jurisdictions that maintain the physician-based standard, required disclosure focuses on the physician's assessment of the scope of the proposed intervention as determined by reference to

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96. Sprung & Winick, *supra* note 33, at 1352.

97. King & Moulton, *supra* note 32, at 477–79.

98. Wilson, *supra* note 93, at 229.

99. *Id.* at 217, 220–21, 239.

100. *See id.* at 217.

101. *See* King & Moulton, *supra* note 32, at 441, 445 (describing what a patient must prove in order to bring a successful breach of informed consent claim under current physician- and patient-based standards).

the actions of other professionals, rather than the extent of the patient's understanding.<sup>102</sup> Those jurisdictions require expert testimony as to the "degree of skill and diligence exercised by a reasonably prudent practitioner in the same field of practice or specialty,"<sup>103</sup> because of the belief that "neither the lay community nor the legal community can appropriately define the parameters regarding treatment alternatives."<sup>104</sup> In doing so, jurisdictions that follow the physician-based standard for informed consent insulate physicians from liability to a greater degree than those that follow the patient-based standard.<sup>105</sup>

Moreover, adoption of the physician-based standard, even if applied consistently across jurisdictions, might still lead to inconsistencies in practice and application of medical standards of care that are inapposite to the best interests of the patient. Jaime King and Benjamin Moulton describe the variations that may exist with regard to the standard of care, explaining that "contrary to the assumptions of the physician-based standard, one appropriate standard of care does not exist for most treatments."<sup>106</sup> Others have opined that reliance on the "reasonably prudent" physician-based standard may shift the medical standard of care, thereby resulting in a "standard-of-care sprawl where actions undertaken for the primary purpose of avoiding liability reset the standard of care against which clinicians will be adjudicated."<sup>107</sup>

In contrast, the patient-based standard seeks to shift the emphasis from physician disclosure to patient comprehension by requiring the physician to disclose all information that a reasonable person in the patient's position would consider material to her decision making.<sup>108</sup> However, courts "have failed to delineate any clear limits on what must be disclosed" under the standard.<sup>109</sup> And it has been argued that the reasonable patient standard is inherently flawed, because there is no uniformity in what patients want

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102. See Sprung & Winick, *supra* note 33, at 1347.

103. Tashman v. Gibbs, 556 S.E.2d 772, 777 (Va. 2002).

104. Boos & Boos, *supra* note 66, at 467.

105. See Kurtz, *supra* note 15, at 1245.

106. King & Moulton, *supra* note 32, at 445–46.

107. Spector-Bagdady et al., *supra* note 55, at 16 (emphasis omitted).

108. See *id.* at 19–20.

109. Timothy J. Paterick et al., *Medical Informed Consent: General Considerations for Physicians*, 83 MAYO CLINIC PROC. 313, 315 (2008).

to know from their doctors.<sup>110</sup> Scholars have noted the lack of uniformity in what patients—even reasonable patients—would want to know from their physicians, which “challenges the validity of an objective patient-based standard and the notion of the ‘reasonable’ patient.”<sup>111</sup> Thus, the uncertainty regarding the extent of required disclosures may, in turn, lead physicians to overprovide information to avoid liability.<sup>112</sup>

## 2. The Objective Causation and Injury Requirements Undermine the Principle of Patient Autonomy

Some have argued that the objective standard for proving causation in informed consent suits, which is relied upon in almost all jurisdictions, undermines personal autonomy.<sup>113</sup> In proving negligence on the part of the physician in informed consent suits, most states require patients to prove that a reasonable person would not have undergone the procedure if given the undisclosed information.<sup>114</sup> However, it has been argued that framing the question of causation in terms of the decision of a reasonable person erodes “the right of individual choice, which may be precisely the right to prefer a course of treatment that a majority of patients would not choose.”<sup>115</sup> Thus, even though the principle of informed consent aims to decrease physician paternalism in the health care system, the legal doctrine of informed consent imposes judicial paternalism in the application of the causation requirement.<sup>116</sup>

Furthermore, patients cannot recover from physicians who fail to seek informed consent in the absence of actual harm leading to consequential damages.<sup>117</sup> E. Haavi Morreim notes, “Because standard informed consent doctrine usually limits recovery to cases featuring a physical or other separate injury, it can fail to

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110. *See id.* at 318.

111. King & Moulton, *supra* note 32, at 446, 451–52.

112. *See id.* at 452.

113. *See, e.g.*, Tenenbaum, *supra* note 35, at 697; Aaron D. Twerski & Neil B. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. ILL. L. REV. 607, 608.

114. *See* Tenenbaum, *supra* note 35, at 697; Twerski & Cohen, *supra* note 113, at 608–09.

115. Katz, *supra* note 24, at 163–64.

116. *See id.* at 139–40, 164–65.

117. Kurtz, *supra* note 15, at 1245.

honor human autonomy in cases where someone's right to choose has been abused without demonstrable physical damage."<sup>118</sup>

Thus, physicians who provide less information to the patient than the law requires can rely on the injury element to absolve themselves of liability by claiming the lack of physical harm,<sup>119</sup> rendering the legal doctrine of informed consent rather meaningless in actually addressing failures of informed consent in practice.

*D. The Legal Doctrine of Informed Consent Is Not as Historically Entrenched as It Seems*

One of the most common arguments in favor of maintaining the tort of informed consent in its current form is the fact that it provides reliability and structure to the doctor-patient relationship.<sup>120</sup> Although it is a relatively new cause of action by historical accounts, this tort is now firmly entrenched in either legal precedent or codified by state statute.<sup>121</sup> Physicians and medical institutions learn—early and often—the legal requirements of informed consent and the consequences of not following the law and ensuring that the patient signs the informed consent form.<sup>122</sup> The law demands particular physician behavior, and in turn, providers have become reliant on the current incarnation of the legal doctrine of informed consent to ensure that they are fulfilling their professional, and ethical, responsibilities.<sup>123</sup>

However, as discussed earlier in this part, the legal doctrine of informed consent may do little to actually protect patient autonomy or ensure voluntary medical decision making. In fact, it has been argued that other (more historically entrenched) torts do much of the work that the tort of lack of informed consent is intended to do.<sup>124</sup> For example, the torts of fraud and battery may ensure deterrence of bad action, such as concealment of the risks

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118. E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUSE J. HEALTH L. & POL'Y 1, 74 (2003).

119. Kurtz, *supra* note 15, at 1245 (“[D]octors provide less information to the patient than by the law the patient is entitled to receive and then rely on the law of negligence to absolve them of liability for their assault on the patient’s autonomy interest by claiming that, in the absence of any physical harm, there was no foul.”).

120. See Shultz, *supra* note 7, at 223–24, 297–98.

121. See Kurtz, *supra* note 15, at 1243–46.

122. See Paterick et al., *supra* note 109, at 313–14.

123. See *id.*

124. See Kurtz, *supra* note 15, at 1259.

of a proposed treatment protocol or failure to obtain consent to a particular intervention.<sup>125</sup> Cathy Jones notes that “[a] return to prior practice has some attractive qualities,” and says of considering a “return to the old days” and relying on the tort of battery to protect patients:

It would reinforce the medical expertise and professional judgment of physicians. If physicians could be held liable only where they failed to gain a patient’s consent to the performance of a procedure—in essence a battery action—rather than where they unreasonably failed to inform a patient of the risks of any given procedure and one of the risks occurred—a negligence action—physicians’ risk of liability would decrease. Presumably patients would be no worse off medically than they were three decades ago before the doctrine of informed consent was first announced, or than they are today when physicians go through the motions of informed consent with the tacit approval of the law, but without really accomplishing the objective of decisionmaking by patients who comprehend the information provided. And perhaps our recent experience with informed consent criteria would cause physicians not to return to the stereotyped parentalistic days of the doctors who know best telling patients only what doctors believe patients need to know, or should know, or “can handle,” but instead to discuss with patients, much as they do now, patient’s conditions and proposed treatment plans.<sup>126</sup>

Further, informed consent does not do a lot of heavy lifting, as it is rarely a stand-alone cause of action.<sup>127</sup>

### III. CONSIDERING SOLUTIONS

In light of these various arguments regarding the failures of the legal doctrine of informed consent, one must consider how to ameliorate the situation so that liability matches up with what we expect of the informed consent process. Cathy Jones succinctly summarized the problems of informed consent in her 1990 article:

The remaining question, then, is what to do about the application of the doctrine of informed consent? Do we continue as we have for three decades requiring physicians to provide patients with information that may meet on its face the legal criteria for disclosure but which generally does not educate patients so they can make truly informed decisions as to their medical care? Do we admit that informed consent as currently applied is a myth which burdens physicians and does not

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125. See Katz, *supra* note 24, at 148.

126. Jones, *supra* note 59, at 428 (footnotes omitted).

127. See *id.* at 389–90, 394–95.

substantially protect patients, and return to prior times when physicians told patients what they thought patients needed to know, when patients were free to ask or not ask questions that physicians were free to answer or not answer, and when physicians were free from liability so long as they told patients what procedures were going to be performed and patients agreed to the performance of those procedures? Or despite difficulty and cost, do we try to comply in a better, more effective way with not only the technical requirements of the informed consent doctrine, but with the doctrine's spirit as well?<sup>128</sup>

#### A. *Eliminating Legal Liability for Informed Consent*

In light of the failings of the legal doctrine of informed consent for medical treatment, the most straightforward solution might be to restrict, or even eliminate, the informed consent claim for medical treatment. Eliminating or restricting existing tort law claims is not without precedent; in fact, other common law tort claims have been limited by contract or eliminated.<sup>129</sup> For example, product liability and personal injury claims<sup>130</sup> have been narrowed over time.

Ideally, in the absence of civil liability for failure of informed consent to medical treatment, health care providers will be empowered to pursue a robust informed consent process allowing for unencumbered access to medical treatment, framed not by “the law,” but by the ethical practice of medicine. It is striking that in the current system (at least in the personal experience of the author) health care providers often jump straight into discussions of legal precedent and state laws to determine the appropriateness of disclosures in proposing medical interventions or therapies. This default position is often a product of institutionalized fear of legal liability, resulting in a less effective informed consent process.<sup>131</sup>

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128. *Id.* at 427.

129. See Alexandra B. Klass, *Tort Experiments in the Laboratories of Democracy*, 50 WM. & MARY L. REV. 1501, 1503 (2009).

130. *Id.* at 1567.

131. See Sage, *supra* note 53, at 1824.



For example, recent emphasis on shared decision making,<sup>132</sup> the use of patient decision aids, scenario planning,<sup>133</sup> and other proposals support health care providers' focus on voluntary, informed medical decision making.

## B. *Alternatives to Legal Liability for Informed Consent*

### 1. A Return to the "Old Days"

Of course, when things go wrong, patients may still seek legal recourse. In the absence of civil liability for failure of informed consent, patients would likely be forced to rely on the common law tort of battery for harms caused due to a failure to disclose information in the course of medical decision making. Thus, eliminating a tort claim for failure of informed consent to medical treatment may result in a throwback to the era preceding *Schloendorff v. Society of New York Hospital*,<sup>134</sup> *Salgo v. Leland Stanford Jr. University Board of Trustees*,<sup>135</sup> *Canterbury v. Spence*,<sup>136</sup> and *Cobbs v. Grant*.<sup>137</sup>

Despite the attractive qualities of returning to the "old days" of relying on the tort of battery to protect patients, scholars have noted that the torts upon which patients relied before the introduction of the legal doctrine of informed consent would insufficiently

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132. See PETER A. UBEL, CRITICAL DECISIONS: HOW YOU AND YOUR DOCTOR CAN MAKE THE RIGHT MEDICAL CHOICES TOGETHER 20 (2012); see also Annette M. O'Connor et al., *Modifying Unwarranted Variations in Health Care: Shared Decision Making Using Patient Decision Aids*, 23 HEALTH AFF. 63, 64 (2004) (describing shared decision making as a "process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives").

133. See, e.g., Jacqueline M. Kruser et al., "Best Case/Worst Case": *Qualitative Evaluation of a Novel Communication Tool for Difficult In-the-Moment Surgical Decisions*, 63 J. AM. GERIATRIC SOC'Y 1805, 1805 (2015); Margaret L. Schwarze & Lauren J. Taylor, *Managing Uncertainty—Harnessing the Power of Scenario Planning*, 377 NEW ENG. J. MED. 206, 206 (2017) (recommending scenario planning to facilitate informed decision making); Skowron & Angelos, *supra* note 64, at 3.

134. 105 N.E. 92 (N.Y. 1914). While not a strict informed consent case, *Schloendorff* involved allegations of unauthorized surgery during a routine examination. *Id.* at 93. Justice Cardozo stated, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." *Id.*

135. 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957) (holding that physicians had a duty to disclose all facts that were necessary for the patient to make an intelligent health care decision).

136. 464 F.2d 772, 783 (D.C. Cir. 1972).

137. 502 P.2d 1, 8 (Cal. 1972).

protect patients in today's medical landscape.<sup>138</sup> It is unlikely that reverting to a system relying on battery for failure of consent alone would sufficiently protect patients because the (imperfect) process of informed consent that became more or less standardized after its introduction has become so institutionalized. Thus, Cathy Jones argued that “return[ing] to the old days” of relying on battery actions is objectionable:

[T]he removal of the informed consent criteria gives legitimacy to the beliefs that patients cannot remember or understand what physicians tell them, that medical information is so specialized it can be understood only by practitioners and will always be out of the reach of the patients, those most affected by it, that testing patients' comprehension of the information takes too much physician time that could be better spent treating other patients, that patients want doctors to make decisions for them, and that physicians can persuade patients to do whatever physicians believe is best for patients. Not only does such a return give validity to these beliefs, it *invites* physicians to make decisions for patients without providing them with relevant information about their condition or proposed treatment, perpetuating the self-fulfilling prophecy that patients are not able to comprehend such information and make such decisions for themselves.<sup>139</sup>

This concern presents the question: will no liability leave patients without protection? If a “return to the old days” is unacceptable, then, in the absence of civil liability for failure to provide informed consent, how do we ensure that the ethical underpinnings and goals of the *process* of informed consent are achieved? Are there alternatives to legal liability for informed consent? Can the law ensure (or seek to ensure) voluntary, autonomous medical decision making? If so, how?

## 2. Creation of a New Tort

One of the most obvious responses to a dearth of civil recourse for failure to disclose necessary medical information is the establishment of a new tort—one that ensures that patients are able to make informed, autonomous medical decisions. Thus, in her seminal 1985 article, Marjorie Maguire Shultz recommended “the creation of a distinct and independently protected interest in patient autonomy.”<sup>140</sup> This proposal would potentially reduce the damages

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138. See Jones, *supra* note 59, at 428.

139. *Id.*

140. Shultz, *supra* note 7, at 283–84 (“A duty to disclose would be triggered by the possession of information important and relevant to the patient, rather than by a proposal to

a plaintiff could recover, but would also potentially have a sufficient deterrent effect on physicians who would otherwise withhold important information in the medical decision-making process.<sup>141</sup> Similarly, E. Haavi Morreim has called for the establishment of a “distinct dignitary tort”—those harms that are “caused by conduct that overrides patients’ autonomy,”<sup>142</sup> treats them as less than human, and denigrates them as human beings—for “serious deficiencies of informed consent.”<sup>143</sup> Ever since the early days of the reliance on claims for informed consent, others have also proposed allowing recovery for so-called dignitary harms.<sup>144</sup> More recently, Victoria Chico, in her 2011 book, *Genomic Negligence*, proposed damages for loss of autonomy as a potential new cause of action.<sup>145</sup> Applying English courts’ approaches to novel types of damages that resulted in interference with autonomy, she considers claims based on advances in genetic technology.<sup>146</sup>

The introduction of a new tort that focuses on autonomous decision making would seem to ameliorate many of the problems that exist with the current tort of informed consent. The legal doctrine of informed consent notoriously emphasizes physician disclosure at the expense of patient understanding.<sup>147</sup> In contrast, the ethical practice of informed consent emphasizes comprehension over the duty to inform, and thus it might make sense to craft a right of action that underscores the duty to obtain consent to treatment. However, this could be problematic, particularly because it is much more straightforward to identify an adequate (or inadequate) level of disclosure than it is to measure individual patient comprehension. For example, two suggestions—requiring patients to repeat back information or take quizzes to demonstrate understanding<sup>148</sup>—would be far too onerous on patients and would unduly

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touch.”).

141. BERG ET AL., *supra* note 34, at 151; see Shultz, *supra* note 7, at 291.

142. Dena S. Davis, *The Ambiguous Effects of Tort Law on Bioethics: The Case of Doctor-Patient Communication*, 21 J. CLINICAL ETHICS 264, 265 (2010); Morreim, *supra* note 118, at 78.

143. Morreim, *supra* note 118, at 78 & n.339.

144. See Leonard L. Riskin, *Informed Consent: Looking for the Action*, 1975 U. ILL. L.F. 580, 603–04; Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533, 1533–34 (1970).

145. VICTORIA CHICO, *GENOMIC NEGLIGENCE: AN INTEREST IN AUTONOMY AS THE BASIS FOR NOVEL NEGLIGENCE CLAIMS GENERATED BY GENETIC TECHNOLOGY* 38 (2011).

146. *Id.* at 3–4.

147. BERG ET AL., *supra* note 34, at 66.

148. Schenker et al., *supra* note 72, at 168.

stress the doctor-patient relationship. Further, despite frequent calls for the recognition of negligence claims allowing recovery for dignitary harms, American courts have generally been reluctant to allow such claims.<sup>149</sup>

### 3. Establishment of a Fiduciary Duty of Care

Alternatively, rather than rooting the patient's claim in negligence, a claim based on a fiduciary standard of care could avoid some of the well-known obstacles to prevailing on a lack of informed consent claim. While the doctrine of informed consent presumably focuses on physician disclosure of the risks, benefits, and alternatives to a proposed intervention, patients may be reluctant to bring an informed consent claim against a physician who fails to make the appropriate disclosures, because the damage awards are often paltry.<sup>150</sup> And even if a patient is able to demonstrate actual physical injury that would result in an adequate damages award, causation can be near-impossible to prove.<sup>151</sup> A claim based on a fiduciary standard of care might circumvent the difficulties of demonstrating actual injury or causation,<sup>152</sup> instead shifting the focus to the fact that the physician (a fiduciary) neglected his duty of care.<sup>153</sup> As John Goldberg explains,

At least in some circumstances, the breach of a fiduciary duty of care, unlike a breach of negligence law's duty of care, can generate liability—i.e., a change in legal relations—even if the breach does not result in injury. In other words, in some instances, the duty of care owed by a fiduciary to a beneficiary is a duty of prudent conduct *simpliciter* rather than a duty to avoid causing injury through imprudent conduct.<sup>154</sup>

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149. See Weisbard, *supra* note 22, at 753 (“The harm, which lawyers refer to as a dignitary injury, is generally too abstract and intangible to result in a damage award large enough to justify the lawsuit.”).

150. Twerski & Cohen, *supra* note 113, at 616 (“Any theory which focuses on the violation of the right to autonomous decision making might yield only trivial dignitary tort damages.”); Weisbard, *supra* note 22, at 753.

151. Tenenbaum, *supra* note 35, at 719; Twerski & Cohen, *supra* note 113, at 617–18.

152. John C.P. Goldberg, *The Fiduciary Duty of Care*, in *THE OXFORD HANDBOOK OF FIDUCIARY LAW* (Evan J. Criddle et al. eds., forthcoming 2019) (manuscript at 15), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3182604](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3182604) [<https://perma.cc/6YZV-4HEJ>] (“[F]iduciary law has historically been bound up with equity. And courts doing equity provide relief on quite different terms than courts applying law, including by providing relief prior to or irrespective of injury.”).

153. *Id.* (manuscript at 4).

154. *Id.*

However, not all courts and scholars are eager to find that the doctor-patient relationship is fiduciary in nature.<sup>155</sup> And to the extent that the relationship is recognized as fiduciary,<sup>156</sup> it raises the question of why reliance on that relationship has not, in fact, led to a proliferation of disclosure claims based on the duties that arise from it.<sup>157</sup> In fact, although it has been proposed that plaintiffs should be able to recover damages for violation of their right to participate in the decision-making process, without having to prove that they would have made a different decision if adequate information had been disclosed,<sup>158</sup> courts “have never adopted this approach in cases involving standard medical treatment.”<sup>159</sup>

#### 4. Self-Regulation

Alternatively, in the absence of a civil claim for failure to obtain informed consent, professional societies or licensure bodies could assume the responsibility of ensuring that the physician engage in a robust shared decision-making process, including making all appropriate disclosures, thereby ensuring voluntary and autonomous medical decision making. This proposal would require the bad actor to pay fines or have her license to practice suspended if she failed to ensure informed consent in her practice.

However, leaving enforcement of informed consent to professional societies or licensure boards could effectively be leaving the fox to guard the henhouse. Physicians might be encouraged by their peers to remain quiet regarding colleagues' malfeasance or improperly claim that the individual's level of disclosure actually met the standard of care. Presumably, this could lead to the estab-

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155. See Marc A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 AM. J.L. & MED. 241, 242 (1995).

156. Maxwell J. Mehlman, *The Patient-Physician Relationship in an Era of Scarce Resources: Is There a Duty to Treat?*, 25 CONN. L. REV. 349, 367 (1993) (noting that most courts and commentators agree that the patient-physician relationship is a fiduciary one); Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 314 n.7 (2002); David Orentlicher, *Health Care Reform and the Patient-Physician Relationship*, 5 HEALTH MATRIX 141, 147 (1995).

157. Shultz, *supra* note 7, at 262 (identifying factors limiting the capacity of general fiduciary duties to resolve problems of disclosure, including “a relatively crystallized conflict of interest may be necessary before courts decide that such [fiduciary] principles should apply”).

158. Twerski & Cohen, *supra* note 113, at 609.

159. Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 447 (2005) (citing Twerski & Cohen, *supra* note 113, at 608).

lishment of an extreme version of the professional standard of materiality.<sup>160</sup> In other words, self-regulation may incentivize physicians to protect their own and disincentivize physicians from policing or reporting a colleague's inappropriate actions.<sup>161</sup> Thus, this proposal is unlikely to deter bad behavior.

### CONCLUSION

As Part III demonstrates, the alternatives to tort liability for failure of informed consent are imperfect.<sup>162</sup> In fact, for the most part, they are less likely to ensure voluntary, autonomous decision making than the status quo. While tort liability for failure of informed consent to medical treatment is an imperfect solution to concerns about inadequate disclosures, leading to involuntary and uninformed medical decision making, it is possible that there is no effective legal remedy to the problem.<sup>163</sup> While there may be no perfect legal remedy for failure to ensure autonomous, informed medical decision making, our current approach serves both deterrent and compensatory roles. Thus, this article concludes that the time has not yet come for a wholesale elimination of the private right of action for informed consent to medical treatment.

Others agree. Jessica Berg has concluded that “the fact that informed consent is something less in practice than it is in theory in no way suggests that it should be abandoned, even if it has certain costs in terms of medical time and effort.”<sup>164</sup> Michelle Mello, in countering a study that concluded that stronger malpractice laws do not improve patient outcomes, explained that, while “[t]his study contributes further evidence that liability pressure doesn't

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160. See Mark Spiegel, *Lawyering and Client Decisionmaking: Informed Consent and the Legal Profession*, 128 U. PA. L. REV. 41, 46 (1979).

161. Paul Starr addresses the frequently raised question of whether the medical profession often advocates for its own self-interest. See PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 5, 12–17, 23–28 (1982); see also Maxwell J. Mehlman, *Can Law Save Medicine?*, 36 J. LEGAL MED. 121, 138 (2015) (“If medicine wants to be a profession, it clearly needs to do a much better job of policing itself. Given that it has not successfully regulated itself, it needs the aid of the law.”).

162. See *supra* Part III.

163. Jay Katz, in his 1984 book, *The Silent World of Doctor and Patient*, stated that “the radically different climate of physician-patient decision making . . . cannot be implemented by judicial, legislative, or administrative orders.” KATZ, *supra* note 42, at 228–29.

164. BERG ET AL., *supra* note 34, at 160.

spur doctors to get better results for patients, . . . neither does adopting reforms to limit liability.”<sup>165</sup>

In a recent article,<sup>166</sup> I challenged the generally accepted distinction between the rights of patients and the rights of research participants to seek remedies directly from actors who fail to communicate the risks of an intervention. While patients have a right to recover for failure of informed consent to treatment, such a right does not extend to a research participant who is harmed due to a lack of informed consent by the investigator in a research protocol.<sup>167</sup> Even if this differential treatment was justifiable in the past, advances in research technology require a new approach.<sup>168</sup> Research projects pose a similar threat to participant autonomy as do medical interventions.

In calling for parity in the treatment of informed consent to treatment and research, I argued for a private right of action for failure to provide informed consent in research, similar to that already in existence in the treatment context.<sup>169</sup> Extending a private right of action for lack of informed consent to the research setting will provide necessary protection against the serious threat to participant autonomy that modern research poses. Doing so would both ensure the deterrent effect that the regulations that govern a majority of human subjects research in the United States—the Common Rule—has for potential bad actors in the research context,<sup>170</sup> and provide a compensatory effect for those who are harmed due to a failure of informed consent while participating in a research protocol.

In contrast to this proposal, eliminating legal liability for failure to provide informed consent to treatment would not only eliminate the patient’s means of compensation, it would leave no deterrent

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165. Rapaport, *supra* note 68.

166. Koch, *supra* note 15, at 177.

167. *Id.* at 174–75.

168. *Id.* at 175–77.

169. *Id.* at 177. Others have come to similar conclusions. See Elizabeth R. Pike, *Recovering from Research: A No-Fault Proposal to Compensate Injured Research Participants*, 38 AM. J.L. & MED. 7, 10 (2012).

170. 21 C.F.R. § 56.121 (2018); 45 C.F.R. § 46.123(a); OFFICE FOR HUMAN RESEARCH PROTS., DEP’T OF HEALTH & HUMAN SERVS., OHRP’S COMPLIANCE OVERSIGHT PROCEDURES FOR EVALUATING INSTITUTIONS 1, 5–7 (2009), <https://www.hhs.gov/ohrp/sites/default/files/ohrp/compliance/evaluation/ohrpcomp.pdf> [<https://perma.cc/HC76-6VQ2>]; Koch, *supra* note 15, at 176.

2019]

ELIMINATING LIABILITY

1241

effect for those physicians who failed to provide informed consent to their patients, thus resulting in a new lack of parity between treatment and research.

While extricating the practice of informed consent from the law may be enticing for various reasons, the reality of medical practice and the doctor-patient relationship continues to necessitate a legal remedy for patients who are denied an opportunity to make voluntary, informed decisions—and are harmed as a result. Abolishing liability for lack of informed consent in treatment will not only eliminate the deterrent effect for potential bad actors, but it would also remove recourse for those who have suffered harm due to a failure of informed consent. Therefore, despite its imperfections, the legal doctrine of informed consent should remain in place to allow all patients who have suffered harm to pursue recourse until a more effective alternative is established.