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## Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation

Evelyn Tenenbaum

*Albany Law School*, etene@albanylaw.edu

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# REVITALIZING INFORMED CONSENT AND PROTECTING PATIENT AUTONOMY: AN APPEAL TO ABANDON OBJECTIVE CAUSATION

EVELYN M. TENENBAUM\*

## *Introduction*

The purpose of informed consent laws is to ensure that patients receive sufficient information about the risks and alternatives of medical procedures to make their own health care decisions based on their personal values, preferences, and priorities.<sup>1</sup> But in practice, informed consent laws are unfaithful to this underlying goal.<sup>2</sup>

In all but four states, a patient cannot prevail on an informed consent claim without proving objective causation. 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. In applying this standard, the courts must focus on the hypothetical preferences of a reasonable person, rather than on the values of the individual patient.<sup>3</sup> As a result, this standard undermines the primary purpose of the doctrine.<sup>4</sup>

The medical information patients receive from physicians reflects the law's focus on the hypothetical reasonable patient.<sup>5</sup> The informed consent process often consists of a formalistic recitation of risks and alternatives intended to protect the physician against liability, rather than a joint process during which the physician and patient coordinate to ensure that the patient's decisions are based on individual preferences and concerns.<sup>6</sup> The Patient Protection and Affordable Care Act of 2010 (PPACA), the new federal health care legislation, recognizes this deficiency and includes a

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1. *See infra* Part I.
2. *See infra* Part II.
3. *See infra* Parts III-IV.
4. *See infra* Parts III-IV.
5. *See infra* Part VII.
6. *See infra* Part VIII.

program to “facilitate[] the incorporation of patient preferences and values into the medical plan.”<sup>7</sup>

An important first step in improving the process of informed consent is to convince the courts and state legislatures to abandon objective causation and choose a standard that recognizes the importance of individual preferences and priorities. This change in focus is more important now than ever before. The increasing complexity of medical care and the ever-widening array of treatment choices make patient health care decisions more dependent on values and preferences than at any time in the past.<sup>8</sup> Moreover, with today’s technology, providing disclosures that take patient priorities into account need not be an undue burden on medical providers. New computer systems can help make the process easy, effective, and relatively inexpensive.<sup>9</sup>

This article begins by tracing the history of informed consent and the evolution of that doctrine—including the adoption of an objective causation standard—to adapt to changes in medical care. It then focuses on how objective causation undermines the purposes of informed consent, addresses the courts’ reasons for choosing that standard, and argues that those reasons do not justify using an objective standard. This article recommends adopting a subjective causation standard and concludes by explaining why this change is essential to keep pace with modern developments in medical care.

### *I. Brief Background on the Development of Informed Consent*

Informed consent is a relatively new concept in medicine.<sup>10</sup> For more than twenty-four centuries, patients were expected to place their trust in their physicians, who made all medical decisions for them.<sup>11</sup> It was not until the twentieth century, when medical care began to rapidly advance,

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7. Patient Protection and Affordable Care Act, 42 U.S.C.A. § 299b-36(a) (West 2011).

8. *See infra* Part X.

9. *See infra* Part IX.

10. Wendy K. Mariner, *Informed Consent in the Post-Modern Era*, 13 LAW & SOC. INQUIRY, 385, 391 (1988) (“Our modern conceptions of disclosure and consent were entirely foreign to the definition of medical practice throughout its professional evolution.”).

11. Grant H. Morris, *Dissing Disclosure: Just What the Doctor Ordered*, 44 ARIZ. L. REV. 313, 314 (2002) (“For twenty-four centuries, physicians heeded Hippocrates’ advice.”); *id.* at 313 (“The physician . . . was not to be questioned or influenced by the patient’s uneducated opinions, irrational concerns, or emotional worries.”).

that the doctrine of informed consent gained traction<sup>12</sup> and patient autonomy gained precedence over the formerly paternalistic role of physicians.<sup>13</sup>

Hippocrates, who was born around 460 B.C.,<sup>14</sup> counseled physicians to “conceal[] most things from the patient while . . . attending to him . . . revealing nothing of the patient’s future or present condition.”<sup>15</sup> Physicians were to use their best judgment<sup>16</sup> and not be influenced by “the patient’s uneducated opinions, irrational concerns or emotional worries.”<sup>17</sup> Correspondingly, the patient’s decision-making role was limited to selecting the best physician.<sup>18</sup> After that, the patient was encouraged to cede all authority to the physician he chose.<sup>19</sup> The American Medical Association formalized this view in its 1847 Code of Ethics, which states that patients should obey “the prescriptions of their physician . . . prompt[ly] and implicit[ly]. They should never permit their own crude opinions . . . to influence their attention to their physicians.”<sup>20</sup>

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12. R. Jason Richards, *How We Got Where We Are: A Look at Informed Consent in Colorado—Past, Present, and Future*, 26 N. ILL. U. L. REV. 69, 73-74 (2005) (“Even into the 19th Century, physicians did not believe they needed to communicate with their patients for the purpose of involving them in the decision-making process. . . . [This] began to change by the turn of the twentieth century.”).

13. Ryan Childers et al., *Informed Consent and the Surgeon*, 208 J. AM. C. SURGEONS 627, 627 (2009) (“[O]ver the past 50 years, patient autonomy and the right to individual self-determination have replaced the previous belief that ‘doctor knows best.’”); Bryan J. Warren, *Pennsylvania Medical Informed Consent Law: A Call to Protect Patient Autonomy Rights by Abandoning the Battery Approach*, 38 DUQ. L. REV. 917, 920 (2000) (“[E]arly tenets of medicine encouraged a paternalistic approach to the patient, and even espoused avoiding discussions with the patient about the patient’s care.”); *id.* at 922 (“The belief among many physicians that a paternalistic and authoritarian approach is in the patient’s best interests remained prevalent well into the late 1900’s.”).

14. JOHN M. BARRY, *THE GREAT INFLUENZA* 16 (Penguin Press 2005).

15. Morris, *supra* note 11, at 313; Warren, *supra* note 13, at 920.

16. Morris, *supra* note 11, at 314 (“The physician’s duty was not merely to make his or her own judgments, but also, to make those judgments for the sole purpose of benefitting his or her patient.”).

17. *Id.* at 313.

18. Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 221 (1985) (“[T]he patient was seen as making only one key decision, to place herself in a given doctor’s care, thereby delegating all subsequent authority to the doctor.”).

19. Mariner, *supra* note 10, at 389 (“The precepts of benevolence begot a conviction in the profession that patients should *obey* their doctors.”).

20. Warren, *supra* note 13, at 921.

Ironically, the enormous deference given to physicians was based in large part on the lack of scientific knowledge concerning medical care. In deciding how to treat their patients, physicians relied heavily on logic coupled with observations made during their clinical experiences.<sup>21</sup> They observed nature passively,<sup>22</sup> rather than using experiments and rigorous scientific methods to test their conclusions and theories.<sup>23</sup> For example, one of the most enduring methods of treating patients was bleeding,<sup>24</sup> otherwise known as phlebotomy.<sup>25</sup> This procedure was popular for so long partly because “[i]f a patient was flushed with a fever, it followed logically that if bleeding alleviated those symptoms—making the patient pale—it was a good thing.”<sup>26</sup>

Meaningful, informed consent would have been almost impossible at this time because physicians had no empirical foundation to support discussions of risks and alternatives.<sup>27</sup> Because their medical judgments were based on their intuition and observations, physicians understandably argued that only

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21. BARRY, *supra* note 14, at 25 (“Hippocratic writings had stated that the physician’s senses mattered far more than any objective measurement, so despite medicine’s use of logic, physicians had always avoided applying mathematics to the study of the body or disease.”).

22. *Id.* at 17 (“Those who wrote the Hippocratic texts, however, observed passively and reasoned actively.”).

23. *Id.* at 17 (“[T]he authors of the Hippocratic texts did not test their conclusions and theories.”), 25 (“Logic and observation failed because neither one tested the hypothesis rigorously.”).

24. *Id.* at 18 (“Bleeding was among the most common therapies employed to treat all manner of disorders.”).

25. *Id.* at 22.

26. *Id.*

27. Herrman L. Blumgart, *Caring for the Patient*, 270 *NEW ENG. J. MED.* 449, 449 (1964) (“Somewhere between 1910 and 1912 in this country . . . a random patient, with a random disease, consulting a [physician] chosen at random had, for the first time in the history of mankind, a better than fifty-fifty chance of profiting from the encounter.”); Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 *J. CONTEMP. HEALTH L. & POL’Y* 69, 76 (1994) (“[U]ntil the beginning of the twentieth century, physicians could not explain to their patients, or—from the perspective of hindsight—to themselves, which of their treatment recommendations were curative and which were not.”); Kristin Madison, *Patients as “Regulators?” Patients’ Evolving Influence Over Health Care Delivery*, 31 *J. LEGAL MED.* 9, 11 (2010) (“Today, the doctrine [of informed consent] typically requires physicians to obtain consent for treatment after disclosing factors such as the patient’s diagnosis, the proposed treatment’s nature and purpose, treatment risks, and treatment alternatives.”); Richards, *supra* note 12, at 74 (“[T]here was little understanding [even into the 19th century] of how one could cure a medical condition, and even less was known about what caused a particular malady.”).

they were qualified to comprehend and apply their medical knowledge and their patients should not interfere.<sup>28</sup>

Medical knowledge hardly advanced at all until the nineteenth century<sup>29</sup> when physicians began to challenge the purely theoretical and test their hypotheses. They started to base medical care on numerical correlations between treatments and results and to use autopsies to correlate the condition of organs with symptoms and pathology.<sup>30</sup> Only then did physicians begin to have a scientific explanation for their medical choices and information that might provide a basis for meaningful informed consent. In fact, not until the twentieth century, as medicine developed a strong scientific foundation,<sup>31</sup> did patients gain the right to be involved in the medical decisions concerning their care.<sup>32</sup>

The cases on informed consent at the beginning of the twentieth century addressed only whether a physician could be held liable if the patient did not consent to a surgical procedure, not whether the patient received sufficient information to make an informed choice.<sup>33</sup> *Pratt v. Davis*<sup>34</sup> and

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28. Mariner, *supra* note 10, at 390 (“[P]hysicians argued that medical knowledge could only be correctly applied by one trained in the field, with a large measure of intuition based on clinical experience.”).

29. BARRY, *supra* note 14, at 16 (“[F]or the bulk of two and a half millennia—twenty-five hundred years—the actual treatment of patients by physicians made almost no progress at all.”). In 1869, Harvard’s president stated that “[t]he ignorance and general incompetency of the average graduate of the American medical schools, at the time when he receives the degree which turns him loose upon the community, is something horrible to contemplate.” *Id.* at 32.

30. *Id.* at 26 (“[T]he real point at which modern medicine diverged from the classic was in the studies of pathological anatomy by Louis and others [that] not only correlated treatments with results to reach a conclusion about the treatment’s efficacy[, but] . . . also used autopsies to correlate the condition of organs with symptoms.”).

31. Mariner, *supra* note 10, at 391 (“In the early 20th century, the medical profession consolidated its status on a growing knowledge base . . . .”); Richards, *supra* note 12, at 74 (“[B]y the turn of the twentieth century . . . [a]dvances in medical science, technology, and training began to distinguish primitive medical practices from conventional medicine.”).

32. Mariner, *supra* note 10, at 391 (“Our modern conceptions of disclosure and consent were entirely foreign to the definition of medical practice throughout its professional evolution.”); Richards, *supra* note 12, at 73 (“Even into the 19th Century, physicians did not believe that they needed to communicate with their patients for the purpose of involving them in the decision-making process.”).

33. Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 270 (1999) (“The first cases to address [informed consent] concerned consent only at its most basic level, i.e., whether the physician had the patient’s permission to perform a surgical procedure, or instead had committed battery by ‘touching’ the patient without consent.”); Elizabeth Sudbury Langston, *TORTS—Changes in*

*Mohr v. Williams*,<sup>35</sup> both decided in 1905, were among the first cases holding physicians liable to their patients for failing to obtain consent for the particular procedures performed,<sup>36</sup> even though those procedures were arguably necessary and skillfully executed.<sup>37</sup> In *Pratt*, the physician performed a hysterectomy on his patient, removing her uterus and ovaries, without her consent, to treat epilepsy.<sup>38</sup> The physician argued that he should not be held liable for battery<sup>39</sup> because, in his opinion, the surgery was “proper and essential to her welfare” and there was a “universal acquiescence of lay and professional minds in the principle that the employment of the physician or surgeon gives him implied license to do whatever in the exercise of his judgment may be necessary.”<sup>40</sup> In *Mohr*, the physician had the patient’s consent to operate on her right ear, but after the patient was anesthetized, he reexamined her and made the decision to operate on her left ear instead.<sup>41</sup> In that case, the physician similarly argued that he should not be held liable because “plaintiff’s left ear was in fact diseased, in a condition dangerous and threatening to her health, [and] the operation was necessary . . . .”<sup>42</sup> In both of these cases, the courts rejected the physicians’ contentions that they were free to use their best judgment in deciding whether to perform surgery for the patients’ welfare and, instead, held them liable for battery based on the patients’ lack of consent to the

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*the Arkansas Law of Informed Consent: What’s Up Doc?* Aronson v. Harriman, 321 Ark. 359, 901 S.W.2d 832 (1995), 19 U. ARK. LITTLE ROCK L.J. 263, 271 (1997) (“The courts in these early battery cases held that a patient has a right to decide whether to undergo medical treatment; however, the courts did not consider whether the physician had given the patient adequate information to make an informed decision.”).

34. 118 Ill. App. 161 (1905).

35. 104 N.W. 12 (Minn. 1905).

36. *Pratt*, 118 Ill. App. at 166.

37. *See id.* at 166-68 (citing *State v. Housekeeper*, 16 A. 382 (Md. 1889)). The court noted that, even before its decision, the law recognized that consent to an operation was necessary. *Pratt* was, however, one of the first cases to hold the physician liable for failing to obtain that consent.

38. *Id.* at 168-72.

39. *Id.* at 181. The court uses the term “trespass on the person of another” rather than battery, but the concepts are the same.

40. *Id.* at 166.

41. *Mohr v. Williams*, 104 N.W. 12, 13 (Minn. 1905).

42. *Id.* at 15.

surgery.<sup>43</sup> The language in both cases strongly supports the principle of patient self-determination.<sup>44</sup>

In 1914, the New York Court of Appeals decided *Schloendorff*,<sup>45</sup> which reconfirmed the holdings in *Pratt* and *Mohr*<sup>46</sup> and is often credited as forming the foundation for informed consent.<sup>47</sup> The court's opinion contains Justice Benjamin Cardozo's oft-quoted statement<sup>48</sup> that "[e]very 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."<sup>49</sup> Soon after the decision in *Schloendorff*, the courts universally accepted the principle that a physician's failure to obtain consent from a patient for the particular procedure performed subjects the physician to liability for battery.<sup>50</sup>

The next major advance in informed consent law did not occur until 1957.<sup>51</sup> At that time, the legal focus changed from determining whether the patient consented to a particular medical procedure to whether the patient received enough information to make an intelligent decision.<sup>52</sup> Advances in

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43. *Pratt*, 118 Ill. App. at 179-80; *Mohr*, 104 N.W. at 15.

44. See Shultz, *supra* note 18, at 224 ("[T]he right to be secure against unconsented touching is close to absolute. Application of battery doctrine to medical care thus establishes an uncompromising base-line of protection for patients' self-determination.").

45. *Schloendorff v. Soc'y of N.Y. Hosps.*, 105 N.E. 92, 93 (N.Y. 1914) (finding that the physician performed surgery on a patient who consented to an examination under anesthesia but allegedly stated that "there must be no operation").

46. *Id.*

47. Derek Kroft, *Informed Consent: A Comparative Analysis*, 6 J. INT'L L. & PRAC. 457, 458 (1997) ("[*Schloendorff*] became the foundation of the doctrine of informed consent . . .").

48. Krause, *supra* note 33, at 270 ("Justice Cardozo's opinion contains one of the most commonly quoted pronouncements on patient self-determination . . ."); Warren, *supra* note 13, at 927 ("Most discussions of medical informed consent begin with the famous 1914 opinion by Associate Justice Benjamin Cardozo in *Schloendorff v. Society of New York Hospitals*.").

49. *Schloendorff*, 105 N.E. at 93.

50. Richards, *supra* note 12, at 77 ("Following *Schloendorff*, it soon became universally accepted that any medical procedure involving the touching of a patient must be authorized or the physician had committed the tort of battery.").

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

52. William J. McNichols, *Informed Consent Liability in a "Material Information" Jurisdiction: What Does the Future Portend?*, 48 OKLA. L. REV. 711, 714 (1995) ("Beginning in the late 1950s, the first cases began to appear in which the courts allowed patients to recover tort damages when physicians wrongfully failed to disclose information about the risks involved in a proposed course of [medical] treatment."); Kroft, *supra* note 47,

medicine during the decades following *Schloendorff* precipitated this change. Treatments became more sophisticated, required additional physician training, and were increasingly difficult for patients to understand and assess.<sup>53</sup> Because medical care was more complex, patients had to rely on their physicians to explain the risks, benefits, and alternatives of recommended procedures.<sup>54</sup>

As the information asymmetry between patients and physicians increased, consent also took on a new meaning.<sup>55</sup> Arguably, patients could intelligently consent to a medical procedure only if they understood the nature of the treatment and the risks and consequences entailed.<sup>56</sup> Stated otherwise, the patient's consent was not legally valid if the physician failed to disclose some essential information concerning a surgical procedure.<sup>57</sup>

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at 459 ("Unlike previous decisions, *Salgo* was not only concerned with whether the patient consented, but whether the patient was properly informed.").

53. Mariner, *supra* note 10, at 392 ("The growing complexity of postwar medical technology meant that the risks of treatment were no longer obvious to the laity.").

54. *Id.* at 391 ("Until about the time of World War II, patients had little need for extensive explanation of the risks and benefits of medical treatment. Judged by today's standards, medical therapies were relatively straightforward, and the risks were often apparent to everyone."). Commentators have also cited other reasons for the expansion of the principle of informed consent. See, e.g., Janet L. Dolgin, *The Evolution of the "Patient": Shifts in Attitudes About Consent, Genetic Information, and Commercialization in Health Care*, 34 HOFSTRA L. REV. 137, 151 (2005) ("In the years following *Schloendorff*, a variety of social and economic trends, including, in particular, the broad generalization of individualism within United States society after World War II, the development of expensive medical technology, new modes of access to information, articulation of an informed consent rule for application to research contexts, and the broad commercialization of health care, encouraged the widespread acceptance and expansion of the informed consent doctrine in clinical settings.").

55. Richards, *supra* note 12, at 81 ("With physicians armed with more understanding about the causes and treatments of disease, courts began to examine the quantity of information they provided to patients and whether patients had been informed as to the risks, benefits, and available alternatives to the proposed medical treatments.").

56. Mariner, *supra* note 10, at 392 ("Consent to treatment meant that the patient was willing to accept its consequences. Yet only the physician knew the possible consequences of more sophisticated therapies."); see also Schultz, *supra* note 18, at 232 ("The doctrine of informed consent . . . recognizes that one way that actionable physical injury may occur is through the failure to disclose information that would have resulted in non-consent to treatment.").

57. George P. Smith, II, *The Vagaries of Informed Consent*, 1 IND. HEALTH L. REV. 109, 111 (2004) ("We then insist that this consent be 'informed,' recognizing that if a patient readily agrees to something about which she understands little or about which she has a false understanding, we have somehow or other abrogated or sidestepped her autonomous decision-making rights.") (quoting WILLARD GAYLIN & BRUCE JENNINGS, *THE REVERSION OF*

In 1957, *Salgo v. Leland Stanford Junior University Board of Trustees* became the first significant case to explicitly extend the physician's duty beyond acquiring bare consent to requiring consent based on adequate disclosure.<sup>58</sup> In that case, the patient sued his physician for performing a diagnostic procedure without informing him of the small risk of paralysis.<sup>59</sup> In its decision, the court used the term "informed consent" for the first time<sup>60</sup> and found that the physician "subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."<sup>61</sup> The court gave the physician considerable discretion regarding the application of this standard to a particular patient,<sup>62</sup> but added that "the physician may not minimize the known dangers of a procedure . . . in order to induce his patient's

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AUTONOMY 159 (1996)); Paula Walter, *The Doctrine of Informed Consent: To Inform or Not to Inform?*, 71 ST. JOHN'S L. REV. 543, 557 (1997) ("With time, cases arose in which plaintiffs who gave consent to medical procedures later argued that their consent was defective because all risks were not fully disclosed. The next logical argument to be advanced was that this defective consent, based as it was on incomplete information, was the legal equivalent of no consent.").

58. Agatha Lambris, Comment, *Informed Consent for All? Not Quite! A Comparison of Informed Consent in the United States and Japan*, 17 TEMP. INT'L & COMP. L.J. 237, 242-43 (2003) ("The most significant of the cases marking the transition from the older simple rule to the contemporary informed consent rule is *Salgo v. Leland Stanford Junior University Board of Trustees* in 1957."); Ben Sones, Note, *A Tale of Two Countries: Parallel Visions for Informed Consent in the United States and the United Kingdom*, 39 VAND. J. TRANSNAT'L L. 253, 258 (2005) ("This judicial trend toward the 'informing' aspect of informed consent began with the famous California case of *Salgo v. Leland Stanford Junior University Board of Trustees* in 1957 . . . . [I]t was the first court to discuss what disclosures were necessary to make a patient's consent informed . . . .").

59. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 177 (Cal. Dist. Ct. App. 1957) ("[A]ll the witnesses agree that paralysis is a rare complication of [the procedure].").

60. Krause, *supra* note 33, at 270 ("[I]t was not until [*Salgo*] that the phrase 'informed consent' appeared in a legal opinion.").

61. *Salgo*, 317 P.2d at 181; Warren, *supra* note 13, at 930 ("*Salgo* established the modern view of informed consent, stating that the physician violates his duty to his patient if he fails to provide information necessary for the patient to form intelligent consent to the proposed treatment.").

62. *Salgo*, 317 P.2d at 181; Langston, *supra* note 33, at 272 ("*Salgo* purported to require what is called 'full disclosure' but also left discretion in the physician regarding the meaning of this standard.").

consent.”<sup>63</sup> Since *Salgo*, all fifty states have required informed consent, either by statute or common law.<sup>64</sup>

Under *Salgo*, the physician was liable for battery if the patient was not properly informed of the risks of surgery.<sup>65</sup> Just three years later, in 1960, the doctrinal underpinning of informed consent began to shift from battery to negligence.<sup>66</sup> The courts decided that characterizing informed consent as an intentional tort was not doctrinally sound<sup>67</sup> and would lead to “widespread and unwarranted” judgments against physicians.<sup>68</sup> Today, almost all informed consent actions are grounded in negligence,<sup>69</sup> and battery is reserved for cases where the patient did not consent at all to the procedure actually carried out.<sup>70</sup>

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63. *Salgo*, 317 P.2d at 181.

64. Morris, *supra* note 11, at 315 n.11 (“In 2000, Georgia became the fiftieth state to accept the common law doctrine of informed consent.”); see *Ketchup v. Howard*, 543 S.E. 2d 371, 381-86 (Ga. Ct. App. 2000).

65. McNichols, *supra* note 52, at 714 (explaining that the first cases establishing physician liability for failing to provide informed consent relied on a battery cause of action).

66. McNichols, *supra* note 51, at 715 (“In the early 1960s, almost immediately after they exposed physicians to liability for inadequate risk disclosure, the courts made an abrupt doctrinal about face [and moved from battery to a negligence cause of action.]”); Richards, *supra* note 12, at 83 (“The first case to base informed consent liability on a negligence theory rather than a battery theory was the Kansas Supreme Court case of *Natanson v. Kline*,” 350 P.2d 1093 (Kan. 1960)).

67. 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, 612 (“To say that a doctor who falls short of meeting a reasonableness standard [for disclosure] is thereby transformed into an intentional tort-feasor does not seem consistent with the traditional perception of an intentional tort.”).

68. McNichols, *supra* note 51, at 715 (“[The courts] sensed that the battery theory would subject the medical profession to widespread and unwarranted liability.”).

69. Barbara L. Atwell, *The Modern Age of Informed Consent*, 40 U. RICH. L. REV. 591, 595 (2006) (“Today, the failure to obtain informed consent generally gives rise to a negligence claim rather than a battery cause of action.”); Krause, *supra* note 33, at 271 (“Today informed consent actions sound almost exclusively in negligence . . . .”); Sones, *supra* note 58, at 258 (“The classification of the doctrine of informed consent under the heading of professional negligence is currently the dominant view, and the battery cause of action is typically reserved for situations where physicians act with no consent at all or with evil intent.” (footnotes omitted)).

70. Shultz, *supra* note 18, at 226 (“The modern allegation of battery typically arises when consent to a particular procedure is given and a different or additional procedure is carried out.”); see also *Conklin v. Weisman*, 678 A.2d 1060, 1069 (N.J. 1998) (“It is a battery if a physician operates without the patient’s consent; it is negligence if the physician operates without the patient’s informed consent.”); Robert Gatter, *Informed Consent Law*

It made sense to hold physicians liable for battery when their only responsibility was to obtain consent from their patients for the procedures they performed.<sup>71</sup> However, this doctrinal foundation made less sense when liability was based on failure to inform patients of the risks and alternatives to treatment. Battery is based on nonconsensual touching,<sup>72</sup> but deficient informed consent is generally premised on the physician's failure to exercise due care in making disclosures to the patient.<sup>73</sup> In informed consent cases, the physician has the patient's consent to the particular procedure performed<sup>74</sup> and is usually acting in good faith and with the patient's best interests in mind.<sup>75</sup> Because the informed consent cause of action is generally based on an unintentional failure to disclose information, rather than on intentional antisocial conduct by the physician,<sup>76</sup> the conduct is more accurately characterized as negligence, rather than as an intentional tort.<sup>77</sup>

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*and the Forgotten Duty of Physician Inquiry*, 31 LOY. U. CHI. L.J. 557, 562 (2000) (“[Battery] permits patients to sue for receiving medical treatments to which they did not consent. This form of informed consent case is rare today, and it generally arises when a physician’s actions exceed the scope of the patient’s consent.” (footnotes omitted)).

71. Morris, *supra* note 11, at 319 (“When the operation was performed without any consent, the tort of battery was well-suited to protect the patient’s autonomy interest.”).

72. Langston, *supra* note 33, at 270 n.75 (“An intentional touching by a physician to which the patient has not consented is considered a battery.”); Smith, II, *supra* note 57, at 115 (“[N]onconsensual touching was, and is, a legal battery.”).

73. See *Cobbs v. Grant*, 502 P.2d 1, 8 (Cal. 1972) (“[T]he doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence.”).

74. See *Natanson v. Kline*, 350 P.2d 1093, 1100-01 (Kan. 1960) (“We are here concerned with a case where the patient consented to the treatment, but alleges . . . the risks of the treatment were not properly explained to her. This relates directly to . . . informed consent . . .”).

75. See *Trogun v. Fruchtmann*, 207 N.W.2d 297, 313 (Wis. 1973) (“[P]hysicians are invariably acting in good faith and for the benefit of the patient.”); see also *Natanson*, 350 P.2d at 1100.

76. See *Natanson*, 350 P.2d at 1100 (“The traditional assault and battery involves a defendant who is acting for the most part out of malice or in a manner generally considered as ‘antisocial’.”).

77. *Trogun*, 207 N.W.2d at 313 (“The failure to inform a patient is probably not, in the usual case, an intentional act and hence not within the traditional concept of intentional torts.”); Shultz, *supra* note 18, at 226 (“Discomfort with treating doctors under a doctrine aimed at antisocial conduct has prompted most jurisdictions to limit the battery action to those relatively unusual situations where a medical procedure has been carried out without any consent, rather than where the consent has merely been insufficiently informed.”); Walter, *supra* note 57, at 558 (“[A]ssault and battery are intentional torts and, as such, do not

The negligence cause of action also covers a broader spectrum of medical procedures than battery. Because battery is premised on nonconsensual touching, it can easily be applied to invasive treatments, such as surgery.<sup>78</sup> However, many treatments, such as prescriptions of oral medication, do not involve physical contact between the doctor and patient, yet patients also need adequate disclosure before agreeing to these treatments.<sup>79</sup> For this additional reason, negligence is a better doctrinal foundation for informed consent.

Courts were also concerned about physician liability in switching to a negligence cause of action. Failure to meet informed consent requirements could theoretically expose physicians to significant damages for relatively minor omissions in the information disclosed.<sup>80</sup> By moving from battery to negligence, the courts ameliorated the harshness of requiring informed consent by choosing a more physician-friendly cause of action.<sup>81</sup> Negligence helps protect physicians because it is more difficult to prove than battery and has additional defenses.<sup>82</sup>

In order to recover on a battery claim, a patient need only prove that (1) the physician failed to give the required information regarding the surgery, and (2) the surgery was performed.<sup>83</sup> The patient need not show that the

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logically apply to situations where a doctor unintentionally fails to disclose adequate information.”).

78. Krause, *supra* note 33, at 310 (“The clearest legacy of the touching requirement is the restriction of informed consent actions in many states to surgical and other ‘invasive’ procedures.”); Morris, *supra* note 11, at 337 (“The tort of battery might require an invasive procedure, such as surgery, but the tort of negligence does not.”).

79. See Morris, *supra* note 11, at 320 (“[F]ailure to disclose is not conceptualized as contact or touching required for intentional tort liability to attach.”).

80. Shultz, *supra* note 18, at 225 (“Given the absolute nature of battery, . . . doctors could end up paying significant damages after providing faultless medical treatment, simply because some minor informational aspect of the consent process was questioned.”).

81. Krause, *supra* note 33, at 309 (“[B]attery generally is viewed as more favorable to patients, and the move from battery to negligence has been characterized as an attempt to protect physicians from liability for minor disclosure failures.”).

82. A battery cause of action would be better for physicians in only two respects. First, battery generally has a shorter statute of limitations. See McNichols, *supra* note 51, at 738. Second, negligence may cover a broader spectrum of cases than battery. See Krause, *supra* note 33, at 310; Morris, *supra* note 11, at 337.

83. Cobbs v. Grant, 502 P.2d 1, 8 (Cal. 1972) (“[I]n a battery count . . . the patient must merely prove failure to give informed consent and a mere touching absent consent.”); Morris, *supra* note 11, at 336 (“All that the plaintiff would have to prove [in a battery case] is that the physician performed the procedure or operation without obtaining the patient’s consent and that the nonconsensual touching caused the plaintiff’s injury.”).

operation was negligently performed<sup>84</sup> or that she suffered any harm.<sup>85</sup> A battery theory would also deprive the physician of the many defenses that are available in a negligence case<sup>86</sup> and, because battery is an intentional tort, it might expose the physician to liability for punitive damages.<sup>87</sup> Punitive damages might be especially burdensome to the physician because these damages are not always covered by malpractice insurance.<sup>88</sup>

But the most important reason why the negligence cause of action is more favorable to physicians than battery rests on the causation element as it has been implemented by the courts and legislatures. Most medical malpractice cases based on lack of informed consent are “rejected due to this one issue known as causation.”<sup>89</sup>

## II. Objective Causation

To meet the causation element of informed consent, plaintiffs must prove both decision-causation and injury-causation.<sup>90</sup> This two-part causation test

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84. Morris, *supra* note 11, at 319 (“[N]egligence in the operation itself [is not] required for the tort of battery . . .”).

85. *Id.* (“Actual physical harm to the patient is not a prerequisite for tort liability; battery is a dignitary tort, protecting individuals from offensive as well as harmful contact.”); *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972) (“[N]egligence unrelated to injury is nonactionable.”).

86. Krause, *supra* note 33, at 309 (“[M]any defenses to negligence, such as an emergency situation or invocation of the therapeutic privilege, are unavailable to a physician charged with battery.”). The most common defenses to a negligence action based on lack of informed consent include (1) an emergency situation, where it is impossible to get the patient’s consent; (2) waiver, where the patient waives the right to receive information; and (3) the therapeutic privilege, which allows the physician, in her discretion, to withhold information that might harm the patient. *Canterbury*, 464 F.2d at 789 (explaining that the therapeutic privilege “must be carefully circumscribed, however, for otherwise it might devour the [informed consent] rule itself.”). For a list of defenses to an informed consent claim sounding in negligence, see, for example, Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 919 (1994); Gerald F. Tietz, *Informed Consent in the Prescription Drug Context: The Special Case*, 61 WASH. L. REV. 367, 412 n.262 (1986); Smith, II, *supra* note 57, at 118; Walter, *supra* note 57, at 555.

87. McNichols, *supra* note 51, at 715 (“[A]s an intentional tort, battery might have entitled the patient to an instruction on punitive damages . . .”).

88. *Cobbs*, 502 P.2d at 8 (“[I]f [physicians are] held liable for the intentional tort of battery [they] might not be covered by . . . malpractice insurance.”); Morris, *supra* note 11, at 320. (“[T]he doctor’s malpractice insurance may not cover intentional misconduct.”).

89. Laura G. Tamaz, *Informed Consent—The Message We May All Be Missing: How to Plead, Persuade, and Prevail in Informed Consent Cases*, 1 Ann. 2004 ATLA-CLE 1331 (2004).

90. Gatter, *supra* note 70, at 562 n.36 (“The causation element has two sub-elements known as decision-causation and injury-causation.”); Richards, *supra* note 12, at 96 n.163

resulted from the shift by the courts from battery to negligence as the doctrinal underpinning of an informed consent cause of action.

Failure to obtain informed consent began as a battery action based on the theory that a patient could not validly consent to a medical procedure unless he had the information necessary to make an intelligent choice.<sup>91</sup> Performing a medical procedure without first giving the patient adequate information was, therefore, considered a nonconsensual touching.<sup>92</sup>

When the courts switched to a negligence cause of action, the concept of consent did not fit neatly into the doctrinal framework.<sup>93</sup> For negligence, the plaintiff must prove that the defendant's breach of duty caused the plaintiff's injury.<sup>94</sup> The breach of duty was the physician's failure to disclose sufficient information for the patient to make an informed choice. The only logical place to include some aspect of consent was within the causation element.<sup>95</sup> The courts added this concept by requiring the

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("[There are] two links in the causal chain: first, that nondisclosure caused the patient to agree to a procedure which otherwise she would have declined ('decision causation'); second, that the procedure actually caused the patient's harm ('injury causation').").

91. See *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Dist. Ct. App. (1957)) ("A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.").

92. Langston, *supra* note 33, at 270 n.75 ("An intentional touching by a physician to which the patient has not consented is considered a battery."); Smith, II, *supra* note 57, at 115 ("[N]onconsensual touching was, and is, a legal battery.").

93. DAN B. DOBBS, *THE LAW OF TORTS* 657 (W. Page Keeton ed., 5th ed. 1984) ("Even if the defendant breaches his duty to disclose information . . . he is not subject to liability unless [the plaintiff] would have rejected the operation had full information been provided. [T]his rule is a concomitant of the decision to treat the claim as one for negligence rather than one for battery."); Krause, *supra* note 33, at 309 ("Informed consent law originated in the intentional tort of battery . . .").

94. *Scott v. Bradford*, 606 P.2d 554, 557 (Okla. 1980) ("[I]f the physician obtains a patient's consent but has breached his duty to inform, the patient has a cause of action sounding in negligence for failure to inform the patient of his options, regardless of the due care exercised at treatment, assuming there is injury."); Tietz, *supra* note 86, at 372 ("However, even when a breach [of duty] occurs, patients must demonstrate that the failure to inform proximately caused their injuries.").

95. See *Bradford*, 606 P.2d at 558-59 ("Decisions discussing informed consent have . . . paid scant attention to the consent element . . . although this is the root of causation."); Morris, *supra* note 11, at 324 n.59 ("The question of whether the patient would have consented to or rejected the proposed operation if the undisclosed information had been revealed involves a consideration of causation."); Shultz, *supra* note 18, at 250 ("[W]here physical well-being is the protected interest, choice is placed in the role of factual cause, linking breaches of duty to the occurrence of harm.").

plaintiff to show that the physician's breach of duty caused the patient to consent to the procedure when he otherwise would have refused.<sup>96</sup> This causation requirement is known as decision-causation.<sup>97</sup>

Decision-causation only established that the physician's breach of duty caused the patient to consent to the medical procedure, but it did not establish that the breach of duty caused any injury.<sup>98</sup> Therefore, the courts added a second prong to the causation element. The patient must show that (1) the breach of duty caused the patient to consent to a medical procedure that he otherwise would have refused,<sup>99</sup> and (2) the medical procedure caused the patient harm.<sup>100</sup> This second prong is called injury-causation.<sup>101</sup>

To further protect physicians, the courts modified decision-causation by making it an objective test.<sup>102</sup> To meet the decision-causation requirement,

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96. Alan J. Weisbard, *Informed Consent: The Law's Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749, 758 (1986) ("The plaintiff must allege and prove that the physician violated a legally established duty to disclose a particular risk, that the undisclosed risk materialized in a physical injury, and that the failure to disclose 'caused' the patient to consent to a procedure which otherwise would have been rejected."); Sones, *supra* note 58, at 261 ("The plaintiff must show that failure to obtain informed consent was a proximate cause of the injury or, stated differently, the patient would have decided not to undergo the treatment if the patient had been adequately informed of the risk.").

97. Richards, *supra* note 12, at 96 n.163 (explaining that decision-causation is met when the plaintiff shows that the "nondisclosure caused the patient to agree to a procedure which otherwise she would have declined . . .").

98. McNichols, *supra* note 51, at 730 ("All states require a plaintiff who relies on lack of informed consent to establish a . . . causal connection between the negligent nondisclosure and the damage for which he seeks relief.").

99. Gatter, *supra* note 70, at 562 n.36 ("To allege decision-causation, the patient must plead that the physician's breach caused the patient to consent to treatment that the patient otherwise would have refused.").

100. *Id.* ("To allege simple injury-causation, the patient must allege that an injury resulted from the treatment.").

101. Twerski & Cohen, *supra* note 67, at 617 ("First, the nondisclosure must have caused the patient to agree to a procedure which otherwise would have been declined (decision causation); second, the procedure must have caused the patient's harm (injury causation).").

There are also issues concerning proof of injury in informed consent cases, which are beyond the scope of this article. For example, should an evaluation of damages include consideration of the risk of injury from the treatment plaintiff claims he would have chosen had adequate information been disclosed? *See* Shultz, *supra* note 18, at 251.

102. Shultz, *supra* note 18, at 249 ("Medical cases potentially impose enormous liability. Fearing that patients' testimony would be self-serving and biased by hindsight, courts have felt it necessary to [require plaintiffs to show] that, had the contested disclosure been made, a reasonable person would not have consented to the treatment."); *see also* Walter, *supra* note 57, at 543 n.3 (noting that New York's informed consent statute, which contains an objective causation standard, "was seen by many commentators as a necessary reaction to a

patients had to prove that the undisclosed information would have caused a reasonable person to refuse the medical treatment or procedure.<sup>103</sup> Under this standard, the jury decides not what the particular plaintiff patient would have decided had he received the undisclosed information,<sup>104</sup> but rather whether a hypothetical reasonable person would have withheld consent to the procedure had he been properly informed.<sup>105</sup> Given this objective standard, a patient could be denied relief even if: (1) the information he received from the physician was totally deficient, (2) the patient himself

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trend in the development of case law that had become overly consumer friendly and exceedingly plaintiff oriented”).

103. *Wilson v. Merritt*, 48 Cal. Rptr. 3d 630, 641 (Cal. Ct. App. 2006) (“[C]ausation must be established by an *objective* test: that is, the plaintiff must show that reasonable ‘prudent person[s]’ in the patient’s position would decline the procedure if they knew all significant perils.”); *McNichols*, *supra* note 51, at 730 (“[T]he *Canterbury* case, and virtually all other courts . . . have determined for practical and policy reasons that health care providers are entitled to the protection of an objective rule: a plaintiff can recover damages only if a reasonable patient would have refused treatment.”).

104. Some courts using the objective standard require the plaintiff to prove that both the plaintiff and a reasonable person would have refused the medical procedure had the required information been disclosed. *See, e.g.*, David E. Seidelson, *Lack of Informed Consent in Medical Malpractice and Product Liability Cases: The Burden of Presenting Evidence*, 14 HOFSTRA L. REV. 621, 626 (1986) (noting that the D.C. Court of Appeals requires the plaintiff to demonstrate that “neither he nor a reasonable person in like circumstances would have consented”); *see Henderson v. Milobsky*, 595 F.2d 654 (D.C. Cir. 1978); *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1980) (“If a plaintiff testifies he would have continued with the proposed treatment had he been adequately informed, the trial is over under either the subjective or objective approach . . . . The jury must be instructed that it must find plaintiff would have refused the treatment if he is to prevail.”). Other courts require that the plaintiff show only that a reasonable person would have refused. *See, e.g.*, *Fain v. Smith*, 479 So. 2d 1150, 1153 (Ala. 1985) (“If adequate disclosure could reasonably be expected to have caused that person to decline the treatment . . . causation is shown, but otherwise not. The patient’s testimony is relevant on that score of course but it would not threaten to dominate the findings.”); *Morris*, *supra* note 11, at 368 (“[C]ourts, in deciding the causation issue, generally do not consider whether the actual patient would have consented if he or she had received the required information, but only whether a reasonable patient would have consented.”); Seidelson, *supra* note 104, at 630 (“[I]f the jury finds that a reasonable person, adequately informed, would not have consented, plaintiff may recover whether or not the jury finds that the particular plaintiff would have withheld consent.”).

105. *Morris*, *supra* note 11, at 335 (“In all but a few states, causation is not measured by a true test of causation. The law does not ask whether the actual patients would have consented if their doctors had not breached the disclosure duty, but rather, whether reasonable patients would have consented.” (footnotes omitted)).

would not have chosen the surgery if he had been informed of the risks and alternatives, and (3) he was severely injured.<sup>106</sup>

Despite this inherent inequity, almost every state statute governing malpractice based on lack of informed consent uses an objective standard for determining causation.<sup>107</sup> The remaining states—which either have no

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106. George J. Annas, *Avoiding Malpractice Suits Through the Use of Informed Consent*, *Current Problems in Pediatrics*, 6 CURRENT PROBS. IN PEDIATRICS 5, 8 (1976) (“[E]ven if this particular plaintiff would not have undergone the procedure had he been properly informed (because of his own beliefs, family experiences, fear of a certain complication, etc.), he cannot prevail unless a jury is convinced that a ‘reasonable person’ in his position would have made the same decision!”).

107. See FLA. STAT. § 766.103 (2010) (“No recovery shall be allowed in any court . . . in an action brought for [medical malpractice based on lack of] informed consent when . . . [t]he patient would reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician . . . .”); GA. CODE ANN. § 31-9-6.1 (2010) (requiring that, in an action for informed consent, a patient must show that “a reasonably prudent patient would have refused the surgical or diagnostic procedure or would have chosen a practical alternative to such proposed surgical or diagnostic procedure if such information had been disclosed . . . .”); LA. REV. STAT. ANN. § 40:1299.40 (2010) (“In a suit against a physician . . . involving a . . . medical malpractice claim which is based on the failure of the physician or other health care provider to disclose or adequately to disclose the risks and hazards involved in the medical care or surgical procedure rendered by the physician or other health care provider, the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent . . . .”); ME. REV. STAT. ANN. tit. 24, § 2905 (2010) (“No recovery may be allowed against any physician, podiatrist, dentist or any health care provider upon the grounds that the health care treatment was rendered without the informed consent of the patient or the patient’s spouse, parent, guardian, nearest relative or other person authorized to give consent for the patient when . . . [a] reasonable person, under all surrounding circumstances, would have undergone such treatment or procedure had that person been advised by the physician . . . .”); NEB. REV. STAT. § 44-2820 (2010) (“Before the plaintiff may recover any damages in any action based on failure to obtain informed consent, it shall be established by a preponderance of the evidence that a reasonably prudent person in the plaintiff’s position would not have undergone the treatment had he or she been properly informed and that the lack of informed consent was the proximate cause of the injury and damages claimed.”); N.M. STAT. ANN. § 13-1116A (West 2010) (“A doctor who fails in [his or her] duty to communicate [alternatives for treatment or inherent and potential hazards] is liable for harm to the patient resulting from the [treatment or operation] if a reasonably prudent patient [or patient’s representative] under similar circumstances would not have consented to the [treatment or operation] had [he or she] known of the [alternatives for treatment and inherent and potential hazards].”); N.Y. PUB. HEALTH LAW § 2805-d (McKinney 2010) (requiring that in a medical malpractice action based on lack of informed consent, it must “be established that a reasonably prudent person in the patient’s position would not have undergone the treatment or diagnosis if he had been fully informed . . . .”); N.C. GEN. STAT. § 90-21.13

informed consent statute covering causation, or have a statute that appears to contain a subjective, rather than an objective, standard—almost universally have case law mandating the use of objective causation.<sup>108</sup>

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(2010) (precluding recovery against healthcare provider where “[a] reasonable person, under all the surrounding circumstances, would have undergone such treatment or procedure had he been advised by the health care provider . . . .”); TEX. CIV. PRAC. & REM. CODE ANN. § 74.101 (West 2010) (“[T]he only theory on which recovery [for lack of informed consent] may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.”); UTAH CODE ANN. § 78B-3-406 (LexisNexis 2010) (requiring the patient to prove that “a reasonable, prudent person in the patient’s position would not have consented to the health care rendered after having been fully informed as to all facts relevant to the decision to give consent . . . .”); VT. STAT. ANN. 12 § 1909 (2010) (allowing as a defense to a malpractice action based on lack of informed consent that “a reasonably prudent person in the patient’s position would have undergone the treatment or diagnosis if he or she had been fully informed”); WASH. REV. CODE § 7.70.050 (2010) (requiring as a necessary element of proof in a negligence case based on lack of informed consent that “a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of such material fact . . . .”).

108. See *Fain v. Smith*, 479 So. 2d 1150, 1155 (Ala. 1985) (adopting an objective standard to determine causation in medical malpractice action based on failure to obtain informed consent, requiring “consideration by the factfinder of what a reasonable person with all of the characteristics of the plaintiff, including his idiosyncrasies and religious beliefs, would have done under the same circumstances.”); *Marsingill v. O’Malley*, 128 P.3d 151, 158 (Alaska 2006) (“[T]he second prong of the materiality test is for the trier of fact to decide whether the probability of that type of harm is a risk which a reasonable patient would consider in deciding on treatment. The focus is on whether a reasonable person in the patient’s position would attach significance to the specific risk.”); *Shetter v. Rochelle*, 409 P.2d 74, 83 (Ariz. 1965) (When determining causation in an informed consent case, the court considered the fact that “[t]he risks of injury are not so great as to cause most reasonable persons to decline to have [the] beneficial operation performed . . . .” (citations omitted)); *Haupt v. Kumar*, 288 S.W.3d 704, 707 (Ark. 2008) (adopting an objective standard for determining proximate cause in informed consent cases, meaning “causation is evaluated in terms of whether a reasonable and prudent patient in the plaintiff’s position would have withheld consent to the treatment or procedure had the material risks been disclosed.” (citations omitted)); *Wilson v. Merritt*, 48 Cal. Rptr. 3d 630, 641 (Cal. Ct. App. 2006) (requiring that in medical malpractice actions based on lack of informed consent, “causation must be established by an *objective* test: that is, the plaintiff must show that reasonable ‘prudent person[s]’ in the patient’s position would decline the procedure if they knew all the significant perils”); *Williams v. Boyle*, 72 P.3d 392, 398 (Colo. 1993) (“To show lack of informed consent, a plaintiff must show . . . that a reasonable person would not have consented to the procedure if information had been given to the plaintiff . . . .”); *Hammer v. Mount Sinai Hosp.* 596 A.2d 1318, 1324-25 (Conn. 1991) (“Under the ‘objective’ standard . . . the question of causality is resolved ‘in terms of what a prudent person in the patient’s position would have decided if suitably informed of all perils bearing significance.’ [Here, the court held] along with a majority of jurisdictions, that the objective test is the better standard” in an informed consent action); *Spencer v. Goodill*, C.A. No. 08C-06-183 RRC, 2009 WL 4652960, at \*1 (Del. Dec. 4,

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2009) (holding that Delaware “follows the objective standard . . . Plaintiff must prove that a hypothetical ‘reasonable person’ in similar circumstances . . . would not have consented to the [procedure] if properly informed of the risks”); *Gordon v. Neviasser*, 478 A.2d 292, 294 (D.C. 1984) (requiring that “[t]he causality determination must be resolved under an objective, not a subjective standard. That is, the question is not what this particular patient would have done if there had been adequate disclosure, but what a reasonably prudent person in the patient’s position would have done if adequately informed.”); *Bernard v. Char*, 903 P.2d 667, 675 (Haw. 1995) (adopting the “objective standard [which] requires consideration by the factfinder of what a reasonable person *with all of the characteristics of the plaintiff, including his idiosyncrasies and religious beliefs*, would have done under the same circumstances”); *Foster v. Traul*, 175 P.3d 186, 193 (Idaho 2007) (“[T]o prove causation [in an informed consent action the patient] must show by a preponderance of evidence that ‘a reasonable person would have chosen no treatment or a different course of treatment had he or she been adequately informed by the physician.’”) (citing *Sherwood v. Carter*, 805 P.2d 452, 465 (1991)); *Schiff v. Friberg*, 331 Ill. App. 3d 643, 657 (2002) (“[A] plaintiff must point to significant undisclosed information relating to the treatment which would have altered her decision to undergo it . . . . If the disclosure would not have changed the decision of a reasonable person in the position of the plaintiff, there is no causal connection between nondisclosure and her postoperative condition; if, however, disclosure would have caused a reasonable person in the position of the patient to refuse the surgery or therapy, a causal connection is shown. (citations omitted)”); *Spar v. Cha*, 907 N.E.2d 974, 984 (Ind. 2009) (“A plaintiff alleging lack of informed consent must establish causation-in-fact, i.e., but for the physician’s negligent nondisclosure, the patient—or a reasonable patient in the same or similar circumstances—would not have consented to the treatment in question.”); *Kennis v. Mercy Hosp. Med. Ctr.*, 491 N.W.2d 161, 166 (Iowa 1992) (requiring a plaintiff to prove that “[d]isclosure of the risk would have led a reasonable patient in plaintiff’s position to reject the medical procedure or choose a different course of treatment . . . .”); *Funke v. Fieldman*, 512 P.2d 539, 550 (Kan. 1973) (determining that “[w]hether a patient would have refused treatment or a medical procedure had the physician made adequate disclosure is to be determined objectively. If adequate disclosure could reasonably be expected to have caused the patient to decline the treatment or procedure because of revelation of the kind of risk or danger which resulted in her harm, causation is shown but otherwise not, and the patient’s testimony is relevant on such issue, but should not be controlling[.]”); *Sard v. Hardy*, 379 A.2d 1014, 1025 (Md. 1977) (holding “that the causality requirement in cases applying the doctrine of informed consent is to be resolved by an objective test: whether a reasonable person in the patient’s position would have withheld consent to the surgery or therapy had all material risks been disclosed”); *Schroeder v. Lawrence*, 359 N.E.2d 1301, 1303 (Mass. 1977) (“Whatever the precise definition or scope of the surgeon’s duty to provide information to the patient, the patient would be required to show, in order to connect any breach of duty to the ultimate injury, that, had the proper information been provided, he or she would have refused the operation; indeed one can well argue that the patient must go further and establish that in all the circumstances a reasonable person would have refused it.”); *K.A.C. v. Benson*, 527 N.W.2d 553, 561 (Minn. 1995) (“To prevail on a claim for negligent nondisclosure plaintiff must demonstrate that a reasonable person knowing of the risk would not have consented to treatment . . . .”); *Reikes v. Martin*, 471 So. 2d 385, 392 (Miss. 1985) (stating that to establish a causality, the test is “whether or not a reasonably prudent patient, fully advised of the material known risks, would have consented to the suggested treatment.”); *Wilkerson v.*

Only four states have statutes and/or case law that follow a subjective standard.<sup>109</sup> Under this standard, the relevant decision-causation

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Mid-Am. Cardiology, 908 S.W.2d 691, 696-97 (Mo. 1995) (“[T]he standard for determining lack of informed consent is whether a reasonable person in plaintiff’s position would have consented to the procedure had the proper disclosure been made. If disclosure would not have changed the decision of a reasonable person in the position of the patient, then no causal connection exists between the nondisclosure and the damages.”); *Smith v. Cotter*, 810 P.2d 1204, 1209 (Nev. 1991) (“The plaintiff’s assertion that he or she would have refused the treatment must be reasonable under the circumstances.”); *Canesi v. Wilson*, 158 N.J. 490, 504-05 (1999) (“In informed consent cases, proximate cause requires the plaintiff to prove that a reasonably prudent patient in the plaintiff’s position would have declined to undergo the treatment if apprised of the risks that the defendant negligently failed to disclose.”); *Koapke v. Herfendal*, 660 N.W.2d 206, 212 (N.D. 2003) (“[A] plaintiff must also show that ‘reasonable persons, if properly informed, would have rejected the proposed treatment.’”) (citing *DAN B. DOBBS, THE LAW OF TORTS* § 250 (2000)); *Nickell v. Gonzalez*, 477 N.E.2d 1145, 1148 (Ohio 1985) (requiring a plaintiff to establish that “a reasonable person in the position of the patient would have decided against the therapy had the material risks and dangers inherent and incidental to treatment been disclosed to him or her prior to the therapy”); *Radinovic v. Abraham*, 16 Pa. D. & C.3d 168, 178 (Com. Pl. 1980) (“In determining whether the patient would have submitted to the treatment, an objective, rather than subjective, test is applied.”) (citation omitted); *Hook v. Rothstein*, 316 S.E.2d 690, 705 (S.C. 1984) (“[A] causal connection exists between a physician’s failure to inform and the patient’s injury only if a reasonable person in the patient’s position would have refused the treatment had he or she been told of the risk that resulted in injury.”); *Savold v. Johnson*, 443 N.W.2d 656, 659 (S.D. 1989) (“[T]he proper rule . . . is whether a reasonable person in [the patient’s] position ‘would not have agreed to the proposed treatment if adequately apprised beforehand of the material risk which resulted in [the] injury.’”); *Hawk v. Chattanooga Orthopaedic Grp., P.C.*, 45 S.W.3d 24, 32 (Tenn. 2000) (“In [an informed consent] case, the issue of causation is based on an objective standard: ‘whether a reasonable person in the patient’s position would have consented to the procedure or treatment in question if adequately informed of all significant perils.’” (citation omitted)); *Adams v. El-Bash*, 338 S.E.2d 381, 386 (W. Va. 1985) (“[A] causal relationship, between [the physician’s] failure to disclose information and damage to the patient, may be shown if a reasonable person in the patient’s circumstances would have refused to consent to the surgery had the risks been properly disclosed.”); *Schreiber v. Physicians Ins. Co. of Wis.*, 588 N.W.2d 26, 33 (Wis. 1999) (“The objective test [applies, which] focuses on what the attitudes and actions of the reasonable person in the position of the patient would have been rather than on what the attitudes and actions of the particular patient of the litigation actually were. It asks two questions. First, did the physician fail to give information that a reasonable patient would want to know? Second, given the additional information, would the reasonable patient have acted differently than they did without the information?” (citations omitted)); *Roybal v. Bell*, 778 P.2d 108, 112-13 (Wyo. 1989) (holding that “the objective test . . . [is] the appropriate test for measuring causation in informed consent cases in Wyoming.”).

109. N.H. REV. STAT. ANN. § 507-E:2 (2010) (containing the following provisions: “(1) Whether the injured person or person giving consent on his behalf could reasonably be expected to know of the risks or hazards inherent in such treatment, procedure, or surgery; (2) Whether the injured person or the person giving consent on his behalf knew of the risks

determination is whether the particular plaintiff patient would have chosen the procedure had the appropriate information been disclosed;<sup>110</sup> “whether an objectively reasonable person would have acted differently is irrelevant.”<sup>111</sup> Kentucky and Michigan do not have statutes or case law governing the issue of causation in informed consent cases.<sup>112</sup> Virginia’s courts have not decided the causation issue either, but the Fourth Circuit found that Virginia courts would apply the objective standard if the issue arose.<sup>113</sup>

The fact that so many states have adopted objective causation is surprising for several reasons. First, the reasonable person standard has been applied in traditional tort cases exclusively to determine breach of duty.<sup>114</sup> It cannot logically be employed to determine whether the breach of duty caused the

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or hazards inherent in such treatment, procedure, or surgery; (3) Whether the injured party would have undergone the treatment, procedure, or surgery regardless of the risk involved or whether he declined to be informed thereof . . . ); *Wilkinson v. Vesey*, 295 A.2d 676, 690 (R.I. 1972) (using a subjective test for causation and finding that “the plaintiff must prove that if he had been informed of the material risk, he would not have consented to the procedure and that he had been injured as a result of submitting to the procedure”); *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979) (rejecting the objective causation standard, holding, “This basic right to know and decide is the reason for the full-disclosure rule. Accordingly, we decline to jeopardize this right by the imposition of a ‘reasonable man’ standard”); *Mandell v. Maurer*, 946 P.2d 706, 708 (Or. Ct. App. 1997) (“[W]hether a physician’s failure to warn of the risks of treatment ‘causes’ a plaintiff’s injuries or damages depends on whether the plaintiff would have consented to the treatment had he or she been informed of all the material risks and alternatives. It is a subjective test of causation, and whether an objectively reasonable person would have acted differently is irrelevant.”).

110. *Goodill*, 2009 WL 4652960 at \*1; *Tietz*, *supra* note 86, at 374-75 (“The objective-patient standard fails to protect the right of ‘subjective’ patients to make their own therapeutic choices.”).

111. *Mandell*, 946 P.2d at 708.

112. 13 KY. PRAC. TORT LAW § 10:22 (2011) (“No Kentucky case addresses the causation issue.”); *Howard v. Zamorano*, No. 244610, 2004 WL 2314553, at \*6 (Mich. Ct. App. 2004) (“Case law is silent with respect to whether a subjective or objective test [would be used to determine] whether plaintiff would have withheld consent and forgone surgery.”)

113. *United States v. Cunningham*, 683 F.2d 847, 849 (4th Cir. 1982) (noting that “[V]irginia courts have yet to consider the question” and concluding that “Virginia courts would apply the objective standard when confronted with such a case”).

114. *Fain v. Smith*, 479 So.2d 1150, 1162 (Ala. 1985) (Jones, J., dissenting) (“Traditional tort law, evolving over several centuries through the common law process and statutory enactments, relegates the application of the ‘reasonable person’ standard exclusively to the *breach of duty* determination.”).

plaintiff's injury.<sup>115</sup> As Dan Dobbs wrote, "if the full disclosure would have led the plaintiff to refuse the operation, both the defendant's breach and its causal role is clearly established, so the [reasonable person requirement in the objective causation] rule does not reflect the causation requirement but imposes some additional and most unusual obstacle."<sup>116</sup>

More importantly, the foundational principle behind informed consent laws is autonomy,<sup>117</sup> the personal right of patients to make informed decisions concerning their medical care.<sup>118</sup> The right to autonomy is now "deeply entrenched in our culture and law"<sup>119</sup> and is a "preeminent bioethical value."<sup>120</sup> The purpose of informed consent laws is to ensure that patient autonomy is respected—that the patient's personal preferences, values, and goals are given deference<sup>121</sup> and that the choice of medical care is ultimately the patient's alone.<sup>122</sup>

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115. *Id.* at 1162-63 ("[The reasonable person standard] has no field of operation in measuring the requisite nexus between the defendant's breach of duty and the cause of the claimant's injuries.").

116. DOBBS, *supra* note 93, at 657.

117. Honorable Armand Arabian, *Informed Consent: From the Ambivalence of Arato to the Thunder of Thor*, 10 ISSUES L. & MED. 261, 267 (1994) ("Of those interests guiding the doctrine of informed consent, the principle of personal autonomy must be considered preeminent."); Sones, *supra* note 58, at 257 ("The doctrine of informed consent in the U.S. healthcare context holds as its driving value the concepts of autonomy and self-determination.").

118. Atwell, *supra* note 69, at 594 ("Today, autonomy is the fundamental principle underlying medical decisionmaking. Competent adults exercise that autonomy by deciding whether or not to consent to medical treatment."); Gatter, *supra* note 70, at 581 ("The doctrine of informed consent is founded on a principle of autonomy. It is designed to give patients more control over their medical decisions and their bodies.").

119. Schuck, *supra* note 86, at 924.

120. Roger B. Dworkin, *Medical Law and Ethics in the Post-Autonomy Age*, 68 IND. L. J. 727, 727 (1993) ("Patient autonomy has long been the dominant rhetorical value in American medical law and medical ethics."); Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice*, 28 J. LEGAL MED. 91, 93 (2007) ("[I]n the United States, . . . autonomy is the preeminent bioethical value . . ."); Krause, *supra* note 33, at 267 ("Informed consent is both a legal doctrine, embodied in state law, and an ethical doctrine, primarily reflecting the ethical principle of patient autonomy."); Lambris, *supra* note 58, at 240 ("Informed consent [is] generally accepted to be a derivative of autonomy and [is] a deep-seated principle in Western ethics.").

121. George J. Annas et al., *The Empire of Death: How Culture and Economics Affect Informed Consent in the U.S., the U.K., and Japan*, 20 AM. J.L. & MED. 357, 364 (1994) ("Informed consent requirements implement the fundamental principle that 'adults are entitled to accept or reject health care interventions on the basis of their own personal values and in furtherance of their own personal goals.'"); Donald T. Ridley, *Informed Consent, Informed Refusal, Informed Choice—What Is It that Makes a Patient's Medical Treatment Decisions Informed?*, 20 MED. & L. 205, 207 (2001) ("In the context of the doctor/patient relationship,

Objective causation is “unfaithful” to these underlying ideals.<sup>123</sup> The objective standard replaces the unique values of the individual patient concerning her medical care with those of a hypothetical prudent person.<sup>124</sup> In so doing, it negates the primary purpose of informed consent by failing to protect the autonomy rights of the individual patient.<sup>125</sup> As the Oklahoma Supreme Court wrote in *Scott v. Bradford*: “[t]o the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient’s right of self determination is *irrevocably lost*.”<sup>126</sup>

Not only does objective causation undermine the central purpose of informed consent, but it also makes the cause of action almost useless to a plaintiff patient. Because juries must find objective causation for a patient to prevail, “few cases are litigated where informed consent is the sole allegation of negligence.”<sup>127</sup>

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respect for the patient’s personal autonomy and bodily self-determination means the doctor’s respect for the patient’s personal values, goals, and sensibilities.”).

122. Eric M. Levine, Comment, *The Constitutionality of a Court-Ordered Cesarean Surgery: A Threshold Question*, 4 ALBANY L.J. SCI. & TECH. 229, 272 (“Recognition of the patient’s right to give informed consent demonstrates society’s respect for a patient’s autonomy and bodily integrity and more importantly, that the physician’s role is that of an adviser while the patient ultimately decides his course of treatment.”).

123. See Sones, *supra* note 58, at 262 (“[T]he objective test for causation is often criticized as being unfaithful to the underlying ideal of individual autonomy and self-determination.”); Walter, *supra* note 57, at 572 (“[Objective causation] seems to undermine the very essence of the principle of patient self-determination.”).

124. *Fain v. Smith*, 479 So. 2d 1150, 1158 (Ala. 1985) (Jones, J., dissenting) (quoting Alexander M. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 420 (1974)) (“To adopt the ‘reasonable person’ standard would be to ‘deny the patient-subject with special ‘fears and hopes,’ or the religious beliefs of a Jehovah’s Witness, the right to make a decision.’”).

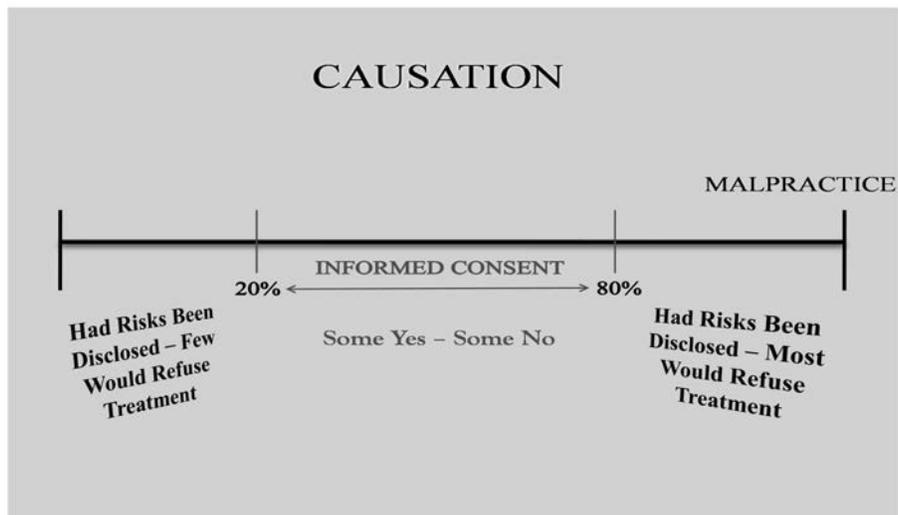
125. See BARRY R. FURROW ET AL., *HEALTH LAW* 334 (2d ed. 2000) (“European courts . . . are more protective of patient autonomy. The German Federal Supreme Court has adopted a subjective test of causality, for example, with a heavy burden on the physician to show that the particular patient would have undergone the procedure even with the information . . . .”); Shultz, *supra* note 18, at 288 (“The projected decision of [the individual patient] rather than ‘a reasonable person,’ should provide the standard; any other standard fails to protect the very autonomy that lies at the heart of the [informed consent] interest.”); Walter, *supra* note 57, at 572 (“If the goal of the principle of autonomy is to grant the patient the right to guide his treatment, . . . then the court’s granting to the jury the ability to fall back on the concept of the ‘reasonably prudent person,’ who may consent to treatment despite the lack of appropriate information for the particular patient-plaintiff, effectively destroys the notion of choice.”).

126. *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979).

127. *McNichols*, *supra* note 51, at 731.

*III. Objective Causation Renders Informed Consent an  
Almost Useless Claim*

Recovery premised only on informed consent is rare when the objective reasonable person causation standard is used. The chart below demonstrates why this is true. The line represents a hypothetical continuum of treatment-condition pairs, in other words, medical procedures for patients with specific medical problems. The treatment-condition pairs have different risks and alternatives. At the beginning of the line, 0% of patients would refuse the treatment for the paired medical condition if the risks and alternatives were known. At the high end of the line, 100% of patients would refuse the treatment for the paired condition if fully informed.



If 100% of informed patients would refuse a medical treatment—a surgery, for example—the operation almost definitely involves substantial risks that could either be easily avoided or substantially reduced by using an alternative medical treatment.<sup>128</sup> In these cases, it would be medical

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128. Shultz, *supra* note 18, at 229 (“[I]f the informed consent action involved nondisclosures that led to reasonably avoided and significant harms, it would seem to be largely duplicative of an action in professional negligence.”).

malpractice<sup>129</sup> to perform or recommend the surgery, whether or not the patient gave her informed consent.<sup>130</sup>

Even if a few patients would agree to the particular surgery knowing the risks and alternatives, juries are likely to find that the operation should not have been recommended or performed. This is especially true if the patient suffers harm from the procedure because juries tend to be sympathetic to those who are injured.<sup>131</sup> In the chart, this category of patients appears as 80% or a higher percentage of informed patients would refuse treatment. Although 80% was selected somewhat arbitrarily, if only 20% or fewer patients would choose to have the surgery knowing the risks and alternatives, the operation is arguably not advisable.<sup>132</sup> Because juries are likely to fully compensate these patients if they bring a medical malpractice action, there is no need for a duplicative informed consent claim.<sup>133</sup>

At the low end of the continuum are treatment-condition pairs where few patients would refuse to have the medical procedure if fully informed of the risks and alternatives. In the chart, this category of treatment-condition pairs is limited to those where 20% or a fewer percentage of informed patients would decline the procedure. The treatments in this category are those where the patient has no real choice. For example, a patient with a broken leg needs it to be set,<sup>134</sup> a patient with a cancerous skin mole must

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129. Medical malpractice occurs “when a patient, as a direct result of a physician’s failure to render that level of care consistent with what would have been given by other practicing physicians in the community in question, is injured.” Smith, II, *supra* note 57, at 115.

130. Twerski & Cohen, *supra* note 67, at 643 (“On [one] extreme, in cases in which the omitted information clearly would have led this patient (or a reasonable patient) to decline the recommended procedure, the doctor’s recommendation of the procedure likely was malpractice.”).

131. Stephen G. Gilles, *On Determining Negligence: Hand Formula Balancing, the Reasonable Person Standard and the Jury*, 54 VAND. L. REV. 813, 837 n.86 (2001) (quoting Francis H. Bohlen, *Mixed Questions of Law and Fact*, 72 U. PA. L. REV. 111, 118 (1924)) (“The concept . . . that an injury should be paid for by him who causes it, irrespective of the moral or social quality of his conduct . . . still dominates the opinion of the sort of men who form the average jury.”).

132. See Twerski & Cohen, *supra* note 67, at 617 (“[W]e will give little consideration to cases in which it was a violation of minimum professional standards to perform or recommend the therapy or lack of therapy at all, whether the risks of the procedure were disclosed or not. In those cases, malpractice doctrine should adequately compensate the patient.”).

133. *Id.* at 645 (“Egregious medical conduct can usually be remedied in a malpractice case in which an informed consent claim would be superfluous.”).

134. Gatter, *supra* note 70, at 592 (“[T]here is almost no risk of a grave consequence [where there is] a non-compound fracture of a bone. The patient has essentially no option other than to allow the fracture to heal . . .”).

have it removed, and a patient who is seriously ill and has one clearly superior choice of treatment with few risks will generally choose that treatment.<sup>135</sup> Under these circumstances, a patient who would not consent to the procedure is aberrational.<sup>136</sup>

Some commentators argue that informed consent should not even be necessary in cases like these where the risks are remote and/or the alternatives are undesirable.<sup>137</sup> Informed consent statutes are not intended to protect patients where there are no meaningful alternatives and so no viable choices for the patient to make. In any event, it would be difficult to find an attorney who would take a case for patients in this condition-treatment category on a contingent fee basis. Even in a subjective causation jurisdiction, the jury would be unlikely to find a patient credible if he testified that he would have refused this category of treatment if he had additional information.<sup>138</sup>

That leaves the treatment-condition pairs in the middle, where between 20% and 80% of patients would choose not to have the treatment knowing the risks and alternatives. In this category, there are genuine choices to be made and reasonable people will differ in their decisions depending on their values and personal preferences.<sup>139</sup> In this category, informed consent matters;<sup>140</sup> information is vital to help patients make the decisions that best

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135. Shultz, *supra* note 18, at 228 (“[A]lthough individualists will stress that in not disclosing all the facts the doctor has injured the patient’s dignity and integrity, [where the information that is undisclosed concerns a remote risk, the patient is seriously ill, and the surgery is the only viable treatment] many—perhaps most—will on these facts construe such an injury to be largely symbolic.”).

136. *Id.* (noting that “a patient who would not have consented to . . . surgery [where there was a remote risk, the patient was seriously ill, and the surgery was the only viable treatment] is aberrational”).

137. *See, e.g., id.* (“Where other important interests such as fairness to doctor-defendants or medical cost escalation are involved, it may plausibly be argued that such absolute protection need not be extended to the relatively less crucial disclosure of information about remote risks.”).

138. McNichols, *supra* note 51, at 731 (“Jurors may hear the court’s instruction that the question is what the individual plaintiff, not what a reasonable patient, would have done, but their instincts of fairness may well lead them to award compensation to a plaintiff only if they think he reasonably refused his doctor’s recommendation.”).

139. B.M. Dickens & R.J. Cook, *Dimensions of Informed Consent to Treatment*, 85 INT’L J. GYNECOLOGY & OBSTETRICS 309, 311 (2004) (“[P]atients exercise choice in the wider context of their perceptions, values, and intentions.”).

140. *Id.* at 310 (“[The role of informed consent] is to assist patients to satisfy their own wishes, even when their wishes do not advance their interests as their physicians perceive them.”).

meet their needs.<sup>141</sup> But this is also the category where objective causation will cause the patient to lose an informed consent claim.

To succeed on an informed consent claim, the patient must prove that a reasonable person knowing the risks and alternatives would not have chosen the condition-treatment option.<sup>142</sup> However, the middle 20% to 80% category, by definition, includes those types of treatments where reasonable patients will differ in their choices. Therefore, in exactly those cases where individual choice and information matter most, patients could not prove that a reasonable informed person would refuse the treatment.<sup>143</sup> In this way, objective causation ensures that informed consent laws will not protect patients.<sup>144</sup>

Wisconsin defines the reasonable person standard in terms of “what a statistical majority of persons would do,” rather than how an average or

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141. See Shultz, *supra* note 18, at 270 (“Because there is no certainty about who is right, the patient should receive information about divergent views and be allowed to arrive at her own decision.”).

142. Shultz, *supra* note 18, at 249; see also Walter, *supra* note 57, at 543 n.3.

143. See Gilles, *supra* note 131, at 815 (noting that pattern jury instructions typically advise juries to use a reasonable person standard, but do not explain how to actually apply that standard). Commentators have classified the reasonable person standard in various ways. Some classify it as an aspirational standard—considering how the ideal person would act. See, e.g., David A. Westenberg, *Buckle Up or Pay: The Emerging Seat Belt Defense*, 20 SUFFOLK U. L. REV. 867, 907 (1986) (“The common law standard of reasonableness is an aspirational standard—how people ought to act.”). Others characterize the reasonable person standard as requiring the jury to determine what an average member of the community would have done. See Gilles, *supra* note 131, at 835 n.78 (“Terry argued that the issue of negligence turns on what ‘a standard man,’ not ‘an ideal or perfect man, but an ordinary member of the community,’ would have done under the circumstances.”). Still others define reasonableness in terms of how a statistical majority of the population would behave. See Heidi M. Hurd, *The Deontology of Negligence*, 76 B.U. L. REV. 249, 269 (1996) (“According to [the Wisconsin Supreme Court], reasonableness is defined by reference to what a statistical majority of persons would do.”); Leslie Gielow Jacobs, *Adding Complexity to Confusion and Seeing the Light: Feminist Legal Insights and the Jurisprudence of the Religion Clauses*, 7 YALE J.L. & FEMINISM 137, 159 (1995) (“The function of the reasonable person standard is normative; it is designed in part to deter behavior that is perceived by a majority of the community to be unreasonable.”); see also Gilles, *supra* note 131, at 846 n.110 (quoting LEARNED HAND, *THE SPIRIT OF LIBERTY* 105-06 (3d ed. 1960) (“What being careful means, it does not try to say; it leaves that to the judge, who happens in this case to be a jury of twelve persons, untrained in the law.”)).

144. See Twerski & Cohen, *supra* note 67, at 619 (“[A] patient can prevail on an informed consent claim only if a reasonable patient, after being appropriately informed of the risks of a procedure which is safe enough to be reasonable to propose, would decline the procedure nonetheless.”).

ideal person would behave.<sup>145</sup> Even in a jurisdiction with this definition of reasonableness, informed consent laws do not protect patients in the middle. Theoretically, if 51% to 80% of patients would refuse treatment knowing the risks and alternatives, the jury should find that a reasonable person—defined as a majority of patients—would not choose the treatment. However, there are usually no statistics to help juries determine these percentages, so they are forced to make decisions based on their own experiences.<sup>146</sup> Also, the statistical majority standard does not make sense in the context of informed consent laws designed to protect patient autonomy. Patients have “the right to prefer a course of treatment that a majority of patients would not choose,”<sup>147</sup> so, theoretically, a jury could find that a reasonable person would choose a reasonable treatment recommended by a physician, even if a majority of patients might not make the same choice.<sup>148</sup> Because the middle category includes the types of treatments that are legitimate options for patients, attorneys would be reluctant to take any of these cases on a contingent fee basis. As Barry Furrow wrote, “a jury is unlikely to find causation in these cases unless . . . the jury ignores its instructions and applies a subjective standard.”<sup>149</sup>

Although patients will rarely prevail on an informed consent claim when objective causation is the standard, some patients will succeed in their claims. As set forth above, patients are likely to succeed when recommending the treatment itself is medical malpractice such that a reasonable patient would not consent knowing the risks and alternatives.<sup>150</sup> But these claims would also succeed on a medical malpractice theory.<sup>151</sup>

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145. Hurd, *supra* note 143, at 269.

146. Gilles, *supra* note 131, at 835 n.78 (noting that juries draw data from common experience or their “knowledge of how an ordinary person would act”).

147. Krause, *supra* note 33, at 319 (quoting Jay Katz, *Informed Consent—A Fairy Tale? Law’s Vision*, 39 U. PITT. L. REV. 137, 164 (1977)) (“[T]he right to medical self-determination is most important not where the patient’s treatment preferences coincide with the majority of patients, but where the patient seeks to make an *atypical choice*: ‘the very right at issue in cases of informed consent, the right of individual choice, may be precisely the right to prefer a course of treatment that a majority of patients would not choose.’”).

148. See Gilles, *supra* note 131, at 822 (“For as long as there has been a tort of negligence, American courts have defined negligence as conduct in which a reasonable man (nowadays, a reasonable person) would not have engaged.”).

149. FURROW ET AL., *supra* note 125, at 334.

150. See McNichols, *supra* note 51, at 732 (“[T]he informed consent cases likely to be litigated are those where there is a fair chance of showing that the defendant was negligent in some other way, as where the decision to perform the procedure was near the line of medical acceptability.”).

151. See *supra* Part II.

Some claims will succeed because juries occasionally apply their own standards of justice despite the objective causation standard.<sup>152</sup> For this reason, informed consent is often included as a secondary cause of action—a back-up claim—in a standard medical malpractice case.<sup>153</sup> Despite these occasional successes, objective causation prevents informed consent claims from serving their main purpose—protecting the autonomy rights of patients. As Jay Katz wrote, “[t]he law of informed consent is substantially mythic and fairy tale-like as far as advancing patients’ rights to self-decisionmaking is concerned. . . . The legal vision of informed consent based on self-determination is still largely a mirage.”<sup>154</sup>

#### *IV. Attempts to Interpret Objective Causation to Better Protect Patient Choice*

Some courts and legislatures have added a subjective component to objective causation to enable juries to take the individual patient’s needs into account. They include language such as a reasonable person “under similar circumstances,”<sup>155</sup> or “in the patient’s position,”<sup>156</sup> or “under all

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152. See M. F. Kraushar & James Steinberg, *Informed Consent: Surrender or Salvation?*, 104 ARCHIVES OPHTHALMOLOGY 352, 353 (1986) (“Juries have been known to apply their own standard of right and wrong, however, even if it is in contravention of the letter of the law, and base their decision on what they believe the specific patient-plaintiff would have done.”); see also Tamaz, *supra* note 89, at 1331 (advising attorneys to “[p]ersuade your jury by arguing informed consent is empowerment of the patient” and “let the jurors know they too have the right to choose”).

153. Christopher G. Kiss et al., *Informed Consent and Decision Making by Cataract Patients*, 122 ARCHIVES OPHTHALMOLOGY 94, 94 (2004) (footnotes omitted) (“[L]ack of informed consent is used as a secondary cause in more than 90% of all ophthalmologic malpractice cases. In contrast, it is the primary reason in only 5% to 6% of claims.”); McNichols, *supra* note 51, at 731 (“[M]ost plaintiffs will use the informed consent doctrine as a backup alternative to their attempts to show that the physician was negligent in some manner in regard to the procedure itself.”); Weisbard, *supra* note 96, at 755 (“[I]nformed consent claims are often ‘tacked on’ to malpractice cases.”).

154. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 83-84 (2002); see also Mariner, *supra* note 10, at 405 n.50 (“[W]hile many judicial opinions are eloquent in describing a patient’s right of self-determination, most of the rhetoric remains dictum.”); Weisbard, *supra* note 96, at 751 (“[T]he law has been far richer in its rhetorical devotion to the ideal of patient self-determination than in its provision of effective legal redress to victimized patients.”).

155. N.M. STAT. ANN. § 13-1116A (West 2010) (“[A] reasonably prudent patient . . . under similar circumstances would not have consented to the [treatment] . . .”).

156. N.Y. PUB. HEALTH LAW § 2805-d(3) (Consol. 2011) (“[A] reasonably prudent person in the patient’s position would not have undergone the treatment . . .”).

[the] surrounding circumstances.”<sup>157</sup> This language appears to open the door to patients to submit evidence about their individual treatment goals. For example, a patient might want another child and therefore her choice of treatment may be affected differently than most patients by a physician’s failure to disclose information. A patient with cancer may prefer a shorter, higher quality life, rather than the longest life possible.<sup>158</sup> This preference may also determine the effect of a physician’s omitted disclosure on the patient’s treatment choice. Including subjective language like “under similar circumstances” should theoretically allow juries to decide informed consent claims on a case-by-case basis, taking subjective desires such as these into consideration.<sup>159</sup>

But this language has not solved the problem of protecting individual choice.<sup>160</sup> “Under all the surrounding circumstances” and similar language have generally been interpreted by the courts to apply only to the patient’s medical condition, not to the patient’s non-medical values and preferences.<sup>161</sup> To deal with this limitation, at least three states have formulated the objective causation standard to broadly include “a

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157. ME. REV. STAT. ANN. tit. 24, § 2905(C) (2010) (“[A] reasonable person, under all surrounding circumstances, would have undergone such treatment or procedure . . .”).

158. See, e.g., Gatter, *supra* note 70, at 568 (“[A] physician may disclose the same information to every patient with colon cancer even if one patient’s primary goal is to participate in his daughter’s wedding rather than to maximize his chances for a cure.”).

159. *Spencer v. Goodill*, No. 08C-06-183, 2009 WL 4652960, at \*10 (Del. Super. Ct. Dec. 4, 2009) (quoting FAY A. ROZOVSKY, CONSENT TO TREATMENT § 1.13.4, at 62-63 (1984) (“Causation in Negligent Consent”)) (“What a reasonable person would agree to depends in large measure on the facts and surrounding circumstances of an individual case. The standard reflects the view that obtaining consent must be accomplished on a case-by-case basis, taking into account the peculiar needs and concerns of each patient.”).

160. See Weisbard, *supra* note 96, at 760 n.26 (“The court’s unelaborated references to reasonable or prudent persons ‘in the patient’s position’ may allow some theoretical leeway for greater individualization within the confines of a formally ‘objective’ test. Thus far, it appears that few if any courts have accepted this invitation . . .”).

161. Gatter, *supra* note 70, at 563 (“[The] duty to assess and account for subjective characteristics of patients is interpreted by the majority of courts to require only that physicians account for each patient’s medical condition in the course of informing patients about their treatment options.”); see, e.g., *Spencer*, 2009 WL 4652960, at \*10 (“The jury may consider factors such as the patient’s ‘medical condition, age, risk factors, etc.’ to come to a determination of whether a reasonable person in the decedent’s condition would have undergone the medical treatment.”). Note that all the factors referenced by the court in *Spencer* relate to the patient’s medical condition, rather than the patient’s values or idiosyncrasies.

reasonable person with all of the characteristics of the plaintiff, including his idiosyncrasies and religious beliefs.”<sup>162</sup>

But even in the few states using this broad standard, that language has generally failed to protect patient autonomy. Although the language instructs the courts to interpret the reasonable person standard to include the unique and idiosyncratic needs of individual patients, courts have usually declined to do so, “making the [ ] language appear like hollow rhetoric.”<sup>163</sup>

In any event, if the courts actually followed this standard, they would essentially be using a subjective causation standard. As Justice Adams of the Alabama Supreme Court wrote in his dissenting opinion in *Fain v. Smith*, “[w]hen we build into the [reasonable person] standard . . . ‘all of the characteristics of the plaintiff, including his idiosyncrasies and religious beliefs,’ we no longer have [a] reasonable person standard.”<sup>164</sup> The standard is subjective<sup>165</sup> and, to avoid confusion and ensure that the subjective standard is properly implemented, the courts should call it what it is.<sup>166</sup>

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162. See *Fain v. Smith*, 479 So. 2d 1150, 1155 (Ala. 1985) (per curiam) (requiring “consideration by the factfinder of what a reasonable person with all of the characteristics of the plaintiff, including his idiosyncrasies and religious beliefs, would have done under the same circumstances”); *Bernard v. Char*, 903 P.2d 667, 675 (Haw. 1995) (adopting the standard set out in *Fain*, which requires the jury to examine whether a reasonable person *with the patient’s characteristics* would have consented to the treatment); *Ashe v. Radiation Oncology Assocs.*, 9 S.W.3d 119, 124 (Tenn. 1999) (“[T]he finder of fact may also take into account the characteristics of the plaintiff including the plaintiff’s idiosyncrasies, fears, age, medical condition, and religious beliefs.”).

163. Gatter, *supra* note 70, at 569 (“Most courts, however, have applied the law much differently, making the [‘including his idiosyncrasies and religious beliefs’] language sound like hollow rhetoric. . . . [C]ourts [generally] do not impose any obligation on physicians to inquire into patient’s treatment goals . . .”).

164. *Fain*, 479 So. 2d at 1164 (Adams, J., dissenting); see also MARK A. HALL ET AL., *MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS* 216 (Aspen 2d ed. 2008) (questioning whether taking the plaintiff’s “idiosyncrasies, fears, age, medical condition, and religious beliefs” into account in the reasonable person objective causation standard makes it “dissolve into a subjective standard”).

165. McNichols, *supra* note 51, at 717 n.36 (“[Alabama] . . . arrives at a subjective standard by building the plaintiff’s idiosyncrasies into the profile of the reasonable person.”).

166. Not all courts would agree with this analysis. See, e.g., *Bernard*, 903 P.2d at 675 (“[V]iewing [objective causation] from a core of reasonableness establishes an initially uniform standard among cases from which adjustments for idiosyncrasies may be made. Under this rationale, the analytical exercise is grounded in objective reasonableness, but the standard may still flexibly accommodate the individual characteristics of each patient.”); see also *Ashe*, 9 S.W.3d at 124 (same). While advocating for objective causation, these two

V. *The Courts' Justification for the Objective Causation Standard*

If objective causation undermines the purpose of informed consent laws, how do the courts justify using it? Essentially, the courts focus on the problems with subjective causation and, in this way, attempt to show that objective causation is a better approach. They posit that subjective causation would be based solely on the plaintiff's testimony,<sup>167</sup> and that testimony would be unreliable due to its speculative nature, hindsight, bitterness, and bias.<sup>168</sup>

If the causation standard was subjective, the plaintiff would introduce testimony about the medical decision he would have made if the physician disclosed information that he did not disclose.<sup>169</sup> Stated otherwise, the plaintiff would give "a speculative answer to a hypothetical question":<sup>170</sup> "[W]ould [he] have decided differently [knowing] something he did not know?"<sup>171</sup> Some courts have found this testimony to have "so much uncertainty that its credibility is minimal."<sup>172</sup>

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cases appear to acknowledge that the standard becomes subjective when the individual idiosyncrasies of the patient are taken into account.

167. *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir. 1972) ("[Subjective causation] calls for a subjective determination solely on [the] testimony of a patient-witness . . ."); Shultz, *supra* note 18, at 251 (noting that "the very existence of any injury would seem to turn solely on the rather shaky reed of the plaintiff's hindsight testimony"); Weisbard, *supra* note 96, at 761 n.30 (noting that in *McPherson v. Ellis*, 287 S.E.2d 892, 896 (N.C. 1982), the court "expressed concern that the only evidence usually available [to prove subjective causation] is the plaintiff's bald assertion, tempered by hindsight, as to what he would have done had he known all the facts").

168. Schuck, *supra* note 86, at 919 ("The plaintiff patient's testimony on decision causation . . . is likely to be biased, offered with the clarity of hindsight, and influenced by the adverse outcome that in fact occurred."); Shultz, *supra* note 18, at 249 ("Fearing that patients' testimony would be self-serving and biased by hindsight, courts have felt it necessary to [use objective causation]."); Sones, *supra* note 58, at 262 ("[A]n objective test neutralizes the effects of the plaintiff's testimony regarding causation, which is likely tainted with self interest and '20/20 hindsight.'").

169. *Ashe*, 9 S.W.3d at 123 ("The objective approach circumvents the need to place the fact-finder in a position of deciding whether a speculative and perhaps emotional answer to a purely hypothetical question shall dictate the outcome of the litigation.").

170. *Canterbury*, 464 F.2d at 791.

171. *Id.* ("Viewed from the point at which he had to decide, would the patient have decided differently had he known something he did not know?").

172. *Roybal v. Bell*, 778 P.2d 108, 117 (Wyo. 1989) (Urbigkit, J., dissenting) ("Unquestionably, the legal system's insistence on determining the hypothetical results of a hypothetical decision-making process incorporates so much uncertainty that its credibility is minimal."); see also *Canterbury*, 464 F.2d at 790 ("[T]he question whether he actually would have turned the treatment down if he had known the risks is purely

The credibility of the patient's testimony is further tainted by bitterness and self-interest. The patient's reconstruction of what he would have chosen given the omitted information will be "shadowed by the occurrence of the undisclosed risk."<sup>173</sup> Even if the risk of harm was remote, it will appear significant "after the uncommunicated hazard has in fact materialized"<sup>174</sup> and the patient has suffered injury.<sup>175</sup> The plaintiff patient also has a significant interest in deciding that the undisclosed information would have affected his treatment choice, especially when a substantial financial recovery rests on his answer.<sup>176</sup> As the D.C. Circuit concluded in *Canterbury v. Spence*, relying on the subjective standard "places the physician in jeopardy of the patient's hindsight and bitterness."<sup>177</sup>

Some courts also contend that subjective causation would preclude recovery if the patient died prior to trial.<sup>178</sup> After death, the plaintiff

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hypothetical . . ."); *Fain v. Smith*, 479 So. 2d 1150, 1152 (Ala. 1985) (per curiam) ("Because any answer to the hypothetical question—'What would the patient in fact have done?'—can only be a guess, posing the causation issue in that form does not promote [a] rational resolution of it."); *Bernard v. Char*, 903 P.2d 667, 673 (Haw. 1995) ("[The] causation question is necessarily conjectural, in that no one, including the patient, much less the factfinder, can provide a definitive answer regarding what decision the plaintiff-patient would have made with respect to undergoing treatment . . .").

173. *Canterbury*, 464 F.2d at 790.

174. *Id.* (explaining that the patient's answer to what he would have done had he been properly informed "hardly represents more than a guess, perhaps tinged by the circumstance that the uncommunicated hazard has in fact materialized"); *Cobbs v. Grant*, 104 Cal. Rptr. 505, 515 (Ct. App. 1972) ("Since at the time of trial the uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had he been informed of the dangers he would have declined treatment.").

175. *Ashe v. Radiation Oncology Assocs.*, 9 S.W.3d 119, 122 (Tenn. 1999) ("Opponents [of subjective causation] focus on the unfairness of allowing the issue of causation to turn on the credibility of the hindsight of a person seeking recovery after experiencing a most undesirable result."); Weisbard, *supra* note 96, at 755 ("However remote a given risk appeared in prospect, hindsight demonstrates that it was sufficiently 'real' that it could result in serious injury—as it did in the very case.").

176. Weisbard, *supra* note 96, at 758 ("Answers to such speculative questions [concerning whether plaintiff would have consented knowing the risks] might well tend to be self-serving, particularly when the potential for substantial financial recovery rides on the answer.").

177. *Canterbury*, 464 F.2d at 790-91.

178. *See, e.g., Ashe*, 9 S.W.3d at 122 ("[T]he adoption of a subjective standard could preclude recovery in an informed consent case in which the patient died as a result of an unforwarned collateral consequence."); *Roybal v. Bell*, 778 P.2d 108, 112 (Wyo. 1989) ("[The subjective] test has been criticized because . . . this test would probably preclude recovery if the patient had died as a result of the treatment received.").

obviously could not testify as to what he would have decided if the omitted information had been disclosed.<sup>179</sup>

For these reasons, the courts generally prefer objective causation, relying on what a hypothetical reasonable person in the plaintiff's position would have decided if suitably informed.<sup>180</sup> As will be shown, while these reasons have some merit, they do not justify "backtracking on the law's protection of self-determination."<sup>181</sup>

#### *VI. The Arguments Against Subjective Causation Do Not Justify Adopting an Objective Standard*

The reasons for using objective, rather than subjective, causation rest mainly on the credibility of the plaintiff's testimony and concern that the jury will uncritically rest its decision on that testimony alone. But juries are regularly asked to determine the credibility of witnesses, and the testimony of witnesses other than the plaintiff could be used to test the veracity of the plaintiff's statements. The jury system has built-in protections to deal with just these concerns.

Issues of hindsight, bitterness, and bias are common during jury trials.<sup>182</sup> To deal with these credibility issues, counsel for the defendant can demonstrate through cross-examination that the plaintiff's statements are not trustworthy. During summation, counsel can also suggest to the jury that the plaintiff's testimony be evaluated "with suspicion," especially if the plaintiff's behavior deviates too much "from common experience without adequate explanation."<sup>183</sup> Counsel can further stress that self-interest is a

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179. See *Fain v. Smith*, 479 So. 2d 1150, 1155 (Ala. 1985) (per curium).

180. Schuck, *supra* note 86, at 919 (explaining that objective causation involves "what treatment decision . . . a prudent person in the plaintiff's position [would] have made 'if suitably informed of all perils bearing significance'").

181. McNichols, *supra* note 51, at 730 ("Protecting physicians from the vagaries of subjective hindsight decision making is no excuse for backtracking on the law's protection of self-determination."); Weisbard, *supra* note 96, at 760 ("The impact of adopting [objective causation] is to replace an approach based on the needs and values of the particular patient . . . with the needs of hypothetical reasonable or prudent patients.").

182. Jay Katz, *Informed Consent-A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, 164 (1977) ("Questions of the influence of hindsight and bitterness are familiar to juries, as is the problem of self-serving testimony generally."); Morris, *supra* note 11, at 332 ("[I]n any civil case, juries are called upon to evaluate the credibility of every witness who testifies.").

183. *Fain*, 479 So. 2d at 1160 (Jones, J., dissenting) (quoting Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 420 (1974)) ("The danger that a physician-defendant will be unfairly prejudiced by the

critical factor in assessing credibility and determining the weight that plaintiff's testimony should be accorded.<sup>184</sup> The court will probably reinforce this message by instructing the jury to consider the plaintiff's bias in making its credibility determinations.<sup>185</sup> Juries are familiar with human nature and capable of making these assessments.<sup>186</sup>

The courts are also concerned with the hypothetical nature of the plaintiff's testimony if a subjective causation standard is used. However, under an objective standard, the jury would have to consider an even more difficult hypothetical. For subjective causation, the individual plaintiff has to speculate about what she would have decided knowing the undisclosed information. For objective causation, the jury must decide the still more speculative issue of what a reasonable person would have decided had the appropriate information been disclosed.<sup>187</sup> Thus, the speculative nature of subjective causation alone does not justify adopting the objective standard.

The courts' concern, therefore, is not simply the hypothetical nature of the plaintiff's testimony, but the belief that this speculative testimony will be the sole evidence on subjective causation submitted to the jury.<sup>188</sup> By

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patient-plaintiff's testimony is slight. It can be minimized through cross-examination and through defense counsel's perfectly legitimate suggestion in argument to the jury that the patient's statements be received with suspicion if they deviate too greatly from common experience without adequate explanation.").

184. *Id.* (quoting David E. Seidelson, *Medical Malpractice: Informed Consent Cases in "Full Disclosure" Jurisdictions*, 14 DUQ. L. REV. 309, 330-31 (1976)) ("[C]ounsel for the defendant, in summation, will underscore that self-interest is a critical factor to be considered by the jury in determining the credibility to be extended [to] the plaintiff and the weight to be given his testimony.").

185. *Id.* (quoting David E. Seidelson, *Medical Malpractice: Informed Consent Cases in "Full Disclosure" Jurisdictions*, 14 DUQ. L. REV. 309, 330-31 (1976)) ("[A]n instruction [will probably be given by] the court to the jury [in a subjective causation case] to take self-interest into account in determining matters of credibility and weight.").

186. *Id.* ("To accept [the argument that the doctor is in jeopardy under a subjective causation standard] is to accept implicitly the idea that juries are devoid of any understanding of human nature.").

187. *Id.* at 1159 ("If there is no *one* reasonable person, each juror is left with subjectively determining what he or she would have done . . ."); Richard A. Heinemann, *Pushing the Limits of Informed Consent: Johnson v. Kokemoor and Physician-Specific Disclosure*, 1997 WIS. L. REV. 1079, 1084 ("[I]t is virtually impossible to determine what a hypothetical, 'reasonable' patient would have done in similar circumstances.").

188. *See, e.g.*, *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir. 1972) ("[Subjective causation] calls for a subjective determination solely on the testimony of a patient-witness shadowed by the occurrence of the undisclosed risk."); *Fain*, 479 So. 2d at 1152 ("The plaintiffs urge us to adopt the minority subjective standard, by which causation is established

contrast, with objective causation, the jury could determine what a reasonable person would have decided knowing the risks and alternatives by relying not only on the plaintiff's testimony concerning the choice she would have made,<sup>189</sup> but also on the physician's and other experts' testimony about what a reasonable person would have decided.

To deal with this concern, both of the dissenting justices in *Fain v. Smith* suggested that physician testimony also be introduced in subjective causation cases to determine "what a reasonable patient under the same or similar circumstances would have done."<sup>190</sup> This testimony would be used by the jury to determine if the plaintiff's behavior deviates too much "from common experience without adequate explanation."<sup>191</sup> If the courts followed this suggestion, the jury's determination would not rest on the plaintiff's testimony alone.<sup>192</sup>

The credibility of the plaintiff's testimony could also be measured by evidence concerning values and inclinations. Patients make decisions concerning their medical care based not only on medical criteria, but also on their individual beliefs and preferences.<sup>193</sup> If decisions were purely medical, physicians would be better equipped than patients to make them.<sup>194</sup> The patient's values and preferences are often subject to proof;

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solely by the testimony of the plaintiff that he would not have consented to the procedure had he been advised of the particular risk in question.").

189. *Roybal v. Bell*, 778 P.2d 108, 112 (Wyo. 1989) ("Under the objective test, the patient's hindsight testimony is relevant but not controlling.").

190. *Fain*, 479 So. 2d at 1164 (Adams, J., dissenting) ("The plaintiff's testimony [under subjective causation] should not be conclusive and should be tested by testimony offered by the doctor as to what a reasonable patient under the same or similar circumstances would have done."); *id.* at 1163 n.7 (Jones, J., dissenting) ("[Under subjective causation] a defendant [would not be] barred from showing what a reasonable person would or would not do under similar circumstances, so long as such evidence bears solely on the issue of witness credibility and not on the ultimate issue of what someone other than the patient would have done.").

191. *See Fain*, 479 So. 2d at 1160 (Jones, J., dissenting) (quoting Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 420 (1974)).

192. Shultz, *supra* note 18, at 288-89 ("Objective evidence . . . could elucidate why this individual might or probably would have chosen a given path. . . . Thus, the court would find useful testimony about choices that other people actually make when confronted with similar risks and odds.").

193. *See*, Dickens & Cook, *supra* note 139, at 311 ("[P]atients exercise choice in the wider context of their perceptions, values, and intentions.").

194. *Id.* at 310 ("[P]hysicians understand better than most patients the physical and other preconditions to patients' disorders, and the most suitable medical measures for prevention, cure, or relief.").

“they are demonstrable through evidence of conduct or words observable by others.”<sup>195</sup>

For example, some individuals would prefer surgical treatment for back problems, while others would choose long-term rest. The choice may depend on the patient’s aversion to surgery, job, or lifestyle.<sup>196</sup> Some with cancer may choose a longer quantity of life, while others would choose a shorter life with more quality.<sup>197</sup> Those who place an emphasis on living as long as possible are more likely to accept toxic treatments than those who would trade quantity for quality of life.<sup>198</sup> Furthermore, “[i]ndividual factors such as family dynamics, religious beliefs, and financial burden may play a strong role in preferences.”<sup>199</sup> In one study, 30% of adults stated that they would rather die “than live permanently in a nursing home.”<sup>200</sup> This preference “may affect patients’ wishes regarding aggressive intervention during hospitalization.”<sup>201</sup> In all of these examples, the patient’s values and preferences would significantly affect the decision the plaintiff would make if properly informed of the risks and alternatives.<sup>202</sup> In an informed consent case, testimony concerning the patient’s expressed philosophical and religious beliefs, past behavior, and prior medical decisions could be used to test the credibility of the patient’s testimony concerning the decision she would have made had the omitted information been disclosed.

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195. Shultz, *supra* note 18, at 288.

196. *Id.* at 272 (“A preference for surgical treatment of a back problem or, alternatively, for long-term rest and traction, may depend on the patient’s job or lifestyle.”).

197. D. J. Perez et al., *A Comparison of Time Trade-Off and Quality of Life Measures in Patients with Advanced Cancer*, 6 *QUAL. LIFE RES.* 133, 138 (1997) (“Those who place emphasis on quality of life or who perceive their quality of life to be unacceptable are likely to trade-off quantity of life in favour of quality in decisions about treatment.”).

198. *Id.* (“Patients who place emphasis on quantity of life may be more ready to accept toxic treatments to prolong life.”).

199. See Lynne W. Stevenson et al., *Changing Preferences for Survival After Hospitalization with Advanced Heart Failure*, 52 *J. AM. C. CARDIOLOGY* 1702, 1707 (2008). Although this quote relates to patients with advanced heart failure, the quoted factors that play a role in choosing to trade quality of time for quantity would be the same.

200. Thomas J. Mattimore et al., *Surrogate and Physician Understanding of Patients’ Preferences for Living Permanently in a Nursing Home*, 45 *J. AM. GERIATRICS SOC.* 818, 823 (1997) (“Fully 30% [of the patients in the study] stated that they would prefer to die rather than live permanently in a nursing home.”).

201. *Id.* at 822.

202. See James L. Bernat & Lynn M. Peterson, *Patient-Centered Informed Consent in Surgical Practice*, 141 *ARCHIVES SURGERY* 86, 87 (2006) (“Patients contribute their unique set of values, preferences, and health care goals through which they interpret the treatment recommendation.”).

Other examples provide even clearer illustrations of how evidence of the patient's prior behavior and statements might affect the credibility of the patient's testimony concerning the medical choice that would have been made. Individuals concerned about chemical additives in food and pregnant women who prefer to avoid prescription drugs until childbirth would be more likely to choose a treatment that involves rest or natural remedies, rather than one that requires medication.<sup>203</sup> A patient who had undergone several elective surgeries would find it difficult to argue that he would be averse to surgery.<sup>204</sup> For example, in *Smith v. Reisig*, the defendant introduced evidence in an informed consent case that the plaintiff patient had consented to prior surgeries after being informed of the far greater risks of those procedures.<sup>205</sup> Testimony concerning a patient's values, prior statements, and behavior could be so compelling that it could be used to prove causation, even if the plaintiff died during the medical procedure.

Using evidence of the patient's prior statements, philosophical and religious beliefs, morals, and patterns of behavior to determine the medical decision a patient would have made is not a new idea.<sup>206</sup> Courts regularly

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203. See Tietz, *supra* note 86, at 393-94 (“[T]he heightened concern about nutrition and health, which often causes a person to stop smoking and to avoid chemical additives in foods, may also lead that person to an aversion to all drugs and to a preference for the nondrug, or least-potent drug, alternative . . . [and] a pregnant woman might want to weigh for herself the benefits from her use of a particular drug against the risks the drug presents to the fetus.”).

204. Kraushar & Steinberg, *supra* note 152, at 353 (“If the plaintiff is a surgery seeker and has undergone countless elective procedures such as a face-lift or blepharoplasty, he may be far more likely to undergo surgery, regardless of the risks, than the prudent man.”).

205. *Smith v. Reisig*, 686 P.2d 285, 288 (Okla. 1984) (“[O]ther evidence indicated that she had been informed of far greater risks in the past than for this surgery, and still consented.”).

206. See, e.g., *In re A.C.*, 573 A.2d 1235, 1250 (D.C. Cir. 1990) (“The court in a substituted judgment case . . . should pay special attention to the known values and goals of the incapacitated patient, and should strive, if possible, to extrapolate from those values and goals what the patient's [medical] decision would be.”); *In re Truselo*, 846 A.2d 256, 271 (Del. Fam. Ct. 2000) (quoting *In re Tavel*, 661 A.2d 1061, 1068 (Del. 1995) (“The surrogate considers the patient's prior statements about and reactions to medical issues, and all the facts of the patient's personality that the surrogate is familiar with—with, of course, particular reference to his or her relevant philosophical, theological, and ethical values—in order to extrapolate what course of medical treatment the patient would choose.”); Lynn E. Lebit, *Compelled Medical Procedures Involving Minors and Incompetents and Misapplication of the Substituted Judgments Doctrine*, 7 J.L. & HEALTH 107, 109-10 (1993) (“The once competent person has developed a system of morals and beliefs, and patterns of

use substituted judgment to determine the medical decision an incompetent person would have made when competent by taking these factors into account.<sup>207</sup>

Thus, counsel and the court can warn the jury that the patient's testimony may be self-serving. The jury can evaluate the credibility of plaintiff's testimony by weighing evidence concerning the medical treatment a reasonable person would have chosen under the circumstances and plaintiff's explanation for deviating from this norm. That evidence, combined with proof of prior statements, behavior, and values, will go a long way toward dealing with the negatives associated with a subjective causation standard.<sup>208</sup>

#### *VII. The Disclosure Standards in Every State Are Objective to Protect Physicians*

The techniques mentioned above should significantly reduce the problems associated with subjective causation, but cannot completely eliminate them. This should not be a substantial concern because physicians can avoid liability entirely by giving appropriate disclosure to their patients. New technologies can help physicians easily accomplish this goal.

In order to succeed on an informed consent claim, the patient must prove (1) there was a duty to disclose, (2) breach of that duty, (3) causation, and (4) damages.<sup>209</sup> Therefore, as the Supreme Court of Oklahoma wrote in

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behavior which the court can examine when evaluating what she would do in a particular situation.”).

207. See, e.g., *Cruzan v. Dir. Mo. Dep't of Health*, 497 U.S. 261, 271 (1990) (“[Under] a ‘substituted judgment’ standard . . . courts were to determine what an incompetent individual’s decision would have been under the circumstances.”); *In re Truselo*, 846 A.2d at 271 (“[The purpose of substituted judgment] is to ensure that the surrogate decision-maker determines, as best it can, what choice the individual, if competent, would have made with respect to medical procedures.”); Jennifer K. Robbennolt et al., *Advancing the Rights of Children and Adolescents to be Altruistic: Bone Marrow Donation by Minors*, 9 J.L. & HEALTH 213, 221 (1995) (quoting *In re Conroy*, 486 A.2d 1209, 1229 (N.J. 1985)) (“When executing a decision based on the substituted judgment standard, a court purports to ‘determine and effectuate, insofar as possible, the decision that the patient would have made if competent.’”).

208. It should be noted that the subjective causation standard may still be “a very significant barrier” to recovery, although much less of a barrier than objective causation. See McNichols, *supra* note 51, at 731.

209. See Kroft, *supra* note 47, at 464-65; Weisbard, *supra* note 96, at 758 (footnote omitted) (“The plaintiff must allege and prove that the physician violated a legally

*Scott v. Bradford*, “a careful practitioner can always protect himself by insuring that he has adequately informed each patient he treats. If he does not breach this duty, a causation problem will not arise.”<sup>210</sup>

Both of the disclosure standards used in the United States are objective, so they are not hard for physicians to meet.<sup>211</sup> Approximately half the states use a physician-based or professional approach.<sup>212</sup> Under this approach, physicians must disclose only the medical information that a reasonable physician in the same or a similar community<sup>213</sup> would disclose under similar circumstances.<sup>214</sup>

Some have criticized the professional standard for deferring too much to the medical community and for requiring the plaintiff to produce an expert

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established duty to disclose a particular risk, that the undisclosed risk materialized in a physical injury, and that the failure to disclose ‘caused’ the patient to consent to a procedure which otherwise would have been rejected.”).

210. *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979).

211. Sones, *supra* note 58, at 260 (“As far as this Author is aware, there are no courts adopting a subjective disclosure standard.”). Generally, to meet informed consent requirements, physicians must disclose the nature and purpose of the treatment, risks, and alternatives. *See, e. g.*, Atwell, *supra* note 69, at 596 (footnote omitted) (“[E]ach patient must be apprised of the nature of the treatment along with any corresponding risks. In addition, the patient should be given information regarding alternatives to treatment.”).

212. Krause, *supra* note 33, at 314 (“According to a recent survey, roughly half of the states have adopted each standard [the ‘professional’ standard and the ‘patient need’ standard], although the professional standard has been adopted by the majority of states that have enacted informed consent statutes.”); Robert Post, *Informed Consent to Abortion: A First Amendment Analysis of Compelled Physician Speech*, 2007 U. ILL. L. REV. 939, 969 (“Jurisdictions are roughly split in defining the scope of a physician’s obligation . . . . Some adopt the ‘professional standard,’ . . . . Others adopt the ‘prudent patient’ standard . . . .”); Richards, *supra* note 12, at 71 (“About twenty-five states adhere to the ‘professional-oriented’ standard of disclosure . . . . An equal number of states measure disclosure in terms of the ‘prudent patient’ standard . . . .”).

213. FURROW ET AL., *supra* note 125, at 310 (“As medicine has become more national in education and practice, the locality rule gave way to a national test for knowledge and skill.”); Richards, *supra* note 12, at 84 (footnote omitted) (“Some jurisdictions apply the ‘locality rule,’ which limits expert testimony to those professionals practicing in the same profession within the same locality. However, in recent years, a growing number of jurisdictions have opted for a ‘national standard,’ which applies to physicians practicing the same specialty in the same or similar community.”).

214. Kroft, *supra* note 47, at 461 (“The traditional standard requires disclosure of information that a reasonable health care provider would disclose in similar circumstances.”); Sones, *supra* note 58, at 259 (“[T]he physician must disclose only the information that a reasonable medical practitioner in the same or similar circumstances would disclose.”).

to testify as to the community disclosure standard.<sup>215</sup> Under the professional standard, the patient has no right to know about any medical risks or alternatives unless physicians collectively decide to disclose them.<sup>216</sup> This would give “virtually unlimited discretion to the medical community to define the proper scope of disclosure.”<sup>217</sup> The professional standard also places a burden on the plaintiff to find an expert because the scope of disclosure is viewed as a medical decision.<sup>218</sup> Finding “an expert witness, such as a physician, who [is] willing to testify against a colleague about what would have been appropriate disclosure in a similar situation” may prove to be an insurmountable burden for a patient.<sup>219</sup>

To deal with these concerns, about half of the states follow the modern trend and have adopted the patient-oriented or patient-centered standard.<sup>220</sup> Under this standard, the physician must disclose the risks and alternatives that a reasonable person in the patient’s circumstances would find material

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215. Other commentators support the professional standard. *See, e.g.*, McNichols, *supra* note 51, at 718-19 n.42 (noting that the reasons supporting the professional standard include: “(1) the complexities of medical science entail that the issue of disclosure, even if not viewed as a medical question, is still better left to the judgment of medical professionals; [and] (2) the professional standard gives professionals a fair way of learning what they must disclose; without its protection they have no real way of knowing what the law proscribes . . . .”); Smith, II, *supra* note 57, at 120 (arguing that the professional standard is preferable because the patient-centered standard “could drive the physician to describe even *quack* treatments for fear that a future jury could find that a reasonable patient might have wished to be informed of such treatments”).

216. Tietz, *supra* note 86, at 372 (“[Under the professional standard,] [t]he patient has no right to know about therapeutic risks unless the medical community collectively has determined to disclose those risks.”).

217. Richards, *supra* note 12, at 97; *see also* McNichols, *supra* note 51, at 719 (quoting *Scott v. Bradford*, 606 P.2d 554, 557 (Okla. 1979)) (“[The professional standard] would perpetuate medical paternalism by giving the profession sweeping authority to decide unilaterally what is in the patient’s best interests.”).

218. Atwell, *supra* note 69, at 596 (“Typically, expert testimony is required to establish the contours of [the professional standard].”); Kroft, *supra* note 47, at 461 (“[The professional standard] requires expert testimony because the determination of what information needs to be disclosed is viewed as a medical question.”); Smith, II, *supra* note 57, at 119 (“[A] jury panel will seek to decide [the professional standard] by comparing the testimony of competing medical experts.”).

219. Lambris, *supra* note 58, at 243-44; *see also* Richards, *supra* note 12, at 98 (“[T]he physician-based standard imposes an insurmountable burden on plaintiffs faced with finding physicians willing to breach the ‘community of silence’ inherent among medical professionals.”).

220. *See supra* note 212.

in making a medical decision.<sup>221</sup> Information is considered material if it is likely to affect the reasonable patient's medical choice concerning treatment.<sup>222</sup> Thus, the professional standard focuses on what the reasonable physician would disclose, while the patient standard focuses on what the reasonable patient would want to know.<sup>223</sup> With the change in standard, the viewpoint switched from the physician to the patient.<sup>224</sup>

For this reason, the patient-oriented standard is more aligned with protecting patient autonomy, the main purpose of informed consent laws.<sup>225</sup> States adopting this standard recognize that physician disclosure obligations

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221. Dolgin, *supra* note 54, at 152 (“[Under the patient-oriented standard,] the physician’s failure to disclose [is] judged with reference to the information that a reasonably prudent person would find ‘material’ in deciding whether to consent to proposed treatment(s).”); Richards, *supra* note 12, at 86 (“[In *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972)], the court determined that the objective standard should be measured by what a reasonable person in the patient’s position would deem material under the circumstances involved.”).

222. *Canterbury*, 464 F.2d at 787 (quoting Jon. R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 Nw. U. L. REV. 628, 640 (1970)) (“[A] risk is thus material when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.”); Gregory D. Jones, *Primum Non Nocere: The Expanding ‘Honest Services’ Mail Fraud Statute and the Physician-Patient Fiduciary Relationship*, 51 VAND. L. REV. 139, 159 (1998) (“[M]aterial information [is] any information that a reasonable patient would deem relevant or want disclosed.”).

223. McNichols, *supra* note 51, at 719 (“[A] patient-oriented standard [is] measured by what patients would want to know, rather than by what physicians think should be disclosed.”); Richards, *supra* note 12, at 82 (footnote omitted) (“The professional standard focuses on what a reasonable physician would disclose in the same or similar circumstances. In contrast, the patient standard focuses on what information a reasonable patient would consider important in order to make an informed medical decision.”).

224. *Canterbury*, 464 F.2d at 787 (“[T]he issue on nondisclosure must be approached from the viewpoint of the reasonableness of the physician’s divulgence in terms of what he knows or should know to be the patient’s informational needs.”); Atwell, *supra* note 69, at 596-97 (“[T]he court in *Canterbury* reasoned that whether or not adequate information has been given to the patient must be determined from the viewpoint of the reasonable patient—not the viewpoint of the medical professional.”).

225. Atwell, *supra* note 69, at 597 n.34 (“From a bioethical perspective, the reasonable patient standard is much more compatible with the notion of patient autonomy than the professional standard.”); Kapp, *supra* note 120, at 97 (“The philosophical rationale . . . for the progression in informed consent doctrine from a reasonable physician to a patient-oriented standard of information disclosure is the belief that the latter approach better promotes the ethical ideal of patient autonomy, while the former approach reinforces the negative practice of physician paternalism . . . .”); Krause, *supra* note 33, at 316 (“On a theoretical level, the patient need standard is far more protective of patient autonomy than a standard that defers to professional medical judgment . . . .”).

should be determined by the patient's needs, rather than the medical judgment of physicians.<sup>226</sup> This standard also avoids the necessity of using expert testimony to prove that the disclosure standard has not been met. Although some expert testimony might be indispensable to explain the medical procedures involved and the risks and alternatives,<sup>227</sup> no expert testimony is necessary with respect to the patient disclosure standard itself.<sup>228</sup> Deciding what a reasonable person would want to know does not require technical expertise.<sup>229</sup>

Some have criticized the patient-oriented standard for not going far enough to protect patient autonomy.<sup>230</sup> Both this standard and the professional standard are objective and neither considers the needs and preferences of the individual patient.<sup>231</sup> While recognizing these concerns, the courts and legislatures selected an objective standard to ensure that diligent physicians could meet the disclosure requirements.<sup>232</sup> An objective

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226. See, e.g., *Sard v. Hardy*, 379 A.2d 1014, 1021 (Md. 1977) (“[P]rotection of the patient’s fundamental right of physical self-determination—the very cornerstone of the informed consent doctrine—mandates that the scope of a physician’s duty to disclose therapeutic risks and alternatives be governed by the patient’s informational needs.”).

227. BARRY R. FURROW ET AL., *HEALTH LAW* 356 (West, 4th ed. 2001) (“[With respect to the patient-oriented standard,] [e]xpert testimony is still needed . . . to clarify the treatments and their probabilities of risks.”).

228. Kroft, *supra* note 47, at 461 (“[The patient-oriented approach] does not require expert testimony . . .”).

229. FURROW ET AL., *supra* note 125, at 356 (“[T]he question of whether a physician disclosed risks which a reasonable person would find material is for the trier of fact, and technical expertise is not required.”).

230. Krause, *supra* note 33, at 316 (“[E]ven the patient need standard has been criticized for relying on the hypothetical ‘reasonable person’ rather than focusing on what would have assisted the particular patient in the exercise of his or her autonomy.”); Tietz, *supra* note 86, at 379-80 (footnote omitted) (“[C]ourts do not impose a duty of full communication on physicians, which is to the detriment of the particular patient, who has needs, priorities, and preferences different from those of the ‘reasonable’ patient.”).

231. Although both disclosure standards are objective, they have a subjective component. The disclosure must be reasonable “under the circumstances.” “Under the circumstances” is generally interpreted to mean medical circumstances, but would probably also require physicians to address the patient’s expressed personal concerns. See Gatter, *supra* note 70, at 568, 576-77 (giving examples of cases where the courts held the physician liable based on the physician’s actual knowledge of the patient’s unique situation at the time of disclosure).

232. Tietz, *supra* note 86, at 380 (noting that the court in *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), chose an objective standard because “physicians cannot know individual patients well enough to determine what information is material to their personal choices”). It should also be noted that under both standards, “physicians are obligated to disclose only those risks ‘of which the physician should have been aware’, which is to say

standard does not unfairly require the physician to guess the peculiar idiosyncrasies and preferences of an individual patient.<sup>233</sup> While the physician cannot know the exact concerns of each patient, she can protect herself by meeting the disclosure needs of the average, reasonable person.<sup>234</sup> Thus, objective disclosure balances the informational needs of the patient and the liability concerns of the physician in an attempt to protect both<sup>235</sup> and, unlike objective causation, provides this protection without eviscerating the informed consent cause of action.

*VIII. Disclosure of Medical Information to Patients Is Often Not Meaningful or Intelligible*

Despite the well-intentioned disclosure standards, disclosure of medical information to patients is far from optimal. Studies have shown that the information given to patients is often not meaningful or intelligible.<sup>236</sup>

Patients frequently receive written forms containing a formalistic recitation of endless potential risks and complicated medical information.<sup>237</sup>

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only those risks that are ‘recognized within the medical community.’” See Post, *supra* note 212, at 969-70.

233. See Katz, *supra* note 153, at 77 (“[In *Canterbury*], Justice Robinson appreciated that a subjective test was more in keeping with the right of self-determination, but he rejected it for fear that such a test would unfairly burden physicians by requiring them to guess the needs of particular patients.”); Sones, *supra* note 58, at 260 (“[O]ne questions whether imposing liability based on a subjective, patient-based standard of disclosure might render physicians, who typically are unaware of the intricacies of each patient’s personal preferences, unable to avoid liability for nondisclosure.”).

234. *Canterbury*, 464 F.2d at 787 (“He cannot know with complete exactitude what the patient would consider important to his decision, but on the basis of his medical training and experience he can sense how the average, reasonable patient expectably would react.”); *Marsingill v. O’Malley*, 128 P.3d 151, 159 (Alaska 2006) (“A doctor’s failure to provide sufficient information will not render him liable unless the doctor knew or reasonably should have known that the patient might have considered the information to be important.”); Richards, *supra* note 12, at 95 (“[E]rring on the side of more disclosure means that a physician is susceptible only to the most obscure of medical catastrophes.”).

235. Krause, *supra* note 33, at 316 (quoting *Canterbury*, 464 F.2d at 787) (“[T]he disclosure [standard] ‘remains objective with due regard for the patient’s informational needs and with suitable leeway for the physician’s situation.’”).

236. Sones, *supra* note 58, at 266 (“[S]tudies and commentary indicate[ ] that actual informed consent practices fail to [communicate reliable risk information in an intelligible and meaningful fashion.]”).

237. Victor Ali, Note, *Consent Forms as Part of the Informed Consent Process: Moving Away from ‘Medical Miranda’*, 54 HASTINGS L.J. 1575, 1578 (2003) (“[C]onsent forms are often used to inundate the patient with legally required information, without regard to the usefulness of this approach in increasing the patient’s level of understanding.”).

The purpose of the forms is usually to protect the physician against liability, rather than to ensure that the patient comprehends the medical procedure, its risks and alternatives.<sup>238</sup> Patients understand this purpose when reading the forms and are skeptical of the disclosures they contain.<sup>239</sup>

Inundating patients with medical facts can result in information overload, especially because there is usually no attempt to highlight the disclosures that are most important.<sup>240</sup> In addition, because the forms are designed to protect physicians, rather than to ensure comprehension,<sup>241</sup> the language is frequently too advanced for the average patient.<sup>242</sup> The forms also do not take cultural or linguistic barriers into account.<sup>243</sup>

To deal with these concerns, commentators have suggested highlighting the most useful information and adopting non-legal language and bullet points.<sup>244</sup> Nonspecific terms, such as “high,” “insignificant,” “probably,” or “may,” could be clarified by comparing risks.<sup>245</sup> For example, the patient

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238. *Id.* at 1577 (“Under [the harm-avoidance model], physicians disclose the risks of and alternatives to a particular treatment to avoid lawsuits, rather than to allow the patient to make an independent and informed decision.”).

239. *See id.* at 1584 (“[B]ecause patients view consent forms as legal protection for physicians, they are skeptical of the forms’ utility as a tool to enhance their own understanding of the medical procedure.”).

240. Krause, *supra* note 33, at 358 (noting that “making an endless variety of information available in the absence of research identifying which data is truly useful” results in “‘information overload’ [and] still leaves consumers without necessary information”).

241. Ali, *supra* note 237, at 1584 (“[W]hile much effort has been dedicated to increasing the content of consent forms, little attention has been paid to how easy they are to read and understand.”).

242. Kapp, *supra* note 120, at 100 (quoting JUDITH HIBBARD ET AL., AARP PUB. POLICY INST., HEALTH LITERACY RESEARCH REPORT: IDENTIFYING MEDICARE BENEFICIARIES WITH POOR HEALTH LITERACY SKILLS: IS A SHORT SCREENING INDEX FEASIBLE I (2005)), available at [http://assets.aarp.org/rgcenter/health/2005\\_01\\_literacy.pdf](http://assets.aarp.org/rgcenter/health/2005_01_literacy.pdf) (“[Literacy levels may] ‘prevent people from being involved and active participants in their care.’”); Melissa M. Bottrell et al., *Hospital Informed Consent for Procedure Forms: Facilitating Quality Patient-Physician Interaction*, 135 ARCHIVES SURGERY 26, 27 (2000) (“Most forms are written with language too sophisticated for the majority of people.”).

243. Bottrell et al., *supra* note 242, at 27 (“[P]atients often do not receive adequate information due to technical jargon or cultural or linguistic barriers.”).

244. *Id.* (“Suggested changes [to informed consent forms] include writing in nonlegalistic language, making less abstract statements, and including graphic features such as bullet points and boldface-type statements.”).

245. Sones, *supra* note 58, at 266 (“General terms such as ‘high’ or ‘insignificant; and ambiguous terms such as ‘may’ or ‘probably will’ give the patient little basis for assessing risk in a refined way.”); *see also* Schuck, *supra* note 86, at 906 (urging physicians to “describe risks in comparative terms”).

could be told that the risk of harm from the surgery is equivalent to the risk of a collision while driving home from work.<sup>246</sup> Even though these suggestions would be easy to implement, the problems remain.

Physician conversations with patients do not fare much better. Meetings with physicians average about seven minutes.<sup>247</sup> During this short time period, physicians often disclose too much information and employ too much medical jargon.<sup>248</sup> Patients do not have sufficient time to absorb the information and express their concerns.<sup>249</sup>

In addition, physicians frequently tailor discussions to convince the patient to choose the treatment the physician has already selected, rather than to elicit the patient's preferences.<sup>250</sup> This practice is likely to affect patient autonomy, especially when the patient is in poor health.<sup>251</sup>

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246. Schuck, *supra* note 85, at 949 (recommending that the physician use a "comparative contextualized framework" when describing risks. For example, the physician "might compare the medical risk to the risk of certain types of common accidents or other adverse outcomes (e.g., collisions from driving at night, lung cancer from smoking, complications from drinking alcohol while pregnant) . . .").

247. Peter Brensilver, *E-Formed Consent: Evaluating the Interplay Between Interactive Technology and Informed Consent*, 70 GEO. WASH. L. REV. 613, 625 (2002) ("The average doctor visit is currently about seven minutes . . .").

248. Ken Berger, *Informed Consent: Information or Knowledge?* 22 MED. & L. 743, 747 (2003) ("Impediments to knowledge include: too much information, contradictory information, too much medical jargon, too much information at one time, and insufficient time to absorb the information."); *see also* David Sobel & Pamela L. Popp, *Informed Consent and Expectation Management: A Case Study*, J. HEALTHCARE RISK MGMT., vol. 26, no. 4, AT 21, 22 (2006) ("Traditional informed consent, where the physician relays the risks and benefits of the procedure or treatment to the patient often leaves the patient feeling overwhelmed and confused by the quantity of the information provided. In fact, on average, approximately 80 percent of the information conveyed to a patient in a clinic setting is summarily forgotten.").

249. *Canterbury v. Spence*, 464 F.2d 772, 783, n.36, 790 (D.C. Cir. 1972) ("Perhaps relatively few patients could in any event identify the relevant questions in the absence of prior explanation by the physician.").

250. Morris, *supra* note 11, at 315 ("[I]nformation is often given to patients not to enable them to choose, but to encourage them to cooperate with doctors and to comply with decisions that have already been made, not by patients as law envisions, but by doctors."); Rachael Andersen-Watts, *The Failure of Breast Cancer Informed Consent Statutes*, 14 MICH. J. GENDER & L. 201, 210 (2008) ("Decisions may have more to do with presentation than information, considering the inherent dependence of patients on doctors."); Madison, *supra* note 27, at 12 ("Physicians may influence patients' decisions through the nature of their disclosures.").

251. Physicians can frame the information they disclose to affect patients' decisions. *See* Roybal, 778 P.2d at 117 (citing a study demonstrating that framing risks in terms of survival or mortality significantly affected the research subject's decisions and noting that "[o]n the

Empirical studies suggest that patients suffering from illness are less assertive and feel compelled to accept the physician's recommendations.<sup>252</sup>

As this discussion illustrates, the courts and physicians focus on patient consent, rather than patient understanding.<sup>253</sup> But to achieve the purpose of informed consent—rather than merely meeting its technical requirements—the focus must be on determining the patient's treatment preferences and delivering information designed to achieve patient understanding.<sup>254</sup>

Researchers recommend that physicians accomplish these goals by implementing shared decision-making,<sup>255</sup> which emphasizes on-going collaboration between the physician and patient.<sup>256</sup> Ideally, the physician would analyze the technical medical facts and deliver that information to the patient in a clear and comprehensible manner.<sup>257</sup> The patient would

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average, subjects preferred radiation therapy to surgery 42% of the time when the information was presented in terms of the probability of dying, but only 25% of the time when information was presented in terms of the probability of living”).

252. Guy A. M. Widdershoven & Frank W.S.M. Verheggen, *Improving Informed Consent by Implementing Shared Decisionmaking in Health Care*, IRB, July-Aug. 1999, at 1, 1 (“Empirical studies suggest that as a result of illness, patients tend to feel they must do whatever the doctor suggests, and tend to become less aggressive in seeking alternatives and passive out of a sense of powerlessness in the face of massive technical information.”).

253. Ali, *supra* note 237, at 1589 (“Both legislatures and courts focus primarily on whether or not there was formalistic consent to a particular medical procedure, rather than on whether the patient fully understood the information and played an active role in making the decision.”); Bottrell et al., *supra* note 242, at 27 (“Physicians rarely assess patients’ understanding of [the] information or treatment decision.”).

254. Schuck, *supra* note 86, at 903 (noting that interactions between doctors and patients should “be dialogic rather than authoritative, tailored to the individual patient’s emotional needs and cognitive capacities rather than formulaic, aimed at maximizing patient autonomy and comprehension rather than mere information flow, and sensitive to the distortions that can be created by power differentials between physician and patient.”).

255. Widdershoven & Verheggen, *supra* note 252, at 4 (“Shared decisionmaking is increasingly advocated as an ideal model of treatment decisionmaking, striving for an adequate balance between physicians and patients in a collaborative process.”).

256. Jeremy Sugarman, *Informed Consent, Shared Decision-Making and Complementary Alternative Medicine*, 31 J.L. MED. & ETHICS 247, 247 (2003) (“[T]here now seems to be a consensus that informed consent should be considered a process rather than a punctuated event consisting of the completion of an informed consent form.”); Widdershoven & Verheggen, *supra* note 252, at 4 (“[I]nformed consent [should be] an ongoing process of communication about what should be done.”).

257. Walter, *supra* note 57, at 547-48 (“The informed consent doctrine envisages a joint decision-making process in which the physician digests the technical information for the patient and transmits this information in a manner comprehensible by a lay person.”).

discuss her personal preferences, goals, fears, and values. Then, together, the physician and patient would agree on an acceptable treatment plan.<sup>258</sup>

The interaction between the physician and patient should generally consist of more than a single, one-time meeting.<sup>259</sup> Patients are often anxious during their initial appointment with a physician<sup>260</sup> and need time to digest the medical information provided.<sup>261</sup> A follow-up meeting would give the patient an opportunity to deal with her questions and concerns. Equally important, the patient should consult with the physician over the course of her illness. As her condition progresses, the patient makes multiple medical decisions.<sup>262</sup> She must ensure that her understanding stays current and that the physician assimilates her preferences and needs into the treatment plan.<sup>263</sup> For these reasons, the treatment of the patient should be a joint process during which the physician and patient coordinate to maximize patient comprehension and autonomy.<sup>264</sup>

The PPACA incorporates these goals by including a “program to facilitate shared decision making.”<sup>265</sup> The express purpose of this program is “to facilitate collaborative processes between patients and [health care

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258. Bernat & Peterson, *supra* note 202, at 87 (“In shared decision-making, the physician and patient compose a decision-making partnership. The physician contributes information . . . . Patients contribute their unique set of values, preferences, and health care goals . . .”).

259. Arabian, *supra* note 117, at 273, n.47 (“[I]t is rare for the decisionmaking of a patient to conform to the single event paradigm . . . .”); Melissa M. Goldstein, *The Effects of Health Information Technology on the Physician-Patient Relationship: Health Information Technology and the Idea of Informed Consent*, 38 J.L. MED. & ETHICS 27, 28 (2010) (“The legal doctrine of informed consent . . . is generally conceived as a one-time event, while the model based in autonomy and authorization emphasizes process and the clinician-patient interaction, which in the treatment context sometimes includes repeated exchanges and de-emphasizes a written document.”).

260. Ali, *supra* note 237, at 1578 (“[If the decision is] at a single discrete point in time, the patient is likely to be experiencing high levels of anxiety at the moment of the decision—another barrier to the effective integration of relevant information.”).

261. *Id.* (“The one-shot nature of the medical decision under this model makes it difficult for patients to assimilate the voluminous and complicated information with which they are being presented.”).

262. *Id.* at 1577-78 (“In reality . . . [t]reatment . . . involves a series of interactions and decisions as more information becomes available and the patient’s understanding of the procedure evolves.”).

263. Bernat & Peterson, *supra* note 202, at 86 (“Surgical consent is not an event or a signature on a form but is an ongoing process of communication that continues throughout the preoperative, perioperative, and postoperative care.”).

264. Schuck, *supra* note 86, at 903.

265. Patient Protection and Affordable Care Act, 42 U.S.C.A. § 299b-36(a) (West 2011).

providers],” provide patients with “information about trade-offs among treatment options, and facilitate[ ] the incorporation of patient preferences and values into the medical plan.”<sup>266</sup>

While implementing these changes is desirable, this article does not suggest that current disclosure standards be modified to actively require shared decision-making or meaningful disclosure. Although the medical community should strive to meet these goals, constructing complex statutes requiring detailed disclosure and physician/patient collaboration does not appear to be the answer.<sup>267</sup> It would be virtually impossible to create a statute that successfully mandates the details of ongoing physician/patient interactions, especially when the goal of those interactions is to achieve an effective physician/patient partnership for decision-making.

Instead, this article advocates a change from objective to subjective causation to give teeth to current informed consent laws. The current laws have done little to encourage physicians to enhance the decision-making process. Moving to subjective causation will make informed consent a viable cause of action and hopefully serve as a catalyst for meaningful disclosure. Also, because subjective causation highlights what the patient would have chosen knowing the risks and alternatives, that standard will help focus attention on individual preferences and concerns. Making informed consent a viable claim is a push in the right direction and that push has a greater likelihood of resulting in serious change than ever before because of exciting new technologies.

#### *IX. Current Technology Can Make Informed Consent Inexpensive and Easy*

Electronic communication has been described as the “‘next transformation’ in healthcare.”<sup>268</sup> This transformation includes the use of

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266. *Id.*

267. Mariner, *supra* note 10, at 405 (“One thing seems clear. We should not inject more law into the physician-patient relationship than absolutely necessary.”).

268. Frances H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, 31 *IND. L. REV.* 1019, 1022-23 (1998) (“On-line services have been described as the ‘next transformation’ in health care . . . .”); Gary L. Kreps & Linda Neuhauser, *New Directions in eHealth Communication: Opportunities and Challenges*, 78 *PATIENT EDUC. & COUNSELING* 329, 329 (2010) (“There is a communication revolution brewing in the modern health care system fueled by the growth of powerful new health information technologies . . . .”); Brensilver, *supra* note 247, at 624 (“The emergence of electronic communication creates a unique opportunity to rectify the broken structure of informed consent . . . .”).

computers to supplement traditional informed consent.<sup>269</sup> Multimedia presentations and extensive databases<sup>270</sup> can be used to increase patient comprehension and improve patient interactions with physicians.<sup>271</sup> The PPACA actively supports the use of effective decision aids to provide patients with information about treatment options. A decision aid is defined in the Act as “an educational tool that helps patients . . . [t]o understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them . . . .”<sup>272</sup>

Computer programs have unparalleled potential to increase patient understanding of medical procedures, risks, and alternatives. There are already several websites that provide all the information necessary to give patients detailed disclosures on many medical treatments,<sup>273</sup> and some of these websites use current educational methods to effectively transmit this information to the patient. Educational tools can include explanatory text, graphics, photographs, animations, diagrams,<sup>274</sup> and questions with

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269. Widdershoven & Verheggen, *supra* note 252, at 2 (“One way to enhance informed consent is to design computer programs that enable patients to actively acquire information and balance options.”).

270. Laura Landro, *Consent Forms that Patients can Understand*, WALL ST. J., Feb. 6, 2008 at D1 (“[Hospitals] are [ ] turning to high-tech solutions, such as Web-based databases to help calculate risks and benefits for patients before consents are signed . . . .”).

271. *See, e.g.*, Brensilver, *supra* note 247, at 624.

272. Patient Protection and Affordable Care Act, 42 U.S.C.A. § 299b-36(b)(1).

273. *See* John Pulley, *The Age of Consent Tools*, GOV'T HEALTH IT (Nov. 7, 2008), <http://govhealthit.com/news/age-consent-tools> (“[iMedConsent] has consent forms for more than 2,100 medical and surgical procedures, patient education documents and an image gallery that doctors use to explain complex procedures.”).

274. *See e.g.*, Arnold J. Rosoff, *Informed Consent in the Electronic Age*, 25 AM. J.L. & MED. 367, 368 (1999) (noting that computer programs can contain thorough explanations, full details on the risks and consequences of the available options, an opportunity to test comprehension, sophisticated diagrams, computer animations, and other cutting-edge instructional devices.); Melissa Bekelja Wanzer et al., *Enhancing the “Informed” in Informed Consent: A Pilot Test of a Multimedia Presentation*, 25 HEALTH COMM. 365, 367 (2010) (noting that multimedia computer presentations can “utilize a number of strategies such as simple language [and] graphics.”); Brensilver, *supra* note 247, at 624 (“Portnoy’s web site depicts approximately 40 operations through text, illustrations, photographs and animation . . . .”); Brensilver, *supra* note 247, at 624, n.98 (“Forbes magazine noted that YourSurgery.com contains ‘detailed descriptions on over 50 surgeries,’ and that “[a]ll the details come complete with anatomy descriptions, complications, and graphics of the incisions.”).

feedback.<sup>275</sup> The disclosures include explanations of preoperative, operative, and postoperative care and the risks, benefits and alternatives to treatment.<sup>276</sup>

The programs can also be personalized based on language preference<sup>277</sup> and planned treatment. Some computer systems have large databases and can tailor the information supplied to the patient's specific medical condition and procedure.<sup>278</sup> They can also deliver personalized consent forms adapted to the patient's individual medical diagnosis.<sup>279</sup>

The use of multimedia on-line sources for supplying necessary disclosures has several advantages over traditional meetings with physicians. A multimedia approach, with diagrams, animations, and other current instructional devices, can vastly improve patient understanding and recall.<sup>280</sup> "In fact, many researchers have found that knowledge increased

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275. Wanzer et al., *supra* note 274, at 367 (noting that there were several studies of multimedia presentations containing questions with feedback); Brensilver, *supra* note 247, at 624 ("Computer-based patient education programs can be used to . . . present[ ] understandable text and diagrams and test [ ] the patient's knowledge as he or she proceeds."); Landro, *supra* note 270, at 35 ("One study at UCSF found that by writing consent forms at a sixth-grade reading level, testing patients' comprehension and explaining things until they understood, the number of patients who could answer comprehension questions correctly rose to 98% from between 15% and 28%.")

276. Sobel & Popp, *supra* note 248, at 23 ("Using multiple learning modalities and medical animations, the [online interactive educational] tool guides patients through the experience from pre-op to post-op, including risks, benefits and alternatives.")

277. Wanzer et al., *supra* note 274, at 367 (noting that multimedia computer presentations can use "oral information presented in different languages to overcome barriers associated with informed consent.")

278. Kreps & Neuheuser, *supra* note 268, at 330 ("[H]ealth educators can use computer systems to select information from large databases and match it with an individual's attributes or preferences ('mass customization' or 'computer tailoring')."); Landro, *supra* note 270, at D1 ("Web-based databases [can] help calculate risks and benefits for patients before consents are signed . . .").

279. *See e.g.*, John A. Valenza, SmartConsent: A Computerized Informed Consent for Dental Patients, AMIA 2008 Symposium Proceedings 1161, 1161 (2008) ("[T]he advent of electronic health records allows an informed consent to be automatically personalized based on the patient's demographic profile, literacy level, language preference, planned treatment, and prior medical history."); Pulley, *supra* note 273 ("[iMedConsent's computer system] has consent forms for more than 2,100 medical and surgical procedures . . .").

280. Rosoff, *supra* note 274, at 373 ("[Videotapes were a] major improvement in terms of the ability to present information in an easily understandable form . . ."); Wanzer et al., *supra* note 274, at 367 (noting that graphics and animation were "shown to increase comprehension" and that several studies of multimedia presentations containing questions with feedback found "that patients viewing the presentations had higher knowledge scores than those that did not").

in groups receiving computer-based information over a traditional oral presentation.”<sup>281</sup> The medical information can also be presented more thoroughly and effectively than in face-to-face meetings with physicians because there are no time constraints.<sup>282</sup>

Another benefit of a computer program is that the patient can set his own pace for getting through the material. He can take as long as necessary to understand the information<sup>283</sup> and can review the disclosures and demonstrations multiple times.<sup>284</sup> The patient also has time to absorb the material presented<sup>285</sup> and to discuss options and concerns with family and friends prior to meeting with the physician.<sup>286</sup>

The physician/patient meeting should take place even when multimedia programs are used. While computer systems improve patient understanding, they should not serve as a substitute for face-to-face interactions with the physician. The patient needs the physician to answer her questions, clear up any confusion, and address her personal concerns.<sup>287</sup>

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281. Wanzer et al., *supra* note 274, at 367; T. H. Moseley et al., *Effects of Presentation Method on the Understanding of Informed Consent*, 90 BR. J. OPHTHALMOL. 990, 991 (2006) (“[T]he use of visual aids improved the ability of our participants to remember facts and risks associated with cataract surgery beyond a verbal presentation alone.”); Kiss et al., *supra* note 153, at 95 (“[I]t has been well documented in several clinical studies that very little of the information given during the [traditional] informed consent procedure can be retained and recalled by the patients even [one] day after the surgery.”).

282. Rosoff, *supra* note 274, at 367 (“[T]he computer program can convey the complex facts that bear on this decision process more fully and effectively than [the physician] has the ability or time to do . . .”).

283. *Id.* (“[Patients] can consider each aspect of the explanation fully, spending as long on each part as they feel is necessary.”); Wanzer et al., *supra* note 274, at 367 (noting that, with computer presentations, patients are “more in control of their learning pace”).

284. Sobel & Popp, *supra* note 248, at 23 (“[O]pportunities are given to . . . review a specific section before proceeding to the end of the [interactive educational] tool.”); Wanzer et al., *supra* note 274, at 367 (“Each patient would see the same information, ensuring that information is not skipped over”).

285. Brensilver, *supra* note 247, at 625 (“Patients can benefit from a web-based disclosure by gaining additional time, privacy (at their home), and confidentiality while perusing a wide scope of information.”).

286. Rosoff, *supra* note 274, at 367 (“[Patients] can discuss the information and the choices more freely than they may feel comfortable doing in the doctor’s presence.”); Sobel & Popp, *supra* note 248, at 21 (“A significant percentage of the patients even engaged their family and friends in reviewing the [on-line interactive educational] tool . . .”).

287. Rosoff, *supra* note 274, at 383 (“[I]t is unlikely that any form of information exchange, however complete in other respects, will be deemed satisfactory unless the patient has the opportunity to meet face-to-face with the physician to ask questions, request clarifications and voice concerns or reservations.”).

The physician must ascertain the patient's values and preferences so that the physician and patient can decide together on a treatment plan.<sup>288</sup> The face-to-face meeting is also invaluable in developing a trusting relationship.<sup>289</sup>

Computer systems can make the meeting between the physician and patient more meaningful and beneficial for both. By the time the meeting takes place, the patient will have digested the medical information provided by the computer program and determined her questions and personal concerns.<sup>290</sup> Because the patient will be focused and prepared, she can make efficient use of the relatively short time she has with the physician.<sup>291</sup> The electronic system will also reduce the information asymmetry between the physician and patient, which will allow "them to communicate more meaningfully and thus give the patient more influence in the decisionmaking process."<sup>292</sup>

With the help of these computer programs, the physician can also make more efficient use of this meeting time. Without these technologies, physicians would have the responsibility for educating their patients on increasingly complex medical procedures.<sup>293</sup> Multimedia electronic programs can assume the initial burden of these explanations and give physicians time to focus on the patient's questions, preferences, and

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288. Brensilver, *supra* note 247, at 625 ("[B]y sacrificing face-to-face interaction, the physician may fail to ascertain the patient's values and priorities . . .").

289. Rosoff, *supra* note 274, at 384 ("If the electronic information disclosure substitutes for, rather than supplements, physician face time, . . . [the] trust relationship may be sacrificed."); Brensilver, *supra* note 247, at 625 ("[T]he establishment of trust, an essential element in the physician-patient relationship, is stymied by dependence on electronic mediums.").

290. Sobel & Popp, *supra* note 248, at 21 ("Utilizing an interactive educational tool enhances the patient's appreciation for the specifics of the treatment/procedure, increases their awareness of risks, [and] provides information and comfort in knowledge . . ."). If these computer technologies are adopted, perhaps health coaches could be employed to help patients who are not computer savvy or need help with the medical information provided. This is not a new idea. There are currently programs that employ health coaches, such as HICAP (Health Care Insurance Counseling and Advocacy Program) in California, which helps Medicare patients understand their "specific rights and health care options." CAL. HEALTH ADVOC., <http://www.cahealthadvocates.org/HICAP> (retrieved Aug. 14, 2011).

291. Brensilver, *supra* note 247, at 625 ("The average doctor visit is currently about seven minutes, and a 'well-informed consumer can make the most of that time.'").

292. Rosoff, *supra* note 274, at 384.

293. Sobel & Popp, *supra* note 248, at 21 ("Physicians are burdened with ever-increasing patient volumes and the need to educate these patients regarding the complex and, at times, unpredictable behavior of disease.").

concerns. In this way also, computers enhance the joint decision-making process.<sup>294</sup>

Physicians can further maximize the effectiveness of the meeting by choosing computer systems that test the patient's knowledge as the program progresses. These programs document that the patient completed the presentation and highlight the concepts the patient did not understand.<sup>295</sup> Armed with this report, the physician can determine the areas of information the patient finds confusing and focus her discussion on those issues.<sup>296</sup>

Computer systems can also protect the physician from liability and save time and administrative costs. Reports on patient performance provide proof that the patient received and, in most cases, understood the information necessary to meet informed consent requirements.<sup>297</sup> Electronic systems can also save the physician time in explaining the medical procedures<sup>298</sup> and provide savings on personnel and upkeep.<sup>299</sup>

Several computer systems are already employing this technology. The Department of Veterans Affairs (VA) adopted the multimedia electronic

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294. Rosoff, *supra* note 274, at 370 (“[T]he physician and patient who navigate together through [medical] information are engaged in a joint undertaking of great sensitivity and significance.”).

295. *Id.* at 368 (“[T]he program will document the patient’s successful completion of the instructional exercise and provide proof that the patient understands the material essential to his informed consent . . . .”); Pulley, *supra* note 273 (“HealthGate Data makes an interactive tool that educates users and tests whether they are sufficiently informed to give consent.”).

296. Brensilver, *supra* note 247, at 624-25 (“[P]hysicians can use these programs to record the areas in which the patient lacks understanding and then address these points more thoroughly.”); Rosoff, *supra* note 274, at 367-68 (“An electronic record will later reveal to the doctor the points on which the patient may be uncertain, helping to focus further conversation between them.”).

297. Rosoff, *supra* note 274, at 368 (“[T]he computer program generates lasting evidence of that communication, in both paper and electronic form, while also documenting the patient’s comprehension.”); Kraushar & Steinberg, *supra* note 152, at 355 (“[I]nforming the patient of the risks, benefits, and alternatives of a proposed procedure . . . may prove vital in the prevention of a lawsuit.”).

298. Rosoff, *supra* note 274, at 368 (For the doctor's part, he is able to convey to the patient all of the relevant and necessary information with significantly less time and effort than was formally required.)

299. Brensilver, *supra* note 247, at 625 (“[W]hile initiating an electronic system may be costly, its maintenance and upkeep often does not require the personnel and materials that often cause immense administrative costs.”); *see also* Landro, *supra* note 270, at D1 (noting that “electronic forms . . . reduce the problem of lost paper forms that delay procedures, adding to hospital costs”).

system, iMedConsent, for use at all of its 155 medical centers.<sup>300</sup> This system has “consent forms, . . . patient education documents and an image gallery that doctors use to explain complex procedures.”<sup>301</sup> The primary function of iMedConsent is to provide information to physicians to use in their meetings with patients.<sup>302</sup> Other programs such as YourSurgery.Com,<sup>303</sup> Emmi Solutions,<sup>304</sup> and X-Plain<sup>305</sup> have been developed as interactive tools to educate patients directly.

Use of these programs in conjunction with meaningful physician input has the potential to rectify many of the problems related to informed consent.<sup>306</sup> This will be especially true if federal regulatory bodies help ensure that the computer sites are up-to-date and give complete information.<sup>307</sup> The PPACA has already directed the Secretary of Health

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300. Pulley, *supra* note 273 (“iMedConsent [was adopted] to obtain and document informed consent at [the VA’s] 155 medical centers. Some Army and Navy centers are also using the product.”); Mary Anne Gates, *The 411 on Informed Consent*, CTAHQ NEWS: A PUBLICATION OF THE CONNECTICUT ASSOCIATION FOR HEALTHCARE QUALITY, Summer 2007, at 4 (“iMedConsent, a comprehensive, computer-based patient education solution developed by Dialog Medical, provides the basis for the informed consent process in every VA medical center. . . . 83,000 health professionals are trained in VA hospitals each year, and more than one half of all practicing physicians receive some professional education in the VA healthcare system.”).

301. *Id.* (“Whereas iMedConsent primarily supports doctors’ interactions with patients, other products educate patients directly.”).

302. *Id.*

303. Brensilver, *supra* note 247, at 624, n.98 (noting that YourSurgery.com contains “detailed descriptions on over 50 surgeries” and comes with “anatomy descriptions, complications and graphics of the incisions.”).

304. Landro, *supra* note 270, at D1 (“Chicago-based Emmi Solutions, for example, is helping hospitals design new informed-consent forms with interactive programs that patients can view on a home computer prior to signing.”).

305. See PATIENT EDUCATION INSTITUTE, <http://www.patient-education.com> (last visited Jan. 31, 2012).

306. Brensilver, *supra* note 247, at 624 (“The emergence of electronic communication creates a unique opportunity to rectify the broken structure of informed consent . . .”).

307. Brensilver, *supra* note 247, at 629 n.142 (“[I]ncreased cooperation and collaboration between state boards is certain to occur, and new and expanded partnerships with federal regulatory bodies are likely as policymakers attempt to weigh the benefits to the public’s health that this technology can bring, with the threats to the public health its misuse can wreak.”) (citing Ross D. Silverman, *Regulating Medical Practice in the Cyberspace: Issues and Challenges for State Medical Boards*, 26 AM. J.L. & MED. 255, 276 (2001)).

and Human Services to develop standards to review and certify patient decision aids.<sup>308</sup>

If states switched to a subjective causation standard, making informed consent a meaningful cause of action, concerns about lawsuits might prompt more hospitals and physicians to use this new technology. After all, using these systems is easy, efficient, and relatively inexpensive,<sup>309</sup> and improves physician/patient relationships.

Multimedia electronic education is already becoming an increasingly popular method of delivering patient information in health care settings.<sup>310</sup> As the use of electronic informed consent increases, the expectations of the reasonable physician and patient regarding required disclosures may change accordingly.<sup>311</sup> As more and more physicians use computerized systems, the easy-to-understand diagrams and detailed information found on these websites may become the standard disclosure for reasonable physicians in the community and set the professional community standard. Similarly, as more and more patients come to expect that they will receive the type of information contained in these systems, easy-to-follow and detailed disclosures may be required to meet the patient-oriented standard. In these ways, a push in the right direction may lead to meaningful informed consent.

#### *X. Informed Consent Laws Should Be Changed to Keep Pace with Developments in Health Care*

This article has shown that meaningful informed consent can be achieved with the help of new technology, but why is change so important now? After all, informed consent laws have been around for a long time. The answer has to do with the complexity of current medical decisions.

The informed consent doctrine began to develop approximately a century ago and evolved as medical science advanced. In the 1970s, roughly half of all states enacted informed consent statutes, but the doctrine has changed

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308. 42 U.S.C. § 299b-36(c)(2)(B); see Rosoff, *supra* note 274, at 382 (noting that a “vendor might [also] undertake a contractual duty to indemnify and hold the physician harmless,” if the information in the electronic information was not correct.).

309. Brensilver, *supra* note 247, at 624 n.96 (“The cost per year for a physician to use YourSurgery.Com is \$100.”).

310. Wanzer et al., *supra* note 274, at 366 (“Using multimedia strategies to deliver patient information is becoming increasingly popular in health care settings.”).

311. Arabian, *supra* note 117, at 281 (“As the expectations of the reasonable person change, the legal standard to which physicians are held will evolve accordingly.”).

little since then.<sup>312</sup> Recent developments in medical care demonstrate that further modification of the informed consent doctrine is essential to protect patient choice.

When the doctrine of informed consent first developed, medical care was generally rudimentary and medical decisions relatively straightforward.<sup>313</sup> Today patients often have several treatment choices, each with different risks and benefits. Because there are multiple options, medical decisions are dependent to an ever-greater extent on individual patient values and life goals.<sup>314</sup> This, in turn, has led to a greater need to protect patient preferences and priorities.<sup>315</sup> Each of the following examples<sup>316</sup>—affecting thousands to millions of Americans each year—demonstrates the importance of medical input from physicians to ensure that patients make the choices that best meet their needs.<sup>317</sup>

There are five treatment options for early prostate cancer, all with about the same chances of success.<sup>318</sup> These options are active surveillance,

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312. Krause, *supra* note 33, at 272 (“Approximately half of the jurisdictions in the United States enacted informed consent statutes in the 1970’s, but little subsequent legislative activity has modified the nature of the doctrine itself.”); FURROW ET AL., *supra* note 227, at 311 (noting that the “period from 1972 to the present, has seen legislative retrenchment and judicial inertia”).

313. Sones, *supra* note 58, at 260 (“[T]he doctrine of informed consent originated at a time when medicine was less sophisticated and surgery was relatively new.”); Atwell, *supra* note 69, at 598 (“The doctrine of informed consent dates back to a time when medical practice was relatively rudimentary. . . . [and] medical treatments [were] far simpler . . .”).

314. Shultz, *supra* note 18, at 276 (“Medical uncertainty forces a high degree of election in decisionmaking, and extra-medical values necessarily shape resulting choices.”).

315. Kathryn Birnie & John Robinson, *Helping Patients with Localized Prostate Cancer Reach Treatment Decisions*, 56 CANADIAN FAMILY PHYSICIAN 137, 139 (2010) (noting that, with respect to prostate cancer, “decision models based on average preferences lead to suboptimal treatment decisions for by far most patients”).

316. For other examples of complex medical choices, see Georgia Akers, *On Death and Dying: Counseling the Terminally Ill Client and the Loved Ones Left Behind*, 1 EST. PLAN. & COMMUNITY PROP. L.J. 1, 4 (2008) (“[M]any aggressive treatments of chronic diseases have side effects that greatly degrade quality of life.”); Emily C. Kmez et al., *The Role of Observation in the Management of Atypical Nevi*, 102 S. MED. J. 45, 45 (2009) (“[T]he question of whether or not partially removed atypical nevi should be re-excised with clear margins in order to prevent their evolution into melanoma remains unanswered.”).

317. See Kapp, *supra* note 120, at 101 (“[M]any find the job of being a modern patient, with its slog through medical uncertainty, to be lonely, frightening, and overwhelming.”).

318. Birnie & Johnson, *supra* note 315, at 137 (“[P]rostate cancer patients are faced with a difficult choice between several medically equivalent treatments. The decision is further confounded by conflicting recommendations from specialists, such as urologists, radiation oncologists, and medical oncologists . . .”).

radical prostatectomy, external beam radiotherapy, brachytherapy, and cryotherapy.<sup>319</sup> Because the treatments are medically equivalent, personal goals and values become the deciding factor in making a well-informed treatment decision.

For instance, the potential side effects of prostate surgery include urinary incontinence and erectile dysfunction.<sup>320</sup> Despite these possible complications, some patients still choose surgery because “it is the most certain and most expeditious, and . . . provides the most tangible knowledge about the cancer.”<sup>321</sup> Those who refuse surgery generally cite the risks of the procedure as the reason for refusing it.<sup>322</sup> Since the treatment’s side effects greatly influence decision-making for some men,<sup>323</sup> the patient’s informational needs and personal preferences must be addressed to minimize “decisional regret.”<sup>324</sup>

Women with early onset breast cancer are often faced with a choice between a mastectomy and a lumpectomy with radiation therapy.<sup>325</sup> The survival rate is the same for both procedures and both treatments are medically justified.<sup>326</sup>

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319. *Id.*

320. *Understanding Prostate Cancer Side Effects*, PROSTATE CANCER FOUND. (Aug. 14, 2011), [http://www.pcf.org/site/c.leJRIORepH/b.5822789/k.9652/Side\\_Effects.htm](http://www.pcf.org/site/c.leJRIORepH/b.5822789/k.9652/Side_Effects.htm).

321. Birnie & Johnson, *supra* note 315, at 138.

322. *Id.*

323. *Id.* at 139 (“[T]reatment side effects do play a substantial role in treatment decision making and . . . some men, even at the time of diagnosis, are not willing to sacrifice physical and sexual function for greater life expectancy.”).

324. *Id.* at 138, 140 (“Passive participation is associated with higher levels of decisional regret [one] year following treatment. . . . Increased patient participation in treatment decision making minimizes decisional regret by addressing information needs, facilitating values clarification around treatment choice, and helping patients to understand any potential side effects.”).

325. Andersen-Watts, *supra* note 250, at 202 (“Today, when diagnosed with early onset breast cancer, a woman will often face a choice between lumpectomy, known as breast-conserving surgery (BCS), and mastectomy.”).

326. *See id.* (“Medical research has yielded conclusive results showing that when faced with early stage breast cancer, a woman’s survival rate is the same whether she undergoes mastectomy or [lumpectomy].”); *see also* Steven J. Katz et al., *Correlates of Surgical Treatment Type for Women with Noninvasive and Invasive Breast Cancer*, 10 J. WOMEN’S HEALTH & GENDER-BASED MED. 659, 659 (2001) (noting that “compared with mastectomy, lumpectomy with radiation therapy provides equal survival benefit . . .”).

Lumpectomy with radiation preserves the breast and may have less psychological consequences.<sup>327</sup> Women who choose mastectomy generally do so because of concerns about the side effects of radiation, fear of recurrence, and the desire to avoid additional surgery.<sup>328</sup> Again, this is a very personal choice, highly dependent on personal concerns and values.<sup>329</sup> Patients making this choice will benefit greatly from a shared decision-making process that is “sensitive to patient preferences regarding the various treatment options.”<sup>330</sup>

Medical decisions related to preventing disease may pose equally complex and vexing choices. For example, women with the BRCA1 gene have a 60% to 90% chance of developing breast cancer some time in their lives<sup>331</sup> and about a 50% chance of developing ovarian cancer.<sup>332</sup>

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327. Katz et al., *supra* note 326, at 659 (noting that lumpectomy with radiation therapy “preserves the breast, and may yield less psychological sequelae and higher patient satisfaction”).

328. Steven J. Katz et al., *Patient Involvement in Surgery Treatment Decisions for Breast Cancer*, 23(24) J. CLINICAL ONCOLOGY 5526, 5530 (2005) (“Concerns about disease recurrence and radiation effects highly favored receipt of mastectomy.”); *see also* Andersen-Watts, *supra* note 250, at 218 (“Fear of recurrence, concerns about the side effects of radiation therapy, and anecdotal reasoning are among the factors that may lead a woman to ultimately choose mastectomy over [a lumpectomy].”); Katz et al., *supra* note 326, at 664 (noting that “women who were greatly influenced by the desire to reduce the need for additional surgery” and “women who were most concerned about the effectiveness of the surgical procedures were more likely to have chosen mastectomy”).

329. Katz et al., *supra* note 326, at 5526, 5530 (“Although there is professional consensus that most women with early-stage breast cancer are good candidates for breast-conserving surgery (BCS), more than one third of women with early-stage breast cancer were treated with mastectomy in 2001 . . . . [M]ore patient involvement in surgical decision making was associated with a greater likelihood of receiving mastectomy.”); Andersen-Watts, *supra* note 250, at 202 (“Breast cancer patients must weigh their own preferences and values in order to make the best personal decision.”).

330. *See* Andersen-Watts, *supra* note 250, at 203 n.7 (citing Paula M. Lantz et al., *Satisfaction with Surgery Outcomes and the Decision Process in a Population-Based Sample of Women with Breast-Cancer*, 40 HEALTH SERVICES RES. 745, 746 (2005); *see also* Katz et al., *supra* note 328, at 5527 (“Patient preferences also play an important role in surgical treatment decisions [between mastectomy and lumpectomy].”).

331. Amy Harmon, *Cancer Free at Age 33, but Weighing a Mastectomy*, N.Y. TIMES, Sept. 16, 2007, <http://www.nytimes.com/2007/09/16/health/16gene.html> (noting that the BRCA1 gene “raises [the] risk of developing breast cancer . . . to between 60 and 90 percent.”); Dolgin, *supra* note 54, at 166, n.160 (“[U]p to fifteen percent of women who test positive for BRCA1, associated with breast cancer . . . will not develop the condition.”).

332. Harmon, *supra* note 331 (noting that ovarian cancer “strikes about 50 percent of BRCA1 carriers, compared with 2 percent of the general population, is rarely detected early and is fatal three-quarters of the time”).

Approximately one-third of these women opt for preventative mastectomies<sup>333</sup> and a majority has their ovaries removed.<sup>334</sup> Others choose drugs to prevent breast cancer or have frequent check-ups.<sup>335</sup> Young women making these decisions face a challenging and emotionally charged choice.

Another complex treatment choice involves women reaching menopause who must decide whether or not to take hormone replacement therapy (HRT).<sup>336</sup> After a study by the Women's Health Initiative (WHI), women were told not to take HRT,<sup>337</sup> but some researchers contend that the age of the participants in the study skewed the research results.<sup>338</sup> Other studies suggest that the increased risk of breast cancer is nonexistent<sup>339</sup> or very small with HRT and that women on HRT live longer<sup>340</sup> and have a reduced risk of coronary artery disease,<sup>341</sup> osteoporotic fractures, and colon

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333. *Id.* (noting that about a third of women with the BRCA1 gene “opt for preventative mastectomies that remove the tissue where the breast cancer develops.”).

334. *Id.* (noting that a majority of women with the BRCA1 gene “have their ovaries removed, halving their breast cancer odds while decreasing the risk of highly lethal ovarian cancer”).

335. *Id.* (noting that some women with breast cancer “take drugs that ward off breast cancer . . . [or] hope that frequent checkups will catch the cancer early, or that they will beat the odds”).

336. Avrum Z. Bluming & Carol Tavis, *Hormone Replacement Therapy: Real Concerns and False Alarms*, *CANCER J.*, Mar.-Apr. 2009, at 93, 93 (“Hormone Replacement Therapy (HRT) is the term used for the administration of estrogen, or estrogen plus progestin, to women who have reached menopause . . . Estrogen replacement therapy (ERT) alone is thus generally given only to women who have had hysterectomies.”).

337. *Id.* (noting that the Women's Health Initiative (WHI) found that “the risks of HRT far outweigh the benefits . . .”).

338. See Cynthia Gorney, *The Estrogen Dilemma*, *N.Y. TIMES*, Apr. 18, 2010, <http://www.nytimes.com/2010/04/18/magazine/18estrogen-.html> (“The average age of the W.H.I. women was just over 63, though the study accepted women as young as 50 . . . . [M]ost of them were many years past . . . menopause, when they began their trial hormones.”).

339. Bluming & Tavis, *supra* note 336, at 97 (noting that “the majority of observational studies have found no increased risk of breast cancer associated with HRT . . .”).

340. *Id.* (“[E]ven if HRT increases the risk of breast cancer by this modest increment, research suggests that women on HRT live longer than those not taking HRT, and that HRT-treated women have a lower death rate from breast cancer.”).

341. *Id.* at 98 (“[A] New England Journal of Medicine editorial reported that a consensus of epidemiological studies had shown that women who are given postmenopausal estrogen have a 40% to 50% reduction in the risk of coronary artery disease in comparison with women who do not receive such therapy.”).

cancer.<sup>342</sup> Clearly, these conflicting studies make decisions concerning whether to take HRT confusing and troublesome.<sup>343</sup>

Complex decisions related to preventative medicine—like those concerning HRT and BRAC1—are likely to increase rapidly as progress in genetics and epidemiology provide more detailed risk information.<sup>344</sup> All of these treatments demonstrate the importance of detailed medical disclosure and shared decision-making to help patients navigate the system and select optimal treatments based on their values, preferences, and concerns. The help of physicians in providing information and evaluating patient preferences is essential, now more than ever before.

### Conclusion

The informed consent doctrine has developed over the past century to keep pace with changes in medical care. But with the adoption of objective causation, the doctrine lost its place as an incentive for positive change. Given recent advances in technology and medical care, informed consent is ripe for its next evolution.

The increasing emphasis on patient autonomy—which is protected by informed consent laws—is directly related to the increasing complexity of medical care and the wider array of choices available to patients. But choice depends on attention to patient preferences and priorities. Congress has already recognized the need to facilitate protection of patient choice in the area of preference sensitive care, defined in the PPACA as involving medical conditions that have more than one clinically acceptable treatment. The Act specifies that, for these conditions, informed patients should choose the appropriate care based on their own preferences or values.<sup>345</sup>

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342. *Id.* at 100 (“Even the WHI confirmed previously published reports of decreased risks of osteoporotic fractures and colon cancer for women on HRT.”).

343. *See id.* at 95 (“[T]he relationship between HRT and breast cancer is still not clear despite a vast amount of research, study, and reporting over many decades . . . . [T]he list [of available research] is a jumble of positive findings, negative findings, and meaningless findings.”); Gorney, *supra* note 338 (“[A] daunting proportion of what we thought we learned about hormone replacement over the last eight years remains unsettled [and] more confusing than ever . . . .”).

344. Peter H. Schwartz, *Disclosure and Rationality: Comparative Risk Information and Decision-Making about Prevention*, 30 THEORETICAL MED. & BIOETHICS 199, 211 (2009) (noting that “medicine’s growing focus on prevention and . . . progress in genetics and epidemiology promis[e] to make much more detailed risk information available to patients and providers in the future.”).

345. Patient Protection and Affordable Care Act, 42 U.S.C.A. § 299b-36(b)(2) (West 2011) (defining preference sensitive care as “medical care for which the clinical evidence does not

Although the PPACA contains provisions to facilitate patient choice, the courts and state legislatures should also play their part. Moving away from objective causation and adopting a subjective causation standard would give vitality to the informed consent cause of action and encourage physicians to adopt new technologies to help provide meaningful disclosure to patients.

Subjective causation is a good choice to help achieve this goal. It focuses on the choice the patient would have made knowing the risks and alternatives. To make this determination, juries must consider the patient's personal preferences and, if juries will consider this issue, the medical community should as well. Although physicians can avoid liability—even with a subjective causation standard—by meeting the requirements of objective disclosure, attention to patient values and preferences will provide physicians with another layer of protection.

Sound informed consent laws that protect patient choice would also reinforce the public's support of patient autonomy and conviction that patients are entitled to make their own treatment decisions.<sup>346</sup> American bioethicists, health scholars, and advocates “remain overwhelmingly, staunchly in support of the informed consent doctrine and optimistic about its serious implementation in clinical practice.”<sup>347</sup> The tort system may just be “the most powerful irritant” to support meaningful change.<sup>348</sup>

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clearly support one treatment option such that the appropriate course of treatment depends on the values . . . or the preferences of the patient, . . . [so that] use of such care should depend on the informed patient choice among clinically appropriate treatment options.”).

346. Levine, *supra* note 122, at 272 (“Recognition of the patient's right to give informed consent demonstrates society's respect for a patient's autonomy and bodily integrity and more importantly, that the physician's role is that of an adviser while the patient ultimately decides his course of treatment.”).

347. Kapp, *supra* note 120, at 101.

348. See Morris, *supra* note 11, at 369.