PERSONALIZING INFORMED CONSENT: THE CHALLENGE OF HEALTH LITERACY

I. INTRODUCTION

The legal doctrine of informed consent does not adequately consider an individual patient's literacy—in particular health literacy.[1] Considering the level of a patient's health literacy is an essential part of the ongoing communication required for obtaining genuinely informed consent. It also influences whether the patient was subjectively informed and understood the terms of the consent. If informed consent is to properly represent a patient's knowledge and understanding of risks, then health literacy must be considered.

The traditional roles of the patient and physician are changing as emerging health policies and processes place a greater burden on patients to acquire and process health information and data.[2] In particular, patient literacy is increasingly important with the advent of consumer-directed healthcare (CDHC) and personal health records (PHR).[3] Supporters of CDHC believe that under this model of care there will be shared decision making between physicians and patients.[4] If this is the case, patients clearly

1. *See infra* notes 18-28 and accompanying text (discussing definitions for health literacy).

2. *See* Jamie Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 431 (2006).

3. Consumer-directed health plans couple catastrophic health insurance coverage with large deductibles. CDHC aims at patients taking more responsibility for their own health and health care, by additional cost sharing, researching, and selecting providers, relying on health information from alternative sources (websites) and maintaining of personal health records. *See id.* at 487 (noting that patients increasingly have more of a role in treatment and medical decisions). *See generally* TIMOTHY STOLTZFUS JOST, HEALTH CARE AT RISK: A CRITIQUE OF THE CONSUMER-DRIVEN MOVEMENT 17-26, 119-49 (2007) (discussing how CDHC can mold patients into better health care consumers and increase overall value of health care through the increase of patient cost sharing obligations; also discussing how cost sharing can force patients to be more selective in choosing a provider); Jane Root & Sue Stableford, *Easy-to-Read Consumer Communications: A Missing Link in Medicaid Managed Care*, 24 J. HEALTH POL. POL'Y & L. 1, 2 (1999) (discussing how patients must now take more responsibility for their health and health care); Nicolas P. Terry, *Personal Health Records: Directing More Costs and Risks to Consumers?*, 1 DREXEL L. REV. (forthcoming 2009).

4. *See* Linda M. Axtell-Thompson, *Consumer Directed Health Care: Ethical Limits to Choice and Responsibility*, 30 J. MED. & PHIL. 207, 224 (2005); *compare* King & Moulton,

need to be health literate to effectively share in the decision making process. Critics of CDHC suggest that this model puts patients at more risk financially and in regards to treatment decisions.[5] Thus, patients' health literacy is important if they are to understand the risks of treatment options. Whichever way consumer directed healthcare is viewed, literacy becomes more of a factor than it was under the traditional model of healthcare delivery. Patients are involved more in healthcare processes that require literacy, yet patient literacy should not be assumed.[6]

This Comment identifies inadequate patient health literacy as a barrier to obtaining genuine informed consent that is not adequately taken into account by the legal system. Genuine informed consent requires patient understanding of disclosures of risks.[7] Proper legal consideration of patient health literacy can be accomplished through a re-evaluation of the legal standards of disclosure, and/or statutory changes to the requirements of informed consent forms, and/or the requirements of disclosure communication. The legal doctrine of informed consent is rich in rhetoric of individual autonomy, yet only on rare occasions have the courts addressed patient literacy when examining the validity of informed consent.[8] This Comment argues that the ethical justifications for informed consent can be used to strengthen the argument for modifying the legal standards for informed consent so that patient health literacy is adequately taken into account.

The standard for determining the adequacy of a patient's informed consent depends on the legal jurisdiction. In some jurisdictions adequacy is determined by the reasonable physician standard, also called the professional custom standard.[9] This is the legal (not ethical) customs of the profession. The reasonable physician standard is influenced by accreditation standards (the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Board of Medical Specialties (ABMS)), regulations (Centers for Medicare & Medicaid Services (CMS)), and the American Medical Association (AMA). In other jurisdictions, adequacy is determined by what a "reasonable" patient expects and/or needs to know.[10] In the ethical domain, genuine informed consent is often viewed as the result of a continuing discussion between physician and

supra note 2, at 487 (arguing that shared decision making is necessary due to the increased role of consumerism in health care).

5. *See* Axtell-Thompson, *supra* note 4, at 225 (discussing that if the CDHC is badly executed, the results could be severe, including "cost shifting rather than cost efficiency").

6. *See infra* Part II (discussing patient literacy).

7. *See infra* Part III.A.

8. *See infra* Part III.A.

9. *See infra* notes 64-67 and accompanying text.

10. *See infra* notes 68-76 and accompanying text.

patient, and is justified by the patient's right of autonomy and self-determination.[11] Adequate consideration of patient health literacy is arguably required under the ethical theories of informed consent, including those based on individual autonomy, the waiver of epistemic and ethical norms, and shared decision making.[12] The reasonable patient standard currently provides the best opportunity to advocate for consideration of health literacy in informed consent litigation. The best option for improving the quality of informed consent of patients with varying levels of health literacy may be to pass state legislation that addresses the process of consent and the readability level of consent forms.

Part II of this Comment begins with an examination of the current literature on general literacy and health literacy of Americans and concludes that inadequate health literacy is a pervasive problem in the United States, health literacy is difficult to accurately measure, and patient illiteracy leads to poor health outcomes. Part III describes the basics of the legal doctrine of informed consent, emphasizing the competing standards for the scope of disclosure—the reasonable physician standard and the reasonable patient standard. The discussion of the legal doctrine is followed by a brief discussion of the ethical perspectives of informed consent, and whether health literacy is consistent with ethical requirements for obtaining genuine informed consent. Part IV explores how literacy affects consent and focuses largely on the readability of informed consent forms. Part V discusses health literacy and the legal informed consent doctrine by analyzing current case law, identifying potential barriers to an increased recognition of the importance of health literacy in achieving legally valid informed consent, identifying potential avenues to increase the consideration of health literacy, and reviewing initiatives that have been implemented to address health literacy in the context of informed consent. This Comment concludes by summarizing the key findings and making recommendations for advocacy approaches to improve the quality of informed consent through recognition of the inadequate health literacy levels of patients.

II. GENERAL LITERACY AND HEALTH LITERACY

In the United States, approximately twenty-one percent of the adult population has low literacy skills, defined as "reading at the sixth grade level or below," and "twenty-seven percent may have limited literacy ability, defined as lacking general reading and numeracy proficiency to function adequately in society."[13] Therefore, nearly half of the adult population has

11. *See infra* Part III.B.

12. *See infra* notes 88-91, 94-99, 102-03 and accompanying text.

13. David I. Shalowitz & Michael S. Wolf, *Shared Decision-Making and the Lower Literate Patient*, 32 J.L. MED. & ETHICS 759, 759 (2004).

deficiencies in reading and/or computational skills.[14] Low literacy is associated with poor patient "understanding of written or spoken medical advice, adverse health outcomes, and negative effects on the health of the population."[15] Low literacy among patients has been described as a "silent epidemic" because physicians and other healthcare providers are often unaware of their patients' low literacy.[16] The average adult in the United States reads at an Eighth or Ninth grade level, and the average Medicaid patient reads at a Fifth grade level.[17] Health literacy may be significantly worse than general literacy since literacy is context specific and medical information can be full of unfamiliar vocabulary (medical jargon) and concepts.[18] Health literacy skills include all the traditional literacy skills (reading and writing), plus several additional or enhanced skill sets, such as, knowledge of common health-related vocabulary, abbreviations, and how the healthcare system works.[19] Thus, patients who have low general literacy also have low health literacy, but patients with low health literacy include some patients who do not have low general literacy. It has been estimated that approximately ninety million Americans have low health literacy.[20]

The 2003 National Assessment of Adult Literacy (NAAL) was the first large-scale assessment to measure health literacy in the United States.[21] The NAAL functional definition of health literacy is "[t]he ability to comprehend and use printed and written health information to function in society, to achieve one's goals, and to develop one's knowledge and

14. Ad Hoc Comm. on Health Literacy for the Council on Scientific Affairs, Am. Med. Ass'n, *Health Literacy: Report of the Council on Scientific Affairs*, 281 JAMA 552, 552 (1999) [hereinafter Ad Hoc Comm., *Health Literacy*].

15. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, LITERACY AND HEALTH OUTCOMES: SUMMARY 1, 1 (2004), *available at* www.ahrq.gov/clinic/epcsums/litsum.pdf (last visited Apr. 16, 2009) [hereinafter AHRQ REPORT].

16. Erin N. Marcus, *The Silent Epidemic — The Health Effects of Illiteracy*, 355 NEW ENG. J. MED. 339, 340 (2006); *see* Jennifer Fisher Wilson, *The Crucial Link Between Literacy and Health*, 139 ANNALS INTERNAL MED. 875, 875-76 (2003) (examining the incredibly low levels of health literacy in the United States).

17. JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., PATIENTS AS PARTNERS: HOW TO INVOLVE PATIENTS AND FAMILIES IN THEIR OWN CARE 72 (Meghan McGreevey ed., 2006) [hereinafter PATIENTS AS PARTNERS]; *see also* Root & Stableford, *supra* note 3, at 5 (reporting "that nearly half of all adults read at the eighth grade level or below[,]" and that "[s]eventy-five percent of welfare recipients read at this same low level.").

18. Ad Hoc Comm., *Health Literacy*, *supra* note 14.

19. SHEIDA WHITE, ASSESSING THE NATION'S HEALTH LITERACY: KEY CONCEPTS AND FINDINGS OF THE NATIONAL ASSESSMENT OF ADULT LITERACY (NAAL) 22 (2008), *available at* www.ama-assn.org/ama1/pub/upload/mm/367/hl_report_2008.pdf (last visited Apr. 16, 2009).

20. Jillanne M. Schulte, *Health Literacy: Closing the Communication Gap Between Doctors and Patients*, HUM. RTS., Fall 2007 at 18, 18.

21. WHITE, *supra* note 19, at 3.

potential."[22] The report states that "health literacy measures the comprehension and use of printed health-related prose and documents and performance on arithmetic operations using health-related information embedded in a text."[23] The assessment reported results in four performance levels: Below Basic, Basic, Intermediate, and Proficient.[24] On the 2003 NAAL, twenty-two percent of adults scored at the Basic level in health literacy and fourteen percent were at the Below Basic level.[25]

According to the Agency for Healthcare Research and Quality (AHRQ), health literacy is "a constellation of skills that constitute the ability to perform basic reading and numerical tasks for functioning in the health care environment and acting on health care information."[26] *Healthy People 2010*, a policy report of the U.S. Department of Health and Human Services, defined health literacy as "[t]he degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[27] Health literacy, according to the Institute of Medicine (IOM), "is a shared function of cultural, social, and individual factors."[28] For the purposes of this Comment, health literacy is defined as the possession of reading, writing, and communication skills that enable patients to obtain, process, and understand health information and services needed to make informed health decisions.

While there is no universally accepted definition of health literacy or way to measure health literacy, several organizations have developed models for evaluating health literacy. The NAAL, discussed *supra*, tested health literacy by measuring comprehension of "printed or written health-related materials and performance on arithmetic operations using health-related information

22. *Id.*

23. *Id.* at 22.

24. *Id.* at 3, 33 tbl.4 ("Below Basic indicates a grasp of no more than the simplest, most concrete literacy skills," for example, "[s]igning a form." "Basic indicates skills needed to perform simple everyday literacy activities," including "[e]ntering names and birth dates in a health insurance application." "Intermediate indicates skills necessary to perform moderately challenging literacy activities," such as, "[c]onsulting reference materials to determine which foods contain a particular vitamin." "Proficient indicates skills necessary to perform more complex and challenging literacy activities," for example "[i]nterpreting a table about blood pressure, age, and physical activity.").

25. *Id.* at 43.

26. AHRQ REPORT, *supra* note 15, at 1.

27. U.S. DEP'T OF HEALTH & HUMAN SERVS., *Understanding and Improving Health*, *in* 1 HEALTHY PEOPLE 2010, at 11-20 (2000), *available at* www.healthypeople.gov/Document/pdf/Volume1/11HealthCom.pdf (last visited Apr. 16, 2009) [hereinafter HEALTHY PEOPLE 2010].

28. COMM. ON HEALTH LITERACY, INST. OF MED., HEALTH LITERACY: A PRESCRIPTION TO END CONFUSION 32 (Lynn Nielsen-Bohlman et al. eds., 2004) [hereinafter IOM].

imbedded in text."[29] The NAAL identified three types of health literacy tasks: clinical, preventive, and navigation.[30] The NAAL did not measure "knowledge of health issues" or "understanding of medical jargons", "scientific terms and symbols", and "[s]kills associated with listening, speaking, and nonverbal communication."[31] The variables that were not measured would be useful in evaluating how health literacy impacts informed consent, because standard informed consent forms are often full of medical jargons, and scientific terms and symbols. Also, informed consent is theoretically an ongoing communication process in which listening and speaking skills are crucial. If a signed consent form is used merely as evidence that a conversation between the patient and physician took place, then listening, speaking, and nonverbal communication skills are essential parts of the informed consent process. Thus, while the NAAL is useful for obtaining a general understanding of health literacy, it lacks important measures of health literacy that relate to a patient's ability to give informed consent.

Since the NAAL first introduced the health literacy questions as an aspect of its assessment in 2003, there have been numerous attempts by others to measure health literacy. Two popular measures of health literacy among researchers are the Test of Functional Health Literacy in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM).[32]

The reading comprehension portion of the TOFHLA involves common materials used in healthcare settings, including standard informed consent forms.[33] A patient is deemed to have inadequate or low literacy if they answer fewer than half of the TOFHLA questions correctly.[34] This means they may have difficulty reading "pill bottle labels, appointment slips,

29. WHITE, *supra* note 19, at 7 (emphasis removed).

30. *Id.*

31. *Id.*

32. Wilson, *supra* note 16, at 875. *But see* RIMA RUDD ET AL., LITERACY AND HEALTH IN AMERICA 3-20 (2004), *available at* www.ets.org/Media/Research/pdf/PICHEATH.pdf (last visited Apr. 16, 2009) (discussing another method of measuring health literacy—the "Health Activities Literacy Scale" (HALS)). Introduced in 2004, the HALS emphasizes the importance of the interaction between the complexity of health material and what individuals are expected to do with the material, instead of focusing only on the structure and complexity of written or printed texts. *Id.* at 3, 17. Approximately 12% of the U.S. adult population is estimated to have Level 1 skills on the HALS and "an additional 7% can be expected to have great difficulty performing even these simple tasks with a high [level] of proficiency" (level 2: 27%; level 3: 36%; level 4: 17%; level 5: 1%). *Id.* at 3, 20 fig.3. The HALS identified the following skills as essential for adults to have health literacy: document reading skills, specific types of writing skills for completing forms, math skills, presentation skills, a descriptive vocabulary, and listening and speaking skills. *Id.* at 42.

33. Wilson, *supra* note 16, at 875.

34. *Id.*

educational brochures, informed[]consent forms," and other health information.[35] "TOFHLA takes up to 22 minutes to administer."[36] Based on the results of TOFHLA patients are placed in one of three categories: inadequate health literacy, marginal health literacy, or adequate health literacy.[37] Even patients classified as having adequate health literacy may have difficulty understanding complex informed consent forms.[38]

The REALM test measures a patient's health literacy based on their ability to read and pronounce medical words from three lists of twenty-two words each.[39] The number of words that the patient reads and pronounces correctly from each list determines their health literacy.[40] The words range in difficulty from "fat" and "eye" to "osteoporosis" and "impetigo."[41] The REALM test can be performed quickly, in approximately three minutes,[42] which makes it practical, but the test does not require that patients define the medical words. Being able to read aloud a consent form is of little use if a patient does not understand the words that they are reading.

Currently, there is no measure that accounts for all of the skills and knowledge associated with health literacy.[43] A model for evaluating health literacy in patients would be most useful in the informed consent context if it measures comprehension of excerpts from informed consent forms, knowledge of health issues, understanding of medical and legal terminology,[44] scientific terms, and skills associated with listening, speaking, and nonverbal communication. While there is no universally accepted measure of health literacy, it is clear that health literacy is a factor for many patients.

It is difficult for physicians and other healthcare providers to identify patients with poor literacy skills.[45] One reason for this difficulty is that

35. *Id.*
36. IOM, *supra* note 28, at 48.
37. *Id.*
38. *Id.*
39. *Id.* at 47-48, 302 tbl.C-1.
40. *Id.* at 48.
41. IOM, *supra* note 28, at 302 tbl.C-1.
42. *Id.* at 47.
43. *Id.* at 50; *see also* Mark Hochhauser, Liabilities of "Unreadable" Consent Forms, *in* 2005 SYMPOSIUM PROCEEDINGS BOOK 115, 117 (Edward F. Gabriele & Valerie J. Ducker eds., 2005), *available at* www-s.med.uiuc.edu/administration/research/resources/SRA/proceedings.pdf (last visited Apr. 16, 2009) (stating there are no readability formulas developed specifically for informed consent forms; "[t]hus, there is no data on the validity and reliability of readability formulas for informed consent forms in [the] adult population.").
44. This Comment is focused on health literacy, but complex informed consent forms may also contain legal jargon/terminology, which could make it more difficult to understand the form.
45. Marcus, *supra* note 16, at 340.

patients are often ashamed and skilled at hiding their low literacy.[46] It has been suggested that as a universal precaution healthcare providers should assume that all patients have low health literacy, whether or not they have low general literacy skills.[47] This precaution would be helpful to achieve genuine informed consent from patients. If time is taken to explain the risks that are being consented to verbally and/or informed consent forms are written in plain language, then it is more likely that patients with low health literacy will understand the risks and be able to give genuinely valid informed consent.

The majority of adults in the United States with low literacy skills are white and natural born citizens.[48] Low literacy is most prevalent among the elderly,[49] persons with low cognitive ability, the less educated, lower socioeconomic groups, the incarcerated, and persons of certain racial or ethnic groups (minorities).[50] A study conducted from 1993-1994 at two urban public hospitals found that many patients could not comprehend basic medical directions that contained numerical information.[51] Research has demonstrated that there is a relationship between low health literacy and poor health status—low health literacy "may lead to poor [healthcare] quality and excess medical services and costs."[52] A relationship has been found between lower literacy skills and "a limited understanding of personal health issues, infrequent use of preventive care services, delayed diagnosis, poor adherence to treatment and medical instructions, inadequate disease self-management skills, and higher health care costs."[53] Literacy skills have been found to be a better predictor of health status than "age, income, employment status, education level, and racial or ethnic group."[54]

Inadequate health literacy is a pervasive problem in the United States. It affects a wide variety of people and has been associated with poor health outcomes. Health literacy is difficult to measure, and it is something that patients are unlikely to volunteer to their physicians. Health literacy affects

46. *Id.*

47. *Id.* at 341.

48. PATIENTS AS PARTNERS, *supra* note 17, at 71.

49. Mark V. Williams et al., *Inadequate Functional Health Literacy Among Patients at Two Public Hospitals*, 274 JAMA 1677, 1681 (1995); *see also* Julie A. Gazmararian et al., *Health Literacy Among Medicare Enrollees in a Managed Care Organization*, 281 JAMA 545, 548 (1999) (finding in a study of Medicare enrollees that "more than one third of respondents had inadequate or marginal health literacy.").

50. AHRQ REPORT, *supra* note 15 at 1; Wilson, *supra* note 16, at 876.

51. Williams et al., *supra* note 49, at 1678-79.

52. Shoou-Yih D. Lee et al., *Health Literacy, Social Support, and Health: A Research Agenda*, 58 SOC. SCI. & MED. 1309, 1316 (2004).

53. Shalowitz & Wolf, *supra* note 13, at 759 (internal citations omitted).

54. Wilson, *supra* note 16, at 875.

consent because it dictates how much of an informed consent conversation and/or consent form is comprehended.

III. INFORMED CONSENT: THE LEGAL DOCTRINE AND ETHICAL PERSPECTIVES

The legal doctrine of informed consent has borrowed justifications from ethics, such as autonomy and self-determination. There are two different senses of informed consent: the autonomous authorization by individuals and the social rules of consent, which includes legally valid consent.[55] This Section covers the basics of the legal doctrine of informed consent that developed out of a judicial deference for autonomy.[56] Noticeably absent from the discussion of legal informed consent in the medical context is any mention of health literacy. In the realm of ethics, autonomy, the waiver of epistemic and ethical norms, and shared decision making have all been proposed as the principles that support informed consent. Obtaining genuinely informed consent from patients with low health literacy can be accomplished by harmonizing legal informed consent doctrine with ethical principles.

A. Legal Doctrine

Under the common law doctrine of informed consent, physicians have a duty to inform patients of material risks of a treatment or procedure and alternative treatment options.[57]

> Informed consent has developed out of strong judicial deference toward individual autonomy, reflecting a belief that an individual has a right to be free from nonconsensual interference with his or her person, and a basic moral principle that it is wrong to force another to act against his or her will.[58]

Courts do not usually consider whether the patient comprehended or was able to comprehend the risk discussion or form as long as the patient is generally competent.[59] Legally recognized exceptions to informed consent are cases of emergency, incompetency, waiver, and therapeutic privilege

55. Nicolas P. Terry, *What's Wrong with Health Privacy?*, *in* LEGAL PERSPECTIVES IN BIOETHICS 68, 73-74 (Ana S. Iltis et al. eds., 2008) (citing TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 143-44 (4th ed. 1994)).

56. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 230 (6th ed. 2008).

57. Ketchup v. Howard, 543 S.E.2d 371, 372-73 (Ga. Ct. App. 2000).

58. FURROW ET AL., *supra* note 56, at 230.

59. *Id.* at 244. Further, as of 2007, there were no "formal practice guidelines from professional societies for the assessment of a patient's capacity to consent to treatment." Paul S. Appelbaum, *Assessment of Patients' Competence to Consent to Treatment*, 357 NEW ENG. J. MED. 1834, 1838 (2007).

(the first three being non-controversial).[60] While there is variability across legal jurisdictions, in general, the legal standards for decision making capacity "embody the abilities to communicate a choice, to understand the relevant information, to appreciate the medical consequences of the situation, and to reason about treatment choices."[61] From a clinical perspective, "[v]alid informed consent is premised on the disclosure of appropriate information to a competent patient who is permitted to make a voluntary choice."[62] The duty of disclosure varies by jurisdiction—in some it is "the medical standard of disclosure", and in others it is the "degree of disclosure sufficient to permit the ordinary patient to make a sound decision."[63]

The medical custom/reasonable physician (professional) standard of informed consent looks at "what information a reasonable, prudent physician would have disclosed to the patient under similar circumstances."[64] The court in *Natanson v. Kline* articulated the reasonable physician standard, but they also noted that the physician has an obligation to "disclose and explain to the patient in language as *simple* as necessary."[65] The physician has discretion as to what is necessary so long as it is "consistent with the full disclosure of facts necessary to assure an informed consent by the patient."[66] Twenty-three states use the reasonable physician (professional) standard for disclosure in informed consent cases.[67]

The reasonable patient standard for the scope of disclosure looks at what information would be material for a reasonable patient in similar circumstances, and was articulated in *Canterbury v. Spence*.[68] Under this standard, valid consent results from "the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available

60. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 124 (6th ed. 2009).

61. Appelbaum, *supra* note 59, at 1835.

62. *Id.* at 1834.

63. Carl E. Schneider, *Void for Vagueness*, HASTINGS CENTER REP., Jan.-Feb. 2007, at 10, 10.

64. Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice*, 28 J. LEGAL MED. 91, 96 (2007); Natanson v. Kline, 350 P.2d 1093, 1106 (Kan. 1960).

65. *Natanson*, 350 P.2d at 1106 (emphasis added).

66. *Id.* at 1107.

67. David M. Studdert et al., *Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risks*, 4 J. EMPIRICAL LEGAL STUD. 103, 105, 106-09 fig.1, tbl.1 (2007) (stating that there are twenty-three states, however figure 1 and table 1 indicate twenty-two states in 2002).

68. Kapp, *supra* note 64, at 96-97; Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972); *see also* Cobbs v. Grant, 502 P.2d 1, 11 (Cal. 1972).

and the risks attendant upon each."[69] Informed consent results from a patient's understanding of risks and alternative treatment options.[70] The physician has a duty of reasonable disclosure of material alternatives and risks.[71] The court rejected the majority view that the physician's duty to disclose is dependent upon the custom of physicians practicing in the community.[72] Instead, the prevailing medical practice has evidentiary value but does not define the standard.[73] The court set an objective standard for material risks, holding that "'[a] risk is . . . 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 undergo the proposed therapy.'"[74] In *Cobbs v. Grant*, the Supreme Court of California justified the reasonable patient standard in informed consent cases with the following postulates:

> The first is that patients are generally persons unlearned in the medical sciences and therefore, except in rare cases, courts may safely assume the knowledge of patient and physician are not in parity. The second is that a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment. The third is that the patient's consent to treatment, to be effective, must be an informed consent. And the fourth is that the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the

69. *Canterbury*, 464 F.2d at 780.

70. *Id.* at 780 n.15.

71. *Id.* at 782, 786-87.

72. *Id.* at 783.

73. *Id.* at 785.

74. *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)). The reasonable or prudent patient standard has been criticized as rejecting "the centrality of the individual patient, in all his or her particularity, and implicitly accepts the view that in any medical choice-making situation, there can be only one 'correct' decision—not a range of possible decisions, each potentially appropriate depending on the tastes, values, and trade offs among conflicting values of the individual patient." Alan J. Weisbard, *Informed Consent: The Law's Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749, 760 (1986). One court rejected the "objective standard for determining the causation issue" in informed consent claims and adopted a subjective standard, "on [the] grounds that 'no consideration is given to the peculiar quirks and idiosyncrasies of the individual,' and that patient's 'supposedly inviolable right to decide for himself what is to be done with his body is made subject to a standard set by others." *Id.* at 761 n.30 (quoting McPherson v. Ellis, 287 S.E.2d 892, 897 (N.C. 1982)). However, the case has no "precedential impact" because subsequent to the court's decision, state legislation was passed "limiting the scope of informed consent . . . ." *Id.* (citing Dixon v. Peters, 306 S.E.2d 477, 480 (N.C. Ct. App. 1983)).

> decisional process, thus raising an obligation in the physician that transcends arms-length transactions.[75]

Twenty-five states and the District of Columbia have adopted the reasonable patient standard either by statute or case law.[76]

While the reasonable patient standard considers the perspective of the patient, and is thus in some respects preferable over the professional standard, the reasonable patient standard still fails to require or encourage a physician to accommodate the health literacy of a particular patient when obtaining informed consent. There may be room to argue that a prudent physician would not depend on the consent form to achieve informed consent without adequate discussion with the patient and accommodations for the patient's health literacy.

The legal doctrine of informed consent has been criticized as being more committed to the rhetorical ideal of patient self-determination than "in its provision of effective legal redress to victimized patients."[77] Realist critics of informed consent argue that, in practice, informed consent "equals little more than a legally worthless piece of paper with signatures obtained and filed away in the medical record."[78] Alan Weisbard argued in 1986 that

> [w]hile purporting to assure respect for individual self-determination, the inaptly named law of informed consent has done little to 'inform' the unique and sometimes idiosyncratic needs, concerns, and fears of individual patients on whose 'consent' so much is said to rest. Indeed, one can plausibly maintain that the legal doctrine has done more to teach physicians how to practice medicine 'defensively' (so as to minimize legal liability) than it has to foster physician-patient relationships that permit and encourage patients to participate actively and knowledgeably in decisions concerning their care.[79]

This criticism begs the question: where did this rhetoric of self-determination originate?

B. Ethical Perspectives of Informed Consent

Both the legal and ethical notions of informed consent feature language of self-determination and autonomy, but despite having similar justifications for informed consent they approach the means to obtaining informed consent differently. There are many different ethical theories that can be

75. Cobbs v. Grant, 502 P.2d 1, 9 (Cal. 1972).

76. Studdert et al., *supra* note 67, at 105-06 & fig.1, 107-09 tbl.1 (stating that there are twenty-five states, however figure 1 and table 1 indicate twenty-six states in 2002. Colorado and Georgia are classified as having hybrid standards).

77. Weisbard, *supra* note 74, at 751.

78. Kapp, *supra* note 64, at 99 (internal citations omitted).

79. Weisbard, *supra* note 74, at 751.

applied to the issue of informed consent, but autonomy-based theories appear to be popular among those interested in the medical context.[80] Generally it is accepted in both ethics and the law that the boundaries of the duty to reveal are defined by the patient's right to self-decision, or self-determination.[81]

Beauchamp and Childress' ethical view of informed consent is often cited.[82] They discuss informed consent from the perspective of respect for autonomy,[83] and argue that "from the moral viewpoint, informed consent has less to do with the liability of professionals as agents of disclosure and more to do with the autonomous choices of patients and subjects."[84] Beauchamp and Childress break down informed consent into the following elements: (1) "[c]ompetence (to understand and decide)[,]" (2) "[v]oluntariness (in deciding)[,]" (3) "[d]isclosure (of material information)[,]" (4) "[r]ecommendation (of a plan)[,]" (5) "[u]nderstanding" (of disclosure and recommendation), (6) "[d]ecision (in favor of a plan)[,]" and (7) "[a]uthorization (of the chosen plan)[.]"[85] While courts narrowly focus on disclosure and jurisdictions are split between the reasonable physician and reasonable patient standards for disclosure, for Beauchamp and Childress disclosure is merely one component of informed consent.[86] The element of understanding significantly identifies understanding of disclosure as necessary for informed consent.[87] A person understands "if they have acquired pertinent information and have relevant beliefs about the nature and consequences of their actions."[88] It is not necessary for understanding to be complete; it suffices to have an understanding of the fundamental facts.[89] The element of understanding emphasizes that while disclosure is an element of informed consent, disclosure to the patient without patient understanding is not sufficient.[90] If a patient cannot understand the pertinent information of the disclosure due to low health literacy, then the

80. Most articles that are not written by ethicists seem to adopt autonomy as the default ethical justification for informed consent. *See, e.g.*, Jennifer Matiasek & Matthew K. Wynia, *Reconceptualizing the Informed Consent Process at Eight Innovative Hospitals*, 34 JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY 127, 127 (2008) (noting that informed consent derives from autonomy).

81. *Id.*

82. *See*, *e.g.*, Terry, *supra* note 55, at 87-91.

83. BEAUCHAMP & CHILDRESS, *supra* note 60, at 117-120.

84. *Id.* at 121.

85. *Id.* at 120-21.

86. *Id.*

87. *Id.* at 120.

88. BEAUCHAMP & CHILDRESS, *supra* note 60, at 127.

89. *Id.*

90. *See generally id.* at 120-24 (noting that physicians may be guilty of negligent disclosure, even if their action conforms to professional practice).

element of understanding is not fulfilled, and informed consent is not achieved. Thus, from the perspective of respect for patient autonomy, when inadequate health literacy prevents patients from understanding disclosure communications, informed consent has not been realized.[91]

Neil Manson and Onora O'Neill have criticized the popular autonomy-based justification of informed consent.[92] Instead of an autonomy-based justification, they propose an approach to informed consent that views informed consent as a waiver of epistemic and ethical norms, including accuracy and honesty.[93] They argue that "[e]pistemically adequate communication is *relevant* communication, and has to be limited to what is appropriate to the actual context."[94] The justification for informed consent is that "it offers a standard and controllable way of setting aside obligations and prohibitions for limited and specific purposes."[95] Informed consent allows for the granting of permission for action that would "*otherwise* constitute a breach of bodily integrity, personal liberty or privacy."[96] Standardized informed consent forms emphasize formalities and uniformity while failing to provide adequate evidence that the underlying obligations have been waived or that the transactions were epistemically sound.[97] "Signatures, let alone ticks in boxes, may have *legal* weight, but they lack *ethical* weight, and often do not provide evidentiary weight that genuinely informed consent has been given."[98] Under this theory, genuine informed consent is obtained when the relevant communication takes place and a patient understands which obligations he or she is consenting to waive, regardless of whether or not a standard informed consent form is signed.[99]

Communication is central to informed consent under the shared decision making theory.[100] Some commentators believe that informed consent should be synonymous with shared decision making between physician and patient; however, there is no agreement on how informed

91. *See id*. at 140 (discussing that patient demands are still unsettled).

92. NEIL C. MANSON & ONORA O'NEILL, RETHINKING INFORMED CONSENT IN BIOETHICS 94 (2007).

93. *Id*. at 94-95, 185.

94. *Id*. at 63.

95. *Id*. at 188.

96. *Id*. (emphasis added).

97. MANSON & O'NEILL, *supra* note 92, at 190-91.

98. *Id*. at 192.

99. *See id*. at 63, 95, 185, 188, 191-92 (noting that good communication between patient and physician is imperative to informed consent).

100. *See generally* Simon N. Whitney et al., *A Typology of Shared Decision Making, Informed Consent, and Simple Consent*, 140 ANNALS INTERNAL MED. 54, 54-56 (2004) (noting that shared decision making involves the exchange of ideas and information between patient and physician); Shalowitz & Wolf, *supra* note 13, at 759-60 (explaining that shared decision making is improved by promoting joint communication between patient and physician).

consent and shared decision making are related.[101] Shared decision making is closely aligned with the ethical autonomy based justification of informed consent. There are three stages in the shared decision making process: (1) "information exchange," (2) "deliberation," and (3) "decision."[102] Under this theory, informed consent does not occur when a consent form is signed, but rather when the patient and physician "discuss a problem and choose an intervention together, a process that may take place in [one] sitting or over the course of several encounters."[103] Within this process low health literacy is an obstacle to the exchange of information and, as a result, deliberation and decision making. Shared decision making would require doctors to discuss information in a manner that permits patients with low health literacy to understand the material information. Shared decision making focuses on interpersonal communication in the informed consent process as opposed to the mechanical signing of a consent form.

Beauchamp and Childress, Manson and O'Neill, and shared decision making represent three different ethical approaches to informed consent. Health literacy is important for understanding disclosure under autonomy-based informed consent, for understanding what underlying obligations are being waived by consent within Manson and O'Neill's framework, and for information exchange and deliberation in the shared decision making process. Consideration of health literacy is justified from multiple ethical perspectives.

Health literacy is not currently an explicit factor that courts consider when determining whether a patient gave informed consent to a medical procedure or treatment.[104] Courts narrowly focus on the physician duty of disclosure while neglecting to investigate whether the patient understood the disclosure given their health literacy level.[105] Ethical theories consist of more elements than mere disclosure for informed consent. Courts initially relied on ethical justifications of autonomy for the doctrine of informed consent, but they should now look to ethics for support for considering health literacy in informed consent cases. The incorporation of health literacy into the legal doctrine of informed consent can be accomplished through advocacy

101. BEAUCHAMP & CHILDRESS, *supra* note 60, at 117-20.

102. Shalowitz & Wolf, *supra* note 13, at 760.

103. Whitney et al., *supra* note 100, at 54 (internal citations omitted).

104. As of March 25, 2009, a document search for cases containing both "health literacy" and "informed consent" produces no cases on both WestLaw and LexisNexis.

105. *See* BEAUCHAMP & CHILDRESS, *supra* note 60, at 119-20, 121-22 (noting the legal doctrine of informed consent is primarily based on a physician's obligation to use reasonable care to provide accurate information to the patient).

around understanding of disclosure and disclosure of communications with the help of ethical principles.

IV. HOW LITERACY AFFECTS CONSENT

Informed consent is contingent upon the general and health literacy of the patient, i.e. the patient's "ability to understand pertinent information."[106] In healthcare, under normal circumstances,[107] patients are required to sign informed consent forms prior to surgery, receiving blood products, or participating in human subjects research.[108] A quick examination of patients with limited English proficiency demonstrates that healthcare organizations recognize the importance of understanding the language of consent communication. The case law surrounding this class of patients also illustrates potential barriers to greater accommodations for health literacy, including the readability of informed consent forms.

A. Limited English Proficiency Patients

There are approximately eleven to twenty-one million Americans who are not proficient in English.[109] In other words, they have limited English proficiency.[110] A physician may be liable for failing to obtain a patient's consent to proceed with treatment if a limited English proficiency (LEP) patient is not provided with interpreter services.[111] Healthcare organizations receiving federal funds (i.e., payments from Medicare and Medicaid) must comply with civil rights laws prohibiting discrimination against anyone

106. Frank McClellan, *Medical Malpractice Law, Morality and the Culture Wars: A Critical Assessment of the Tort Reform Movement*, 27 J. LEGAL MED. 33, 42 (2006).

107. As opposed to an emergency in which there is no time to get consent from the patient or a family member. Or when a patient is not legally competent in which case a family member is often asked to sign the consent form.

108. Michael K. Paasche-Orlow, *The Challenges of Informed Consent for Low-Literate Populations*, *in* UNDERSTANDING HEALTH LITERACY: IMPLICATIONS FOR MEDICINE AND PUBLIC HEALTH 119, 125 (Joanne G. Schwartzberg et al. eds., 2005) [hereinafter Paasche-Orlow, *The Challenges of Informed Consent*].

109. Siddharth Khanijou, Comment, *Rebalancing Healthcare Inequities: Language Service Reimbursement May Ensure Meaningful Access to Care for LEP Patients*, 9 DEPAUL J. HEALTH CARE L. 855, 856 (2005); *see also* Matiasek & Wynia, *supra* note 80, at 127-28 (noting there are twenty-two million Americans with limited English proficiency).

110. *See* Khanijou, *supra* note 109, at 870 (discussing that a language barrier exists between patients and physicians that results in communication difficulties); *see also* Matiasek & Wynia, *supra* note 80, at 127-28 (discussing that English proficiency poses a barrier to efficient healthcare communication).

111. Khanijou, *supra* note 109, at 870.

seeking healthcare services.[112] CMS recommends that medical institutions provide patients with informed consent forms written in simple sentences in the primary language of the patient.[113] However, consent forms are typically written in English,[114] although some hospitals have begun using translated consent forms.[115] Although this is helpful for LEP patients who are literate in their written native language, translated consent forms pose the same barriers—they are difficult to read and understand—to low-literate LEP patients as English forms do for patients with low health literacy. The CMS recommendation that consent forms be written in simple sentences in the primary language of the patient should be applied to forms in English as well.

Even when the physician agrees that lack of understanding of the English language would prevent a signed consent form from being valid, it may be difficult to win an informed consent case, as evidenced by *Rodriguez v. New York City Health and Hospitals Corp.*[116] In this 2008 case a patient alleged that, although she signed a consent form, the consent was invalid due to her inability to read English.[117] New York State, where the case was brought, uses the professional standard for disclosure in informed consent cases.[118] The court seemed to doubt the patient's sincerity that she could not understand the form because she did not ask to have a Spanish consent form or interpreter provided.[119] The patient had also acted as a translator for another Spanish-speaking patient during her hospital stay.[120] The opinion does not discuss the extent to which she translated and the nature of what she translated.[121] She may have simply translated the symptoms that the patient was experiencing. If that was the case, a person with low health literacy would likely be able to orally explain symptoms in any language, but

112. PATIENTS AS PARTNERS, *supra* note 17, at 74; *see* Matiasek & Wynia, *supra* note 80, at 132 ("Not providing adequate language assistance can . . . breach Title VI of the Civil Rights Act of 1964 . . . .").

113. PATIENTS AS PARTNERS, *supra* note 17, at 75.

114. Matiasek & Wynia, *supra* note 80, at 129.

115. *Id.* at 132.

116. Rodriguez v. N.Y. City Health & Hosps. Corp., 50 A.D.3d 464, 466 (N.Y. App. Div. 2008).

117. *Id.* at 465.

118. *See id.* (noting, as part of informed consent, the plaintiff must prove "the defendant physician failed to disclose the material risks, benefits, and alternatives to the contemplated medical procedure which a reasonable medical practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation").

119. *Id.* at 466.

120. *Id.*

121. *See generally Rodriguez*, 50 A.D.3d at 464-66 (no mention about the extent to which plaintiff translated).

may still have difficulty comprehending a standard consent form, risks, and alternatives that use medical terminology. In this case the court was reluctant to take the patient's word for it that she did not understand the form.[122] The judicial reluctance to consider a patient's comprehension of a form written in her non-native language suggests that the courts will be resistant to considering whether a native English speaker's inadequate health literacy prevented them from comprehending a consent form.

B. Readability Level of Informed Consent Forms

The readability of informed consent forms is important because in most states a signed consent form leads to a legal presumption that informed consent was obtained.[123] Pre-printed informed consent forms are "commercially prepared and distributed."[124] These standard informed consent forms lack a tailoring to the informational needs of a particular patient based on that patient's educational level and health literacy level.[125] "There is growing reason for concern that consent forms are becoming substitutes for, rather than documentary evidence of," a conversation between physician and patient that facilitates informed consent.[126] If informed consent forms are being used in the place of a conversation between physicians and patients, it is crucial that patients are able to understand the contents of the forms in order for them to make autonomous or shared decisions, and arguably for the physician to satisfy his duty to disclose.[127]

122. *See id.* at 466 (noting that there was insufficient evidence that plaintiff did not comprehend what the defendant surgeon said or did).

123. *See, e.g.*, LA. REV. STAT. ANN. § 40:1299.40(A)(1) (2008) (a patient signature marking or affirmative action through electronic means of a consent form "shall be presumed to be valid and effective, in the absence of proof that execution of the consent was induced by misrepresentation of material facts."); GA. CODE ANN. § 31-9-6.1(b)(2) (2006) (rebuttable presumption of valid consent); FLA. STAT. ANN. § 766.103(4)(a) (West 2009) (signed written consent raises a rebuttable presumption of valid informed consent); OHIO REV. CODE ANN. § 2317.54 (West 2004) ("written consent . . . [is] presumed to be valid and effective, in the absence of proof by a preponderance of the evidence . . . that the person executing the consent was not able to communicate effectively in spoken and written English or any other language in which the consent is written.").

124. Weisbard, *supra* note 74, at 756.

125. *Id*. At most hospitals, after a patient has spoken with a physician and agreed on a course of action, the patient is provided with an informed consent form to sign. "[B]ecause the forms are presented only after a conversation during which actual understanding and consent are presumably ensured, the consent forms themselves are sometimes presented to be signed quickly, along with a number of other forms. As a result, patients rarely read, let alone understand, the consent forms they sign." Matiasek & Wynia, *supra* note 80, at 129.

126. Weisbard, *supra* note 74, at 756-57.

127. *See supra* Part III.

The average adult in the United States reads at an Eighth grade level, but consent forms are often written at college or graduate school reading levels.[128] Informed consent forms utilize structured and technical language that can result in confusion, poor understanding, and misinformed consent.[129] Fear of malpractice vulnerability has contributed to the complexity of informed consent documents, for example, "the typical informed consent document used for oncology randomized controlled trials is five to eight pages long and is written at the grade 13 to 14 level."[130]

After agreeing to or receiving care, at least sixty percent of patients "do not read or understand the information contained in informed consent forms."[131] It is doubtful that those patients are truly informed about the decisions made.[132] A study conducted by Mark Williams and his colleagues found that 59.5% of patients at two urban public hospitals could not understand a standard consent document.[133] "Patients unable to understand informed consent forms cannot intelligently participate in their

128. *See* Matiasek & Wynia, *supra* note 80, at 129 (stating that because consent forms are intended to legally protect providers, "these forms often contain complex medicolegal terms and are written at the college or even postgraduate [reading] level[s]."); PATIENTS AS PARTNERS, *supra* note 17, at 78 (stating that the informed consent forms at several hospitals in the Iowa Health System "were written at the 17th grade level or higher."); Ad Hoc Comm., *Health Literacy*, *supra* note 14, at 554 (noting that most consent forms are written "far above [an] 8th-grade reading level . . . .").

129. IOM, *supra* note 28, at 187; *see also* Michael K. Paasche-Orlow et al., *Readability Standards for Informed-Consent Forms as Compared with Actual Readability*, 348 NEW ENG. J. MED. 721, 723 tbl.1 (2003) (The following are examples of informed consent language describing "New Information about Risks" at different reading levels:

Fourth Grade	"We may learn about new things that might make you want to stop being in the study. If this happens, you will be informed. You can then decide if you want to continue to be in the study."
Sixth Grade	"We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information."
Eighth Grade	"We will tell you about new information that may affect your willingness to stay in this study."
Tenth Grade	"We will tell you about new information that may affect your health, welfare, or willingness to stay in this study."

130. Williams et al., *supra* note 49, at 1681.

131. PATIENTS AS PARTNERS, *supra* note 17, at 73; Ad Hoc Comm., *Health Literacy*, *supra* note 14, at 553.

132. PATIENTS AS PARTNERS, *supra* note 17, at 73; *see* Wilson, *supra* note 16, at 875 (explaining that literacy affects a patient's ability to follow instructions given by his or her physician).

133. Williams et al., *supra* note 49, at 1677-82.

own care."[134] Given that approximately ninety million Americans have low health literacy, it is likely that poor health literacy is contributing to patient lack of understanding of information contained in informed consent forms.[135]

Michael Paasche-Orlow and his colleagues reason that since nearly fifty percent of adults read at or below an Eighth grade level, plain language should be used for informed consent forms.[136] They recommend that informed consent forms be written at a Fourth grade to Sixth grade reading level in order to convey risks simply and directly to low-literate patients.[137] The National Quality Forum recommends that informed consent forms be written at a Fifth grade reading level or lower and that they incorporate pictures or symbols to enhance understanding.[138] It has been suggested that a patient's low health literacy could invalidate a written informed consent.[139]

Courts have been reluctant to look beyond the signature on an informed consent form to determine if the patient understood the document.[140] In most states a signed consent form creates a legal presumption that the patient's informed consent was obtained, regardless of the readability level of the form and the patient's own health literacy level.[141]

V. INFORMED CONSENT DOCTRINE AND HEALTH LITERACY

Informed consent does not work as intended because "[d]octors generally tell patients too little and patients generally understand too little for patients to make the choices that lawmakers had imagined."[142] Also, patients and providers have different views of when consent is necessary and whether true informed consent was obtained.[143] If informed consent is to represent the autonomous decision of an individual patient, then consideration of health literacy needs to be recognized within the legal doctrine of informed consent. This Section explores the limited case law that involves patient literacy and identifies ways in which those cases open the way for arguments concerning health literacy. Potential barriers to

134. *Id.* at 1681.

135. Schulte, *supra* note 20, at 18.

136. Paasche-Orlow et al., *supra* note 129, at 725.

137. *Id.*

138. PATIENTS AS PARTNERS, *supra* note 17, at 76.

139. McClellan, *supra* note 106, at 47.

140. *See* Rodriguez v. N.Y. City Health and Hosps. Corp., A.D.3d 464, 466 (N.Y. App. Div. 2008) (noting that "there was insufficient evidence that plaintiff did not understand the discussions with defendant's surgeon or other hospital staff.").

141. *See supra* note 123 and accompanying text.

142. Schneider, *supra* note 63, at 10.

143. IOM, *supra* note 28, at 189.

advancing the importance of health literacy in the legal arena are discussed, and opportunities for legal recognition of the importance of health literacy are then proposed. This Section concludes with a review of initiatives to improve the informed consent process for patients with limited health literacy outside of the legal domain.

A. Case Law Involving Signed Consent Forms and Patient Understanding

Currently, tort law does not specifically address the problem of patients with limited general literacy and/or limited health literacy.[144] Only a handful of cases discuss both a patient's literacy level and informed consent forms as evidence of informed consent. The courts in *Keomaka v. Zakaib*,[145] *Ditto v. McCurdy*,[146] and *Hidding v. Williams*[147] considered signed consent forms, literacy, and informed consent. An analysis of case law illustrates some of the barriers and opportunities for advocating for consideration of health literacy within the legal framework of informed consent.

In *Keomaka v. Zakaib*, the Intermediate Court of Appeals of Hawaii held that a physician does not fulfill his affirmative duty of disclosure "by merely having the patient sign a printed informed consent form."[148] The court identified the problem regarding consent forms, noting that

> [t]here is a growing reason for concern that consent forms are becoming substitutes for, rather than documentary evidence of, an ongoing process of disclosure, discussion, and decisionmaking between physician and patient. If physicians come to believe (often incorrectly) that their obligation to obtain the patient's informed consent can be satisfied by securing a signature—even that of a drowsy, drugged, or confused patient on an abstruse, jargon-ridden, and largely unintelligible preprinted consent form—the law's reliance on written documentation may come to pervert its central purpose in requiring informed consent.[149]

The patient in *Keomaka* had not read the consent form before signing it.[150] However, the court reasoned that even if he had read the form, it did not disclose the possible risks or alternative forms of treatment.[151] The court concluded that the patient had "neither the knowledge nor the duty" to ask questions in order to receive the information that the doctor was required by

144. *Id.* at 184.

145. Keomaka v. Zakaib, 811 P.2d 478 (Haw. Ct. App. 1991).

146. Ditto v. McCurdy, 947 P.2d 961 (Haw. Ct. App. 1997) *aff'd in part, rev'd in part, vacated in part, remanded*, 947 P.2d 952 (Haw. 1997).

147. Hidding v. Williams, 578 So. 2d 1192 (5th Cir. 1991).

148. *Keomaka,* 811 P.2d at 486.

149. *Id.* at 486-87 (quoting Weisbard, *supra* note 74, at 756-57).

150. *Id.* at 487.

151. *Id.*

law to disclose.[152] Thus, the burden is on the physician to make sure that the patient has the requisite understanding to give informed consent.

The Intermediate Court of Appeals of Hawaii held six years later in *Ditto v. McCurdy* that a patient's signature on a standard informed consent form does not fulfill a physician's affirmative duty of disclosure.[153] In *Ditto*, the patient had a fourth grade education, was a first generation Korean immigrant, and could not read English when she signed the form.[154] The patient was fluent in spoken English, but not written English.[155] The consent form stated that the "'physician has informed [the patient] of the . . . risks or complications involved in [the] treatment or procedures . . . and alternative forms of treatment, including nontreatment, available.'"[156] Yet the patient testified that the physician did not explain alternative procedures or possible complications.[157] It was clear at trial that the physician believed that because the patient spoke English she would be able to read and comprehend the consent form.[158] At no point was the patient asked by the physician or medical staff "whether she *could actually read or understand* the consent form."[159]

The court explained that the doctrine of informed consent is based upon principles of individual autonomy, and that informed consent imposes an affirmative duty on physicians and surgeons to "fully disclose to a patient 'the type of risks and alternatives' to a proposed treatment or surgery."[160] In Hawaii, the doctrine of contributory negligence was replaced with a modified comparative negligence statute.[161] Therefore, the court reasoned that a patient "'is not contributorily negligent for failing to read a consent form[.]'".[162] The court emphasized that it was a pre-printed informed consent form.[163] The *Ditto* court endorsed the reasoning of the *Keomaka* court and added "'[or uneducated]'" to the list of patient characteristics that includes "'drowsy, drugged, . . . confused,'" that would cause concern for reliance solely on a signed consent form.[164] The court thus signaled that education affects a person's ability to understand a consent form. A

152. *Id.*
153. *Ditto*, 947 P.2d at 988.
154. *Id.* at 968, 987.
155. *Id.* at 969-70.
156. *Id.*
157. *Id.* at 987.
158. *Ditto*, 947 P.2d at 970, 987 n.27.
159. *Id.* at 970 (emphasis added).
160. *Id.* at 987 (quoting Keomaka v. Zakaib, 811 P.2d 478, 482 (Haw. Ct. App. 1991)).
161. *Id.* at 987 n.26.
162. *Id.* at 987.
163. *Ditto*, 947 P.2d at 987.
164. *Id.* at 988 (quoting *Keomaka*, 811 P.2d at 487).

signature of a competent and *literate* adult is evidence to be considered when determining whether a physician has satisfied his or her affirmative duty, but "a signature, standing alone, cannot be equated with any alleged comparative negligence on the part of the patient."[165] Thus, the patient has no duty to speak up if he or she does not understand a pre-printed consent form's contents.[166] It is the physician who has the burden to satisfy the duty of disclosure.[167]

Though the *Ditto* court did not specifically address health literacy, it did address illiteracy. It is unclear how the court's ruling would be applied to a case in which the informed consent form was not pre-printed. The court may have purposefully added "uneducated" to the reasoning used in *Keomaka* to question the usefulness of having a signed consent form as proof of informed consent.

Health literacy is related to education and should be added to the list of reasons that securing a signature on a consent form is not conclusive evidence that genuine informed consent has been given. The *Ditto* court emphasized in its reasoning that the form was "'abstruse, jargon-ridden, and largely unintelligible,'"[168] suggesting that it was full of technical and complex language, and likely written at a high reading level. In comparison, a pre-printed form that uses plain English and is written at a Fourth to Eighth grade reading level with a patient signature might be weighted as strong evidence of true informed consent by a court in this jurisdiction for patients who have low general and/or health literacy. This reasoning should be adopted by courts in other jurisdictions because it weighs patient education—and by association literacy—as a factor and encourages physicians to ensure that patients understand the risks and can therefore make true informed consent.

In *Hidding v. Williams*, the Court of Appeals for the Fifth Circuit found that "[i]n order for a reasonable patient to have awareness of a risk he should be told in lay language the nature and severity of the risk and the likelihood of its occurrence."[169] The patient in *Hidding* had a Sixth grade education and "minimal" reading skills.[170] The patient's wife would accompany him to his appointments so that she could help him understand the doctor's orders and instructions.[171] A consent form was signed by the

165. *Id.* at 988.

166. *See id.* (explaining that when patients do not completely understand the consent form, the physician has a duty to help them understand).

167. *Id.*

168. *Ditto*, 947 P.2d at 988 (quoting *Keomaka*, 811 P.2d at 487).

169. Hidding v. Williams, 578 So. 2d 1192, 1196 (5th Cir. 1991).

170. *Id.*

171. *Id.*

patient, but according to his wife, he would not have been able to understand the document on his own.[172] The generic consent form identified one risk of treatment as "'loss of function of body organs'", but the wife interpreted the phrase to mean "'you can't get up and walk around or that when you do, you may stumble or fall or be very weak or wobbly on your feet.'"[173]

According to the *Hidding* court, the doctrine of informed consent is based on the principle that every competent adult has the right to determine what is done to his or her own body.[174] "A doctor is required to provide his patient with sufficient information to permit the patient himself to make an informed and intelligent decision on whether to submit to a proposed course of treatment."[175] The court adopted the Second Restatement of Torts, which states that in order to "establish consent to a risk it must be shown both that the patient was aware of the risk and that he agreed to encounter it."[176] A Louisiana state statute requires that patients be "afforded the opportunity to ask questions and must acknowledge in writing his consent to the treatment."[177] According to the statute, a patient is presumed to have understood and consented when the form is signed.[178]

The *Hidding* court stated that a bland statement as to a risk, such as "'loss of function of body organs,'" when not accompanied by an estimate of its frequency, is inadequate.[179] The court found that Mrs. Hidding "successfully rebutted the presumption attached to the signed consent form."[180] The physician has a duty "to disclose material risks in such terms as a reasonable doctor would believe a reasonable patient would understand."[181] The *Hidding* court's ruling suggests that a consent form is evidence of informed consent, but is not conclusive.[182]

These cases are significant because they addressed the legal presumption of valid informed consent when an informed consent form was signed by a patient with limited literacy skills. If courts are willing to recognize the importance of education and the duty of the physician to ensure patients understand material information, then courts may be

172. *Id.*
173. *Id.*
174. *Hidding*, 578 So. 2d at 1194.
175. *Id.*
176. *Id.* at 1196 (citing RESTATEMENT (SECOND) OF TORTS § 892A (1979)).
177. *Id.* at 1195.
178. *Id.*
179. *Hidding*, 578 So. 2d at 1196.
180. *Id.*
181. *Id.*
182. IOM, *supra* note 28, at 190-91 (discussing *Hidding* to illustrate the potential issues that must be considered when examining literacy and informed consent).

persuaded that limited health literacy and the readability level of consent forms are valid reasons to overcome the presumption that a signed form means valid informed consent was obtained.

B. Potential Barriers and Obstacles

It has been over a decade since *Keomaka*,[183] *Ditto*,[184] and *Hidding*[185] were decided and health literacy has yet to be discussed in the context of the validity of signed consent forms. In many states if a patient signs an informed consent form they are presumed to have understood and consented to the risks.[186] It will be difficult to overcome that presumption. As of the writing of this Comment, there are no published cases that address low health literacy as a possible factor that can overcome the presumption of understanding when an informed consent form is signed.

The reasonable physician standard for disclosure provides little opportunity to argue that consent was not sufficiently informed based on an individual patient's health literacy because it is based on the objective reasonable physician. The *Hidding* court stated that disclosure must be in "such terms as a reasonable doctor would believe a reasonable patient would understand."[187] With that rule, advocacy is necessary around the definitions of "reasonable doctor" and "reasonable patient." As discussed *supra*, nearly half of adults in the United States have limited literacy skills, and it is likely that many more have low health literacy.[188] Does a "reasonable doctor" consider that their patients may have limited reading skills? It might be fair to presume that a "reasonable patient" cannot understand medical jargon and the complex wording of standard informed consent forms. Under the reasonable physician/professional standard of disclosure, the best argument for consideration of health literacy may be that it is unreasonable for physicians to rely on pre-printed consent forms written at reading levels well above the average American's reading ability to obtain patients' informed consent.

A barrier to taking literacy into account is that physicians have difficulty recognizing when patients have low health literacy, because patients with low literacy are adept at hiding it from their physicians.[189] Further, the

183. Keomaka v. Zakaib, 811 P.2d 478 (Haw. Ct. App. 1991).

184. Ditto v. McCurdy, 947 P.2d 961 (Haw. Ct. App. 1997).

185. *Hidding*, 578 So. 2d at 1192.

186. *See supra* note 123 and accompanying text. However, "[u]nder the common law, consent did not need to be written, and written consent did not provide airtight insulation against liability." Weisbard, *supra* note 74, at 757 n.17.

187. *Hidding*, 578 So. 2d at 1196.

188. *See* discussion of literacy *supra* notes 13-20 and accompanying text.

189. *See* Shalowitz & Wolf, *supra* note 13, at 760 (noting physicians sometimes are unable to judge how much lower literate patients understand); Marcus, *supra* note 16, at 339

majority of functionally illiterate adults "are able to sign their own names without difficulty."[190] The 2003 NAAL classified signing a form as one of the simplest, concrete literacy skills that a patient with Below Basic health literacy skills can do.[191] A physician (and a court) may see the patient's signature and mistakenly assume that the patient was able to read and comprehend the text of the consent form.[192] Thus, physicians are likely to overestimate a patient's understanding of written materials.[193] Currently, it appears that many doctors assume that a patient understands an informed consent form, taking away that assumption will mean that healthcare providers will need to spend more time with patients. The time necessary for a physician to ensure a patient understands the risks and is consenting would vary upon the patient's health literacy and the communication skills and tools of the physician. One solution is to allow physicians to bill for the consent process.[194] If this type of financial incentive were used, the consent process should be clearly defined in order to incorporate appropriate consideration of patient health literacy.

Many hospital lawyers, risk managers, and consultants are skeptical that simplified consent forms (which are easier to read for patients with low health literacy) will suffice to meet regulatory, accreditation, and state requirements for valid consent because they lack the legal jargon and medical terminology typical of standard informed consent forms.[195] This skepticism stands in the way of a shift towards informed consent forms written in plain English. It does appear that JCAHO and CMS would find simplified consent forms satisfactory based on their current guidelines, but simplified forms may not satisfy individual state informed consent laws.[196] State informed consent statutes that do not clearly permit simplified or plain English consent forms are a barrier to accommodation for health literacy in the informed consent process because of the fear that using them will open the doors to more, not less, liability.[197]

(discussing how one patient's reading problem was unknown to nurses, social workers, and physicians).

190. Paashe-Orlow, *The Challenges of Informed Consent*, *supra* note 108, at 126.

191. WHITE, *supra* note 19, at 33 tbl.4.

192. *See generally* Paashe-Orlow, *The Challenges of Informed Consent*, *supra* note 108, at 125-26 (explaining some may mistakenly apply attributes from other signed documents to informed consent forms).

193. Shalowitz & Wolf, *supra* note 13, at 760.

194. Paashe-Orlow, *The Challenges of Informed Consent*, *supra* note 108, at 133; *see also* Akira Akabayashi & Michael D. Fetters, *Paying for Informed Consent*, 26 J. MED. ETHICS 212, 212 (2000) (explaining that Japan allows physicians to bill the Ministry of Health and Welfare for the consent process).

195. Matiasek & Wynia, *supra* note 80, at 135.

196. *Id*. at 131-32.

197. *But see* discussion on current initiatives *infra* notes 215-34 and accompanying text.

C. *Opportunities for Consideration of Health Literacy*

While patients with low health literacy are capable of consenting, they need to understand the informed consent information in order to provide genuine informed consent. In the words of the Pennsylvania Superior Court, "[the] information must give the patient 'a true understanding.'"[198]

The elements of disclosure and understanding of disclosure and recommendation are both recognized by Beauchamp and Childress as ethically necessary for informed consent.[199] If a physician does not have a verbal discussion with his or her patient regarding the risks and alternatives of treatment, but instead relies on a complex consent form filled with medical jargon (a college reading level), then it can be argued that under the reasonable patient standard of disclosure, the physician has failed. If a patient cannot understand the consent form—whether because of the language in which it is written, the reading level of the form, or the medical jargon used—then he or she cannot truly exercise his or her right to self-determination. This does not mean that all forms need to be written at a lower grade level. Physicians can use the teach-back/relate-back method and/or explain the form in plain English to the patient to enhance understanding and overcome the shortcomings of the form.[200] This argument is supported by the the Supreme Court of Kansas, which held in *Natanson v. Kline* that a physician has an obligation "to disclose and explain to the patient in language as simple as necessary."[201]

It is important to remember that informed consent is supposed to be supported by physician-patient communication and discussion, not by the consent form itself. The absence of written consent does not necessarily mean that there was no consent. In *Yahn v. Folse*, the patient was functionally illiterate and hard of hearing, and prior to surgery no written consent was obtained.[202] Dr. Folse believed that he had received oral consent when the patient said "'[o]kay.'"[203] On rehearing, the court found that Dr. Folse had obtained informed consent.[204] Dr. Folse sat close to the patient and used a loud voice because he was informed that the patient was hard of hearing.[205] Further, the physician spent fifteen to twenty minutes with the patient prior to the procedure, which the court found was enough

198. Isaac v. Jameson Mem'l Hosp., 932 A.2d 924, 929 (Pa. Super. Ct. 2007).

199. BEAUCHAMP & CHILDRESS, *supra* note 60, at 117-18.

200. *See* discussion of the teach-back and relate-back methods *infra* notes 224-31 and accompanying text.

201. Natanson v. Kline, 350 P.2d 1093, 1106-07 (Kan. 1960).

202. Yahn v. Folse, 639 So. 2d 261, 264 (La. Ct. App. 1993).

203. *Id.*

204. *Id.* at 270.

205. *Id.*

time and opportunity for questions. This case illustrates that informed consent does not legally require a signed consent form—absent a state statute requiring one—and that a physician can accommodate patients who are illiterate and hard of hearing. By having the material risks explained verbally, the patient did not have to try to read a consent form. This case could be used to placate physician fears that simplified consent forms will not hold up in court because, absent a state statute, written consent is not required. If a simplified consent form is used as a tool to help the consent communication process. As suggested in *Yahn v. Folse*, it is that communication that validates the informed consent, not the form itself.

In response to the concern that consent forms written at lower reading levels will not be legally sufficient, state legislation can explicitly make those consent forms valid. Ideally, state legislation would endorse plain English consent forms and explicitly state that a signed consent form is insufficient if a discussion between the physician and patient about the relevant risks and alternatives did not take place.

Quintanilla v. Dunkelman, emphasizes how the existence of informed consent is fact- sensitive.[206] In *Quintanilla* the physician argued that a signed consent form is conclusive evidence of informed consent, and that to hold otherwise would allow plaintiffs to deny having read and understood consent forms in order to sue physicians.[207] The physician contended that this would lead to more lawsuits and have a negative impact on the practice of medicine.[208] The court disagreed and stated that the existence of informed consent is "'a peculiarly fact-bound assessment which juries are especially well-suited to make.'"[209] Each patient presents a separate unique problem; the patient's mental and emotional conditions, as well as other individual circumstances, are important to whether informed consent was obtained.[210] Thus, the court held that "the validity of written consent" is "a question of fact for the jury to decide based upon conflicting evidence."[211] Whether a person has sufficient health literacy to comprehend a written consent form should also be a question of fact for the jury to decide.

In states that have a reasonable patient standard for disclosure, health literacy can be incorporated by advocating that the reasonable person is an individual with a similar health literacy level as the patient at issue. Advocacy should focus on making this standard more subjective. Another argument is that the reasonable patient should be defined based upon

206. Quintanilla v. Dunkelman, 133 Cal. App. 4th 95, 115 (Cal. Ct. App. 2005).
207. *Id.*
208. *Id.*
209. *Id.* (quoting Arato v. Avedon, 5 Cal.4th 1172, 1186 (1993)).
210. *Id.*
211. *Quintanilla*, 133 Cal. App. 4th at 118.

statistical data of health literacy in the United States or the particular patient population.

One way of alleviating the difficulty of obtaining genuine informed consent from patients with low health literacy would be to legislatively mandate that all medical informed consent forms be written in plain English, without medical jargon. "Federal securities laws require that certain documents geared toward investors conform to the 'plain English' rule, requiring that documents be written on a sixth or seventh grade reading level, in the active voice, and with no double negatives."[212] Jillanne Schulte suggests that it would be reasonable for the law to mandate a plain English rule for informed consent forms because "[t]he financial information contained in Securities and Exchange Commission documents is as complex, dense, and sophisticated as any information found in the medical field."[213]

D. Current Initiatives to Improve the Consent Process

As discussed *supra*, evidence suggests that many standard informed consent forms are written at a readability level well above the Eighth grade reading level of the average adult in the United States.[214] While within the legal arena there has been little recognition of the problems posed to the informed consent doctrine by inadequate health literacy among patients, the following are methods that have been undertaken to improve the communications with patients prior to their giving informed consent outside of the legal domain: simplified forms with plain language and simple illustrations, drawing analogies,[215] audiotapes, videotapes, and multimedia resources.[216] This Section describes some of the initiatives that have tried to improve either the readability of consent forms or the disclosure communication process.

JCAHO "requires medical instructions to be given on a level understandable to patients."[217] According to JCAHO, an organization must obtain and document informed consent in accordance with the organization's policy.[218] Further, an organization's policy must include a *discussion* of risks, benefits, side effects, alternatives, and likelihood of achieving goals.[219] Some states have statutes that describe alternative

212. Schulte, *supra* note 20, at 18.
213. *Id.*
214. See discussion on the readability level of informed consent forms, *supra* Part IV.B.
215. BEAUCHAMP & CHILDRESS, *supra* note 60, at 128.
216. Williams et al., *supra* note 49, at 1681-82.
217. Lee et al., *supra* note 52, at 1317.
218. Matiasek & Wynia, *supra* note 80, at 131.
219. *Id.*

means of disclosure that may be used in the informed consent process.[220] CMS guidelines on informed consent forms state that they must include a statement that the treatment, benefits, risks, and alternative therapies were *explained*.[221] The JCAHO and CMS guidelines were "intended to address common concerns about the legality of simplifying consent forms[,]" but it is important to note that both guidelines "defer to state law" when state statutes require more detailed consent forms.[222] Non-uniform state law requirements may make a simplified consent form legally valid in one state and insufficient in another.[223]

Some innovative hospitals have initiatives "to create a more unified informed consent process, in which consent forms are used to structure a conversation, teach, and ensure patient understanding, as well as for documentation and legal protection."[224] One such practice involves incorporating systematic redundancies into the informed consent process, or the repeat-back method.[225] This method is used to make sure that informed consent is more than just the signing of a form—it simultaneously allows patients the opportunity to ask questions and helps physicians and nurses confirm patient understanding.[226] Another method is to incorporate repeat-back into the consent form, by requiring physicians and/or nurses to check a

220. *See, e.g.*, GA. CODE ANN. § 31-9-6.1(c) (2006) (stating the information that must be disclosed to obtain consent "may be disclosed through the use of video tapes, audio tapes, pamphlets, booklets, or other means of communication or through conversations with" listed medical personnel). While the statute lists numerous communication tools, it does not list informed consent forms. *Id.* Consent forms presumably fall under "other means of communication." *Id.*

221. Matiasek & Wynia, *supra* note 80, at 132. By stating that the risks, benefits, and alternatives to a given treatment must be explained, and not that they must be explicitly listed/described, the door is opened for simplified consent forms.

222. *Id.*

223. *See id.* at 135-36 (noting that legislatures should address the lack of uniform guidelines on informed consent at the state level).

224. *Id.* at 129. For example, one hospital in the study, conducted by the American Medical Association's Ethical Force Program and the American Hospital Association's Health Research and Educational Trust, revised some of its consent forms in collaboration with external liability consultants and hospital staff (including interpreters and translators). *Id.* at 131 sidebar.1. The hospital also incorporated the repeat-back method. *Id.* Another hospital lowered the reading level of its surgical consent form from the Sixteenth grade level to the Seventh to Eighth grade level. *Id.* The form now includes a large space for the staff member to write out in the patient's own words their description of the procedure (another form of repeat- or teach-back method). *Id.* The form does not list the risks or benefits, but asks patients to affirm that they were reviewed with them. *Id.* Patients have found the new forms more clear and straightforward, and the nursing staff prefers them because they are easier to read and review with patients. *Id.*

225. *Id.* at 133.

226. Matiasek & Wynia, *supra* note 80, at 133.

box confirming that a patient was able to correctly repeat back the purpose of the procedure, the main risk, and the potential benefit.[227] Studies have shown that the repeat back method does improve patient comprehension and recollection of healthcare information.[228] The AHRQ, the Leapfrog Group, and the National Quality Forum have all recommended the repeat back method for informed consent.[229]

Similarly, a strategy that focuses on physician-patient communication and patient understanding is the teach-back method, which is used prior to obtaining a patient's signature for consent. With the teach-back method, the physician explains the risks to the patient and then asks the patient to repeat the information in their own words so that the physician can gauge whether they understood what was conveyed.[230] Computer-based programs that teach patients about conditions and treatment options, test patient understanding, and document informed consent are also being used by some hospitals and health systems.[231]

Videotapes can also be used as a tool to communicate the information needed for informed consent to patients. In *Winkle v. Tullos*, the patient was shown a videotape that explained the procedure and discussed the risks prior to surgery, and she signed a disclosure and consent form that satisfied the state statute requirements.[232] The court found that the evidence was sufficient to support the jury's failure to find lack of informed consent.[233] Thus, as long as a consent form complies with state legislation, a videotape appears to be a valid substitution for a physician-patient discussion of the risks.[234] Videotapes could be an efficient way to improve informed consent for patients with limited health literacy—assuming that the video's dialogue is in plain English and not filled with medical jargon— without consuming more of the physician's valuable time.

VI. CONCLUSIONS AND RECOMMENDATIONS

A major flaw in the current legal doctrine of informed consent is that it assumes that patients can read and understand the information on informed consent forms, and thus does not adequately consider patient health

227. *Id.* at 134.
228. *Id.*
229. *Id.*
230. PATIENTS AS PARTNERS, *supra* note 17, at 72 sidebar 4.2.
231. Matiasek & Wynia, *supra* note 80, at 134. There is some concern that overreliance on computer-based programs will discourage physician-patient informed consent discussions. *Id.*
232. Winkle v. Tullos, 917 S.W.2d 304, 315 (Tex. App. 1995).
233. *Id.*
234. *Id.*

literacy.[235] Inadequate health literacy is a pervasive problem in the United States, affects a wide variety of people, and is not easily recognized by physicians.[236] The legal doctrine of informed consent emphasizes the importance of disclosure, while ethics supports the importance of understanding and communication in the consent process, an aspect that is currently overlooked in the legal system. The legal presumption that informed consent was obtained if a patient signed an informed consent form does not encourage genuine informed consent. Informed consent forms are often written far above the reading level of an average patient.[237] Policies and practices should be more closely aligned with the ethical requirements of informed consent: understanding and communication.[238]

Consideration of health literacy in informed consent is important because a patient's literacy level can greatly impact their ability to understand the contents of a consent form and/or discussion with a healthcare provider. Without comprehending the consent information, a patient is denied their right to make informed, autonomous decisions about their healthcare. The law has done little to encourage the ethical justifications and legal rhetoric behind informed consent: patient self-determination and autonomy.[239] "The physician who punctiliously recites the litany of potential risks and secures the patient's signature on the proper form, but who fails even to attempt to engage the patient as a person in the decisionmaking process at more than this superficial level, may well be legally protected."[240] A consent form that says that the patient's signature means that they have read and understood the form is irrelevant if they cannot even read that line.

As pointed out by Paasche-Orlow, the complexity of pre-printed informed consent forms is evidence that the focus of the form "is not patient education but an attempt to avoid professional liability."[241] When seeking the informed consent of patients with low health literacy, complex and technical consent forms should increase, not decrease, professional liability,

235. *See* PATIENTS AS PARTNERS, *supra* note 17, at 73 (noting the entire system of informed consent is built on the assumption that a patient can read and understand informed consent forms).

236. See discussion of literacy, *supra* Part II.

237. See discussion of the readability level of informed consent forms, *supra* Part IV.B.

238. *See, e.g.*, Matiasek & Wynia, *supra* note 80, at 129 (noting that in a study of how eight hospitals "use patient-centered communication to improve health care", "[l]eaders and staff at each hospital expressed a strong desire to improve the informed consent process and align it with ethical standards . . . .").

239. *See supra* Part III.

240. Weisbard, *supra* note 74, at 757.

241. Paasche-Orlow, *The Challenges of Informed Consent*, *supra* note 108, at 126.

if additional measures are not taken by the provider to ensure that the patient understands and consents—more than just receiving a signed form.

Opening the floodgates for more informed consent litigation against physicians is not the goal of this Comment. This Comment simply seeks to highlight that genuine informed consent cannot be achieved by reliance on consent forms that patients with limited health literacy cannot understand. If a form is not too lengthy, has a good layout, a readable text size, and uses plain language, then the signature of a patient with low health literacy, but not those who are completely illiterate, would be stronger evidence of informed consent. Utilization of accommodations for literacy, that is, simpler language in consent forms and enhanced communications processes, such as the teach-back or repeat-back methods, should free physicians of liability for obtaining informed consent. Such methods should be encouraged by state law so that the physician's own motivation to be free from liability is aligned with the goal of informed consent: enabling patients to understand and make autonomous decisions about their healthcare.

Another approach to ensure that health literacy is adequately considered in informed consent is to advocate for state legislatures to adopt the reasonable patient standard of disclosure. For states that have adopted the reasonable patient standard, advocacy should revolve around defining a reasonable patient as one who has low health literacy, or using a more subjective standard. An additional avenue for advocacy would be to propose or support state legislation that declares that a mere signature on a consent form is not enough to satisfy genuine informed consent.

Currently, the legal duty of informed consent is significantly different than the ethical theories of informed consent. Instead of encouraging discussion, understanding, and patient autonomy, the doctrine of informed consent emphasizes the formality of obtaining a patient's signature. If informed consent is to represent a patient's knowing and understanding of risks, then health literacy must be considered as well. An appropriate consideration of health literacy can be achieved by either extending current theories through advocacy around the definitions of "reasonable physician" and "reasonable patient," or through legislation.

If informed consent forms are intended to serve as educational documents to facilitate the decision making process, then they should be treated as such.[242] Physicians should no longer be permitted to avoid liability by procuring a signature on a consent form without having disclosed the risks and alternatives to patients with different health literacy levels in a manner that enables patients to understand to what they are consenting. At the very least, courts should consider the readability level of consent forms

242. *Id.* at 131-32.

before courts presume that they are representative of a patient's informed consent. As patients take on more personal responsibility for their healthcare with the rise in popularity of CDHC, it is becoming increasingly important that the law recognize physicians' duties to obtain genuine informed consent.

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