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Using Law to Fight a Silent Epidemic¹: The Role of Health Literacy in Health Care Access, Quality, & Cost

Brietta Clark^{*}

One of the most important challenges facing the federal, state, and local governments is rising health care costs. At the federal level, the need to reign in health care costs has been cited as the reason for expanding federal legislation to prevent fraud and abuse, reworking payment incentives do not reward more care, and even for enacting the individual mandate under the new health reform legislation, the Patient Protection and Affordable Care Act (PPACA). At the state and local level, the struggle to reduce health care costs is prominent as governments face severe budget crises and look for ways to cut deficits. Hospital closures, Medicaid payment cuts, and eliminating health and welfare services are used as quick budget fixes throughout the country. Cost concerns are also driving states' decisions to participate in or oppose the state health insurance exchanges and Medicaid expansion in PPACA.

The dominant rhetoric in the health care policy debate about cost has described an inherent tension between access and quality on the one hand, and cost effectiveness on the other. Health care rationing and payment incentives to reduce unnecessary care, and thus health care costs overall, have been important themes in this debate.² We are told that in order to

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1. COMM. ON HEALTH LITERACY, INST. OF MED., HEALTH LITERACY: A PRESCRIPTION TO END CONFUSION xiii (Lynn Nielsen-Bohlman et al. eds., 2004) [hereinafter PRESCRIPTION TO END CONFUSION] (explaining why some refer to the problem of limited health literacy as a "silent epidemic").

2. Unnecessary services are attributed to a number of problems: a fee for service system that rewards physicians for doing more, regardless of quality; defensive medicine, defined as physicians ordering services due to their fear of malpractice liability, but without a benefit in terms quality of care; cultural norms in medicine that reinforce doctors' control over decision-making; and preference for doing more and utilizing new technologies to learn as

reduce costs, we must make hard choices to ration services or our insatiable appetites will threaten scarce public resources. Implicit (and sometimes explicit) in these arguments is the assumption that we cannot trust doctors and patients to make cost effective decisions because they always want more care – more tests and more procedures – regardless of cost. High profile battles between patients and providers on one side, and insurance companies³ and government health programs⁴ on the other, may help fuel this narrative.

An emerging discourse challenges this dominant narrative by presenting a more nuanced relationship between cost, access, and quality.⁵ One area

much as possible regardless of cost. *See Waste Not, Want Not: The Right Care for Every Patient*, ISSUE BRIEF (Nat'l Quality Forum), no. 15, June 2009 [hereinafter *Waste Not, Want Not*].

3. Larry Abramson, *Family Wins Suit for Autistic Son's Health Care*, NPR (Sept. 26, 2007), <http://www.npr.org/templates/story/story.php?storyId=14577821> (describing the tension between parents' fight for better coverage for autistic children and the increased cost for plans and other insurers); Milt Freudheim, *Battling Insurers Over Autism Treatment*, N.Y. TIMES, Dec. 21, 2004, http://www.nytimes.com/2004/12/21/business/21autism.html?_r=1&scp=1&sq=Battling%20Insurers%20Over%20Autism%20Treatment&st=cse; Robert A. Rosenblatt et al., *HMOs Perform Best for the Healthy Doctors Say*, L.A. TIMES, Jul. 29, 1999, at A17, <http://articles.latimes.com/1999/jul/29/news/mn-60702> (“The nation’s physicians overwhelmingly view managed care plans as reducing the quality of care they are able to give their patients. . . . Almost nine of 10 doctors said that they had patients who had been denied coverage for services by a health plan over the last two years”). A number of legal disputes arising out of coverage denials and delayed care, attributed to managed care cost-controls, have also reached the U.S. Supreme Court. *See Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004); *see also* *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002); *see also* *Pegram v. Herdrich*, 530 U.S. 211 (2000); *see also* *Shaw v. Delta Air Lines, Inc.* 463 U.S. 85 (1983).

4. *See, e.g.*, Steve Teske, *President Obama Tells Seniors Reform Would Not Reduce Medicare Benefits*, BNA’S HEALTH CARE DAILY REPORT (Aug. 12, 2009) (noting that Obama tried to garner seniors’ support for health reform by allaying their fears that it would cut Medicare benefits); Kevin Sack, *For Governors, Medicaid Looks Ripe for Slashing*, N.Y. TIMES, Jan. 29, 2011, at A1 (describing cuts for services, such as organ transplants, and dental, vision and podiatry treatments; noting that a number of governors are considering vast expansions of managed care plans in an attempt to control costs). *See also* SARA ROSENBAUM, CAL. HEALTH CARE FOUND., *MEDICAID PAYMENT RATE LAWSUITS: EVOLVING COURT VIEWS MEAN UNCERTAIN FUTURE FOR MEDI-CAL* (Oct. 2009). The U.S. Supreme Court recently agreed to review a lawsuit brought by Medicaid patients and providers against the State of California for enacting cuts in violation of the Equal Access Provision of the Medicaid Act. *See* *Indep. Living Ctr. v. Shewry*, 572 F.3d 644 (9th Cir. 2009), *cert. granted*, 2011 U.S. LEXIS 835 (2011).

5. This more nuanced understanding is a part of the mainstream debate about health care reform due in large part to repeated claims by President Obama and his administration that the PPACA would help ensure improved access for the right kind of care. This would lead to better quality and reduced costs through improved access for expanded coverage preventive care and reduced cost-sharing, payment incentives that reward improved quality, rather than rewarding more or less care, and community education. *See, e.g.*, Katherine Brandon, *The President on Health Care: “We are Going to Get this Done”*, WHITE HOUSE BLOG (July 17, 2009, 5:42 PM EDT), <http://www.whitehouse.gov/blog/The-President-on-Health-Care-We-are-Going-to-Get-this-Done>; *see also* Peter Orzag, *To Save Money, Save*

where we see this nuanced relationship revealed is in the discourse surrounding health literacy. As will be developed more below, evolving research suggests that low health literacy among patients, and the public generally, is a significant problem that can undermine health care access and quality in ways that increase costs to patients, providers and taxpayers. Moreover, cost concerns may prove to be an important catalyst for health policy and legal reforms to improve health literacy, and thus health care access and quality.

Medical and policy research provides growing evidence of the nuanced relationship between access, quality, and cost, and it challenges common assumptions about patients' and providers' understanding of this relationship. Modern science now understands that more services and tests do not necessarily equate to better care, but can actually increase the risk of harm to patients. Since the *To Err is Human* report was published in 2000, physicians and patients have become much more aware of the health risks of iatrogenic injuries,⁶ while institutional providers and the government have increasingly focused on their costs.⁷ Patients who fear doctor visits share anecdotes about someone they know who may have gone in for a "simple" procedure or test, but ended up getting sicker or dying; there is a real fear among many patients of getting sick from our health care system.⁸ Moreover, there are scientific gray areas in which one or more medical options may be equally effective, but have significantly different effects on a patient's quality of life. Clinical research shows that when patients are

the Health Care Act, N.Y. TIMES, Nov. 4, 2010 at A29; *The Right Care at the Right Time: Leveraging Innovation to Improve Health Care Quality for All Americans: Hearing Before the Senate Comm. on Finance*, 110th Cong. 57-69 (2008) (statement of Peter R. Orszag, Director of Congressional Budget Office).

6. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1* (Linda T. Kohn, et al. eds. 2000) [hereinafter *TO ERR IS HUMAN*] (estimating that between 44,000 and 98,000 Americans die each year from medical errors); see *Waste Not, Want Not*, *supra* note 2, at 6 (describing the quality and cost implications of medical errors).

7. See *TO ERR IS HUMAN*, *supra* note 6, at 1-2 (estimating that the total national costs of preventable adverse events due to medical errors, including lost income, lost household productivity, disability, and health care costs, are between \$17 billion and \$29 billion, half of which is represented by the health care costs).

8. See generally LAURIE ABRAHAM, *MAMA MIGHT BE BETTER OFF DEAD: THE FAILURE OF HEALTH CARE IN URBAN AMERICA* (1993) (describing the hardships of many poor Americans in the struggle to receive adequate healthcare); REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* (2010) (describing the legacy of fear resulting from discrimination, research abuses, and unwanted medical procedures); see also Brietta R. Clark, *Hospital Flight from Minority Communities: How Our Existing Civil Rights Framework Fosters Racial Inequality in Health Care*, 9 DEPAUL J. HEALTH CARE L. 1022-23 (2005) (describing the poor quality of care provided in underserved communities, including one example of a South Los Angeles hospital that was called Killer King by the community). See *infra* Part I.A. for a discussion of the cultural factors that instill a mistrust and fear of health care providers.

given complete information about these alternatives, they do not necessarily opt for more procedures or tests.⁹

Patients' advocates, providers, and health policy analysts have helped shape this different narrative, especially with respect to access. They show that rather than clamoring for more and better care, too many people do not seek the care they need, even when their condition becomes serious.¹⁰ Others have trouble getting the help they need because of their own economic situation or other impediments that make it difficult to navigate the health care system. These barriers not only lead to poorer health for patients, but also accrue high costs for patients, providers, insurers, and society in the long run.

Although a real tension can exist between access, quality, and cost, at times, the discourse around health literacy reveals a complimentary relationship between these goals. Health literacy is typically touted as an important tool for overcoming access barriers and empowering patients to be better health care partners, and evidence indicates that higher health literacy levels are associated with better health care access and outcomes. Increasingly, claims are also made that improving health literacy will significantly reduce the money that patients, providers, insurers, and the government currently spend on unnecessary or inappropriate treatment.¹¹ Notably, health literacy proponents suggest these cost reductions will occur if patients are empowered to be more active health care decision makers, rather than being treated as insatiable consumers who cannot be trusted.

It seems that every sector of the health care system is embracing this vision of health literacy as a tool for achieving access, quality, and cost reduction goals. The federal government listed improving health literacy and patient-provider communication as high priorities in Healthy People

9. CTR. FOR THE EVALUATIVE CLINICAL SCIS., DARTMOUTH ATLAS OF HEALTH CARE, DARTMOUTH ATLAS PROJECT TOPIC BRIEF: PREFERENCE-SENSITIVE CARE 6 (2005) [hereinafter PREFERENCE-SENSITIVE CARE], available at http://www.dartmouthatlas.org/downloads/reports/preference_sensitive.pdf. See *infra* Part II.B. for a more in-depth discussion of the role of patient preference in health care decision-making.

10. One of the biggest threats to access of care for disadvantaged communities is dwindling health care resources, such as hospitals and outpatient centers, and the lack of qualified and culturally competent health care professionals. See Clark, *supra* note 8, at 1024.

11. Inappropriate treatment includes different kinds of treatment: discretionary treatment a patient would not choose if provided complete with information or given a chance to participate in the decision, as well as the overuse of care that can be avoided with better health care management. See THE DARTMOUTH INST. FOR HEALTH POLICY & CLINICAL PRACTICE, AN AGENDA FOR CHANGE: IMPROVING QUALITY & CURBING HEALTH CARE SPENDING: OPPORTUNITIES FOR THE CONGRESS AND THE OBAMA ADMINISTRATION 15 (2008) [hereinafter AN AGENDA FOR CHANGE], available at http://www.dartmouthatlas.org/downloads/reports/agenda_for_change.pdf; Waste Not, Want Not, *supra* note 2, at 2.

2010 and 2020,¹² and it developed a National Action Plan that identifies key strategies and resources for achieving these goals.¹³ Professional and accrediting organizations have established standards and toolkits to help providers improve communication and account for poor health literacy, and more insurers are doing their own health literacy outreach.¹⁴ Health literacy organizations are working with patients, providers, educators, and the government to learn more about how health literacy impacts health, and to develop health literacy tools for use within and outside of the health care delivery system.¹⁵

This Article explores the possibilities and challenges of using the legal system to promote health literacy in light of this growing recognition of its significance in shaping health care access, quality, and cost. Part I explains what is meant by health literacy. Health literacy impacts one's ability to understand and use health information from a number of sources, including physicians' instructions, medication leaflets, informed consent documents, insurance forms, and health information communicated in the mainstream media. Part II describes how health literacy may reduce cost, while improving quality and access. Although causal links are always difficult to prove and more research is needed, there is significant evidence suggesting that better health literacy may increase access to appropriate care, while decreasing access to inappropriate care and empowering patients to check physician "overuse".

Part III describes some key proposals and tools developed to help improve health literacy, but such efforts have been largely voluntary, slow, and often limited to specific areas. Despite increasing evidence of health literacy's impact on quality, access, and cost, low health literacy has been called the "silent epidemic"¹⁶ and the most neglected aspect of patient

12. U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010: UNDERSTANDING AND IMPROVING HEALTH pt. A., at 11-20 (2nd ed. Nov. 2000) [hereinafter HEALTHY PEOPLE 2010]. Healthy People 2010 is the federal government's ten-year set of disease prevention and health promotion objectives for America. See also U.S. Dep't of Health & Human Servs., *2020 Topics & Objectives*, <http://healthypeople.gov/2020/topicsobjectives2020/pdfs/HealthCommunication.pdf> (last visited May 4, 2011) [hereinafter HEALTHY PEOPLE 2020].

13. OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL ACTION PLAN TO IMPROVE HEALTH LITERACY 3 (2010) [hereinafter NATIONAL ACTION PLAN]. The National Action Plan is based in part on the Institute of Medicine's 2004 comprehensive report on health literacy, *Health Literacy: Prescription to End Confusion*, and its 2007 report, *Preventing Medication Errors*, which highlighted the connections between medication errors and poor health literacy and provider communication. Preparation of the National Action Plan was led by the Health Literacy Workgroup of HHS, and a number of government, professional, insurer, and consumer organizations provided input. *Id.* at 4, 63-68.

14. See *infra* at Part II.B.

15. See *infra* at Part II.B.

16. PRESCRIPTION TO END CONFUSION, *supra* note 1, at xiii.

safety. The health literacy movement has not yet transformed the health care delivery or financing system for the many patients who suffer from poor health literacy.

If one believes that health literacy has a meaningful impact on patients' access and quality, then naturally a question arises about the role of law when problems occur that are linked to poor health literacy. Although the health literacy movement is still relatively young, it has roots in longstanding bioethical principles of patient autonomy, justice, and beneficence, and the corresponding legal principles of informed consent, nondiscrimination, and the right to receive quality care. The final parts of this Article consider the relationship between health literacy and these existing legal promises of quality and access. Part IV examines the relationship between health literacy and informed consent and malpractice liability, while Part V examines the relationship between health literacy and Title VI, the federal law that prohibits federal funding recipients from discriminating on the basis of race, ethnicity, and national origin. Assumptions about health literacy seem to do important, yet subtle work in these legal doctrines; however, the legal relevance of patients' health literacy for determining provider liability when problems arise is unclear.

Part VI returns to the theme of a complimentary relationship between cost, access, and quality in the health literacy context. Section A reflects on the weaknesses of existing access and quality laws revealed through a health literacy lens. Not only are such laws of limited effectiveness in promoting health literacy, the absence of a clear and robust consideration of health literacy undermines the laws' broader access and quality aims. Ironically, these legal standards may be strengthened by health literacy reforms that are largely driven by cost concerns as such reforms may be the catalyst for improvements in quality and access. Section B considers evidence of this phenomenon in government, payor and provider attempts to reduce costly medication errors.

I. HEALTH LITERACY IN THE UNITED STATES

The concept of health literacy may sound simple, but it is not as easily defined or measured as one might think. The U.S. Department of Health and Human Services (HHS) defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."¹⁷ The American Medical Association defines health literacy as the "ability to read and comprehend prescription bottles, appointment slips, and the other essential health-related materials" required to successfully function as a

17. HEALTHY PEOPLE 2010, *supra* note 12, at 11-20.

patient.¹⁸ The Institute of Medicine provides a more expansive definition of health literacy as: “a shared function of cultural, social, and individual factors,” “mediated by education . . . affected by culture, language, and the characteristics of health-related settings,” and shaped by a health context which “includes the media, the marketplace, and government agencies.”¹⁹

Because health literacy is still a relatively new concept, its definition has evolved as our understanding about it has grown.²⁰ Some fundamental themes are clear, however. Health literacy is not only shaped by a patient’s own literacy skills; provider communication skills, the level and complexity of reading materials, and even systemic factors, such as the time allotted and compensation provided for patient education, are instrumental in promoting or impeding health literacy. Moreover, health literacy skills and knowledge influence patients’ health in a myriad of ways: through their interaction with their doctors, pharmacists, insurance companies, and public agencies charged with health oversight, and even their individual day-to-day lifestyle choices.

A. *Measuring Health Literacy*

Health literacy is determined in part by one’s basic literacy skills, but these concepts are not synonymous. Both require reading, comprehension, and numeracy skills; however, health literacy depends specifically on peoples’ ability to process the kind of information that is typically required for health care decision-making, as well as their ability to understand information in a format commonly used in health forms, such as insurance documents, consent forms, disclosures for medical products, and prescriptions.²¹ Many of these forms are written at a much higher level than other kinds of consumer materials or written media, which means it is possible for a person to have a higher literacy level than health literacy level, or a lower health literacy level than would be predicted based on education.²²

In its recent National Action Plan to Improve Health Literacy, the

18. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 36 (quoting the Ad Hoc Comm. on Health Literacy, Am. Med. Ass’n (1999)).

19. *Id.* at 32; *see also* NATIONAL ACTION PLAN, *supra* note 13, at 4 (“Health literacy is a complex phenomenon that involves the skills, knowledge and expectations that health professionals have of the public’s interest in and understanding of health information and services.”).

20. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 36.

21. *Id.* at 37-43 (describing the constellation of skills – reading, writing, math, and speech – that determine literacy and noting the additional skills needed for health literacy in particular).

22. *See* NATIONAL ACTION PLAN, *supra* note 13, at 5 (explaining that forty-five percent of high school graduates have limited health literacy).

government labeled poor health literacy a “public health problem”²³ and others have called it a “silent epidemic.”²⁴ According to the 1992 National Adult Literacy Survey (NALS) survey of English-speaking adults in the U.S., approximately ninety million people have literacy below a high school level and, accordingly, lack the literacy necessary to successfully navigate the health system.²⁵ In 2003, the National Assessment of Adult Literacy (NAAL) found that literacy had not significantly improved, and, for the first time, it tested health literacy specifically.²⁶ This NAAL Health Literacy Survey found that of 19,000 adults surveyed, only twelve percent were proficient in health literacy, while fifty-three percent had intermediate health literacy, twenty-two percent had basic health literacy, and fourteen percent had below basic health literacy.²⁷

These surveys do not reveal the full scope of the health literacy problem. The NAAL survey focuses only on health literacy *skills* as opposed to the

23. *Id.* at 7.

24. See PRESCRIPTION TO END CONFUSION, *supra* note 1, at xiii.

25. See NAT'L CTR. FOR EDUC. STATISTICS, U.S. DEP'T OF EDUC., ADULT LITERACY IN AMERICA: A FIRST LOOK AT THE FINDINGS OF THE NATIONAL ADULT LITERACY SURVEY, xvii (2003) available at <http://nces.ed.gov/pubs93/93275.pdf>. See also PRESCRIPTION TO END CONFUSION, *supra* note 1, at 1.

26. NATIONAL ACTION PLAN, *supra* note 13, at 8. See also NAT'L CTR. FOR EDUC. STATISTICS, U.S. DEP'T OF EDUC., THE HEALTH LITERACY OF AMERICA'S ADULTS: RESULTS FROM THE 2003 NATIONAL ASSESSMENT OF ADULT LITERACY, iv (2006) available at <http://nces.ed.gov/pubs2006/2006483.pdf> [hereinafter NAAL HEALTH LITERACY SURVEY]. The NAAL Health Literacy Survey tried to measure literacy using the kind of information patients would need to access in clinical care, for prevention, and to navigate the health system. It also asked questions about how patients get health information to try and determine whether there were any notable correlations between health literacy and method of acquiring health information. *Id.*

27. *Id.* at v. “Below basic” health literacy refers to the simplest and most concrete literacy skills. These skills include the ability to circle the date of a medical appointment on a hospital appointment slip, identify what is permissible to drink before a medical test, and identify how often a person should have a certain test. “Basic” skills are those necessary to perform simple and everyday literacy activities. These skills include the ability to give two reasons why an asymptomatic person should be tested for a disease based on a *clearly* written pamphlet, and to explain why it is difficult for people with a chronic medical condition to know they have it after reading a one-page article about the condition. “Intermediate” health literacy describes skills necessary to perform moderately challenging literacy activities. These activities include the ability to determine a healthy weight range for certain height based on a graph, finding the ages when children should receive vaccines using a chart, determining what time a person can take a prescription medication based on the prescription drug label, and identifying three substances that may interact with an over-the-counter drug to cause a side effect based on the drug label. “Proficient” health literacy refers to skills necessary to perform more complex and challenging literacy activities. These include the ability to evaluate information to determine which legal document is applicable to a specific health care situation, locating information defining a medical term by searching a complex document, and calculating an employee’s share of health insurance costs for a year using a table of cost based on income and family size. See *generally id.* at 5-7.

level of *knowledge* people have about basic health facts and terminology.²⁸ Yet health literacy organizations explain that knowledge of our body, healthy behaviors, and how the health system works impacts our ability to make appropriate health decisions.²⁹ Other tests for measuring health literacy, such as the Rapid Estimate of Adult Literacy in Medicine (REALM)³⁰ and the Test of Functional Health Literacy in Adults (TOFHLA),³¹ provide more comprehensive measures of basic health knowledge and understanding of medical terms and jargon. Research to identify gaps in basic knowledge is important because such gaps can lead to unhealthy behavior, undue delay in seeking preventive care or medical treatment, and the inability to access benefits that would facilitate care. Identifying these gaps may also help identify disparities in health literacy among different groups and the reasons for these disparities, an area where current health literacy research falls short.

One compelling example of this is illustrated by research conducted by the National Council of Disabilities (NCD). Patients who are deaf or blind experience obvious communication barriers that can impede their ability to obtain, understand, and communicate information critical to access and good quality care. When one focuses only on a patient's skills in understanding information, one might assume that as long as the patient is provided with an adequate accommodation, like an interpreter, this would improve communication and thus the patient's health literacy. But this is not necessarily true.

In the government's most recent proposal for its Healthy People 2020 plan on health literacy and communication, the NCD highlighted the fact that access barriers to mainstream media, a key source of health information for people generally, means that deaf patients may not have basic health facts that many of us take for granted – facts essential for identifying health risks and signs of a problem, and especially for knowing when to seek medical attention.³² For example, an NCD survey of deaf adults revealed

28. *See id.* at 3-4 (“The NAAL health literacy scale did not include tasks that did not fit the definition of prose, document, or quantitative literacy even if they were consistent with the definition of health literacy used by *Healthy People 2010*. For example, none of the NAAL health tasks required knowledge of specialized health terminology.”).

29. NATIONAL ACTION PLAN, *supra* note 13, at 5.

30. REALM is a medical-word recognition and pronunciation test for screening adult reading ability in medical settings. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 47.

31. TOFHLA assesses numerical ability and reading comprehension based on actual materials from a health care setting. *Id.* at 48. The test takes much longer to administer than REALM and thus, is not as useful for screening in a clinical setting, though a shorter version, the S-TOFHLA, has been developed. *Id.* at 48-49.

32. *See* NAT'L COUNCIL ON DISABILITY, THE CURRENT STATE OF HEALTH CARE FOR PEOPLE WITH DISABILITIES 62 (2009), available at <http://www.ncd.gov/newsroom/publications/2009/HealthCare/HealthCare.html>. This is due in part to structural barriers in traditional media, and in part, because of incorrect assumptions by many people

the following troubling knowledge gaps:

Forty percent could not identify any of the seven most common warning signs of a heart attack;

Sixty-three percent could not identify the most common warning signs of a stroke;

One-third could not define the word cancer;

Fifty percent did not know the meaning of HIV positive, and

Seventy percent thought deaf people could not get HIV.³³

According to the NCD, more research is needed to understand the impact of multiple barriers experienced by people who are deaf and blind, as well as those suffering from mental health conditions, to understand the true scope of the health literacy problem within these groups.

There is also a significant gap in our understanding about the health literacy skills and knowledge of non-English speaking populations within their native language, which requires research beyond simply measuring English proficiency. For example, in the NAAL surveys, patients who did not speak English or had only limited English proficiency (LEP individuals) were simply lumped into the category of people with limited proficiency based on their inability to communicate meaningfully in English.³⁴

Again, one might assume that simply providing a translator would ensure health literacy, but, like deaf patients, the language barriers suffered by LEP individuals may deprive them of health information communicated through mainstream media that is essential for knowing how to stay healthy, when to seek care, and how to obtain the resources necessary to help pay for this care. Moreover, as discussed further below, English proficiency is merely one factor that can impede a patient's ability to effectively communicate symptoms and problems to the provider when care is sought, as well as to understand a provider's explanation of the condition and treatment recommendations. Currently, there are no national data on the health literacy skills of LEP individuals in their native languages, however, some providers and health literacy organizations have begun doing research within specific non-English speaking populations, especially among Hispanic patients.³⁵

(including health care providers) that written materials are an accessible and adequate substitute. People who are born deaf or become deaf pre-lingually may not have adequate writing or reading skills to ensure proficient written literacy. *See id.* at 65.

33. *Id.* (including information about health literacy and challenges for people with disabilities).

34. *See* NAAL HEALTH LITERACY SURVEY, *supra* note 26, at 5.

35. NATIONAL ACTION PLAN, *supra* note 13, at 8.

B. Factors that Influence Health Literacy

In addition to education level and English literacy skills, a number of other factors can influence health literacy. Low socioeconomic status (SES) increases the risk for poor health literacy because patients with low SES may have less flexibility, time, and opportunity to obtain important health information through their own research or through regular interaction with a health care provider. This is exacerbated for the uninsured and patients living in resource-poor communities without adequate providers to establish regular medical homes for patients. Low SES patients also may not have access to certain forms of media, such as the internet, that can provide health care information quickly and at little to no cost. Finally, low SES may be associated with a lack of assertiveness in seeking care and information, making it less likely that these individuals would be able to easily overcome the barriers described above.³⁶

Patients' cultural norms and experiences can also influence health literacy.³⁷ "A substantial [sic] research literature in psychiatry and psychology, sociology, and anthropology documents large differences in how people experience, understand, and discuss illness," as well as their willingness to seek help.³⁸ For example, some patients belong to communities that have a well-known history of mistreatment and abuse at the hands of health care providers: African-Americans, poor women, and patients with certain disabilities have been used for medical research without their knowledge and subjected to medical treatments, such as sterilization or confinement, without their consent.³⁹ For these groups, a legacy of mistrust may keep them from building a relationship with health care providers – a critical source of health care information.⁴⁰

36. *See id.*

37. *See generally* PRESCRIPTION TO END CONFUSION, *supra* note 1, at 110-19 (providing examples of the way culture can impede patient understanding and lead to medical problems); GERI-ANN GALANTI, CARING FOR PATIENTS FROM DIFFERENT CULTURES: CASE STUDIES FROM AMERICAN HOSPITALS 1 (1997) (discussing the effect of a cultural gap on health care in the US).

38. INST. OF MED., UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE 128 (2003) [hereinafter UNEQUAL TREATMENT]. For example, patients' experience and reporting of pain and other symptoms have been found to vary greatly, as has patients' help-seeking behavior relative to health professionals. *Id.*

39. *See* SKLOOT, *supra* note 8, at 29-30 (giving other examples and renewing public attention to how the legacy of mistrust impacts minority communities today); DOROTHY ROBERTS, KILLING THE BLACK BODY 22-23 (1997) (detailing an even longer history of medical experimentation and abuse of blacks during slavery); DAVID BARTON SMITH, HEALTH CARE DIVIDED: RACE AND HEALING A NATION 3-31 (1999) (providing a history of race discrimination and disparities in healthcare).

40. There is no shortage of anecdotes about black men and women who refuse to see a

Legal status is another barrier for immigrants of uncertain or undocumented status, and even those present in the U.S. legally. Many immigrants fear that seeking help will lead to disclosure of their or their family member's lack of proper documentation or increased scrutiny into any other grounds for deportation by immigration officials.⁴¹ Finally, many patients experience multiple levels of cultural, social, legal, linguistic and economic isolation that compound health literacy problems and makes the barriers to health literacy even more challenging to overcome.

While certain groups may be particularly vulnerable to poor health literacy, research demonstrates that certain cognitive factors can influence any person's ability to absorb or process health information.⁴² For example, cognitive bias may lead us to overestimate or underestimate the risks and benefits of our medical choices.⁴³ Moreover, the emotional stress that often accompanies illness, especially when the illness interferes with our activities of daily living due to constant pain, fatigue, or disability, can further impede decision-making skills and information processing.⁴⁴

Although health literacy is often discussed as a "patient" characteristic (i.e. patients' skills or knowledge), provider and structural factors, as well as the interaction between different factors, can profoundly influence health literacy. For example, patients' understanding of treatment options is often shaped by the quality and content of provider-patient communication, which includes providers' ability to communicate health concepts in a clear

doctor because of what they heard about Tuskegee and other research horror stories. *See, e.g.*, PRESCRIPTION TO END CONFUSION, *supra* note 1, at 31 (detailing an anecdote about a twenty nine year-old African-American woman with abdominal pain and fever, who refused an "exploratory laparotomy" because the term "exploratory" triggered fears of being made a "guinea pig" for research; she refused to consent to any procedures and later died of appendicitis.). *See also* ABRAHAM, *supra* note 8, at 142-44; ROBERTS, *supra* note 39, at 23; SKLOOT, *supra* note 8, at 29-30. These fears are often reinforced by "bad experiences" or outcomes of their friends, even though the bad outcomes are often the result of a patient waiting too long before receiving help.

41. *See infra* note 253 and accompanying text.

42. COMM. ON IDENTIFYING & PREVENTING MEDICATION ERRORS, INST. OF MED., PREVENTING MEDICATION ERRORS 194-95 (Philip Aspden et al. eds., 2007) [hereinafter PREVENTING MEDICATION ERRORS] (noting that studies of content and design of medication information should include cognitive factors, such as information load, study time, depth of processing, chunking, linguistic coding, prior knowledge, and cognitive task scenarios).

43. *See* Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 477-78 (2006) [hereinafter *Rethinking Informed Consent*]. Examples of biases that can affect patient decision making include: "1) *compression bias*, which results in patients overestimating small risks and underestimating large ones; 2) *small numbers bias*, where patients misinterpret their individual risk based on a small number of known cases (my two friends both had complications after their hysterectomies, so I probably will too); and 3) *miscalibration bias*, in which patients tend to be overly confident about the extent or accuracy of their knowledge." *Id.* at 478.

44. *Id.*

and effective manner, as well as their ability to assess whether patients understand the information.⁴⁵ Providers' own beliefs, experiences, and culture may influence this communication in ways that either encourage or discourage patient understanding.⁴⁶ Some physicians appear openly hostile to patient questions and do not spend time on patient education, possibly because of a culture of paternalism and physician dominance in health care decision-making, and lack of confidence in patients' decision-making ability.⁴⁷ Other physicians may want to spend time answering questions and doing more patient education, but nonetheless rush patients through because of a delivery and financing structure that does not build in time or compensation for adequate patient education, or because the providers are located in underserved communities that are perpetually understaffed and overburdened.

Physicians may also operate with prior beliefs about the likelihood of their patients' conditions being different according to age, gender, SES, and possibly race or ethnicity.⁴⁸ Some "priors" are taught as a cognitive heuristic to medical students and explicitly influence medical decisions. Others, like conscious or unconscious stereotypes about patients based on providers' own cultural experience and social conditioning, may influence provider actions in a more subtle way. For example, providers may tend to discount reports of pain symptoms by certain groups,⁴⁹ and may be less inclined to believe that certain patients will comply with treatment.⁵⁰ These priors can influence not only medical decisions about what treatment should

45. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 41; NATIONAL ACTION PLAN, *supra* note 13, at iii.

46. UNEQUAL TREATMENT, *supra* note 38, at 131.

47. See *Rethinking Informed Consent*, *supra* note 43, at 455, 477-78 (describing physician resistance to sharing information with patients based on their belief that patients may not be able to process and use the information effectively); PRESCRIPTION TO END CONFUSION, *supra* note 1, at 180-81.

48. UNEQUAL TREATMENT, *supra* note 38, at 174.

49. See Sandra H. Johnson, *The Social, Professional, and Legal Framework for the Problem of Pain Management in Emergency Medicine*, J.L. MED. & ETHICS 741, 745 (2005) (noting that children, individuals with cognitive impairments, and the elderly tend to be viewed as inaccurate reporters of pain); see also Mark Pletcher et al., *Trends in Opioid Prescribing by Race/Ethnicity for Patients Seeking Care in US Emergency Departments*, 299 J. AM. MED. ASS'N, no. 1, Jan. 2, 2008 at 72 ("[b]lack were prescribed opioids at lower rates than any other race/ethnicity group for almost every type of pain visit"); Vence L. Bonham, *Race, Ethnicity, and Pain Treatment: Striving to Understand the Causes and Solutions to the Disparities in Pain Treatment*, 29 J.L. MED. & ETHICS 52, 52 (2001) (describing studies showing that minorities are more likely to receive no or less analgesia than non-minorities, despite similar pain complaints and insurance status); Diane Hoffmann & Anita Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29 J.L. MED. & ETHICS 13, 13 (2001) (noting that women are at risk for under-treatment of pain).

50. See UNEQUAL TREATMENT, *supra* note 38, at 90-91; ABRAHAM, *supra* note 8, at 198-212 (describing the Banes family interaction with white doctors).

be recommended, but can also shape the manner and content of communication with patients. For example, research demonstrates that implicit prejudice may be manifested through providers' nonverbal behaviors, and may implicitly play a role in *how* providers communicate and in the *amount* of time they are willing to spend with patients.⁵¹ Unfortunately, this can impede patient understanding during a particular interaction, as well as discourage on-going dialogue that is a critical source of health literacy.⁵²

In fact, many minority patients describe communication they believe evidence provider bias and mistrust. Some examples include explicitly racialized assumptions communicated in a disrespectful tone that does not encourage further dialog.⁵³ In many cases, however, patients cannot point to a specific racialized comment, but rather a general feeling or tone they experience: These feelings often include a lack of respect, prejudice, or unwelcoming feeling they believe is due to their race, ethnicity, citizenship status, or language difficulty.⁵⁴ While patients' own perceptions of bias may be due, in part, to societal racial or cultural isolation more broadly, provider communication can either reaffirm or counter such perceptions.

The fact that providers' communication skills and cultural competence are relevant factors in determining patient health literacy⁵⁵ implicates certain policy and structural characteristics of medical education, and the health care delivery and financing system as a whole. The extent to which communication skills and cultural competency are valued and required as part of medical training, and the amount of time that health professionals are able or encouraged to spend with patients to explain their condition and treatment, are critical factors that can help overcome barriers to health literacy or exacerbate them. When providers do not have the capacity, opportunity, or motivation to assess patients' conditions fully and deliberately, implicit attitudes about race are more likely to shape their responses.⁵⁶ Time pressure, high cognitive demand, and stress are conditions that are common to many health care settings and make these settings "ripe" for the activation of stereotypes and other heuristics.⁵⁷

Finally, information that shapes health literacy comes from within and

51. See UNEQUAL TREATMENT, *supra* note 38, at 162-74.

52. See *id.* at 174-75. One area where this has been examined more closely is in the area of race and ethnicity, specifically to determine whether racial and ethnic bias may influence provider communication in ways that impact patient understanding or willingness to comply with provider instructions. See *infra* Part V.B.

53. UNEQUAL TREATMENT, *supra* note 38, at 90-91; ABRAHAM, *supra* note 8, at 201.

54. UNEQUAL TREATMENT, *supra* note 38, at 90-91.

55. See PRESCRIPTION TO END CONFUSION, *supra* note 1, at 181; NATIONAL ACTION PLAN, *supra* note 13, at 5.

56. UNEQUAL TREATMENT, *supra* note 38, at 173.

57. *Id.*

outside of the health care system. Information communicated through mass media, schools, and public health campaigns by government agencies and private organizations help determine peoples' basic knowledge and understanding of health.⁵⁸ If people cannot access these sources, or if the information is incorrect or biased, poor health literacy can result.⁵⁹

II. IMPACT ON ACCESS, QUALITY & COST

Based on the understanding of health literacy developed in Part I, it should be clear that any person potentially could have poor health literacy or at least difficulty understanding health information in certain contexts.⁶⁰ People from all backgrounds are affected, and providers and insurers generally overestimate the average literacy age of the population.⁶¹ Moreover, there are potentially many different ways that health literacy and communication can impact access, quality, and cost:

For individuals, effective health communication can help raise awareness of health risks and solutions, provide the motivation and skills needed to reduce these risks, [and] find support from other[s]. Health communication also can increase demand for appropriate health services and decrease demand for inappropriate health services. It can make available information to assist in making complex choices, such as selecting health plans, care providers, and treatments. For the community, health communication can be used to influence the public agenda, advocate for policies and programs, promote positive changes in the socioeconomic and physical environments, improve the delivery of public health and health care services, and encourage social norms that benefit health and quality of life.⁶²

This part looks more closely at specific claims that promoting health literacy can improve access and quality, while reducing cost. As will be developed below, promoting health literacy can empower patients to seek preventive care early and improves patient management of their own care, which can lead to better health overall and prevent more expensive care

58. HEALTHY PEOPLE 2010, *supra* note 12, at 11-3.

59. NATIONAL ACTION PLAN, *supra* note 13, at 5.

60. *Id.*

61. K. James Kallail, *Communicating with Patients at Risk for Low Health Literacy*, 1 KAN. J. MED. 22, 23 (2007).

62. HEALTHY PEOPLE 2010, *supra* note 12, at 11-3. Health communication is relevant in a number of contexts, including (1) health professional-patient relations, (2) individuals' exposure to, search for, and use of health information, (3) individuals' adherence to clinical recommendations and regimens, (4) the construction of public health messages and campaigns, (5) the dissemination of individual and population health risk information, that is risk communication, (6) images of health in the mass media and the culture at large, (7) the education of consumers about how to gain access to the public health and health care systems, and (8) the development of telehealth applications. *See id.*

later. Better health literacy may also empower patients to take a more active role in decision-making to ensure they receive appropriate care, and in ways that check physician “overuse.” Nonetheless, the extent to which health literacy actually impacts access, quality or cost is incredibly challenging to measure and prove.

A. How Health Literacy Shapes Access and Quality

Health literacy is considered an important link to patient safety, although the extent to which health literacy actually impacts access and quality is still largely unknown. Low health literacy leads to difficulty completing intake forms, enrolling in insurance programs, and accessing services,⁶³ as well as following medical instructions and giving informed consent once care is obtained, all of which can interfere with patients’ care in profound ways. A number of studies suggest some correlation between health literacy and poor outcomes or access.⁶⁴ For example, studies have found that patients with low functional literacy are five times more likely to misinterpret prescriptions,⁶⁵ twice as likely to be hospitalized from an emergency room visit,⁶⁶ and are more likely to have incomplete understanding of their health problems and treatment.⁶⁷ People with low health literacy are also more likely to report or suffer from poor health.⁶⁸ In fact, one study found that “literacy skills are a stronger predictor of an individual’s health status than age, income, employment status, education level, or racial/ethnic group.”⁶⁹

63. CTR. FOR HEALTH CARE STRATEGIES, INC., HEALTH LITERACY FACT SHEETS, at 4 (Aug. 2005) [hereinafter CHCS], http://www.chcs.org/usr_doc/Health_Literacy_Fact_Sheets.pdf (citing a study of 979 emergency room patients with inadequate health literacy: eighty-one percent could not read the rights and responsibility of the Medicaid application; seventy-four percent did not know if they were eligible for care); see also 16 QUINLAN, *Health Literacy Impacts WC Claims, WORKERS’ COMP BOTTOM LINE* No. 4, 1 (Apr. 2007) (health literacy can also impact workers’ compensation claims).

64. NATIONAL ACTION PLAN, *supra* note 13, at 9; CHCS, *supra* note 63, at 1; THE JOINT COMM’N, WHAT DID THE DOCTOR SAY?: IMPROVING HEALTH LITERACY TO PROTECT PATIENT SAFETY 37 (Feb. 2007) [hereinafter WHAT DID THE DOCTOR SAY?] http://www.jointcommission.org/assets/1/18/improving_health_literacy.pdf; PRESCRIPTION TO END CONFUSION, *supra* note 1, at 82.

65. WHAT DID THE DOCTOR SAY?, *supra* note 64; CHCS, *supra* note 63, at 1.

66. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 82, 85.

67. NATIONAL ACTION PLAN, *supra* note 13, at 9; see also PRESCRIPTION TO END CONFUSION, *supra* note 1, at 82.

68. NAAL HEALTH LITERACY SURVEY, *supra* note 26, at 16 (at each higher level of self-reported level of overall health, adults had higher average health literacy than adults in the next lower level); HEALTHY PEOPLE 2010, *supra* note 12 at 11-9; PRESCRIPTION TO END CONFUSION, *supra* note 1, at 82-83.

69. PARTNERSHIP FOR CLEAR HEALTH COMM’N, NAT’L PATIENT SAFETY FOUND., HEALTH LITERACY: STATISTICS AT-A-GLANCE 1 (2008),

Particular attention has been paid to the relationship between low health literacy and chronic conditions,⁷⁰ probably because of the prevalence of low health literacy among people with chronic conditions and because this is where the adverse health and financial effects are most compelling. Successful management of chronic disease depends heavily on patients' ability to self-manage their condition, which involves several components: communicating important information to health care providers for an accurate diagnosis; following a regular and sometimes complicated treatment regimen; identifying potential problems or risks early enough to prevent a crisis and hospitalization; and locating credible health care information with respect to their condition.⁷¹ Poor health literacy can undermine patients' ability to perform each of these tasks. In fact, research shows that individuals with poor health literacy are more likely to have a chronic disease and less likely to get the care they need.⁷² Additionally, people with chronic conditions and low reading skills have less knowledge of their conditions than people with higher reading skills.⁷³

While the majority of people with marginal or low literacy are white native-born Americans, certain groups – people with certain kinds of disabilities,⁷⁴ older people,⁷⁵ non-whites and LEP individuals,⁷⁶ and people

http://www.npsf.org/askme3/pdfs/STATS_GLANCE_EN.pdf

70. HEALTHY PEOPLE 2010, *supra* note 12, at 11-9 (estimating that seventy-five percent of persons in the United States with chronic physical or mental health problems are in the limited literacy category).

71. WHAT DID THE DOCTOR SAY?, *supra* note 64, at 38.

72. See, e.g., HEALTHY PEOPLE 2010, *supra* note 12, at 11-9 (stating “[a]n estimated 75 percent of persons in the United States with chronic physical or mental health problems are in the limited literacy category.”); CHCS, *supra* note 63, at 1 (one study of asthma patients found that reading ability was the single strongest predictor of asthma knowledge, and twice as many patients reading below the third-grade reading level had poor metered-dose inhaler technique as patients reading at high-school level (eighty nine percent versus forty eight percent)); *Id.* at 4 (HIV positive adults with low functional health literacy missed more treatment doses than patients with higher literacy because of confusion understanding instructions).

73. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 82 (reviewing studies showing that patients with lower health literacy suffering from hypertension, diabetes, asthma, and HIV/AIDS have less knowledge of their chronic illness and their management than those with higher knowledge scores); see also HEALTHY PEOPLE 2010, *supra* note 12, at 11-9.

74. As noted *infra* Part I.B., people with certain kinds of disabilities – particularly those with communicative disorders (such as the deaf and blind) and those with mental illness – are also at a greater risk for having lower functional health literacy because they face multiple barriers to accessing health care information within and outside of the health care system.

75. See NAAL HEALTH LITERACY SURVEY, *supra* note 26, at 12-13; see also HEALTHY PEOPLE 2010, *supra* note 12, at 11-10 (citing studies of Medicare enrollees that found inadequate health literacy in thirty-four percent of English speakers and fifty-four percent of Spanish speakers, and a study finding that eighty-one percent of patients sixty years and older at a public hospital could not read or understand basic materials such as prescription labels and appointment slips).

with low income – are at greater risk for poor health literacy. In fact, there is growing concern about the extent to which low health literacy contributes to health disparities among racial and ethnic minorities.⁷⁷ Racial and ethnic minorities tend to experience disproportionately high rates of mortality and morbidity, and they are more likely to suffer from chronic and debilitating illnesses as well as infectious diseases.⁷⁸ Minorities also experience disparities in access, which may be the result of underinsurance or lack of insurance, low SES, and a lack of adequate, quality providers in resource poor communities.⁷⁹

It is not clear to what extent poor health literacy may be contributing to or compounding these problems, but there are several possibilities. First, poor health literacy makes it more difficult to learn about and apply for public benefit programs, or access free health care, and racial and ethnic minorities are at greater risk for being uninsured. A common problem is that free or low cost benefits available for underserved communities are often not being utilized by the people that need them—either because they do not know about it, cannot complete the application or eligibility documents, or give up after being denied because they do not know about their rights to appeal.⁸⁰ Second, although minorities may be at greater risk for health care problems due to individual risk factors or environmental degradation, some of these risks could be mitigated through healthy lifestyle choices and preventive measures. Limited health literacy is a barrier to accessing this kind of information.

Finally, health literacy may be shaped by, or interact with, race and ethnicity more directly in the patient-provider interaction in ways that

76. See HEALTHY PEOPLE 2010, *supra* note 12, at 11-18; NATIONAL ACTION PLAN, *supra* note 13, at 8; PRESCRIPTION TO END CONFUSION, *supra* note 1, at 62-63.

77. HEALTHY PEOPLE 2010, *supra* note 12, at 11-9. See *infra* Part V. for further exploration of this relationship and its implications for providers' obligations under antidiscrimination law.

78. See generally UNEQUAL TREATMENT, *supra* note 38, at 1-2. "African Americans, for example, experience the highest rates of mortality from heart disease, cancer, cerebrovascular disease, and HIV/AIDS than any other U.S. racial or ethnic group. American Indians disproportionately die from diabetes, liver disease and cirrhosis and unintentional injuries. Hispanic Americans are almost twice as likely as non-Hispanic whites to die from diabetes. In addition, some Asian-American subpopulations experience rates of stomach, liver, and cervical cancers that are well above national averages." *Id.* at 29.

79. *Id.* at 81-82. Hispanics, Asian Americans, American Indians, Alaska Natives, and African Americans are less likely than whites to have health insurance, have more difficulty getting healthcare, and have less choice in where to receive care. Hispanic and African-American patients are also more likely to receive care in hospital emergency rooms, and are less likely than whites to have a regular primary care provider. *Id.*

80. See, e.g., ABRAHAM, *supra* note 8, at 167-78 (describing this problem with respect to prevention programs for low income children) & 46-59 (describing the difficulty adults have navigating the various eligibility requirements and bureaucracy in trying to access public health benefits).

undermine access and quality. Since a 1999 report by the Institute of Medicine revealed disparities in access, even after controlling for income, insurance coverage, and medical need, much more attention has been paid to the independent role of race in health care, specifically how cultural factors and discrimination influence care.⁸¹ As will be discussed in greater detail in Part V, conscious and unconscious bias can infect the manner and content of patient-provider communication, which, in turn, can impact patient decision-making. Poor health literacy increases the risk that incorrect assumptions and stereotypes by patients and providers will taint the patient-provider interaction in ways that undermine the communication and trust central to accurate diagnosis and choice of treatment. Promoting better health literacy helps to combat these stereotypes and mistrust, and mitigate the deleterious impact that racial and cultural factors can have on health care.

Health literacy is particularly important for ensuring good quality of care in “preference-sensitive” cases. These are cases in which appropriate treatment should be determined with respect to a patient’s preferences because there are meaningful diagnostic or treatment alternatives of comparable efficacy, but the risks of treatment touch on important patient-preferences or quality of life concerns.⁸² Common examples include diagnostic and treatment alternatives for certain kinds of cancer, and the choice between more invasive or more conservative treatment for certain conditions, especially where accompanied by chronic pain. Clinical research has shown that patients, not physicians, are in the best position to make treatment decisions among these alternatives,⁸³ yet limited health literacy may impede patient’s decision-making ability or willingness to engage with physicians.⁸⁴ Improving health literacy and patient-provider communication can ensure that patient preferences are taken into account, which, in turn, enables patients and providers to make better decisions by

81. UNEQUAL TREATMENT, *supra* note 38, at 30.

82. See PREFERENCE-SENSITIVE CARE, *supra* note 9, at 1; *see also* Annette M. O’Connor et al., *Toward the ‘Tipping Point’: Decision Aids and Informed Patient Choice*, 26 HEALTH AFF. 716, 716 (2007).

83. *See, e.g.*, James N. Weinstein, *Informed Patient Choice: Patient-Centered Valuing of Surgical Risks and Benefits*, 26 HEALTH AFF. 726 (2007) (looking at the use of shared decision-making tools in cases involving musculoskeletal surgery with devices); *see also* Alyssa D. Throckmorton & Laura J. Esserman, *When Informed, All Women Do Not Prefer Breast Conservation*, 27 J. CLINICAL ONCOLOGY 484, 484 (2009) (finding that for women facing a choice between mastectomy and breast conservation surgery, both with equivalent survival rates, it is important to elicit information about their preferences on three issues: how much they want to preserve their breast, how important peace of mind is, and how important it is for the patient to avoid radiation).

84. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 82-83 (study showing patients had decreased ability to share in decision-making about prostate cancer treatment).

promoting patient autonomy and increased patient trust.⁸⁵

Despite the obvious potential for health literacy to impact health care access and quality, drawing causal links between health literacy levels and particular health literacy interventions on one hand, and improved access and quality of care on the other, is challenging. This is especially true in light of the many other variables that impact access and quality. For example, better literacy will have a limited impact if patients cannot act on the information because of inadequate health care resources and quality personnel.⁸⁶ Additional research is needed to determine the extent to which specific health literacy interventions improve health literacy, whether health literacy influences patient decision-making, and the extent to which improvements in health literacy or patient decision-making actually reduce access barriers and bad outcomes.⁸⁷

B. *Bending the Cost Curve Through Health Literacy*

Although health literacy proponents have traditionally focused on improvements in access and quality, increasingly they claim that better health literacy will have significant cost savings for providers, insurers, and the government.⁸⁸ According to proponents, better health literacy may reduce health costs in three ways. First, it can help reduce costly and preventable care that occurs as a result of the underuse of important diagnostic, preventive, and on-going medical treatment.⁸⁹ This is supported

85. *See id.* at 83 (describing that individuals with lower health literacy are less likely to seek or use preventive health care services). According to the Dartmouth Atlas Project at the Center for the Evaluative Clinical Services, clinical trials show that patient decision-aids for conditions that involve discretionary surgery have quality and cost benefits. Trials have looked at the following patient choices: (i) lumpectomy or mastectomy for early stage breast cancer; (ii) invasive cardiac treatment or more conservative medical management for chest pain due to coronary artery disease; and (iii) surgery or conservative management for patients with back pain due to disc disease. The following conclusions were drawn from these trials: 1) when compared to a control group, “patients who use decision aids are better informed about the risks, benefits and clinical uncertainties associated with the treatment options available to them;” 2) “the choices patients make in the shared decision making environment (aided by patient decision aids) are ‘better’ decisions [because] they more closely reflect the patient’s own individual values;” and “most clinical trials show a net reduction in demand for the more invasive surgical options.” PREFERENCE-SENSITIVE CARE, *supra* note 9, at 2.

86. HEALTHY PEOPLE 2010, *supra* note 12, at 11-9.

87. *Id.* at 11-9 - 11-10.

88. Michael Villaire & Gloria Mayer, *Health Literacy: The Low Hanging Fruit in Health Care Reform*, 36 J. HEALTH CARE FIN. 55, 55-56 (2009); PRESCRIPTION TO END CONFUSION, *supra* note 1, at 100-02.

89. Underuse of effective care is common and is often due to discontinuity of care. Such care is exacerbated when more physicians become involved in care due to the lack of adequate resources and systems to facilitate this access. Overuse of certain kinds of care, such as hospitalization, is a significant problem for chronic illness due in part to an overdependence on the acute care sector and a lack of health care personnel and

by studies that show patients with higher health literacy are more likely to access preventive care and comply with treatment, which can prevent more expensive complications later.⁹⁰ Studies have also demonstrated a relationship between limited health literacy and hospitalization rates, including preventable hospitalization.⁹¹ Data also suggests that people with low functional literacy use other health care services more than people with higher literacy.⁹² Studies have estimated additional health care costs ranging from \$29 billion to \$236 billion due in part to poor health literacy.⁹³

The potential of increased costs from poor health literacy is most compelling for patients with chronic health conditions. Hospitalizations due to mismanagement of chronic conditions and medication errors are common, expensive, and preventable, yet patients with low health literacy are more likely to misinterpret prescriptions and less likely to understand important information about their chronic conditions.⁹⁴ This burdens the entire health care system by increasing costs for patients, providers, and the public safety net.⁹⁵ People with low functional health literacy are more likely to receive health care services through publicly financed programs,⁹⁶ and incur higher health care costs.⁹⁷ Moreover, some of the groups who have an increased risk for poor health literacy are more likely to be

infrastructure to support better management in less costly outpatient settings. PREFERENCE-SENSITIVE CARE, *supra* note 9, at 1.

90. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 82-83.

91. *Id.* at 82.

92. CHCS, *supra* note 63, at 3 (stating that in 1998, adults with functional literacy in the bottom twenty percent were more than one and a half times more likely to visit a physician than adults with higher functional literacy and were likely to have three times as many prescriptions filled. Those in the lowest twenty percent of functional literacy used substantially more health care services, resulting in greater health care expenditures).

93. See PRESCRIPTION TO END CONFUSION, *supra* note 1, at 100 (citing a 1996 study estimating that an additional \$29 billion in health care costs may be due to inadequate health literacy and a study showing that patients with a reading level at or below third-grade level had a mean Medicaid cost almost \$8,000 more than patients with a higher reading level); see also Marsha Dolan et al., *Patient Navigators: New Advocacy Role a Good Fit for HIM Professionals*, 81 J. AM. HEALTH INFO. MGMT. ASS'N 41, 42 (2010) (stating “[i]n 2001, low functional literacy resulted in an estimated \$32 to \$58 billion in additional health care costs”); see also CHCS, *supra* note 63, at 1 (stating that the average annual health care costs of persons reading at a third-grade level or below – may be four times greater than the average population); see also NATIONAL ACTION PLAN, *supra* note 13, at 10 (citing a study that estimated health costs at \$106-\$236 billion).

94. CHCS, *supra* note 63, at 3.

95. *Id.*

96. *Id.* at 1.

97. *Id.* at 3 (stating “the direct medical costs of low functional literacy are financed through additional hospitalizations and office visits, longer hospital stays, extra tests, procedures and prescriptions.”). It also notes that much of this is paid by taxpayers through public resources: Medicaid finances forty-seven percent of additional health expenditures, and Medicare nineteen percent. *Id.*

uninsured, underinsured, or to receive care in hospital emergency rooms, and less likely to have a primary care provider.⁹⁸

Second, health literacy may reduce costs in preference-sensitive cases because empowering patients with better information and decision-making skills should lead to a decrease in the demand for inappropriate health services — one cause of rising health care costs.⁹⁹ A number of medical and legal scholars have lamented a medical culture that prefers more testing and procedures, even invasive ones, when more conservative, less expensive, and comparably effective alternatives are available. Under this scenario, the patient is viewed as a check on physician overuse or misuse of services.¹⁰⁰

While this claim may have intuitive appeal, it is very difficult to determine whether improving patient health literacy would actually lead patients to refuse more costly care against a physician's advice, and if so, whether this would lead to significant savings. This scenario presumes some important facts: First, that there is a gray area about what is appropriate; second, that there are meaningful alternatives of comparable efficacy, but with significant cost differential; and third, that the risks and benefits of treatment touch on important patient-preferences or quality of life concerns.¹⁰¹ Clearly in cases where a physician recommends life-saving treatment to an otherwise healthy adult, and there is no meaningful alternative, the patient will do what the doctor recommends and more information would not likely change her mind. However, even in preference-sensitive cases, patients still may defer to the physician's judgment. As already noted above, clinical research makes clear that patient preferences cannot be predicted or assumed, which is why providers should elicit information about patient preferences in order to determine what care is appropriate.¹⁰² To the extent physician preferences to do more

98. See, e.g., LEIGHTON KU & TIMOTHY WAIDMANN, KAISER COMM'N ON MEDICAID AND THE UNINSURED, HOW RACE/ETHNICITY, IMMIGRATION STATUS AND LANGUAGE AFFECT HEALTH INSURANCE COVERAGE, ACCESS TO CARE AND QUALITY OF CARE AMONG THE LOW-INCOME POPULATION 5 (2003).

99. See AN AGENDA FOR CHANGE, *supra* note 11, at 10; see also *Waste Not, Want Not*, *supra* note 2, at 4-5; JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 431 (2002).

100. See PREFERENCE-SENSITIVE CARE, *supra* note 9, at 1 ("Misuse of preference-sensitive care refers to situations in which there are significant tradeoffs among the available options Misuse results from the failure to accurately communicate the risks and benefits of the alternative treatments, and the failure to base the choice of treatment on patient's values and preferences.")

101. *Id.* at 1. See also O'Connor et al., *supra* note 82, at 716.

102. See e.g., Throckmorton & Esserman, *supra* note 83, at 485. See also O'Connor et al., *supra* note 82, at 716; PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. AND BIOMEDICAL AND BEHAVIORAL RESEARCH, DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT: A REPORT ON THE ETHICAL, MEDICAL, AND LEGAL ISSUES IN TREATMENT DECISIONS 88 (1983), available at http://bioethics.georgetown.edu/pcbe/reports/past_

testing or invasive procedures are inconsistent with strong patients' preferences, promoting health literacy among patients certainly increases the likelihood patients can resist such physician overuse.¹⁰³

A related claim by proponents is that health literacy combats the overuse of services attributable to a culture of "defensive medicine" and fear of malpractice liability. Better health literacy can mitigate this problem by empowering patients to be more proactive in the decision-making process, and to take more responsibility for medical choices.¹⁰⁴ This yields two potential benefits. First, it minimizes the risk that a bad outcome could lead to a malpractice suit, for the reasons discussed in the previous section. Second, better health literacy depends on improving patient-provider communication and increasing the flow of information between patients and providers.¹⁰⁵ This encourages a trusting and respectful relationship that decreases the likelihood that a patient would sue the provider even if a bad outcome occurs.¹⁰⁶

Despite these intuitively appealing arguments for the relationship between health literacy and health care cost, it is very difficult to measure or estimate the actual impact on cost for a number of reasons. The same challenges to establishing a causal link between health literacy levels and access and quality of care described in the prior section apply to cost studies.¹⁰⁷ For example, it is not enough to find a general correlation between poor health literacy and higher costs: one must also demonstrate that specific health literacy tools improve patient decision-making in ways that significantly reduce costs, and how. Though a number of pilot projects studying tools for improving health literacy offer evidence that improving health literacy may reduce health care costs by preventing expensive hospitalization and helping patients better manage chronic illness, this may not be true for all interventions.¹⁰⁸ Moreover, the cost of implementing a health literacy intervention or program must be considered, and this cost

commissions/deciding_to_forego_tx.pdf.

103. See PREFERENCE-SENSITIVE CARE, *supra* note 9, at 2 (noting that most clinical trials on the impact of patient decision-aids on patient choice of discretionary surgery show a net reduction in demand for the more invasive surgical options, which has cost benefits).

104. *Rethinking Informed Consent*, *supra* note 43, at 435.

105. See *infra* Part III.

106. See *Rethinking Informed Consent*, *supra* note 43, at 474-75, 478-79. Proponents point to studies that show an association between communication and malpractice rates to suggest that better health literacy can reduce health care costs by reducing the communication barriers that may make patients more likely to bring malpractice suits. See *id.*

107. See PRESCRIPTION TO END CONFUSION, *supra* note 1, at 102 ("[S]ince the causal relationships between literacy and health-care utilization and cost have not been discovered, it is not possible to establish a valid cost figure for the impact of limited health literacy.").

108. See HEALTHY PEOPLE 2010, *supra* note 12, at 11-9 (discussing interventions that did not work).

may not be insignificant, especially for providers in underserved areas. There is a vast array of different interventions that could be implemented to help improve health literacy,¹⁰⁹ each of which may yield a different cost-benefit analysis, when the expense of implementation is compared against the potential cost savings.

Finally, even in the most compelling case linking low literacy and high health care costs – chronic health care – the true cost implications are unknown. An estimate of the additional costs of improving health care access and better management of chronic care is needed to determine whether better literacy ultimately saves money. Improving health literacy may save money by preventing recurring medical crises and hospitalization, but this must be measured against the cost of additional care that the patient would need, assuming that the patient's life is extended. Keeping people healthier extends the aging process in ways that can lead a patient to use more health care resources later in life.¹¹⁰ In these cases, the total amount of healthcare an individual receives over a lifetime may increase.¹¹¹

III. POLICY RECOMMENDATIONS TO PROMOTE HEALTH LITERACY

In light of the multiple ways that health literacy is defined, shaped, and potentially influences health care access and quality, solutions will be equally varied and complex. Nonetheless, there are important guiding principles that animate the various health literacy tools and reform proposals developed so far. This part reviews these guiding principles, and considers their implementation through specific recommendations and health literacy tools.

109. See NAT'L CENTER FOR THE STUDY OF ADULT LITERACY AND LEARNING, THE HEALTH LITERACY ENVIRONMENT OF HOSPITALS AND HEALTH CENTERS (2006) (audit tool for Health Literacy Environment of Hospitals and Health Centers) available at http://www.ncsall.net/fileadmin/resources/teach/enviro_title.pdf; *infra* notes 140-41 and accompanying text.

110. See CONG. BUDGET OFFICE, A CBO STUDY: THE LONG-TERM OUTLOOK FOR HEALTH CARE SPENDING 4 (2007) (noting that although some advocate for disease management and care coordination as mechanisms for reducing costs, studies show that this may not significantly reduce costs for many patients). The CBO's report notes that aging of the population is one factor that may contribute to increased health care spending, especially as the number of people covered by Medicare and using long-term services financed by Medicaid expands. *Id.* at 14. It also points to technological developments as another factor resulting in expanded treatment and higher health care spending. *Id.* at 15.

111. I am not making a normative claim about the importance of cost or whether such a cost calculus should be made when deciding to encourage preventive care as a health policy matter. I am making a much narrower claim: although cost savings may be significant in certain instances, and seem like a helpful strategic argument for promoting health literacy generally, proponents should be careful about relying too heavily on this argument given how little information we really have. In certain instances better literacy may not reduce cost but still be desirable because of the other goals it achieves.

A. Principles Underlying Health Literacy Reform

First, many factors help shape health literacy – education level, literacy, SES, cultural values, psychological factors, access to information provided through the media, the form and content of information provided, the time a patient is given to absorb information and ask questions, and the patient-provider relationship. An understanding of how each of these factors influences patient-provider communication and health literacy depends on research from various disciplines, including education, psychology, sociology, and science. Thus, the best approach to understanding and improving health literacy is a multi-disciplinary one.

Second, because information communicated through numerous channels shapes health knowledge, all sources of information should be considered as a means for improving health literacy, while being inspected for barriers. Health literacy tools must come in different forms and be implemented in the health care and non-health care sectors. Schools, community organizations, government health agencies, and mainstream media have important roles to play in promoting health literacy.

Third, although this effort needs a multidisciplinary and multi-sectored approach, it is also important to try to achieve some coordination among the different actors. HHS's National Action Plan is an important attempt to coordinate these efforts, but it acknowledges the challenges of doing this and particularly the need for better oversight of health literacy research and the development of health literacy interventions.¹¹² Currently, there is no government body or private organization that evaluates the objectivity or clinical accuracy of the various materials developed by health literacy organizations.¹¹³

The final, and perhaps most important principle, is that proposals to improve health literacy should be patient-centered, though not solely patient-focused. Because health literacy is not determined solely by patient-specific factors, improving health literacy cannot only be patients' responsibility. Improving patients' health literacy skills and knowledge requires affirmative action by patients, providers, government, and other sources of health information in tandem with patient involvement at every stage of health literacy research and development. Only by involving patients (and ensuring diverse representation of patients belonging to different groups) can we understand the scope of the health literacy problem, barriers to health literacy and their impact, and which interventions are effective in overcoming these barriers.

112. NATIONAL ACTION PLAN, *supra* note 13, at 14, 43.

113. See *Rethinking Informed Consent*, *supra* note 43, at 466-467 (discussing the importance of credentialing organizations that develop decision aids to ensure unbiased and informed disclosures).

B. Health Literacy Tools & Proposals

Despite its relative youth, the health literacy movement has already produced important guidance and tools for improving health literacy. Below are examples of reforms designed to address patient-specific, provider-specific, and structural factors that shape health literacy.

One consistent recommendation from health literacy organizations is to alter the form and comprehension level of information presented to patients based on our evolving understanding of the scope of health literacy problems in general and the challenges that all patients face processing complex information under stressful circumstances. Recommendations include lowering the level of verbal communication and written materials to the fifth, sixth, or seventh grade reading level, as well as supplementing such information with pictures and video tapes illustrating the desired behavior, auditory aids, and interactive computer programs where possible.¹¹⁴ Simplifying the form of the message to emphasize the most important information is also critical for ensuring clear and effective communication.¹¹⁵ For example, material should use a large font size and headings, there should be a limited number of objectives per item distributed, and materials should emphasize desired behavior as opposed to medical facts.¹¹⁶

Where patients suffer particular impediments to the dominant form of communication – such as LEP, deafness, or blindness – patients and providers should employ appropriate accommodations.¹¹⁷ For example, language assistance services, including oral interpretation and written translation, should be available for LEP patients. Interpreters and visual aids appropriate to the written literacy level of the patient should be employed for deaf patients. And devices that give medication or other medical information orally should be used for blind patients.

Another important recommendation is to provide patient coaching or patient-centered materials to assist patients in making health decisions.¹¹⁸ These tools can empower patients to ask the right questions to help them make medical decisions about diagnostic or treatment options, particularly where treatment alternatives present different risks and quality of life concerns. Such decision guides have been developed in a number of areas, such as to help patients choose appropriate diagnostic procedures or

114. See NATIONAL ACTION PLAN, *supra* note 13, at 10; CHCS, *supra* note 63, at 5, 7. See also *infra* note 130 (describing an initiative by the Iowa Health System to rewrite informed consent forms at sixth and seventh grade reading levels).

115. See PRESCRIPTION TO END CONFUSION, *supra* note 1, at 214.

116. CHCS, *supra* note 63, at 6.

117. See NATIONAL ACTION PLAN, *supra* note 13, at 26.

118. See PRESCRIPTION TO END CONFUSION, *supra* note 1, at 215-20.

treatments for cancer and to educate patients about reproductive and sexual health.¹¹⁹

In addition to providing decision aids and clinical information materials, providers should take affirmative steps to encourage patient questions, and to engage in a dialogue with patients to make sure they understand the information provided and can comply with treatment instructions.¹²⁰ Health literacy experts recommend providers use disarming questions to create a safe space for patients to ask for clarification without triggering the shame they might otherwise feel if they had to reveal literacy problems.¹²¹ The teach-back method is a particularly effective tool for eliciting patient understanding.¹²² Finally, because of the important role that race, ethnicity, and culture may play in the patient-provider interaction, clinical materials, decision aids, and provider communication should be culturally sensitive.¹²³

Literacy experts do not expect individual health professionals to bear the entire burden of developing all of this information, recognizing the overwhelming time necessary to create these tools. Rather, information is developed by various organizations and made available for physicians and patients to use as necessary. Informational materials and decision tools that promote health literacy come from many different sectors: government regulatory bodies,¹²⁴ accreditation organizations,¹²⁵ consumer advocacy

119. For example, tools have been developed to help patients decide whether to undergo certain diagnostic procedures, treatments for cancer, or have an amniocentesis.

120. Because medication errors and mismanagement of chronic disease are so prevalent, harmful, and costly, clinical materials promoting better communication and patient literacy in these areas are a priority. Materials have been developed to help physicians provide patients a clear schedule with easy reminders to improve medication compliance, such as color coding that helps patients identify which medications they must take and when. There are also tools to help physicians assess patients' ability to comply with a particular schedule, so they can identify a potential problem and tailor a medication schedule to fit the patient's routine if necessary. CHCS, *supra* note 63, at 5; WHAT DID THE DOCTOR SAY, *supra* note 64, at 30, 35-36.

121. NATIONAL ACTION PLAN, *supra* note 13, at 9-11.

122. In the "teach back" method, a patient is asked to repeat or explain to the treating clinician the information that was just communicated in order to make sure that the patient has understood the instructions. *See id.* at 11 (emphasizing that providers should assume that most patients will have difficulty understanding health information); *see also* CHCS, *supra* note 63, at 5; WHAT DID THE DOCTOR SAY?, *supra* note 64.

123. HEALTHY PEOPLE 2010, *supra* note 12, at 11-6, 11-7; NATIONAL ACTION PLAN, *supra* note 13, at 13, 25-27.

124. *See* PRESCRIPTION TO END CONFUSION, *supra* note 1, at 191-201.

125. The Joint Commission has taken several steps to promote health literacy among the hospitals it accredits. *See, e.g.*, WHAT DID THE DOCTOR SAY?, *supra* note 64, at 5 (discussing the problem of health literacy and proposing several recommendations to improve it); THE JOINT COMMISSION, HOSPITAL ACCREDITATION PROGRAM STANDARDS 7-18 (2010) [hereinafter, JOINT COMMISSION STANDARDS] (establishing standards and policies for hospitals designed to ensure patient-centered communication, culturally competent communication, and patient education generally and for medication compliance

groups, professional organizations,¹²⁶ insurers,¹²⁷ health literacy experts,¹²⁸ and other educators.¹²⁹ Increasingly, we see collaborations among these sectors to improve health communication.¹³⁰ Nonetheless, provider implementation of these tools requires time (and possibly additional expense), research, training of other health care personnel, and patient education. Health literacy experts acknowledge that this proactive approach is less likely to take place without the proper financial incentive so they also recommend reforming the health care financing system to compensate for time spent on patient education and to reward the use of health literacy tools

specifically); THE JOINT COMMISSION, ADVANCING EFFECTIVE COMMUNICATION, CULTURAL COMPETENCE, AND PATIENT- AND FAMILY-CENTERED CARE: A ROADMAP FOR HOSPITALS 3 (2010) [hereinafter A ROADMAP FOR HOSPITALS].

126. The American College of Physicians, American Dental Association, American Medical Association, American Academy of Pediatrics, Association for Clinicians for the Underserved, and the American Society for Nutrition have issued standards to promote health literacy, identified health literacy as an important goal for improving quality of care, and/or developed patient education pamphlets on specific health conditions and medical procedures.

127. United Healthcare, Kaiser, and LA Care are implementing health literacy tools such as visual and other aids to explain health care concepts and providing decision coaches to assist patients with medical decisions. LA Care has even launched its own health literacy project. See L.A. CARE HEALTH PLAN, HEALTH LITERACY: 10 THINGS YOU CAN DO IN YOUR PRACTICE RIGHT NOW (2010), available at <https://www.lacare.org/providers/resources/newsletters>.

128. See, e.g., *Decision Support*, FOUNDATION FOR INFORMED MEDICAL DECISION MAKING, http://www.fimdm.org/decision_sdms.php (last visited May 3, 2011) (developing programs that present clinical information from clinical and patient experience perspectives); *What is Health Literacy: Fact Sheets*, CTR. FOR HEALTH CARE STRATEGIES, INC., 1, http://www.chcs.org/usr_doc/Health_Literacy_Fact_Sheets.pdf; *Health Literacy in Action: Helping People Understand Their Care*, HEALTH DIALOG 1, 4-5 (April 2010), http://www.healthdialog.com/Libraries/Research_Documents/Health_Literacy_in_Action.sflb.ashx; *Ottawa Personal Decision Guide*, OTTAWA HOSPITAL RESEARCH INSTITUTE, <http://decisionaid.ohri.ca/decguide.html> (last visited May 3, 2011).

129. See WHAT DID THE DOCTOR SAY?, *supra* note 64, at 43 (describing a literacy intervention in the health care encounter designed to promote reading among young children, called the Reach Out & Read Program, as well as referrals of patients with limited literacy to adult education centers); PRESCRIPTION TO END CONFUSION, *supra* note 1, at 41 (“Educators need skills to engage students in health-related issues and to incorporate health messages into science, language, and math curricular materials.”).

130. See, e.g., NATIONAL ACTION PLAN, *supra* note 13, at 41 (describing the Iowa Health System (IHS) Health Literacy Collaborative, launched in 2003, which is a collaboration between adult learners, patients and family, medical pharmacy industry, and the Iowa department of public health). The IHS recreated informed consent forms to adjust the reading level from collegiate to sixth and seventh grade levels. It also proposed the Partnership for Clear Health Communication to encourage patients to ask questions about their care, called the “Ask me 3” initiative. See also *id.* at 37 (describing a collaboration between the Adult Learning Center, New York City Office of Mayor, Harvard School of Public Health, the Literacy Association Center, and Harlem Hospital to incorporate health literacy into adult education curriculum).

that improve health care quality.¹³¹ Because better patient health literacy depends on providers having good communication skills, provider education and training in communication, health literacy, and cultural competency should be reformed.¹³² Interpersonal skills and communication are one of six core competencies of graduate medical education tested on the U.S. Medical Licensing Examination;¹³³ however, many physicians continue to report a lack of adequate training in medical school or through continuing medical education programs in areas critical to improving patient-provider communication.¹³⁴

Better health literacy depends on improving the quality and accessibility of information outside the health care system as well. Health literacy organizations and the government use mainstream media to communicate accurate public health information, though the focus has largely been on the English-speaking mainstream media. Health literacy initiatives should use different forms of media and be audience-centered.¹³⁵ Some work has been done to develop culturally competent health intervention strategies in non-English media,¹³⁶ but more work is needed. Disability rights groups have

131. See generally WHAT DID THE DOCTOR SAY, *supra* note 64, at 47 (suggesting broader reimbursement policies for patient education, pay for performance rewards to encourage patient-centered and culturally competent care, and discounts in medical liability insurance for physicians who receive education on techniques for making such improvements).

132. See HEALTHY PEOPLE 2010, *supra* note 12, at 11-5, 11-7; see also NATIONAL ACTION PLAN, *supra* note 13, at 11-12 (emphasizing the importance of organizational changes to meeting the communication needs of patients); UNEQUAL TREATMENT, *supra* note 38 (Chapter 6 discusses the importance of cross-cultural education in the health care profession). One study showed success with patient intervention, but also demonstrated the need for provider training as part of any reform to improve communication and patient participation. A randomized sample was assigned to intervention and non-intervention groups. Results indicated that patients in the intervention group asked more direct questions and fewer indirect questions than did non-intervention group patients. Within the intervention group, however, there was more negative effect, anxiety, and anger in the patient-provider interaction, while in the placebo group, patient-provider interaction was characterized as mutually sympathetic. The intervention group patients were less satisfied with care received in the clinic on the day of their visit than were placebo patients, but they demonstrated higher appointment-keeping (accounting for average number of appointments made) during a four month prospective monitoring period. These findings suggest that efforts directed at increasing patient activation must also target physicians' behavior and how providers receive and respond to patients' increased participation. *Id.* at 197.

133. Historically, little attention was paid to communication skills in undergraduate and post graduate training for physicians. This began to improve in the 1990s when the Association of American Medical Colleges initiated the Medical Schools Objective Project. PREVENTING MEDICATION ERRORS, *supra* note 42, at 171.

134. See *id.*; UNEQUAL TREATMENT, *supra* note 38, at 202; WHAT DID THE DOCTOR SAY?, *supra* note 64, at 31.

135. HEALTHY PEOPLE 2010, *supra* note 12, at 11-5 – 11-7.

136. *Id.* at 11-6 – 11-7 (describing successful mass media interventions such as a national telephone services for Spanish speakers to get AIDS information; breastfeeding

stressed the importance of increasing access to media, generally for those with communicative disorders.¹³⁷ Others highlight the importance of increasing all patients' access to digital tools and the internet, which are becoming increasingly important for delivering health information to the public generally and as vehicles for patients to access public or private benefits, as well as health care itself (for example through on-line interactions with medical professionals).¹³⁸

Finally, health literacy experts, HHS, and consumer groups emphasize the need for more research and better oversight of health literacy generally. Despite growing evidence of an association between provider-patient communications, quality of the patient-provider interaction, and health outcomes, more information is needed to link health literacy, information seeking, and the role of health information in patient decision-making. The extent to which all of these vary for different patient populations also deserves more attention in light of growing diversity and evidence of health disparities for certain groups.¹³⁹

Given the potential importance of health literacy tools for patient decision-making, there should be a mechanism for ensuring the quality of these tools: specifically, an accrediting organization or some other oversight body to ensure the accuracy, objectivity, and efficacy of health literacy

promotion among Navajo women; and use of the Novela, a popular form of mass media among Spanish-speakers, to improve family communication and attitudes about alcohol).

137. A positive step in this direction is the Twenty-First Century Communications and Video Accessibility Act of 2009, which seeks to close existing accessibility gaps in current telecommunications law and requires that new internet-enabled products and services (phone and television) are accessible to people with disabilities. Twenty-first Century Communications and Video Accessibility Act of 2009, H.R. 3101, 111th Cong. (2009). The proposed law extends closed captioning obligations, requires captions decoder circuitry or display capability in video programming devices. *Id.* For a fuller discussion of the proposed law and its impact on barriers for people with disabilities, see *This is NOT a Test: Will the Nation's Emergency Alert System Deliver the President's Message to the Public?: Hearing on H.R. 3101 Before the Subcomm. on Econ. Dev., Pub. Bldg., and Emergency Mgmt.*, 111th Cong. (2009) (testimony of John R. Vaughn, Chairperson, Nat'l Council on Disability), available at http://www.ncd.gov/newsroom/testimony/2009/john_vaughn_9-30-09.htm.

138. See HEALTHY PEOPLE 2010, *supra* note 12, at 11-9 (discussing how the digital divide contributes to poor health literacy among groups with lower education and low income); Edward Alan Miller et al., *Where's the Revolution? Digital Technology and Health Care in the Internet Age*, 34 J. HEALTH POL. POL'Y & L. 261, 261 (Apr. 2009) (finding that "few people are using digital technology to get information, communicate with health personnel, or make online medical purchases. Furthermore, less educated, lower-income individuals living in rural areas tend to use the health care Internet less than others. Several policy measures need to be undertaken in order to accelerate the appropriate use of digital technology by health care consumers of all kinds. These include improving education and technological literacy and providing access to low-cost digital technology").

139. See HEALTHY PEOPLE 2010, *supra* note 12, at 11-8; PRESCRIPTION TO END CONFUSION, *supra* note 1, at 118-37; PREVENTING MEDICATION ERRORS, *supra* note 42 at 194-95.

tools.¹⁴⁰ Comprehensive and nuanced testing of health literacy is also needed to help us better understand the varying skill levels required to successfully navigate different parts of the health care system.¹⁴¹ For example, people with adequate health literacy tend to do well reading medication dosage instructions, appointment slips and medical instructions, but still have difficulty comprehending more difficult tasks like determining financial eligibility and informed consent documents. A patient's ability to understand benefit and financial information relevant for choice among different insurance plans or types of insurance savings accounts may require higher financial literacy skills than other kinds of health materials. Moreover, financial decisions may be more susceptible to certain kinds of cognitive barriers that are more difficult to overcome than other kinds of health care decisions. More research is needed to understand the relationship between health and financial literacy, and its impact on patients as consumers in the health insurance market.

C. Role of Law

Despite the increasing research and development of tools for promoting health literacy, this movement has not yet made the health care delivery or financing system more accessible for the many patients who suffer from poor health literacy, which means that access and quality problems related to poor health literacy are likely occurring every day. If one believes that health literacy has a meaningful impact on patients' access to and quality of health care, and that viable and effective tools for promoting health literacy

140. Some interventions are not unsuccessful. *See, e.g., id.* at 195-96 (discussing one study that showed the use of pictograms did not work due to a disconnect between the leaflet and the picture, nonuse of text to clarify the picture, and too many visual elements; some pictograms, such as those meant to convey "don't drive" and "don't share medicines" did not translate at all). Some tools to help providers audit their own materials for readability are available. The Agency for Health Research and Quality (AHRQ) has also developed a Pharmacy Health Literacy Assessment Guide to help organizations assess how well they improve health literacy. *See also* CHCS, *supra* note 63, at 7 (describing other provider assessment tools such as the Suitability Assessment of materials and the Medicaid Checklist).

141. PRESCRIPTION TO END CONFUSION, *supra* note 1, at 66. There has been a great deal of work on financial literacy that must be considered in trying to determine what kind of information and coaching would be required to enable consumers to make informed choices between health insurers. *See generally*, Lauren Willis, *Evidence and Ideology in Assessing the Effectiveness of Financial Literacy Education* (2008) (Scholarship at Penn Law, Paper 206), available at http://lsr.nelco.org/upenn_wps/206; but *see* Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice*, 2 J. HEALTH & BIOMED. L. 1, 3 (2006) (arguing "the same considerations supporting respect for an adult patient's right to make voluntary, informed decisions about clinical matters ought to be applied to the sorts of non-clinical consumer choices about enrollment in particular insurance plans, savings accounts, and managed care arrangements that are embodied in the concept of consumer-driven health care.").

exist, then a question arises about the role that law should play in encouraging their implementation generally, and, more specifically, for addressing problems that arise.

As noted above, health literacy is shaped and thus should be promoted through a multi-sector and multi-disciplinary approach, and law is certainly relevant in these various sectors. Laws eliminating communication barriers in mainstream media and proposals to reform existing continuing medical education are two examples mentioned in the previous section. Law can also be used to structure financial incentives that encourage providers to promote health literacy. Providing compensation for professionals that engage in patient-education would create the strongest incentive, but payments tied to quality generally could provide an indirect incentive for providers who believe that there is a strong causal link between health literacy interventions and patient outcomes, and that such interventions are cost effective in light of the health and financial benefits realized.

The remainder of this Article will focus on law that directly regulates the patient-provider interaction, and consider the relevance of health literacy for determining provider liability or compliance when access and quality problems arise. Exploring the relationship between law and health literacy through this particular lens is useful for three reasons. First, the potential access, quality, and cost harms are most visible at this point: the provider is a critical source of health information and care for patients, and communication is an essential aspect of medical care. Second, health care delivery is highly regulated, especially in the areas of access and quality. Providers must be mindful of this regulation and are vulnerable to liability or other penalties when problems occur because of legal violations. Finally, concerns about health literacy and patient-provider communication are already implicated by existing laws that govern quality and access. These concerns are rooted in longstanding bioethical principles of patient autonomy, justice, and beneficence, and the corresponding legal principles of informed consent, nondiscrimination, and the right to quality care.

The next two parts of this Article identify a number of places where health literacy concepts either overtly or subtly influence providers' legal obligations. Part IV focuses on laws that create provider liability for violations of substantive standards of quality, such as informed consent and traditional malpractice liability. Part V looks at federal antidiscrimination law that prohibits discrimination on the basis of race, ethnicity, color, or national origin. Both parts explore the extent to which health literacy concerns are relevant for purposes of determining violations of access and quality laws and identify the promise and limits of such laws as tools for promoting health literacy.

IV. LAWS REGULATING QUALITY OF CARE & THE ROLE OF HEALTH LITERACY

Although poor health literacy is shaped in part by provider communication and can impact quality of care, the relevance of health literacy to provider liability, when a bad outcome occurs, is not very clear. This part explores the potential relevance of health literacy in two situations: informed consent liability and malpractice liability generally. Section A describes the link between health literacy and the informed consent doctrine because of the centrality of patient understanding and provider communication in defining disclosure standards. Section B considers a less obvious role for health literacy in malpractice liability generally in at least two circumstances: (i) liability for medical coverage or treatment decisions that depend on the patient as a health care partner; and (ii) mitigation for provider liability due to patients' failure to follow medication instructions.

A. Informed Consent

Informed consent doctrine is rooted in the common law protections against battery, constitutional due process liberty protections, and ethical principles promoting patient autonomy. Originally, the doctrine arose to prevent forced medical treatment or unwanted bodily intrusions, and thus focused on whether a patient *consented* to a particular test or procedure. It has evolved into a negligence-based malpractice claim that focuses on ensuring *informed* consent—that is, whether a patient is receiving enough information, and the right kind of information, to be able to make an informed decision. Typically, informed consent cases turn on questions about the scope of disclosure – what kind and how much information a patient should have in order to be able to make an informed choice. A number of cases also focus on the manner of disclosure – that is, whether the information is communicated to the patient in a way that ensures patient understanding. Both inquiries implicate health literacy concerns.

1. Scope of Disclosure

Two standards exist for determining what information is necessary for informed consent: the physician-based standard and the patient-based standard.¹⁴² The physician-based standard requires physicians to disclose information that a reasonably prudent practitioner of the same skill would

142. See *Rethinking Informed Consent*, *supra* note 43, at 430 (discussing these two standards and noting an almost even jurisdictional split).

provide. The patient-based standard requires physicians to inform a patient of the risks, benefits, and alternatives that the average reasonable patient (TARP) would consider material in making a decision. Historically, the debate about the proper scope of disclosure has involved which of these two standards adequately protect patients' rights while accounting for the fact that physicians must make judgments about materiality with incomplete information.¹⁴³

The latter standard is more patient-centered, and thus presumably provides better protection for patients' rights to information. Both standards, however, rely on certain assumptions: that TARP exists, that certain information should or should not be material to TARP's decision to undergo medical treatment or a diagnostic procedure, and that information communicated would be understandable to TARP. If these assumptions do not mirror the reality of an individual patient's health knowledge or expectations, however, then not even the patient-based standard can adequately guide physicians or protect patients.

The relevance of health literacy to informed consent liability is illustrated in a well-known California case, *Truman v. Thomas*. In *Truman*, a patient who refused to undergo a pap smear despite repeated recommendations by her doctor ultimately developed cervical cancer and died.¹⁴⁴ The patient's family sued the doctor for negligently failing to disclose the risks of forgoing the pap smear: the doctor never informed her that the purpose of the test was to detect cervical cancer, or of the risks of failing to detect and treat it early.¹⁴⁵ *Truman* is considered significant for expanding the scope of disclosure beyond simply ensuring informed consent for a procedure or test that a patient does choose; it required giving information about the risks of doing nothing. The opinion is also important because it reflects an early recognition of the relevance of health literacy in determining the appropriate scope of disclosure, despite the fact that the court never explicitly used the term health literacy.

The court made clear that "[i]f the physician knows or should know of a patient's unique concerns or *lack of familiarity with medical procedures*, this may expand the scope of required disclosure."¹⁴⁶ The court also rejected the defendant's claim that the facts he failed to disclose were commonly appreciated,¹⁴⁷ finding that "it was not reasonable for Dr. Thomas to assume that Mrs. Truman appreciated the full consequences of

143. *Id.* at 452-459.

144. *Truman v. Thomas*, 611 P.2d 902, 903 (Cal. 1980).

145. *Id.* at 904.

146. *Id.* at 906.

147. *Id.* at 907.

her decision.”¹⁴⁸ According to court, the plaintiff’s stated reasons for refusing the test—that she did not feel like having it and the cost¹⁴⁹—evidenced a lack of appreciation of the risks, which should have made clear to the doctor that a fuller explanation of the risks and benefits was needed.

In its reasoning, the court highlighted the problem with assumptions about TARP in determining the scope of disclosure and emphasized the importance of dialog between physicians and patients to address the gap in patients’ knowledge.¹⁵⁰ Based on research that demonstrates how many people have limited health literacy, physicians would seem to have a greater obligation to affirmatively address this knowledge gap to ensure an informed choice. Decisions by a provider or court about what information TARP needs assumes some level of basic health knowledge by TARP basic health knowledge.

The *Truman* facts illustrate the severe consequences that can occur when patients forego care due to poor understanding or lack of information. But as noted in Part II, failure to provide a patient with an adequate understanding of her health care options and risks may also lead the patient to choose inappropriate care, or care the patient would not have chosen with full information at the time of her decision. In *Jackson v. State*, a patient sued for malpractice after she had surgery to remove a uterine fibroid, apparently for the purpose of increasing her fertility.¹⁵¹ The procedure unfortunately resulted in a total abdominal hysterectomy and the patient sued her surgeon based on lack of informed consent.¹⁵² The defendant informed the patient that the risks of the procedure included removal of her reproductive organs and infertility, but did not specifically inform her about the risk of induced menopause.¹⁵³

Questions about the materiality of the risk and the significance that TARP would place on this risk were central to the case. Yet, there was little discussion about the basis for the physician’s or the court’s assumptions. Although health literacy was not specifically mentioned, assumptions about patient knowledge were subtly at work. The case arose in a jurisdiction that used a patient-based standard,¹⁵⁴ but the opinion is unclear as to whether the physician thought that induced menopause was something the patient should have realized was a possibility from the other risks described, or whether the physician simply did not believe that it was

148. *Id.*

149. *Id.*

150. *See Truman*, 611 P.2d at 907.

151. *See Jackson v. State*, 938 So. 2d 688, 689 (La. 2006).

152. *Id.*

153. *Id.* at 689-90.

154. *See Rethinking Informed Consent*, *supra* note 43 at 596 (identifying the informed consent standards for different jurisdictions in the United States).

a material risk. The court of appeals found that induced menopause was a material risk and should have been disclosed, but the Louisiana Supreme Court did not address this issue because it found a causation problem.¹⁵⁵ Instead, the court simply concluded that a reasonable patient who was willing to accept the other risks disclosed (removal of reproductive organs and infertility) would not have declined treatment out of a fear of induced menopause.¹⁵⁶

In drawing this conclusion, the court did not explain whether it assumed that TARP would understand the probability of getting induced menopause and how it could physically and emotionally impact one's life, let alone whether this particular patient had such knowledge. This is problematic given the importance of patient-preference in preference-sensitive cases, like this one, for determining appropriate treatment. Perhaps fertility was so important to the patient that risk of inducing menopause would not have been enough to deter her. On the other hand, fertility may have only been one consideration in her decision to remove the fibroid—fibroids can also cause pain, excessive bleeding, and fatigue that can disrupt one's daily activities.¹⁵⁷ A patient who has some or all of these symptoms to a significant degree might be less concerned about fertility and more about quality of life. Indeed, because such a decision likely depends on a patient's age, the intensity of her desire to have children, and the value she places on the quality of life impact caused by fibroids versus induced menopause, TARP in this context seems illusory.

As noted in Part I, as health literacy research undermines traditional assumptions about the basic health knowledge of TARP, clinical research challenges the extent to which any assumptions can be made about materiality for TARP in preference-sensitive cases. Although the Louisiana Supreme Court seemed to ignore this information in its causation analysis, other courts may view a patient's health literacy as important in cases where patient preference is relevant to determining appropriate care, and where providers fail to ensure that patients' preferences are considered before choosing care.

2. Manner of Disclosure

Regardless of whether courts apply a physician or patient-based standard, informed consent requires information to be communicated in a way that is understandable for TARP.¹⁵⁸ Courts have made clear that a failure to

155. *Jackson*, 938 So. 2d at 690.

156. *Id.*

157. *See supra* Part II.A.

158. *See, e.g.,* *Macy v. Blatchford*, 8 P.3d 204, 210 (Or. 2000) (requiring physicians to “explain in general terms” the procedure, alternatives, and risks, which means “to make plain

communicate information in a clear and effective manner can undermine a patient's ability to make an informed choice.

For example, the use of technical language or medical jargon will not satisfy the duty of disclosure; providers must use language that a layperson can understand.¹⁵⁹ In *Hidding v. Williams*, a patient sued for malpractice when he suffered loss of bowel and bladder control as the result of a laminectomy.¹⁶⁰ The doctor warned the patient that surgery could result in a "loss of function of body organs," but the court found that such a warning was not specific or clear enough, and that "[a]n ordinary layperson would not gather from [this warning] that he or she is asked to encounter the specific material risk of being rendered permanently incontinent through loss of bladder control."¹⁶¹ Though the court did not explicitly mention the role of literacy or health literacy in determining whether language is understandable, the court did note that the patient only had a sixth grade education, minimal reading skills, and that his wife regularly accompanied him because he was afraid that he would miss important information.¹⁶²

Courts have also held that physicians cannot solely rely on written consent forms to satisfy their disclosure obligations.¹⁶³ Although written forms may be evidence of informed consent, this may be rebutted by a showing that the physician failed to explain the information in terms that would be understandable to TARP or that the patient was unable to read and understand the information in the form provided. In several cases, literacy problems have been explicitly identified as undermining informed consent, usually in conjunction with language barriers.¹⁶⁴

or understandable" and "almost by definition, takes into account the mental state and capabilities of the recipient"); *Rodriguez v. N.Y. City Health & Hosps. Corp.*, 50 A.D.3d 464, 465 (N.Y. App. Div. 2008) (applying a physician-based standard, but noting that providers must disclose material risks, benefits, and alternatives "in a manner permitting the patient to make a knowledgeable evaluation"); *Hidding v. Williams*, 578 So. 2d 1192 (1991) ("physician is required to disclose material risks in such terms as a reasonable doctor would believe a reasonable patient would understand"); *Foard v. Jarman*, 387 S.E.2d 162 (N.C. 1990) (applying a physician-based standard, but noting that a "health care provider must impart enough information to permit a reasonable person to gain a "general understanding" of both the treatment or procedure and the "usual and most frequent risks and hazards" associated with the treatment").

159. *Jackson*, 938 So. 2d at 690; *Macy*, 8 P.3d at 210; *Keomaka v. Zakaib*, 811 P.2d 478, 487 (Haw. Ct. App. 1991); *Hidding*, 578 So. 2d at 1196.

160. *Hidding*, 578 So. 2d at 1194.

161. *Id.* at 1196.

162. *Id.*

163. *Quintanilla v. Dunkelman*, 133 Cal. App. 4th 95, 115 (Cal. Ct. App. 2005) ("signed form is not entitled to conclusive proof of informed consent"); *Ditto v. McCurdy*, 947 P.2d 961, 987 ("a signed consent form is no substitute for the required disclosure by a physician"). See also *Macy*, 8 P.3d at 210-11 (holding that a question of fact existed about informed consent despite signed consent form).

164. *Quintanilla*, 133 Cal. App. 4th at 101 (patient was an immigrant who was fluent in

Courts have specifically acknowledged the difference between verbal and written literacy for both English and non-English speakers and found it relevant in determining whether the form of communication was adequate.¹⁶⁵ For example, in *Quintanilla v. Dunkleman*, the court held the patient's inability to read a consent form invalidated a signed consent, and shifted the burden to the physician to prove that informed consent was provided in some other way.¹⁶⁶ The patient and her husband sued for negligent medical care, including lack of informed consent and battery.¹⁶⁷ The patient had a possible lesion on her vagina for which her physician recommended a dilation and curettage ("D&C"), in addition to a laparoscopy.¹⁶⁸ Several things, however, were either not disclosed or not clearly explained to the patient.¹⁶⁹

The patient did not have a basic understanding of the terminology for the parts of her body affected, and she did not understand what procedures the doctor planned to perform or why they were needed. She thought the physicians were going to do a "simple procedure" to get rid of a "pimple" "down there," a procedure she had undergone previously.¹⁷⁰ The physician tried to explain the procedure to the patient in Spanish, but used the term "raspado" to describe the D&C, a term that translates literally into cleaning or scraping, which the patient did not know.¹⁷¹ The court noted that the patient, while fluent in Spanish and English, could not read Spanish and only attended school in the U.S. through the tenth grade.¹⁷² From the opinion, it seems that literacy, LEP, and health literacy problems combined to prevent an adequate understanding of the procedure that vitiated any apparent consent, even though the court never explicitly mentioned the term "health literacy."

By contrast, in another case brought by a plaintiff with limited English skills, the court did not seem to appreciate the difference between literacy

Spanish and English, but only attended school through the tenth grade, took classes in Spanish in grades seven and eight, and had trouble reading Spanish and English); *Ditto*, 947 P.2d at 968, 987 (patient was a Korean immigrant with a fourth grade education who could not read English); *Rodriguez v. N.Y. City Health & Hosps. Corp.*, 50 A.D.3d 464, 466 (N.Y. App. Div. 2008) (patient had difficulty reading and speaking English; Spanish was her native language); *Hidding*, 578 So. 2d at 1196 (patient had a sixth grade education and minimal reading skills).

165. See, e.g., *Quintanilla*, 133 Cal. App. 4th at 101 (patient spoke Spanish fluently but could not read it); *Hidding*, 578 So. 2d at 1196 (patient was a native English speaker, but had minimal reading skills).

166. *Quintanilla*, 133 Cal. App. 4th at 101.

167. *Id.* at 98.

168. *Id.* at 102-03.

169. *Id.* at 102-04.

170. *Id.* at 101.

171. *Id.* at 102.

172. *Quintanilla*, 133 Cal. App. 4th at 101.

and health literacy, and placed great weight on the failure of the patient to request a Spanish consent form. In *Rodriguez v. NYC HHC*, the defendant appealed a jury verdict that awarded the plaintiff damages in a malpractice action based on lack of informed consent.¹⁷³ The plaintiff claimed the defendant failed to disclose that the recommended breast reduction surgery would leave hypertrophic scars and did not advise her of alternatives.¹⁷⁴ She also said that her difficulty in understanding English prevented her from giving informed consent.¹⁷⁵ The court emphasized that providers have a duty to disclose information in a manner permitting the patient to make a knowledgeable evaluation, and noted that a lack of understanding of the English language would invalidate a signed written consent in English.¹⁷⁶ The court reversed the jury's verdict, however, making assumptions that are inconsistent with health literacy research and the practical experience of patients with limited literacy.

First, despite plaintiff's testimony that she had difficulty reading English and did not understand the written consent for surgery, the court emphasized that, she did not ask for a Spanish consent form or interpreter, even though she had earlier signed a Spanish consent form for general medical service.¹⁷⁷ The court assumed that because she had received a Spanish consent form at some other point in her contact with the hospital, she would have the presence of mind to expect and to ask a different doctor for another Spanish consent form before surgery. This is a very high expectation for a patient with limited literacy skills and English proficiency who is likely also experiencing stress and fear because of the impending surgery. The facts of the case do not say when the plaintiff received the earlier form or under what conditions: it could have been at admission, when she may or may not have been under the same level of stress or when she may or may not have been dealing with intake people or nurses who had more experience assisting Spanish-speaking patients. Moreover, as will be discussed further in Part V, health care providers are not legally obligated to have, nor do they typically have, all of their written forms translated into Spanish. To expect patients to ask for or even to be able to get a written translation at every point in the health care delivery system is unrealistic. It also suggests an affirmative duty on the part of the patient to ask for information in a more appropriate format, which is inconsistent with other courts' approaches to informed consent.

The court also found it troubling that although the patient claimed to

173. *Rodriguez v. N.Y. City Health & Hosps. Corp.*, 50 A.D.3d 464, 464-65 (N.Y. App. Div. 2008).

174. *Id.* at 465.

175. *Id.* at 465.

176. *Id.* at 465-66.

177. *Id.* at 466.

have difficulty understanding English when spoken, she acted as a translator for another Spanish-speaking patient while at the hospital.¹⁷⁸ The implicit assumption by the court seemed to be that any ability to understand English demonstrates the ability to adequately comprehend health care information in English. But health literacy research demonstrates that a limited ability to speak English does not mean that the patient is proficient in English, let alone health literate enough to understand complex medical terms or information.¹⁷⁹ Unfortunately, the fact that the plaintiff interpreted for another patient reflects the reality that many providers fail to offer adequate language assistance services for LEP patients, who are then forced to rely on family, friends, and other patients for assistance that is inadequate and can undermine health care quality.¹⁸⁰

Courts have made clear that when a physician is aware of an impediment to patient understanding, like poor literacy or a communication barrier, the physician has a legal duty to address the impediment in order to get informed consent.¹⁸¹ But how far must the physician go to *ensure* that the patient is *in fact* informed? The rhetoric used to describe the goals of informed consent is not consistent with the application of the doctrine. As noted above, courts typically express concern about patients' understanding and knowledge used to make an informed choice.¹⁸² Moreover, in allowing plaintiffs to rebut written proof of informed consent, courts warn that such formalistic disclosures are not adequate substitutes for "an ongoing process of disclosure, discussion, and decision making between physician and patient."¹⁸³

Unfortunately, when courts apply the doctrine to consider whether

178. *Id.*

179. The opinion does not give facts about the circumstances under which she provided this ad-hoc interpretation. For example, the plaintiff may have provided interpretation for another patient during intake, or to help the patient communicate her symptoms to a nurse or physician, but we do not know whether she translated a more complex explanation of condition/risks from the provider to patient, and, if so, whether she did so correctly. Perhaps the court had trouble reconciling these facts because of other inconsistencies in the plaintiff's testimony that affected her credibility; however there is nothing incredible about a significant difference between one's written and spoken literacy, or one's basic and health literacy. Indeed health literacy research tells us that this is far more common than assumed. *Rodriguez*, 50 A.D.3d at 466.

180. When patients are forced to rely on other patients or family to communicate confidential health information to providers and interpret complex medical information from providers because of inadequate language assistance, this implicates informed consent concerns and the antidiscrimination prohibition under Title VI. *See infra* notes 253 and 255 and accompanying text.

181. *See, e.g.,* *Macy v. Blatchford*, 8 P.3d 204, 210 (Or. 2000).

182. *See supra* note 158 and accompanying text.

183. *Keomaka v. Zakaib*, 811 P.2d 478, 486-87 (Haw. Ct. App. 1991) (quoting Alan J. Weisbard, *Informed Consent: The Law's Uneasy Compromise With Ethical Theory*, 65 Neb. L. Rev. 749, 755-57 (1986)).

disclosure has been satisfied, it is typically applied in a unidirectional way, with the focus on the provider's disclosure, not the patient's understanding. Courts often find obligations met when disclosure is rendered upon the patient as a passive recipient of information – not as an active participant. While some statutes and courts specifically require the provider to give patients the opportunity to ask questions,¹⁸⁴ the duty to impart additional information is only triggered upon this affirmative act by the patient. This approach assumes the patient is knowledgeable, assertive, and skilled enough to ask specific follow-up questions, which is something health literacy research tells us is not true for many patients.

This disconnect between theory and application is illustrated clearly in *Yahn v. Folse*, which triggered a vigorous disagreement about the scope of a physician's duty to elicit patient understanding.¹⁸⁵ In *Yahn*, a patient who was eighty-two years old, illiterate, and hard of hearing, sued the defendant doctor and hospital for failure to obtain informed consent before performing an arteriogram that ultimately resulted in a stroke.¹⁸⁶ The doctor, who obtained consent, knew of the patient's illiteracy and hearing issues, so he sought verbal consent.¹⁸⁷ The plaintiff lost at the trial level based on the court's finding that informed consent was provided, and the appellate court refused to overturn the trial court's determination.¹⁸⁸ The court cited several factors in support of its finding of informed consent: Yahn was mentally alert and able to communicate with others in the room; the physician was aware of the hearing problem and sat close to Yahn and spoke loudly; and the physician spent fifteen to thirty minutes communicating with Yahn and gave him a chance to ask questions.¹⁸⁹

A concurring opinion and two dissenting opinions strongly disagreed that these findings evidenced informed consent. The judges were particularly troubled by the lack of dialog: “[t]he patient's participation in the decision-making process was limited to one word, ‘OK,’ which others testified was Yahn's typical response to most things . . . [The defendant] made no effort to determine which parts (if any) of the explanation the patient heard or understood.”¹⁹⁰ The judges argued that the literacy and hearing problems of the patient created an affirmative duty for the physician to assess the

184. See, e.g., Uniform Consent Law, LA. REV. STAT. ANN. § 40:1299.40(A), (C) (West 2010); see also OR. REV. STAT. §677.097 (2009).

185. See *Yahn v. Folse*, 639 So. 2d 261, 273 (La. Ct. App. 1994) (Norris, J. and Brown, J. dissenting).

186. *Id.* at 263.

187. *Id.* at 263-64.

188. *Id.* at 269, 271 (At the first hearing, the appellate court found clear error in the trial court's finding that informed consent was provided; however, it upheld the trial court's finding on rehearing).

189. *Id.* at 270.

190. *Id.* at 274 (Brown, J. dissenting).

patient's understanding; the defendant's "impression" that he had consent was not enough.¹⁹¹ In finding that the physician failed to satisfy his duty to obtain informed consent, the dissenting judges took seriously the goal of patient-participation and informed choice.¹⁹² They also seemed to invite an expanded interpretation of a provider's duty that requires a provider to take steps to assess patient understanding as a means for ensuring informed choice, at least where the physician is put on notice of serious communication barriers. To date, however, no courts have accepted this invitation.

3. Limits of Existing Doctrine to Promote Health Literacy

For many reasons, the informed consent doctrine seems like the natural legal space within which to incorporate an evolving understanding of health literacy and standards for patient-provider communication. First, courts have made clear that patient understanding is important, providers cannot solely rely on written consent forms, and patient literacy and language skills are relevant in determining whether informed consent has been given. Moreover, today's scholars and practitioners have a greater understanding about the extent to which patient-provider communication influences health literacy, the scope of the health literacy problem, and its impact on patient decision-making in ways that can undermine quality health care. To ignore these factors essentially renders informed consent meaningless as a doctrine designed to promote better health communication and decision-making. Finally, while courts have not expressly identified health literacy as an important factor in the informed consent doctrine, assumptions about patients' health literacy seem to animate legal decisions in ways that demand greater conscientiousness by courts applying the doctrine.

Nonetheless, there are many challenges to solidifying health literacy as part of the framework of informed consent. First, there is no coherent legal framework that defines effective communication, explains how evolving health literacy and psychological research influence the TARP standard for the scope and manner of disclosure,¹⁹³ or discusses when, if ever, a physician has an affirmative duty to assess patient understanding in cases

191. *Yahn*, 639 So. 2d at 273-74 (Norris, J. and Brown, J. dissenting).

192. *See id.* at 274 (Brown, J. dissenting).

193. For example, although the court in *Macy v. Blatchford* says that a provider's duty to make information plain or understandable to patients takes into account the patient's mental state and capabilities, the court only lists examples where lack of capacity is obvious: infants, comatose patients, and non-English speaking patients. 8 P.3d 204, 210 (Or. 2000). It is not clear whether evidence of poor health literacy and challenges to processing health information generally would be considered by a court in determining whether a provider has satisfied the duty of disclosure.

where literacy or health literacy problems may not be clear.¹⁹⁴ Some scholars argue that existing informed consent standards should explicitly incorporate health literacy factors, which is more likely in jurisdictions using a patient-based standard.¹⁹⁵ Even a patient-based standard, however, relies heavily on assumptions about TARP, which may not reflect the reality of most patients. Thus, a growing number of scholars are calling for an even more patient-centered informed consent model based on shared decision-making.¹⁹⁶ Shared decision-making is “a process in which the physician shares with the patient all relevant risk and benefit information on all treatment alternatives and the patient shares with the physician all relevant personal information that might make one treatment or side effect more or less tolerable than others. Then, both parties use this information to come to a mutual medical decision.”¹⁹⁷ For this model to succeed, physicians must employ tools designed to promote better health literacy and ensure patients can be effective partners in this care.¹⁹⁸ Patient-centered care should also promote better health literacy by keeping patients more engaged in the process.

Any attempt to expand the informed consent doctrine to explicitly incorporate health literacy will likely meet the same provider resistance that other expansions of informed consent have encountered.¹⁹⁹ Some physicians express concern about giving patients too much information or information too difficult for them to process accurately.²⁰⁰ Proponents of the shared decision making model argue that health literacy tools and better communication reduces this risk. Thus, literature supporting a shared decision-making model and the use of health literacy tools often go hand-

194. See, e.g., Benjamin Moulton & Jaime S. King, *Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice*, 38 J.L. MED. & ETHICS 85, 87 (2010) [hereinafter *Aligning Ethics*].

195. See generally Jessica Flinn, *Personalizing Informed Consent: The Challenge of Health Literacy*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 379 (2009) (arguing for a standard of informed consent law that would require the physician to take patients' health literacy into account).

196. See, e.g., *Rethinking Informed Consent*, *supra* note 43, at 436-37 (discussing patient-centered informed consent models and explaining how physicians can be more patient-centered in the informed consent process).

197. *Id.* at 481.

198. See David I. Shalowitz & Michael S. Wolf, *Shared Decision-Making and the Lower Literate Patient*, 32 J.L. MED. & ETHICS 759, 759-60 (2004) (noting that even the most evolved informed consent standard will not be effective at promoting patient choice without also using tools to promote health literacy).

199. See *Rethinking Informed Consent*, *supra* note 43, at 429 (arguing that “[h]ealth care research conducted over the last three decades has produced a body of empirical evidence that suggests an overhaul of our current legal standards of informed consent is overdue.”).

200. See *Truman v. Thomas*, 611 P.2d 902, 909-12 (Cal. 1980) (Clark, J. dissenting) (vigorously dissenting based on concerns that expanding the doctrine would create unwieldy burdens for physicians that in turn would jeopardize health care access for patients).

in-hand.

Other common fears driving this resistance are fears of intrusion into physician decision-making and malpractice liability. Providers worry that giving patients too much information will encourage them to second guess provider medical judgment.²⁰¹ They also fear that a more patient-centered standard is amorphous and creates a potentially limitless duty of disclosure that significantly increases the chance that physicians could be liable for failing to disclose information.

These fears pervade the medical profession, but have also become a hot button issue among lawmakers in the health policy debate because of claims that malpractice liability contributes to rising health care costs. As reforms to limit malpractice liability sweep the nation, it is clear there is little taste for expanding liability. The lack of clarity in informed consent doctrine generally, the relative newness of health literacy research and decision aids, and the reality that understanding and improving health literacy is a multi-sectored, multidisciplinary initiative, all raise legitimate concerns about whether a liability framework could effectively promote quality in this way. Physicians are already overwhelmed with medical information for their specific field; it is unrealistic to expect that the evolving and multidisciplinary approach to solving health literacy can be absorbed easily by physicians, and thus, be fair game for liability purposes.

Ironically, expansion of disclosure obligations could have the perverse effect of undermining patient understanding if not implemented properly. The traditional focus of informed consent has been on *how much* information should be disclosed, as opposed to *how* such information is presented and whether there is a meaningful dialog between physician and patients. Under this framing, liability is punishment for missing information. Thus, liability fears drive many providers to err on the side of disclosing more information in an attempt to be thorough and accurate, which often results in long and complicated written forms and pamphlets with a lot of complex medical information. This can undermine the “less is more” approach recommended by health literacy experts, and can create a real legal and ethical tension for physicians. The current legal framework for informed consent does not reflect this more nuanced concern about communicating the right amount of information in an effective way.

201. This reasoning has also been used by courts to resist expansion of the informed consent doctrine. *McGeshick v. Choucair*, 9 F.3d 1229, 1233 (7th Cir. 1993). In refusing to follow the *Truman* approach, the court recognized that the plaintiff urged the court to “impose upon a physician the duty to apprise a patient of any knowledge the physician may have regarding the condition of the patient, and the duty to inform the patient of all possible methods of diagnosis. “*Essentially [the plaintiff] urges us to transform the doctrine of informed consent into a general right to all information which the physician possesses.*” *Id.* (emphasis added).

One way to use the law to promote better health literacy, without triggering these fears, is to consider the implementation of health literacy tools and methods as legally relevant support for physicians defending against informed consent claims. Some courts already have considered the use of patient-friendly informational materials as evidence of informed consent under existing doctrine.²⁰² Moreover at least one state has enacted a statute that affirmatively encourages a more engaged process of patient decision-making and gives physicians who use patient decision aids greater protection from failure-to-inform suits.²⁰³

B. Malpractice Liability

An important limit on the informed consent doctrine is the context in which it arises. It is always about a specific decision whether to undergo or refuse a particular treatment or test, but does not typically address broader concerns about patient understanding, generally or specifically, a patient's ability to follow a medical regimen. For laws designed to regulate the quality of care more broadly, a closer look at provider-patient communication and health literacy reveal the role that these factors play in determining health care outcomes, and potentially in determining liability when things go wrong. Health literacy is potentially relevant to malpractice liability in at least two ways: (i) defining the standard of care for health care decisions by providers when outcomes depend, at least in part, on patients' self-management; and (ii) determining when providers can assert patient responsibility as a defense to malpractice liability or a mitigating factor in assessing damages.

1. Patient as Health care Partner: Defining Adequate Care

One strand of malpractice cases reflects the traditional tension between cost and access/quality described at the start of this Article. These are cases in which malpractice or tort claims are brought against a payor, institutional

202. For example, in *Foard v. Jarman*, the court upheld summary judgment for a physician who was sued for failure to obtain informed consent. 387 S.E.2d 162, 167 (N.C. 1990). It found adequate disclosure where the defendant gave the plaintiff an information booklet geared for patients, titled "What You and Your Family Should Know about Gastric Operations for the Treatment of Obesity." *Id.* at 165-66. The court noted that it contained a detailed description in "readily comprehensible lay terms", including diagrams, and detailed lifestyle changes the patient must make to ensure the operation is a success. *Id.* at 165. The patient also admitted to reading and understanding the booklet and provided no evidence that she was incapable of reading or understanding it. *Id.* at 166.

203. See WASH REV. CODE § 7.70.060(2) (2011). In addition to giving physicians this protection, Washington also endorses a more patient-centered approach to medical decision making, called "informed patient choice." *Id.* Failure to use a patient decision aid or to engage in shared decision-making cannot be used as evidence of the failure to obtain informed consent, however. *Id.* § 7.70.060(5).

provider, or individual physicians because of a decision to delay, deny, reduce, or otherwise alter care recommended by a physician based, in part, on cost concerns, which ultimately results in a bad outcome. Claims against private insurance companies received particular notoriety in the era of managed care horror stories, but such claims have also been brought against public insurers and institutions. The essence of the claim is that the defendant either had a policy in place that systematically discouraged or prevented patients from receiving quality, medically necessary care, or that in a particular instance, institutional or insurer cost concerns trumped the treating physician's medical judgment.

Some cases reflect a clear conflict between payor and provider judgment about whether a diagnostic test, procedure, or medication is or is not medically necessary. A number of cases, however, reflect fuzzier disputes over *how much* of a certain kind of care is required or whether more cost-efficient alternatives are equally efficacious. A common example concerns how many in-patient days are medically necessary, and at what point should a patient be discharged and treated on an out-patient basis. Indeed, identifying and reducing "unnecessary" hospitalization is one of the critical areas identified by public and private payors and institutions for cost reduction. Yet when bad outcomes occur, early discharge may be the basis for a wrongful denial and/or malpractice suit.

In one such case, *Wickline v. State*, a patient sued the State of California for harm caused when the State authorized only four additional days of hospitalization rather than the eight requested by the treating physician.²⁰⁴ The patient had undergone two vascular surgeries and her recovery was described as "stormy."²⁰⁵ Her surgeon requested that she remain in the hospital an additional eight days because he was concerned about the possibility of infection and wanted the ability to respond quickly to an emergency.²⁰⁶ The Medi-Cal consultant, a board certified surgeon, rejected the physician's request and authorized only four days beyond the original discharge date.²⁰⁷ At the time of discharge, the patient appeared stable and there was no evidence that her leg was in danger.²⁰⁸ She began having problems with her leg a few days after discharge, however, and was ordered back to the hospital nine days later. As a result of infection, the patient's leg was amputated.²⁰⁹

204. *Wickline v. State*, 192 Cal. App. 3d 1630, 1633, 1638 (Cal. Ct. App. 1987).

205. *Id.* at 1635.

206. *Id.* at 1636.

207. *Id.* at 1637-38.

208. *Id.* at 1638.

209. *Id.* at 1640-41. The opinion addressed several legal issues: the standard of care for discharge generally; the standard of care for payors making medical necessity determinations; whether payors can be liable for malpractice due to early discharge; and a

Wickline is notable as one of the earliest attempts to hold payors liable for denying coverage for medically necessary care. The case is a compelling example of the tension between cost and access/quality, and the difficult line that insurers draw. The court also highlighted the important role of providers' judgment and their duty to advocate for patients when medically necessary care is denied.²¹⁰ What was missing, however, was an acknowledgment that decisions about when and how to discharge patients may also depend on patients' ability to monitor their own condition and act quickly to prevent deterioration. *Wickline* does not mention patient health literacy, the quality of the patient-provider communication, or the provider's responsibility to ensure patient understanding and the ability to manage her own care. Yet the facts of the case provide strong evidence that poor health literacy and provider communication may have contributed to the bad outcome.

The treating physician testified that if the patient had still been in the hospital at the time the infection developed, he would have observed the leg's change in color, realized a clot had formed, and then performed surgery right away to save her leg.²¹¹ Apparently no special testing or monitoring was needed – just observation of the leg's color and immediate notification of the provider. Presumably, if the patient had received clear instructions and understood the risks and signs of infection, she would have recognized the signs immediately and notified the doctor. Indeed, the plaintiff testified that in the first few days after discharge, she started feeling pain and noticing that her leg was starting to lose color, and that the pain continued to worsen over time, until the right leg eventually took on a “whitish, statue-like marble appearance.”²¹² It is not clear from the opinion if the patient assumed that these were normal recovery symptoms, but apparently she did not tell any of her physicians until the pain got much worse.²¹³ When the patient finally called the doctor for help, she still did not report the change in color, and it is not clear whether anyone asked her about it.²¹⁴ It was not until the pain became “excruciating” that the plaintiff was ordered back to the hospital and her doctors discovered the infection.²¹⁵

What was the relevance of the patient's health literacy to the court's decision given that it was not explicitly mentioned in the opinion? The court only seemed to focus on the patient's medical condition at time of

physician's duty to advocate on behalf of a patient denied coverage of medically necessary care. Ultimately the court found for the State. *Wickline*, 192 Cal. App. 3d at 1630-48.

210. *Id.* at 1645-46.

211. *Id.* at 1641-1642.

212. *Id.* at 1640.

213. *Id.*

214. *Id.* at 1641.

215. *Wickline*, 192 Cal. App. 3d at 1641.

discharge. It did not discuss any connection between the timing of discharge and the patient's understanding of the risks of infection or her ability to monitor her condition and act quickly if symptoms develop.²¹⁶ This seems odd given that the patients' understanding of the risks and her ability to act quickly to prevent infection during the time she is at the greatest risk would seem to be critical factors in determining how many days of hospitalization are medically necessary and whether recovery at home is a safe alternative to inpatient monitoring.

Assumptions about the patient's understanding of her condition may have implicitly supported the court's finding that the discharge was based on sound medical judgment. Indeed, if we assume that a patient is capable of self-monitoring, then it makes sense to discharge her so this can be done at home. If this assumption is correct, then the patient's failure to inform the physician about her leg immediately violates expectations of what TARP would do and may be viewed as the real cause of the bad outcome.

Thus, although *Wickline* is often used to illustrate the tension between administrative decisions to save cost and medical judgment about quality, it reveals much more. It demonstrates the subtle way that patient health literacy can exacerbate or mitigate this tension in health care decisions. It provides a compelling example of how providers' failure to address health literacy can increase the risk of bad outcomes and thus exposure to malpractice liability. And it raises an important question about the failure of courts to expressly consider the role of patient health literacy in certain cases: To what the extent are unstated and incorrect assumptions about patient health literacy influencing courts' determinations of provider liability?

Patients and providers are often presented with less costly alternatives for diagnosis or treatment where efficacy depends on patient self-monitoring and disease management.²¹⁷ The viability of less costly alternatives may turn on a patient's ability to be an effective health care partner, which, in turn, depends on the patient's health literacy and quality of patient-provider communication. In these instances, a provider's failure to take adequate steps to ensure that the patient understands her role should have legal implications. Health literacy research that challenges traditional assumptions about patient understanding supports a heightened standard of care, and thus liability, when providers' failure to elicit patient understanding leads to harm.²¹⁸ Yet this approach is not reflected in

216. *Id.* at 1638-1640, 1646.

217. Early discharge cases are one example of this. Other examples include: taking a wait and see approach versus more invasive diagnostic testing or opting for a less invasive procedure over a more invasive one. *See* PREFERENCE-SENSITIVE CARE, *supra* note 9, at 2, 5.

218. *See* PRESCRIPTION TO END CONFUSION, *supra* note 1, at 191.

Wickline or even modern malpractice cases.

2. Patient Responsibility as Defense to Malpractice Liability

While cases like *Wickline* may rely on implicit assumptions about the role of patient as health care partner, patient responsibility is explicitly considered in malpractice cases where defendants use a patient's failure to follow treatment instructions, or slow response to a problem, to avoid liability or mitigate damages.²¹⁹ Patients have a legal duty to follow reasonable medical instructions, and physicians will not be liable for the consequences of a patient's failure to do so.²²⁰

Missing in these cases, however, is meaningful discussion about the quality of provider-patient communication, patient understanding, or the relevance of health literacy in determining when patients are able to meet this obligation. Implicit assumptions about patients' ability to understand and act responsibly with respect to their own health care seem to animate the outcome in these cases, despite health literacy research, which shows that the failure to follow physician instructions may be due to confusion or a lack of patient understanding.²²¹ A closer look at cases in which patient failures were successfully used to avoid liability reveals that patient confusion, rather than an informed refusal, may have led to the bad result.

For example, in *Bryant v. Clanatone*, a patient sued his dentist for malpractice when the dentist did not give him enough antibiotics.²²² After dental treatment, the patient became very ill and ultimately required two

219. See, e.g., *Ostrowski v. Azzarra*, 545 A.2d 148, 156 (N.J. 1988) (holding that a patient's post-treatment conduct, failing to follow doctor's instructions to stop smoking and alter diet, could be used to mitigate or apportion damages according to patient's fault, but would not be a bar to recovery); *Bryant v. Calantone*, 669 A.2d 286, 288 (N.J. Super. Ct. App. Div. 1996) (finding that the plaintiff's post-treatment conduct in failing to consult his cardiologist for antibiotics is relevant to the issue of damages but not to comparative negligence); *Aimonette v. Hartmann*, 574 N.E.2d 776, 782 (Ill. App. Ct. 1991) (noting that the failure to follow a physician's instructions can mitigate damages); *Segedy v. Cardiothoracic and Vascular Surgery of Akron, Inc.*, 915 N.E.2d 361, 380 (Ohio Ct. App. 2009) ("Disregarding a physician's orders may constitute contributory patient negligence if there is also evidence that it was 'an active and efficient contributing cause of the injury that is the basis of the patient's claim.'"); *Keomaka v. Zakaib*, 811 P.2d 478, 487 (Haw. Ct. App. 1991) (defendant argued unsuccessfully that the patient's failure to read the consent form before signing it constituted contributory negligence in an informed consent claim).

220. *Brady v. McNamara*, 724 N.E.2d 949, 951 (Ill. App. Ct. 1999).

221. Certainly there are cases in which medical instructions are clear and the patients simply choose not to follow them, for example, where the instructions require difficult lifestyle changes, such as quitting smoking or changing diet. There is a legitimate debate about the extent to which such changes are truly within the control of certain patients, either because of addiction, socioeconomic status, and/or other barriers to the support or goods needed to make such changes; however, patient understanding, at least in many of these cases, does not appear to be the problem.

222. See *Bryant*, 669 A.2d at 288.

heart surgeries.²²³ Two years before, the patient was diagnosed with a heart murmur, and was referred to a cardiologist who told him that he would need antibiotics in the event that he has any dental work performed.²²⁴ At that time, he also became a dental patient of the defendant and informed him about his condition and the cardiologist's recommendation.²²⁵ There are no facts about whether or how antibiotics were administered over the next two years when dental work was performed.

In 1991, however, when the plaintiff had dental work scheduled, he reminded the defendant about his heart condition and told the dentist what he thought the cardiologist had recommended: antibiotics for one week before and after the procedure.²²⁶ The dentist told the patient that he was mistaken, and that he only need an antibiotic before the procedure.²²⁷ It turned out that both the patient and dentist were wrong: at trial the cardiologist testified that he'd told the patient that he needed two doses of antibiotics to prevent a heart problem – one before the procedure and one six hours later.²²⁸ The dentist failed to give the patient the second dose after the procedure, and the patient, believing that the dentist knew the correct dose to give him, did not ask the dentist or contact the cardiologist for another dose.²²⁹

On appeal, there was a dispute about whether the jury should have been given instructions concerning the mitigating effect of plaintiff's actions (or inaction) after the dental treatment for purposes of determining damages. The appellate court found that the trial court should have given the instructions.²³⁰ In its reasoning, the court emphasized the relevance of the patient's knowledge and responsibility in his own care:

Plaintiff clearly was aware of his medical condition and was advised that he needed to be given antibiotics both before and after dental treatments. Although plaintiff's testimony was inconsistent with that of [his cardiologist] in terms of the duration for taking antibiotics, plaintiff knew of their necessity. After defendant's failure to provide post-procedure medication, plaintiff did not ask him about it, nor did he contact his cardiologist. A reasonable jury could conclude that a patient who was told he had to be medicated for one week both before and after his dental procedure, who was only medicated one hour prior thereto, could have

223. The patient was diagnosed with bacterial endocarditis, which required an aortic valve replacement. *Id.* at 288 .

224. *Id.* at 287.

225. *Id.*

226. *Id.*

227. *Id.* at 288.

228. *Bryant*, 669 A.2d at 287.

229. *Id.* at 288.

230. *Id.* at 290.

mitigated his damages by inquiring of defendant or his cardiologist about the post dental procedure medication in an effort to insure that he received proper care.²³¹

While it seems reasonable to consider a plaintiff's failure to follow physicians' instructions in determining liability or apportioning fault, health literacy research challenges our assumptions about how effectively physicians are communicating instructions and many patients' ability to understand them. Looking at this case through a health literacy lens, the facts suggest that poor provider-patient communication may have impacted the patients' actions. The court acknowledged that the patient clearly misunderstood or did not remember correctly what the cardiologist recommended. Moreover, the patient was relying on two different providers for care – the dentist and the cardiologist – and received medication advice from both.

In addition to what health literacy research teaches us about patient health literacy generally, medication errors are one of the most common and significant problems attributable to inadequate provider knowledge, poor provider communication with patients, and low functional health literacy of patients. In light of this, several questions must be answered in order to decide whether a patient's inaction can be viewed as an unreasonable act and mitigate the dentists' liability: How long before the incident had the patient seen cardiologist? Did the cardiologist communicate this information orally and expect the patient to remember it in the future whenever he scheduled a dental appointment, or did he write it down clearly and in a permanent form that could be kept in a prominent place? Given that the patient informed the dentist of his condition and had been a patient of his for at least two years, wouldn't it be reasonable of him to expect his dentist as a health care professional familiar with his medical history to know what is required?

Indeed, the dentist seemed to encourage this reliance – the facts suggest that the dentist expressed no doubt in “correcting” the patient's belief that he needed antibiotics for one week, and seemed confident that he knew what was required; at no time did he call the cardiologist or suggest that patient call the cardiologist to double-check. Perhaps this additional information would come out on retrial, but the opinion did not address any of the questions above – the court seemed to assume that the patient should have adequate health understanding and recollection, and be empowered enough to challenge one health care provider by checking with another.

In another case, *Aimonette v. Hartmann*, an Illinois court upheld similar jury instructions, affirming a patient's duty to follow reasonable treatment

231. *Id.*

advice.²³² In *Aimonette*, the plaintiff saw two doctors because of chest pains and difficulty breathing.²³³ The first doctor, Dr. Chowattukunnel, examined the plaintiff and found his chest x-rays were negative but the EKG revealed an abnormality.²³⁴ Subsequently, the plaintiff checked into a hospital for additional tests and consultation with a cardiologist, Dr. Hartmann.²³⁵ The plaintiff told Dr. Hartmann he was having difficulty with breathing, chest pains, and numbness in his right arm occasionally.²³⁶ Dr. Hartmann ordered a treadmill EKG test, but concluded there was nothing wrong except the patient was simply “out of shape.”²³⁷ The plaintiff continued to have trouble breathing, but did not call the cardiologist again until about two weeks later when he began to slur his words.²³⁸ He did not receive a callback from the cardiologist, and two days later he went jogging and suffered a stroke.²³⁹

Evidence existed that both doctors committed malpractice. Dr. Chowattukunnel failed to consider alternative causes of the plaintiff’s symptoms after ruling out the initial diagnosis, while Dr. Hartmann failed to take an adequate medical history, did not continue to monitor the plaintiff following his initial discharge from the hospital, and failed to explain to the plaintiff the need for further monitoring after he eliminated coronary artery disease as a diagnosis.²⁴⁰ Essentially, evidence of malpractice was linked to poor provider communication in terms of gathering adequate information and giving the patient enough information to enable the patient to appreciate the severity of his condition. Nonetheless, the defendants alleged that the patient failed to take reasonable action to mitigate damages because he failed to comply with the first doctor’s instructions to contact him after he returned from vacation and to seek urgent care when the slurring began.²⁴¹

In finding the plaintiff’s failure relevant to the question of damages, the court’s opinion and the jury’s verdict reflect certain assumptions about the patient’s understanding and ability to act. The Illinois appellate court began its recitation of the facts by describing the plaintiff as an attorney who had received his law degree in 1969 (11 years prior to the injury occurring), and

232. *Aimonette v. Hartmann*, 214 Ill. App. 3d 314, 319, 323-24 (App. Ct. 1991).

233. *Id.* at 316.

234. *Id.*

235. *Id.*

236. *Id.*

237. *Id.* at 316-17.

238. *Aimonette*, 214 Ill. App. 3d at 317.

239. *Id.*

240. *Id.* at 318.

241. *Id.* at 317-19.

the defense attorney emphasized this fact in the statement to the jury.²⁴² At trial, the defense attorney appealed to the jury's intuitive understanding of what would have been reasonable for this patient:

Now I know I am talking to a bunch of patients, potential patients, but I don't think that the law is putting an unreasonable standard on somebody. If you have something wrong with you and you are worried about it, you don't sit at home. If you are a child or a baby or you can't think properly or – but a 36-year-old attorney . . . *he is still not entitled to recover in this case because he didn't follow the advice of this doctor.* And the advice was, hey, if you have a problem, come back. And [the first doctor] told him to come back in 10 days anyway. And he didn't do it, and he admitted he didn't do it.²⁴³

Although neither literacy nor health literacy were expressly mentioned, the plaintiff's age, high education level, and profession suggested the plaintiff had a capacity for understanding complex information and the ability to advocate for himself. Though this assumption seems reasonable, looking at the facts through a health literacy lens suggests that patient confusion or lack of understanding due to poor communication could have led to his failure to follow instructions. First, age and high literacy are not necessarily a prediction of proficient health literacy. Second, it is noteworthy that two of the allegations of malpractice - failure to take adequate medical history and failure to communicate the importance of continued monitoring (the risk of doing nothing) - are precisely the kind of communication failures that contribute to poor health literacy and lack of patient understanding among patients of all backgrounds.

Finally, in order to determine how the provider's communication may have impacted the patient's understanding, one would need to ask more questions about that communication: Did the doctor simply suggest that the patient contact him when he got back from vacation or did he explain to the patient the reason for a follow-up appointment and the risks of not coming back? What risks, if any, were communicated to the patient, especially once the doctor ruled out a serious heart condition? Did the patient understand the potential severity of an undiagnosed condition or think that nothing was wrong with him? What kind of danger would the patient

242. *See id.* at 316, 325-26. The legal issue on appeal concerned a challenge to the jury instructions. The plaintiff argued, and the dissent agreed, that the jury instructions blurred the distinction between the plaintiff's duty to mitigate damages and the separate question of whether his conduct was a contributing cause of the stroke; thus the jury may have improperly considered the plaintiff's failure as a bar to the claim, rather than simply as a mitigating factor for damages. *Id.* at 320, 325. Nonetheless, the implicit assumption underlying both inquiries is that the patient understood the physician's instructions and their significance, and therefore could be found legally responsible for failing to follow them.

243. *Aimonette*, 214 Ill. App. 3d at 316, 325-26.

believe existed from the fact that slurring began, in light of the fact that his cardiologist did not call back the same day when he reported it, he was only thirty-six, and the extent (i.e., severity and temporal nature) of his symptoms?

It is clear from health literacy research that patients' failure to comply with medical instructions, and thus the failure to mitigate harm, may be due to a lack of comprehension about the patient's medical condition and risk, or confusion about how to address new problems or symptoms that arose, as opposed to a conscious disregard of physician's instructions.²⁴⁴ While it is certainly unfair to punish a physician for a bad result brought about by a patient's disregard of the physician's instructions, it seems equally troubling to hold patients accountable for information that is often not communicated in a clear or understandable way. To what extent can or should health literacy be relevant in helping courts make this distinction?

V. HEALTH LITERACY & ANTIDISCRIMINATION LAW

While health literacy affects all populations, certain groups are at greater risk for low functional health literacy, gaps in basic health knowledge, and difficulty in communicating with providers. Racial and ethnic minorities are among these groups. As discussed in Part II.A., low health literacy may contribute to health disparities in a number of ways, and when health literacy is shaped by, or interacts with, race or ethnicity in the patient-provider interaction in ways that undermine access and quality, antidiscrimination law may be implicated. This Part considers the legal significance, if any, that our evolving understanding of health literacy has in antidiscrimination claims, and whether antidiscrimination law is an

244. See, e.g., ABRAHAM, *supra* note 8, at 7, 201-02 (providing a look at the challenges of provider-patient communication showing that in many cases patients misunderstand the nature of their condition and what they can do to prevent it from getting worse). For example, Robert Jackson, one of the individuals profiled in the book, discovered that he had focal glomerulosclerosis in a job physical in 1977. Although there is no cure for it, there is treatment that can slow its progress. Robert did not get this treatment or even see a doctor again until he showed up in the emergency room in April 1981. Robert explained why he did not get follow-up treatment: "I was thinking there wasn't that much wrong. I thought whatever it was might clear up on its own. They told me I had something on my kidney, but nobody told me to come back." *Id.* at 31. This was likely the case since it was a physical performed by a doctor hired by a company as opposed to his own treating doctor. It seemed that Robert did not understand the gravity of his illness or that treatment could have delayed deterioration of his kidneys. *Id.* at 31. According to Patricia Barber, a nurse and clinical transplant specialist at the University of Illinois, interviewed in the book, this response is not uncommon: "[w]hen patients come into Cook County with chronic renal failure and say, 'Nobody ever told me this could happen,' they're partly right. They've been told but not in a way that sticks." *Id.* at 31. For lower SES patients, this can be exacerbated by a fatalistic attitude or passivity that keeps patients from seeking more information from providers even when they are confused. *Id.* at 32-33.

effective tool for promoting health literacy by focusing on Title VI.²⁴⁵ Section A looks at this in the specific context of Title VI enforcement of language assistance obligations for LEP patients. Section B explores Title VI as a tool for combating racial and ethnic disparities linked to problems in the patient-provider interaction generally.

A. Title VI & Language Barriers

Health literacy research indicates that communication between providers and patients who speak the same language can be confusing and lead to bad results. Language barriers increase this risk dramatically. According to the 2000 Census, over forty-seven million people speak a language other than English at home, and only fifty-five percent of this population speaks English “very well.”²⁴⁶ Basic literacy is an important determinant of health literacy, and LEP patients suffer a severe disadvantage as a result of their inability to speak or understand English proficiently. The Institute of Medicine identifies language barriers as one cause of health disparities.²⁴⁷

LEP patients experience numerous access and quality of care problems as a result of language barriers. These include, difficulty scheduling appointments, undue delay in waiting rooms, inability to comprehend medical information and consent forms provided in English,²⁴⁸ poor

245. Health literacy concerns may also have implications for laws prohibiting discrimination on the basis of disability. For example providers, insurers, and public agencies that fail to ensure adequate access to information for patients who are deaf or blind may be violating the Americans with Disabilities Act or Section 504 of the Rehabilitation Act. See GUIDANCE TO FEDERAL FINANCIAL ASSISTANCE RECIPIENTS REGARDING TITLE VI PROHIBITION AGAINST NATIONAL ORIGIN DISCRIMINATION AFFECTING LIMITED ENGLISH PROFICIENT PERSONS, 68 Fed. Reg. 47323 (Aug. 8, 2003) [hereinafter *LEP Guidance*]. The LEP guidance notes that sign language and oral interpreters should be provided for people with hearing impairments, and that people with visual impairments should be provided materials in adequate alternative formats, such as large print, Braille, or audio tape. See *id.* Moreover, Part I.A. of this Article also describes how people who are deaf or blind may suffer from gaps in basic health knowledge due to societal barriers to information more broadly that can undermine patient understanding and access. This raises the same fundamental question being explored in Parts IV and V: whether the law creates an affirmative duty on providers to try to discover such knowledge deficits and elicit patient understanding.

246. HYON B. SHIN & ROSALIND BRUNO, U.S. CENSUS BUREAU, LANGUAGE USE AND ENGLISH-SPEAKING ABILITY: 2000, at 2-3 (Oct. 2003), <http://www.census.gov/prod/2003pubs/c2kbr-29.pdf>. Those surveyed could choose among four categories in response to the question about how well they spoke English: “Very Well”, “Well”, “Not Well”, and “Not at all.” *Id.* at 1. Those who chose any other category except “Very Well” were considered to have difficulty with English. *Id.*

247. UNEQUAL TREATMENT, *supra* note 38, at 141 (“[t]o the extent that healthcare systems and institutions fail to address language barriers and assist communication between patients and providers, language mismatches are a fertile source of racial and ethnic disparities in care.”).

248. Indeed, we see language barriers playing a role in some of the informed consent

communication with providers, and even denial of care.²⁴⁹ LEP patients cannot explain their symptoms and concerns adequately to providers nor can they understand providers' explanations of their condition, what additional treatment or medication they require, or other health care instructions.²⁵⁰ These problems can lead to misdiagnosis, unnecessary testing, patients' refusal of necessary testing, poor compliance and follow-up, and low patient satisfaction.²⁵¹ Language barriers can also make it difficult for LEP individuals to complete insurance forms and obtain health care benefits, and citizenship status may compound these barriers.²⁵² Legal restrictions on some public benefits programs and a hostile political climate creates a culture of exclusion or marginalization that makes noncitizen patients (and LEP patients with noncitizen family members), more likely to assume that they are not entitled to benefits and fearful of seeking help because of the risk of government scrutiny and possible deportation.²⁵³ Language barriers make it more difficult for providers to overcome immigration-related fears by ensuring that patients have accurate information.

LEP patients are often forced to rely on their children (including young children), other family members, friends, or even other patients they do not know to help them communicate with health care providers.²⁵⁴ These

cases discussed in the prior section, and many of the quality and cost effects predicted for poor health literacy are evident in populations with language barriers. *See generally supra* Part IV.A.2 (discussing the *Quintanilla* and *Rodriguez* cases).

249. *See LEP Guidance, supra* note 245, at 47311, 47316.

250. UNEQUAL TREATMENT, *supra* note 38, at 90 (in one survey seventy-one percent of providers believed that language and culture are important in health care delivery, and "fifty-one percent believe their patients did not adhere to medical treatment as a result of cultural or linguistic barriers").

251. *Id.* at 141.

252. *See* discussion *supra* Part II.A. *See also* UNEQUAL TREATMENT, *supra* note 38, at 190-93; *Rosen v. Tennessee Comm'r of Fin. & Admin.*, 280 F. Supp. 2d 743, 756-57 (Tenn. D. Ct. 2002) (plaintiffs alleged that the TennCare Medicaid managed care plan did not adequately accommodate LEP enrollees in the plan's communication about eligibility reverification and appeals of benefits termination, which would likely result in benefits denial and coverage termination without due process).

253. *See e.g.*, Mary Engel, *Latinos' Use of Health Services Studied*, L.A. TIMES, Nov. 27, 2007, available at <http://articles.latimes.com/print/2007/nov/27/local/me-immigrants27>; *see* Erin Fuchs, *Medical Needs of Hispanics Targeted*, Chattanooga Times/Free Press, July 29, 2007, <http://www.timesfreepress.com/news/2007/jul/28/Medical-needs-of-Hispanics-targeted> (describing how many immigrants will not go to the clinic to get children immunized for fear of having to show immigration papers). *See generally* Julia Field Costich, *Legislating a Public Health Nightmare: The Anti-Immigrant Provisions of the "Contract With America" Congress*, 90 KY. L.J. 1043, 1052-60 (2002) (noting that underutilization of health care by documented immigrants is due to the fact that they are part of mixed families comprised of persons of illegal or uncertain status, and they worry that seeking benefits will expose undocumented family members to immigration scrutiny or deportation).

254. UNEQUAL TREATMENT, *supra* note 38, at 142-43.

informal or “ad hoc” interpreters may speak English more fluently than the patient, but there is still no way to ensure that they speak English well enough to clearly and accurately communicate information, especially complex health concepts.²⁵⁵ There is a heightened risk of incorrect interpretation with young children because of their age or family members who cannot objectively interpret: they may selectively share information, add information they think is relevant without telling the patient, or put their own spin on the patient’s disclosure based on their own observations or beliefs – for example, by downplaying or exaggerating concerns.²⁵⁶ Reliance on these informal interpreters may also cause patients to leave out important, yet sensitive medical information that they do not want to disclose in front of family or friends.²⁵⁷

1. Language Services & Title VI Enforcement

For LEP patients, ensuring adequate language services is a necessary first step toward ensuring health literacy and improving health care access and quality, and Title VI is a potentially significant tool in this regard. Title VI provides that no person shall “on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.”²⁵⁸ The act also empowers federal agencies in control of federal funding to issue regulations designed to effectuate this protection, and the former Department of Health, Education and Welfare Human Services promulgated regulations prohibiting the utilization of “criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.”²⁵⁹ This regulation has been interpreted by the United States Supreme Court²⁶⁰ and various executive agencies,²⁶¹ including the

255. See *LEP Guidance*, *supra* note 245, at 47316-17; *UNEQUAL TREATMENT*, *supra* note 38, at 143 (describing a study of the error rate in interpretation by untrained persons; finding that twenty-three to fifty-two percent of words and phrases were incorrectly interpreted).

256. See *LEP Guidance*, *supra* note 245, at 47316-17. For an informative study about interpreter error and the difference in error rates between ad hoc interpreters (like family and untrained employees) and trained interpreters, see *WHAT DID THE DOCTOR SAY?*, *supra* note 64, at 19 (finding that for each encounter there were, on average, thirty-one interpreter errors due to omissions, false fluency, substitution, editorializing and additions. The rate of error was significantly higher by ad hoc interpreters than those who were trained.).

257. See *UNEQUAL TREATMENT*, *supra* note 38, at 141-43.

258. 42 U.S.C. § 2000(d) (2006).

259. 45 C.F.R. § 80.3(b)(2) (2005).

260. *Lau v. Nichols*, 414 U.S. 563, 569 (1974) (finding that a San Francisco school

HHS, as prohibiting policies that have a harmful impact on LEP persons, such as the failure to provide appropriate language services.

Framing language assistance services as a Title VI violation has certainly led some providers to take this obligation more seriously; however, language barriers persist due in part to lack of Title VI enforcement. Title VI challenges to improve language assistance for non-English speaking patients have yielded mixed success, and in 2001, the Supreme Court severely limited Title VI's power as a litigation tool.²⁶² The Court held that only intentional discrimination can be enforced through a private cause of action; policies that have discriminatory effects, such as the failure to provide adequate language services, cannot be the subject of a private lawsuit.²⁶³ In light of the fact that many violations are not due to intentional discrimination,²⁶⁴ and that proving intent is difficult even where bias is involved, patients are forced to rely on the complaint process of HHS's Office of Civil Rights (OCR) and to investigate violations.

Unfortunately, OCR enforcement has generally been ineffective, and the language services requirement has gone unenforced for years.²⁶⁵ The problem of Title VI *under* enforcement is due to a number of factors: inadequate resources, personnel, and expertise;²⁶⁶ lack of legal power by

district failed to provide a significant number of non-English speaking students of Chinese origin with a meaningful opportunity to participate in a federally funded educational program in violation of Title VI).

261. See Exec. Order No. 13,166, 65 Fed. Reg. 501201 (Aug. 16, 2000) (requiring federal agencies to publish guidance on how recipients of federal funding can provide meaningful access to LEP persons); Dept. of Justice, *Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency*, 65 Fed. Reg. 50123 (Aug. 16, 2000) (setting forth general principles for agencies to apply in developing guidance documents pursuant to Executive Order 13166); Ralph F. Boyd, Jr., *Memorandum for Heads of Departments and Agencies, General Counsels and Civil Rights Directors* (Oct. 26, 2001) available at <http://www.justice.gov/crt/about/cor/lep/Oct26memorandum.pdf> (reaffirming the DOJ's Title VI guidance for providing meaningful access for LEP persons after *Alexander v. Sandoval*).

262. Siddharth Khanijou, *Rebalancing Healthcare Inequities: Language Service Reimbursement May Ensure Meaningful Access to Care for LEP Patients*, 9 DEPAUL J. HEALTH CARE L. 855, 861-64 (2005).

263. See *Alexander v. Sandoval*, 525 U.S. 275, 280-84 (2001).

264. For example, many providers cite cost as the reason for not complying with language assistance requirements, but the cost of compliance is debated. See, e.g., *LEP Guidance*, *supra* note 245, at 5-6 (stressing the availability of low cost alternatives, such as telephonic interpretation); but see Khanijou, *supra* note 262, at 871 (noting providers' complaints that Title VI is too burdensome and that if individual and small group physicians were subject to these requirements, they might leave Medicaid; also explaining that while some funding is provided for language assistance, it is not enough).

265. See WHAT DID THE DOCTOR SAY?, *supra* note 64, at 19.

266. UNEQUAL TREATMENT, *supra* note 38, at 656.

the OCR to effectively penalize noncompliant providers;²⁶⁷ the failure to gather data on disparities and LEP policies in order to proactively monitor federal recipients;²⁶⁸ and the lack of political will by certain administrations to take Title VI enforcement seriously.²⁶⁹

The OCR is ineffective largely due to passivity. Identification of Title VI violations depends heavily on the patients who are discriminated against – they must know their rights and then file a complaint with the OCR, which is an unrealistic expectation for many LEP patients. Moreover, HHS relies heavily on voluntary compliance by providers, yet the regulations do not require program recipients to submit written plans for compliance and no active monitoring by the OCR exists.²⁷⁰ Finally, the OCR seems willing to act in only egregious cases, and even then, the action is tantamount to a slap on the wrist.²⁷¹

2. LEP Guidance & the Legal Relevance of Health Literacy

Despite the judicial and administrative limits of Title VI enforcement generally, HHS has issued specific policy guidance for program recipients²⁷² regarding when providers must supply language assistance and

267. Title VI's effectiveness is, ironically, limited by the severity of the punishment: Termination of federal funding is the only sanction authorized legally, but this is considered such a severe punishment for providers, and potentially other patients if it puts the provider out of business. HHS seems reluctant to do this given that it has never terminated funding based on a Title VI violation.

268. See generally Sidney Watson, *Reforming Civil Rights with Systems Reform: Health Care Disparities, Translation Services, & Safe Harbors*, 9 WASH. & LEE RACE & ETHNIC ANCESTRY L.J. 13 (2003); Clark, *supra* note 8, at 1047, 1058-60.

269. Watson, *supra* note 268, at 25-26.

270. Although not required, written compliance plans may be required in the event in the course of investigating complaints or compliance reviews. *Questions and Answers, LIMITED ENG. PROFICIENCY*, www.LEP.gov/faqs/faqs.html (last visited May 3, 2011) (Response to Question #8 under the section titled Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals).

271. For example, after a long period of inactivity, Title VI enforcement saw a period of brief revival in 1999, under the then-Director Tom Perez. Perez gave a speech at the New England Regional Minority Health Conference about the problem of disparities and identifying some of the actions the OCR had taken. Thomas Perez, Dir. Office for Civil Rights, Dep't of Health & Human Servs., Address at the New England Regional Minority Health Conference (Apr. 13, 1999). Among the examples provided, three involved hospital practices which seemed aimed at discouraging or refusing care to non-English speaking patients, particularly of Latin descent. *Id.* For example, the OCR cited a number of hospitals in border states and New York for failing to provide appropriate care, including epidurals, for non-English speaking pregnant women, and cited another hospital for requiring its security personnel to wear uniforms that resembled border patrol. *Id.* In all three cases, the failure to provide language services seem likely tied to a discriminatory motive, and the harm or potential harm to patients was severe – depriving them of adequate care for labor and emergency treatment, required under federal and state law; yet even in such egregious cases, the OCR only “cited” the hospitals. *Id.*

272. Among the many recipients to whom the guidance applies are: hospitals, nursing

what constitutes adequate language assistance. The policy makes clear that Title VI and implementing regulations “require recipients to take reasonable steps to ensure meaningful access by LEP persons,” by providing some kind of language assistance.²⁷³ It also educates providers on the different type of language assistance available for example, distinguishing written translation (“translation”) from oral interpretation (“interpretation”) services), and discussing the viability and appropriateness of the different means through which to provide this assistance.²⁷⁴ This is important because the guidance is designed to be flexible to account for the specific linguistic needs of patients generally served by different providers, the circumstances in which these needs are likely to arise, and the resources available to the provider. Rather than create a bright-line requirement, HHS uses a balancing test that reflects the government’s attempt to prevent discrimination and ensure better access and quality, while giving providers the flexibility to determine what is appropriate based on the needs of the population they serve and their own fiscal limitations.²⁷⁵

The extent to which Title VI can promote health literacy for LEP individuals in particular is questionable because the government expressly disclaims a legally significant connection to health literacy in its LEP guidance. In the *Frequently Asked Questions* portion of the guidance, HHS addressed this issue directly:

Q: How do low health literacy, non-literacy, non-written languages, blindness and deafness among LEP populations affect the responsibilities of federal fund recipients?

A: Effective communication in any language requires an understanding of the literacy levels of the eligible populations. *However, where a LEP*

homes, home health agencies, and managed care organizations; university and other entities with health or social service research programs; state, county and local health and welfare agencies; State Medicaid agencies; public and private contractors; and physicians and other providers. See *LEP Guidance*, *supra* note 245, at 47313.

273. *Id.*

274. Interpretation services can be provided by professional interpreters, bilingual employees who may or may not be professionally trained, and “ad hoc” interpreters, such as community volunteers, family members or friends, who typically are not trained. They may be provided in person or via telephone interpretation services, and in-person interpretation may be provided by a bilingual staff person, on-site interpreter or through professional interpreter retained on an as-needed basis. In some instances, such services will be required on an expedited basis; in other cases, referral to another provider may be warranted as long as there is no discriminatory intent, the purpose is beneficial, and the referral will result in better access for LEP persons. *Questions and Answers*, *supra* note 270.

275. The policy notes that the level and type of language assistance required in a particular case depends on an individualized assessment by the program recipient that balances four factors: (i) the number of LEP persons eligible to be served; (ii) the frequency with which LEP individuals come in contact with the program; (iii) the nature and importance of the program or activity; and (iv) the resources available to the recipient and costs. *Id.*

*individual has a limited understanding of health matters or cannot read, access to the programs is complicated by factors not generally directly related to national origin or language and thus is not a Title VI issue. Under these circumstances, a recipient should provide remedial health information to the same extent that it would provide such information to English-speakers. . . .*²⁷⁶

This approach to Title VI claims narrowly focuses on whether a patient has a basic understanding of English, and when providers must provide language assistance to ensure this basic understanding. Title VI does not expressly require providers to look beyond English proficiency in order to determine how “health literate” a patient is in her native language, or how effectively the translator is able to communicate or translate terms in a manner that ensures health literacy. Nor does it establish a minimal substantive standard for ensuring patient understanding that accounts for health literacy. Rather this approach reflects a more limited goal of equalizing LEP patients with respect to others in their ability to communicate in and understand English.²⁷⁷

By divorcing general literacy and health literacy barriers from Title VI’s focus on national origin discrimination, HHS ignores the reality that LEP patients may suffer health literacy gaps due to their LEP and marginalization from mainstream forms of health communication. More than nine million adults in the U.S. report feeling linguistically isolated,²⁷⁸ which means they cannot communicate well with public officials, medical personnel, and other service providers.²⁷⁹ As noted in Parts I and II, lack of access to much of the health information communicated through mainstream English media is also a problem, especially where such information is not present in media specifically targeting non-English speaking populations. LEP individuals are less likely to have the same basic health information as English-speakers – information about when they should see the doctor, the importance of certain lifestyle choices, and compliance with medical care. In fact, the federal government has identified this linguistic and cultural isolation as one cause of health disparities.

Finally, although interpretation or translation services help accommodate

276. *LEP Guidance*, *supra* note 245 at *Appendix A*.

277. If a provider chooses a form and scope of communication for patients that are designed to promote better health literacy, then Title VI helps to ensure LEP patients’ access to this material in their language. As already noted above, however, health literacy is still a relatively young movement, and our evolving understanding and development of health literacy tools are being incorporated in slow, sporadic and inconsistent ways.

278. U.S. CENSUS BUREAU, TABLE 3: LANGUAGE USE, ENGLISH ABILITY, AND LINGUISTIC ISOLATION FOR THE POPULATION 18 YEARS AND OVER BY STATE: 2000, <http://www.census.gov/population/www/cen2000/briefs/phc-t20/tables/tab03.pdf>.

279. *Id.* at 9.

for limited English proficiency, but this may or may not significantly improve patient-provider communication overall. Health literacy research demonstrates the importance of dialog, trust, and creating a safe space within which patients feels free to ask questions, and physicians should be more active in trying to elicit patient understanding. In a medical situation, where complex scientific terms and sensitive information may be involved, as well as the common mental stress or anxiety that often accompanies these situations, inserting one more person between the provider and the patient may have the unintended effect of signaling greater distance between patient and physician. This can further undermine health literacy and communication goals. Physicians can counter this effect by engaging the patient through questions, spending more time with the patient to account for the interpretation challenges, and taking time to assess cultural and other important patient values that impact health.²⁸⁰ Title VI, however, is not understood as requiring this kind of affirmative education and communication by providers.

3. Implicit Role of Health Literacy in Determining “Meaningful Access”

Title VI, nonetheless, may hold some promise as a tool for promoting health literacy because although the antidiscrimination paradigm is primarily comparative, courts and HHS have made clear that language assistance services must provide “meaningful access” to care. In the LEP Guidance and Frequently Asked Questions, HHS devotes much of its guidance to addressing the competency of interpreters and translators and whether certain accommodations facilitate “meaningful access.” Despite expressly disclaiming a direct relationship between health literacy and Title VI obligations, many of the concerns and recommendations in this discussion overlap with or seem informed by health literacy research and goals.

First, the guidance notes that “[t]ranslators should understand the expected reading level of the audience and, where appropriate, have fundamental knowledge about the target language group’s vocabulary and phraseology.”²⁸¹ Second, it says that competency is determined by whether the person has knowledge in both languages of any specialized term or concepts peculiar to the recipient’s program or activity. The requirement that the interpreter has knowledge of specialized terminology in different languages implicitly presumes that this terminology is shared *and understood* by the LEP person being helped. But it is hard to see how an interpreter can be sure of this without some affirmative attempt to elicit the

280. See UNEQUAL TREATMENT, *supra* note 38, at 18.

281. LEP Guidance, *supra* note 245, at 14187.

patients' understanding in this process.

Ironically, this standard seems to presume a greater knowledge of health care facts by the interpreter than would ordinarily be required of patients, and a greater duty for the interpreter to be aware of a patient's literacy and other linguistic factors that can impact patient understanding than is typically placed on providers. A patient's literacy level, different idiomatic expressions among subgroups, and specialized medical facts are all factors that health literacy experts consider critical for evaluating and improving health literacy in all patients. To the extent that professional interpreters must be conscious of patient's literacy and other linguistic characteristics to facilitate understanding, this means that interpreters will often end up addressing health literacy concerns by filling in knowledge gaps and simplifying otherwise complicated information.

In fact, the growing awareness of the difference between literacy and health literacy, and the link between health literacy and health care access and quality seem to animate some of HHS's concerns about ensuring competency. HHS has expressed concern about the use of untrained interpreters like family or friends²⁸² and particularly about the use of children as interpreters.²⁸³ Many adult LEP patients, as well as providers believe that children are capable of acting as interpreters. Indeed providers that have challenged the LEP guidance have used as one argument the ability to rely on children as young as 10 for interpretation.²⁸⁴ As we learn

282. *Id.* at 14185.

283. The guidance specifically provides that while a program recipient should respect the LEP person's desire to use an interpreter of his/her own choosing, a recipient may not require an LEP person to use a family member or friend. *Id.*

284. *See, e.g., Colwell v. DHHS*, 558 F.3d 1112 (9th Cir. 2009). Several plaintiffs brought a pre-enforcement challenge to the 2003 LEP Policy Guidance issued by DHHS. The plaintiffs included ProEnglish, an organization that promotes English-only policies, the Association of American Physicians & Surgeons, an organization that "opposes government interference in the one-on-one patient-physician relationship," and three individual physicians. The suit was ultimately dismissed as unripe. The plaintiffs challenged the policy on several grounds. ProEnglish seemed primarily concerned with how the policy would undermine their "ProEnglish" agenda and viewed physicians' right to speak English only as a constitutionally protected right. The physicians seemed more concerned about cost; however, the physician-plaintiffs incorrectly assumed that they would have to hire an interpreter or translator, ignoring the balancing test set forth by HHS and the less costly alternatives identified in the LEP policy. *Id.* The more troubling claim was the physicians' belief that such accommodations are often unnecessary because they can simply use a relative of the patient to interpret if the relative is fluent in English and the illness is not serious. There are at least three problems with using severity of illness as a standard for determining when more formal language assistance is required: "severity" is not defined and apparently minor conditions can become quite serious if not adequately treated; there is no basis for the assumption that it is easier to interpret information about a "minor" condition than it is for a serious one; and this standard does not account for the privacy or confidentiality concerns that can impede full and honest communication between patients and providers. Moreover, it is not clear what the physician means by "fluent in English" –

more about the low functional health literacy of English speaking adults of various educational backgrounds, however, the notion that a ten-year-old child could be competent to interpret health specific terms between different languages is no longer credible.²⁸⁵ Relying on family or friends could also impede health care access by making it difficult for the LEP patient to disclose sensitive information that the physician needs, or result in a forced disclosure of medical information in violation of the patient's right to privacy. Such a policy effectively creates two different standards of care and privacy rights for English proficient and LEP persons that violate Title VI.

The guidance may also implicitly encourage action that promotes better health literacy with respect to written translation. For example, HHS notes that a direct translation of English documents will not necessarily satisfy Title VI obligations, and that the quality of the translation is important. Specifically, a direct translation that results in a document that is written at a much more difficult level than the English language version or that does not have equivalent meaning is not adequate. Perhaps HHS is simply using the English version as a benchmark for determining one's Title VI duty, requiring program recipients to be mindful of the quality of translation. However, HHS also emphasizes the importance of involvement by LEP patients and the use of questions to determine patients' understanding to facilitate more patient-centered communication and better health literacy. Patient involvement in the design of health materials is another recommendation of health literacy advocates.

Finally, the LEP guidance says an entire document may not need to be translated, allowing someone to review and significantly condense some information. This raises an obvious concern is whether LEP individuals are getting the same amount of information as English-speaking patients. But it may actually benefit LEP patients, given the fact that most informed consent forms contain too much information and are too complex for patients to easily comprehend, and allowing translation into an abridged form may result in LEP individuals receiving information more clearly and effectively than other patients. If done correctly, translated forms would reflect the "less is more" approach advocated by health literacy experts.

Although health literacy is not expressly treated as a factor in defining Title VI obligations, as noted in Parts I – III of this Article, HHS has made

given the varying levels of fluency, literacy, and health literacy among people in English and in their native language; a basic ability to interpret some information does not mean that a person is competent to interpret medical terms and concepts. A fundamental lack of understanding or sensitivity to these problems was revealed by one of the physician plaintiffs who complained that the HHS policy would make him provide language assistance services instead of allowing him to rely on the patient's ten-year old daughter. *See id.* at 1120.

285. *See supra* Part I.

improving health literacy a national priority and has acknowledged its significant relationship to patient-provider communication, patient decision-making, and disparities in access and quality. It is hard to see how Title VI's "*meaningful access*" requirement can be fulfilled without considering the formal and substantive barriers patients face as a result of the LEP status, which necessarily involves consideration of patients' limited health literacy. To the extent providers take seriously the broader goal of ensuring better informed patients, insurers, and beneficiaries, Title VI guidance seems to create some legal space for promoting better health literacy.

B. Health Disparities & the Patient-Provider Interaction

As noted in Part II.A, racial and ethnic minorities tend to experience disproportionately high rates of mortality, chronic and debilitating illnesses, and infectious diseases, and they are less likely to receive certain kinds of diagnostic testing, medical procedures, and medication than non-minorities.²⁸⁶ Many factors may contribute to these disparities: underinsurance or lack of insurance, low SES, lack of quality providers in resource-poor communities, individual risk factors, environmental degradation, cultural factors, and discrimination. More attention is being paid specifically to the role of that race and ethnicity play in health care decision-making, however, since the 1999 Institute of Medicine report revealed disparities in access and outcomes even after controlling for income, insurance coverage, and medical need.

As challenging as it is to use Title VI to eliminate language barriers, it is even more difficult to address the problem of health disparities more generally. Beyond the resource and structural limits to administrative enforcement identified above, the biggest challenge to eradicating health disparities is linking a discrete policy or practice to disparities.²⁸⁷ Numerous studies have tried identifying the causes of health disparities to determine when race and ethnicity, as opposed to access-related factors or clinical need, influence provider decision-making. However, even studies that find racial and ethnic disparities after controlling for these factors cannot definitively conclude that race or ethnicity is a causal link that influences physician judgment.

Considering health disparities through a health literacy lens raises the

286. See generally UNEQUAL TREATMENT, *supra* note 38, at 2-3.

287. See *supra* Part V.A. The obvious exception is language assistance for LEP individuals. In these cases, there is a discrete act or policy (the failure to provide language assistance) that can be linked to a protected characteristic under Title VI (national origin), and for which the potential harm or differential treatment (the inability to get and communicate information essential to providing care; the failure to provide care at all; or subjecting LEP patients to privacy violations as a condition of care by requiring them to rely on family) is clear.

possibility of identifying a more discrete problem in the patient-provider interaction, illuminating how racial and ethnic factors that may infect communication in harmful ways. As discussed in Parts I and II above, health literacy research shows that patient understanding of treatment options is often shaped by the quality and content of provider-patient communication; and this communication, in turn, may be influenced by providers' beliefs, experiences, and culture.²⁸⁸ Physicians may be operating with prior beliefs about the likelihood of their patient's conditions – “priors” that will be different according to age, gender, SES, and possibly race or ethnicity.²⁸⁹ The priors – some of which are taught as a cognitive heuristic to medical students – combined with the physician's own cultural experience and social conditioning can influence medical decisions.²⁹⁰

Conscious and unconscious racial and ethnic stereotypes are heuristics that typically efficiently guide the perception, interpretation, storage and retrieval of information, particularly under conditions of high cognitive demand. [W]hen individuals do not have the time, capacity, opportunity, or motivation to assess situations fully and deliberately, implicit attitudes automatically shape people's responses to objects, individuals, and groups. These conditions of time pressure, high cognitive demand, and stress are common to many health care settings, making these settings “ripe” for the activation of stereotypes.²⁹¹

Much of our evidence about the role of race and ethnicity is anecdotal, but many patients share health care experiences they believe evidence provider bias or mistrust. Some examples contain explicitly racialized assumptions that are clear - an African-American patient recounts one such experience:

I've had both positive and negative experiences. I know the negative one was based on race. It was [with] a previous primary care physician when I discovered I had diabetes. He said, 'I need to write this prescription for these pills, but you'll never take them and you'll come back and tell me you're still eating pig's feet and everything. . . then why do I still need to write this prescription.' And I'm like 'I don't eat pig's feet.'²⁹²

In most cases, however, patients cannot point to a specific racialized

288. UNEQUAL TREATMENT, *supra* note 38, at 162, 166.

289. *Id.* at 164-66.

290. *Id.* at 167, 173.

291. *Id.* at 173 (citation omitted) (“empirical support for the presence of biased or prejudicial attitudes among healthcare providers is limited but growing” and suggests it may be conscious or unconscious); *Id.* at 162-63 (while reasonable to assume most providers find prejudice morally objectionable and inconsistent with their professional values, they may not recognize manifestations of prejudice in their own behavior); *Id.* at 172-73 (more research is needed on the extent to which such factors influence patient's perceptions, provider's communication, and the interplay between these and the impact on quality of care generally).

292. UNEQUAL TREATMENT, *supra* note 38, at 90-91.

comment; rather they experience a general feeling or tone they identify as a lack of respect, prejudice, or unwelcoming feeling they believe is due to their race, ethnicity, citizenship status, or language proficiency.²⁹³ Research confirms that implicit prejudice may be manifested in health care providers' nonverbal behaviors reflecting anxiety (e.g. increased rate of blinking), aversion (e.g. reduced eye contact) or avoidance (e.g. more closed postures) when interacting with minority rather than white patients.²⁹⁴

Studies suggest that bias may implicitly play a role in the *how* providers communicate and in the *amount* time they are willing to spend with patients, finding that racial concordance may be associated with greater participatory decision-making, greater patient-centered care, lower levels of physician verbal dominance, and greater patient satisfaction. This is significant because of evidence that patient satisfaction is associated with greater patient compliance with treatment regimens, participation in treatment decisions, and use of preventive care services.²⁹⁵

One study compared how white and black patients interacted with white and black primary care doctors using post-visit surveys and audiotape analysis. Several findings suggested that race influenced the interaction:

The average length of visits was shortest among white physicians with black patients and longest among black physicians with white patients;

Visits by black patients were characterized by greater physician verbal dominance overall, but physician verbal dominance was highest in visits between white physicians and black patients, and lowest among white patients seen by black physicians.

Visits between white physicians and black patients were the least patient-centered, while the black physicians-white patient interaction was characterized by the highest levels of patient centeredness; and

Patients in race-concordant relationships rated their physicians' decision-making styles as more participatory.

These findings suggest that race or ethnicity play a role in determining patient centeredness, participation, and satisfaction, all of which are important for ensuring better health literacy and care overall. These studies do not prove, however, that bias or stereotyping by physicians causes less patient-centered care and communication. Moreover, without more information about the effect on outcomes or clear standards for patient-provider communication, it is difficult to show that patients whose interactions were less patient-centered or lasted a shorter duration were harmed or received worse care as a result.²⁹⁶ Furthermore, despite

293. *Id.* at 91.

294. *Id.* at 162-63.

295. See discussion of impact *supra* Part II.A.

296. Even the link between disparities in access and bad outcomes has been questioned.

widespread evidence of race disparities, some studies suggest that racial and ethnic minorities are not necessarily unsatisfied with their care overall.²⁹⁷

To the extent that bias is operating, it is more likely to be unconscious, affecting provider behavior in subtle ways that make it impossible to identify for Title VI purposes. Recall that private Title VI actions are not available unless there is intentional discrimination, an incredibly high burden to meet. This is especially true for health care providers who are typically oriented toward helping people, trained in a culture that expressly rejects discrimination, and who honestly view discrimination as anathema to their own moral values. Moreover, the risk that unconscious bias will influence physician decision-making about the kind or amount of care provided is greatest where there is room for discretion due to medical uncertainty; yet this discretion and uncertainty make it almost impossible to identify a clear harm. To the extent that patients can document evidence of bias and file a complaint with the OCR, the problem would likely be treated as an isolated incident, not an investigative priority, especially if no obvious denial of medical treatment or tangible harm occurred.

Another challenge is that the patient's own beliefs and experiences may impact the patient-provider interaction. For example, many racial and ethnic minorities experience a general sense of racial and cultural isolation that may influence their perception of the encounter or cause them to be less engaged in the process. Even where patients' perceptions are due to such isolation, provider communication can either reaffirm or counter such perceptions. This raises similar questions to those in the informed consent context about a provider's duty to affirmatively elicit patient understanding to overcome potential communicative barriers. Should physicians have a legal duty to be cognizant of racial and cultural factors that may impede patient understanding and compliance with treatment? What affirmative steps must they take to overcome these impediments through better communication?

HHS, along with professional and accrediting organizations, expressly recognize this problem and the importance of culturally competent care. They encourage providers to become knowledgeable about cultural and other barriers that may impede care, and to take affirmative steps to communicate with patients in ways that are sensitive and responsive to cultural needs. Such steps help facilitate patient trust and understanding, which can lead to greater patient satisfaction and better health outcomes. In

For example, some people argue that disparities may be due to an overuse of services by whites that does not promote better care. UNEQUAL TREATMENT, *supra* note 38, at 164, 181.

297. *Id.* at 174-75; *but see* PRESCRIPTION TO END CONFUSION, *supra* note 1, at 179 ("Across all populations, the individuals most likely to be dissatisfied with seeking care are members of minority groups. These minority groups indicated they felt their race, ethnicity, and ability to pay for services directly affected their level of care.).

fact, HHS has developed Standards for Culturally and Linguistically Appropriate Services (CLAS Standards) for health care organizations that reflect a patient-centered and preference-sensitive approach to health care that helps promote health literacy.²⁹⁸ Providers who take these CLAS Standards seriously are more likely to communicate in effective and culturally sensitive ways, but these standards are not yet treated as Title VI obligations that will or can be meaningfully enforced.

VI. THE ROLE OF COST: HEALTH LITERACY & MEDICATION ERRORS

This Article began by describing the health literacy movement as challenging the traditional paradigm that views cost reduction in conflict with goals to improve quality and expand access. This Part returns to this theme as it considers the limits of existing law in promoting health literacy identified in Parts IV and V, and the work that cost could do to fill in the gap. Specifically, reforms driven by cost concerns may ultimately lead to more robust legal standards for quality and access related to health literacy. This possibility is reflected in the current approach by government, payors, and providers to preventing medication errors.

A. *Limits of Quality & Access Laws*

If one believes that better health literacy is a critical link to access and quality, then the limited and uncertain role of health literacy in existing law reveals two problems. First, existing informed consent, malpractice liability, and antidiscrimination prohibitions do not effectively promote health literacy. It is true that health literacy concerns and assumptions are probably doing important legal work in these areas: assumptions about health literacy seem to drive decisions about patient understanding in informed consent cases, assessing patient versus provider responsibility for harm in malpractice cases, and determining “meaningful access” under Title VI. Unfortunately, neither courts nor HHS expressly acknowledge the role

298. CLAS Standards include several recommendations to combat cultural and linguistic barriers: “healthcare organizations should ensure that patients/consumers receive from all staff members effective, understandable, and respectful care provided in a manner compatible with their cultural health beliefs and practices and preferred language; that staff at all levels and across all disciplines receive ongoing education and training in culturally and linguistically appropriate service delivery; and that data on the individual patient’s/consumer’s race, ethnicity, and spoken and written language are collected in health records.” UNEQUAL TREATMENT, *supra* note 38, at 182. CLAS Standards also state that health care organizations should have a written strategic plan that outlines clear goals, policies, operational plans to provide culturally and linguistically appropriate services; have accountability mechanisms and perform self-assessments regularly; maintain a current demographic, cultural, and epidemiologic profile of the community served; perform a needs assessment of the cultural and linguistic characteristics of the community; and develop a participatory, collaborative partnership with the community. *Id.*

of health literacy in its analysis or guidance; nor do they articulate a coherent framework for incorporating evolving health literacy research that challenges traditional assumptions about health care decision-making.

More importantly, considering these laws through a health literacy lens exposes significant weaknesses in the current doctrine with respect to core quality and access goals. Health literacy research illustrates the wide gap between the theoretical underpinnings of informed consent and the doctrine in practice. It is difficult to see how courts can use informed consent doctrine to promote better patient understanding, or how HHS can use Title VI to ensure meaningful access for LEP patients, without a robust and realistic assessment of patients' health literacy and the efficacy of provider communication. In malpractice cases, courts ignore these critical factors in assessing provider liability for bad outcomes associated with poor self-care by patients, which undermines fairness and quality goals. Moreover, health literacy research illuminates the subtle relationship between race and patient-provider communication that seems impossible to remedy using Title VI, despite its implications for the kind of health disparities that Title VI regulations are supposed to prevent.

Enter Cost. Although reform driven by cost concerns is typically viewed as (and sometimes can be) a threat to access and quality guarantees, this is not necessarily true in the case of health literacy. In this case, cost may be the necessary catalyst to spark reform that strengthens existing quality and access standards for improved health literacy. The next section examines this possibility through the problem of medication errors.

B. Medication Errors & Evolving Standards of Care

Preventing medication errors has been identified as a priority by government, accreditation organizations, and health care institutions. The impact of medication errors is so significant because of the ubiquity of medication use, the frequency of errors and preventable medication-related injuries, as well as their obvious link to medical complications and bad outcomes, and the increased health care cost that results.²⁹⁹ The federal government has been particularly concerned about the problem because it bears much of this cost through the Medicare and Medicaid programs.

To reduce health care costs generally, the government has experimented with various reimbursement structures that align providers' financial interests with its own, so that providers would have the incentive to try to prevent unnecessary and preventable care, including that resulting from

299. PREVENTING MEDICATION ERRORS, *supra* note 42, at 3-6, 180 (discussing rates of inaccurate medication use by consumers); TO ERR IS HUMAN, *supra* note 6, at 2 (estimating increased hospital costs for preventable adverse drug events at \$2 billion).

medication errors.³⁰⁰ Apparently, existing attempts to slow or reduce health care costs are not working quickly enough. Recently, the government has specifically targeted the problem of medication errors as a key source of preventable health care problems and expenses, and has tried to address it in a thoughtful and comprehensive way.

In 2007, the Centers for Medicare and Medicaid Services sponsored a study by the Institute of Medicine to develop a national agenda for reducing medication errors published in a report titled *Preventing Medication Errors*.³⁰¹ This report is significant for several reasons. First, it thoroughly documents the scope and impact of the problem. Second, it pulls together a massive amount of research to identify the causes of, and factors contributing to, the problem. Third, it provides thoughtful and comprehensive recommendations for reform to be undertaken at multiple points in the health delivery and regulatory system - from the FDA's regulation of pharmaceutical information to the provider-patient interaction. In fact, encouraging better patient-provider communication is one of its significant concerns.

A prominent theme throughout the study is the importance of patient understanding, provider communication, and the critical role that health literacy plays. It focuses heavily on the patient-provider relationship because of the need to improve communication to ensure better patient understanding of medication and enable providers to properly reconcile multiple drug regimens.³⁰² The study acknowledges an apparent link between medication errors and health literacy, finding that people with "low literacy, low English proficiency, or cognitive impairment; the uninsured; those over age 70; and those with polypharmaceutical regimens"³⁰³ are most

300. An early example of this occurred in the reimbursement of hospital services and the transition from per diem rates to reimbursement based on diagnosis. More recently we have seen examples of this through proposals to prohibit reimbursement for extended hospital care due to provider error. See Robert M. Wachter, Nancy E. Foster & R. Adams Dudley, *Medicare's Decision to Withhold Payment for Hospital Errors: The Devil is in the Details*, 34 JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORG. 116, 117-18 (2008). This will likely also play an important role in for Accountable Care Organizations under PPACA as provider reimbursement is linked more directly to quality measures. See, e.g., Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 3022, 124 Stat. 119 (2010) (codified in scattered sections of 21, 25-26, 29 & 42 U.S.C.).

301. PREVENTING MEDICATION ERRORS, *supra* note 42, at 1.

302. The report discusses the potential causes of medication errors both within institutional settings, like hospitals and nursing homes, as well as by individuals taking prescribed and over-the-counter medications at home. *Id.* at 43-49. It also proposes multiple reforms including better provider training and knowledge of drugs, improved communication and data sharing between different health care providers that can minimized transcription errors and ensure proper drug reconciliation, and other structural reforms to improve the drug delivery process. See, e.g., *id.* at 143-265.

303. Medication reconciliation depends on knowledgeable consumers and a process to get and coordinate information where multiple providers are involved. See *id.* at 180.

vulnerable to medical errors. It also found that consumers' low health literacy and providers' lack of cultural competence contribute to knowledge deficits about medications.³⁰⁴

One of the study's critical recommendations is that patients should be empowered as health care partners with strengthened capacities for sound medication self-management. The report touts "patient-centered care" and improved information flow between patients and providers as critical for empowering patients, reflecting core health literacy principles discussed in Part III.³⁰⁵ It also expressly rejects the traditional unidirectional disclosure model or "provider-centric" paradigm, where the physician does most of the talking, as inadequate for patient care and education. Rather, for patient education to work, "practitioners . . . should have the requisite training in communication to *elicit* their patients' understanding of the medication regimen and education needs."³⁰⁶ This demands a more active role for the provider as investigator and listener, as well as a meaningful patient-provider dialog through which patients and providers share decision-making power.

Finally, the report stresses the importance of communicating information in an understandable manner, orally and in written form, and appropriate to the patient's level of literacy, age, language, and culture.³⁰⁷ It establishes expectations that all health care organizations should *immediately* make complete patient-information and decision-support tools available to clinicians and patients.³⁰⁸ Thus it contemplates a more active role for all participants in the health care delivery system to understand and address barriers to patient-centered care, patient-provider communication, and consumer medication self-management.³⁰⁹

One of the most important contributions of the report is its recognition of the weaknesses of the existing delivery and regulatory system to fix this problem, and its call for health and legal reform. For example, physicians and pharmacists typically rely on information leaflets provided by drug manufacturers, but these are not usually written in a format that is

304. *Id.* at 182-83. This is reinforced by data that people with poor health literacy use three times as many medications as those with higher health literacy, have a more difficult time understanding instructions, and are more likely to end up in the ER or hospitalized. *See supra* Part II.B.

305. PREVENTING MEDICATION ERRORS, *supra* note 42, at 154, 156. Indeed, the reports states that improved patient-provider communication is vital and all of the report's recommendations or action agendas are framed as "moving toward a patient-centered, integrated medication-use system." *Id.* at 6-7, 143-45, 151-58.

306. *Id.* at 172 (emphasis added).

307. *Id.* at 172-73. For example, "[p]atients may misunderstand the instruction to "take a tablet X times a day" but understand "take a table every X hours." *Id.* at 173.

308. *Id.*

309. PREVENTING MEDICATION ERRORS, *supra* note 42, at 154.

understandable or useful to consumers. Moreover, the FDA, which oversees the quality of drug manufacturing and disclosure, has not addressed problems in the form or efficacy of communication. Thus, one recommendation is that the FDA to work with the National Library of Medicine, industry, and consumer and patient safety organizations to improve the content and design of medication materials based on health literacy concerns.

This kind of proactive regulatory action can be much more effective than the threat of malpractice liability because it helps to establish standards for communication that can prevent medication errors in the first place, while providing useful guidance to courts for determining liability when problems do occur.³¹⁰ It also addresses the more practical problem of the lack of resources facing many physicians: it is much easier to comply with a duty to provide information in an effective and culturally competent manner when such materials have been developed and are readily accessible. Proactive oversight of pharmaceutical companies by the FDA will force them to share in this responsibility by developing better materials on which physicians and patients can rely.

This report has likely sparked reform from another source: the Joint Commission, an accrediting and standard-setting body for hospitals and other health care organizations. Concerns about medication reconciliation led the Joint Commission to establish standards for this specific problem a while ago;³¹¹ but now it is proposing more comprehensive standards to encourage patient-centered care, improved provider communication, and patient education broadly – goals highlighted in *Preventing Medication Errors*.³¹² Thus, the focus on medication errors may have benefits that

310. The effect of the recommendations and standards proposed in the report on malpractice and informed consent claims is uncertain. *Preventing Medication Errors* describes medication therapy management as a “relatively ill-defined set of services aimed at optimizing the outcomes of drug therapy.” *Id.* at 333. Such standards may be evidence of an evolving standard of care that increases physicians’ obligations with respect to patient education and communication; but courts will be reluctant to draw upon these standards for liability purposes if they cannot be clearly defined. The report’s recommendations also emphasize structural reforms that do not assign individual blame for errors, such as payment incentives that force institutions to absorb the cost of medication errors and encourage them to implement health literacy tools. *See id.* at 4-11.

311. *See* THE JOINT COMM’N, NATIONAL PATIENT SAFETY GOAL ON RECONCILING MEDICATION INFORMATION: NPSG.03.06.01, http://www.jointcommission.org/npsg_reconciling_medication/ (last visited May 3, 2011).

312. *See* THE JOINT COMM’N, NEW & REVISED STANDARDS & EPS FOR PATIENT-CENTERED COMMUNICATION—ACCREDITATION PROGRAM: HOSPITAL 2-6 (2010), *available at* http://www.jointcommission.org/Advancing_Effective_Communication/ (hard copy also on file with the author.). Standard HR.01.02.1 addresses hospital staff qualifications and was amended to address qualifications for language interpreters and translators, and to note the relevance of legal obligations arising under the ADA, Rehabilitation Act of 1973, and Title VI. *Id.* at 2. Standard PC.020.1.21 addresses effective communication between patients and

reach far beyond this one problem. Evolving standards of provider communication and patient education that incorporate health literacy concerns and recommendations, should improve health literacy generally, which should, in turn, improve quality and access in other aspects of patient care.

VII. CONCLUSION

The complexity and nuance that makes health literacy a potentially powerful tool for balancing access, quality, and cost goals, also create challenges for understanding its impact and using law effectively to encourage health literacy reforms. Though many are convinced of the importance of this goal, exerting legal pressure on providers to incorporate health literacy tools can trigger deep fears by providers of encroachment on their professional judgment, greater administrative burdens when they already overwhelmed, a threat to their ever dwindling reimbursement, and unpredictable exposure to malpractice liability due to shifting and increasingly subjective standards of care. Moreover, even though government agencies have deemed health literacy as a priority and generated helpful guidance for providers, regulatory agencies are not using existing enforcement mechanisms effectively. The multi-disciplinary and multi-sectored character of the health literacy problem, in addition to its relative newness as a distinct concept capable of measure, exacerbates the challenges of using law to promote health literacy – providers are concerned that they will be penalized for a problem that is not squarely within their control or their expertise to address, and courts and agencies may think it unfair to do so.

The stakes are too high to ignore this problem. Although more research is needed, health literacy's potential impact on access, quality, and cost is compelling. Moreover, the potential for better health literacy to reduce health care costs makes it a goal that should engender widespread consensus and broad collaborations among key stakeholders. Finally, the time is ripe: the current federal health care reform of the health care financing and delivery system provides an unprecedented and invaluable

their providers, and it specifically identifies “difficulty understanding health information” as one factor providers should consider in their assessment of patient communication needs. *Id.* at 3. Standard RC.02.01.01 covers documentation of information in the medical record, and it was amended to make clear that in documenting a patient's communication needs, the patient's preferred language for discussing health care should be included. *Id.* at 4-5. Standard R1.01.01.03 requires hospitals to respect the patient's right to receive information in a manner that he or she understands. *Id.* at 6. These standards became effective Jan. 1, 2011. *Id.* at 1. See generally THE JOINT COMM'N, ADVANCING EFFECTIVE COMMUNICATION, CULTURAL COMPETENCE, AND PATIENT-AND FAMILY-CENTERED CARE: A ROADMAP FOR HOSPITALS (2010), available at <http://www.jointcommission.org/assets/1/6/ARoadmapforHospitalsfinalversion727.pdf>.

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opportunity for lawmakers and regulators to use the law to promote health literacy, for its own sake, and as a tool for achieving cost, access and quality goals.

