Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law

Thaddeus Mason Pope

Introduction

A giant chasm lies between the theory and the practice of informed consent. On the one hand, in terms of *theory*, scores of appellate court opinions and medical ethics codes describe informed consent in terms of honoring and supporting patient autonomy and self-determination. After all, the doctrine of informed consent is supposed to assure that the patient's preferences and values match the medical interventions the patient gets.

On the other hand, in terms of *practice*, this laudable goal is rarely actually achieved. The doctrine of informed consent has been a part of U.S. law for decades. But it has failed to meaningfully empower patients to make diagnostic and treatment decisions that match their preferences. Too frequently, clinicians fail to appropriately elicit their patients' preferences. Too frequently, the interventions that clinicians administer are unwanted by the patients who receive them.[1]

Virtually all clinicians aspire to excellence in diagnosing disease. Unfortunately, far fewer aspire to the same standards of excellence in diagnosing what patients *want*. A powerful recent report shows that "preference misdiagnosis" is commonplace.[2] Moreover, clinicians are rarely even aware that they have made a preference misdiagnosis. It is the "silent misdiagnosis."[3]

Perturbing illustrations of preference misdiagnosis are easy to find. Recent studies measuring the quality of patient consent report downright alarming results.[4] For example, a 2014 study of patients scheduled for elective cardiac catheterization found that 88% of patients held fundamentally mistaken beliefs about the potential benefits of the procedure, despite having signed an informed consent document.[5]

Similar examples abound. Only 19% of patients with colorectal cancer understood that chemotherapy was not likely to cure their cancer.[6] Only 10% of spine clinic patients could answer basic questions about their spinal surgery.[7] Only 5% of cancer patients understood essential aspects of their diagnosis.[8] Only 3% of patients scheduled for percutaneous coronary intervention understood that procedure.[9]

There is no reason to think these studies are unique outliers.[10] The failure rate exceeds 90%. This is not cause for mere consternation or concern. It is cause for horror and dread. It seems that the quality of physician patient communication is often so poor, that patient consent cannot fairly be described as "informed."[11] If patients do not understand their options, then they

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cannot form or express relevant preferences about those options.[12]

Fortunately, policymakers are building a new "bridge" to narrow the gap between the theory and practice of informed consent. That bridge is being built with patient decision aids (PDAs). These evidence-based educational tools include decision grids, videos, and interactive websites.[13] Already, over 130 randomized controlled studies show that PDAs help patients gain significant knowledge and understanding of their choices.[14]

The evidence on PDA effectiveness is substantial. But their use remains mostly limited to investigational trials. It is time to move PDAs from research to practice, from the laboratory to the clinic. Taking the lead on this challenge, Washington State has begun "certifying" PDAs.[15] Certification incentivizes PDA use by assuring clinicians, patients, and payers that its information is accurate, up-to-date, complete, and understandable.[16] Washington State serves as a model for other states and for the federal government to follow.[17]

To better appreciate both the current state of informed consent law and where it is heading next, it is helpful to examine informed consent law within a broader historical context. Accordingly, I recount the complete evolution of informed consent law in the United States. I do this by dividing the evolution of informed consent law into five epochs. These five epochs do not map neatly onto a precise chronological account. But they do correlate to fundamentally different legal approaches.

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In sections I and II, I describe the antecedents of informed consent. In section I, I start in the 1800s. Before the 20th century, physician paternalism prevailed. Patient consent, much less informed consent, was no part of American medicine. But this began to change by the early 1900s.

In Section II, I show that there was growing judicial recognition of patient autonomy between 1900 and 1920. During the Progressive Era, appellate courts across the United States held that it was a tortuous battery for clinicians to administer a diagnostic or treatment intervention to a patient without any authorization. Compared to the paternalism of the 1800s, this was an important advance for patient rights. But it was a small one. The "consent" required under medical battery doctrine was minimal and bare.

In Section III, I explain that not until the 1970s did clinicians have a duty to help assure that patient consent was voluntary. Not until the 1970s, did clinicians have a legal duty to assure that patients understood the risks, benefits, and alternatives to the procedures they authorized. In short, not until the 1970s, did courts recognize the doctrine of "informed consent." I explain the elements of tort based informed consent law. While informed consent was an undeniable landmark in the development of patient rights and bioethics, it was hardly a panacea. I conclude by describing the doctrine's key limitations.

In Section IV, I show that as major gaps in informed consent law were recognized, legislatures frequently made attempts to "plug" those gaps on an *ad hoc* basis. Particularly over the past decade, an increasing number of states have mandated clinicians to make specific disclosures in specific situations. Unfortunately, these mandated disclosures have been limited stop gap measures. Legislatures simply lack the resources and agility to cover the waterfront of diagnostic and therapeutic interventions.

In contrast, the certification of patient decision aids (PDAs) heralds a more systematic and revolutionary approach to remedying the defects of informed consent law. They are considerably more fluid and dynamic than legislative or regulatory mandates. In Section V, I describe PDAs and the extensive data demonstrating their effectiveness. I also explain that despite the robust data on the positive impact of PDAs, they remain rarely used in clinical practice.

Finally, in Section VI, I argue that translating PDAs from research to treatment requires certification. I

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explain the origins of certification before reviewing how it is already working in Washington State. I end by outlining the case for certification at the federal level.

I. Physician Paternalism

The debates of today focus on the appropriate degree and manner of engaging patients in their own medical decision making. One might say that academics and policymakers are "fine-tuning" legal and practice mechanisms to better achieve the goal of respecting patient autonomy. But until the early 1900s, respecting patient self-determination was not even understood or recognized as a goal at all.[18]

Until the beginning of the 20th century, physician paternalism was the order of the day. For example, in 1847, the American Medical Association *Code of Medical Ethics* stated that "the obedience of a patient to the prescriptions of his physician should be prompt and implicit." The *Code* even advised physicians not to consider the patient's "own crude opinions."[19]

Similarly, in 1871, Oliver Wendell Holmes made the following remarks in an address to the graduating class of the Bellevue Hospital Medical College: "Your patient has no more right to all the truth than he has to all the medicine in your saddle-bags…He should get only just so much as is good for him."[20]

II. Medical Battery

By the beginning of the 20th century, this overt medical paternalism gave way to (at least limited) legal recognition of patient autonomy and self-determination. This shift was most famously illustrated and captured by Justice Cardozo in 1914: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."[21]

Notably, by the time Justice Cardozo wrote his opinion for the New York Court of Appeals, he was able to cite to other appellate authority.[22] Courts across the United States had already begun to recognize claims for "medical battery."[23] These cases confirmed that a physician may not administer treatment without the patient's consent, notwithstanding either "good" motives or "good" results.[24]

A. Elements of Tortious Battery

Battery is a simple tort with just two elements.[25] Medical battery is even simpler. The clinician is liable for battery, if: (1) he or she "acts intending to cause a harmful or offensive contact with the person" and (2) "a harmful [or offensive] contact with person of the other directly or indirectly results."[26] Intent is broadly defined "to denote that the actor desires to cause consequences of his act as well as the situation in which the defendant merely believes the consequences are substantially certain to result from it."[27]

Today, medical battery is a well-established intentional tort.[28] And the elements have barely changed over the past 100 years. In short, a battery is established when the clinician acts without any consent whatsoever. And a battery is also established when the clinician acts outside the scope of the patient's consent, whether spatially, temporally, or otherwise.[29]

Intent is easy to establish. The clinician knows that intervention is harmful or offensive. Many of these procedures are "highly intrusive, and some are violent in nature."[30] Even if the procedure is not harmful, the clinician at least knows that, without consent, the treatment would be offensive, infringing on a patient's reasonable sense of personal dignity.[31]

It does not matter how skillfully or successfully the intervention is provided.[32] It does not matter that the administration of treatment is (objectively) beneficial on balance.[33] Nor does it matter if the clinician's intent was to benefit the patient.[34] Instead, whether that treatment constitutes a "benefit" is a value judgment for the patient to make.[35] In short, neither "good" motives nor "good" results are relevant to a finding of battery.[36]

B. Limitations of Medical Battery

A cause of action for battery is particularly attractive to a plaintiff's attorney. First, she does not need to establish a standard of care.[37] Consequently, she does not need to retain any expert witnesses.[38] Second, while the plaintiff likely will be able to prove actual (economic or non-economic) damages, she does not need to establish any.[39] She can recover nominal and punitive damages without showing any compensatory damages.[40] Third, she need not navigate tort reform procedural hurdles such as damages caps and prefiling review.[41] Fourth, the prospect of damages sends a very powerful signal, because a judgment or settlement may not be covered by insurance.[42]

Nevertheless, medical battery recognizes a rather narrow and limited patient right. It focuses solely on whether the patient minimally authorized medical treatment, not on whether the patient actually understood the risks, benefits, and alternatives to that treatment. For example, a patient who agreed to undergo spine surgery would have no claim for battery even if the physician failed to disclose a significant (say 20%) risk of paralysis. In short, battery focuses on only the bare existence of patient consent, not on its quality or substance.

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III. Informed Consent Law

It was not until the 1970s that U.S. courts began to widely recognize and articulate an entirely separate and independent legal theory, "informed consent."[43] Under this doctrine the patient concedes that she minimally authorized the medical treatment at issue. Thus, the administration of that treatment is not a battery. Instead, the patient claims that her consent was not sufficiently voluntary. The patient asserts that she would not have consented, if the physician had disclosed certain information regarding the treatment's risks, benefits, and alternatives.[44]

In essence, the patient claims that her consent was procured by the physician's negligent failure to disclose information about risks, benefits, or alternatives to treatment. The patient claims that the physician's failure to disclose is a form of medical malpractice. In this section, I first describe tort based informed consent law. I then outline four major limitations on the ability of informed consent law to protect patient rights.

A. Tort Based Informed Consent Law

Informed consent is typically based in the state common law tort doctrine of negligence.[45] Failure to obtain a patient's informed consent is a form of medical malpractice.[46] The patient must establish the standard elements of a tort cause of action: duty, breach, injury, and causation.

1. DUTY OF DISCLOSURE

The first element in an informed consent action is the duty of disclosure. There is general agreement that physicians should give the patient the following information: (a) the nature and purpose of the proposed intervention, (b) the intervention's probable risks and benefits, and (c) alternative interventions and their risks and benefits.

But the exact scope and extent of this disclosure varies from jurisdiction to jurisdiction. The states are almost evenly split between two disclosure standards: (1) the malpractice (aka "physician-based," "professional" or "custom-based") standard and (2) the material risk (aka "patient-based" or "lay") standard.[47]

The malpractice standard requires physicians to provide the information that a (hypothetical) reasonably prudent physician would disclose in the same circumstances. This disclosure duty is measured by the standards of the medical profession. In most of these jurisdictions the physician's disclosure duty is measured by a nationwide standard of care. The physician must disclose the information that a reasonable physician in the United States would disclose under the circumstances.

But in a significant number of states the physician's duty is measured in one of three geographically narrower ways: (a) strict locality, (b) statewide, or (c) same or similar community.[48] In other words, the physician's duty to disclose is measured by what information would be disclosed under the circumstances by a reasonable physician: (a) in that town, (b) in that state, or (c) in town like the treating physician's town.

While the malpractice standard is physician-defined, the material risk standard is patient-defined. It requires physicians to provide the information that a (hypothetical) reasonable patient would consider significant in making a treatment decision. This disclosure duty is not controlled by the medical profession. Instead, it is measured by the patient's presumed need for information.[49]

The contrast between the two dominant disclosure standards is nicely illustrated by recent events in Wisconsin. For decades, Wisconsin had followed the "material risk" standard for informing a patient.[50] But in December 2013, the Wisconsin legislature passed a bill that amended Wisconsin's informed consent statute, overruling a long line of Wisconsin State Court cases.[51] The new statute adopts the weaker "reasonable physician" standard.

Therefore, instead of a Wisconsin physician's duty being measured by what a reasonable person in the patient's position would want to know, it is now measured by what a "reasonable physician in the same or a similar medical specialty would know and disclose under the circumstances."[52] In its plain language analysis of a rule implementing the new statute, the Medical Examining Board observes that this duty "is not as broad as the former standard and in fact lessens the burden on physicians."[53]

2. BREACH, INJURY, AND CAUSATION

Establishing the scope and content of the physician's disclosure duty is only the first element in an informed consent action. In both malpractice and material risk jurisdictions, the patient must satisfy three additional elements: (1) breach, (2) injury, and (3) causation.

First, the patient must establish breach. She must show that the physician failed to disclose what she had a duty to disclose. In the easiest cases, the physician admits that she failed to make the requisite disclosure. In the toughest cases, the patient must overcome the presumption established by the physician's contemporaneous medical record notes that she made the disclosure.[54]

Second, the patient must establish injury. She must show that she was harmed as a result of the treatment. Even if the physician failed to disclose a risk that she

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had a duty to disclose, the patient has no cause of action unless that risk actually materialized.

Third, the patient must establish causation. This element has three subparts. The patient must show: (a) that had the physician made the appropriate disclosure, the reasonable person would not have consented to that treatment; (b) that she herself would not have consented to the treatment; and (c) that not undergoing the treatment would probably have avoided the injury.[55]

B. Limitations of Informed Consent Law

The doctrine of informed consent is an important milestone in the history of bioethics and patient rights.[56] But over the past two decades it has become increasingly clear that the traditional informed consent process is seriously deficient.[57] It often fails to ensure that patients have the information and understanding that they need to make truly informed decisions regarding their medical treatment.[58] In part, this failure was inevitable.

The doctrine of informed consent suffers from at least four limitations that significantly impede patient empowerment. (1) The scope of the duty to disclose is narrow. (2) Objective causation ignores individual preferences and values. (3) The goal of informed consent is only disclosure, not understanding. (4) Informed consent protects only physical injuries.

1. SCOPE OF THE DUTY TO DISCLOSE IS NARROW

The first major limitation of traditional informed consent doctrine is that the required informational disclosures are themselves circumscribed and modest. In around half of U.S. states the physician's duty to disclose is measured by professional custom, by what the reasonable physician does or would disclose under similar circumstances. But the professional custom governing the informational exchange may be parsimonious and severely restricted.[59] Moreover, even to the extent that the professional custom is to disclose, the informational content of that disclosure may not be evidence based.[60] In other words, the prevailing custom and practice may be to disclose inaccurate information.

In the other half of U.S. states, the physician's duty is measured by what information a hypothetical "objective" patient would deem important under the circumstances. While more patient-focused than the malpractice standard, the objective nature of the material risk standard is still hindering.[61] It fails to recognize that patients have different preferences and that they value risks and benefits very differently.[62]

In other words, this material risk standard, while patient-based, is almost always defined by reference to what an objective hypothetical patient would consider material, not to what information any specific patient would consider material. Indeed, two or three states have found the objectivity in this standard insufficiently protective of patient autonomy. So, they have adopted a pure subjective standard.[63] Their rather compelling rationale is that "[t]o the extent the plaintiff, given an adequate disclosure would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient's right to self-determination is irrevocably lost."[64]

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2. OBJECTIVE CAUSATION IGNORES INDIVIDUAL PREFERENCES AND VALUES

The second major limitation of traditional informed consent doctrine is the "objective" causation requirement. A patient suing for negligence based on a claim of inadequate informed consent must establish more than the physician's breach (failure to disclose). She must also establish causation: that the injury probably would have been avoided through disclosure, because the informed hypothetical reasonable person would have chosen differently.

In other words, it is not sufficient for the patient to prove that they would have not chosen the procedure had the defendant accurately conveyed its risks. The plaintiff must also prove that the "reasonable patient"

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would have also chosen otherwise.[65] This is a demanding and difficult standard to satisfy.

An objective inquiry wrongly presumes that there is always one best option. Indeed, sometimes, there are situations in which one single treatment is "correct" or clearly indicated above all others by the available medical evidence.[66] But there is often more than one good option, more than one reasonable path forward.[67] With respect to this "preference sensitive treatment," the balancing of benefits and harms is heavily value-laden.[68] Current informed consent law fails to recognize these common situations.

Take, for example, the birth of a child with a disorder of sex development. Is it a boy or a girl? Should there be surgery? What kind? When?[69] In such instances, there is more than one good option, more than one reasonable path forward. Similarly, take patients with a herniated disk that causes back and leg pain. Patients must weigh the quicker fix that surgery may bring against the risks of surgery.[70] The best course of treatment for a particular patient depends on that patient's preferences, values, and cultural background.

Consequently, commentators have called for courts and legislatures to abandon the "objective" causation standard in the context of informed consent suits. They argue that it should be replaced with a standard that recognizes the importance of the individual patients' values and preferences.[71] Under this standard, instead of determining whether the hypothetical reasonable patient would still have consented with disclosure, the jury determines only whether this particular patient would still have consented.[72]

3. goal is only disclosure, not understanding

The third major limitation of traditional informed consent doctrine is that the focus is only on disclosure, not on patient understanding. The physician's duty is only to "deliver" certain information to the patient, not to ensure that the patient actually receives and appreciates it.[73] The underlying assumption is that given the information, the patient "will be able to identify the information that is relevant to her choice and will be in a position to make a decision aligned with her values and goals (i.e. she will 'know what to do')."[74]

In other words, informed consent works like the "mailbox rule" in contract formation.[75] The general rule is that a contract is made when acceptance to an offer is dispatched, even if the letter of acceptance is lost and never reaches the offeror. Contract acceptance is deemed to be fully communicated when the offeree has placed his acceptance in the course of transmission to the offeror.[76] Similarly, in informed consent law the physician fulfills her duty by making a disclosure, even if it is not understood or meaningfully "received" by the patient.

Indeed, the "letters" of informed consent are often lost in the "mail." While the patient may receive the envelope, she does not get the message inside. Even when physicians (technically) make required disclosures, they often convey risk data through extemporaneous conversation, which is not an effective means of communication. Over 40 years ago, the California Supreme Court warned about fulfilling informed consent through "lengthy polysyllabic discourse."[77] But that is still the primary means of physician-patient communication.

In short, there is a massive incongruence between the medical interventions administered and patients' desires for those interventions.[78] Despite its name, "informed consent" fails to assure that the patient's consent is actually informed. It fails to assure that relevant patient questions and concerns are adequately answered.

4. only physical injuries are protected

The fourth major limitation of traditional informed consent doctrine is that it protects patients only from physical injuries, not from financial or dignitary detriments.[79] Just as patients can be physically harmed but not legally wronged by iatrogenic injuries when there is no negligence, they can be wronged but not physically harmed when there is inadequate informed consent.

For example, suppose the patient consented to knee replacement surgery without understanding her options.[80] If the surgery is physiologically successful, then the patient has no remedy. It does not matter that the patient has incurred both expense and discomfort in exchange for a "benefit" that she would not consider worth the "costs" had she been fully informed.[81]

IV. Mandated Disclosures

The limitations of traditional informed consent law have been well documented. Consequently, lawmakers have increasingly recognized that traditional informed consent law has failed to assure that patients are engaged in the decision making process. It has failed to assure that patients understand their medical treatment choices. To address this gap, state legislatures began enacting statutory disclosure mandates for a number of diagnostic and treatment situations.

For example, in the late 1970s and early 1980s, physicians were not disclosing less invasive treatment options to their breast cancer patients.[82] In response, 14 states enacted statutes that require physicians to present the advantages, disadvantages, and risks of all medically viable alternative therapies. Some of these

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statutes even require use of "standardized written information."[83]

More recently, many states have increasingly enacted informed consent statutes itemizing exact information that must be disclosed under specific circumstances.[84] One of the most common mandates concerns end-of-life treatment options. To provide a sense of this legal approach to informing patients, I describe end-of-life disclosure mandates in some detail. I then more briefly describe some other new disclosure mandates.

A. Statutorily Mandated Disclosures Related to End-of-Life Counseling

A number of studies have determined that individuals nearing the end of their lives often do not receive the care that they want or need. They are frequently unaware of the full range of options, including hospice and palliative care services.[85] Nondisclosure of diagnostic and prognostic information remains common.[86]

The evidence of gaps seems overwhelming. For example, only 31% of patients with advanced cancer had end-of-life discussions.[87] Worse, even when these discussions do occur, they happen very late.[88] Earlier advance care planning discussions are correlated to earlier hospice referral, better patient quality of life, and better family bereavement.[89] But many patients never get these benefits, because end-of-life discussions happen late or not at all.[90]

In response, a growing number of states have enacted statutes that require physicians to provide terminally ill patients with "comprehensive information and counseling regarding end-of-life options." These mandates are of two basic types: (1) those focused on clinicians, and (2) those focused on healthcare facilities.

1. INFORMATION AND COUNSELING FROM CLINICIANS

In 2009, both California[91] and Vermont[92] enacted "right to know" legislation in the context of end-of-life care. Since then, both New York (in 2010)[93] and Massachusetts[94] (in 2012) have enacted similar legislation. Arizona considered similar legislation in 2013.[95]

The New York and Massachusetts statutes both mandate that:

> If a patient is diagnosed with a terminal illness or condition, the patient's attending health care practitioner shall offer to provide the patient with information and counseling regarding palliative care and end-of-life options appropriate for the patient, including but not limited to: the range of options appropriate for the patient, the prognosis, risks, and benefits of the various options; and the patient's legal rights to comprehensive pain and symptom management at the end-of-life.[96]

This information and counseling may be provided orally or in writing.[97] If a health care provider is unwilling or unqualified[98] to provide the statutorily-mandated information and counseling regarding palliative care and end-of-life options, Massachusetts and New York require the provider to "arrange for another physician or nurse practitioner to do so, or [] refer or transfer the patient to another physician or nurse practitioner willing to do so."[99]

Importantly, while the California disclosures are triggered only "upon the patient's request," New York law states that providers "shall offer to provide" the mandated information and counseling. And, unlike California, the New York statute includes civil and criminal penalties.

2. DISCLOSURES REQUIRED FROM HEALTH CARE FACILITIES

States have adopted statutes and regulations mandating disclosures not only by clinicians but also by health care *facilities* regarding their end-of-life or palliative care policies.[100] For example, in 2011, New York expanded on its 2010 Palliative Care Information Act by enacting the Palliative Care Access Act.[101] This law requires hospitals, nursing facilities, home health agencies, and special needs and enhanced assisted living facilities to provide patients with advanced life-limiting conditions and illnesses with access to information and counseling regarding options for palliative care, including pain management consultation.

More recent notable developments are from Maryland and Massachusetts. In 2013, Maryland enacted legislation establishing at least five "palliative care pilot programs" in hospitals around the state.[102] This legislation impacts end-of-life counseling by requiring pilot program hospitals to establish policies and procedures that "provide access to information and counseling regarding palliative care services appropriate to a patient with a serious illness or condition" and that "require providers to engage in a discussion of the benefits and risks of treatment options in a manner that can be understood easily by the patient or authorized decision maker."[103]

Massachusetts's 2012 right to know statute, discussed above, applies not only to clinicians. It also includes a provision requiring the Department of Public Health to develop regulations guiding health care facilities' distribution of information to patients or residents regarding palliative care services.[104] In 2013, the MDPH began the process of promulgating regu-

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lations to implement the statute. It proposed amendments to the rules for hospital licensure, licensure of clinics, and licensing of long-term care facilities.

Basically, the MDPH proposed requiring these facilities to distribute to appropriate patients in its care, culturally and linguistically suitable information regarding the availability of hospice and palliative care. The MDPH later clarified that this informational obligation must be fulfilled by providing the patient with either an MDPH-issued informational pamphlet or a facility-created informational pamphlet.[105] MDH implemented the regulations in 2014.[106]

3. Enforcement of information and counseling mandate

There is limited data measuring the impact of these end-of-life disclosure mandates. But at least one lawsuit has resulted in a settlement. In September 2009, Michelle Hargett Beebee, a 43-year-old mother of three young children, was diagnosed with advanced pancreatic cancer. Her pain and symptoms escalated quickly, and soon after Michelle was referred to hospice care at Vitas, the nation's largest for-profit hospice chain. Michelle entered Vitas hospice in November 2009, with the goal of bringing her pain and symptoms under control and to have a peaceful death. Instead, Michelle died in misery.

In 2010, Michelle's family sued Vitas, alleging, among other things, that the hospice was negligent for failing to inform Michelle about medications that would have eased her acute pain.[107] The Complaint specifically referenced the new California right to know law. In early 2014, Vitas and the Hargetts were able to resolve to their mutual satisfaction the issues raised in the lawsuit.[108]

4. Disclosure mandates on patient rights at end of life

Most end-of-life disclosure mandates focus on the risks, benefits, and alternatives to medical treatment. But a growing number focus on apprising patients of their rights. Three notable examples are from Michigan, Oklahoma, and Washington.

In 2013, Michigan enacted legislation requiring a "health facility or agency" to, if requested by a patient or resident or prospective patient or resident, "disclose in writing any policies related to a patient or resident or the services a patient or resident might receive involving life-sustaining or non-beneficial treatment within that health facility or agency."[109] This law does not require Michigan health facilities to adopt certain policies regarding life-sustaining or non-beneficial treatment. It focuses solely on the issue of disclosure.[110]

In 2014, Oklahoma enacted the Medical Treatment Laws Information Act.[111] This law requires the State Board of Medical Licensing and Supervision to prepare a disclosure statement to inform patients and families of their rights under the Nondiscrimination in Treatment Act and other Oklahoma treatment statutes. Among other things, the law assures that patients know if they or their surrogate directs life-preserving treatment, their health care provider may not deny it except under narrow conditions.

This Oklahoma disclosure statement must include contact information for officials to whom violations can be reported. Furthermore, the Medical Treatment Laws Information Act requires that healthcare entities covered by the Patient Self Determination Act must distribute this disclosure statement with its PSDA notices.[112]

Finally, in late 2013, responding to a directive from Governor Inslee to improve transparency for consumer information, the Washington Department of Health enacted rules that bring any change in control of a hospital under the Certificate of Need process.

Due to mergers spurred by the Affordable Care Act, the percentage of Washington State hospital beds in religiously affiliated (mostly Catholic) hospitals rose from 25% in 2010 to nearly 50% in 2014. Catholic health systems are required to follow the Ethical and Religious Directives promulgated by the United States Conference of Bishops.[113] These directives forbid many reproductive and end-of-life health services, including contraception, vasectomies, fertility treatments, tubal ligations, abortion, Death with Dignity, and advance directives that are contrary to Catholic teachings. Consequently, facilities that affiliate with Catholic health systems are often required to restrict health services and information on the basis of religious doctrine.[114]

The new rules require that, among other things, all Washington hospitals must submit to the WDOH its policies related to access to care in the areas of admission, non-discrimination, end-of-life care, and reproductive healthcare.[115] The WDOH must post a copy of these disclosed policies on its website.[116] This is supposed to enable consumers to know which hospitals are asserting conscience-based objections.[117]

B. Other Disclosure Mandates

End-of-life counseling is not the only area in which disclosure mandates have been proliferating. Particularly with controversial procedures, policymakers want to ensure that the patient's choice is voluntary and informed. Five notable examples are: (1) medical aid in dying, (2) abortion (3) telehealth, (4) vaccination opt-outs, and (5) other mandates.

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1. MEDICAL AID IN DYING

California, Colorado, the District of Columbia, Oregon, Vermont, and Washington affirmatively authorize medical aid in dying. All six statutes are nearly identical.[118] All six require the physician to make a number of specific disclosures, including: (1) the patient's medical diagnosis; (2) the patient's prognosis, with an "acknowledgement" that any statements of life expectancy are only an estimate and that "the patient could live longer than predicted"; (3) the range of appropriate treatment options; (4) the range of feasible end-of-life options, including palliative, hospice, and comfort care; (5) the range of possible results associated with taking the prescribed medication; and (6) the probable result of taking the prescribed medication.[119]

2. ABORTION

Perhaps nowhere has there been more legal activity regarding informed consent than with respect to abortion. And nowhere else is such regulation so controversial. Other legislative interference in the physician-patient relationship (like that related to end-of-life counseling) seems warranted by persistent defects in informed consent. In contrast, mandates focused on pregnant women appear to be driven by partisan aims.[120] Many disclosures are factually inaccurate.[121] Consequently, many statutorily mandated disclosures related to abortion have been challenged as unconstitutional.[122]

3. TELEHEALTH

Telehealth services are emerging as an important alternative to in-person consultations with physicians and other health care professionals, particularly in rural areas.[123] As telehealth services grow in scope and popularity, questions have emerged regarding informed consent required for telehealth services.

In addition to the usual risks associated with a physician-patient encounter, telehealth services involve risks associated with remote communication, including the potential for an equipment or technology failure, which could result in misdiagnosis.[124] Telehealth services also raise unique data security and confidentiality concerns.[125] And there are obvious limits to the comprehensiveness of examination. Accordingly, some states have imposed additional or heightened requirements for informed consent.[126]

4. VACCINATION OPT-OUTS

Across the county many parents and guardians assert personal beliefs opposed to vaccination for their children.[127] Several states have recently enacted statutes to ensure that these individuals understand the benefits of vaccination and the risks of forgoing vaccination. For example, Colorado enacted a statute requiring the completion of an educational module as a requirement for a non-religious exemption from the vaccination requirement.[128] Similar requirements were recently enacted in California,[129] Oregon,[130] Vermont,[131] and Washington.[132]

5. OTHER DISCLOSURE MANDATES

While most recent statutorily mandated disclosure laws relate to end-of-life options, aid in dying, abortion, telemedicine, and vaccination; these are not the only disclosure mandates.[133] Over the past few years, state legislatures have also proposed or enacted informed consent laws addressing a variety of other subjects, including: (1) prescription drugs, (2) investigational products, (3) breast density, (4) scope of practice limitations, (5) egg donation, and (6) hospital observation status.[134]

C. Limitations of Disclosure Mandates

Disclosure mandates are a popular solution to the problems of informed consent. But they suffer from four major limitations: (1) insufficient resources, (2) political corruption, (3) political opposition, and (4) a near-exclusive focus on content at the expense of clarity and explanation.

First, legislation or regulation is hardly workable for the broad range of medical interventions that patients receive every day. Rulemaking processes are too slow and cumbersome to address more than a handful of interventions. Moreover, these same processes are too slow and cumbersome to assure that mandated disclosures remain accurate and up-to-date.[135]

Second, disclosure mandates are sometimes not evidence-based. Sometimes, they were initially evidence-based but became outdated.[136] Sometimes legislatures act too quickly to address salient but poorly understood risks.[137] Other times, the information in the disclosure mandate was never evidence based. These mandates were enacted to "steer" patients to a particular choice rather than to empower the patient to make choices that align with her own preferences and values.[138]

Third, even when they are evidence based, disclosure mandates are vociferously opposed. To the consternation of some medical professionals, the trend toward legally mandated disclosures appears to be growing.[139] A number of medical associations have advocated against legislative interference with patient care and the patient-physician relationship.[140]

Fourth, disclosure mandates only address one part of the problem with informed consent. They focus on only the *content* of physician-patient communication. At best, disclosure mandates help to clarify and

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to assure "what" is disclosed. But they fail to address "how" it is disclosed. They neglect the manner in which the information is conveyed.[141] Compelling evidence indicates that they simply do not work.[142]

V. Patient Decision Aids

In contrast to the deficiencies and limitations of disclosure mandates, patient decision aids (PDAs) herald a more systematic and revolutionary approach to remedying the defects of informed consent law. In contrast to the one-way disclosure focus of informed consent, in "shared decision making" the patient and physician engage in two-way interactive discussion and reflection, in personalized bilateral conversations.[143] Patient decision aids (PDAs) are an important tool that can inform and guide these discussions.

After first describing the nature of PDAs, I summarize some of the extensive evidence demonstrating their effectiveness. Numerous studies show that "shared decision making" meaningfully empowers patients. But despite robust data on the positive impact of PDAs, they remain rarely used in clinical practice. I conclude this section by reviewing federal and state efforts to promote wider use of PDAs. In the next section, I examine certification as a key way to promote PDAs.

A. Definition of Patient Decision Aid

Patient decision aids are evidence-based educational "tools" that help patients do three things.[144] First, PDAs help patients understand the various treatment options available to them, including the risks and benefits of each choice. Second, they help patients communicate their beliefs and preferences related to their treatment options. Third, PDAs help patients decide with their clinicians what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.[145]

PDAs take various forms. They include educational literature with graphics, photographs, and diagrams. They also take the form of decision grids, videos, and website-based interactive programs such as sequential questions with feedback.[146] PDAs might even include "structured personal coaching."[147]

No matter what form they take, the best PDAs provide an appropriate presentation of the condition and treatment options, benefits, and harms. They have three key advantages over the traditional informed consent process. First, the information in the PDA is accurate, complete, and up-to-date. Second, the PDA presents the information in a balanced manner. Third, the PDA conveys the information in a way that helps patients understand and use it. PDAs are truly patient-centered.

In short, by using PDAs, patients gain significant knowledge and understanding of their choices. For example, a PDA could help a pregnant woman who previously had a cesarean section to determine if she is a good candidate for a vaginal birth after cesarean.

Importantly, despite their typically self-directed and self-paced nature, PDAs do not supplant physician-patient conversation about treatment options. Instead, they supplement it, by better preparing patients to engage in that conversation. In other words, PDAs should not be equated as constituting shared decision making. Instead, PDAs are the facilitator to the essential bilateral communication between provider and patient which is the crux of shared decision making.[148]

One physician explains:

> PDAs will allow me to have a very different discussion with my patients. PDAs do a better job than I can at helping patients understand their options. I then have more time to explore the issues that matter most to them and understand how their condition impacts their lives.[149]

In short, PDAs allow physicians to focus their patient communication efforts more effectively.[150]

Decision aids are already available for a large number of conditions, including breast cancer, prostate cancer, osteoarthritis, and childbirth.[151] And many more decision aids are being developed by both non-profit and for profit companies as well by as government entities.[152]

Non-profit developers include: Advance Care Planning Decisions,[153] Decision Box,[154] Healthwise,[155] the Informed Medical Decisions Foundation,[156] the Mayo Clinic,[157] the Option Grid Collaborative,[158] and the University of Sydney.[159] For-profit developers include: Dialog Medical,[160] Emmi Solutions,[161] Health Dialog,[162] Krames StayWell,[163] the Patient Education Institute,[164] the NNT,[165] and Welvie.[166] Government developers include the Agency for Healthcare Research and Quality[167] and NHS Right Care.[168]

B. PDAs Are Very Effective

In contrast to the deficiencies and limitations of traditional informed consent, robust evidence shows that shared decision making meaningfully empowers patients.[3] In contrast to traditional informed consent, shared decision making deliberately takes into account both the best scientific evidence available, as well as the patient's values and preferences.[169]

PDAs meaningfully inform and guide both of these elements. First, PDAs provide relevant information on healthcare options, helping patients gain significant knowledge and understanding of their choices.

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Second, PDAs give patients control over the pace and timing of their education. And they permit patients to share that information with family.

Finally, PDAs prompt reflection, helping patients to form and clarify their values and preferences.[170] PDAs thereby enhance deliberation by helping patients discover and associate their values and preferences with their healthcare options, and then communicate those associations to their provider. Together, the provider and patient make a treatment choice that aligns with the patient's values. PDAs help make the patient engaged, equipped, empowered, and enabled.[171]

Randomized controlled trials are considered the most reliable form of scientific evidence in the hierarchy of evidence that influences healthcare policy and practice. Over 130 RCTs demonstrate that PDAs significantly enhance patients' knowledge of treatment options, risks, and benefits.[172] Summarizing the benefits identified in these RCTs, a recent Cochrane review concluded that using PDAs can lead to patients: (1) gaining knowledge; (2) having a more accurate understanding of risks, harms and benefits; (3) feeling less conflicted about decisions; and (4) rating themselves as less passive and less often undecided.[173] In short, once patients understand their choices, they are better able to align their care with their preferences and values.

C. PDAs Reduce Cost and Liability

Furthermore, PDAs do more than improve patient knowledge and satisfaction. They also reduce the cost of care.[174] Patients using PDAs are more likely to choose conservative treatment options. For example, they are less likely to choose surgical interventions.[175] They are less likely to be admitted to the hospital.[176] And they are less likely to choose CPR.[177] One study estimates that implementing decision aids for just eleven procedures would yield $9 billion in savings over ten years.[178] That is real value: improved patient satisfaction at lower cost.

Using PDAs can reduce not only healthcare costs but also healthcare liability. Most immediately, PDAs can reduce liability for informed consent claims, because they help assure that the patient gets appropriate information. But the liability benefits of PDAs do not stop there. PDAs can also reduce claims based on other theories of medical malpractice.[179]

Commentators and insurers have long recognized communication failures as an important source of malpractice litigation.[180] If patients are well-informed of potential risks, then they are less surprised (or angry) when those risks later materialize. Well informed patients have less decisional regret and take more ownership of their own decisions.[181]

Significant evidence indicates that patients do not typically bring malpractice suits simply because they have bad outcomes. They bring lawsuits when those bad outcomes are accompanied by bad feelings. Those bad feelings can be avoided with good patient communication.[182] In short, PDAs improve the quality of physician-patient communication. Better communication means lower liability exposure.[183]

In sum, using PDAs produces four important benefits: (1) they protect and promote patient autonomy; (2) they reduce medical errors and bolster patient safety, (3) they reduce healthcare costs, and (4) they reduce malpractice claims. Influential healthcare organizations from the Institute of Medicine to the Joint Commission have recognized these benefits.[184] And they have encouraged the widespread adoption of PDAs.

For example, in its influential 2001 *Crossing the Quality Chasm* report, the Institute of Medicine recommended greater use of decision aids to ensure that patients' treatment decisions are consistent with their preferences and values.[185] In 2014, the Institute of Medicine again reviewed the literature on shared decision making in clinical practice and reaffirmed the value of PDAs. It found that PDAs "trigger the robust communication that is necessary for shared decision making to occur."[186]

D. Few Clinicians Use PDAs

Despite robust evidence of effectiveness and despite influential recommendations to expand PDA use, widespread adoption has not happened. The use of PDAs has "not become the norm."[187] They remain "seldom adopted"[188] and "rare in everyday practice."[189] The research is here. But implementation remains sparse and incomplete.[190] "Practice lags behind" the evidence.[191]

Indeed, in light of its earlier endorsements, the Institute of Medicine recently lamented that "the promise of shared decision making remains elusive."[192] Others agonize that the potential of PDAs remains "unrealized."[193] In short, a key challenge is to move PDAs from research to use, from the laboratory to the clinic.[194]

But making this move is not easy. Even patently superior medical interventions are often slow to get adopted.[195] For PDAs, the challenges may be even greater. Perhaps the most significant hurdle to implementation is the need to incentivize and train clinicians to use PDAs.[196] Two pervasive physician and system-level barriers have been summarized as "professional indifference" and "organizational inertia."[197] Other barriers include lack of physician comfort, time constraints, competing priorities, lack of reimbursement, perceived burden, and cost.[198]

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Importantly, one barrier is intrinsic to the nature of PDAs: they reduce and constrain physician discretion and judgment. One of the key motivations for using PDAs is to convey more complete, up-to-date, and balanced information than patients are now receiving. But physicians may react negatively to this "intrusion" in much the same way that they have reacted to mandated disclosures.[199]

E. Legal Efforts to Promote PDA Use

Given that patient decision aids are a relatively recent development in clinical practice, it is not terribly surprising that there is relatively little government oversight of the development and use of such tools.[200] But there have been some efforts to "break the logjam" and facilitate the implementation of PDAs as a routine part of clinical practice.[201]

Three initiatives are notable. First, the federal government has spurred the development of PDAs through several grant programs. Second, the federal government has even built PDA use into reimbursement criteria for some procedures. Third, some states have also moved to promote PDA use through consumer websites, demonstration programs, and licensing criteria.

1. FEDERAL PDA PROMOTION THROUGH GRANTS

The most notable source of federal law that directly deals with PDAs is Section 3506 of the 2010 Patient Protection and Affordable Care Act (ACA). The express purpose of Section 3506 is to facilitate shared decision making.[202] It aims to do this in three ways.

First, Section 3506 directs the U.S. Department of Health and Human Services (DHHS) to develop a mechanism to certify PDAs. Second, Section 3506 promotes the development and clinical use of PDAs by directing DHHS to make grants or contracts to develop, update, produce, and test patient decision aids and to "educate providers on the use of such materials."[203] Third, Section 3506 directs DHHS to provide grants for the implementation and effective use of decision aids.[204]

As discussed below, the Center for Medicare Services (CMS) has not yet moved forward on the first aim by selecting an entity to certify patient decision aids.[205] However, CMS *has* moved forward on supporting the initiation of decision aid demonstration projects. For example, MaineHealth and the Mayo Clinic have been selected as "Shared Decision Making Resource Centers" to "disseminate best practices and other information to support and accelerate adoption, implementation, and effective use" of decision aids."[206] Furthermore, there are a number of other federal programs that authorize the funding of research on decision aids.[207]

For example, Section 3021 of the ACA establishes the Center for Medicare and Medicaid Innovation (CMMI).[208] The CMMI is charged with testing and evaluating "innovative payment and service delivery models" to identify approaches that will provide cost savings or improve the quality of care for populations served by Medicare, Medicaid, or the Children's Health Program (CHIP).[209] CMMI tests and evaluates models to determine if they either decrease program costs without reducing the quality of care, or increase the quality of care without increasing spending. When CMMI identifies such models, it has the authority to promulgate rules implementing these models on a nationwide basis, through federal health programs.[210]

One of several models specifically identified by Section 3021 as an opportunity for CMMI to address costs or quality of care is in assisting individuals to make "informed health care choices by paying providers of services and suppliers for using patient decision-support tools" that "improve applicable individual and caregiver understanding of medical treatment options."[211] Thus, it is likely that CMMI will address payment and delivery models involving patient decision aids.[212]

Indeed, part of CMMI's work has involved the funding of grants to organizations that will implement "the most compelling ideas to deliver better health, improved care, and lower costs to people enrolled in Medicare, Medicaid, and Children's Health Insurance Program."[213] In 2012, CMMI awarded the first batch of these "Health Care Innovation Awards." While none of the awarded projects appear to specifically focus on patient decision aids, multiple projects address the larger issue of shared decision making and probably involve the use of PDAs.[214]

Like CMMI, the Agency for Healthcare Research and Quality (AHRQ) has also promoted the development and implementation of PDAs. The AHRQ Effective Health Care Program funds "effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers," including multiple studies related to development, testing, or implementation of PDAs.[215] Additionally, this program has made several PDAs ("plain-language guides") publicly available, including for post-menopausal osteoporosis and "clinically localized" prostate cancer.[216]

A separate potential source of federal funding for the development, testing, or implementation of patient decision aids, is the Patient-Centered Outcomes Research Institute (PCORI).[217] The ACA mandated the establishment of PCORI as a non-governmental, non-profit corporation, and charged it with funding comparative clinical effectiveness research.[218] This will increase the availability and quality of evi-

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dence that patients and health care providers need to make "informed health decisions."

In May 2012, PCORI indicated that one of its national priorities for research funding will be "communication and dissemination research," including support of "shared decision making between patients and providers."[219] This strongly suggested that PCORI would support decision aid research. PCORI's subsequent award of its first cycle of grants has confirmed this. Of 25 grants initially awarded, at least two directly deal with assessing the efficacy of PDAs for improving medical decisions by patients and their families.[220]

2. federal pda promotion through payment incentives

While the federal government has not established criteria or processes for the certification of PDAs, it has incorporated shared decision making as a quality measure benchmark into several programs.[221] And it continues to more broadly incorporate shared decision making into other conditions of participation and conditions of payment.[222]

For example, the Centers for Medicare & Medicaid Services issued two proposed Decision Memos that would predicate payment on a shared decision making visit and use of one or more decision aids.[223] The first CMS decision memo concerns screening for lung cancer with low-dose computed tomography scan imaging (LDCT).[224] Medicare will cover this annual preventive screening only if the patient has a "shared decision making visit" that includes "the use of one or more decision aids."

The second CMS decision memo concerns left atrial appendage closure devices.[225] Before Medicare will pay for such devices, the patient must have a "formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool." Since private payers typically follow Medicare reimbursement models, shared decision making will spread even more widely.[226]

More broadly, shared decision making is one of 33 performance standards in the Medicare Shared Savings Program (MSSP).[227] Specifically, Accountable Care Organizations (ACOs) must "promote patient engagement" by addressing "shared decision making that takes into account the beneficiary's unique needs, preferences, values, and priorities."

Under the MSSP, groups of physicians, hospitals and other health care providers contract with the Centers for Medicare and Medicaid Services to accept responsibility for the "quality, cost and overall care" of an assigned group of Medicare beneficiaries.[228] To incentive these ACOs to provide quality, cost-efficient care, providers will continue to be paid under the Medicare fee-for-service model, but will be eligible for "shared savings" payments if the ACO meets certain cost and quality benchmarks.[229]

One of the quality benchmarks required of ACOs is that these organizations "define processes to promote… patient engagement."[230] CMS regulations issued in 2011 clarified this requirement, explaining that measures that would promote patient engagement "may include, but are not limited to, the use of decision support tools and shared decision making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions."[231]

Most recently, in December 2016, CMS launched a pair of demonstration projects aimed at evaluating different approaches to shared decision making between physicians and patients. The Shared Decision Making Model will focus on integrating this approach into clinical workflow in ACOs. The ACOs will receive $50 per SDM service delivered by their practitioners. The Direct Decision Support Model will use outside "decision support organizations" to educate patients about their treatment choices so they can have informed conversations with their physicians.[232]

3. state pda promotion through consumer websites, demonstration projects, and licensing rules

Since patient decision aids both improve care and reduce costs, federal policymakers have not been the only ones incentivizing their use. State policymakers have also been enacting legislation and administrative regulation that promotes the use of decision aids.[233] Most notable among these states is Washington. As discussed in the next section, Washington has already implemented a mechanism to certify PDAs.[234] But other states have taken some smaller steps to incentivize the use of PDAs. Notable among these are Massachusetts, Vermont, and Maine.

In 2012, Massachusetts established a Center for Health Information and Analysis.[235] Among other things, this Center must "maintain a consumer health information website containing "information comparing the quality, price and cost of health care services." The statute mandates that, to the extent possible, this website must include decision aids "on but not limited to, long-term care and supports and palliative care."

In 2009, Vermont enacted legislation calling for a shared decision making demonstration project.[236] In 2010, the Vermont Blueprint for Health commenced a one-year shared decision making pilot in the Barre Hospital Service Area.[237] Similarly, in 2009, Maine enacted legislation calling for an "advisory group of stakeholders" to "develop a plan to implement a

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program for shared decision making."[238] In 2011, the group issued its final report, recommending a demonstration project.[239]

At the regulatory level, in 2010, the Maine Board of Licensure in Medicine incorporated shared decision making principles into its guidelines on informed consent.[240] That same year, the Minnesota Department of Health incorporated such principles into its certification requirements for Health Care Homes.[241]

Several other states have also explored promoting the use of decision aids. In 2016, New Jersey considered a bill that would provide Medicaid coverage for advance care planning.[242] The bill defined "advance care planning" as including the physician:

> facilitating shared decision making with the patient, making use of: *decision aids; patient support tools, provided in an easy-to-understand format* which incorporates patient preferences and values into the medical plan; an advance directive; and a physician order for life-sustaining treatment, as appropriate.[243]

Legislation has also been considered in Connecticut and Oklahoma.[244] In Minnesota, bills in 2009 and 2011 proposed requiring shared decision making for certain surgical procedures before reimbursement could be paid by a health plan company under contract with the state commissioner of human services or finance.[245] More legislation and regulation is sure to be considered and enacted by additional states over the next few years.

While the measures taken by these states may help to promote the use of PDAs, they are insufficient. They fail to address the preliminary issues of exactly which PDAs clinicians should use. Not all PDAs are created equal. Therefore, more PDA use is not necessarily better – unless the PDAs are accurate, up-to-date, and unbiased. To assure this, we need certification.

VI. Certification of Patient Decision Aids

There is a plethora of PDAs. And there is a plethora of PDA developers.[246] Unfortunately, they are highly variable in their competence and motives. Some PDAs may not include all the relevant risks, benefits, and alternatives. Some may include them all but fail to present them in a fair and balanced manner. Indeed, sometimes a slanted presentation is intended, because the PDA developer has an interest in steering the patient to a particular treatment. For example, a pharmaceutical company and an insurer might have very different PDAs for the same intervention.

Which PDAs should clinicians use? We need a process for assessing and evaluating PDAs. We need a way to determine whether a PDA is a source of reliable health information that can help in decision making. After first explaining the need for PDA certification, I describe its origins in private expert collaboratives. I then describe the new certification criteria and process now implemented in Washington State. I conclude by examining the case for federal PDA certification.

A. Need for Certification

The relative newness of PDAs means that there is little systematic oversight of their development or use. While PDAs have been promoted as a positive movement toward both more meaningful informed consent and more cost-effective care, there is also an emerging recognition that some kind of quality-control measures are needed to ensure that PDAs do not do more harm than good.[247]

The purpose of PDA certification is to help drive the evolution of informed consent from a one-way (disclosure-oriented) process to a two-way (participation-oriented) shared decision making process. "Providers will be more comfortable using [PDAs] that have gone through some kind of independent vetting or certification process."[248]

Certification improves and incentivizes the use of PDAs by assuring their quality.[249] It is a formal process that ensures their integrity. This is important, because "patients, clinicians, and payers need to be assured that the [PDAs] they choose to use have been developed in a legitimate manner and carefully scrutinized for quality and transparency."[250] PDA certification helps assure that evidence-based criteria are met and conflicts of interest are mitigated.[251]

The risks are significant. There is a real "possibility of the introduction of poor quality tools."[252] As discussed above, numerous for-profit, non-profit, and government developers have produced a multitude of PDAs.[253] Unfortunately, they are widely diverse in quality. Many are incomplete, inaccurate, or misleading.[254] Many are not supported by evidence of effectiveness.[255] Consequently, just as drugs and devices must be approved by the Food and Drug Administration to ensure that they are safe and effective, here too, regulatory oversight is needed to ensure that PDAs meet a minimum level of quality and safety.[256]

Indeed, a bad PDA can be just as dangerous as a bad drug or device. Several features of PDAs increase the likelihood of misinformation or bias, relative to other types of patient educational materials.[257] First, PDAs are generally developed by third parties not involved in a patient's care, including professional associations, government agencies, hospitals and health centers, non-profit organizations, and for-profit companies.[258] Some of these developers "have little incentive to main-

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tain the integrity of their products other than market pressures to maintain good business practices."[259] But in other contexts, such as environmental regulation, products liability, and pharmaceuticals; it has become clear that market pressures are often insufficient to protect consumers.[260]

Second, PDAs are "powerful tools that can influence clinical care decisions."[261] Some developers have a financial conflict of interest to direct the patient toward a particular option.[262] The American Medical Association has expressed concern about the use of PDAs "by insurers and others" as a vehicle to steer patients toward less expensive treatment options on the basis of biased or misleading information.[263]

Third, the potential for the creation and use of biased or misleading decision aids is exacerbated by the fact that PDAs are generally used by patients outside interactions with their physicians, meaning that "physicians may have limited opportunities to mediate or interpret the information" provided by third parties.[264]

Fourth, further complicating the issue is the fact that PDAs are commonly used in medical decisions that "involve moral and political controversies that may impact the way information is provided to patients," (e.g. reproductive issues).[265] The interaction of these elements raises concerns of quality and objectivity that are not yet addressed in a systematic way by private or government oversight.[266]

B. Origins of PDA Certification

Fortunately, there is a growing recognition of the need for some kind of formal credentialing process.[267] A few nongovernmental organizations have already begun compiling and assessing the quality of available patient decision aids.[268]

Notable among these efforts is the International Patient Decision Aid Standards Collaboration (IPDAS). This group of researchers, practitioners, patients, policymakers, and other stakeholders from more than a dozen countries around the world was established in 2003 to enhance the quality and effectiveness of PDAs.[269]

To this end, IPDAS has developed a detailed set of evidence-based criteria to guide evaluation of the quality of decision aids.[270] These include: (a) describing the health condition, (b) listing the options, (c) listing the option of doing nothing, (d) using visual diagrams, (e) using stories that represent a range of positive and negative experiences, (f) reporting the source of funding used to develop the materials, and (g) describing the quality of scientific evidence presented.

Similar to IPDAS, the Ottawa Hospital Research Institute (OHRI) has compiled a library of decision aids that meet a few basic criteria. To be included in OHRI's database, a decision aid must: (a) provide information about the "options and outcomes that are relevant to a patient's health status;" (b) must report the date it was most recently updated and be no more than five years old; (c) must "provide references to scientific evidence used;" (d) must report conflicts of interest; and (e) must be publicly available.[271]

But IPDAS and OHRI are mere private organizations. Neither has been formally recognized as a certifying entity in the way that, for example, the Joint Commission is widely recognized by state licensing authorities.[272] They have no legal authority to promulgate certification standards, much less evaluate and certify specific PDAs. This means that, at the moment, the issue of patient decision aids is largely devoid of oversight or standardization. The notable exception is Washington State.

C. Certification in Washington State Is Already Here

Washington State, seizing the opportunity to promote shared decision making, has moved forward with PDA certification. It began with a series of statutes enacted between 2007 and 2012. Then, in 2015, the state Health Care Authority (HCA) drafted certification criteria and built a certification process. In 2016, it issued a call for proposals and began certifying PDAs. Finally, Washington State is not only certifying PDAs but also is incentivizing clinicians to use them.

1. LEGISLATIVE AND REGULATORY FOUNDATIONS

In 2007, the Washington State legislature found that there is "growing evidence that, for preference-sensitive care… patient-practitioner communication is improved through the use of high-quality decision aids that detail the benefits, harms, and uncertainty of available treatment options."[273] So, the legislature enacted legislation that called for a demonstration project.[274] The goal of this demonstration project was to "increase the extent to which patients make genuinely informed, preference-based treatment decisions, by promoting…the development, certification, use, and evaluation of effective decision aids."[275]

The demonstration project was a success. So, in 2011, Washington enacted further legislation, directing the HCA to convene a joint working group, the Robert Bree collaborative, to "identify health care services for which there are substantial variations in practice patterns or high utilization trends."[276] For such services, the statute directs the collaborative to "consider strategies that will promote improved care outcomes, such as patient decision aids."[277]

In 2012, Washington enacted a third statute. The 2007 legislation had anticipated the emergence of a

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"national certifying organization."[278] Since that still had not happened five years later, the legislature outlined a state-specific process for certifying decision aids.[279] Specifically, the legislature empowered the Chief Medical Officer of the Health Care Authority to independently assess and certify PDAs.

By the end of 2012, the HCA had already promulgated regulations defining the process by which it would certify PDAs.[280] Basically, these regulations authorized the HCA medical director to establish minimum scores in three categories: (1) content criteria, (2) development process criteria, and (3) effectiveness criteria, based on the IPDAS Collaboration criteria.[281] The 2012 regulations also authorized the HCA to charge a "certification fee" to defray the costs of assessment and certification.[282]

But despite these regulations, the HCA still did not have a specific process or criteria for certification. Fortunately, in 2014, Washington State won a State Innovation Models grant from the Centers for Medicare and Medicaid Innovation to bring shared decision making into mainstream clinical practice. And the project received additional financial support from the Gordon and Betty Moore Foundation. So, finally, in 2015, with the requisite resources in place, the HCA proceeded to draft certification criteria and create a certification process.[283]

2. building the criteria and process

In 2015, the HCA drafted tentative certification criteria based on the IPDAS standards. [284] It then convened more than 60 stakeholders (including providers, payers and consumers) to provide feedback on those draft criteria. In April 2016, the HCA published its certification criteria.[285] They require that the PDA adequately:

- Describe the health condition or problem
- Explicitly state the decision under consideration
- Identify the eligible or target audience
- Describe the options available for the decision, including non-treatment
- Describe the positive features of each option (benefits)
- Describe the negative features of each option (harms, side effects, disadvantages)
- Help patients clarify their values for outcomes of options by a) asking patients to consider or rate which positive and negative features matter most to them AND/OR b) describing each option to help patients imagine the physical, social (e.g. impact on personal, family, or work life), and/or psychological effects
- Make it possible to compare features of available options
- Show positive and negative features of options with balanced detail
- If outcome probabilities are included, allow comparison across options using the same denominator
- Provide information about the funding sources for development
- Report whether authors or their affiliates stand to gain or lose by choices patients make using the PDA
- Include authors/developers' credentials or qualifications
- Provide date of most recent revision (or production)[286]

The Washington State certification criteria further ask whether the PDA and/or the accompanying external documentation (including responses to the application for certification) adequately:

- Disclose and describe actual or potential financial or professional conflicts of interest
- Fully describe the efforts used to eliminate bias in the decision aid content and presentation
- Demonstrate developer entities and personnel are free from listed disqualifications[287]
- Demonstrate that the Patient Decision Aid has been developed and updated (if applicable) using high quality evidence in a systematic and unbiased fashion
- Demonstrate that the developer tested its decision aid with patients and incorporated these learnings into its tool[288]

3. implementing the certification process

In April 2016, the HCA began accepting PDAs for certification. It prioritized PDAs relating to obstetrics and maternity care. Over the next few years, the HCA has prioritized the certification of PDAs for orthopedic, cardiac, and end-of-life care. The HCA is publishing a list of certified PDAs upon completion of each certification process.

By summer 2016, the HCA had already completed the certification process and certified several maternity-related PDAs, including "Prenatal Genetic Testing: Understanding Your Options"; "Amniocentesis Test: Yes or No?"; "Pregnancy: Your Birth Options after Cesarean"; and "Pregnancy: Birth Options if Your Baby is Getting Too Big."[289] The HCA began the next round of PDA reviews in early 2017.

4. incentivizing wider use of certified pdas

By developing PDA certification criteria and processes, Washington State has paved the way for CMS

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and other states. But Washington State did not stop there. It further incentivizes the wider use of PDAs in two important ways.[290]

First, Washington State is acting as a "first mover," using its enormous purchasing power to transform the health care marketplace. The state's HCA purchases health care for more than two million individuals through two programs at a price tag of $10 billion annually. 1.8 million are enrolled in Washington Apple Health (Medicaid). Another 350,000 are enrolled in the Public Employees Benefits Board (PEBB) Program that covers eligible employees and retirees of state agencies and higher education institutions. Together, these two programs cover 30% of Washingtonians.

The HCA already requires the use of certified PDAs in its PEBB accountable care organization contracts. Two accountable care programs are integrating certified PDAs at pilot sites. And the HCA plans to further promote the use of certified PDAs in clinical practice. For example, through a practice transformation support hub, providers will have the opportunity to participate in training to learn shared decision making skills, and receive technical assistance for implementation of shared decision making with the use of certified PDAs.

The second way in which Washington State is incentivizing the use of certified PDAs is by linking their use to enhanced liability protection for providers. A 2007 statute offers physicians a higher degree of protection against a failure to inform lawsuit, if the clinician engaged in shared decision making with a certified PDA.[291]

Under Washington law, a "regular" signed consent form constitutes prima facie evidence that the patient gave her informed consent to the treatment administered. The patient has the burden of rebutting this by a preponderance of the evidence (showing it >50% likely that her consent was not informed). In contrast, a patient's signed "acknowledgment" of shared decision making also constitutes prima facie evidence that the patient gave his or her informed consent to the treatment administered. But the patient has the heavier burden of rebutting this presumption by "clear and convincing evidence."

In short, the use of a certified PDA offers clinicians added legal protection by materially changing the patient's burden of proof. In contrast to the usual preponderance of the evidence standard under which a patient would have to show that her consent was probably (>50%) not informed, a patient must instead more confidently establish (>75%) that her consent was not informed.[292]

Linking the use of PDAs to legal protection parallels broader trends to rationalize and standardize medical practice by linking evidence-based clinical practice guidelines to safe harbor legal immunity.[293] Even more directly analogous experience with standardized written disclosures in Texas demonstrates that the incentive of exculpatory protection spurs wider use.[294]

Eventually, shared decision making and the use of certified PDAs may become a new standard of care, such that failure to use them may be considered a deviation from acceptable practice and hence potential malpractice. Surely, more and more Washington physicians will use PDAs because of either state purchaser mandates or liability protection. At some point, using a certified PDA is what the reasonable Washington physician would do.[295]

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Nearly 90 years ago, Justice Brandeis advised that "a state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments."[296] Washington State is serving as the laboratory for PDA certification and promotion of shared decision making as an enhanced form of informed consent. Washington State is leading the way forward. Washington State's leadership in creating a PDA certification process provides a model that CMS can adopt.

Arguably, Washington State's model can be followed not only by CMS but also by other states. But

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that seems like an imprudent long-term strategy. With 56 separate certification processes, PDA producers would face a "regulatory patchwork."[297] Instead, it is now time to build on Washington State's experience at the national level.

D. Federal Certification Is Coming

Federal legislation concerning PDA certification was first introduced in 2009.[298] The Empowering Medicare Patient Choices Act called for "a certification process for patient decision aids for use in the Medicare program and by other interested parties." To achieve this, the bill directed Department of Health and Human Services to contract with an entity to "synthesize evidence and convene a broad range of experts and key stakeholders to establish consensus-based standards, such as those developed by [IPDAS], to determine which [PDAs] are high quality [PDAs]." The 2009 legislation further charged this entity to apply the standards it established to "review [PDAs] and certify whether [PDAs] meet those standards."[299]

While Congress did not enact the Empowering Medicare Patient Choices Act, key provisions from that legislation were included in the bill that ultimately became the 2010 Patient Protection and Affordable Care Act. Most importantly, like the 2009 legislation, the ACA anticipated moving PDAs into practice by creating a certification process.[300]

Specifically, the ACA requires the DHHS to contract with an entity that will "synthesize evidence" and establish "consensus based standards" for evaluating PDAs. This entity would then develop a "certification process" to endorse PDAs that meet these standards. But nearly seven years after enactment of the ACA, the Department of Health and Human Services has not yet implemented this PDA certification mandate.[301]

Fortunately, a key funder of the Washington State program, the Gordon and Betty Moore Foundation, also funded the development of *national* standards for PDAs and a process for their certification.[302] In particular, the Foundation funded the National Quality Forum (NQF) to convene a multi-stakeholder expert panel to define concepts for how to measure decision quality and shared decision making.[303]

The NQF is a non-profit organization that works to improve the quality of the nation's healthcare system by: (1) building consensus about national priorities and performance improvement goals, (2) endorsing national performance measures and other consensus standards for use in quality improvement and public reporting, and (3) using education and outreach to help reach national goals.[304] Since its founding in 1999, NQF measures and standards have served as a critically important foundation for initiatives to enhance healthcare value, make patient care safer, and achieve better outcomes.[305]

The NQF panel on PDAs convened in May and June 2016. It was able to efficiently build upon prior work conducted by both the International Patient Decision Aid Standards (IPDAS) Collaboration and the Washington State HCA. In September 2016, the NQF promulgated a draft report for comment. It issued a final report in December 2016.[306]

But for broader healthcare policy waves created by the new Trump Administration, one might have expected the NQF publication of criteria and processes for PDA certification to prompt CMS to formally recognize them in rulemaking pursuant to the ACA mandate. Still, while not immediate, that result seems inevitable. At that point, other states, including Washington State, could deem PDAs certified for purposes of state law, so long as those PDAs were certified pursuant to the CMS-approved mechanism. Increasingly, those states and private insurers in those states will require clinicians to use certified PDAs as a condition of insurance reimbursement and for liability protection.[307]

Conclusion

Today, there is a discernible (albeit slow) shift away from traditional informed consent processes, toward shared decision making processes incorporating the use of PDAs. Indeed, the use of PDAs is perhaps both the most rapidly growing and the most promising means of addressing the failure of traditional informed consent.[308]

The law is an important lever that can help reduce and eliminate barriers to the wider adoption of shared decision making and PDAs in clinical practice. Current and emerging legal incentives and penalties are helping to drive the evolution from a one-way, disclosure-oriented informed consent to a two-way, participation-oriented shared decision making process.

Since its origins in the early 1970s, the doctrine of informed consent has been largely a creature of the common law. Depending on the jurisdiction, the physician must disclose either what a reasonable patient would deem material or what a prudent physician would disclose under the circumstances. The federal certification of PDAs may soon displace these inadequate state standards, and impose much-needed consistency and uniformity to informed consent processes. We may finally close (or at least narrow) the persistent gap between the theory and the clinical reality of informed consent.

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Note

This article is adapted from the author's presentations at June 2016 meetings of the American Society of Law, Medicine and Ethics, the International Association of Bioethics, and the Institute of Medical Ethics. This article also draws on Professor Pope's work as an expert panel member on the 2016 National Quality Forum Decision Aids Project.

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15. See *infra* Section VI.C.
16. See *infra* Section VI(C).
17. See *infra* Section VI.D.
18. See generally P. Starr, *The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry* (New York: Basic Books, 1982): at 79-144; R. R. Faden and T. L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986): 76-100, 114-124; D. J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York: Basic Books, 1991); J. Katz, *The*

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23. See, e.g., *Mohr v. Williams*, 104 N.W. 12, 13 (Minn. 1905); *Rolater v. Strain*, 137 P. 96 (Okla. 1913); *Schloendorff v. Soc'y N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).
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26. Restatement (Second) Torts § 13 (1965).
27. Restatement (Second) Torts § 8A (1965).
28. *Scott v. Bradford*, 606 P.2d 554, 557 (Okla. 1979) (stating unauthorized medical treatment constitutes battery); *Chambers v. Nottebaum*, 96 So. 2d 716, 718 (Fla. Dist. Ct. App. 1957) (characterizing medical operation without patient consent as battery).
29. See, e.g., *Scholendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914) (addressing patient consented to biopsy, not surgery); *Pizzalotto v. Wilson*, 437 So. 2d 859 (La. 1983) (addressing patient consented to exploratory surgery, not removal of reproductive organs); *Perna v. Pirozzi*, 457 A.2d 431 (N.J. 1983) (consenting to operation with only one specific doctor); *Paulsen v. Gunderson*, 260 N.W. 448 (Wis. 1935) (analyzing patient consent to a "simple" ear operation, and instead underwent a "radical" ear operation); *Franklyn v. Peabody*, 228 N.W. 681 (Mich. 1930) (operating on thumb without consent); *Gill v. Selling*, 267 P. 812 (Ore. 1928) (performing spinal puncture on wrong patient), *overruled by* Fredeen v. Stride, 525 P.2d 166 (Ore. 1974); *Hively v. Higgs*, 253 P. 363 (Ore. 1927) (noting removal of tonsils during septum operation); *Hershey v. Peake*, 223 P. 1113 (Kan. 1924) (concerning wrong tooth); *Throne v. Wandell*, 186 N.W. 146 (Wis. 1922) (addressing patient consent to examination, not extraction of six teeth); *Moos v. U.S.*, 225 F.2d 705 (8th Cir. 1955) (operating on wrong leg); *Kaplan v. Mamelak*, 75 Cal. Rptr. 3d 861 (Cal. Ct. App. 2008) (operating on wrong spinal disk); *Perry v. Shaw*, 106 Cal. Rptr. 2d 70, 72 (Cal. Ct. App. 2001) (concerning patient consent to removal of excess skin, not breast augmentation); *Ashcraft v. King*, 278 Cal. Rptr. 900 (Cal. Ct. App. 1991) (analyzing patient imposed condition on consent); *Bommareddy v. Superior Ct.*, 272 Cal. Rptr. 246 (Cal. Ct. App. 1990) (concerning patient agreed to tear duct surgery, not cataract extraction); *Lane v. U.S.*, 225 F. Supp 850 (E.D. Va. 1964) (addressing surgery on wrong knee); A. H. McCoid, "A Reappraisal of Liability for Unauthorized Medical Treatment," *Minnesota Law Review* 41, no. 4 (1957): 381-434.
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31. D. B. Dobbs, *The Law of Torts* § 33, at 81 (St. Paul: West Academic, 2000) ("It is enough that the defendant intends bodily contact that is 'offensive,' which is to say a bodily contact that does not appear acceptable to the plaintiff."); N. J. Moore, "Intent and Consent in the Tort of Battery: Confusion and Controversy," *American University Law Review* 61, no. 6 (2012): 1585-1656, at 1595; Horace, "Ars Poetica," line 467 (Transl. A.S. Kline 2005) ("[W]ho saves one, against his will, murders him").
32. See, e.g., *Mohr*, 104 N.W. at 15 (requiring consent in non-emergency situations), *overruled in part by Genzel v. Halvorson*, 80 N.W.2d 854 (Minn. 1957); Restatement (Second) of Torts §§ 892, illus. 1, at 435 (1965); see also *Montgomery v. Bazaz-Seghal*, 742 A.2d 1125, 1130 (Pa. Super. Ct. 1999), *aff'd*, 798 A.2d 742 (Pa. 2002) (discussing urologist implanted penile prosthesis without patient's knowledge or consent); *Taylor v. Johnston*, 985 P.2d 460 (Alaska 1999) (obtaining patient consent by fraud); Millard v. Nagle, 587 A.2d 10 (Pa. 1991) (seeking damages for unauthorized surgery despite physician intention); *Perna v. Pirozzi*, 457 A.2d 431, 439 (N.J. 1983) ("A nonconsensual operation remains a battery even if performed skillfully and to the benefit of the patient."); *Pugsley v. Privette*, 263 S.E.2d 69 (Va. 1980) (holding that unconsented medical treatment constitutes a battery, even though such medical treatment may be beneficial to the plaintiff); *Rogers v. Lumbersmens Mut. Casualty Co.*, 119 So. 2d 649 (La. 1960); *Genzel v. Halvorson*, 80 N.W.2d 854 (Minn. 1957) (performing surgery without consent is battery); *Kennedy v. Parrott*, 90 S.E.2d 754 (N.C. 1956) (analyzing causation between doctor's action and patient's harms in battery action); *Franklyn v. Peabody*, 228 N.W. 681 (Mich. 1930) (operating on patient's right thigh without consent to obtain tissue for a procedure on patient's thumb constitutes battery); *Perry v. Hodgsen*, 148 S.E. 659 (Ga. 1929) (noting patient consent required unless emergency); *Barrette v. Lopez*, 725 N.E.2d 314 (Ohio Ct. App. 1999) (distinguishing medical negligence from battery); *Rodriguez v. Pino*, 634 So. 2d 681 (Fla. Dist. Ct. App. 1994) (holding physician not liable for patient's refusal to consent); *Lounsbury v. Capel*, 836 P.2d 188, 199 (Utah Ct. App. 1992) (remanding for damages even though surgery somewhat beneficial); *Estate of Leach v. Shapiro*, 469 N.E.2d 1047, 1051 (Ohio Ct. App. 1984) ("A physician who treats a patient without consent commits a battery, even though the procedure is harmless or beneficial."); *Mims v. Boland*, 138 S.E.2d 902 (Ga. Ct. App. 1964) (recognizing physician treatment without consent is guilty of technical battery); *McCandless v. State*, 162 N.Y.S.2d 570 (N.Y. App. Div. 1957) (affirming $2,000 in damages even though procedure less harmful and improved patient's mental health); *Church v. Adler*, 113 N.E.2d 327 (Ill. App. Ct. 1953) (reviewing cause of medical negligence); *Mulloy v. Hop Sang*, 1 W.W.R. 714 (Can. A.R. 1935) (holding that even a successful operation, contrary to patient instructions, was still a battery).
33. Dobbs, *supra* note 31, at 80 ("Even beneficial touchings such as medical procedures may warrant damages if they are batteries."). The Second Restatement of Torts provides an applicable example:

    > A has a wart on his neck. His physician, B, advises him to submit to an operation for its removal. A refuses to do so. Later A consents to another operation…B removes the wart. The removal in no way affects A's health, and is in fact beneficial. A has suffered bodily harm.

    Restatement (Second) of Torts § 15, illus. 1 (1965).
34. See Meisel, Cerminara & Pope § 2-24 n.104; *Chambers v. Nottebaum*, 96 So. 2d 716 (Fla. Dist. Ct. App. 1957) (concerning lack of consent for spinal anesthesia); *Corn v. French*, 289 P.2d 173 (Nev. 1955) (alleging mastectomy without consent); *Woodson v. Huey*, 261 P.2d 199 (Okla. 1953) (affirming need for consent to give anesthesia); *Tabor v. Scobee*, 254 S.W.2d 474 (Ky. Ct. App. 1952) (addressing removal of fallopian tubes during operation for appendicitis); *Williams*, 104 N.W. at 15-16 (discussing operation on left ear but consent obtained only for right ear), *overruled in part by Genzel v. Halvorson*, 80 N.W.2d 854 (Minn. 1957); Rolater v. Strain, 137 P. 96

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(Okla. 1913) (addressing removal of sesamoid bone without consent); *Hively v. Higgs*, 253 P. 363 (Or. 1927) (addressing removal of tonsils with only consent for septum surgery); *Wells v. Van Nort*, 125 N.E. 910 (Ohio 1919) (analyzing physician decision to remove fallopian tubes); *Schloendorff v. Soc'y N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914) (addressing unauthorized surgery), *abrogated by Bing v. Thunig*, 143 N.E.2d 3 (1957); *Sekerez v. Rush Univ. Med. Ctr.*, 954 N.E.2d 383 (Ill. App. Ct. 2011) (reversing directed verdict for defendants who administered Lovenox to terminally ill cancer patient against his stated and documented wishes); *Gragg v. Calandra*, 696 N.E.2d 1282, 1290 (Ill. App. Ct. 1998) ("Although a defendant may reasonably believe that his objective is legitimate, it does not provide him with carte blanche to pursue that objective by outrageous means."); *Kaplan v. Blank*, 419 S.E.2d 127 (Ga. Ct. App. 1992) (claiming lack of written consent for tubal ligation); *Markart v. Zeimer*, 227 P. 683 (Cal. Ct. App. 1924) (reviewing negligence in hernia surgery).

35. Medical associations and policymakers are focused on identifying commonly performed tests and procedures that offer little or no clinical benefit. This is a great start on reducing overuse and improving healthcare quality. But it is not enough. Benefit is a function not only of medical science but also of patient preferences. A. L. Schwartz et al., "Measuring Lower-Value Care in Medicare," *JAMA Internal Medicine* 174, no. 7 (2014): 1067-1076.
36. *Moore* at 1611, 1621; *Curtis v. Jaskey*, 326 Ill. App. 3d 90, 94 (2001) (noting that it is unnecessary for plaintiff to prove defendant physician had hostile intent); *McNeil v. Brewer*, 304 Ill. App. 3d 1050, 1154-55 (1999).
37. Dobbs, *supra* note 31, at 342 ("Even beneficial…medical procedures warrant damages if they are batteries."). "A person is entitled to refuse well-intentioned medical treatment." *Id.*, *at* § 29, at 54; *see Urlaub v. Select Specialty Hosp. Memphis*, No. W2010-00732-COA-R3-CV, 2011 WL 255281 1, 6 (Tenn App. Jan. 20, 2011) (administering dialysis contrary to instructions could constitute a battery by not following the standard of care necessitated by informed consent); *Mink v. Univ. Chicago*, 460 F. Supp. 713, 717 (N.D. Ill. 1978); *Beane v. Perley*, 109 A.2d 848, 850 (N.H. 1954) (recognizing the difficulty in providing medical expert testimony as required in malpractice suits). But see *Pleasure v. Louisiana Organ Procurement Ass'n*, 83 So. 3d 174 (La. App. 2011) (affirming judgment that continuing life-support and removing organs without consent sounded in medical malpractice), *rev. denied,* 85 So. 3d 1248 (La. 2012). While the conferral of "benefit" by the unwanted treatment does not affect the cause of action, it is considered in determining the amount of the award. F. V. Harper et al., *Harper, James and Gray on Torts,* 3d ed. (New York: Aspen, 2006): at 348. Nevertheless, it is problematic to characterize as a "benefit" a state of life the person living that life finds intolerable.
38. As litigation costs decrease, clinician compliance rates should rise. K. N. Hylton, "Litigation Cost Allocation Rules and Compliance with the Negligence Standard," *Journal of Legal Studies* 22, no. 2 (1993): 457-476, at 459.
39. See Dobbs, *supra* note 31, at § 42, at 79 ("When the trespassory tort causes no physical harm, the traditional tort rule is that the plaintiff can nevertheless recover substantial as distinct from nominal damages…The invasion of the plaintiff's rights is regarded as harm in itself…"); *id.*, § 100, at 234 n.17 ("The difference is that a battery is actionable without proof of bodily harm or economic loss; the offensive touching is harm in itself."); *id.*, § 28, at 54 ("Battery today vindicates the plaintiff's rights of autonomy and self-determination, her right to decide for herself how her body will be treated by others"); *B v. NHS Hosp. Trust* [2002] EWHC 429 (awarding £100 nominal damages).
40. See, e.g., *Whitley-Woodford v. Jones*, 600 A.2d 946, 947-48 (N.J. Super. Ct. App. Div. 1992) (noting that an operation undertaken without consent, even if perfectly performed with good medical results, may entitle the plaintiff to at least nominal damages and even punitive damages).
41. This has been confirmed in battery cases involving life-sustaining treatment. See generally R. E. Shandell and P. Smith, *The Preparation and Trial of Medical Malpractice Cases* § 1.06[6] (New York: Law Journal Press, 2006); *Gragg v. Calandra*, 696 N.E.2d 1282, 1286 (Ill. App. 1998); Russell v. Murphy, 86 S.W.3d 745, 748-50 (Tex. App. 2002) (holding medical standards irrelevant where anesthesiologist administered sedative despite patient's specific request for local anesthetic); *Jones v. Ruston La. Hosp. Co.*, 71 So. 3d 1154 (La. App. 2011) (holding Medical Malpractice Act and review by "medical review panel" inapplicable where clinician resuscitated Agnes Liles despite "knowledge of the DNR order"); *Abeyta v. HCA Health Servs. of Tenn.*, No. M2011–02254–COA–R3–CV, 2012 WL 5266321 (Tenn. App. Oct. 24, 2012) (having not filed a certificate of good faith did not amount to malpractice, but ordinary negligence, not requiring expert testimony). *But cf. Shuler v. McGrew*, No. 12–2003–STA–dkv, 2012 WL 3260685 1, 6 (W.D. Tenn. Aug. 8, 2012) (holding that administration of Heparin over patient's objections was not battery because it was a "component part of the treatment process" and providers had patient's consent to be treated at the hospital).
42. See Harper et al., *supra* note 37, at § 3.10, at 351.
43. See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); *Wilkinson v. Vesey*, 295 A.2d 676 (R.I. 1972); *Cobbs v. Grant*, 8 Cal.3d 229 (1972); *Holt v. Nelson*, 523 P. 2d 211 (Wash. 1974); *Riedinger v. Colburn*, 361 F. Supp. 1073 (D. Idaho 1973); *Scaria v. St. Paul Fire & Marine Ins. Co.*, 227 N.W.2d 647 (Wis. 1975); *Sard v. Hardy*, 379 A.2d 1014, 1021 (Md. 1977). A handful of cases had earlier articulated a theory of informed consent. See, e.g., *Salgo v. Leland Stanford, Jr., University Board of Trustees*, 154 Cal. App. 2d 560, 317 P. 2d 170 (Dist. Ct. of App. 1957); *Natanson v. Kline*, 186 Kan. 393, 402, 350 P.2d 1093, 1100 (1960). But the doctrine was not more fully articulated and more widely adopted until the 1970s. *Cf.* J. H. Krause, "Reconceptualizing Informed Consent in an Era of Cost Containment," *Iowa Law Review* 85, no. 1 (1999): 261-386, at 270-271.
44. J. Staples King and B. Moulton, "Rethinking Informed Consent: The Case for Shared Medical Decision Making," *American Journal of Law & Medicine* 32, no. 4 (2006): 429-501.
45. In some states, there is no common law duty of informed consent. It exists solely as a matter of statute and is often more narrowly circumscribed. *Alicea* (Ga. 2016); *Pruette v. Ungarino*, No. A131833 (Ga. App. 27 Mar. 2014); *Pagani v. Weiss*, No. J-A05017-14 (Penn. Super. Ct. 27 Mar. 2014). See also N. N. Sawicki, "Modernizing Informed Consent: Expanding the Boundaries of Materiality," *University of Illinois Law Review* 2016, no. 3 (2016): 821-872 (collecting citations from Iowa, Louisiana, and Pennsylvania).
46. The most salient enforcement of informed consent obligations occurs through medical malpractice litigation. But there are other mechanisms to enforce clinicians' obligation to obtain informed consent. The state medical boards are particularly frequent enforcers of informed consent duties. T. Miller, "Informed Consent: A Medical Board Analysis," *Journal of Medical Regulation* 96, no. 3 (2010): 16-22. For example, the Maine Board of Licensure in Medicine recently reported that approximately one-third of the cases it investigates each year includes allegations of failure to obtain adequate and meaningful informed consent. D. Nyberg, "Obtaining Meaningful Informed Consent: Guidelines from the Maine Board of Licensure in Medicine," *Journal of Medical Regulation* 99, no. 3 (2013): 18-21. Similarly, a recent report by the Wisconsin Medical Examining Board reviewed eleven years of final decisions and orders by the board. This report shows that informed consent violations were one of the most common reasons for discipline. Furthermore, Maine and Wisconsin are not alone. Other state medical boards have also been regularly enforcing informed consent duties. *In re George Der Mesropian*, No. 13-418, 2013 WL 6869796 (N.Y. Board of Profes-

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sional Medical Conduct 16 Dec. 2013); *In re Richard Godt*, No. 13-181, 2013 WL 3288372 (N.Y. Board of Professional Medical Conduct 14 June 2013); *J.V. v. D.G.C.*, 2013 CanLII 40382 (ON HPARB); Fitness to Practice Medicine: Robert Theodore Henri Kees Trossel, General Medical Council (29 Sept. 2010). While rare, breaches of informed consent have sometimes resulted in criminal liability. T.M. Pope and M. Hexum, "Legal Briefing: Informed Consent in the Clinical Context," *Journal of Clinical Ethics* 25, no. 2 (2014): 152-174.

47. See King and Moulton, *supra* note 44. This article includes an appendix of state informed consent laws. Similar appendices can be found in other recent articles. D. M. Studdert et al., "Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risks," *Journal of Empirical Legal Studies* 4, no. 1 (2007): 103-124; W.G. Cobb, "Defending the Informed Consent Case," *Defense Counsel Journal* 72, no. 4 (2005): 330-346. Some states, like Minnesota, are identified as using a "modified" or "hybrid" approach. 48 . M. H. Lewis, J. K. Gohagan, and D. J Merenstein, "The Locality Rule and the Physician's Dilemma: Local Medical Practices versus the National Standard of Care," *JAMA* 297, no. 23 (2007): 2633-2637.
49. See, e.g., *Wheeldon v. Madison*, 374 N.W.2d 367, 374 (S.D. 1985); *Largey v. Rothman*, 540 A.2d 504, 508 (N.J. 1988); *Cross v. Trapp*, 294 S.E.2d 446, 455 (W. Va. 1982). *Cf. Montgomery v. Lanarkshire Health Board*, [2015] UKSC 11 ¶ 46 ("The doctor cannot form an objective, "medical" view of these matters, and is therefore not in a position to take the "right" decision as a matter of clinical judgment."); *id.* ¶ 115 ("[A] responsible body of medical opinion, becomes quite inapposite. A patient is entitled to take into account her own values, her own assessment of the comparative merits."). Recognizing the subjectivity of benefit, many encourage clinicians to do as much as possible "for" the patient and as little as possible "to" the patient.
50. See, e.g., *Jandre v. Physicians Ins. Co.*, 340 Wis.2d 31, 813 N.W.2d 627 (2012). See generally A. R. Derse, "Flying Too Close to the Sun: Lessons Learned from the Judicial Expansion of the Objective Patient Standard for Informed Consent in Wisconsin," *Journal of Law, Medicine & Ethics* 45, no. 1 (2017): 51-59.
51. Wis. A.B. 139 (2013), enacted as 2013 Wis. Acts 111, *amending* Wis. Stat. § 448.30.
52. *Id.*
53. Wisconsin Department of Safety and Professional Services, *Analysis of Proposed Order of the Medical Examining Board* (May 21, 2014), *available at* <http://dsps.wi.gov/Documents/Board%20Services/Agenda%20Materials/Medical/2014/20140521%20MED%20Open%20Session.pdf> (last visited January 31, 2017). See also A. Szczygiel, "Beyond Informed Consent," 21 *Ohio Northern University Law Review* 21, no. 1 (1994): 171-262; J. L. Dolgin, "The Legal Development of the Informed Consent Doctrine: Past and Present," *Cambridge Quarterly Healthcare Ethics* 19, no. 1 (2010): 97-109, at 101 (noting how other state legislatures replaced court adopted reasonable patient standard with the professional standard, and noting how that standard is preferred by physicians).
54. The plaintiffs may also have to contend with the physicians' argument that one or more "exceptions" applies.
55. For both an overview and in-depth analysis of informed consent law, see F. A. Rozovsky, *Consent to Treatment: A Practical Guide*, 4th ed. (New York: Wolters-Kluwer, 2009); S. E. Pegalis, *American Law of Medical Malpractice*, 3rd ed. (St. Paul: Thomson/West, 2009): at chap. 4.
56. On some measures, the impact was dramatic. In 1961, 90% of physicians refrained from telling patients about a cancer diagnosis. By 1979, that dropped to just 2%. See Dolgin, *supra* note 53, at 100 (citing D. Oken, "What to Tell Cancer Patients: A Study of Medical Attitudes," *JAMA* 175, no. 13 (1961): 1120-1128; D. H. Novack et al., "Changes in Physicians' Attitudes toward Telling the Cancer Patient," *JAMA* 241, no. 9 (1979): 897-900.
57. See *supra* notes 4 to 12. Indeed, some of the limitations were recognized early on. See President's Commission for the Study of Ethical Problems in Medicine, *Making Health Care Decisions A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship Volume One: Report* (October 1982).
58. D. McCarthy et al., "What Did the Doctor Say? Health Literacy and the Recall of Medical Instructions," *Medical Care* 50, no. 4 (2012): 277-282; F. J. Fowler Jr. et al., "Improving and Involving Patients to Improve the Quality of Medical Decisions," *Health Affairs* 30, no. 4 (2011): 699-706; M. Brezis et al., "Quality of Informed Consent for Invasive Procedures," *International Journal for Quality Health Care* 20, no. 5 (2008): 352-357; D. B. White et al., "Toward Shared Decision Making at the End of Life in Intensive Care Units Opportunities for Improvement," *Archives of Internal Medicine* 167, no. 5 (2007): 461-467; see Staples King and Moulton, *supra* note 44; M. M. Bottrell et al, "Hospital Informed Consent for Procedure Forms: Facilitating Quality Patient-Physician Interaction," *Archives of Surgery* 135, no. 1 (2000): 26-33; C. H. Braddock et al., "Informed Decision Making in Outpatient Practice: Time to Get Back to Basics," *JAMA* 282, no. 24 (1999) (finding less than 10% of decisions met minimum standards for informed consent): 2313-2320; K. E. Covinsky et al., "Communication and Decision Making in Seriously Ill Patients: Findings of the SUPPORT Project: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment," *Journal of American Geriatrics Society* 48, no. 5 Supp. (2000): S187-S193 (only 41% of Medicare patients believe their treatment reflected their preferences).
59. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972) ("Any definition of scope in terms purely of a professional standard is at odds with the patient's prerogative to decide on projected therapy himself. That prerogative, we have said, is at the very foundation of the duty to disclose, and both the patient's right to know and the physician's correlative obligation to tell him are diluted to the extent that its compass is dictated by the medical profession.").
60. See, e.g., D. Merenstein, "A Piece of My Mind: Winners and Losers," *JAMA* 291, no. 1 (2004): 15-16; D. Merenstein, "PSA Screening - I Finally Won!" *JAMA Intern Medicine* 175, no. 1 (2015): 16-17; see M. Hall, "The Defensive Effect of Medical Practice Policies in Malpractice Litigation," *Law and Contemporary Problems* 54, no. 2 (1991): 119-145, at 129-30 (noting that medical practice is guided by instinct and localized habit).
61. See, e.g., Faden and Beauchamp, *supra* note 18, at 305-306 (arguing that a subjective standard is more in line with the principles underlying informed consent); E. M. Tenenbaum, "Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation, *Oklahoma Law Review* 64, no. 4 (2011): 697-758, at 717-719 (arguing that an objective standard is "unfaithful" to the underlying autonomy-based ideals of informed consent).
62. *Montgomery v. Lanarkshire Health Board*, [2015] UKSC 11 ¶ 46 ("The relative importance attached by patients to quality as against length of life, or to physical appearance or bodily integrity as against the relief of pain, will vary from one patient to another. Countless other examples could be given of the ways in which the views or circumstances of an individual patient may affect their attitude towards a proposed form of treatment and the reasonable alternatives.").
63. See Tenenbaum, *supra* note 61. On the other hand, courts have recognized that a subjective standard may be difficult one for physicians to comply. See, e.g., *Canterbury,* 464 F.2d at 790-91.
64. *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979). While other states have considered and rejected Oklahoma's approach, Oklahoma continues to adhere to a subjective standard. M. P. Opala and S. S. Sanbar, "Informed Consent and Informed

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Refusal in Oklahoma," *Oklahoma State Medical Association Journal* 102, no. 3 (2009): 86-91.

65. Only four states – New Hampshire, Rhode Island, Oklahoma, and Oregon – have case law or statutes that reject the objective "reasonable patient" standard. See Tenenbaum, *supra* note 61; Pickering Cause of Action.
66. BMJ Clinical Evidence, "Efficacy Categorisations," see <http://www.clinicalevidence.bmj.com/x/set/static/cms/efficacy-categorisations.html> (last visited March 23, 2017) (finding that only 11% of treatment is "clearly" beneficial).
67. Canadian Task Force (2014).
68. 42 U.S.C. § 299b-36(b)(2) (defining "preference sensitive care" as "medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option.").
69. 42 U.S.C. § 299b-36(b)(2); Patient-Centered Outcomes Research Institute, *PCORI PFA Cycle I Awardees* (December 21, 2012), at 2, *available at* <http://www.pcori.org/assets/PFA-Awards-Cycle-1-2012.pdf> (last visited February 1, 2016) (Decision Support for Parents Receiving Genetic Information about Child's Rare Disease).
70. See Fowler et al., *supra* note 10, at 700. See also D. Khullar, "Helping Patients Make the Right Decisions," *New York Times*, September 15, 2016 ("Should you choose six months of life with chemotherapy and intractable nausea, or three months at home chemo-free?").
71. See Tenenbaum, *supra* note 61.
72. *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979).
73. C. J. Jones, "Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy," *Washington and Lee Law Review* 47, no. 2 (1990): 379-430. *But cf.* Montgomery v. Lanarkshire Health Board, [2015] UKSC 11 ¶ 90 ("[T]he doctor's advisory role involves dialogue, the aim of which is to ensure that the patient *understands* the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is *comprehensible*. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp…") (emphasis added).
74. Siegal et al., *supra* note 1, at 359; Alston, *supra* note 12, at 3 (describing informed consent as a "one-way information delivery scheme").
75. Other commentators have analogized the practice of informed consent to "banking" in which the physician "deposits" information into the patient's "bank." A. E. Volandes et al., "The New Tools: What 21st Century Education Can Teach Us," *Healthcare* 1, no. 3-4 (2014): 79-81, at 79. The practice might also be analogized to giving someone the keys to a new experimental vehicle without explaining how to drive it.
76. See Restatement of Contracts 2d § 63. See also *Adams v. Lindsell*, 106 Eng. Rep. 250 (K.B. 1818); Cal. Civ. Code § 1583.
77. *Cobbs v. Grant* (Cal. 1972).
78. See *supra* notes 2 to 12. See also Wennberg, *supra* note 2, at 1565 ("Policymakers have assumed that physician's decisions reflect both medical need and patient demand. However, the remarkable degree of variation in the utilization rates of discretionary surgery raises questions about these assumptions."); *id.*, at 1570 (describing the current realm as "delegated decision making"); A. D. Kennedy et al., "Effects of Decision Aids for Menorrhagia on Treatment Choices, Health Outcomes, and Costs: A Randomized Controlled Trial," *JAMA* 288, no. 21 (2002): 2701-2708. Substantial evidence shows that the treatment patients get depends more on the physician than on the patient's preferences. See <http://www.dartmouthatlas.org> (last visited February 1, 2017).
79. But see Sawicki, *supra* note 45.
80. G.A. Hawker et al., "Determining the Need for Hip and Knee Arthroplasty: The Role of Clinical Severity and Patient Preferences," *Medical Care* 39, no. 3 (2001): 206-216.
81. Moreover, most states hold there is not even a duty to disclose non-medical information such as costs, even in material risk jurisdictions. See Sawicki, *supra* note 45.
82. CDC, *State Laws Relating to Breast Cancer* (Atlanta: CDC, 2000).
83. See, e.g., Cal. Health & Safety Code § 109275.
84. See, e.g., Ga. Code. Ann. § 31-9-6.1; Ark. Code Ann. § 17-95-108; Cal. Health & Safety Code § 1690.
85. G. M. Chinn et al., "Physicians' Preferences for Hospice if They Were Terminally Ill and the Timing of Hospice Discussions with their Patients," *JAMA Internal Medicine* 174, no. 3 (2014): 466-468; A.B. Astrow and B. Popp, "The Palliative Care Information Act in Real Life," *New England Journal of Medicine* 264, no. 20 (2011): 1885-1887.
86. E. Panagopolou et al., "Concealment of Information in Clinical Practice: Is Lying Less Stressful Than Telling the Truth?" *Journal of Clinical Oncology* 26, no. 7 (2008): 1175-1177; I. Torjesen, "1 in 4 GPs Remains Reluctant to Initiate End-of-Life Discussion with Patients," *BMJ* 348, no. g3195 (2014): 1-2; D. K. Heyland et al., "Failure to Engage Hospitalized Elderly Patients and Their Families in Advance Care Planning," *JAMA Internal Medicine* 173, no. 9 (2013): 778-787; W. G. Anderson, S. Kools, and A. Lyndon, "Dancing around death: Hospitalist-Patient Communication about Serious Illness," *Qualitative Health Research* 23, no. 1 (2013): 3-13; Royal College of Physicians and Marie Curie Palliative Care Institute Liverpool, *National Care of the Dying Audit for Hospitals, England: National Report* (2014).
87. B. Zhang et al., "Health Care Costs in the Last Week of Life: Associations with End of Life Conversations," *Archives of Internal Medicine* 169, no. 5 (2009): 480-488.
88. J. W. Mack et al., "End-of-Life Care Discussions among Patients with Advanced Cancer: A Cohort Study," *Annals of Internal Medicine* 156, no. 3 (2012): 204-210; S. M. Dunlay et al., "A Survey of Clinician Attitudes and Self-Reported Practices Regarding End-of-life Care in Heart Failure," *Palliative Medicine* 29, no. 3 (2015): 260-267 (reporting that only 12% of clinicians had end-of-life discussions as advocated by the American Heart Association).
89. A. A. Wright, "Associations between End-of-Life Discussions, Patient Mental Health, Medical Care near Death, and Caregiver Bereavement Adjustment," *JAMA* 300, no. 14 (2008): 1665-1673.
90. Moreover, the quality of these discussions is questionable. See, e.g., Douglas B. White et al., "Prevalence of and Factors Related to Discordance About Prognosis Between Physicians and Surrogate Decision Makers of Critically Ill Patients," *JAMA* 315, no. 19 (2016): 2086-2094 (finding common discordant expectations about prognosis between patients' physicians and surrogate decision makers).
91. Cal. A.B. 2747 (2009), codified at Cal. Health & Safety Code § 442.5.
92. Vt. H.B. 435 (2009) (Patient Bill of Rights for Palliative Care and Pain Management), enacted as Vt. Laws No. 25, codified at Vt. Stat. tit. 18, § 1871.
93. N.Y. A.B. 7617 (2010), enacted as 2010 Sess. Laws of N.Y. Ch. 331, codified at N.Y. Pub. Health Law § 2997-c; amended in 2012 by N.Y. S.B. 7596 (2012), enacted as 2012 Sess. Laws of N.Y. Ch. 256.
94. Mass. S.B. 2400 (2012), enacted as 2012 Mass. Legis. Serv. Ch. 224 § 103 (Massachusetts Act Improving the Quality of Health Care and Reducing Costs through Increased Transparency, Efficiency, and Innovation"), codified at Mass. Stat. 111 § 227.
95. Ariz. S.B. 1304 (2013). Other states considered similar bills. Md. S.B. 546 (2009); Md. H.B. 30 (2009); Ariz. S.B. 1304 (2009). Similar information and counseling was earlier required in the 1996 Michigan Dignified Death Act. Mich. Comp. Laws § 333.5651.

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96. N.Y. Pub. Health Law § 2997-c(2)(a); Mass. Stat. 111 § 227(c).
97. N.Y. Pub. Health Law § 2997-c(2)(b); Mass. Stat. 111 § 227(c).
98. N.Y. Pub. Health Law § 2997-c(3).
99. N.Y. Pub. Health Law § 2997-c(3); Mass. Stat. 111 § 227(c).
100. I called for this nearly 20 years ago. T. M. Pope, "The Maladaptation of Miranda to Advance Directives: A Critique of the Implementation of the Patient Self-Determination Act," *Health Matrix* 9, no. 1 (1999): 139-202, at 196-200.
101. N.Y. Pub. Health Law § 2997-d.
102. Md. H.B. 581 (2013), enacted at 2013 Maryland Laws Ch. 379, codified at Md. Code, Health-Gen. § 19-308.9. The Maryland Health Care Commission is working on the pilot project. See meeting archives at <http://mhcc.maryland.gov> (last visited March 7, 2017).
103. Md. Code, Health-Gen. § 19-308.9.
104. Mass. S.B. 2400 (2012), enacted as 2012 Mass. Legis. Serv. Ch. 224, codified at Mass. Stat. 111 § 227(b) ("The Commissioner shall adopt regulations requiring each licensed hospital, skilled nursing facility, health center or assisted living facility to distribute to appropriate patients in its care information regarding the availability of palliative care and end-of-life options.").
105. The Department indicated that the pamphlet must contain at least five components: (1) a definition and explanation of advanced care planning, hospice care and palliative care; (2) FAQs about hospice, palliative care, and patient rights under the law; (3) a MOLST form and explanation; (4) conversation tools to encourage discussions with the patient's family and providers; (5) a list of licensed hospice providers near the facility; and (6) other requirements defined in the guidance of the Department. M. Biondolillo, "Informational Briefing on Proposed Amendments to 105 CMR 130.000, 105 CMR 140.000 and 105 CMR 150.000: Provision of Information on Palliative Care and End-of-Life Options," October 16, 2013, *available at* <http://blog.mass.gov/publichealth/wp-content/uploads/sites/11/2013/10/End-of-Life-Care.pdf> (last visited February 1, 2017).
106. Massachusetts Department of Public Health, Circular Letter: DHCQ 14-12-623: "Amendments to 105 CMR 130.000: Hospital Licensure, 105 CMR 140.000: Licensure of Clinics and 150.000: Licensing of Long-Term Care Facilities—New Regulations Requiring Distribution of Information Regarding Patients with Serious Advancing Illness (Dec. 10, 2014), <http://www.mass.gov/eohhs/docs/dph/quality/hcq-circular-letters/2014/dhcq-1412623.pdf> (last visited March 7, 2017).
107. *Hargett v. Vitas Healthcare Corp.*, No. RG10547255 (Alameda County Superior Court, Cal. filed 6 July 2011).
108. Law Offices of James Geagan, "Firm Settles Hospice Suit," <http://jgeaganlaw.com/manu_pages/firm_news.php > (last visited March 7, 2017).
109. Mich. S.B. 165 (2013), enacted as 2013 Mich. Legis. Serv. P.A. 57, codified at Mich. Comp. Laws § 333.20403.
110. Mich. Comp. Laws § 333.20405. *See also* Kan. S.B. 85 (2017) (requiring disclosure of hospital "futility" policies).
111. Okla. H.B. 2603, codified at Okla. Stat. tit. 63 § 3163(A).
112. T. M. Pope, "Legal Briefing: The New Patient Self Determination Act," *Journal of Clinical Ethics* 24, no. 2 (2013): 156-167.
113. United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (2009), *available at* <http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf> (last visited February 2, 2017).
114. L. Uttley et al., *Miscarriage of Medicine: The Growth of Catholic Hospitals and the Threat to Reproductive Health Care* (New York: ACLU Foundation and MergerWatch Project, 2013).
115. WAC 246-320-141(5). WSR 14-02-040, S 246-320-141, filed 12/23/13, effective 1/23/14
116. WAC 246-320-141(6). WSR 14-02-040, S 246-320-141, filed 12/23/13, effective 1/23/14
117. The state website was not a model of clarity. See <http://www.doh.wa.gov/DataandStatisticalReports/HealthcareinWashington/HospitalandPatientData/HospitalPolicies> (last visited February 1, 2017). So, in 2016, the ACLU, End-of-Life Washington, and others launched a new website, ClearHealth Washington, to decode the often murky policies. http://www.clearhealthwa.org.
118. D. Orentlicher et al., "Clinical Criteria for Physician Aid in Dying," *Journal of Palliative Medicine* 19, no. 3 (2016): 259-262; Colo. Rev. Stat. § 28-48-101 to -123; D.C. Act No. A21-0577 Law No. L21-0182 (2017).
119. *Id.*
120. A. Charo, "Physicians and the (Woman's) Body Politic," *New England Journal of Medicine* 370, no. 3 (2014): 193-95.
121. C. Daniels et al., "Informed or Misinformed Consent? Abortion Policy in the United States," *Journal of Health Politics, Policy & Law* 41, no. 2 (2016): 181-209; C. Daniels, "Informed Consent Project," *available at* <http://informedconsentproject.com/> (last visited February 1, 2017).
122. Pope and Hexum, *supra* note 46.
123. National Conference of State Legislatures, "State Coverage for Telehealth Services," *available at* <http://www.ncsl.org/research/health/state-coverage-for-telehealth-services.aspx> (last visited February 1, 2017).
124. See D. Hoffmann and V. Rowthorn, "Legal Impediments to the Diffusion of Telemedicine," *Journal of Health Care Law and Policy* 14, no. 1 (2011): 1-54.
125. R. J. Kupchynsky and C. S. Camin, "Legal Considerations of Telemedicine," *Texas Bar Journal* 64 (2001): 20-28, at 24; S. E. Volkert, "Telemedicine: Rx for the Future of Health Care," *Michigan Telecommunications & Technology Law Review* 6, no. 1 (2000): 147-246, 215-216.
126. Pope and Hexum, *supra* note 46.
127. S. B. Omer et al., "Legislative Challenges to School Immunization Mandates, 2009-2012," *JAMA* 311, no. 6 (2014): 620-621.
128. Colo. H.B. 1288 (2013).
129. Cal. A.B. 2109 (2012).
130. Ore. S.B. 132 (2012).
131. Vt. S.B. 199 (2012).
132. Wash. H.B. 1015 (2011).
133. T. M. Pope, "Legal Briefing: Informed Consent," *Journal of Clinical Ethics* 21, no. 1 (Spring 2010): 72-82.
134. See Pope and Hexum, *supra* note 46; Medical Board of California, *Required Written Information Physicians Must Provide Patients in Specific Circumstances*, *available at* <http://www.mbc.ca.gov/Publications/publication_matrix.pdf> (last visited February 1, 2017).
135. See, e.g., A. Sorrel, "Conversation Counts," *Texas Medicine* 113, no. 3 (Mar. 2016): 41-45 (reporting that mandated disclosures in Texas become outdated and that the relevant state authority cannot keep pace with medical advances); N.J. Division of Consumer Affairs, "Rule Proposal," 49, no. 1 (Jan. 3, 2017) (deleting specific standards for assessing brain death because they became outdated).
136. See Sorrel, *supra* note 135.
137. M. McCullough, "Breast Cancer Density Laws Mean More Tests, Unclear Benefit," *Philadelphia Inquirer* (Aug. 14, 2016) (breast density).
138. "The Informed Consent Project," http://informedconsentproject.com (last visited Mar. 7, 2017).
139. Pope and Hexum, *supra* note 46. Admittedly, opponents will assert similar objections against PDAs, since they too intrude upon physicians' professional autonomy and discretion.
140. American College of Physicians, "Statement of Principles on the Role of Governments in Regulating the Patient-Physician Relationship," *available at* <http://www.acponline.org/acp_policy/policies/patient_physician_relationship_2012.pdf (last visited Mar. 7, 2017); American College of Obstetricians and Gynecologists, *Statement of Policy: Legislative Interference with Patient Care, Medical Decisions, and the Patient-Physician Relationship* (May 2013); J. E. Brody, "Law on End-of-Life Care Rankles Doctors," *New York Times*, June 6, 2011.

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141. The California statute allow providers to use "information from organizations specializing in end-of-life care that provide information on factsheets and Internet Web sites." Cal. Health & Safety Code § 442.5(b). But the statute sets no minimum requirements for the accuracy or clarity of such materials.
142. O. Ben-Shahar and C. E. Schneider, *More Than You Wanted to Know: The Failure of Mandated Disclosure* (2014).
143. 1133, 111th Cong., 1st Sess. (2009) (Wyden)(defining "shared decision making" as a "collaborative process between patient and clinician that engages the patient in decision making, provides patients with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan."). See also Alston, *supra* note 12; M.-A. Durand et al., "Incentivizing Shared Decision Making in the USA – Where Are We Now?" *Healthcare* 3, no. 2 (2014): 97-101. In informed consent, the patient is like the president who can either sign or veto a bill but cannot help craft it.
144. When patients lack capacity, PDAs may be used by their legally authorized surrogates. T. M. Pope, "Legal Fundamentals of Surrogate Decision Making," *Chest* 141, no. 4 (2012): 1074-1081.
145. 42 U.S.C. § 299b-36(b)(1).
146. Similar decision tools are being developed for human subjects in the medical research context. See, e.g., P. Grootens-Wiegers, "Comic Strips Help Children Understand Medical Research: Targeting the Informed Consent Procedure to Children's Needs," *Patient Education & Counseling* 98, no. 4 (2015): 518-524.
147. See, e.g., Expert Medical Navigation, Inc. <https://www.exmednav.com> (last visited February 1, 2017); B. L. McAneny, "Report of the Council on Medical Services," *CMS Report 7-A-10: Shared Decision Making* (2010), *available at* <http://www.ama-assn.org/resources/docs/cms/a10-cms-rpt-7.pdf> (last visited February 1, 2017); G. Elwyn et al., "Investing in Deliberation: A Definition and Classification of Decision Support Interventions for People Facing Difficult Health Decisions," *Medical Decision Making* 30, no. 6 (2010): 701-711; A. Gorman, "Inviting patients to Help decide their Own Treatment," *Kaiser Health News* (March 16, 2015).
148. Durand et al., *supra* note 143 (stressing "the need to be very clear that the delivery of [PDAs] is not equivalent to shared decision making").
149. Washington HCA, "HCA Certifies First Patient Decision Aids," (August 22, 2016 (quoting Matt Handley), http://www.hca.wa.gov/about-hca/health-care-authority-certifies-first-patient-decision-aids (last visited March 7, 2017).
150. V. Montori et al., "The Optimal Practice of Evidence-Based Medicine: Incorporating Patient Preferences in Practice Guidelines," *JAMA* 310, no. 23 (2013): 2503-2504 (warning that PDAs must not "replace clinicians' compassionate and mindful engagement of the patient"). On the other hand, the discretion left to physicians can be abused, for example, by describing a particular option more positively than warranted. L.I. Iezzoni et al., "Survey Shows that at Least Some Physicians Are Not Always Open or Honest with Patients," *Health Affairs* 31, no. 2 (2012): 383-391.
151. "Patient Decision Aids," Ottawa Research Hospital Institute, *available at* <http://decisionaid.ohri.ca/AZlist.html> (last visited February 1, 2017).
152. Glyn Elwyn at Dartmouth is compiling a broad and comprehensive inventory of PDA developers. More are joining all the time. See, e.g., Australian Commission on Safety and Quality in Healthcare, *Corporate Program 2016-2017* (2016).
153. ACP Decisions, *available at* <http://www.acpdecisions.org/> (last visited February 1, 2017).
154. Decision Box, *available at* <http://www.decisionbox.ulaval.ca/> (last visited February 1, 2017).
155. Health Wise, *available at* <http://www.healthwise.org/> (last visited February 1, 2017).
156. Informed Medical Decisions Foundation, *available at* <http://www.informedmedicaldecisions.org/> (last visited February 1, 2017).
157. Mayo Clinic Shared Decision Making National Resource Center, *available at* <http://shareddecisions.mayoclinic.org/> (last visited February 1, 2017).
158. Option Grid, *available at* <http://optiongrid.org/> (last visited February 1, 2017).
159. <http://sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php> (last visited March 7, 2017).
160. Taylor Healthcare, *available at* <http://www.dialogmedical.com/> (last visited February 1, 2017) (developer of "iMedConsent").
161. <http://www.emmisolutions.com> (last visited March 7, 2017).
162. Health Dialogue, *available at* <http://www.healthdialog.com/Main/default> (last visited February 1, 2017).
163. Stay Well, *available at* <http://kramesstaywell.com/Home> (last visited February 1, 2017).
164. X-Plain Education, *available at* <http://www.patient-education.com/> (last visited February 1, 2017) (developer of "X-Plain").
165. The NNT, *available at* <http://www.thennt.com/> (last visited February 1, 2017).
166. Welvie, *available at* <https://www.welvie.com/index.aspx> (last visited February 1, 2017).
167. USDHHS, Agency for Healthcare Research and Quality, *available at* <http://www.effectivehealthcare.ahrq.gov/ehc/decisionaids/prostate-cancer/
168. NHS RightCare, *available at* <http://www.rightcare.nhs.uk/> (last visited February 1, 2017).
169. To emphasize the difference between traditional informed consent, many employ the term "shared decision making." See D. deBrokart, "From Patient Centered to People Powered: Autonomy on the Rise," *BMJ* 350, no. h148 (2015): 1-2. Because I contend the legal doctrine of informed consent is malleable enough to evolve to take the shape of shared decision making, I continue to use the term "informed consent." L. Butcher, "The Patient's Role in Achieving Value," *HFMA Leadership* (Spring 2014): 11-21.
170. See Brehaut et al., *supra* note 10, at 709 ("Patient decision aids not only present the information…but also prompt decision makers to compare the different decision options, determine which issues are most important to them, and establish what additional information they need."). So, not any patient pamphlets or literature are PDAs.
171. See deBrokart, *supra* note 169.
172. See, e.g., A. El-Jawahri, "Randomized, Controlled Trial of an Advance Care Planning Video Decision Support Tool for Patients with Advanced Heart Failure," *Circulation* 134, no. 1 (2016): 52-60.
173. S. Munro et al., "Choosing Treatment and Screening Options Congruent with Calues: Do Decision Aids Help? Sub-analysis of a Systematic Review," *Patient Education and Counseling* 99, no. 4 (2016): 491-500; D. Stacey, F. Légaré, N. F. Col et al., "Decision Aids for People Facing Health Treatment or Screening Decisions," *Cochrane Database Systems Review* 1, no. CD001431 (2014): 1-335. PDAs can also help overcome heuristics. P. Ubel, "Creating Value in Health by Understanding and Overcoming resistance to Deinnovation," *Health Affairs* 34, no. 2 (2015): 239-244.
174. If clinicians used PDAs, then patients would be getting consistent information, thus reducing variability. *Cf.* D. L. Stilwell, IMDF Blog, "Shared Decision Making - A Better Way to Encourage Appropriate Use," (July 14, 2016), *available through* <http://informedmedicaldecisions.org> (noting high rates of lumbar spinal fusion surgery even though it is no better than non-surgical approaches or simpler surgeries).
175. D. Arterburn et al., "Introducing Decision Aids at Group Health Was Linked to Sharply Lower Hip and Knee Surgery Rates and Costs," *Health Affairs* 31, no. 9 (2012): 2094-2104; A. D. Kennedy et al., "Effects of Decision Aids for Mennor-

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aghia on Treatment Choices, Health Outcomes and Costs," *JAMA* 288, no. 21 (2002): 2701-2708.

176. D. Veroff et al., "Enhanced Support for Shared Decision Making Reduced Costs of Care for Patients with Preference-Sensitive Conditions," *Health Affairs* 32, no. 2 (2013): 285-293.
177. A. E. Volandes et al., "Randomized Controlled Trial of a Video Decision Support Tool for Cardiopulmonary Resuscitation Decision Making in Advanced Cancer," *Journal of Clinical Oncology* 31, no. 3 (2013): 380-386; A. E. Volandes et al., "A Randomized Controlled Trial of a Goals-of-Care Video for Elderly Patients Admitted to Skilled Nursing Facilities," *Journal of Palliative Medicine* 15, no. 7 (2012): 805-811; J. McCannon et al., "Augmenting Communication and Decision Making in the Intensive Care Unit with a Cardiopulmonary Resuscitation Video Decision Support Tool: A Temporal Intervention Study," *Journal of Palliative Medicine* 15, no. 12 (2012): 1382-1387; A. El-Jawahri et al., "Use of Video to Facilitate End-of-Life Discussions with Patients with Cancer: A Randomized Controlled Trial," *Journal of Clinical Oncology* 28, no. 2 (2010): 305-310.
178. The Lewin Group, *Bending the Curve: Technical Documentation* (New York: The Commonwealth Fund 2008), *available at* <http://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/3888.pdf> (last visited March 7, 2017); see also L. Trenamon, "The Cost Effectiveness of Patient Decision Aids: A Systematic Review," *Healthcare* 2, no. 4 (2014): 251-257.
179. R. A. Lindor et al., "Liability and Informed Consent in the Context of Shared Decision Making," *Academic Emergency Medicine* 23, no. 12 (2016): 1428-1433. There are several ways in which PDAs can reduce liability. For example, PDAs better enable patients to participate in their own healthcare, thus reducing the risk of injury in the first place. A complete analysis is beyond the scope of this Article.
180. B. Huntington and N. Kuhn, "Communication Gaffes: A Root Cause of Malpractice Claims," *Baylor University Medical Center Proceedings* 16, no. 2 (2003): 157-161; M. Colaco et al., "Influencing Factors Leading to Malpractice Litigation in Radical Prostatectomy," *Journal of Urology* 191, no. 6 (2014): 1770-1776.
181. D. Stacey et al., "Implementation of a Patient Decision Aid for for Men with Localized Prostate Cancer: Evaluation of Patient Outcomes and Practice Variation," *Implementation Science* 11, no. 87 (2016): 1-9.
182. See, e.g., P. J. Moore et al., "Medical Malpractice: The Effect of Doctor-Patient Relations on Medical Patient Perceptions and Malpractice Intentions," *Western Journal of Medicine* 173, no. 4 (2000): 244-250.
183. A. D. Spiegel and F. Kavaler, "Better Patient Communications Mean Lower Liability Exposure," *Managed Care* 6, no. 8 (Aug. 1997): 119-124.
184. The Joint Commission, "Informed Consent: More Than Getting a Signature," *Quick Safety* Issue 21 (February 2016), *available at* <https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf> (last visited February 1, 2017).
185. Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington, D.C.: National Academy Press, 2001).
186. See Alston et al., *supra* note 12.
187. *Id.*, at 12.
188. See Gillick, *supra* note 10.
189. L. Hole-Curry, *State Legislation Promotes Use of Shared Decisionmaking through Demonstration Project, Learning Collaborative and Recognition of Decision Aids as Informed Consent*, AHRQ Health Care Innovations Exchange (August 28, 2013), *available at* <https://innovations.ahrq.gov/profiles/state-legislation-promotes-use-shared-decisionmaking-through-demonstration-project-learning> (last visited February 1, 2017).
190. See Durand et al., *supra* note 143 ("The well-documented implementation challenge has led to significant interest in developing incentives..."); Trenamon, *supra* note 179; A. M. O'Connor et al., "Toward the Tipping Point: Decision Aids and Informed Patient Choice," *Health Affairs* 26, no. 3 (2007): 716-725; A. Engelen et al., "Patients' Views on Using Decision Support Tools: A Systematic Review," *European Journal for Person Centered Healthcare* 4, no. 1 (2016); C.A. Austin, "Tools to Promote Shared Decision Making in Serious Illness: A Systematic Review," *JAMA Internal Medicine* 175, no. 7 (2015): 1213-1221; J.A. Tulsky, "Decision Aids in Serious Illness: Moving What Works into Practice," *JAMA Internal Medicine* 175, no. 7 (2015): 1221-1222; C.L. Lewis et al., "Developing and Evaluating a Clinic-Based Decision Aid Delivery System," *MMD Policy & Practice* 1 (2016): 1–8; M.J. Barry, "Resolving the Decision Aid Paradox," *JAMA Internal Medicine* 175, no. 5 (2015): 799-800. See also C. E. Cox et al., "Development and Pilot Testing of a Decision Aid for Surrogates of Patients with Prolonged Mechanical Ventilation," *Critical Care Medicine* 40, no. 8 (2012): 2327-2334, at 2327 ("Although the use of shared decision making is endorsed by many major critical care professional societies, its implementation in the intensive care unit is incomplete and infrequent."); G. Sinha, "Decision Aids Help Patients but Still Are Not Widely Used," *Journal of the National Cancer Institute* 106, no. 7 (2014): 6-7; *Cf.* M. L. Schwarze and M. J. Nabozny, "How People Die in 2014," *Annals Surgery* 260, no. 6 (2014): 958-959 ("In contrast to the pace and complexity of technological innovation, innovation in communication has been nearly stagnant.").
191. See Alston et al., *supra* note 12, at 2.
192. *Id.*
193. See Hole-Curry, *supra* note 189.
194. "[T]he road to fully integrating SDM into clinical practice likely will be long and winding." Alston et al., *supra* note 12, at 25. While overall use remains low, PDAs are used in some facilities and systems, like the Massachusetts General Hospital and Seattle-based Group Health. See, e.g., K. R. Sepucha, "Ten Years, Forty Decision Aids, and Thousands of Patient Uses: Shared Decision Making at Massachusetts General Hospital," *Health Affairs* 35, no. 4 (2016): 630-636; M. Hostetter and S. Klein, *Quality Matters: Helping Patients Make Better Treatment Choices with Decision Aids*, The Commonwealth Fund (2012).
195. See A. Gawande, "Slow Ideas: Some Innovations Spread Fast. How Do You Speed the Ones That Don't?" *New Yorker* (July 29, 2013).
196. G. A. Lin et al., "An Effort to Spread Decision Aids in Five California Primary Care Practices Yielded Low Distribution, Highlighting Hurdles," *Health Affairs* 32, no. 2 (2013): 311-320; M. W. Friedberg, "A Demonstration of Shared Decision Making in Primary Care Highlights Barriers to Adoption and Potential Remedies," *Health Affairs* 32, no. 2 (2013): 268-275; V. A. Shaffer, "Why Do Patients Derogate Physicians Who Use a Computer-Based Diagnostic Support System?" *Medical Decision Making* 33, no. 1 (2013): 108-118; D. L. Frosch et al., "Authoritarian Physicians and Patients' Fear of Being Labeled 'Difficult' among Key Obstacles to Shared Decision Making," *Health Affairs* 31, no. 5 (2012): 1030-1038; see Gillick, *supra* note 10.
197. E. S. Spatz et al., "The New Era of Informed Consent: Getting to a Reasonable Patient through Shared Decision Making," *JAMA* 315, no. 19 (2016): 2063-2064. Health information technology can help overcome some of these barriers. For example, at Massachusetts General Hospital when providers enter a new problem into a patient's EHR, a reminder icon appears to indicate the available of a PDA. With a single click the PDA can be prescribed. See Fowler et al., *supra* note 10, at 701.
198. See Lin et al., *supra* note 196; F. Legare and H. Witteman, "Shared Decision Making: Examining Key Elements and Barriers to Adoption into Routine Clinical Practice," *Health Affairs* 32, no. 2 (2013): 276-284; Hole-Curry, *supra* note 189 (noting the "difficulty of changing entrenched practices" and "the high cost of many SDM tools"); CMS, "Beneficiary Engagement and Incentives: Shared Decision Making (SDM)

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Model," available at <https://innovation.cms.gov/initiatives/beneficiary-engagement-sdm> (last visited March 7, 2017) (citing "overworked physicians, insufficient practitioner training, inadequate clinical information systems, lack of consistent methods to measure that shared decision making is taking place, and uncertainty as to whether, or how, to promote change and invest in the time, tools, and training required to achieve meaningful shared decision making.").

199. See *supra* notes 139 to 140 and accompanying text.
200. Even before the ACA, the Empowering Medicare Choices Act would have required the U.S. Department of Health and Human Services to promulgate regulations establishing standards and requirements for shared decision making under Medicare, based on the results of a pilot program. H.R. 2580, 111th Cong., 1st Sess. (2009) (Blumenauer, D-Ore.); S. 1133, 111th Cong., 1st Sess. (2009) (Wyden, D-Ore.). The companion bills ultimately died in committee.
201. See Alston et al., *supra* note 12, at 2.
202. The stated purpose of this section of the Affordable Care Act is to "facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages [sic] the patient, caregiver or authorized representative in decision making, provides patients, caregivers or authorized representatives with information about treatment options, and facilitates the incorporation of patient preferences and values into the medical plan." 42 U.S.C. § 299b-36(a).
203. 42 U.S.C. § 299b-36(d).
204. 42 U.S.C. § 299b-36(e).
205. See *infra* Section VI.D. The intended entity appears to have been the National Quality Forum.
206. 42 U.S.C. § 299b-36(e).
207. In addition to those measures described below, Section 3013 of ACA authorizes DHHS to award grants to develop, improve, update, or expand "quality measures." 42 U.S.C. § 299b-31. Section 3013 directs DHHS to prioritize those measures that allow the assessment of "use of shared decision making tools." 42 U.S.C. § 299b-31(c)(2).
208. ACA § 3021, *codified at* 42 U.S.C. § 1315a(a).
209. 42 U.S.C. § 1315a(a).
210. 42 U.S.C. § 1315a(c).
211. 42 U.S.C. § 1315a(b)(2)(B)(ix).
212. See Acumen, *Evaluation of the Shared Decision Making (SDM) & Medication Management (MM) Health Care Innovation Awardees: Second Annual Report* (March 2016), *available at* <https://downloads.cms.gov/files/cmmi/hcia-shareddecisionmakingmedicationmnmgt-secondevalrpt.pdf> (last visited February 2, 2017).
213. Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation, "Health Care Innovation Awards," *available at* <http://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/> (last visited February 2, 2017).
214. Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation, "Healthcare Innovation Award Project Profiles," *available at* <http://innovation.cms.gov/Files/x/HCIA-Project-Profiles.pdf> (last visited February 2, 2017). A search of the document for the term "decision" turned up a handful of projects with a focus on implementation of shared decision making models, including: (1) MedExpert International, Inc.'s Quality Medical Management System, (2) the Trustees of Dartmouth College's "Patient and Family Activators" project, and (3) Welvie, LLC's "Shared decision making for preference-sensitive surgery" project. [update] 215 42 U.S.C. § 299b-7; USHHS, AHQR, "Who Is Involved in the Effective Health Care Program," *available at* <http://www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/> (last visited February 2, 2017); USHHS, AHQR, "Grants On-Line Database," *available at* <http://gold.ahrq.gov/projectsearch/grant_search.jsp> (last visited February 2, 2017). Search in abstract title field for "decision aid" or "decision tool" for AHRQ-funded projects related to patient decision aids.
216. USHHS, AHQR, "Patient Decision Aids," *available at* <http://effectivehealthcare.ahrq.gov/index.cfm/tools-and-resources/patient-decision-aids/> (last visited February 2, 2017).
217. R. Fleurence et al., "How The Patient-Centered Outcomes Research Institute Is Engaging Patients and Others in Shaping its Research Agenda," *Health Affairs* 32, no. 2 (2013): 393-400.
218. ACA § 6301, *codified at* 42 U.S.C. § 1320e.
219. Patient-Centered Outcomes Research Institute, *National Priorities for Research and Research Agenda* (May 21, 2012), *available at* <http://www.pcori.org/assets/PCORI-National-Priorities-and-Research-Agenda-2012-05-21-FINAL.pdf> (last visited February 2, 2017).
220. Patient-Centered Outcomes Research Institute, *PCORI PFA Cycle I Awardees* (December 21, 2012), *available at* <http://www.pcori.org/assets/PFA-Awards-Cycle-1-2012.pdf> (last visited February 2, 2017). At least two studies sought to assess whether decision aids improved the quality of decision making or clinical outcomes (for pediatric type I diabetes, *Shared Medical Decision Making in Pediatric Diabetes*; for chest pain patients in the emergency department, *Shared Decision Making in the Emergency Department: The Chest Pain Trial*, at 4). One study sought to develop a decision tool to inform the medical decision making of parents of children with disorders of sex development (*Decision Support for Parents Receiving Genetic Information about Child's Rare Disease*, at 21).
221. See Alston, *supra* note 12. Current trends suggest that over the next few years, policymakers will further clarify that treatment inconsistent with patient preferences is treatment without benefit. As that proposition becomes more widely accepted, healthcare providers will find it more difficult (if not impossible) to obtain public or private reimbursement for tests and procedures administered without adequate informed consent. Already, two "Stage Two" use "meaningful use" criteria focus on better patient engagement: "7. Provide patients the ability to view online, download and transmit their health information…17. Use secure electronic messaging to communicate with patients on relevant health information." Centers for Medicare and Medicaid Services, *Eligible Professional's Guide to STAGE 2 of the EHR Incentive Programs* (September 2013): at 14, *available at* <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2_Guide_EPs_9_23_13.pdf> (last visited February 2, 2017).
222. See DHHS 2014; Durand et al., *supra* note 143; E. O. Lee and E. J. Emanuel, "Shared Decision Making to Improve Care and Reduce Costs," *New England Journal of Medicine* 368, no. 1 (2013): 6-8.
223. See R. Winslow, "Heart Beat: Medicare Asks: What Does the Patient Think Is Best?" *Wall Street Journal*, August 9, 2016.
224. Centers for Medicare & Medicaid Services (CMS), "Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N)," *available at* <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274> (last visited February 2, 2017).
225. Centers for Medicare and Medicaid Services, "Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N)," *available at* <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281> (last visited February 2, 2017).
226. *Cf.* DHHS, "Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services Tuesday," *Federal Register* 80 (November 24, 2015): 73,274-73,554, 73,502 ("Many commenters recommended…the use of certified or patient-reported outcome decision aids…Based on the comments we received, we will consider the future development of measures related to shared decision making. Should we decide to implement a shared decision making measure in the future, we will do so through notice-and-comment rulemaking."). On the other hand, CMS sometimes

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seems to miss the point of PDAs. For example, a commenter recommended a PDA for dialysis. But CMS simply responded that it "encourages nephrologists and dialysis facilities to discuss treatment options with their patients on an ongoing basis." DHHS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program," *Federal Register* 80, (Nov. 6, 2015): 68,968-69,077, 69,036.

227. ACA § 3022, *codified at* 42 U.S.C. § 1395jjj.
228. ACA § 3022, *codified at* 42 U.S.C. § 1395jjj(a-b).
229. ACA § 3022, *codified at* 42 U.S.C. § 1395jjj(b) & (d).
230. ACA § 3022, *codified at* 42 U.S.C. § 1395jjj(b)(2)(G).
231. Department of Health & Human Services, "Final Rule: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations," *Federal Register* 76 (November 2, 2011): 67,802-67,990, at 67,828.
232. CMS SDM Model, *supra* note 199.
233. A. Shafir and J. Rosenthal, *Shared Decision Making: Advancing Patient-Centered Care through State and Federal Implementation* (2012), Informed Medical Decisions Foundation; D. L. Frosch et al., "Shared Decision Making in the United States: Policy and Implementation Activity on Multiple Fronts," *German Journal for Evidence and Quality in Health Care* 105, no. 4 (2011): 305-312.
234. J. King and B. Moulton, "Group Health's Participation in a Shared Decision-Making Demonstration Yielded Lessons, Such as Role of Culture Change," *Health Affairs* 32, no. 2 (2013): 294-302.
235. 2012 Mass. Acts. Ch. 224 § 19, *codified at* Mass. Gen. Laws Ann. 12C § 20.
236. Vt. S.B. 129 (2009) (Lunge); *enacted as* 2009 Act 49.
237. Vermont Department of Health, "VERMONT2009: Shared Decision Making: Report to the Legislature on Act 49, Section 4," January 15, 2010, *available at* <http://www.leg.state.vt.us/reports/2010ExternalReports/252637.pdf> (last visited February 2, 2017).
238. Me. LD 1358 (2009) (Mills), *enacted as* 2009 Maine Laws Ch. 104. The original bill would have required health insurance carriers and the Maine Care program to implement shared decision making.
239. Shared Decision Making Study Group for the Dirigo Health Agency's Maine Quality Forum, *The Practice and Impact of Shared Decision Making* (February 2011), *available at* <http://muskie.usm.maine.edu/Publications/PHHP/Shared-Decision-Making_Final-Report.pdf> (last visited February 2, 2017).
240. "INFORMED CONSENT: Guidelines from the Maine Board of Licensure in Medicine," *available at* <maine.gov/md/law-statutes/policies.html> (last visited March 7, 2017).
241. Minn. Admin. Rules 4764.0040.
242. N.J. A.B. 2867 (2016) (Singleton).
243. *Id.* (emphasis added).
244. Conn. H.B. 5193 (2009) (Sayers); Okla. S.B. 1002 (2012) (Adelson).
245. Minn. S.F. 696, 86th Legis. Sess. (2009); Minn. H.F. 1140, 86th Legis. Sess. (2009); Minn. S.F. 542, 87th Legis. Sess. (2011) (Berglin).
246. See *infra* notes 151 to 168.
247. The American Medical Association Council on Medical Services notes that "the clinical quality and ethical design of patient decision aids will become increasingly important as the concept of shared decision making gains popularity." See McAneny, *supra* note 147. Legal commentators have also indicated the need for "credentialed, neutral bodies" to approve the information provided by patient decision aids to address the real potential for "biased" or "misleading" decision aids. See King and Moulton, *supra* note 234.
248. See Hole-Curry, *supra* note 189.
249. J. W. Altschild, *Accreditation, Certification, and Credentialing: Relevant Concerns for U.S. Evaluators: New Directions for Evaluation* (Washington, DC: American Evaluation Association and Jossey-Bass, 2015).
250. See Alston et al., *supra* note 12, at 15.
251. Commentators have expressed similar concerns about the development of clinical practice guidelines. See, e.g., R. Avraham, "Overlooked and Underused: Clinical Practice Guidelines and Malpractice Liability For Independent Physicians," *Connecticut Insurace Law Journal* 20, no. 2 (2014): 273-333; R. Avraham, "Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System," *American Journal of Law & Medicine* 37, no. 1 (2011): 7-40; M. J. Mehlman, "Medical Practice Guidelines as Malpractice Safe Harbors: Illusion or Deceit?" *Journal of Law, Medicine & Ethics* 40, no. 2 (2012): 286-300. Advance directives are also often developed by non-clinicians, yet meant for implementation by clinicians.
252. See Alston et al., *supra* note 12, at 14 ("quality varies widely").
253. See *supra* Section V.A.
254. U. Poddar et al., "Patient Decision Aids: A Case for Certification at the National Level in the United States," *Journal of Clinical Ethics* 26, no. 4 (2015): 306-311.
255. Austin, *supra* note 191; Tulsky, *supra* note 191; Poddar, *supra* note 254, at n.3.
256. Poddar, *supra* note 254; Volandes, *supra* note 75, at 80 ("As with all new technologies, issues regarding quality control will arise…How can be adequately evaluate [PDAs] regarding content, objectivity, point of view, and authenticity?"). Similar calls for clinical practice guidelines. C. Taylor, "The Use of Clinical Practice Guidelines in Determining Standard of Care," *Journal of Legal Medicine* 35, no. 2 (2014): 273-290. (describing efforts to evaluate the growing number of CPGs such as AGREE and the National Guidelines Clearinghouse); The AGREE Collaboration, "Development and Validation of an International Appraisal Instrument for Assessing the Quality of Clinical Practice Guidelines," *Quality and Safety in Health Care* 12, no. 1 (2003): 18-23; USDDS, AHQR, "National Guideline Clearinghouse," *available at* <http://www.guideline.gov> (last visited February 2, 2017).
257. N. Sawicki, "Patient Protection and Decision-Aid Quality: Regulatory and Tort Law Approaches," *Arizona Law Review* 54, no. 3 (2012): 621-672. Regardless of whether the trend toward shared decision making and the emergence of patient decision aids effectively address all the problems associated with the traditional informed consent framework, it is clear that these changes have important legal implications.
258. *Id.* (Sawicki), at 633-635.
259. *Id.*, at 627.
260. *Id.*
261. See Alston et al., *supra* note 12, at 15.
262. G. Elwyn et al., "Trustworthy Patient Decision Aids: A Qualitative Analysis Addressing the Risk of Competing Interests," *BMJ Open* 6, no. 9 (2016): e012562. *Cf.* Avraham (2011), *supra* note 251 (discussing conflicts of interest concerning clinical practice guidelines).
263. See McAneny, *supra* note 147, at 4; S. F. Hansen, "The Role of Decision Aids in the Affordable Care Act," *Stanford Journal of Public Health* (2013), *available at* <http://web.stanford.edu/group/sjph/cgi-bin/sjphsite/the-role-of-decision-aids-in-the-affordable-care-act/> (last visited February 2, 2017).
264. See Sawicki, *supra* note 257, at 634.
265. *Id.*, at 634-635.
266. *Id.*, at 626.
267. Jaime Staples King and Benjamin Moulton assert that, "a rigorous accreditation process [for patient decision aids], such as the Cochrane System Review, is necessary to protect the interests of physicians and patients." They note that "[w]hile many creators of decision aids have spent significant time and resources developing their instruments and techniques, these efforts have largely been ad hoc and may differ substantially from one another. Additionally, these aids may be biased toward or against treatments." See King and Moulton, *supra* note 44, at 490.
268. See Brehaut et al., *supra* note 10; Wennberg, *supra* note 2.
269. G. Elwyn et al., "Developing a Quality Criteria Framework for Patient Decision Aids: Online International Delphi Consensus

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Process," *BMJ* 333, no. 7565 (2006): 417, 1-6; IPDAS, *available at* <http://ipdas.ohri.ca/> (last visited February 2, 2017).
270. G. Elwyn et al., "Assessing the Quality of Decision Support Technologies Using the International Patient Decision Aid Standards Instrument (IPDASi)," *PLOS ONE* 4, no. 3 (2009): e4705, 1-9.
271. Ottawa Hospital Research Institute, "Decision Aid Library Inventory (DALI)," *available at* <http://decisionaid.ohri.ca/cochinvent.php> (last visited February 2, 2017). For an exploration of the decision aids in the Ottawa Hospital Research Institute's Library, see <http://decisionaid.ohri.ca/AZinvent.php> (last visited February 2, 2017).
272. The Joint Commission, *Facts about Federal Deemed Status and State Recognition* (Nov. 18, 2015), <https://www.jointcommission.org/facts_about_federal_deemed_status_and_state_recognition/> (last visited February 2, 2017).
273. Wash. Rev. Code § 41.05.033(1).
274. Wash. S.B. 5930 (2007), *enacted as* 2007 Laws Ch. 259, *codified at* Wash. Rev. Code § 41.05.033. As discussed below, the 2007 legislation also amended state informed consent liability law. Wash. Rev. Code § 7.70.060.
275. *Id.*
276. Wash. H.B. 1311 (2011), *enacted as* 2011 Laws Ch. 313, *codified at* Wash. Rev. Code § 70.250.050(1). See Dr. Robert Bree Collaborative, *available at* <http://www.breecollaborative.org> (last visited February 2, 2017).
277. Wash. Rev. Code § 70.250.050(3).
278. Wash. Rev. Code § 7.70.060(4).
279. Wash. H.B. 2318 (2012), *enacted as* 2012 Laws Ch. 101, *codified at* Wash. Rev. Code § 7.70.060(4).
280. Wash. Admin. Code §§ 182-60-005 to -030.
281. Wash. Admin. Code §§ 182-60-025(5).
282. Wash. Admin. Code §§ 182-60-030.
283. Washington State Health Care Authority, "Shared Decision Making," *available at* <http://www.hca.wa.gov/about-hca/healthier-washington/shared-decision-making> (last visited February 2, 2017).
284. See *supra* notes 270-271.
285. See *supra* note 283.
286. Washington State Health Care Authority, "Patient Decision Aid Certification Criteria," *available at* <http://www.hca.wa.gov/assets/program/sdm_cert_criteria.pdf> (last visited March 7, 2017). Additional Criteria for Screening and/Testing, if applicable, require the PDA to: (1) describe what the test is designed to measure, (2) describe next steps taken if test detects a condition/problem, (3) describe next steps if no condition/problem detected, (4) describe consequences of detection that would not have caused problems if the screen was not done, (5) include information about chances of true positive result, (6) include information about chances of true negative result, (7) include information about chances of false negative result. *Id.*
287. These are specified in an attachment to the application materials.
288. Washington State Health Care Authority, *supra* note 287. *See also* T. M. Pope and D. S. Lessler, "Revolutionizing Informed Consent: Empowering Patients with Certified Decision Aids," *The Patient — Patient Centered Outcomes Research* 10 (forthcoming 2017).
289. Washington State Health Care Authority, "Patient Decision Aids (PDAs)," *available at* <http://www.hca.wa.gov/about-hca/healthier-washington/patient-decision-aids-pdas> (last visited February 2, 2017).
290. See Hostetter and Klein, *supra* note 194 ("To achieve implementation of [PDAs]…it will take some combination of leadership commitment, financial support, clinician support, and possibly external pressure via performance measurement or legislative mandate.") (quoting Karen Sepucha).
291. Wash. Rev. Code § 7.70.060.
292. This is my own ballpark estimate. The law does not assign specific percentage values to various burdens of persuasion. J. P. McBaine, "Burden of Proof Degrees of Belief," *California Law Review* 32, no. 3 (1944): 242-268. But in one survey of judges, most selected 75% as the appropriate percentage value for "clear and convincing evidence." M. B. Steinberg, "Burdens of Persuasion: Burdened by Too Many Burdens," *Baltimore Law Forum* 23, no. 2 (1992): 3-8, at 6.
293. See Avraham (2014), *supra* note 251; see Taylor, *supra* note 256.
294. Tex. Civ. Pr. & Rem. Code § 74.106.
295. Wash. Rev. Code § 7.70.040. See M. Huckaby Lewis et al., "The Locality Rule and the Physician's Dilemma Local Medical Practices vs the National Standard of Care," *JAMA* 297, no. 23) (2007): 2633-2637.
296. *New State Ice Co. v. Liebmann*, 285 U.S. 262 (1932).
297. See Alston et al., *supra* note 12, at 18.
298. *Empowering Medicare Patient Choices Act*, S. 1133, 111th Cong., 1st Sess. (2009) (Wyden); H.R. 2580, 111th Cong., 1st Sess. (2009) (Blumenauer).
299. The bill directed the certification entity to prioritize PDAs for: (1) arthritis of the hip and knee, (2) chronic back pain, (3) chest pain (stable angina), (4) enlarged prostate (benign prostatic hypertrophy, or BPH), (5) Early-stage prostate cancer, (6) early-stage breast cancer, (7) end-of-life care, (8) peripheral vascular disease, (9) gall stones, and (10) threat of stroke from carotid artery disease.
300. *Patient Protection and Affordable Care Act*, Pub. L. No. 111-148 (2010), § 3506, codified at 42 U.S.C. § 299b-36.
301. On the other hand, as discussed above, CMS has incorporated shared decision making as a quality measure benchmark into several programs. See *supra* notes 221 to 232 and accompanying text.
302. Gordon & Betty Moore Foundation, *NQF to Develop National Standards, Measurement for Patient Decision Aids* (January 4, 2016), *available at* <https://www.moore.org/article-detail?newsUrlName=nqf-to-develop-national-standards-measurement-for-patient-decision-aids> (last visited February 2, 2017).
303. National Quality Forum, "Decision Aids Project," *available at* <http://www.qualityforum.org/Decision_Aids.aspx> (last visited February 2, 2017).
304. National Quality Forum, "About Us," *available at* <http://www.qualityforum.org/About_NQF/> (last visited February 2, 2017).
305. The NQF is known for having developed a list of 28 medical errors it deemed serious reportable events (more commonly referred to as "never events").
306. National Quality Forum, "National Standards for the Certification of Patient Decision Aids," (Dec. 15, 2016), *available at* <http://www.qualityforum.org/Publications/2016/12/National_Standards_for_the_Certification_of_Patient_Decision_Aids.aspx > (last visited March 7, 2017).
307. See Lee and Emanuel, *supra* note 222, at 7.
308. *Cf.* Gillick, *supra* note 10 ("Decision aids are perhaps the best hope for rescuing shared decision making from the fate of being a great idea that failed.").

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