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# Informed Consent Beyond the Physician-Patient Encounter: Tort Law Implications of Extra-Clinical Decision Support Tools.

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evolving informed consent practices.

### I. SHARED DECISION-MAKING AND THE DEVELOPMENT OF EXTRA-CLINICAL DECISION SUPPORT TOOLS

The shared decision-making (“SDM”) movement developed over the past thirty years as a response to growing disenchantment with existing informed consent practices among the medical and patient communities. Spurred in part by Jack Wennberg’s influential research on practice variations in preference-sensitive care,<sup>1</sup> the SDM movement seeks to assist patients in choosing among medical interventions when clinical evidence alone does not identify a favored option. The SDM model has been touted as potentially improving patient satisfaction, clinical outcomes, cost of care, and physician time management. The American Medical Association (“AMA”) notes that use of SDM “could help improve the medical liability climate” by reducing the practice of defensive medicine.<sup>2</sup> The 2010 Salzburg Statement on Shared Decision Making describes the use of SDM as “an ethical imperative” for clinicians,<sup>3</sup> and the United States’ recent health reform promotes SDM as a model for clinical practice.<sup>4</sup>

The SDM model is able to accomplish these goals in part by virtue of its reliance on decision support tools to supplement the conversation between physician and patient. Decision support tools can take a variety of forms, including brochures, videos, interactive websites, and CD-ROMs, as well as “structured personal coaching” with a trained intermediary.<sup>5</sup> These tools “collect and analyze the latest clinical evidence regarding the risks and benefits of different treatment options,” including why there may be a lack of evidence to support one treatment over another, “and then present the information in a manner patients can understand.”<sup>6</sup> Unlike traditional

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1. *See generally*, JOHN E. WENNBURG, *TRACKING MEDICINE: A RESEARCHER’S QUEST TO UNDERSTAND HEALTH CARE* (Oxford 2010).

2. BARBARA L. MCANENY, REPORT OF THE AMA COUNSEL ON MEDICAL SERVICE, CMS REPORT 7-A-10, SHARED DECISION-MAKING 4, *available at* <http://www.ama-assn.org/resources/doc/cms/a10-cms-rpt-7.pdf>.

3. The author was one of 58 people from 18 countries who attended a Salzburg Global Seminar in December 2010 to consider the role patients should play in healthcare decisions. The Salzburg Statement on Medical Decision Making is the result of this collaboration. It is forthcoming in the *British Medical Journal*, and is currently available at <http://www.bmj.com/content/342/bmj.d1745.full.pdf>.

4. Patient Protection and Affordable Care Act, Pub. L. 111-148, § 3506 [hereinafter PPACA].

5. MCANENY, *supra* note 2, at 2.

6. Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 464 (2006). *See also* PPACA § 936 (“The term ‘patient decision aid’ means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care

informed consent documents, however, decision aids not only provide factual information, but also assist patients in identifying the values and preferences that are important to them, and guiding them in the process of matching their values with available treatment options. Decision support tools are available for a variety of clinical conditions; the most common ones address the treatment of breast cancer, prostate cancer, osteoarthritis and osteoporosis, childbirth, and end of life care.

While some decision support tools are used by physicians in face-to-face clinical encounters, many are intended for independent patient use.<sup>7</sup> Often, a physician may “prescribe” such a tool for the patient to review before her next appointment, which then better prepares the patient for the in-office informed consent conversation.<sup>8</sup> Decision aids are intended as complements to, not replacements for, the physician-patient interaction. They encourage the patient to engage in a deliberative process earlier and more thoroughly than in traditional informed consent practice.

This article focuses primarily on SDM, which, given its reliance on decision aids and third-party coaching, may be the most obvious example of the gradual shift towards the use of extra-clinical tools to supplement the informed consent process. However, SDM’s use of decision support tools is part of a much larger trend. One of the earliest examples of this shift occurred in the mid-1970’s, with the involvement of genetic counselors in patient decisions about genetic testing, treatment, and reproductive options. Although primary care physicians would often order genetic tests for their patients, these physicians were not always best situated to counsel patients about the implications of testing. As a result, many would arrange for genetic counseling by other health professionals (often trained in masters’ level programs) who would assist the patient in choosing an appropriate course of action. A more modern example of extra-clinical informed consent tools is the state-written abortion pamphlet, which many states require patients to review as part of the informed consent process. While state laws require that these pamphlets be distributed in physicians’ offices, at least one state has taken more extreme steps to exclude medical providers from the informed consent process – Michigan allows a woman seeking an abortion to complete the consent process entirely online, by clicking through information on the internet, printing out a confirmation of completion, and presenting it to her physician.

This shift away from the traditional physician-patient model of informed

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provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.”).

7. See Glyn Elwyn et al., *Investing in Deliberation: A Definition and Classification of Decision Support Interventions for People Facing Difficult Health Decisions*, 30 MED. DECISION MAKING 701, 703 (2010).

8. MCAHENY, *supra* note 2, at 3.

consent is grounded in distinct concerns about physicians' ability to execute the informed consent process effectively. Concerns range from the physicians' lack of time to engage in comprehensive informed consent conversations, to a lack of communication skills, to societal pressures towards incorporating third party values into the medical encounter. Whatever the reasons for this trend, however, it has dramatically changed existing models of informed consent and, in turn, their legal implications.

## II. EXISTING LIABILITY CONCERNS

Despite the promise of SDM and its incorporation of extra-clinical tools into the informed consent encounter, real-world implementation of SDM has been limited, in part due to liability concerns. Some commentators fear that physicians who use SDM may be opening themselves up to expanded tort liability for deviating from the existing standard of care. Articles in both legal and medical journals advocating the use of SDM and patient decision aids typically cite the possibility of physician liability as a barrier to implementation.<sup>9</sup> Legislators in at least one state have responded to these concerns by providing additional statutory protections for physicians who use SDM. Washington, which defines SDM as the process by which a patient and her health care provider discuss information about proposed treatment “with the use of a patient decision aid,”<sup>10</sup> establishes a legal presumption in favor of the physician when SDM is used. The Washington law provides that a patient’s signature on an “acknowledgement of shared decision making” constitutes *prima facie* evidence of informed consent that can only be rebutted by clear and convincing evidence.<sup>11</sup> In contrast, a patient who signs a traditional informed consent form need only satisfy a preponderance of evidence standard to rebut the presumption of consent. As commentators have noted, Washington’s approach provides physicians who use decision support tools in accordance with SDM “significant legal protection” above and beyond that provided by traditional informed consent

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9. In 2008, for example, the Journal of Law, Medicine & Ethics published the results of a study evaluating potential jurors’ reactions to a hypothetical SDM malpractice suit. Michael J. Barry et al., *Reactions of Potential Jurors to a Hypothetical Malpractice Suit Alleging Failure to Perform a Prostate-Specific Antigen Test*, 36 J.L. MED. & ETHICS 396 (2008). The study varied the level of disclosure by the physician, specifically varying the types of decision aids the patient was exposed to. *Id.* See also, Elwyn et al., *supra* note 7, at 704 (“[I]t seems only a matter of time until the legal accountabilities of patient decision support interventions will need further specification.”); Benjamin Moulton & Jaime S. King, *Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice*, 38 J.L. MED. & ETHICS 85, 92 (2010) (suggesting that providing legislative protections for physicians who use SDM, as was recently done in Washington State, would facilitate SDM implementation).

10. Wash. Rev. Code § 7.70.060(3) (2011).

11. *Id.*

laws.<sup>12</sup>

### III. THE EXPANDING SCOPE OF LIABILITY FOR EXTRA-CLINICAL INFORMED CONSENT

Limiting liability for physicians who use decision aids as part of SDM is an important first step in developing a legal regime that accommodates extra-clinical informed consent. However, because existing concerns about physician liability are only part of a multitude of potential legal challenges to the implementation of this model, legislative responses such as Washington's may be inadequate. In moving the locus of informed consent outside the clinical encounter, SDM fundamentally changes the nature of informed consent practice – and, therefore, its legal risks. First, it expands the scope of traditional malpractice liability for participating medical providers. Second, it raises additional legal risks associated with faulty decision aids.

#### A. *Expanded Liability for Participating Medical Providers*

Physicians have long faced tort liability for breach of informed consent if a patient is harmed as a result of the physician's failure to provide the information needed to make an informed medical decision. However, with increased reliance on extra-clinical informed consent mechanisms comes an increased risk of malpractice liability.

First, a physician might face liability for over-reliance on patient decision aids. While decision aids are designed to support (rather than replace) the physician-patient conversation, one can imagine the SDM process going the way of traditional informed consent, with physicians relying on documentation at the expense of discussion. The physician who simply instructs her patient to consult a decision aid and then asks for the patient's decision at the next appointment would, under even the most traditional tort principles, be liable for malpractice. Failure to engage fully in the informed consent process, even if decision support tools are made available, is a clear breach of the standard of care for both traditional informed consent and SDM.

Second, because SDM may involve patient consultation and discussion with other medical personnel – including nurses, social workers, counselors, and decision coaches – the risk of informed consent liability will also be expanded to these providers. A patient who is harmed as a result of receiving misinformation, biased information, or inadequate guidance from a decision coach might bring suit against this person in addition to the patient's physician. In the context of genetic counseling, for

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12. Moulton & King, *supra* note 9, at 92.

example, patients have sometimes sought to recover against genetic counselors whose negligence makes it impossible for the patient to make a truly informed choice, even where the counseling is non-directive in nature.

### *B. Liability Associated with Faulty Decision Aids*

A more significant source of expanded liability may arise if a decision aid used in the SDM process is faulty, misleading, or biased. While providing outdated or otherwise factually incorrect information is always a risk in informed consent, decision aids also pose a significant possibility of explicit or implicit bias. The AMA, for example, has expressed concern about the creation of decision support tools that are “misleading or biased toward or against certain treatment choices,” perhaps with the goal of “encourag[ing] patients to choose less expensive options.”<sup>13</sup> The risk of bias may be even greater when the decision at issue is highly controversial, such as end-of-life care or abortion. For example, many state pamphlets designed to educate women about the abortion process appear to favor pregnancy over abortion, either explicitly or implicitly, by means of biased framing of facts and inclusion of images or other information not typically provided in traditional informed consent.<sup>14</sup>

Virtually all commentators who have written about SDM recognize that the success of a process that relies greatly on extra-clinical tools and materials is dependent on the quality of those materials. For this reason, some private organizations provide oversight and evaluation of decision support tools, particularly with respect to potential conflicts of interest by the creators.<sup>15</sup> More importantly, the Patient Protection and Affordable Care Act’s (“PPACA”) provisions supporting the use of SDM provide for the establishment of a committee of “a broad range of experts and key stakeholders” that will develop “consensus-based standards” for evaluating and certifying patient decision aids.<sup>16</sup> Such regulatory mechanisms are clearly aimed at ensuring that decision support tools are accurate and unbiased. However, it is naïve to think that regulatory and certification standards alone will be absolutely effective in ensuring quality. If the certification process fails for any reason – whether as a result of bias, industry capture, or simple human error – patients using faulty decision aids may be harmed. And because the current tort system, described below, makes it quite difficult for patients in this situation to recover from decision

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13. MCANENY, *supra* note 2, at 4.

14. *See generally*, Nadia N. Sawicki, *The Abortion Informed Consent Debate: More Light, Less Heat*. 21 CORNELL J.L. & PUB. POL’Y (forthcoming, 2011)

15. Examples of such organizations include the Ottawa Hospital Research Institute, the International Patient Decision Aid Standards (IPDAS) Collaboration, and the New America Foundation. *See generally*, MCANENY, *supra* note 2, at 3.

16. PPACA § 936(c).

aid creators, certifiers, or physician users, patients will have few opportunities for compensation to make them whole. Accordingly, it is not unreasonable to expect that the tort system will soon shift to accommodate claims by patients who are harmed by faulty decision aids. This section explores these possibilities.

### 1. Decision Aid Creators

When a patient suffers a legally-cognizable harm as a result of using an inaccurate, biased, or otherwise faulty decision aid, she may wish to pursue a tort claim against the creator of the decision aid. For a number of reasons, however, it is very unlikely that such a claim would succeed.<sup>17</sup>

First, although products liability law sometimes subjects creators of faulty products to strict liability (that is, liability regardless of fault), decision support tools do not fall within the legal definition of a “product” and so are not subject to strict liability. Written pamphlets, brochures, and books occupy a unique position in modern tort law. Courts have consistently held that strict liability will not apply where harm arises as a result of the words or ideas within a book or similar product. As the Ninth Circuit wrote in *Winter v. G.P. Putnam’s Sons*, “[w]e place a high value on the unfettered exchange of ideas. . . . The threat of liability without fault could seriously inhibit those who wish to share thoughts and theories.”<sup>18</sup>

Given that strict liability is not an option, the most promising alternative may be to bring suit against the author or publisher under a theory of negligent misrepresentation. However, most negligent misrepresentation claims against authors and publishers of informational brochures fail for lack of privity. Authors of books aimed at the general public, for example, have consistently been found to owe no duty of care to readers, even where the book provides instructions and information about improving one’s health.<sup>19</sup> In *Roman v. City of New York*, the only case this author was able to identify dealing with medical publications, plaintiff brought a negligent misrepresentation claim against Planned Parenthood on the basis of faulty

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17. The limitations on liability for creators of faulty medical tools has already been recognized in the context of clinical practice guidelines. See generally Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J.L. & MED. 7 (2011); Daniel Jutras, *Clinical Practice Guidelines as Legal Norms*, 148 CAN. MED. ASS’N. J. 905, 908 (1993).

18. *Winter v. G.P. Putnam’s Sons*, 938 F.2d 1033, 1035 (9th Cir. 1991) (affirming district court’s grant of summary judgment to defendant, publisher of a mushroom encyclopedia that allegedly caused plaintiff’s collection and ingestion of toxic mushrooms).

19. See, e.g., *Gorran v. Atkins Nutritionals, Inc.*, 464 F.Supp.2d 315 (S.D.N.Y. 2006) (plaintiff injured by high-fat and high-protein diet failed to demonstrate a duty on the part of defendant, a diet advocate and author); *Bailey v. Huggins Diagnostic*, 952 P.2d 768 (Colo. App. 1997) (no duty owed by dentist who wrote a book encouraging removal of dental amalgams).

information provided in a booklet she was given at her physician's office. The court found no duty on the part of Planned Parenthood, noting that the defendant "pointedly intended the booklet to provide information to the general public, including plaintiff, and the fact that it could have reasonably foreseen plaintiff's reliance thereon, does not change the result. . . . [T]he relational duty sufficient to give rise to a cause of action in negligent misrepresentation is not present."<sup>20</sup> Based on this precedent, it is extremely unlikely that a company that creates decision aids for use by medical consumers would be found to owe a duty of care to the users of these decision aids under existing tort law.

Patients raising tort claims against creators of faulty decision aids are likely to face problems of proof as well. While it may be easy to prove that factual information included in a decision aid is incorrect or outdated, patients alleging bias or misrepresentation may have trouble convincing a jury that such bias rises to the level of negligent misrepresentation or fraud. For example, although studies clearly establish that presenting risk in absolute, rather than relative terms is more effective when communicating information to patients, a jury may be unwilling to impose liability based on a difference in framing. Moreover, as in many informed consent cases, the patient may have difficulty proving causation – namely, that had the decision aid been different, a reasonable patient would not have been harmed.

## 2. Decision Aid Certifiers

Given that the likelihood of liability for creators of faulty decision support tools is currently limited, patients who are harmed by these tools may wish to pursue claims against any certifying bodies that approved the tools for patient use.

PPACA, for example, envisions that patient decision aids would be certified by an independent committee of impartial experts, who would also be responsible for establishing relevant standards. Although the details of the process are as yet unspecified, PPACA provides that the committee would be part of an entity under contract with the Federal government.<sup>21</sup>

However, these entities are unlikely to face tort liability for the certification of faulty decision aids. If the certifying body is a government agency, its liability would be clearly preempted by Tort Claims Act, as is the case with the Food and Drug Administration, Environmental Protection Agency, and other agencies responsible for establishing and enforcing regulatory standards. If, instead, the certifying body is a private

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20. *Roman v. City of New York*, 442 N.Y.S. 2d 945 (Sup. Ct. 1981).

21. PPACA § 936(c).



organization, the privity considerations applicable to decision aid creators (described above) are likely to limit liability. Generally, third parties who guarantee or endorse a product whose primary purpose is the circulation of information to consumers or the general public will not face liability unless privity is established.

### 3. Physician and Institutional Users of Decision Aids

Finally, a patient harmed by a faulty decision aid might seek tort recovery against the physician who recommended or prescribed it. Such liability would presumably be grounded in the learned intermediary doctrine, which establishes that physicians' special knowledge of medical practice may, in some cases, relieve product manufacturers and information providers (typically, pharmaceutical companies that distribute package inserts) from liability. Where the information provided by the product manufacturer itself is faulty, however, it is unclear whether physicians will be liable. Liability may depend in part on whether the physician read or reviewed the information before providing it to the patient. Ultimately, these decisions come down to a weighing of competing policy factors – on the one hand, that physicians are entitled to rely on the advice of third parties and should not bear liability for the negligence of those over whom they have no control, and on the other, that physicians ought not abdicate their duty to provide quality care just because they are relying on third-party information. Similar arguments can be raised with respect to institutional enterprise liability – for example, if a hospital system requires physicians to use decision aids as part of the informed consent process for particular conditions.

## IV. CONCLUDING THOUGHTS

It is clear that medical providers who prescribe or use decision support tools in accordance with the tenets of SDM may face tort liability if they misuse the tools or provide negligent counseling. This is a simple and relatively uncontroversial expansion of traditional malpractice liability. But the use of decision support tools also poses a secondary problem – namely, that patients may be harmed if the decision aids they use are faulty, misleading, or biased. If the regulatory or certification process aimed at ensuring the quality of decision aids fails, injured patients will look to tort law to provide a remedy. And since current tort doctrine makes it extremely difficult for such claims to succeed, it is time for policymakers and legal scholars to evaluate the costs and benefits of expanding tort liability in these cases.

If a physician prescribes a decision aid that is faulty as a result of the creator's negligence, but was nevertheless certified by a regulatory entity,

should the patient who is harmed as a result be able to recover from any or all of these parties? This question can only be answered once a number of key policy questions are resolved – for example, which party is in the best position to prevent patients from harm, and which party bears greatest moral responsibility for the patients' injuries. My preliminary conclusion on this issue is that, if the regulatory process fails, the creators of faulty decision aids ought to bear liability for any resulting harms.<sup>22</sup> They are in the best position to correct the problem, and despite the lack of formal privity, they are marketing their products with the expectation and intent that medical consumers will rely on them when making important medical decisions. Although certifiers of decision aids are also in a position to prevent harm, our legal system is generally reluctant to impose tort liability on those who merely guarantee or certify products created by third parties, particularly when they are complying with statutory and regulatory requirements. Finally, physicians, while obviously responsible for the quality of care they provide to patients, cannot be expected to have absolute expertise in every area of medical treatment, and ought not be held liable for the negligence of third party information providers over whom they have no control.

Regardless of how we resolve the issue of tort liability for injuries resulting from faulty decision aids, however, this discussion highlights a key lesson about the expanded use of extra-clinical informed consent tools – namely, that by significantly changing the nature of the informed consent process, this development is likely to change the landscape of legal liability. Only once we recognize this fact and begin to weigh the policy arguments for and against the expansion of liability can we effectively implement much-needed reforms to an informed consent process that is widely perceived as flawed.

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22. I explore this conclusion further in a subsequent article, Nadia Sawicki, *Regulatory Failures and Patient Safety: Using Tort Law to Ensure Decision Support Tool Quality* (Oct. 30, 2011) (unpublished manuscript, on file with author).

# Using Informed Consent to Reduce Preventable Medical Errors

*Evelyn M. Tenenbaum\**

Experts are increasingly recognizing that informed consent can be a valuable tool in advancing patient safety. Preventable medical errors kill and seriously injure thousands of Americans each year, causing personal tragedy and costing the healthcare system billions of dollars. Giving patients more information about their treatments can make them important partners in reducing these mistakes. The Patient Protection and Affordable Care Act (“PPACA”), the new federal health care legislation, provides grants for “integrat[ing] quality improvement and patient safety in the clinical education of health professionals.”<sup>1</sup> These grants are a perfect opportunity to educate future healthcare providers on the importance of giving patients the information they need to assist in preventing medical errors. The informed consent process is an ideal vehicle to convey this information because the process is already in place, making it a convenient and inexpensive route to the patient.

More than a decade ago, the Institute of Medicine (“IOM”) released its groundbreaking report, *To Err is Human: Building a Safer Health Care System* (“1999 IOM report”), estimating that 44,000 to 98,000 patients die annually in hospitals as a result of preventable medical errors. This large number of mistakes made medical errors the eighth leading cause of death in the United States for that year, exceeding deaths from car accidents, breast cancer, and AIDS. The costs associated with these errors were estimated to be as high as 29 billion dollars in 1999.<sup>2</sup> In response to this report, federal and state governments and private industry instituted various programs to improve patient safety. But those efforts were generally unsuccessful in significantly reducing preventable medical errors.

A 2008 study by the Department of Health and Human Services (“HHS”) found that one out of every seven hospitalized Medicare

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1. Patient Protection and Affordable Care Act, Pub.L. 111-148, § 3508 (2011) (codified at 42 U.S.C. §§ 299(b), 3508(a), 294(j)) [hereinafter PPACA].

2. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 1, 2 (Linda T. Kohn et al. eds., 1999) [hereinafter *TO ERR IS HUMAN*].