

PATIENT PROTECTION AND DECISION-AID QUALITY: REGULATORY AND TORT LAW APPROACHES

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This Article considers a new development in medical practice—the use of medical decision-support tools—and positions it within one of the most enduring debates at the intersection of administrative law and tort law. The Article identifies key factors that policy-makers in medical, environmental, and other contexts use to decide between regulatory and tort approaches to public protection, and argues that ex ante regulation may be insufficient to guarantee the quality of decision-support tools in the absence of a complementary tort remedy. The Article concludes by identifying the steps that would need to be taken to establish a system of ex post tort liability for creators of faulty decision aids and explaining the challenges associated with such a move.

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INTRODUCTION

After scheduling a routine checkup with a new general practitioner, John, age 55, received confirmation of the appointment by mail. The letter from the doctor's office suggested that John consider the possibility of having his prostate-specific antigen ("PSA") levels tested and asked that he read an enclosed booklet entitled "Prostate Cancer and You," published by the Association for Patient Advocacy and Education ("APAE"), for more information.¹ John was surprised at this request, because his previous physician had a policy of routinely ordering PSA tests for all men over 50 without question.²

1. The APAE is a fictional organization, as is the "Prostate Cancer and You" booklet. The materials that form the basis of this case study have been compiled from actual decision-support tools for prostate cancer screening and treatment published by a variety of public and private organizations, which are cited throughout this Article.

2. See CTRS. FOR DISEASE CONTROL & PREVENTION, PROSTATE CANCER SCREENING: A DECISION GUIDE 11, available at <http://www.cdc.gov/cancer/prostate/pdf/prosguide.pdf> ("Medical experts who encourage regular screening . . . recommend that all men who have a life expectancy of at least 10 years should be offered the PSA test and DRE

John opened the booklet and began to read:

If you are concerned about prostate cancer, you may already know about PSA (prostate-specific antigen) testing. There may be benefits and risks to PSA testing. However, research has not yet proven that the benefits of testing outweigh the risks.³ This booklet will help you decide whether testing is right for you.⁴

Additional information followed:

PSA screening tests the level of PSA in your bloodstream. PSA values below four (4) are considered normal. PSA values above four (4) are associated with, but cannot diagnose, prostate cancer. Only a biopsy can confirm the presence or absence of cancer. Approximately 10–15% of men screened for PSA will have levels above four (4).⁵

- *Biopsies reveal that only 30% of men with elevated PSA levels actually have prostate cancer; the remaining 70% are “false positives.”⁶*

annually beginning at age 50.”); Daniel Merenstein, *Winners and Losers*, 291 JAMA 15, 15 (2004) (noting testimony of four medical experts that customary practice is to “*have no discussion with the patient about prostate cancer screening [and] simply do the test*”); Shannon Brownlee & Jeanne Lenzer, *Do I Have Cancer?*, N.Y. TIMES, Oct. 9, 2011, at MM40 (“Today it’s common for doctors to order the P.S.A. test and patients to take it without talking about what it might really mean.”).

3. The U.S. Preventive Services Task Force’s 2012 recommendation on PSA screening concluded that there is no evidence of benefit from regular PSA testing and that the risks of harm resulting from biopsies and preventive treatment exceed the benefits of testing. *Prostate Cancer Final Recommendation Statement*, U.S. PREVENTIVE SERVS. TASK FORCE (May 2012), <http://www.uspreventiveservicestaskforce.org/prostatecancerscreening/prostatefinalrs.htm>. The Task Force ultimately recommended against routine PSA screening for prostate cancer. *Id.*

4. Similar language is used in many publicly available decision aids. See, e.g., AM. CANCER SOC’Y, TESTING FOR PROSTATE CANCER (2010), available at http://www.cancer.org/downloads/PRO/Testing_Prostate.pdf; HEALTH DIALOG, IS A PSA TEST RIGHT FOR YOU? (2010), available at https://www.healthcrossroads.com/content/1a6532e8-f545-4b72-bd5a-850493b9ad1a/c254bc46-a52c-4c02-9e1b-c1624c016a15/PSA001B_v04.pdf.

5. See CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 2, at 10 (noting that 85% of men over age 50 will have normal PSA test results); HEALTH DIALOG, *supra* note 4, at 10 (“About 8 out of 100 men who have PSA tests have an abnormal result . . .”).

6. See AM. CANCER SOC’Y, *supra* note 4, at 10 (30% men with elevated PSA have prostate cancer); CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 2, at 10 (20% men with elevated PSA have prostate cancer); HEALTH DIALOG, *supra* note 4, at 10 (37.5% of men with elevated PSA are diagnosed with cancer after biopsy); Informed Health Choice, *PROSDEX: A PSA Decision Aid*, PROSDEX, http://www.prosdex.com/index_content.htm (last visited June 30, 2012) (approximately 33% of men with a raised PSA level will have prostate cancer); Alex Krist, *The PSA, Prostate Cancer and You*, VCU DEP’T OF FAM. MED., <http://www.familymedicine.vcu.edu/research/misc/psa/index.html> (last visited June 30, 2010) (citing the rate of false positives at about 70%).

- *Biopsies reveal that very few men with normal PSA levels actually have prostate cancer (“false negatives”).*⁷

The booklet emphasized that prostate cancer is usually slow-growing; often, it causes no symptoms.⁸ Most men with prostate cancer—85% or more by some estimates—live long lives and die of unrelated causes.⁹ In contrast, the majority of men who do get treatment for prostate cancer (prostatectomy or radiology) report significant side effects, including incontinence and impotence.¹⁰

The booklet concluded with three patient testimonials—one from a man who was tested for PSA, found that his levels were normal, and felt peace of mind;¹¹ one from a man who was tested for PSA, discovered that his levels were high, and pursued aggressive early treatment;¹² and one from a man who decided not to get tested for PSA. The third man was quoted as saying:

I worry about prostate cancer, but I don’t want to have any unnecessary procedures. Given how few men actually die of

7. See, e.g., CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 2, at 10 (85% men have normal PSA levels, “though a small number of these men will have a cancer that was missed by the PSA test.”); Krist, *supra* note 6 (1–2% false negatives); Informed Health Choice, *supra* note 6 (“A normal PSA level suggests that probably, but not definitely, you do not have prostate cancer.”).

8. AM. CANCER SOC’Y, *supra* note 4, at 4; Informed Health Choice, *supra* note 6.

9. The U.S. Preventive Services Task Force’s draft recommendation on PSA screening reported that 95% of men with PSA-detected cancer do not die of the cancer within 12 years, even in the absence of treatment. *Draft Recommendation Statement*, U.S. PREVENTIVE SERVS. TASK FORCE (Oct. 11, 2011), www.uspreventiveservices.org/uspstf12/prostate/draftrecprostate.htm. This fact, however, was not included in the Task Force’s final recommendation. *Prostate Cancer Final Recommendation Statement*, *supra* note 3. See also Krist, *supra* note 6 (“In 2007, only 27,050 Americans died from prostate cancer, compared to 218,890 men diagnosed with the disease.”).

10. Brownlee & Lenzer, *supra* note 2 (“About half of men who undergo radiation or surgery will have permanent side effects like impotence and incontinence. Up to 1 in 200 men die within 30 days from complications related to the surgery.”); Krist, *supra* note 6 (explaining that up to 63% of men treated for prostate cancer experience problems with sexual function, and 42% with urination).

11. AM. CANCER SOC’Y, *supra* note 4, at 15 (“I will have peace of mind when I know the test results.”); see also Eila Watson et al., *Informed Decision Making and Prostate Specific Antigen (PSA) Testing for Prostate Cancer*, 63 PATIENT ED. & COUNSELING 367, 372 tbl.2 (2006) (between 59.7% and 74% of men “strongly agree” with the statement, “[h]aving a PSA test would give me peace of mind.”).

12. See, e.g., CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 2, at 13 (“I will take the screening tests because they will give me peace of mind. It could mean finding a problem, taking further tests, and treating a potentially serious prostate cancer. And since there’s no way to tell if the prostate cancer will cause problems in the future, I want it found early when treatments might be more effective.”).

*prostate cancer, and given the significant side effects of treatment, I don't want PSA testing. I'd rather take a wait-and-see approach.*¹³

The booklet concluded:

*You have been given a lot of information. Be sure to talk to your doctor.*¹⁴

When John visits his general practitioner the following week, the doctor reiterates the general risks and benefits of PSA screening and asks John whether he has any additional questions. John asks to be screened for PSA, explaining that although he does not want to suffer through unnecessary treatments, he would like to have a more realistic sense of his chances of having prostate cancer. If his PSA levels are normal, John thinks, he can take comfort in the fact that his chances of actually having prostate cancer are, according to the booklet, very small.¹⁵

In fact, John's PSA test results are just as he had hoped—they are below four, which the doctor informs him is normal for a man of his age. Based on this result, John tells his doctor that he does not want to be tested for PSA again until he reaches the age of 60. The doctor, satisfied that John has made a decision based on the best available evidence, agrees to this plan.

Three years later, John begins to experience pain and bleeding while urinating. He visits a urologist, who conducts a digital rectal exam and finds a large tumor in John's prostate. A biopsy reveals that John has an advanced stage of prostate cancer. Based on the size of the tumor and the severity of John's symptoms, the urologist estimates that John's chances of five-year survival are very low. He suggests that John consider radiation or surgery but cautions that these procedures may not be successful at this late stage.

John does everything he can to educate himself about prostate cancer and available treatments. He first consults the booklet his general practitioner had given him three years ago; he then looks for other sources of information. In an article in *Men's Health*, John learns about research (available at the time of his PSA test) establishing that up to 30% of normal PSA tests may be false negatives.¹⁶ In John's view, this seems to conflict with the booklet's description of

13. *Id.* (“I will not take the screening tests until medical experts agree that finding and treating prostate cancer in its early stages reduce the chance of dying from it. Screening tests could lead to further tests and treatment of a prostate cancer that may never cause problems. And treatment can have serious side effects.”); HEALTH DIALOG, *supra* note 4, at 18 (“I'd rather take the watchful waiting approach until my physician recommends otherwise and not suffer the problems that have occurred with other men that I have talked to . . . with impotence and incontinence.”).

14. *See, e.g.*, AM. CANCER SOC'Y, *supra* note 4, at 17 (“Starting at age 50, talk to your doctor about the pros and cons of testing. Then decide if testing is the right choice for you.”); CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 2, at 17 (“To decide whether screening is right for you, discuss the pros and cons of screening with your doctor and the people important in your life.”).

15. *See supra* note 7.

16. *See* AM. CANCER SOC'Y, *supra* note 4, at 10 (15% of men with PSA levels below four are diagnosed with prostate cancer after biopsy); HEALTH DIALOG, *supra* note 4,

the number of men with false negatives as “very few.” The article also notes that the false positive rate is much lower than the 70% cited in the booklet: a report by the U.S. Preventive Services Task Force found that false positives occur in only 12–13% of men randomly assigned to PSA-based screening.¹⁷ Had John known this information at the time of his PSA test—that the likelihood of false negatives is higher than represented to him and that the number of false positives is fewer—he would have certainly asked his doctor for regular annual screenings, rather than delaying his next test for five years.

John also learns that nearly 90% of men with elevated PSA test results ultimately go on to have radiation or surgery.¹⁸ Had his later test results been abnormal, John thinks, he would have sought treatment as well. According to his urologist, if John’s prostate cancer had been caught at an earlier stage, it would have significantly increased his chances of survival.

* * *

The above scenario is just one example of the problems that can arise when the informed consent process incorporates information provided by someone other than the patient’s treating physician. This happens more frequently in modern medical care as more physicians and patients adopt the emerging model of shared decision-making (“SDM”). SDM, which encourages patients to consult brochures, videos, or computer programs (“decision aids” or “decision-support tools”) before making decisions about preference-sensitive care, has been touted as an important and valuable supplement to the traditional process of informed consent.¹⁹ Indeed, decision aids targeted to patient needs appear to be more effective than standardized informed consent documents in achieving patient comprehension, recall, and satisfaction.

Unlike the traditional informed consent process, which is highly regulated and governed by decades of common law, the creation and use of decision-support tools is currently controlled only by market forces. No administrative regulations exist to delineate the appropriate scope of decision aids, and no tort remedy is available to patients who are injured by faulty decision aids. The only move

at 11 (same); William J. Catalona, *Clinical Utility of Measurements Free and Total Prostate-Specific Antigen (PSA): A Review*, 29 PROSTATE 64, 64 (1996) (finding a 20% false negative rate); Evelyn C. Y. Chan et al., *Do Men Know That They Have Had a Prostate-Specific Antigen Test?: Accuracy of Self-Reports of Testing at 2 Sites*, 94 AM. J. PUB. HEALTH 1336, 1337 (Aug. 2004) (finding false negative rate of 33–36%).

17. Roger Chou et al., *Screening for Prostate Cancer: A Review of the Evidence for the U.S. Preventive Services Task Force*, 155 ANNALS INTERNAL MED. 762, 762 (2011).

18. *Prostate Cancer Final Recommendation Statement*, *supra* note 3 (“[N]early 90% of men with PSA-detected prostate cancer undergo early treatment with surgery, radiation, or androgen deprivation therapy.”); *see also* Brownlee & Lenzer, *supra* note 2 (“For many people, not being treated after a diagnosis of cancer is psychologically unbearable.”).

19. *See infra* Part I.

toward a legal mechanism for control of decision aids is a modest proposal in the 2010 Patient Protection and Affordable Care Act (“PPACA”) for the creation of an entity to certify decision aids used as part of SDM. Creators of decision aids—some of which are for-profit corporations—have little incentive to maintain the integrity of their products other than market pressures to maintain good business practices. In other contexts, such as environmental regulation, products liability, and pharmaceuticals, it has become clear that market pressures are often insufficient to protect consumers.²⁰

This Article asks whether a regulatory proposal like the one in the PPACA is sufficient to ensure the quality of decision-support tools and to protect patients. To answer this question, this Article engages in the long-standing debate about the use of regulatory versus tort mechanisms to control industry behavior.²¹ In some circumstances, standard-setting administrative regulations may be sufficient to protect consumers from harm while at the same time supporting the growth of valuable industries. In other circumstances, policy-makers find that regulations need to be complemented by a tort regime that fills the compensation gap when consumers suffer injury. The discussion among policy-makers and legal scholars about which system to favor is continually playing out in a variety of arenas—among them environmental regulation, product design, vaccines, drugs and, medical devices. Indeed, two recent Supreme Court decisions analyzing the preemptive effect of regulation in the pharmaceutical and medical-device industries have directly addressed this critical issue.²²

The scholarly conversation about regulatory and tort law approaches to improving quality has always been active. This Article, however, makes a significant contribution in synthesizing the available thinking on this topic and identifying a set of five concrete characteristics that help policy-makers when choosing between a regulatory and tort regime. These characteristics include the regulatory regime’s ability to satisfy compensatory and information-gathering goals, the nature of the injury to be prevented, the comprehensiveness and precision of the regulation, and the difficulty of proving causation. While there has been little consistency in how courts and policy-makers have applied these characteristics in their analyses of controversial cases, scholars of administrative and tort law have long recognized the salience of each of these characteristics to the resolution of these debates.

20. See Jennifer H. Arlen, *Compensation Systems and Efficient Deterrence*, 52 MD. L. REV. 1093, 1120–21, 1126 (1993).

21. See, e.g., Keith N. Hylton, *Preemption and Products Liability: A Positive Theory*, 16 SUP. CT. ECON. REV. 205 (2008); Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. art. 4 (2006); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049 (2000); W. Kip Viscusi, *Toward a Diminished Role for Tort Liability: Social Insurance, Government Regulation, and Contemporary Risks to Health and Safety*, 6 YALE J. ON REG. 65 (1989).

22. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Wyeth v. Levine*, 555 U.S. 555 (2009).

This Article demonstrates that decision-support tools, although essential to improving an informed consent process widely viewed as flawed, possess characteristics associated with a significant risk of patient harm; therefore, decision-support tools, and the information they provide, would benefit from the development of a set of controlling legal mechanisms. One option would be to rely exclusively on a regulatory regime, such as the one proposed in PPACA. An alternative would be to supplement administrative regulation with a complementary compensatory remedy grounded in tort law. To decide between these two options, this Article applies the five factors described in Part IV to the context of patient decision aids, and concludes that although the proposed regulatory mechanisms are an important first step in ensuring decision-aid quality, they will likely be insufficient to protect consumers from harm when implemented on their own. Rather, much like the contexts of vaccines and pharmaceuticals, patient decision aids are best suited to a robust regulatory regime supplemented by a complementary tort remedy for injured patients. The Article concludes by identifying the steps that would need to be taken to establish a system of *ex post* tort liability for creators of faulty decision aids and explains the challenges associated with such a move.

I. HISTORY OF DECISION-SUPPORT TOOLS

The average American patient no longer relies exclusively on her physician to obtain health information. Modern patients have a variety of tools at their disposal, including informational websites such as those provided by the Mayo Clinic²³ and the National Institute of Health (“NIH”);²⁴ patient networking sites like e-patients.net; direct advertising by pharmaceutical companies; state and federal public health campaigns; targeted mailings by insurance plans; and recommendations from professional associations. Patients often consult these resources on their own, or with the encouragement of their healthcare providers, to learn more about care and treatment options than they could during the typical doctor’s appointment.

This Article focuses on an increasingly important category of patient health information—physician-mediated decision-support tools that are provided by third parties and often used by the patient outside the clinical context. These decision aids can come in the form of brochures, videos, computer programs, or third-party consultations, and are largely unregulated.²⁵ Their integration as part of contemporary informed consent practice plays directly into the debate about the relative merits of regulatory and tort enforcement mechanisms.

23. MAYO CLINIC, <http://www.mayoclinic.com/> (last visited July 1, 2012).

24. *Health Information*, NAT’L INSTS. OF HEALTH, <http://health.nih.gov/> (last visited July 1, 2012).

25. See Nadia N. Sawicki, *Informed Consent Beyond the Physician-Patient Encounter: Tort Law Implications of Extra-Clinical Decision Support Tools*, 21 ANNALS HEALTH L. 1, 9–10 (ASLME Special Ed. 2012).

While patient educational materials created by state departments of public health are part of the history of American public health,²⁶ the increased prominence of the SDM movement is shining new light on patient decision aids, which are an integral part of SDM. The SDM movement developed over the past 30 years as a response to growing disenchantment among the medical and patient communities with existing informed consent practices.²⁷

A vast body of evidence demonstrates that the process of informed consent as currently practiced has failed to live up to its goals.²⁸ Studies show that physicians “often fail to disclose even major side effects of treatment;”²⁹ that informed consent forms are far too technical, failing to take into account varying degrees of health literacy;³⁰ that the informed consent process often does not improve patient understanding of critical aspects of treatment;³¹ and that many patients are unable to accurately recall information provided during informed consent.³² One study, evaluating 540 informed consent forms currently used by 157 hospitals, concluded that the forms “provide little substantive content to help

26. JOHN DUFFY, *THE SANITARIANS: A HISTORY OF AMERICAN PUBLIC HEALTH* 216 (1990); GEORGE ROSEN, *A HISTORY OF PUBLIC HEALTH* 369 (1993).

27. See Jaime Staples King & Benjamin Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 459–63 (2006); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 904 (1993).

28. As early as 1982, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research found “enormous variation . . . in the decision-making process” in various settings and concluded that it was “rare” for the idealized vision of informed consent to be realized in practice. 1 PRESIDENT’S COMM’N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMED. & BEHAVIORAL RESEARCH, *MAKING HEALTH CARE DECISIONS: A REPORT ON THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP* 10 (1982), available at http://bioethics.georgetown.edu/pcbe/reports/past_commissions/making_health_care_decisions.pdf; see also Melissa M. Bottrell et al., *Hospital Informed Consent for Procedure Forms: Facilitating Quality Patient–Physician Interaction*, 135 ARCHIVES SURGERY 26, 26–27 (2000); C. Lavelle-Jones et al., *Factors Affecting Quality of Informed Consent*, 306 BMJ 885, 885 (1993); Danielle M. McCarthy et al., *What Did the Doctor Say? Health Literacy and Recall of Medical Instructions*, 50 MED. CARE 277, 277 (2012).

29. Bottrell et al., *supra* note 28, at 26.

30. See *id.* at 30; Savyasachi C. Thakkar et al., *Accuracy, Legibility, and Content of Consent Forms for Hip Fracture Repair in a Teaching Hospital*, 6 J. PATIENT SAFETY 153, 156 (2010).

31. See Bottrell et al., *supra* note 28, at 30; Eric S. Holmboe et al., *Perceptions of Benefit and Risk of Patients Undergoing First-Time Elective Percutaneous Coronary Revascularization*, 15 J. GEN. INTERNAL MED. 632, 632 (2000) (only 46% of patients were able to identify a possible complication the day prior to undergoing their procedure).

32. See Bottrell et al., *supra* note 28, at 27, 30; Mayer Brezis et al., *Quality of Informed Consent for Invasive Procedures*, 20 INT’L J. FOR QUALITY HEALTH CARE 352, 352 (2008); Lavelle-Jones et al., *supra* note 28, at 888 (noting that only between 14% and 66% of patients are “able to recall basic details of their surgery” after engaging in the informed consent process); McCarthy et al., *supra* note 28, at 277 (highlighting that despite adequate health literacy, fewer than 30% of patients recognized pain and fever as signs of infection even after the informed consent process).

patients make decisions, or even meet basic standards for informed consent.³³ It found that 12.9% of forms failed to mention general risks of treatment and 54.1% failed to mention serious risks. Moreover, more than 80% of forms failed to identify specific treatment alternatives or discuss the consequences of choosing not to be treated.³⁴ Another study, tracking 265 surgical patients at a large teaching hospital, found that 69% of patients “admitted to not reading the consent form before signing it.”³⁵ A third study found that fewer than 10% of patients were able to restate what they were told during the informed consent process.³⁶ Finally, another long-standing criticism of modern informed consent practice is that its purpose seems to be more to protect healthcare providers and institutions from liability than to truly inform patients.³⁷

The SDM movement has been proposed as a substantial improvement on existing informed consent practices. Spurred in part by Jack Wennberg’s influential research on practice variations in preference-sensitive care,³⁸ SDM seeks to assist patients in choosing among medical interventions when clinical evidence alone does not identify a favored option (also known as “preference-sensitive care”). The SDM model has been touted as potentially improving patient satisfaction,³⁹ clinical outcomes,⁴⁰ cost of care,⁴¹ and physician time

33. Bottrell et al., *supra* note 28, at 30.

34. *Id.* at 29 tbl.1.

35. Lavelle-Jones et al., *supra* note 28.

36. Brezis et al., *supra* note 32.

37. *See, e.g.*, Bottrell et al., *supra* note 28, at 30 (noting that the “legal appearance” of informed consent forms may explain “why patients believe forms were created to protect hospitals or physicians.”).

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

39. *See, e.g.*, King & Moulton, *supra* note 27, at 468–69; Annette M. O’Connor et al., *Modifying Unwarranted Variations in Health Care: Shared Decision Making Using Patient Decision Aids*, HEALTH AFF., 63, 65–66 (2004); Edward H. Wagner et al., *The Effect of a Shared Decisionmaking Program on Rates of Surgery for Benign Prostatic Hyperplasia Pilot Results*, 33 MED. CARE 765, 770 (1995).

40. *See, e.g.*, BARBARA L. MCANENY, REPORT OF THE COUNCIL ON MED. SERV., CMS REPORT 7-A-10: SHARED DECISION-MAKING 4 (2010) [hereinafter CMS REPORT], available at <http://www.ama-assn.org/resources/doc/cms/a10-cms-rpt-7.pdf>; King & Moulton, *supra* note 27, at 469–70; Jaime S. King et al., *The Potential of Shared Decision Making to Reduce Health Disparities*, 39 J.L. MED. & ETHICS 30, 31 (2011).

41. *See, e.g.*, CMS REPORT, *supra* note 40, at 1 (noting that the use of decision-making tools may “help increase the value of health care spending in the United States, while also maximizing clinical quality.”); Sandy Leitch, *Chairman’s Statement*, in BUPA ANNUAL REPORT 2010 at 3, 3, available at http://www.bupa.com/media/42158/bupa_ar_br_chairman.pdf (“In 2010, The New England Journal of Medicine independently found that Health Dialog’s chronic disease management services deliver a 400% return on investment.”); King & Moulton, *supra* note 27, at 472–73; O’Connor et al., *supra* note 39, at 67.

management.⁴² Notably, the United States' recent health reform, PPACA, promotes SDM as a model for clinical practice.⁴³

The SDM model is able to accomplish all these goals in part by virtue of its reliance on decision-support tools to supplement the informed consent process. 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.⁴⁴ These tools can take a variety of forms, including brochures, videos, interactive websites, CD-ROMs, as well as “structured personal coaching” with a trained intermediary.⁴⁵ Such 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.”⁴⁶ These tools are written in simple and easy-to-understand language that is accessible to patients with varying degrees of health literacy. They are self-directed, which means that a patient can spend as much or as little time exploring the information as she needs to. They often include graphics or diagrams to help explain the underlying medical issue and how it can be treated. They provide opportunities for the patient to take notes and identify questions to discuss with her physician. The process of reviewing a decision aid is, in short, exactly the sort of

42. See David C. Wheeler et al., *Applying Strategies from Libertarian Paternalism to Decision Making for Prostate Specific Antigen (PSA) Screening*, 11 BMC CANCER 148, 149 (2011) (noting that some physicians have been slow to adopt shared decision-making because of “the time required for a detailed discussion of clinical options with patients” and that the use of patient decision aids may remedy this problem).

43. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3506, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 299b-36 (2012)).

44. See *Patient Decision Aids*, OTTAWA RES. HOSP. INST., <http://decision.aid.ohri.ca/AZlist.html> (last modified June 27, 2012).

45. CMS REPORT, *supra* note 40, at 2.

46. King & Moulton, *supra* note 27, at 464; see also Patient Protection and Affordable Care Act § 3506 (codified as amended at 42 U.S.C. § 299b-36(b)(1)) (“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 provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.”); CMS REPORT, *supra* note 40, at 2 (“Formal shared decision-making processes are generally facilitated through the use of electronic or paper-based patient decision support aids, which are often developed by third parties and licensed for use by health plans, hospitals or physicians. Through tools such as booklets, videos, interactive computer programs, and structured personal coaching, patients receive evidence-based information about treatment options and outcomes that is specifically designed to help them evaluate tradeoffs in the context of their own feelings and preferences. Decision support aids supplement direct communication between the physician and patient by offering patients an opportunity to process complex—and possibly frightening—information at their own pace, using information that addresses the emotional as well as the clinical aspects of medical care. Patient decision aids have three core elements: clinical information, ‘values clarification,’ and guidance to help patients make and communicate their treatment decisions.”).

process envisioned by advocates of informed consent—a step-by-step tutorial aimed at ensuring patient comprehension of the facts necessary to make an informed medical decision.

Moreover, unlike traditional informed consent documents which only provide factual information, decision aids also assist patients in identifying the values and preferences that are important to them and in guiding them through the process of matching their values with available treatment options.⁴⁷ For example, a prostate cancer patient who hopes to live as long as possible will have different treatment preferences than a patient who hopes to avoid the unpleasant side effects of treatment, such as incontinence and impotence. Many tools provide opportunities for patients to take note of the values that are most important to them and to track their changing opinions as they learn new information about treatment options.

While some decision-support tools are used by physicians in face-to-face clinical encounters, others are intended for independent patient use.⁴⁸ Sometimes, a physician may “prescribe”⁴⁹ 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.⁵⁰ Viewed as part of the SDM process, decision aids are intended as complements to, not replacements for, the physician–patient interaction.⁵¹ They encourage the patient to engage in a deliberative process earlier and more thoroughly than has often been the case in traditional informed consent practice and have been lauded as a significant improvement over the status quo.⁵²

Decision-support tools for SDM have been written and published by a variety of organizations,⁵³ including professional associations,⁵⁴ government

47. See generally 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, 702 (2010); King & Moulton, *supra* note 27, at 464–65; Annette M. O’Connor et al., *Toward the ‘Tipping Point’: Decision Aids and Informed Patient Choice*, 26 HEALTH AFF. 716, 716–17 (2007).

48. Elwyn et al., *supra* note 47, at 703.

49. CMS REPORT, *supra* note 40, at 3.

50. Historically, the informed consent process is conducted as a conversation between doctor and patient about the risks and benefits of, and alternatives to, various treatment options. This discussion is documented in the patient’s chart, and more importantly, via the patient’s signature on a formal informed consent document. Schuck, *supra* note 27, at 935. The legal requirements for informed consent may be set forth in statutes and regulations, as well as common law doctrine. See *id.* at 901, 916–19 (discussing regulatory disclosure requirements, and statutory and common law grounds of informed consent doctrine).

51. See Elwyn et al., *supra* note 47, at 702–03.

52. See, e.g., Suzanne V. Arnold et al., *Converting the Informed Consent from a Perfunctory Process to an Evidence-Based Foundation for Patient Decision Making*, 1 CIRCULATION: CARDIOVASCULAR QUALITY & OUTCOMES 21, 27 (2008); King & Moulton, *supra* note 27, at 463; Harlan M. Krumholz, *Informed Consent to Promote Patient-Centered Care*, 303 JAMA 1190, 1191 (2010).

53. *Patient Decision Aids*, *supra* note 44.

agencies,⁵⁵ hospitals and health centers,⁵⁶ non-profit organizations,⁵⁷ and for-profit companies.⁵⁸ This is in contrast to traditional informed consent documents, which are most commonly prepared by the healthcare institutions that are actually providing the treatment.

II. QUALITY CONCERNS

In its report on the implementation of SDM through the use of decision-support tools, the American Medical Association (“AMA”) Council on Medical Service recognized that “[a]ssuring the clinical quality and ethical design of patient decision aids will become increasingly important” as they are incorporated into the decision-making process.⁵⁹ Virtually every commentator who has written on this topic has expressed similar concerns.⁶⁰ In particular, many have called attention to the likelihood of conflict-of-interest or bias in the development of decision-support tools. The AMA, for example, has noted the possibility that “[d]ecision support tools could be created that are misleading or biased toward or against certain treatment choices, in an effort to encourage patients to choose less expensive options.”⁶¹ Jamie King and Benjamin Moulton, the leading legal scholars writing about SDM, have also noted that “decision aids have the potential to be biased or potentially misleading.”⁶²

To be sure, today’s patients obtain a great deal of medical information that is created by third parties and used outside the physician–patient relationship. The Internet is perhaps the most frequented source of such information—websites

54. See, e.g., AM. SOC’Y OF CLINICAL ONCOLOGY, DECISION AID: STAGE IV NON-SMALL CELL LUNG CANCER (NSCLC) FIRST-LINE CHEMOTHERAPY (2004), available at [http://www.asco.org/ASCO/Downloads/Cancer%20Policy%20and%20Clinical%20Affairs/Clinical%20Affairs%20\(derivative%20products\)/NSCLC/NSCLC%20First%20line%20Decision%20Aid%2011.6.09.pdf](http://www.asco.org/ASCO/Downloads/Cancer%20Policy%20and%20Clinical%20Affairs/Clinical%20Affairs%20(derivative%20products)/NSCLC/NSCLC%20First%20line%20Decision%20Aid%2011.6.09.pdf).

55. See, e.g., CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 2; U.S. Dep’t Health & Human Servs., *Patient Decision Aids*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.effectivehealthcare.ahrq.gov/index.cfm/guides-cmece-and-other-resources-for-clinicians/patient-decision-aids> (last visited July 2, 2012).

56. See, e.g., *Hormone Therapy: Is it Right For You?*, MAYO CLINIC (May 31, 2012), <http://www.mayoclinic.com/health/hormone-therapy/WO00046>.

57. See, e.g., COCHRANE MUSCULOSKELETAL GROUP, <http://musculoskeletal.cochrane.org/> (last visited July 2, 2012); HEALTHWISE, <http://www.healthwise.org/> (last visited July 2, 2012).

58. See, e.g., EMMI SOLUTIONS, <http://www.emmisolutions.com> (last visited July 2, 2012); HEALTH DIALOG, <http://www.healthdialog.com/Main/default> (last visited July 2, 2012); OPTUMHEALTH, <http://www.optumhealth.com/> (last visited July 2, 2012).

59. CMS REPORT, *supra* note 40, at 3.

60. Indeed, concerns about decision-aid quality initially prompted the International Patient Decision Aids Standards Collaboration’s development of a quality framework. See Glyn Elwyn et al., Int’l Patient Decision Aids Standards (IPDAS) Collaboration, *Developing a Quality Criteria Framework for Patient Decision Aids*, 333 *BMJ* 417, 417 (2006).

61. CMS REPORT, *supra* note 40, at 4.

62. King & Moulton, *supra* note 27, at 466.

such as the Mayo Clinic's,⁶³ the NIH's,⁶⁴ and those of many private insurers, provide a wealth of information about health and medical treatment. A patient who has already been diagnosed can also peruse dozens of patient-support websites where people post about their experiences with various forms of treatment.⁶⁵ The quality of the health information available on the Internet varies widely,⁶⁶ and many physicians recognize the need to counsel their patients to be more discerning consumers of Web-based information. While one might explain some of the erroneous health information provided on the Internet by reference to the ease with which anyone can publish their views, even more traditional forms of information can be equally faulty. Case law is rife with suits by plaintiffs alleging injury as a result of misinformation in printed books or materials,⁶⁷ including a dieting book written by an osteopathic surgeon⁶⁸ and a pamphlet published by the National Hemophilia Foundation.⁶⁹ Moreover, both the frequency of litigation against healthcare providers and institutions for failure of informed consent, as well as the body of research about the failures of the traditional informed consent process,⁷⁰ suggest quality issues with the status quo.

Third-party decision aids, however, share three important features that increase the likelihood of misinformation or bias as compared to other patient educational materials. First, while traditional informed consent documents are typically drafted by the healthcare institution treating a patient, decision-support tools are often created by third parties not otherwise involved in the patient's care—for example, non-profit organizations, insurance companies, or for-profit medical education companies.⁷¹ Second, many decision aids, although "prescribed" by physicians and so bearing the imprimatur of medical authority, are intended for independent patient use outside the clinical encounter, which means that physicians may have limited opportunities to mediate or interpret the information provided by these tools.⁷² Finally, decision aids are used primarily in the context of preference-sensitive decisions that implicate personal values; many of these decisions, such as those related to end-of-life care and reproductive care,

63. MAYO CLINIC, *supra* note 23.

64. *Health Information*, *supra* note 24.

65. See, e.g., *Stories of Hope*, AM. CANCER SOC'Y, <http://www.cancer.org/Treatment/SurvivorshipDuringandAfterTreatment/StoriesofHope/index> (last visited July 2, 2012); *A Voice of Patient Engagement*, E-PATIENT DAVE, <http://epatientdave.com/> (last modified June 18, 2012).

66. Gretchen P. Purcell et al., *Quality of Health Information on the Internet*, 324 *BMJ* 557, 557 (2002).

67. See, e.g., *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1034 (9th Cir. 1991).

68. *Smith v. Linn*, 563 A.2d 123, 125 (Pa. Super. Ct. 1989).

69. *In re Factor VIII or IX Concentrate Blood Prods. Litig.*, 25 F. Supp. 2d 837 (N.D. Ill. 1998).

70. See *supra* Part I.

71. See *infra* Part II.A.

72. See *infra* Part II.B.

involve moral and political controversies that may impact the way information is provided to patients.⁷³

A. *Third-Party Development*

Receiving information from a physician or reviewing it with a physician's guidance is certainly no guarantee of accuracy. When health information is provided by parties with financial or other conflicts of interest, the possibility of misinformation is significantly increased.⁷⁴ To cite just one example, consider the recent outcry surrounding the development and use of clinical pathways and practice guidelines in medical care.⁷⁵ Clinical practice guidelines are tools used by physicians to determine the best course of treatment for a given patient's condition; such guidelines represent "best practices" for treatment in light of available medical evidence. There may be a variety of clinical guidelines on any given condition created by professional associations seeking to improve quality of care, hospitals seeking to standardize care, or insurers seeking to limit the cost of care. As noted by Ronen Avraham, although all clinical guidelines are developed with significant physician input, the guidelines "notoriously vary depending on which group is giving them."⁷⁶ With respect to mammograms, for example, Avraham posits that "[m]alpractice insurers . . . may recommend yearly mammograms, even if they are not necessary, because they bear the costs of lawsuits for late diagnoses of breast cancer."⁷⁷ Even when professional associations write guidelines, their "validity . . . may be questionable for a variety of reasons," including obsolescence and changes in practice, insufficient evidence, and conflicts of interest (especially where professional associations partner with pharmaceutical or medical device companies).⁷⁸

73. See *infra* Part II.C.

74. Nananda Col et al., Abstract, *Empirical Evidence of Bias in Decision Aids*, 15 J. GEN. INTERNAL MED. 81, 82 (supp. 3, 2010) (concluding that decision aids sponsored by government agencies and insurance companies more strongly emphasize the benefits of watchful waiting and the risks of surgery as compared to decision aids sponsored by academic institutions); Allan S. Detsky, *Sources of Bias for Authors of Clinical Practice Guidelines*, 175 CMAJ 1033, 1033 (2006) (describing financial conflicts, professional conflicts, and "participants' previously established 'stake' in an issue" as sources of potential bias).

75. While the Institute of Medicine has issued standards for promulgating clinical guidelines, "I worry about the extent to which these standards will be followed." Ronen Avraham, Op-Ed., *A Market Solution for Malpractice*, N.Y. TIMES, Mar. 29, 2011, at A31.

76. *Id.*

77. *Id.* Therefore, Avraham suggests that private for-profit regulators be in charge of creating guidelines and that they be "liable if their guidelines were found to deviate from optimal care." *Id.* Avraham writes, "Almost every other product Americans encounter is subject to laws that guarantee that the producer suffers when its product is subpar. There's no reason medical guidelines should be any different." *Id.*

78. Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J.L. & MED. 7, 29 (2011).

The problems with decision aids produced by third parties can be illustrated by examining the fictional brochure discussed in this Article's Introduction.⁷⁹ The brochure begins with the statement that "research has not yet proven that the benefits of testing outweigh the risks," a statement which in itself is subject to dispute. The U.S. Preventive Services Task Force ("USPSTF") recently gave PSA screening a "Grade D" recommendation, finding insufficient evidence "to assess the balance of benefits and harms of prostate cancer screening in men younger than age 75 years."⁸⁰ However, this recommendation has been extremely controversial.⁸¹ In fact, the USPSTF made a similar recommendation in 2009, which was sent back for review as a result of "public uproar."⁸² Some commentators have described the USPSTF's final report as "riddled with errors" and arguably "biased" against PSA screening.⁸³

The booklet also states that "very few men" with normal PSA levels actually have prostate cancer. A qualitative description of this kind ("very few") is likely to give John a less accurate perspective than a quantitative one (e.g., "1%").⁸⁴ Moreover, although some research suggests that only 1–2% of men get false negative results from PSA screening,⁸⁵ other studies have demonstrated that the rate of false negatives may be as high as 36%.⁸⁶ If APAE had chosen to use the higher figure (or a range of values), the reasonable patient in John's position might have a very different perception of the implications of a negative PSA result.

Further, the booklet includes three patient testimonials. Of the three, only one patient decides to pursue both PSA testing and treatment. The booklet does not, however, mention that despite the 60% chance of side effects like incontinence and impotence, the vast majority of men diagnosed with prostate cancer—90%—nevertheless seek treatment.⁸⁷ As noted by the International Patient Decision Aid Standards Collaboration, "even a 'balanced' presentation of views can potentially give false impressions that there is an equal split in opinion about

79. While fictional, the brochure contains information compiled from a number of publicly available patient decision aids. *See, e.g., supra* notes 4–15.

80. *Prostate Cancer Screening Communication Conference*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/cancer/prostate/what_cdc_is_doing/conference.htm (last modified May 22, 2012).

81. Gardiner Harris, *Panel's Advice on Prostate Test Sets up Battle*, N.Y. TIMES, Oct. 8, 2011, at A1; *cf.* Gina Kolata, *Behind Cancer Guidelines, Quest for Data*, N.Y. TIMES, Nov. 23, 2009, at A19.

82. Brownlee & Lenzer, *supra* note 2.

83. Andrew J. Vickers & Hans Lilja, *Urological Cancer: Time for Another Rethink on Prostate Cancer Screening*, 9 NATURE REVIEWS CLINICAL ONCOLOGY 7 (2012).

84. Annette M. O'Connor et al., *Decision Aids for People Facing Health Treatment or Screening Decisions*, 1 COCHRANE DATABASE SYST. REV. CD001431 (2009); Malcolm Man-Son-Hing et al., *The Effect of Qualitative vs. Quantitative Presentation of Probability Estimates on Patient Decision-Making: A Randomized Trial*, 5 HEALTH EXPECTATIONS 246, 253 (2002).

85. *See supra* note 7.

86. *See supra* note 16.

87. *See supra* note 18.

treatment, when in fact 90% of patients recommend or accept a particular option.”⁸⁸

Finally, the booklet does not include citations to the original sources of the statistics it presents, so neither John nor his physician have the opportunity to double-check the factual information in the booklet.⁸⁹ Because we do not have any information about the fictional group that created the booklet, we cannot speculate on its motivations for choosing and presenting information in the way that it did. APAE’s presentation of the options available to John, however, is certainly influenced by its motivations and is likely very different from how the options would have been presented had the booklet instead been prepared by a professional organization of urologic surgeons and radiation oncologists.⁹⁰

B. Imprimatur of Authority and Limited Physician Mediation

A second factor relevant to the likelihood of harm arising from faulty decision aids is the way patients are intended to use them. While decision-support tools are intended as complements to, not replacements for, the physician–patient interaction,⁹¹ proponents value them in part because they lessen the burden on physicians in discussing treatment options with their patients. Of course, when physicians “prescribe” decision aids for patient use at home, the chances of

88. Phyllis Butow et al., *Using Personal Stories*, in IPDAS COLLABORATION BACKGROUND DOCUMENT 24, 25 (Annette O’Connor et al. eds., Feb. 17, 2005), available at ipdas.ohri.ca/IPDAS_Background.pdf. The IPDAS Collaboration Background Document also notes that “inclusion of written patient testimonials . . . significantly influenced hypothetical treatment choices. The number of testimonials in favour of either option strongly influenced choice.” *Id.* at 26; see also Peter A. Ubel et al., *The Inclusion of Patient Testimonials in Decision Aids: Effects on Treatment Choices*, 21 MED. DECISION MAKING 60, 65 (2001) (concluding that patient testimonials “can significantly influence hypothetical treatment choices”).

89. Tim Whelan & Michael Pignone, *Basing Information on Up-to-Date Scientific Evidence*, in IPDAS COLLABORATION BACKGROUND DOCUMENT 50, 51 (Annette O’Connor et al. eds., Feb. 17, 2005), available at ipdas.ohri.ca/IPDAS_Background.pdf (noting that only 15.8% of decision aids provided specific citations to original sources, 52.6% provided directions to a separate resource where patients could find citations to original sources, and 31.5% provided neither); see Michael Barry, *Disclosing Conflicts of Interests*, in IPDAS COLLABORATION BACKGROUND DOCUMENT 36, 37 (Annette O’Connor et al. eds., Feb. 17, 2005), available at ipdas.ohri.ca/IPDAS_Background.pdf (noting that although financial interests or specialty-specific management preferences could bias decision aids, “only the minority of relevant financial relationships on the part of the original authors were actually disclosed as part of the publication process”).

90. See Barry, *supra* note 89, at 37 (“Specialty perspective can also have a strong effect on views regarding optimal medical management. For example, for clinically localized prostate cancer (a common topic for patient decision aids), urologic surgeons are much more positive about radical prostatectomy while radiation oncologists are much more positive about radiation therapy as a treatment option . . .”); Brownlee & Lenzer, *supra* note 2 (“The dueling narratives of PSA testing boil down to the way each side frames the potential for harm from the disease compared with the collateral damage from the test and subsequent treatment.”); Col et al., *supra* note 74, at 82.

91. See Elwyn et al., *supra* note 47, at 702–03.

informative conversation with the physician at the next appointment are certainly greater—indeed, that is part of their appeal. However, patients may find decision-support tools on their own—many are available on the Internet—and there is no guarantee that the physician will be available to mediate this content. Thus, faulty decision aids may impact patient choices in such a way that their physicians do not have an opportunity to correct. Moreover, when a decision aid is offered to the patient by a medical provider, it may bear the imprimatur of authority in the patient's eyes, despite the fact that it was created by a third party uninvolved in the patient's care.

Michigan allows patients to bypass the physician interaction altogether by offering an online alternative to the traditional informed consent process. A patient seeking an abortion may view state-sponsored abortion materials at the website of the Michigan Department of Community Health, print and sign a confirmation form, and present it to her physician as evidence of informed consent.⁹² In this situation, third-party decision-support tools replace the traditional informed consent process.

Another example of the use of decision-support tools in situations with limited opportunities for physician mediation is recent legislation passed by South Dakota, which requires women seeking abortions to obtain a consultation at a pregnancy counseling center before consenting to the procedure.⁹³ Around the country these centers, which many claim are aimed at dissuading women from getting abortions,⁹⁴ are often staffed by laypersons with no clinical expertise.⁹⁵ It is

92. Dep't of Cmty. Health, *Michigan's Informed Consent for Abortion Law*, MICHIGAN.GOV, http://www.michigan.gov/mdch/0,4612,7-132-2940_4909-45202--,00.html (last visited July 4, 2012).

93. Note, however, that the U.S. District Court for the District of South Dakota enjoined the implementation of this law on June 30, 2011 and the state of South Dakota has chosen not to appeal the injunction. *AG: State Will Not Appeal Abortion Law Injunction*, SIOUX CITY JOURNAL.COM (July 26, 2011, 5:55 PM), http://siouxcityjournal.com/news/state-and-regional/south-dakota/article_2064e882-b7c6-11e0-a15c-001cc4c002e0.html.

94. See Rachel Benson Gold & Elizabeth Nash, *State Abortion Counseling Policies and the Fundamental Principles of Informed Consent*, GUTTMACHER POL'Y REV., Fall 2007, at 12.

95. NARAL PRO-CHOICE N.C. FOUND., *THE TRUTH REVEALED: NORTH CAROLINA'S CRISIS PREGNANCY CENTERS* 11, 17 (2011), available at http://www.prochoice.nc.org/assets/bin/pdfs/2011NARAL_CPCReport_V05_web.pdf (comparing state licensing requirements for social workers and pregnancy center volunteers, and noting that 92% of crisis pregnancy centers surveyed do not have medical professionals on staff); S. MALIA RICHMOND-CRUM & MELISSA KLEDER, NARAL PRO CHOICE MD FUND, MARYLAND CRISIS PREGNANCY CENTER INVESTIGATIONS: THE TRUTH REVEALED 4 (2008) (“[V]ery few of the centers employ medical professionals or are required to adhere to medical regulations.”); see also *Crisis Counseling Training*, SANFORD CRISIS PREGNANCY CENTER http://www.sanfordcpc.com/wp/?page_id=21 (last visited Aug. 14, 2012) (targeting “volunteer lay-counselors” to counsel women about “abortion risks and alternatives”). In contrast to the highly regulated medical fields, there is as yet no legal oversight of these centers or the information their staff provides. NARAL PRO-CHOICE N.C. FOUND., *supra* note 95, at 11 (noting that neither North Carolina regulations nor federal regulations like

unclear whether patients who receive medical information in this context have sufficient opportunity to clarify or confirm information with their own physicians. This is particularly troubling in light of a 2006 report by the U.S. House of Representatives Committee on Government Reform finding that 87% of federally funded pregnancy resource centers provided “false or misleading information about the health effects of abortion.”⁹⁶

C. Values and Controversy

Finally, the possibility of misinformation or bias is particularly high when the decision aids deal with value-laden medical decisions, which is commonly the case because decision aids are used primarily for preference-sensitive care. One obvious example of this arises in the context of abortion, where state laws often require women to use decision aids before consenting to an abortion.

More than 30 states have enacted abortion-specific informed consent laws (also called “Women’s Right to Know Laws”) that establish statutory disclosure requirements for women seeking to terminate a pregnancy.⁹⁷ Although physicians typically make disclosures about the risks of a procedure during the informed consent process, many states permit these disclosures to be made by way of a pamphlet published and distributed by the state’s department of health.⁹⁸ These

HIPAA govern crisis pregnancy centers, because these centers are not medically licensed); Vitoria Lin and Cynthia Dailard, *Crisis Pregnancy Centers Seek to Increase Political Clout, Secure Government Subsidy*, GUTTMACHER REP. PUB. POL’Y, May 2002, at 4, 6 (describing lack of public scrutiny and government regulation of crisis pregnancy centers); Mark L. Rienzi, *The History and Constitutionality of Maryland’s Pregnancy Speech Regulations*, 26 J. CONTEMP. HEALTH L. & POL’Y 223, 241 (2009) (noting that pregnancy centers are not engaged in the practice of medicine and therefore not subject to medical regulatory requirements). However, efforts toward this type of regulation have been made in New York, Maryland, and California. See Michael Howard Saul, *Judge Blocks NYC’s Abortion-Disclosure Law*, WALL ST. J. (July 13, 2011, 2:20 PM), <http://blogs.wsj.com/metropolis/2011/07/13/judge-blocks-citys-abortion-disclosure-law/>; Jesse McKinley, *Politicians Open Front on Abortion in Bay Area*, N.Y. TIMES, Aug. 3, 2011, at A12.

96. SPECIAL INVESTIGATIONS DIV., MINORITY STAFF OF H. COMM. ON GOV’T REFORM, 109TH CONG., FALSE AND MISLEADING HEALTH INFORMATION PROVIDED BY FEDERALLY FUNDED PREGNANCY RESOURCE CENTERS 7, available at <http://www.chsourcebook.com/articles/waxman2.pdf>.

97. Gold & Nash, *supra* note 94, at 7. Like any patient seeking medical treatment, a woman seeking an abortion must provide informed consent for the procedure she is about to undergo. Many states require the physician, as part of the informed consent process, to provide the patient with an informational pamphlet published by the state department of health; such pamphlets often emphasize the risks of abortion as compared to the risks of childbirth and sometimes include scientifically questionable information. Critics have argued that the information provided by the state as part of the informed consent process is unfairly biased against abortion; indeed, some proponents of abortion informed consent laws have admitted that their purpose is to dissuade women from having abortions. See generally *id.*; Nadia N. Sawicki, *The Abortion Informed Consent Debate: More Light, Less Heat*, 21 CORNELL J.L. & PUB. POL’Y 1 (2011).

98. See, e.g., A WOMAN’S RIGHT TO KNOW (Tex. Dep’t of Health ed., 2003), available at <http://www.dshs.state.tx.us/wrtk/pdf/booklet.pdf>.

pamphlets comply with the disclosure requirements of abortion informed consent statutes and typically explain the characteristics of the fetus at various stages of development (incorporating statutorily required images or photographs), the various types of abortion procedures and their risks, the risks of childbirth, and the various social-support services available to women with children.⁹⁹ According to critics, many of these documents are explicitly or implicitly aimed at dissuading women from choosing abortion.¹⁰⁰ According to the Guttmacher Institute, for example, the information presented in state-mandated abortion disclosures is often “either out-of-date, biased or both.”¹⁰¹ Many physicians and researchers have challenged these brochures as being biased or factually incorrect, especially with respect to risk factors that have not been scientifically proven, such as the risk of psychological and emotional harm,¹⁰² the risk of future infertility,¹⁰³ the risk of

99. Sawicki, *supra* note 97, at 7–10.

100. See, e.g., *id.* at 12; Howard Minkoff & Mary Faith Marshall, *Government-Scripted Consent: When Medical Ethics and Law Collide*, 39 HASTINGS CTR. REP. 21, 21 (2009) (describing state informed consent laws as “a coercive process focusing almost exclusively on risks, misinformation, and implied governmental opprobrium,” and “grounded in dogmatic and uncompromising ideological speech”); Chinué Turner Richardson & Elizabeth Nash, *Misinformed Consent: The Medical Accuracy of State-Developed Abortion Counseling Materials*, GUTTMACHER POL’Y REV., Fall 2006, at 6 (noting that abortion requirements “do not always measure up to the gold standard of informed consent. . . . [T]he information presented is either out-of-date, biased or both.”); Jeremy A. Blumenthal, *Abortion, Persuasion, and Emotion: Implications of Social Science Research on Emotion for Reading Casey*, 83 WASH. L. REV. 1, 22 (2008); Rebecca Dresser, *From Double Standard to Double Bind: Informed Choice in Abortion Law*, 76 GEO. WASH. L. REV. 1599, 1599 (2007).

101. Richardson & Nash, *supra* note 100, at 6.

102. A WOMAN’S RIGHT TO KNOW, *supra* note 98, at 16 (highlighting “serious psychological effects after their abortion, including depression, grief, anxiety, lowered self-esteem, regret, suicidal thoughts and behavior, sexual dysfunction, avoidance of emotional attachment, flashbacks, and substance abuse.”); see *Planned Parenthood v. Rounds*, 653 F.3d 662, 671 (8th Cir. 2011) (“[T]he record does not demonstrate a generally recognized causal connection between abortion and suicide.”), *vacated in part on reh’g en banc*, 662 F.3d 1072 (8th Cir. 2011); Trine Munk-Olsen et al., *Induced First-Trimester Abortion and Risk of Mental Disorder*, 364 NEW ENG. J. MED. 332, 332 (2011) (finding that the prevalence of mental health problems increases after childbirth but not after abortion); Gail Erlick Robinson et al., *Is There An “Abortion Trauma Syndrome”? Critiquing the Evidence*, 17 HARV. REV. PSYCHIATRY 268, 278 (2009) (finding methodological problems among empirical studies drawing a connection between abortion and later psychological trauma).

103. A WOMAN’S RIGHT TO KNOW, *supra* note 98, at 17 (noting that some abortion-related complications “may make it difficult or impossible to become pregnant in the future or to carry a pregnancy to term” and citing the risk of premature birth after abortion doubled); see Janet R. Daling & Irvin Emanuel, *Induced Abortion and Subsequent Outcome of Pregnancy in a Series of American Women*, 297 NEW ENG. J. MED. 1241 (1977) (finding no relationship between history of induced abortion and subsequent pregnancies involving low birth rate, premature delivery, stillbirth, miscarriage, or other complications); Peter Frank et al., *The Effect of Induced Abortion on Subsequent Fertility*, 100 BJOG 575, 575 (1993) (finding no relation between induced abortion and subsequent infertility); Kaisa Raatikainen et al., *Induced Abortion: Not an Independent Risk Factor for Pregnancy*

breast cancer,¹⁰⁴ and the presence or absence of fetal pain.¹⁰⁵ This is particularly problematic in light of the fact that purportedly neutral state departments of health draft these publications; there is unfortunately no information on how they do so or whether they offer any opportunity for public comment or notification. South Dakota's requirement that women seeking abortions first obtain anti-abortion counseling at a crisis pregnancy center demonstrates even more clearly how ideological beliefs about value-laden decisions may impact the nature of legally required disclosures and the content of associated decision aids.

Women's reproductive health, however, is hardly the only context in which value judgments might arise within decision aids. End-of-life medical care has generated heated public debates about whether providing patients with information about end-of-life planning is useful for furthering patient autonomy or indicative of malicious state efforts to limit access to care for the elderly.¹⁰⁶

Outcome, but a Challenge for Health Counseling, 16 ANNALS OF EPIDEMIOLOGY 587, 587 (2006) (finding "no evidence of adverse pregnancy outcomes" after induced abortion); Carol J. Rowland Hogue et al., *The Effects of Induced Abortion on Subsequent Reproduction*, 4 EPIDEMIOLOGIC REVIEWS 66, 88 (1982) (finding that complications in pregnancies occurring after induced abortions "occur[] so infrequently that . . . risk is not significantly elevated").

104. A WOMAN'S RIGHT TO KNOW, *supra* note 98, at 17 ("While there are studies that have found an increased risk of developing breast cancer after an induced abortion, some studies have found no overall risk."). See Lynne L. Bartholomew & David A. Grimes, *Focus on Primary Care: The Alleged Association Between Induced Abortion and Risk of Breast Cancer: Biology or Bias?*, 53 OBSTETRICAL & GYNECOLOGICAL SURV. 708, 714 (1998) (concluding that there is fair evidence that abortion does not increase the risk of breast cancer); Valerie Beral et al., *Breast Cancer and Abortion: Collaborative Reanalysis of Data from 53 Epidemiological Studies, Including 83 000 Women with Breast Cancer from 16 Countries*, 363 LANCET 1007, 1010 (2004) (finding pregnancies that end as a spontaneous or induced abortion do not increase a woman's risk of developing breast cancer); Katherine DeLellis Henderson et al., *Incomplete Pregnancy is Not Associated with Breast Cancer Risk: The California Teachers Study*, 77 CONTRACEPTION 391, 391-96 (2008) (finding no statistically significant association between any measure of incomplete pregnancy and breast cancer risk); Gillian K. Reeves et al., *Breast Cancer Risk in Relation to Abortion: Results from the EPC study*, 119 INT. J. CANCER 1741, 1743 (2006) (showing evidence of the lack of an adverse effect of induced abortion on breast cancer risk); see also Am. Coll. of Obstetricians and Gynecologists, *ACOG Committee Opinion No. 434: Induced Abortion and Breast Cancer Risk*, 113 OBSTETRICS & GYNECOLOGY 1417, 1417 (2009) (noting that early studies had "significant methodological problems," and concluding that "there is no association between induced abortion and breast cancer").

105. Compare A WOMAN'S RIGHT TO KNOW, *supra* note 98, at 5 (noting that "[s]ome experts have concluded that the unborn child is probably able to feel pain" at 20 weeks), with Susan J. Lee et al., *Fetal Pain: A Systematic Multidisciplinary Review of the Evidence*, 294 JAMA 947, 947 (2005) (concluding that fetal perception of pain is "unlikely" before the third trimester), and Harper Jean Tobin, *Confronting Misinformation on Abortion: Informed Consent, Deference, and Fetal Pain Laws*, 17 COLUM. J. GENDER & L. 111, 143 (2008) (concluding that some statements in state-mandated educational material on fetal pain conflicts with scientific literature and that all statements are misleading).

106. See Jim Rutenberg & Jackie Calmes, *False 'Death Panel' Rumor Has Some Familiar Roots*, N.Y. TIMES, Aug. 14, 2009, at A1.

Moreover, the debate about values is not limited to specific treatment contexts. Consider, for example, a widely contested provision within PPACA relating to the use of comparative effectiveness research, generally defined as research that systematically compares the effectiveness of various treatment options to determine which healthcare interventions are most appropriate for which patients. While supporting the development of comparative effectiveness research, PPACA prohibits the U.S. Department of Health and Human Services (“HHS”) from using such research in making coverage or reimbursement decisions “in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment *based on how the individual values the tradeoff between extending the length of their life and the risk of disability.*”¹⁰⁷ Given that decision-support tools are used primarily for preference-sensitive and value-based decisions, even those tools that are used in the context of seemingly uncontroversial conditions—prostate cancer or breast cancer, for example—may implicate political concerns about the balance of patient values regarding quality and length of life.

III. CURRENT CONTROL OF DECISION-SUPPORT TOOLS

Despite concerns about the quality of third-party decision-support tools, there has been no *ex ante* governmental regulation of decision-support tools to date and only limited private oversight. Moreover, there currently exists no opportunity for *ex post* recovery under the tort system by patients harmed as a result of faulty or misleading decision aids. It is commendable, then, that PPACA’s proposal for incorporating patient decision aids as part of SDM establishes a framework for a quasi-governmental certification process. This Part describes existing and proposed measures for controlling the quality of decision aids.¹⁰⁸

A. Private Oversight

Some commentators concerned with the quality of decision-support tools have recommended a formal credentialing process to ensure that the tools produced are high quality. King and Moulton recommend that “the information provided in decision aids . . . be approved by credentialed, neutral bodies made up of lay people, physicians and researchers who are trained to make such decisions[.]”¹⁰⁹ Harlan Krumholz recommends that the information in patient decision aids be “written by expert groups empanelled by the Department of Health and Human Services.”¹¹⁰ No legal mechanism, however, currently exists for evaluating and certifying decision-support tools before they are adopted for patient use.

107. Patient Protection and Affordable Care Act, Pub. L. 111–148, § 6301, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 1320e-1(d)(1) (2012)) (emphasis added).

108. Discussion of non-legal mechanisms for controlling the quality of medical care, such as professional ethics, is beyond the scope of this Article.

109. King & Moulton, *supra* note 27, at 466.

110. Harlan M. Krumholz, *Informed Consent to Promote Patient-Centered Care*, 303 JAMA 1190, 1190 (2010).

A few private organizations have begun taking steps to evaluate the quality of available decision aids.¹¹¹ The Ottawa Hospital Research Institute, for example, collects an inventory of publicly available decision aids that meet a limited set of quality criteria: they must be recent, provide references to scientific evidence used, and report any conflicts of interest.¹¹² More compelling is the International Patient Decision Aid Standards (“IPDAS”) Collaboration, which has developed a more thorough checklist for evaluating the quality of decision-support tools.¹¹³ Their checklist is broken up into categories: Content, Development Process, and Effectiveness. Many of the quality measures in the IPDAS checklist speak to the kinds of quality concerns highlighted in Part II, including “present[ing] probabilities of outcomes in an unbiased and understandable way,” using “up to date scientific evidence that is cited in a reference section or technical document,” and “disclos[ing] conflicts of interest.”¹¹⁴ The IPDAS Collaboration expects its criteria to be “helpful to a wide variety of individuals and organizations that use and/or develop patient decision aids.”¹¹⁵ The New America Foundation (“NAF”), a nonprofit public policy institute, has recently begun a similar effort to “produce a consensus document outlining the criteria for certification of aids and the process by which certification should take place.”¹¹⁶ NAF plans to circulate the final document to the Secretary of HHS, with the goal of “guiding the establishment of [national] standards for decision aids.”¹¹⁷

B. Ex Ante Regulation and Credentialing

As of yet, there is no public regulation or oversight of decision-support tools. This is both problematic and surprising because nearly every other aspect of medical care and health information, from physician licensure to pharmaceutical marketing, is subject to statutory requirements and administrative regulations. Indeed, medicine is one of the most highly regulated industries in the United States. History has demonstrated that few industries, medicine included, are able to self-regulate in a way that offers sufficient protections for consumers. In the vast majority of cases the government has stepped in to take control.¹¹⁸

Although there is currently no regulatory mechanism for patient decision aids, a proposal to this effect was passed as part of PPACA’s efforts to facilitate

111. See generally CMS REPORT, *supra* note 40.

112. *Patient Decision Aids*, *supra* note 44.

113. INT’L PATIENT DECISION AID STANDARDS COLLABORATION, IPDAS 2005: CRITERIA FOR JUDGING THE QUALITY OF PATIENT DECISION AIDS (2005), *available at* http://ipdas.ohri.ca/IPDAS_checklist.pdf.

114. *Id.*

115. INT’L PATIENT DECISION AID STANDARDS (IPDAS) COLLABORATION, <http://ipdas.ohri.ca/> (last visited July 16, 2012).

116. New America Foundation, *Certification of Patient Decision Aids*, NEWAMERICA.NET, http://newamerica.net/events/2011/patient_decision_aids (last visited July 7, 2012).

117. *Id.*

118. See Arlen, *supra* note 20, at 1121, 1126.

shared decision-making.¹¹⁹ PPACA defines a patient decision aid as “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 provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.”¹²⁰ The proposal requires the Secretary of HHS to contract with an entity that will evaluate and certify decision aids. The entity, which must include “a broad range of experts and key stakeholders,” will be charged with developing “consensus-based standards” for evaluating and certifying patient decision aids.¹²¹ Although the details of the process are unspecified, additional procedures will surely develop as the regulations are drafted, which makes this a prime opportunity for evaluating the optimal means of ensuring patient safety. For the purposes of this Article, the regulatory proposal established in PPACA will be used as a representative example of the pure *ex ante* regulatory approach.

C. Ex Post Recovery

Given that the use of decision-support tools is a relatively recent development, it is perhaps understandable that there are as yet no regulatory mechanisms for ensuring their quality. In the absence of regulations, however, one might expect that tort law would provide some remedy for those injured by faulty decision aids, in turn incentivizing decision aid creators to maintain a high-quality product.¹²² Surprisingly, however, the tort system is poorly equipped to deal with such claims, leaving most (if not all) plaintiffs who wish to bring suit against the creator of a faulty, misleading, or biased decision-support tool without an opportunity for redress.¹²³

Although a strict product liability claim is likely the most appealing claim from the plaintiff’s perspective, decision-support tools do not satisfy the legal definition of a “product” for these purposes. Courts have consistently held that

119. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3506, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 299b-36 (2012)).

120. *Id.* (codified as amended at 42 U.S.C. § 299b-36(b)(1)).

121. *Id.* (codified as amended at 42 U.S.C. § 299b-36(c)). PPACA also establishes the availability of grants to support Shared Decisionmaking Resource Centers that will “provide technical assistance to providers” and develop best practices for the effective use of decision aids. *Id.* (codified as amended at 42 U.S.C. § 299b-36(e)).

122. This Article does not fully address the prospect of liability on the part of physicians who “prescribe” faulty decision aids to their patients. *See infra* Part V. I have argued in a prior article that physicians who use decision aids may face traditional malpractice liability if they over-rely on decision aids at the expense of an informed consent conversation. However, policy arguments suggest that where the decision aid itself is faulty, the physician who prescribes it ought not face liability for the negligence of third-party information providers beyond their control. Sawicki, *supra* note 25, at 9.

123. The limitations on liability for creators of faulty medical tools have already been recognized in the context of clinical practice guidelines. *See generally* Avraham, *supra* note 78, at 32; Daniel Jutras, *Clinical Practice Guidelines as Legal Norms*, 148 CMAJ 905, 908 (1993).

products liability does not apply where injury arises as a result of the words or ideas within a book, pamphlet, brochure, or similar product.¹²⁴ As the Ninth Circuit wrote in *Winter v. G.P. Putnam's Sons*, "We place a high priority on the unfettered exchange of ideas The threat of liability without fault could seriously inhibit those who wish to share thoughts and theories."¹²⁵

An obvious alternative would be for the plaintiff to bring suit under a theory of negligent misrepresentation. According to the Second Restatement of Torts, a defendant will be liable for negligent misrepresentation if he "negligently gives false information to another" and such information causes physical harm to that person or to a foreseeable third party.¹²⁶ Negligence is defined as the failure to exercise reasonable care in "ascertaining the accuracy of the information," or "the manner in which it is communicated."¹²⁷ Under this definition, then, decision-aid creators who negligently provide false information, or negligently communicate information in a manner giving a "misleading impression,"¹²⁸ may be liable to patients who are thereby harmed.¹²⁹ However, the actual prospects for liability

124. See *Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1036 (9th Cir. 1991) (declining to expand products liability law to embrace the ideas and expression in a book); *Cardozo v. True*, 342 So. 2d 1053, 1056–57 (Fla. Dist. Ct. App. 1977) (bookseller's strict liability limited to the physical properties of books, binding, and printing, not the material communicated); *Herceg v. Hustler Magazine, Inc.*, 565 F. Supp. 802, 803 (S.D. Tex. 1983) (finding no case law to support strict liability for the content of a magazine or other publication as a product within the meaning of section 402A of the Restatement (Second) of Torts); *Smith v. Linn*, 563 A.2d 123, 126 (Pa. Super. Ct. 1989) (noting no appellate court in any jurisdiction has held a book to be a product for purposes of section 402A).

125. 938 F.2d 1033, 1034–35 (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). The only situation in which defendants have been held strictly liable for harms to readers is in cases involving "charts which graphically depict geographic features or instrument approaches for airplanes." *Winter*, 938 F.2d at 1035 (citing *Saloomey v. Jeppesen & Co.*, 707 F.2d 671, 676, 679 (2d Cir. 1983) (holding that aeronautical charts classified as products were grounds for strict liability)). In *Winter*, the Ninth Circuit Court of Appeals expressly distinguished cases involving aeronautical charts from those involving "how-to books." 938 F.2d at 1035–36.

126. RESTATEMENT (SECOND) OF TORTS § 311 (1965).

127. *Id.*

128. *Id.* at cmt. e, illus. 9.

129. Many courts have held that section 311 of the Restatement (Second) of Torts does not apply to those who merely publish false information. See *Smith*, 563 A.2d at 126; *Alm v. Van Nostrand Reinhold Co.*, 480 N.E.2d 1263, 1266–67 (Ill. App. Ct. 1985); *MacKown v. Ill. Publ'g & Printing Co.*, 6 N.E.2d 526, 530 (Ill. App. Ct. 1937) (a publisher is not liable for physical injuries resulting from the procedures it publishes). Rather, a publisher will be liable for negligent misrepresentation only if he also authored or otherwise guaranteed the information. *Birmingham v. Fodor's Travel Publ'ns, Inc.*, 833 P.2d 70, 75 (Haw. 1992) ("It appears from a review of relevant case law that no jurisdiction has held a publisher liable in negligence for personal injury suffered in reliance upon information contained in the publication, unless the publisher authored or guaranteed the information."); see also *Lewin v. McCreight*, 655 F. Supp. 282, 283 (E.D. Mich. 1987) (applying this rule in a products liability context). In the case of decision-aid creators, of course, the publisher,

under a theory of negligent misrepresentation are extremely unlikely for two significant reasons.

First, courts adjudicating negligent misrepresentation claims typically require that the plaintiff demonstrate privity with the defendant.¹³⁰ Where the misrepresented information has been circulated to consumers or the general public,¹³¹ however, few courts are willing to find privity. Authors of printed materials aimed at the general public have consistently been found to owe no duty of care to readers, even where the material provides instructions and information about improving one's health.¹³² In *Roman v. City of New York*, for example, plaintiffs brought a negligent misrepresentation claim against Planned Parenthood on the basis of faulty information provided in a booklet she was given at her physician's office.¹³³ 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."¹³⁴ Based on this precedent, it is 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, unless the circumstances indicated some special relationship that would support a finding of privity. That said, in cases where a plaintiff is able to prove that a

author, and guarantor are one and the same; thus, a cause of action for negligent misrepresentation would be applicable.

130. In contrast, third parties who guarantee or endorse the quality of a product may be found liable for negligent misrepresentation if a plaintiff is injured as a result of a defect in that product, even in the absence of privity. *Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519, 523 (Ct. App. 1969) (holding that plaintiff successfully pled a cause of action against Good Housekeeping for issuing its Consumers' Guaranty Seal to a pair of defective shoes).

131. See, e.g., *First Equity Corp. of Fla. v. Standard & Poor's Corp.*, 670 F. Supp. 115, 116, 118 (S.D.N.Y. 1987) (declining to find the publisher of *Corporation Records* liable even though "[t]he defendant tout[ed] the reliability" of its publication, noting that: "It is one thing to say that the defendant extols the virtues of its publication. . . . It is quite another to say that it anywhere assumes responsibility for 100 percent accuracy.").

132. See, e.g., *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 327 (S.D.N.Y. 2006) (denying negligent misrepresentation claim for relying on a diet education book); *Bailey v. Huggins Diagnostic Ctr.*, 952 P.2d 768, 771, 773 (Colo. App. 1997) (finding that a dentist who wrote a book encouraging removal of dental amalgams owed no duty of care to members of the public who read the book).

There have been few cases in which readers have sought to recover based upon statements made by authors, and none has been discovered that has allowed recovery, except in those instances in which the publication was intended to be used as a "product." In all other instances, in light of First Amendment implications, it has been concluded that no duty of due care is owed by an author to a reader.

Id. at 773 (internal citation omitted).

133. 442 N.Y.S.2d 945, 948 (Sup. Ct. 1981).

134. *Id.*

decision-aid creator's misrepresentation or bias was *intentional*, she might recover on traditional negligence grounds, and privity would not be an issue.¹³⁵

The second, and more intractable, barrier to tort recovery for victims of faulty decision aids (whether on grounds of negligence or negligent misrepresentation) is the problem of proving causation. In order to succeed on a traditional negligence-based claim, a plaintiff must demonstrate causation in fact—namely, the plaintiff would not have been injured had the defendant acted reasonably. However, in negligence claims based on failure of informed consent, this standard is modified. Causation in informed consent cases is judged by an objective standard, whereby the plaintiff must prove that the “reasonable patient” would have declined the procedure (or chosen a different procedure) had the defendant accurately disclosed its risks.¹³⁶

This brings us to the problem of causation in claims for injuries suffered as a result of faulty decision aids. By definition, decision-support tools are used primarily for preference-sensitive medical decisions—that is, decisions as between multiple clinically viable options. The very nature of preference-sensitive medical decisions is that it is impossible to predict what a “reasonable patient” would choose. For example, for women with a family history of breast cancer and the BRCA1 or BRCA2 genes, prophylactic mastectomy and “watchful waiting” are both legitimate clinical options.¹³⁷ Depending on their values, patients may have different opinions about which treatment is best for them. In such a situation, because of the value-based nature of the decision, few plaintiffs would be able to

135. The tort of “intentional misrepresentation” is not applicable in this context, as it is used almost exclusively where misrepresentation leads to commercial rather than physical harm. DAN B. DOBBS, *THE LAW OF TORTS* § 469, at 1343 (2000). Where intentional misrepresentation instead leads to physical injury, the underlying act of “misrepresentation” tends to be subsumed by the resulting (intentional or negligent) tort. *Id.*; see also W. PAGE KEETON ET AL., *PROSSER AND KEETON ON TORTS* § 104, at 725–26 (5th ed. 1984) (“A great many of the common and familiar forms of negligent conduct, resulting in invasions of tangible interests of person or property, are in their essence nothing more than misrepresentation . . . [In such cases,] misrepresentation has been merged to such an extent with other kinds of misconduct that neither the courts nor legal writers have found any occasion to regard it as a separate basis of liability.”); and *infra* Part V.C.

136. *Canterbury v. Spence*, 464 F.2d. 772, 786–88 (D.C. Cir. 1972); see also Peter H. Schuck, *supra* note 27, at 919. This objective element of the causation claim is referred to as “decision causation.” A plaintiff in an informed consent case must also prove “injury causation”—namely, that the undisclosed risk actually caused the plaintiff’s injury. *Id.* at 918–19; Evelyn Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. (forthcoming 2012) (on file with author).

137. See, e.g., Victor R. Grann et al., *Decision Analysis of Prophylactic Mastectomy and Oophorectomy in BRCA1-Positive or BRCA2-Positive Patients*, 16 J. CLINICAL ONCOLOGY 979 (1998); Ellen S. Tambor et al., *Should Women at Increased Risk for Breast and Ovarian Cancer Be Randomized to Prophylactic Surgery? An Ethical and Empirical Assessment*, 9 J. WOMEN’S HEALTH & GENDER-BASED MED. 223 (2000); Peter A. Ubel, “What Should I Do, Doc?”: *Some Psychologic Benefits of Physician Recommendations*, 162 ARCH. INTERN. MED. 977 (2002).

prove that a reasonable patient faced with accurate and unbiased information about both options would have made a different choice. If a medical decision is challenging precisely because there are reasonable differences of opinion about the best treatment option, a patient harmed as a result of misinformation during this decision will have great difficulty satisfying the causation element of the claim.¹³⁸

A final point worth noting is that some of the flaws we are likely to see in decision-support tools may not fall squarely within the definition of negligence or negligent misrepresentation. 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 more difficulty 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,¹³⁹ a jury may be unwilling to impose liability based on a difference in framing. That said, the Restatement Second of Torts suggests that negligence in providing information may include not only “false information,” but also the manner in which the information is communicated.¹⁴⁰ And in the rare case where a plaintiff is able to demonstrate intentional use of framing effects or other cognitive biases by the decision-aid creator, recovery for subsequent physical harm could be obtained on traditional negligence grounds, as described above.

IV. THE SPECTRUM FROM REGULATION TO TORT LAW: FACTORS TO CONSIDER

Administrative regulation and tort liability are the primary mechanisms by which American law serves to protect the public from potentially harmful products and activities. Administrative agencies establish *ex ante* standards with which industries and professions are required to comply to minimize public risk. If consumer injury nevertheless occurs as a result of an entity’s failure to satisfy the appropriate standard of care, *ex post* tort liability may then be used to compensate individuals for their pecuniary and non-pecuniary losses. Regulation and tort are often viewed as complementary systems, with tort liability picking up where administrative regulation leaves off.¹⁴¹

138. See, e.g., Evelyn Tenenbaum, Presentation at the ASLME’s 34th Annual Health Law Professors Conference: The Causation Element of Informed Consent and Why Current Trends in Health Care Support the Need for Change (June 10, 2011).

139. Alex Barratt, *Presenting Probabilities*, in IPDAS COLLABORATION BACKGROUND DOCUMENT 11, 13 (Annette O’Connor et al. eds., Feb. 17, 2005), available at ipdas.ohri.ca/IPDAS_Background.pdf.

140. RESTATEMENT (SECOND) OF TORTS § 311 cmt. e (1965) (“The negligence for which the actor is liable under the statement in this Subsection consists in the lack of reasonable care to furnish accurate information. It is, therefore, not enough that the actor has correctly ascertained the facts on which his information is to be based and has exercised reasonable competence in judging the effect of such facts. He must also exercise reasonable care to bring to the understanding of the recipient of the information the knowledge which he has so acquired.”).

141. See, e.g., Nagareda, *supra* note 21, at 1.

When ordering professional and industrial behavior, policy-makers can choose among a variety of options within the wide spectrum between exclusively regulatory regimes and tort regimes; as is often the case, most situations fall somewhere in the middle. The choice of where on this spectrum a given situation should fall can be viewed as a decision about who is in the best position to define and enforce the standard of care—an administrative agency or a court.¹⁴² Where policy-makers decide that the standard of care should hew closely to an agency's determination, they may explicitly or implicitly preempt state tort actions that would impose additional requirements above and beyond those established by regulations. Similar goals can be achieved using the doctrine of regulatory compliance,¹⁴³ which states that defendants' compliance with duly enacted regulations is a defense in tort actions and effectively prohibits courts from second-guessing agency decisions relating to the standard of care. In other contexts, however, policy-makers may leave open the possibility of using tort law to complement existing regulatory requirements.¹⁴⁴

Decisions about where on this spectrum a given case should fall are inherently challenging,¹⁴⁵ and it can be unclear why policy-makers choose to preempt tort liability in some cases but not others. Thankfully, a surfeit of recent academic work in this area has been helpful in clarifying the benefits of each approach and in elucidating some of the reasons why policy-makers might choose one over another.¹⁴⁶ This Part builds upon prior scholarship by identifying five

142. Hylton, *supra* note 21, at 212 (2008); Rabin, *supra* note 21, at 2061.

143. See W. Kip Viscusi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1463–64 (1994).

144. Such contexts include pharmaceutical and environmental regulation. See *infra* text accompanying notes 156–61.

145. Occasionally, Congress clarifies its expectations by including express preemption language in a statute authorizing agency regulation. However, more often than not, statutory grants of agency authority do not include clear and unambiguous directives with respect to the preemption of tort claims. See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 574 (2008) (“If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history. But . . . Congress has not”); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166 (1989) (“Both the law of unfair competition and state trade secret law have coexisted harmoniously with federal patent protection for almost 200 years, and Congress has given no indication that their operation is inconsistent with the operation of the federal patent laws.”). Accordingly, judges and agency officials are frequently charged with determining whether Congress intended to establish a purely regulatory regime or whether individuals injured as a result of regulatory violations ought to be permitted to bring tort claims for recovery.

146. See, e.g., Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 277–78 (1985) (distinguishing between public and private risks); Hylton, *supra* note 21, at 211–14 (considering error cost in determining whether preemption is appropriate); Nagareda, *supra* note 21, at 8–37 (identifying situations in which we might be more confident in regulatory approaches than tort approaches); Eric A. Posner & Cass R. Sunstein, *Dollars and Death*, 72 U. CHI. L. REV. 537 (2005) (highlighting differences between tort law and administrative law); Rabin, *supra*

factors¹⁴⁷ that ought to be considered in determining whether a primarily regulatory system or one incorporating substantial tort remedies is more appropriate to a given context.¹⁴⁸ Then, this Part evaluates each of these factors as applied to patient decision aids. It concludes that while there is a great deal of uncertainty about whether the regulations contemplated by PPACA would be sufficient to control the creation of decision aids, many of these factors weigh in favor of a complementary tort regime.

A. Remedies, Compensation, and Deterrence

The principal difference between regulatory and tort approaches is that the tort system, unlike administrative regulation, has as one of its primary concerns the compensation of individuals who have been harmed.¹⁴⁹ Regulatory regimes, in contrast, are typically aimed at setting comprehensive standards that efficiently balance costs and benefits at a more global level, rather than rectifying individual harms. Accordingly, policy-makers' perceptions of the likelihood of individual harm as well as their opinions about the need for victim compensation in light of existing regulations are likely to influence decisions about which system is more appropriate in a given context. Where some of the compensatory goals of tort law are already satisfied by a regulatory regime—either through a no-fault

note 21, at 2050 (discussing the risks and benefits of the regulatory compliance defense); Viscusi, *supra* note 21, at 67–71 (highlighting the risks and benefits of market-based approaches, tort law, social insurance, and regulation in controlling risks). The wealth of recent work on this topic may be the result of recent trends toward elimination of tort remedies in favor of administrative regimes. See Abigail R. Moncrieff, *The Supreme Court's Assault on Litigation: Why (and How) It Might Be Good for Health Law*, 90 B.U. L. REV. 2323, 2382 (2010).

147. This list of five factors is by no means exhaustive. Additional factors that may affect decisions about whether to adopt a primarily regulatory regime or one supplemented with tort liability include: the degree of conflict between regulatory and common law requirements, Hylton, *supra* note 21, at 217; the comparative administrative costs of each approach, *id.* at 212–13; Posner & Sunstein, *supra* note 146, at 540–42; the importance of predictability, Hylton, *supra* note 21, at 213–14; and the relative values of agency expertise and local knowledge. *Id.* at 214. I have not included them in the list of five essential factors in part because they may not be applicable to every situation, whereas the five factors described herein tend to be relevant for all policy decisions in this arena. For example, where common law requirements are unclear or regulatory requirements have not been established, it is impossible to analyze the degree of conflict between the two. Moreover, the five factors I selected are those that tend to be analyzed most frequently by courts and commentators.

148. Although policy-makers may not engage in a formalistic analysis of each of these five factors when making such decisions, scholars of administrative and tort law consistently recognize the salience of these characteristics to legislatures' and courts' reasoning. See *supra* note 146. There is, moreover, no single way of calculating which of these factors is most important in a given context; most authors simply refer to a “weighing” or “balancing” approach. See, e.g., Hylton, *supra* note 21, at 214.

149. Rabin, *supra* note 21, at 2073 (“Regulatory agencies are not in the business of compensating for accidental harm arising from activities within the ambit of their authority.”).

compensation system¹⁵⁰ or some other remedy¹⁵¹—policy-makers may determine that additional victim recovery is unnecessary and provide for complete or partial preemption of tort suits.¹⁵² The most notable example of a broad preemptive regime in the medical context is that of medical devices, which are heavily regulated by the Food and Drug Administration (“FDA”) pursuant to the Medical Device Amendments (“MDA”) of 1976.¹⁵³ In *Riegel v. Medtronic*, the Supreme Court held that federal regulations completely preempt the possibility of state tort claims against device manufacturers for defective design, manufacturing, or labeling of devices that have been approved through the FDA’s pre-market approval process.¹⁵⁴ Injured patients do, however, have a right to pursue claims against medical device manufacturers for violating FDA regulations—for example, if their product deviates from the specifications provided during pre-market approval.¹⁵⁵ In essence, policy-makers have determined that the MDA’s protections are enough to protect consumers and that consumers will have a

150. For example, the federal public health statute establishing the National Vaccine Program also establishes a National Vaccine Injury Compensation Program (“NVICP”). 42 U.S.C. §§ 300aa-1 to -34 (2012). The NVICP enables individuals with vaccine-related injuries to obtain remedies through a no-fault compensation system or, under certain circumstances, to pursue civil actions. *Id.*

151. An example of this is in the context of ERISA, which regulates employee benefit plans, including health benefit plans. ERISA grants beneficiaries an affirmative right to sue in federal court to recover benefits due under a plan, enforce rights under the terms of a plan, or clarify rights to future benefits. Although beneficiaries are precluded under ERISA from recovering most monetary damages resulting from a claim denial, Congress has determined that the statutory remedies described above are sufficient. Accordingly, state tort suits against most health plans and providers are completely preempted to the extent they seek to recover the remedies already granted by ERISA. 29 U.S.C. § 1132 (2012); *Aetna Health, Inc. v. Davila*, 542 U.S. 200, 200–01 (2004); see John D. Shire, Comment, *Varity Corp. v. Howe in the Wake of Martens v. Hewitt Associates: Did the Supreme Court Impermissibly Authorize a Damages Award Under ERISA Section 502(a)(3)(B)?*, 102 DICK. L. REV. 411, 438 (1998) (“The issue whether ERISA section 502(a)(3)(B) authorizes damages is unsettled. . . . Nonetheless, while consequential damages are not authorized under section 502(a)(3)(B), direct damages should be available under that section. . . . Damage awards outside of the benefits due under the express terms of the plan are extracontractual and should not be recoverable.”); see also *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993) (“All that ERISA has eliminated, on these assumptions, is the common law’s joint and several liability, for *all* direct and consequential damages suffered . . .”). ERISA’s treatment of victim injury makes plain that the extent to which victims are able to recover is dependent on how their rights are legally defined and that narrowly defined rights may offer consumers only limited opportunities for recovery.

152. Note that a variety of other factors also play into the preemption decision, most notably the degree of congruence between regulatory and common-law requirements. See Hylton, *supra* note 21, at 217.

153. Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360c–360k (2012)).

154. 552 U.S. 312, 330 (2008). Medical devices that have been exempted from the pre-market approval process under Section 510(k) of the MDA are, however, still vulnerable to state tort suits. *Medtronic v. Lohr*, 518 U.S. 470, 493–94 (1996).

155. *Riegel*, 552 U.S. at 330.

satisfactory remedy if they are injured as a result of a manufacturer's failure to comply with federal regulations.

The regulation of pharmaceuticals, in contrast, is an example of a system that falls more toward the tort side of the spectrum. In *Wyeth v. Levine*, the Supreme Court held that consumers may bring state law failure-to-warn suits against pharmaceutical companies, even if the drug labeling was approved by the FDA.¹⁵⁶ In interpreting Congress's intent in drafting the Food, Drug, and Cosmetic Act ("FDCA"), the Court determined that consumers will be inadequately protected and inadequately compensated if they are only permitted to sue drug manufacturers for regulatory non-compliance.¹⁵⁷ Thus, in pharmaceutical cases, judges and juries are given the opportunity to "second-guess" agency determinations about the appropriate balance between risks and benefits. We see a similar approach in the context of environmental regulations, which generally do not provide a compensatory remedy for individual injuries¹⁵⁸ and have long been viewed as insufficient for public protection.¹⁵⁹ Indeed, the prevalence of environmental tort suits has increased over the past few decades¹⁶⁰ in part due to the growing recognition that civil liability is a "necessary complement" to regulation from the perspective of victim compensation.¹⁶¹

Accordingly, the first questions we should ask when deciding between primarily regulatory and primarily tort-based regimes are: (1) whether individual consumers are likely to be harmed by a regulatory violation (or by a faulty regulation itself); and (2) if so, whether the regulation in question offers a sufficient opportunity for a compensatory remedy, while taking into account deterrence. If the likelihood of consumer harm is high and the regulation does not provide a satisfactory individual remedy, a complementary tort regime may be necessary.

156. 555 U.S. 555, 575–76 (2008).

157. *Id.*

158. See Kenneth S. Abraham, *The Relation Between Civil Liability and Environmental Regulation: An Analytical Overview*, 41 WASHBURN L.J. 379, 382 (2002); Peter Cane, *Using Tort Law to Enforce Environmental Regulations*, 41 WASHBURN L.J. 427, 452 (2002). However, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA"), does allow injunctive remedies and recovery of costs for individual injuries. Abraham, *supra* note 158, at 386–88.

159. See Abraham, *supra* note 158, at 391.

160. Troyen A. Brennan, *Environmental Torts*, 46 VAND. L. REV. 1, 1–3 (1993) (describing environmental torts as increasing, and "informed . . . by environmental regulation"); Sheila G. Bush, *Can You Get There from Here?: Noncompliance with Environmental Regulations as Negligence Per Se in Tort Cases*, 25 IDAHO L. REV. 469 (1988) (describing a "recent frenzy of toxic tort litigation"). *But see* Albert C. Lin, *Beyond Tort: Compensating Victims of Environmental Toxic Injury*, 78 S. CAL. L. REV. 1439, 1441–42 (2004) (arguing that tort law leaves many victims of environmental torts uncompensated, in part due to the difficulties of proving causation); Christopher H. Schroeder, *Lost in the Translation: What Environmental Regulation Does that Tort Cannot Duplicate*, 41 WASHBURN L.J. 583, 589 (2001) (same).

161. Abraham, *supra* note 158, at 379.

In the case of patient decision aids, the possibility of consumer injury is significant, for the reasons outlined in Part II. Since there are currently no legal restrictions on the creation or distribution of decision aids and no obvious opportunities for tort recovery, consumers' compensatory goals are not being well served. Thus, in order to ensure that injured parties have some remedy, policy-makers in this area have two options—either they could draft regulations for the creation and use of patient decision aids that provide some compensatory remedy or they could leave the issue of compensation to tort law. Let us consider each of these options in turn.

PPACA requires that HHS contract with an entity that will develop “consensus-based standards”¹⁶² for decision-support tools and establish a certification process. It remains to be seen to what extent HHS regulations will guide this standard-setting, but it seems reasonable to assume that HHS will provide, at the very least, general directives about the goals patient decision aids ought to satisfy to be consistent with PPACA.¹⁶³ If faulty decision aids result despite these precautions, whether because HHS has not provided sufficient guidance to or oversight of the contracting entity, or because decision-aid creators have failed to comply with the standards, patients are likely to be injured.

A regulatory approach to remedying such injury might provide a federal remedy to parties injured by regulatory non-compliance. Alternatively, it might seek to establish, with Congress's approval, a no-fault compensation system for patients injured by faulty decision aids. No-fault systems, like workers' compensation and the National Vaccine Injury Compensation Program, provide injured parties with the opportunity to receive compensation through administrative means, without having to bring a tort case in court or prove liability on the part of a defendant. The primary benefit of such systems is the efficiency and uniformity of their administration. Victims can resolve their claims more quickly and easily than they would through the tort system, and potential defendants need not fear bankruptcy as a result of a groundswell of tort suits.¹⁶⁴ No-fault compensation systems are particularly useful where victims might have difficulty proving fault under traditional theories of causation.¹⁶⁵

Establishing such a program, however, is likely to be extremely difficult in the context of decision-support tools. The most significant challenge relates to the fact that establishing a no-fault system requires a solid financial foundation that is unlikely to be found in the context of patient decision aids. Existing no-fault programs—like worker's compensation, Florida's Birth-Related Neurological Injury Compensation Plan,¹⁶⁶ the National Vaccine Injury Compensation

162. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3506, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 299b-36(c)(1)(A) (2012)).

163. See *id.* (codified as amended at 42 U.S.C. § 299b-36(d)(1)(B)).

164. Randall R. Bovbjerg et al., *Administrative Performance of “No-Fault” Compensation for Medical Injury*, 60 L. & CONTEMP. PROBS. 71, 74–75 (1997).

165. *Id.* at 72.

166. Established by FLA. STAT. § 766.303 (2012).

Program,¹⁶⁷ and the September 11th Victim Compensation Fund¹⁶⁸—are funded by the parties who would most likely be defendants in associated tort suits. Generally, no-fault programs are established only where the entities contributing premiums or funds to the programs (e.g., employers, physicians, pharmaceutical companies, and airline carriers) are significant in number or otherwise well funded. A no-fault system of compensation for victims of faulty decision aids, in contrast, would need to be funded by the creators and marketers of decision aids, a much shallower pool. The market for patient decision aids has only recently developed, and until a critical mass of well-funded entities begin participating in the creation and distribution of patient decision aids, it is difficult to see how a no-fault system would be funded.

Moreover, most no-fault programs are established to compensate only for unavoidable harms—that is, situations where no degree of due care could prevent the injury in question.¹⁶⁹ The September 11th Victim Compensation Fund is a prime example—victims of this disaster would likely have suffered harms even if the airline industry had taken every step reasonably possible to prevent terrorist attacks. Likewise, the National Vaccine Injury Compensation Program recognizes that some vaccine-related injuries are simply unavoidable. In contrast, harms arising from faulty decision aids seem clearly traceable to fault or negligence on the part of decision-aid creators.¹⁷⁰ Finally, according to some commentators, the model of no-fault compensation as a whole is slowly going the way of the dinosaur.¹⁷¹ For the practical and policy reasons described above, few, if any, no-fault programs have been created in the past few years. It would be highly unusual, then, to establish a no-fault system for compensating victims of faulty decision aids, particularly where their harms are clearly traceable to a defendant's negligence and could conceivably have been prevented.

The alternative, then, is to provide a tort remedy to injured patients under traditional negligence principles. For the reasons outlined in Part III.B, however, the tort system as it currently exists is not well equipped to resolve disputes arising from faulty decision aids. To prove liability, a plaintiff must demonstrate privity

167. Established by 42 U.S.C. §§ 300aa-1 to -34 (2012).

168. Established by Air Transportation Safety and Stabilization Act, Pub. L. No. 107-42, §§ 401-409, 115 Stat. 230, 237-41 (2001) (codified as amended at 49 U.S.C. § 40101 (2012)).

169. David M. Studdert & Troyen A. Brennan, *No-Fault Compensation for Medical Injuries*, 286 JAMA 217, 220 (2001).

170. Other criticisms of no-fault systems may be relevant as well. For example, many argue that no-fault compensation systems are ineffective due to their limited deterrent effect. Because potential defendants are not forced to absorb financial losses directly, they may have less incentive to exercise due care in their business. See Arlen, *supra* note 20, at 1116; Studdert & Brennan, *supra* note 169, at 220-21. *But see* Randall R. Bovbjerg & Frank A. Sloan, *No-Fault for Medical Injury: Theory and Evidence*, 67 U. CIN. L. REV. 53, at 71-72 (1998) (“[C]ompensation should be improved through no-fault because periodic payment of benefits provides a form of insurance protection against unanticipated changes in needs.”).

171. See, e.g., Nora Freeman Engstrom, *An Alternative Explanation for No-Fault's Demise*, 61 DEPAUL L. REV. (forthcoming 2012) (on file with author).

with the defendant; to date, courts have been unwilling to find privity where an author or publisher provides information aimed at the general public. Moreover, because decision aids are targeted to situations where a patient is choosing between multiple reasonable options, an injured patient would have difficulty demonstrating causation under current informed consent doctrine. In order to provide plaintiffs with a tort remedy, policy-makers would need to resolve the two problems described above, and furthermore clarify that the legislation and regulations relating to decision-support tools do not preempt tort liability.

It seems that either option for recovery—an administrative system for compensating injured patients or a traditional tort regime—has its difficulties (some of which will be addressed in further detail in Part V). The analysis above does not clearly favor one approach over another. Thus, approaching the issue from the perspective of compensation may not help resolve the decision of whether regulation alone or a complementary tort law approach are best suited for controlling decision-support tools.

B. Nature of Risk

The above discussion of compensation reinforces the need, in many cases, to provide remedies to individuals who are harmed as a result of industry failures. Whether compensation is appropriate is, of course, influenced in part by the nature of the risks expected to occur despite the presence of regulation.

Typically, tort law is viewed as an effective means of dealing with “private risks,” whereby specific acts of negligence cause individualized harms.¹⁷² In contrast, purely regulatory mechanisms are aimed at “public risks”—namely, those that arise inevitably from the operation of beneficial industries and cause generalized risks that may or may not manifest themselves in individual injury.¹⁷³ Peter Huber, who has argued against the expansion of tort liability in areas with already robust regulatory regimes, cites as prime examples of “public risks” those arising from “vaccines, pesticides, aircraft, power plants, and the like.”¹⁷⁴ While contemporary law does in fact permit individuals to bring claims for compensation in many of these contexts, the distinction between inevitable public harm and preventable private harm is instructive when determining how best to protect consumers.

Consider, for example, the law’s approach to two very different types of medical regulation. Medical practice is governed by a vast set of regulations, including federal conditions of participation under Medicare and Medicaid, as well as state medical board requirements. Despite these mandatory standards, it is widely acknowledged that injuries caused by medical negligence vary significantly on a case-by-case basis, and cannot be prevented by generalized rules that do not take into account the particularities of an individual physician–patient

172. Rabin, *supra* note 21, at 2052.

173. *Id.*; see also Moncrieff, *supra* note 146, at 2332 (discussing whether a regulation confers individual rights, or just enforces a general scheme).

174. Huber, *supra* note 146, at 334.

interaction.¹⁷⁵ In contrast, the regulation of faulty medical devices, which are more fungible in nature, appears to be aimed at finding a balance between fostering innovation while at the same time preventing public risks. Congress has therefore determined that a regulatory regime is more appropriate to control the risks arising from medical devices; accordingly, state tort suits for victim compensation are fully preempted.¹⁷⁶

Judged by reference to unavoidable “public injuries” versus potentially preventable “private injuries,” decision-support tools appear much better suited to an approach that complements regulation with tort liability. When a decision-support tool provides incorrect or biased information, the injury suffered by a patient is individualized in nature. The best analogy may be to traditional medical malpractice: state medical licensing boards and federal agencies establish standards for competent physician practice in part because the risks of negligent practice affect individuals in very different ways. Any determination of whether a physician acted inappropriately will depend on the facts of the case; such harms cannot be effectively remedied by a one-size-fits-all regulatory system.

Likewise, the injury suffered by a patient who is provided with a faulty decision aid is also a very personalized injury. Imagine that a patient uses a faulty decision aid to choose Treatment B over Treatment A, both of which are clinically appropriate options for her condition. The patient is consequently injured as a result of her choice to proceed with Treatment B. The nature of her injury may be very different in kind from the injury suffered by another patient in a similar situation—there are a variety of ways in which Treatment B could go wrong. Moreover, not every patient will end up choosing Treatment B over Treatment A, and many patients who choose Treatment B will not suffer any injury as a result. Given the variability of the injuries that might arise from the use of faulty decision aids, a purely regulatory approach that protects against somewhat fungible public harms seems suboptimal.

Furthermore, the kinds of public risks that are typically addressed with a purely regulatory approach tend to be deemed, as noted above, inevitable consequences of even the most carefully regulated industries. Regulations in the airline, automobile, manufacturing, and hazardous materials industries, for example, are drafted to strike an appropriate balance between industry efficiency and public safety. Regulators are acutely aware of the fact that consumers will be injured even with the exercise of due care, and they consider the risk of these injuries acceptable in light of the overall benefits that accrue to society as a whole.¹⁷⁷ While policy-makers may view medical regulations as attempting to strike a similar balance, the public perception of medical practice is very different indeed. Atul Gawande describes Western medical practice as “dominated by a

175. See Moncrieff, *supra* note 146, at 2346 (citing CMS and board discipline as being ineffective in addressing medical errors and malpractice).

176. Riegel v. Medtronic, Inc., 552 U.S. 312, 324 (2008).

177. The distinction between inevitable and preventable injuries is also reflected in policy approaches towards no-fault compensation. See *supra* note 169 and accompanying text.

single imperative—the quest for machinelike perfection in the delivery of care.¹⁷⁸ When a patient is injured, she does not consider her injuries inevitable consequences of a complex system; rather, she may explain her injuries by finding fault in individual healthcare providers and institutions and may pursue medical malpractice claims to recover for what she considers to be a very personal and unique harm. Faulty decision-support tools, as part of the healthcare process, are likely to be viewed similarly and so will require some targeted mechanism for recovery that would not be available under a pure regulatory regime.

C. Regulatory Specificity and Comprehensiveness

Decisions about where a particular issue should lie on the spectrum between pure regulation and tort are influenced in large part by the details of existing or proposed regulations. Policy-makers are more likely to find a regulatory regime sufficient when it directly addresses contemplated harms, sets optimal standards for industry conduct, and is mandatory in nature.

Typically, if a regulation does not contemplate or address a given problem, it will not prevent injured parties from seeking alternative forms of recovery.¹⁷⁹ An instructive example can be found in the context of pharmaceutical safety. When the FDA grants pre-market approval for marketing and distribution of a drug, it does so only for the particular conditions and populations that were evaluated in clinical trials. The FDA has no control over “off-label” usage, whereby a physician prescribes a drug for a condition or to a patient for whom the drug has not been deemed safe and effective.¹⁸⁰ Because the FDCA does not regulate the risks arising from off-label usage, it is common to see tort law being used to fill in these gaps.¹⁸¹ In contrast, had the FDA retained authority for controlling “off-label” usage, it is less likely that courts would permit consumers injured by off-label uses to turn to the tort system for compensation.¹⁸²

Whether a regulation is comprehensive—that is, whether it establishes both a floor and a ceiling for industry conduct—also has an impact on these

178. ATUL GAWANDE, *COMPLICATIONS: A SURGEON’S NOTES ON AN IMPERFECT SCIENCE* 37 (2003).

179. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (1998) (establishing that regulatory compliance may be a successful defense in a tort action if the regulation specifically addresses particular type of harm). Another situation in which complementary tort liability may be appropriate is when it addresses a risk that does not call into question the agency’s regulatory expertise or discretion—for example, cases where plaintiffs are injured as a result of an entity’s fraud on the agency. *Id.* at cmt. e.

180. *See* Randall S. Stafford, *Regulating Off-Label Drug Use: Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427 (2008).

181. *See, e.g.*, *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 624–25 (E.D. Pa. 2008) (denying defendant’s motion for summary judgment as to plaintiff’s allegations of off-label promotion); *United States v. Caronia*, 576 F. Supp. 2d 385, 403 (E.D.N.Y. 2008) (denying defendant’s motion to dismiss as to drug sales representative for alleged misbranding of a drug for off-label uses).

182. *See* Viscusi et al., *supra* note 143, at 1478 (noting that where the FDA has made “an explicit judgment” on an issue, tort liability should be preempted).

decisions. Policy-makers recognize that regulations that merely set minimum benchmarks (or that are voluntary rather than mandatory) may not be sufficient to protect consumers from harm. In *Wyeth v. Levine*, for example, the Supreme Court held that Congress had not preempted state law failure-to-warn claims in the pharmaceutical context, finding that the FDA “cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to preempt failure-to-warn claims.”¹⁸³ Similarly, in the environmental context, compliance with federal regulations typically does not protect defendants from suit under more stringent state standards.¹⁸⁴ Where, instead, regulations set optimal standards (in effect, defining the standard of care) that are mandatory for an industry, supplementing them with additional tort liability may be inefficient.¹⁸⁵

As noted in the introduction to this Part, it is difficult to reach any firm conclusion with respect to the certification of patient decision aids as contemplated by PPACA because the regulations associated with this provision have not yet been drafted. That said, history suggests that they will likely be voluntary regulations setting a floor for quality, in which case supplemental tort liability may be needed to bridge the gap between what is adequate and what is optimal.

In terms of regulatory aims, the general purpose behind PPACA’s proposal to certify decision aids is to ensure some degree of standardization and quality in an effort to protect patient users.¹⁸⁶ The details of the certification process are still unknown, but the text of PPACA suggests that considerations of accuracy and impartiality will be paramount. In a provision about grants to entities that develop and test decision aids, the statute refers to testing of decision aids to ensure that they are “balanced and evidence based”¹⁸⁷ and reflect “the varying needs of consumers [from a variety of cultural and educational backgrounds] and diverse levels of health literacy.”¹⁸⁸ The statutory references to “consensus,”¹⁸⁹ “balance[],”¹⁹⁰ and “evidence”¹⁹¹ strongly suggest that Congress was aware of the possibility of misinformation or bias and intended to direct regulators to address

183. 555 U.S. 555, 577–78 (2009).

184. William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. REV. 1547, 1582 (2007) (noting that federal environmental regulations, among others, are “typically construed as merely setting a minimum requirement or floor [and] leave room for nonconflicting state action and tort suit conclusions that the standard of care is greater than the one approved by federal actors.”); Paul S. Weiland, *Federal and State Preemption of Environmental Law: A Critical Analysis*, 24 HARV. ENVTL. L. REV. 237, 282 (2000) (citing the “Floor-not-Ceiling Model” as having been “expressly adopted by Congress in numerous federal environmental laws.”).

185. See Viscusi et al., *supra* note 143, at 1478.

186. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3506, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 299b-31(c)(2) (2012)).

187. *Id.* (codified as amended at 42 U.S.C. § 299b-36(d)(1)(B)).

188. *Id.* (codified as amended at 42 U.S.C. § 299b-36(d)(2)(B)).

189. *Id.* (codified as amended at 42 U.S.C. § 299b-36(c)(1)(A), (2)(A)).

190. *Id.* (codified as amended at 42 U.S.C. § 299b-36(d)(1)(B)).

191. *Id.* (codified as amended at 42 U.S.C. § 299b-36(b)(1), (b)(2), (c)(2)(A), (d)(1)(B)).

these issues in the certification process. If they are able to do so successfully, there may be less need for a supplemental compensatory program.

Based on the nature of the product being regulated, it seems clear that any contemplated regulations would merely establish minimum benchmarks that decision-support tools must satisfy, rather than set a ceiling on their quality. If these regulations are viewed as a floor upon which states may build, then they are unlikely to be the exclusive form of recourse for injured consumers. And as to whether the administrative standards established for decision-support tools will be voluntary or mandatory, it seems very unlikely that the certification process would be mandatory. A number of factors lead to this conclusion. First, given that decision-support tools have, thus far, operated in an environment with no regulations at all, implementing a mandatory certification system will be difficult. Second, any proposal for mandatory certification is likely to be opposed by the entities that create decision-support tools and potentially even by the physician community, which has been notoriously slow in adopting mechanisms for standardizing care. Finally, given that the practice of medicine is traditionally regulated by states pursuant to their police powers, implementing a system of mandatory federal certification may be difficult, particularly in situations where state agencies are the ones creating and publishing decision-support tools. If, as suggested herein, it is unlikely that a certification process for patient decision aids will be mandatory, then a supplementary tort remedy may be necessary, even if federal regulations aim specifically at addressing these types of harms.

D. Information

Another significant difference between regulatory and tort law regimes is the manner in which they collect and take advantage of information about public risks and benefits. Accordingly, the informational characteristics of regulatory and tort law regimes are likely to influence policy-makers' decisions.

At their best, administrative regulations are based on comprehensive research about the industry to be regulated and its impact on the public. For example, environmental regulations are set only after thorough investigation of the safety of various levels of environmental pollutants, the cost of requiring industries to limit environmental contamination (or to remediate existing contamination), and the number of individuals affected.¹⁹² In contrast, the information collected in tort suits is primarily aimed at proving individual causation after an injury has already occurred; indeed, the tort system is often criticized for its reliance on potentially biased expert testimony and anecdotal (rather than systematic) evidence.¹⁹³

That said, there are legitimate criticisms of the regulatory system's approach to information. First, some regulatory agencies may be subject to "capture" by industry influences, resulting in a system that is industry-friendly,

192. See, e.g., 42 U.S.C. § 7408 (2012); EPA Innocent Landowners, Standards for Conducting All Appropriate Inquiries, 40 C.F.R. pt. 312 (2012).

193. See, e.g., PETER WILLIAM HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 204 (1991).

rather than neutral and unbiased.¹⁹⁴ Second, the regulatory system may not be flexible enough to accommodate rapidly changing evidence in developing fields. The FDA, for example, has been widely criticized for failing to monitor post-market drug safety as new data about patient injuries arises.¹⁹⁵ Tort law, on the other hand, may be able to respond somewhat more quickly to changing data¹⁹⁶ and often serves as an effective means for circulating new information to the public.¹⁹⁷

The informational characteristics of regulatory and tort law are therefore relevant to policy-makers' decisions. Policy-makers may be more willing to rely primarily on a regulatory regime where the regulatory process is fair, unbiased, comprehensive, and grounded in recent research and high-quality expert reports.¹⁹⁸ However, if there are faults in the regulatory process—whether by way of agency inefficiency, industry capture, or failure to take into account changes in evidence over time—a complementary tort regime may be necessary to remedy these informational failures.

In light of PPACA's proposed system of oversight, the inherent characteristics of decision-support tools, and existing regulations in the context of health and medicine, it is likely that the development of regulations associated with patient decision aids will proceed with the goal of ensuring accurate and unbiased information, but may fall short if political or industry influences intervene.

PPACA's proposed system of oversight for decision-support tools relies on a team of qualified experts to evaluate and certify these tools.¹⁹⁹ As written, the law seems promising; an interdisciplinary team of experts is more likely to be impartial and unbiased when evaluating decision-support tools. Moreover, because

194. Hylton, *supra* note 21, at 213–17.

195. Rabin, *supra* note 21, at 2077. Public criticism of the FDA's ineffectiveness in protecting consumers through post-market surveillance may be one reason that the Supreme Court has interpreted the FDCA to permit state law tort claims against pharmaceutical manufacturers. *See Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

196. Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. HEALTH CARE L. & POL'Y 27, 55 (2007) (“[T]he [tort] process may identify risks and seek corrective action more quickly than entrenched political or administrative structures.”). *But see* Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 312–13 (2008) (noting that the review process proposed by the authors to alleviate anti-innovation bias of the tort system may take months to complete).

197. *See* Rabin, *supra* note 21, at 2068–69; Weeks, *supra* note 196, at 31. Classic examples of this phenomenon include the nationwide tobacco litigation of the late twentieth century, and the recent torts suits brought against the Catholic Church for its failure to act on evidence of child sexual abuse by clergy.

198. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b) (1998) (establishing that regulatory compliance may be a successful defense in a tort action if the regulation is recent and subject to full deliberation); *see also* Rabin, *supra* note 21, at 2051, 2068.

199. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3506, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 299b-36(c)(2)(A) (2012)).

the law is new and will be implemented over the next few years, those involved in the regulatory process will be able to take advantage of the latest evidence and so maintain the highest standards of information-gathering.

However, despite the appeal of this proposal, it is possible that the regulatory decision-making process may nevertheless be biased. The characteristics of decision aids highlighted in Part II—namely, their development by third parties with possible conflicts of interest, their incorporation of value-based judgments, and their application in controversial contexts where there is no medically preferred course of care—suggest a significant possibility of bias or industry capture.²⁰⁰ For example, consider the written materials many states provide about abortion risks. These materials, although prepared by purportedly neutral state agencies acting on best evidence, have been widely criticized as misleading, biased, and factually inaccurate.²⁰¹

Looking to approaches the United States has taken in other areas of health and medicine may be instructive as well. There is no question that laws in this sphere often develop against a backdrop of tension and negotiation between interested parties—negotiation that has often been criticized as detrimental to the American public. From its earliest days, the American medical profession has actively pressured policy-makers to refrain from interference in the provision of medical practice. Such professional lobbying is, according to many scholars, the single most important factor slowing positive changes in the delivery and financing of American healthcare—from the creation and development of the health insurance industry to the passage of laws increasing access to care (Medicare, Medicaid, and PPACA).²⁰² The pharmaceutical and medical device industry's lobbying efforts have unquestionably influenced the development of FDA policy—again, often to the detriment of American consumers. Political pressures by specialists and patient groups have delayed policy changes in areas such as mammography and PSA screening, where new evidence has called into question existing medical practices.²⁰³ In controversial areas such as end-of-life²⁰⁴ and reproductive care,²⁰⁵ political and religious influences may trump evidence-based recommendations.²⁰⁶ This process of policy negotiation between conflicted parties is certainly not limited to the sphere of healthcare. However, the frequency with which scientific evidence relevant to policy-making is dismissed because of

200. See, e.g., Hylton, *supra* note 21, at 213–14 (noting that “political distortion” is less likely under a court regime).

201. See *supra* notes 98–105 and accompanying text.

202. See generally PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 235–334 (1982); Jill Quadagno, *Why the United States Has No Health Insurance: Stakeholder Mobilization Against the Welfare State, 1945–1996*, 45 J. HEALTH & SOC. BEHAV. 25 (2004).

203. Harris, *supra* note 81.

204. Rutenberg & Calmes, *supra* note 106.

205. Gardiner Harris, *F.D.A. Overruled on Availability of After-Sex Pill*, N.Y. TIMES, Dec. 8, 2011, at A1.

206. For example, a certifying entity might defer to political arguments that the existence of a few discredited studies is indicative of legitimate scientific controversy.

lobbying and political pressures appears to be particularly high in the healthcare context.²⁰⁷

In conclusion, while I have high hopes that regulators will be able to achieve the goal of having a neutral certifying entity as contemplated by PPACA, such neutrality cannot be assured. Concerns about industry capture will certainly be relevant, given that the certifiers will be evaluating decision aids created by insurers and other interested third parties. Political pressures may also affect how certifiers deal with conflicting evidence, particularly with respect to controversial or value-laden decisions. If these concerns about bias and conflicts of interest in the regulatory regime are significant—as I believe they are—a purely administrative approach to decision-support tools may be inadequate.

E. Proof and Causation

A final consideration in choosing between regulatory regimes is the challenge of proof and causation. In order for a plaintiff to succeed in a tort suit, he must demonstrate that the defendant's actions caused his injury. Accordingly, the tort system may be ill-suited to situations where an injury arises from multiple causes, or where causation cannot be proven. Consider, for example, a toxic tort plaintiff who has developed cancer, allegedly as a result of workplace exposure to toxins. In a tort suit against his employer, the plaintiff may cite epidemiological studies showing that the prevalence of cancer in individuals who have been exposed to this particular toxin is significantly higher than in non-exposed individuals. While the epidemiological evidence may be unassailable, it simply cannot prove as a matter of law that this particular exposure caused this particular plaintiff's cancer; accordingly, such suits often fail.²⁰⁸ In cases such as these, where there is inherent difficulty in drawing causal connections between a public

207. See Christopher J. Jewell & Lisa A. Bero, "Developing Good Taste in Evidence": Facilitators of and Hindrances to Evidence-Informed Health Policymaking in State Government, 86 MILBANK Q. 177, 178 (2008) ("The role of evidence based on research [in healthcare policy-making] is often minimal, and even when it is used by policymakers, such evidence is greatly affected by cognitive and institutional features of the political process."); *id.* at 186 ("[L]egislators 'can be pretty close [sic] minded about evidence' . . ."); Linda Rosenstock & Lore Jackson Lee, *Attacks on Science: The Risks to Evidence-Based Policy*, 92 AM. J. PUB. HEALTH 14, 15 (2002) (describing the 1996 withdrawal of all funding from the Department of Health and Human Services' Agency for Health Care Quality and Research in response to its unpopular evidence-based recommendations for managing back problems).

208. See, e.g., *Nat'l Bank of Commerce v. Associated Milk Producers, Inc.*, 22 F. Supp. 2d 942, 983 (E.D. Ark. 1998) (plaintiff experts failed to use proper scientific method to show that exposure to milk toxin caused laryngeal cancer); *Henricksen v. Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1161–63 (E.D. Wash. 2009) (court barred testimony of plaintiff's epidemiology expert, deeming it "unreliable" on issue of whether plaintiff's laryngeal cancer was directly caused by benzene exposure).

risk and a private plaintiff's injury, a regulatory approach is the more efficient way of balancing risks.²⁰⁹

In contrast, a patient wishing to bring a tort suit against the publisher of a faulty decision aid is likely to face only those problems of proof faced by any plaintiff in a traditional informed consent or misrepresentation action. An injured patient would need to show that the publisher was at fault in publishing the decision aid, and that, had the decision aid not been faulty, the reasonable patient would have chosen a different treatment option that would not have caused injury. Unfortunately, as noted in Part II.C, this may be particularly difficult in the case of decision-support tools, which are meant to be used precisely in those situations where reasonable patients could reach differing decisions. Given how challenging it may be for patients harmed by faulty decision aids to prove the causal element of their claims, additional consideration may be required before concluding that tort law is an appropriate mechanism for recovery.

Notably, however, the issue of proof and causation is the only factor among the five identified herein that weighs more strongly in the direction of a purely regulatory remedy. In contrast, the other four all suggest that administrative regulations such as those proposed in PPACA may not be sufficient to protect consumers. Given the likelihood of fault or bias in the creation and use of patient decision aids,²¹⁰ the probability of individualized patient harms is high. As noted in Part IV.B, these harms are not inevitable consequences of an inherently dangerous practice, but rather are the type of "private harms" policy-makers consider appropriate for compensation. Because regulatory approaches of the type proposed by PPACA do not provide a remedy for such harms, a complementary tort remedy will be needed—both to restore injured patients to their positions before relying on faulty decision aids, and to incentivize decision-aid creators to ensure the quality of their products. Moreover, while the regulations proposed by PPACA are expected to directly address the possibility of harms arising from bias or misrepresentation within patient decision aids, it is unlikely that they will set forth mandatory standards for industry conduct that establish a "ceiling" rather than a floor. If the proposed regulations merely set forth minimal or voluntary standards of care, they will not be sufficient to protect consumers. Finally, one of the most promising elements of the proposed regulation is its reliance on a team of qualified experts to evaluate and certify decision aids; indeed, if this approach works as anticipated, one might have greater confidence in the choice of a pure regulatory regime over a complementary regime. Unfortunately, the prevalence of industry lobbying and political pressures in the context of healthcare policy suggests that this goal may not be realized.

209. See, e.g., Posner & Sunstein, *supra* note 146, at 561; Viscusi, *supra* note 21, at 105.

210. See *supra* Part II.

V. COMPLEMENTING PROPOSED REGULATION WITH TORT LIABILITY: RECOMMENDATIONS AND CHALLENGES

In light of the above analysis, what, if anything, can we conclude about the optimal means of controlling the quality of patient decision aids?

First, given the unique characteristics of decision aids—namely, their creation by parties outside the clinical sphere, their potential for patient reliance in the absence of substantial physician oversight, and their application to value-laden decisions—the likelihood of patient harm resulting from false or misleading products is significant. Therefore, any system for controlling decision-aid quality must incorporate some opportunity for recovery by those injured.

When viewed exclusively in terms of compensatory goals, the choice between a regulatory regime and one that incorporates tort law remedies is a difficult one. A comprehensive regulatory approach that establishes no-fault compensation for injuries caused by faulty decision aids would serve these goals, but so would a well-crafted tort law regime. This leaves us in a bit of a conundrum, however. If we are committed to compensating patients for harms suffered as a result of faulty decision aids, we must either use a tort system that is ill-equipped to deal with such claims or a no-fault compensation system that would need to be built from the ground up, with limited financial guarantees, and subject to the problems highlighted in Part IV.A.

In comparing the two options, I believe a stronger case can be made for the tort law option, because a number of the other factors identified in Part IV weigh in favor of a tort law remedy as opposed to a regulatory mechanism for patient compensation. First, the nature of the injuries likely to be suffered is private, rather than public, as distinguished in Part IV.B. Second, given the types of value-laden situations in which many decision aids are used, there is significant risk that any regulations ultimately drafted may be influenced by political pressures rather than scientific principles. Finally, it is likely that any regulations will be voluntary and will merely set a floor for decision-aid quality. Each of these factors suggests that a purely regulatory approach may not be sufficient for patient protection. Moreover, the practical challenges in implementing a no-fault compensation system in a developing industry, highlighted in Part IV.A, are not to be underestimated.

However, relying on a complementary tort system for ensuring decision-aid quality faces a significant challenge as well: existing tort law is not currently well-structured to resolve such disputes. To succeed in a negligence claim against the creator of a faulty decision aid, the injured patient would need to prove causation under the “reasonable patient” standard, and, if bringing a negligent misrepresentation claim, would also need to demonstrate privity with the defendant—both of which, for the reasons outlined in Part III.C, may be difficult.

One way of addressing this challenge might be to abandon the idea of targeting creators of faulty decision aids and instead consider pursuing claims against healthcare providers who prescribe faulty decision aids to patients. Such a move would eliminate privity challenges, leaving only the issue of causation as a barrier to recovery. However, there are important policy reasons why physicians,

in the absence of independent negligent conduct, ought not be held liable for the negligence of third-party information providers over whom they have no control.²¹¹ Physicians, while obviously expected to meet professional standards of care when advising patients during the informed consent process,²¹² cannot be expected to have the expertise needed to evaluate the accuracy of all the information presented in third-party decision aids on a variety of clinical issues. Rather, creators of decision aids are in the best position to ensure the quality and accuracy of their products.

The context of pharmaceutical advertising and labeling may provide a helpful analogy. The “learned intermediary” doctrine 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.²¹³ However, case law does not clarify whether a physician would face tort liability where the information provided by the product manufacturer itself is faulty. Logically, however, it is difficult to imagine that a physician who made a good-faith effort to review the drug company’s information before providing it to a patient would be liable if the underlying information were faulty, but not obviously so.²¹⁴ The alternative, of course, would be to burden physicians with a standard of care that requires them to double-check pharmaceutical companies’ claims against the latest published research before prescribing drugs to patients. While physicians ought not abdicate their duty to provide quality care simply because they are relying on third-party information, it seems unreasonable to argue that physicians should bear liability where they have relied in good faith on information provided by companies whose business it is to provide patients with healthcare information.

A second alternative would be to return to the original idea of tort liability for creators of faulty decision aids, which would necessitate substantial changes to tort law to achieve this goal. Such a project, moreover, would have an impact far beyond the world of medical decision aids, potentially affecting information providers in a variety of contexts. This Part further examines the challenges inherent in making such a change.

A. Privity

The first challenge in using tort law to recover for harms resulting from faulty decision aids is that privity between litigants is traditionally required in

211. Sawicki, *supra* note 25, at 9.

212. Accordingly, a physician who relies on a decision aid as a replacement for, rather than a supplement to, the informed consent conversation would certainly be subject to independent liability. *Id.*

213. See Rabin, *supra* note 21, at 2079 (“In off-label use cases, as in drug defect litigation generally, the learned intermediary defense is applicable—that is, the manufacturer is shielded from liability for failure to adequately warn users if it has supplied a reasonable warning to the physician.”).

214. The Author’s thorough review of case law related to the learned intermediary doctrine failed to discover any cases directly dealing with the issue of physician liability for faulty information provided by pharmaceutical companies.

negligent misrepresentation cases. As noted in Part III.C, courts are reluctant to find privity where a defendant circulates misinformation to the general public, rather than targeting it to a particular individual or small group.

However, this challenge may not be as significant as it initially appears. Twentieth-century tort law has shifted away from the privity requirement in many contexts, sometimes eliminating it altogether. In products liability cases, for example, plaintiffs are no longer required to demonstrate privity with the defendant in order to recover.²¹⁵ Moreover, privity is not required in cases where the defendant's fraudulent misrepresentation is intentional,²¹⁶ further suggesting that the elimination of privity in negligent misrepresentation cases may not be an unwelcome change. At the very least, a patient who is harmed as a result of intentional misrepresentations by decision-aid creators would be able to pursue a traditional negligence claim without demonstrating privity.²¹⁷

The existing privity requirement as applied to negligent misrepresentation cases may not be appropriate in the context of patient decision aids. As a preliminary matter, decision-aid creators market their products with the explicit expectation and intent that medical consumers will rely on them when making important medical decisions. Furthermore, there are reasons why medical information, such as information incorporated in decision-support tools, might justifiably be treated differently from investment information²¹⁸ or self-help books.²¹⁹ First, the direct consequence of relying on faulty medical information is likely to be bodily injury, which the American legal system generally treats differently from pecuniary losses.²²⁰ Another point in support of treating medical information differently is the fact that no privity is required for liability in pharmaceutical advertising and labeling cases, despite the fact that the patient and pharmaceutical manufacturer are separated by at least two intermediaries—the prescribing physician and the pharmacist.

B. Causation

The second challenge plaintiffs are likely to face when bringing tort suits against the creators of faulty decision aids—whether on the grounds of negligence or negligent misrepresentation—is proving causation.²²¹ Because decision-support tools are used primarily in the context of preference-sensitive care where patients

215. *MacPherson v. Buick Motor Co.*, 217 N.Y. 382, 389 (1916) (finding a duty “irrespective of contract”); *see also supra* note 130.

216. *See DOBBS, supra* note 135, § 480, at 1370–71.

217. *See supra* note 135.

218. *First Equity Corp. of Fla. v. Standard & Poor's Corp.*, 670 F. Supp. 115, 118, 119 (S.D.N.Y. 1987).

219. *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 327 (S.D.N.Y. 2006).

220. To cite just one example, the Uniform Commercial Code typically allows consumers to waive their right to sue makers of defective goods, but holds that such waivers are “prima facie unconscionable” if they waive the right to sue for personal injuries arising from defective goods. U.C.C. § 2-719(3) (2012).

221. *See supra* Part III.E.

are choosing between multiple reasonable options, it may be difficult for a patient to prove causation under the traditional informed consent standard. Had the disclosure not been faulty, a reasonable patient would not have been injured. As noted in Part III.C, because preference-sensitive decisions are so dependent on patient values, jurors may have trouble predicting what option the “reasonable patient” would have chosen had she relied on a more accurate decision-support tool.

At first glance, this problem may seem intractable. However, the shift from an objective standard of causation to a subjective standard is perhaps not as unlikely as it initially seems. A number of tort law scholars,²²² most recently Evelyn Tenenbaum, have argued that the objective “reasonable patient” standard of causation is unfaithful to and inconsistent with the goals of informed consent doctrine.²²³ Dan Dobbs has referred to the objective standard of causation as “controversial” and “more or less unique to the medical informed consent cases.”²²⁴ He argues that this rule “imposes some additional and most unusual obstacle” not required in any other type of negligence action.²²⁵ Both authors note that the objective standard of causation is particularly problematic because it does not take into account the patient’s own values and preferences,²²⁶ which, as noted in Part I, are of paramount importance in making the kinds of preference-sensitive decisions for which decision-support tools are commonly used.²²⁷ While some legislatures have attempted to remedy this problem by adding a subjective component to the causation standard—for example, referring to the “reasonable

222. Some courts have taken this view as well. *See, e.g.*, *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979) (holding that the reasonable man standard does not apply in the context of causation for informed consent because applying an objective standard would result in the “patient’s right of self-determination [being] irrevocably lost”).

223. Tenenbaum, *supra* note 136; *see also*, DOBBS, *supra* note 135, § 250, at 657; Alexander Morgan Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 418–28 (1974); Jay Katz, *Informed Consent—A Fairy Tale? Law’s Vision*, 39 U. PITT. L. REV. 137, 160–64 (1977).

224. DOBBS, *supra* note 135, § 250, at 657.

225. *Id.*

226. *Id.* (“The real effect of the rule is to limit the defendant’s duty of disclosure for the protection of patients who have the same feelings about the risks and advantages of the [procedure] that the mainstream of reasonable people would have. The special concerns of an individual get no protection under the rule and ‘a patient’s right of self-determination is irrevocably lost.’”); Tenenbaum, *supra* note 136 (“[W]here between 20 and 80 percent of patients would choose to have [a] treatment knowing the risks and alternatives[,] there are genuine choices to be made and reasonable people will differ in their decisions depending on their values and personal preferences.”).

227. *See* Tenenbaum, *supra* note 136 (highlighting the various reasonable options available to patients making treatment decisions in the context of early prostate cancer, early breast cancer, disease prevention, and menopause).

patient under similar circumstances”²²⁸—courts have generally refused to apply this language to patients’ non-medical preferences.²²⁹

The substantial contemporary criticism of the objective standard of causation may now gain purchase as both the public and the legal community become more aware of how prevalent preference-sensitive decisions are. The fast pace of scientific and technological development in modern medical practice means that today’s patients have the opportunity to choose between many more treatment options than they used to. As Tenenbaum notes, this may be an optimal time to reevaluate the “reasonable person” standard of causation; doing so would bring informed consent law closer in line with its original intent.²³⁰ If, indeed, tort law is shifting away from the objective standard of causation in medical information cases, the possibility of a tort remedy for patients harmed by faulty decision aids may be greater than it initially appears.

C. Broader Implications

If the problems of privity and causation are resolvable through reasonable modifications to tort law, a final challenge remains. Were the standards for negligent misrepresentation modified to eliminate the existing requirements of privity and objective causation, the impact might extend far beyond the narrow context of decision-support tools to information providers more generally—including authors of books, articles, and websites that provide factual information. Many critics, this Author included, would be reluctant to make such a dramatic move. Proposing substantial changes to a large body of law is rarely an appropriate response to a single, context-specific problem, and it would be foolhardy to use the case of medical decision aids as a basis for a large-scale shift in tort doctrine, particularly one that would threaten millions of potential defendants who had previously been insulated from liability. After all, it is partly in an attempt to protect “those who wish to share thoughts and theories” that product liability law excludes printed informational materials from its purview.²³¹ However, a shift away from the traditional privity and objective causation requirements could be accomplished in such a way that results in a far more limited expansion of liability, addressing the concern highlighted above.

Consider the following: Completely eliminating the formal privity requirement for negligent misrepresentation cases would indeed open up the floodgates of litigation—any person or entity who presents faulty information could be liable, regardless of how distanced they are from the injured plaintiff. Rather than eliminating the privity requirement altogether, however, this issue could be resolved in a more targeted manner by making one of two modifications to (or reinterpretations of) the requirement.

228. *Id.* (citing New Mexico, New York, and Maine statutes); *see also* Fain v. Smith, 479 So. 2d 1150, 1155 (Ala. 1985).

229. Tenenbaum, *supra* note 136 (citing Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOY. U. CHI. L.J. 557, 569 (2000)).

230. *See generally id.*

231. Winter v. G.P. Putnam’s Sons, 938 F.2d 1033, 1035–36 (9th Cir. 1991).

One option might be to allow negligent misrepresentation claims to proceed in the absence of privity only where the defendant *intends* that his informational product be used by consumers. Courts have traditionally found that authors of printed materials aimed at the general public do not owe a duty of care to their readers, even if they foresee reader reliance.²³² Foreseeability, however, is distinct from intent. An information provider who merely *foresees* reader reliance might legitimately be treated differently from an information provider who *intends* that his informational product be used by consumers (particularly in making choices that might result in physical, rather than merely pecuniary injury). If courts were to find privity between consumers and those information providers who specifically intend that their materials be used by consumers, the expansion of negligent misrepresentation claims would be far more limited than if we were to abandon privity entirely. While some might object that the line between foreseeability and intent is a difficult one to draw, courts have had hundreds of years of practice distinguishing between intentional and negligent torts, and between different degrees of criminal activity.²³³ To demonstrate intent in a negligent misrepresentation case, for example, a plaintiff might introduce evidence about the information provider's business practices, its public statements, its target audience, and its reliance on profits from the informational materials in question. In this manner, many private individuals (authors of personal websites, for example) might be excluded from liability.²³⁴

A second option, and one that would limit the expansion of liability even more significantly, would be to take a cue from traditional negligence cases based on intentional misrepresentation.²³⁵ As noted above, where a plaintiff suffers physical injury as a result of a defendant's intentional misrepresentation, the plaintiff need not demonstrate privity to recover.²³⁶ Under existing law, that is, a patient would be permitted to bring a traditional negligence suit against the creator of a faulty decision aid if she is able to prove that the underlying flaw in the

232. See *supra* notes 130–34 and accompanying text.

233. Note that limiting liability to information providers who *intend* reader reliance (suggesting greater privity than those who merely *foresee* reader reliance) would not transform a negligent misrepresentation claim to a negligence claim based on intentional misrepresentation claim, as the provider's intent (or lack thereof) to furnish faulty information would remain unchanged.

234. While potentially more controversial, another possibility might be to limit the expansion of privity only in contexts involving medical information. The field of health law has developed in response to a growing recognition that healthcare is “different” or “special,” and that American law frequently deviates from precedent and norms in healthcare contexts. Norman Daniels, *Health Care Needs and Distributive Justice*, 10 PHIL. & PUB. AFF. 146, 146 (1981); Theodore W. Ruger, *Health Law's Coherence Anxiety*, 96 GEO. L.J. 625, 645–46 (2008) (a treating physician owes legally enforceable duties to his patients, even in the absence of a written or oral contract setting outside the scope of the agreement). Modifying the privity requirement in cases of negligent misrepresentation of medical information might be consistent with this approach.

235. See *supra* Part III.C.

236. See *supra* Part III.C.

decision aid was intentional²³⁷—for example, where political or financial motivations cause a decision-aid creator to take advantage of cognitive biases, to selectively present information, or to misrepresent the current state of scientific knowledge. The problem with this approach, however, is that injured plaintiffs are likely to face tremendous difficulty in proving the element of intent. Absent incriminating letters or memoranda (that say, for example, “Let’s not include figures from the Smith study, because it doesn’t support our position”), a defendant would likely be able to claim ignorance or human error as the source of any faults in information. For example, an organization of radiologists that recommends chemotherapy over surgical intervention in a decision aid is likely far more familiar with the literature on the positive outcomes associated with radiology. Merely neglecting to do additional research on the outcomes of surgery in preparing a decision aid would not satisfy the standard of intentional misrepresentation—at best, such conduct could be described as gross negligence or willful ignorance. Thus, while relying on intent to form the basis of a traditional negligence claim against decision-aid creators would certainly be effective in controlling the truly “bad actors,” it remains to be seen whether this will be enough to protect consumers.

To address this concern, one might propose a compromise that would eliminate the privity requirement for misrepresentation-related negligence only in situations where the provision of faulty information could be described as intentional, grossly negligent, or deliberately ignorant. Such a step would capture those entities who provide faulty information as a result of financial, political, or other conflicts of interest, while protecting most typical information providers from liability.

With respect to the proposed modification to the causation requirement, moreover, limitations are already built into this recommendation. Medical informed consent suits are the only contexts in which plaintiffs are required to demonstrate objective decision causation (that the *reasonable patient*, if provided with information about medical risk, would have chosen a different procedure) as well as traditional injury causation (that *this particular plaintiff* actually suffered injury as a result of the undisclosed risk). In other words, eliminating the objective causation would, as a matter of definition, only affect claims of medical misrepresentation and negligence, not negligence claims more broadly.

For a practical example of how such modifications might play out, consider the case highlighted in this Article’s Introduction. John’s diagnosis of prostate cancer is delayed in part because he opted not to be screened for PSA for another five years after his initial PSA test. John might consider pursuing a tort claim against APAE, the organization that authored and published “Prostate Cancer and You.” Under traditional tort principles of informed consent and negligent misrepresentation, John would not be successful in his suit unless he could demonstrate: (i) that APAE negligently misrepresented facts in its brochure;

237. The claim would nevertheless be grounded in negligence because, even if the information provider’s presentation of faulty information was intentional, the causation of physical harm was merely reasonably foreseeable. *See supra* Part III.C.

(ii) that these facts were relevant to John's condition and that John justifiably relied on them in deciding not to pursue ongoing screening for PSA; (iii) that, if the facts presented by APAE had been accurate, a reasonable patient would have chosen PSA screening; (iv) that choosing not to be screened for PSA was the actual cause of John's delayed diagnosis; and (v) that there was a direct relationship of privity between John and APAE.

Presumably, John would have little difficulty satisfying factors (ii) and (iv). Factor (i), whether APAE acted negligently in publishing faulty medical information, would be highly dependent on the facts of John's case, as it should be. However, his case would be stymied by factors (iii) and (v). First, because PSA screening is a decision that is based on the values and preferences of each patient and may vary from person to person, it is unlikely that John will be able to satisfy the objective causation standard. Secondly, it will likely be impossible for John to demonstrate privity with APAE, an organization with which he has had no prior connection before his receipt of its brochure. Thus, regardless of APAE's state of mind when publishing "Prostate Cancer and You," John will be unable to recover.

In contrast, consider the privity and causation modifications described above. As to factor (iii), replacing objective causation with subjective causation would permit John to proceed with his claim despite the impossibility of proving what a "reasonable patient" would have chosen in his situation; as noted above, for preference-sensitive decisions, there is no such thing as a reasonable patient. Moreover, factor (v), the privity requirement, would be modified in one of two ways. As one option, we might require that John instead demonstrate that APAE *intended*, rather than merely foresaw, that consumers rely on and make medical decisions on the basis of its publications. As a second option, we might do away with factor (v) altogether and instead modify factor (i) to require a showing that APAE's presentation of faulty information was grossly negligent or willfully ignorant. Either option would put the focus on the facts of John's unique circumstances, and particularly on the motivations and conduct of APAE.

Allowing creators of faulty decision aids to be liable in tort for the harms caused by their products would surely be a significant burden and imposition on the industry. However, if liability is dependent on the decision-aid creator's intent with respect to public use of its informational product, or takes into account the degree of its misconduct beyond mere negligence, concerns about dramatic expansions of liability are buffered. Organizations that create decision aids in good faith and based on solid and unbiased evidence, for example, would have little to fear if regulation of decision aids were complemented by a system of tort liability in this manner. As demonstrated above, it is possible to modify the privity and causation requirements for cases of misrepresentation-related negligence by decision-aid creators without having as dramatic an impact on information provider liability as initially suggested. The elimination of objective decision causation would only affect claims relating to medical information; the modification of privity to embrace only information providers who intend that consumers rely on their information, or whose conduct rises above traditional negligence, would limit the number of affected claims even further. While these changes will surely have an impact beyond the narrow context of patient decision aids, they will not result in widespread changes to the application of tort law.

CONCLUSION

The legal landscape surrounding decision-support tools is wide open. These tools are currently unregulated, and although PPACA contemplates a certification system that may serve a regulatory function, it will likely be years before this system is implemented. Moreover, contemporary tort law does not effectively recognize claims by injured patients against the creators of faulty decision aids. Given this backdrop, now is the time for policy-makers to evaluate the best mechanisms for ensuring decision-aid quality.

Viewing decision-aid quality within the context of the debate between purely administrative and complementary tort law approaches to consumer protection is an optimal way to do this. Analyzing the five factors policy-makers typically use to make decisions between regulatory and tort law approaches seems to suggest the adoption of both administrative regulations similar to those proposed by PPACA and a tort law complement for ensuring decision-aid quality.

Although tort doctrine would need to incorporate two significant changes to enable injured patients to bring negligence suits against creators of faulty decision aids, both changes seem feasible, whether by way of legislation or common law development. First, modifying the privity requirement in cases of faulty decision aids would be consistent with tort law's contemporary shift towards abandoning privity in many other contexts, including medical contexts like pharmaceutical labeling. Ideally, the privity modification could be done in a limited fashion, allowing patients to bring negligence misrepresentation claims only against those who intend (rather than foresee) consumer reliance on their informational products or whose misrepresentation is intentional, grossly negligent, or deliberately ignorant, even in the absence of privity. Second, modifying the causation requirement to permit suits by patients who are injured by misinformation when making preference-sensitive decisions would be an effective way of adapting informed consent law to a changing medical environment.

Although the use of patient decision aids offers substantial benefits over the current system of informed consent, these aids (like any provision of medical information) pose a significant possibility of harms. Accordingly, policy-makers ought to consider these changes to misrepresentation-related claims of negligence when evaluating mechanisms for ensuring consumer safety in this developing industry.