

# MODERNIZING INFORMED CONSENT: EXPANDING THE BOUNDARIES OF MATERIALITY

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## INTRODUCTION

The doctrine of informed consent is now so firmly entrenched in medical practice and legal theory that it is easy to forget how recent its origins are. It was not until the early 1960's that most medical and legal professionals began to recognize that malpractice liability could attach to a physician's failure to properly inform her patient of the risks and benefits of proposed clinical treatment.<sup>1</sup>

In the past fifty years, however, little has changed. Certainly, physicians have become far more sensitive to issues of patient autonomy; greater attention is being paid to health literacy; and shared conversation rather than one-sided disclosure is now considered the optimal model for obtaining informed consent. But the *substantive scope* of clinicians' disclosure duties under the doctrine of informed consent has remained essentially unchanged. With very few exceptions, disclosures in clinical practice are limited to information that is considered material from a purely medical perspective: the patient's diagnosis and prognosis, the nature of the proposed treatment, the treatment's risks and benefits, and any reasonable alternative treatments.<sup>2</sup>

It is time to reconsider the merits of this basic model.

Contemporary understandings of the nature of human decision-making support the finding that patients choosing between various types of medical treatment do so by considering many factors, not just the physiological consequences of treatment. Most notably, a wealth of recent literature about values-based decision-making and preference-sensitive care demonstrates that many patients' medical decisions are driven by personal

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<sup>1</sup> See generally, RUTH R. FADEN AND TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (Oxford University Press, 1986), at 88-91; JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (Johns Hopkins University Press, 2002), at 59-80.

<sup>2</sup> See Parts II-B and II-C, *infra*.

preferences about risk-taking, cost, the prevention of suffering, and the value of extending life.<sup>3</sup>

While debates about whether informed consent should incorporate non-medical facts that patients consider relevant have been taking place for decades, these debates have not resulted in any large-scale changes in medical practice or tort liability. The groundswell of managed care in the late 1980's and 1990's, for example, triggered a nationwide discussion about physicians' obligations to disclose the financial incentives guiding their treatment decisions.<sup>4</sup> Prominent cases like Johnson v. Kokemoor,<sup>5</sup> Moore v. University of California,<sup>6</sup> and Estate of Behringer v. Princeton<sup>7</sup> led to questions about whether a physician's personal characteristics – whether her qualifications,<sup>8</sup> financial interests in medical research,<sup>9</sup> or HIV status<sup>10</sup> – ought to be disclosed as part of the informed consent process.<sup>11</sup>

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<sup>3</sup> The phrase “preference-sensitive care” was coined by Jack Wennberg, whose influential research on practice variations led to the development of modern models of shared decision-making. *See generally*, John E. Wennberg, *Unwarranted Variations in Healthcare Delivery: Implications for Academic Medical Centres*, 325(7370) *BRITISH MED. J.* 961 (2002) (demonstrating that many variations in clinical practice “cannot be explained by type or severity of illness or by patient preferences”); Jaime Staples King and Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 *AM. J. L. & MED.* 429, at 430-431 (2006) (discussing research on variability in patient values and preferences, and the implications for medical practice).

<sup>4</sup> *See, e.g.*, E. Haavi Morreim, *Economic Disclosure and Economic Advocacy: New Duties in the Medical Standard of Care*, 12 *J. L. & MED.* 275 (1991); Susan M. Wolf, *Toward a Systemic Theory of Informed Consent in Managed Care*, 35 *HOUSTON L. REV.* 1631(1999); Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 *IOWA L. REV.* 261 (1999); Mark Hall, *A Theory of Economic Informed Consent*, 31 *GA. L. REV.* 511 (1997).

<sup>5</sup> Johnson v. Kokemoor, 545 N.W.2d 495 (Wis. 1996).

<sup>6</sup> Moore v. Regents of Univ. of California, 793 P.2d 479, 485 (Cal. 1990)

<sup>7</sup> Estate of Behringer v. Medical Center at Princeton, 592 A.2d. 1251 (N.J. Super. Ct. 1991).

<sup>8</sup> *See, e.g.*, Richard A Heinemann, *Pushing the Limits of Informed Consent: Johnson v. Kokemoor and Physician-Specific Disclosure*, 1997 *WISC. L. REV.* 1079 (1997); Richard J. Veerapen, *Informed Consent: Physician Inexperience is a Material Risk for Patients*, 35(3) *J. L. MED. & ETHICS* 478 (2007); Emmanuel O. Iheukwumere, *Doctor, Are You Experienced? The Relevance of Disclosure of Physician Experience to a Valid Informed Consent*, 18 *J. CONTEMP. HEALTH L. & POL'Y* 373 (2001-2002); Aaron D. Twerski and Neil B. Cohen, *The Second Revolution in Informed Consent: Comparing Physicians to Each Other*, 94 *NORTHWESTERN U. L. REV.* 1 (1999).

<sup>9</sup> *See, e.g.*, Joseph M. Healey, Jr. and Kara L. Dowling, *Controlling Conflicts of Interest in the Doctor-Patient Relationship: Lessons from Moore v. Regents of the University of California*, 42 *MERCER L. REV.* 989 (1990); Jeffrey A. Potts, *Note: Moore v. Regents of the University of California*, 86 *NORTHWESTERN U. L. REV.* 453 (1992).

<sup>10</sup> *See, e.g.*, Michelle Wilcox DeBarge, *The Performance of Invasive Procedures by*

More recently, increased public awareness of the dramatic differences in the cost of medical treatment across various health care settings<sup>12</sup> has led some commentators to suggest that patients cannot grant truly informed consent without knowing the cost of their proposed treatment.<sup>13</sup>

As a result of these debates, there is already a wealth of academic literature analyzing the merits of requiring physicians to disclose their financial conflicts of interests, their qualifications, their HIV status, and, more recently, the price of treatment.<sup>14</sup> Beyond these very narrow contexts, however, there is little discussion and no consensus about what constitutes “materiality” in informed consent more broadly, or whether there is any justification for expanding the doctrine of informed consent to include information that may be relevant to patients but falls outside the traditional scope of medical materiality.<sup>15</sup>

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*HIV-Infected Doctors: The Duty to Disclose Under the Informed Consent Doctrine*, 25 CONN. L. REV. 991 (1992); Theodore R. LeBlang, *Obligations of HIV-Infected Health Professionals to Inform Patients of their Serological Status: Evolving Theories of Liability*, 27 JOHN MARSHALL L. REV. 317 (1993); Lawrence Gostin, *HIV-Infected Physicians and the Practice of Seriously Invasive Procedures*, 19(1) HASTINGS CENTER REPORT 32 (1989).

<sup>11</sup> See generally, Mary Ann Bobinski, *Autonomy and Privacy: Protecting Patients from Their Physicians*, 55 U. PITTSBURGH L. REV. 291 (1994); Marc D. Ginsberg, *Informed Consent: No Longer Just What the Doctor Ordered?*, 15 MICH. STATE U. J. MED. & LAW 18 (2010).

<sup>12</sup> Public attention was drawn to the high (and variable) costs of American medical care due to a series of very high-profile articles published by the New York Times in 2013-2014 as part of a series titled *Paying Till it Hurts*, available at <http://www.nytimes.com/interactive/2014/health/paying-till-it-hurts.html>. See also Elizabeth Rosenthal, *The Price for a Hip Replacement? Many Hospitals Are Stumped, Research Shows*, New York Times (Feb. 12, 2013), A21 (discussing research findings reported in J. A. Rosenthal, X. Lu, and P. Cram, *Availability of Consumer Prices from US Hospitals for a Common Surgical Procedure*, 173(6) JAMA INTERNAL MEDICINE 427 (2013)).

<sup>13</sup> See, e.g., Peter A. Ubel, *Doctor, First Tell Me What It Costs*, New York Times (Nov. 4, 2013), A25; Alicia Hall, *Financial Side Effects: Why Patients Should be Informed of Costs*, 44(3) HASTINGS CENTER REPORT 41 (May-June 2014); Kevin R. Riggs and Peter Ubel, *Overcoming Barriers to Discussing Out-of-Pocket Costs With Patients*, 174(6) JAMA INTERNAL MEDICINE 849 (2014); Peter A. Ubel, Amy P. Abernethy, and S. Yousuf Zafar, *Full Disclosure—Out-of-Pocket Costs as Side Effects*, 369(16) NEW ENGLAND J. MED. 1484 (2013).

<sup>14</sup> See references at notes 4-13, *supra*.

<sup>15</sup> In 1995, after two state courts decided informed consent cases dealing with information arguably outside the scope of medical materiality, Judith Daar wrote an influential article discussing the potential expansion of the materiality doctrine. Judith Daar, *Informed Consent: Defining Limits Through Therapeutic Parameters*, 16 WHITTIER L. REV. 187 (1995) (discussing the “therapeutic limitation” on informed consent in light of Arato v. Avedon and Faya v. Almaraz). However, with the exception of Daar’s article,

This Article begins, in Part II, by explaining the ethical and legal theories that form the basis of the doctrine of informed consent, and identifying the limited guidance provided by courts in defining materiality for the purposes of informed consent. It demonstrates that common law has traditionally limited the scope of disclosure to medically material facts, but makes the normative argument that the ethical foundations of informed consent doctrine (together with contemporary understandings of patient decision-making processes) would support broader disclosure duties.

In Part III, the Article develops a descriptive taxonomy of non-medical disclosures that are relevant to patient decision-making and have been proposed – by litigants, policymakers, and scholars – as potentially suitable for inclusion within the process of informed consent. These include not only disclosures about physicians’ financial conflicts of interest, personal risk factors, and cost of treatment, but also disclosures about physicians’ other personal characteristics, practice patterns, and conscientious commitments; about social and societal implications of treatment (as with prenatal genetic testing); about risks to third parties (as in the cases of organ donation and abortion); and about government and third-party resources available to assist patients (such as adoption resources and TANF assistance).

Part IV of the Article crafts a normative framework for expanding the doctrine of materiality in informed consent. It recognizes that while ethical theories of decisional autonomy would likely support broader disclosure duties, practical limitations restrict the feasibility of a significant expansion. Moreover, while expanding disclosure obligations would likely benefit patients, doing so might be unreasonable for the physicians who bear the primary burden of identifying and sharing material non-medical information, as well as the secondary burden of tort liability for non-disclosure. Part IV argues that the legal doctrine of informed consent in clinical practice can and should be expanded to include some non-medical information, subject to the following limitations: the disclosed information

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most other commentary examining the potential expansion of informed consent on a larger scale has only addressed the disclosure of physician-specific information – not the other categories of information identified in Part III of this Article. *See, e.g.,* Bobinski, *supra* note 11 (discussing statutory and common law disclosure duties relating to provider characteristics and financial conflicts of interest); Ginsberg, *supra* note 11 (discussing expansion of informed consent doctrine to include physician-specific information); Twerski & Cohen, *supra* note 8 (discussing disclosure of information relating to physician qualifications).

must be material to the reasonable patient, within the physician's knowledge and expertise, and its disclosure must not violate public policy.

Required disclosures based on the physician-expertise standard would include not only medical information about the proposed treatment, but also some non-medical information about the physician's own characteristics (such as her experience, financial conflicts of interest, health status, etc.); information about a treatment's medical impact on third parties (in the case of surrogacy and organ donation, for example); any specialized knowledge the physician might have about the real-world implications of living with disability; as well as the cost of treatment in those very limited areas of medical practice where cost information is readily known (like psychiatry and plastic surgery). However, many categories of information that some commentators believe ought to be disclosed will not be captured by this expanded definition of materiality. Information about the cost of treatment will be excluded, at least in most practice areas; as will physician-specific disclosures that implicate privacy or policy concerns; and information about the social, ethical, legal, and privacy implications of treatment. Some categories of disclosure that are currently required by law – most notably, information about social and financial support resources available to women seeking abortions – would also be excluded.

We live in an era where patients' medical decisions are often driven by factors that were not contemplated (or were simply not relevant) when the doctrine of informed consent was first developed. To bring informed consent law into the 21<sup>st</sup> century, we must re-evaluate the under-theorized doctrine of materiality, and recognize that the ethical principles of decisional autonomy that underlie informed consent demand a broader understanding of materiality. In offering both a descriptive taxonomy of non-medically material disclosures as well as a normative proposal for expanding the doctrine of informed consent, this author hopes to assist readers in interpreting existing legal precedent, and in setting normative goals for future policymaking and clinical practice.

## I. DOCTRINAL FOUNDATIONS OF INFORMED CONSENT AND MATERIALITY

The ethical and legal doctrines of informed consent to medical treatment arose in the mid-20<sup>th</sup> century, partly in response to growing patient dissatisfaction with the paternalistic standards of the medical

profession.<sup>16</sup> As the medical community began to recognize the value of patient autonomy and integrate conversations about patient choice into the treatment process, American law followed suit. By the late 1960's and early 1970's, most courts recognized the failure to obtain informed consent as a form of medical negligence, and were willing to impose tort liability on physicians who breached this duty.<sup>17</sup> In defining the scope of the informed consent duty, courts uniformly concluded that physicians have a legal obligation to inform patients of material information about a proposed course of treatment, which includes its risks and benefits as well as those of any alternative treatments.

This common law standard for informed consent soon became entrenched in both legal doctrine and responsible medical practice. However, perhaps because there was such widespread consensus across jurisdiction about the scope of required disclosures, neither courts nor commentators devoted much attention to the question of whether the materiality standard might be interpreted more broadly.

In this Part, I explain the ethical foundations of the doctrine of informed consent, and provide a brief history of how this doctrine manifested itself in early common law.

#### *A. Ethical Foundations: Decisional Autonomy*

The doctrine of informed consent is grounded in the ethical principle of patient autonomy.<sup>18</sup> Patients have a right to control their own bodies, and

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<sup>16</sup> See generally, KATZ, *supra* note 1. Informed consent doctrine in the research ethics context arose somewhat earlier than in the clinical context, but tracked it through the 1960's and 1970's. Discussions about informed consent to human subjects research began in earnest as a result of the Nuremberg trials of 1945-1946; they then continued through Henry Beecher's 1966 article in the *New England Journal of Medicine* about ethical violations in American research, the 1972 revelation of the Tuskegee syphilis trials, and ultimately the Office of Human Subjects Research Protection's 1979 publication of the Belmont Report.

<sup>17</sup> While the modern doctrine of informed consent is grounded in negligence principles, it originated as a cause of action for battery. See generally, JESSICA W. BERG, PAUL S. APPELBAUM, CHARLES W. LIDZ, LISA S. PARKER, *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* (Second Edition) (Oxford University Press, 2001), at 41-44; BARRY FURROW *et al*, *HEALTH LAW* (Second Edition) (West, 2000), at 310-313.

<sup>18</sup> See generally, GERALD DWORKIN, *THE THEORY AND PRACTICE OF AUTONOMY* (Cambridge University Press, 1988), at 100-120; FADEN AND BEAUCHAMP, *supra* note 1, at 7-9; TOM L. BEAUCHAMP AND JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (Sixth Edition) (Oxford University Press, 2008), at 103-105, 117-120; BERG *et al*, *supra* note 17, at 22-24.

to make free and unencumbered choices about the medical interventions imposed on their bodies. While the theory of decisional autonomy is grounded in Kantian deontological values (the notion that the exercise of autonomy is a good in and of itself, regardless of its consequences), autonomous decision-making often has utilitarian benefits as well – that is, allowing patients to make autonomous choices ultimately promotes their welfare by leading to objectively better choices.<sup>19</sup> Furthering autonomy requires recognizing the patient’s subjective goals and values, and providing the patient with the information needed to make a coherent decision in accordance with these goals and values.<sup>20</sup>

Autonomous decision-making requires the satisfaction of a variety of conditions, including capacity, voluntariness, and factual understanding.<sup>21</sup> In the context of medical treatment, however, patients are often unable to make informed choices because they lack the information necessary to understand their options. Physician disclosure is thus a necessary component for satisfying the conditions of autonomous decision-making in medical care.<sup>22</sup> Beyond general reference to “materiality” or “relevance,” however, ethical theories of informed consent rarely provide specific guidance about the substantive information that ought to be disclosed as part of the consent process.<sup>23</sup> Indeed, medical ethicists

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<sup>19</sup> DWORKIN, *supra* note 18, at 111-112 (discussing both intrinsic and utilitarian arguments for autonomous medical decision-making).

<sup>20</sup> See Tom L. Beauchamp, *Autonomy and Consent*, in THE ETHICS OF CONSENT: THEORY AND PRACTICE, FRANKLIN G. MILLER AND ALAN WERTHEIMER, EDS. (Oxford University Press, 2010), at 62 (recognizing that the principle of respect for autonomy demands that we “respect an autonomous agent’s right to control his or her affairs in accordance with personal values and beliefs.”); BERG *et al*, *supra* note 17, at 24 (noting that autonomous and informed decision-making promotes subjective well-being); President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* (Oct. 1982), at 42-43 (noting the importance of informed consent in achieving patients’ subjective goals).

<sup>21</sup> See generally, BEAUCHAMP AND CHILDRESS, *supra* note 18, at 120-121; BERG *et al*, *supra* note 17, at 65-70.

<sup>22</sup> BEAUCHAMP AND CHILDRESS, *supra* note 18, at 121-122.

<sup>23</sup> See, e.g., BEAUCHAMP AND CHILDRESS, *supra* note 18, at 121 (noting that health care professionals must disclose “those facts or descriptions that patients or subjects usually consider material in deciding whether to refuse or consent to the proposed intervention or research” as well as “information the professional believes to be material”); FADEN AND BEAUCHAMP, *supra* note 1, at 9 (referring to the question of what kinds of information must be disclosed to facilitate autonomous decision-making “remain[s] unsettled”) and 308 (identifying a “core disclosures” those facts that patients and health care professionals believe to be “material”). The American Medical Association’s Council on Ethical and Judicial Affairs’ opinion on the requirements of informed consent is

frequently criticize the law's emphasis on defining the substantive scope of required disclosure; instead, they argue, the ethical duty to obtain informed consent ought to be context-specific, focusing on the patient's actual understanding rather than the physician's satisfaction of rote disclosure requirements.<sup>24</sup> In framing the ideal informed consent process as an ongoing process of shared decision-making and conversation,<sup>25</sup> medical ethicists recognize that there is no single disclosure standard that will suffice for all doctors and all patients.<sup>26</sup> Thus, they may see less need to delineate the specific boundaries of what ought to be disclosed – at least as compared to attorneys and their clients, who typically require greater clarity about substantive disclosure standards and the boundaries of tort liability.

### *B. Legal Foundations: The Common Law Duty of Informed Consent*

The modern legal doctrine of informed consent allows a patient who suffers injury as a result of a medical procedure's undisclosed risks to recover in tort from the physician who failed to adequately disclose those risks. To prevail in a typical informed consent action, the patient must demonstrate that (1) her physician breached a duty to disclose a material

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likewise vague; it requires the disclosure of "all relevant medical information," but notes that "quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients." American Medical Association, Council on Ethical and Judicial Affairs, *Opinion 8.08: Informed Consent* (issued March 1981; updated November 2006) (hereafter, *AMA Opinion 8.08*).

<sup>24</sup> See, e.g., FADEN AND BEAUCHAMP, *supra* note 1, at 305-308 (criticizing the disclosure standards of informed consent law, and arguing that informed consent ought to focus on communication aimed at achieving "substantial shared understanding," rather than relying simply on "core disclosures"); Beauchamp, *Autonomy and Consent*, *supra* note 20, at 57-58 ("Physicians who obtain consent under institutional criteria can fail – and often do fail – to meet the more rigorous standards of an autonomy-based model."); Steven Joffe and Robert Truog, *Consent to Medical Care: The Importance of Fiduciary Context*, in MILLER AND WERTHEIMER, EDS., *supra* note 20, at 368-369 (noting that a single set of disclosure standards may not be able to satisfy both legal and ethical standards of informed consent). Some legal scholars share this concern as well. See, e.g., Dayna Bowen Matthew, *Race, Religion, and Informed Consent – Lessons from Social Science*, 36(1) J. L. MED. & ETHICS 150, 168 (Spring 2008) (noting that "[t]he error of informed consent law has been in oversimplifying the complexity of the relationship between physician and patient by regulating the disclosure rather than the relationship"); Jay Katz, *Informed Consent, A Fairy Tale?*, 39 U. PITT. L. REV. 137, 173 (1977) (noting the impossibility of "promulgat[ing] an informed consent doctrine which articulates the extent of communication required for *all* medical encounters[.]").

<sup>25</sup> King and Moulton, *supra* note 3.

<sup>26</sup> *AMA Opinion 8.08*, *supra* note 23 (noting the necessity of tailoring disclosure requirements to individual patients).



risk associated with a medical procedure; (2) that the reasonable patient would more likely than not have opted not to undergo the procedure had she known of the undisclosed risk; (3) that the patient suffered a compensable injury as a result of her decision; (4) and that the patient's injury was in fact caused by the undisclosed risk.<sup>27</sup> The disputed issue in the vast majority of informed consent cases – and the issue that legal and medical scholars debate with greatest intensity – is the substantive scope of the disclosure duty.<sup>28</sup>

The scope of the physician's duty varies depending on the jurisdiction in which she practices. In the United States, jurisdictions are more or less evenly divided between a patient-based standard and a physician-based standard for identifying the information that must be disclosed as part of the informed consent process.<sup>29</sup>

The physician-based standard, which was more prevalent in the early history of informed consent, defines the scope of disclosure by reference to what a reasonable physician would customarily disclose.<sup>30</sup> The Kansas Supreme Court's 1960 decision in Natanson v. Kline (which is still cited by some courts today) held that a physician has a duty to "assure that an informed consent of the patient is obtained," but that this duty is limited to "those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."<sup>31</sup>

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<sup>27</sup> Patients may also bring informed consent cases associated with decisions *not* to pursue medical treatment or testing – for example, a patient who chooses not to undergo a Pap smear because her physician failed to adequately disclose the risks of inaction may bring a tort suit if she suffers injury as a result of the ill-informed decision. Truman v. Thomas, 611 P.2d 902 (Cal. 1980).

<sup>28</sup> As Peter Schuck wrote, "Everyone, it seems, favors the principle of informed consent; it is 'only' the specific details and applications of the doctrine that arouse serious debate." Peter H. Schuck, *Rethinking Informed Consent*, 103 Yale L. J. 899, 902 (1994).

<sup>29</sup> FURROW *et al*, *supra* note 17, at 314 (noting that "more than twenty-five states" have adopted a physician-based standard, either by judicial decision or by statute, but that the patient-based standard is now "approaching a majority position"); King and Moulton, *supra* note 3, at Appendix A. For a more thorough explanation of the history of and distinction between the two standards, see BERG *et al*, *supra* note 17, at 46-52; FURROW *et al*, *supra* note 17, at 313-314; FADEN AND BEAUCHAMP, *supra* note 1, at 30-34.

<sup>30</sup> Under the physician-based standard, expert testimony is required to establish the scope of required disclosures. *See, e.g., Hamilton v. Bares*, 678 N.W.2d 74 (Neb. 2004); Aronson v. Harriman, 901 S.W.2d 832 (Ark. 1995); Roark v. Allen, 633 S.W.2d 804, 809 (Tex. 1982); Roberts v. Young, 119 N.W.2d 627 (Mich. 1963).

<sup>31</sup> Natanson v. Kline, 350 P.2d 1093, 1106 (Kan. 1960), decision clarified on denial of reh'g, 354 P.2d 670 (Kan. 1960).

The physician-based standard has been widely criticized on the grounds that it does not accurately reflect the autonomy-based principles underlying the doctrine of informed consent. In Canterbury v. Spence, perhaps most broadly-cited informed consent case in American jurisprudence, the U.S. Court of Appeals for the District of Columbia Circuit rejected the physician-based standard, noting that the “root premise” of informed consent doctrine is “the concept, fundamental in American jurisprudence, that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body. . . .”<sup>32</sup> Accordingly, the court held, it is “the patient’s right of self-decision [that] shapes the boundaries of the duty to reveal.”<sup>33</sup>

Under the patient-based standard established in Canterbury and adopted by numerous courts since then, the scope of the disclosure duty is defined by reference to the reasonable patient’s needs and expectations. Key to the patient-based standard of disclosure is the question of what information a reasonable patient would find “material.”<sup>34</sup> According to the court in Canterbury, a risk qualifies as material when a “reasonable person . . . would be likely to attach significance to the risk or cluster of risks in

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<sup>32</sup> Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972) (citing Schloendorff v. Society of New York Hospital, 105 N.E. 92, 93 (N.Y. 1914))

<sup>33</sup> *Id.* at 786-87. *See also* Wheeldon v. Madison, 374 N.W.2d 367, 374 (S.D. 1985) (holding that “the right to know - to be informed - is a fundamental right personal to the patient and should not be subject to restriction by medical practices that may be at odds with the patient’s informational needs.”); Sard v. Hardy, 379 A.2d 1014, 1021 (Md. 1977) (holding that “protection of the patient’s fundamental right of physical self-determination [is] the very cornerstone of the informed consent doctrine [and] mandates that the scope of a physician’s duty to disclose therapeutic risks and alternatives be governed by the patient’s informational needs”); Largey v. Rothman, 540 A.2d 504, 508 (N.J. 1988) (identifying as one of the reasons for rejecting the physician-based standard “the notion that the physician’s duty of disclosure ‘arises from phenomena apart from medical custom and practice’: the patient’s right of self-determination”); Cross v. Trapp, 294 S.E.2d 446, 455 (W. Va. 1982) (holding that liability under the patient-based standard depends on “the reasonableness of the physician’s disclosure or nondisclosure in terms of what the physician knows or should know to be the patient’s informational needs”).

<sup>34</sup> Canterbury v. Spence, 464 F.2d 772, at 787 (D.C. Cir. 1972) (holding that physicians have a common law duty to disclose all risks “material to the [patient’s] decision”); Wheeldon v. Madison, 374 N.W.2d 367, 375 (S.D. 1985) (“Materiality, therefore, is the cornerstone upon which the physician’s duty to disclose is based. “); FADEN AND BEAUCHAMP, *supra* note 1, at 32 (referring to materiality as the “legal litmus test” for determining extent of disclosure under the reasonable patient standard); Jon R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 NORTHWESTERN U. L. REV. 628, 637 (1969) (describing materiality as the “traditional legal litmus for measuring the significance of decision-making).

deciding whether or not to forego the proposed therapy.”<sup>35</sup> This definition of materiality has been widely adopted.<sup>36</sup>

While the determination of what information counts as “material” is ultimately one for the jury,<sup>37</sup> most courts adopting the patient-based standard have identified a set of disclosures they consider essential for an informed decision. This includes substantive information about the patient’s diagnosis and proposed treatment; the treatment’s risks and benefits; alternative procedures and their risks and benefits; and the risks and benefits of taking no action (hereafter referred to as the “standard risk-and-benefit disclosure”).<sup>38</sup> Interestingly, although physician-based jurisdictions reject

<sup>35</sup> Canterbury v. Spence, 464 F.2d 772, at 787 (D.C. Cir. 1972).

<sup>36</sup> See, e.g., Wilkinson v. Vesey, 295 A.2d 676, 689 (R.I. 1972) (“Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient’s position, would attach to the disclosed risk or risks in deciding whether to submit or not to submit to surgery or treatment.”); Wheeldon v. Madison, 374 N.W.2d 367, 371 (S.D. 1985) (“Material information is information which the physician knows or should know would be regarded as significant by a reasonable person in the patient’s position when deciding to accept or reject a recommended medical procedure.”); Sard v. Hardy, 379 A.2d 1014, 1022 (Md. 1977) (“A material risk is one which a physician knows or ought to know would be significant to a reasonable person in the patient’s position in deciding whether or not to submit to a particular medical treatment or procedure.”).

<sup>37</sup> Wilkinson v. Vesey, 295 A.2d 676, 688 (R.I. 1972); Downs v. Trias, 49 A.3d 180, 186 (Conn. 2012); Smith v. Weaver, 407 N.W.2d 174, 178 (Neb. 1987).

<sup>38</sup> See, e.g., Canterbury v. Spence, 464 F.2d 772, at 787-88 (D.C. Cir. 1972) (“The topics importantly demanding a communication of information are the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated.”); Wheeldon v. Madison, 374 N.W.2d 367, 375 (S.D. 1985) (“We deem a reasonable disclosure to be one which apprises the patient of all known material or significant risks inherent in a prescribed medical procedure, as well as the availability of any reasonable alternative treatment or procedures.”); Sard v. Hardy, 379 A.2d 1014, 1020 (Md. 1977) (“This duty to disclose is said to require a physician to reveal to his patient the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment”); Cross v. Trapp, 294 S.E.2d 446, 455 (W. Va. 1982) (adopting the patient-based standard, and identifying the following as material facts: “(1) the possibility of the surgery, (2) the risks involved concerning the surgery, (3) alternative methods of treatment, (4) the risks relating to such alternative methods of treatment and (5) the results likely to occur if the patient remains untreated.”); Duffy v. Flagg, 905 A.2d 15, 20 (Conn. 2006) (adopting the patient-based standard, and requiring disclosure of “(1) the nature of the procedure; (2) the risks and hazards of the procedure; (3) the alternatives to the procedure; and (4) the anticipated benefits of the procedure.”); Howard v. Univ. of Med. & Dentistry of New Jersey, 800 A.2d 73, 79 (N.J. 2002) (adopting the reasonably prudent patient standard, and requiring disclosure of “information concerning the risks of the procedure or treatment, the alternatives, or the potential results if the procedure or treatment were not undertaken”).

the idea that the scope of disclosure should be guided by the patients' informational needs, states that retain the physician-based standard rely on the same set of standard risk-and-benefit disclosures when framing the issue of physician liability.<sup>39</sup> Most statutory codifications of informed consent requirements use similar language, although they vary in their specificity.<sup>40</sup>

It is worth noting, however, that a minority of courts and legislatures interpret the informed consent disclosure duty more narrowly. Relying on Canterbury v. Spence's language about "the inherent and potential hazards of the proposed treatment,"<sup>41</sup> some courts limit informed consent disclosure to the purely medical or physiological risks and benefits inherent in a procedure. Such courts have rejected tort claims alleging physician non-disclosure of the method by which a procedure is performed (on the grounds that this does not constitute a risk),<sup>42</sup> as well as non-disclosure of the risk of provider negligence (on the grounds that this risk is not "inherent in the procedure").<sup>43</sup> Some courts and legislatures have narrowed the

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<sup>39</sup> See e.g., Natanson v. Kline, 350 P.2d 1093, 1106 (Kan. 1960) decision clarified on denial of reh'g, 354 P.2d 670 (Kan. 1960) (establishing a physician-based standard of disclosure, and identifying required disclosures as "the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body"); Shadrick v. Coker, 963 S.W.2d 726, 732 (Tenn. 1998) (holding that the scope of the disclosure duty depends on "the usual and customary advice given to patients to procure consent in similar situation," and requiring specific disclosure of "the diagnosis or nature of the patient's ailment, the nature of and the reasons for the proposed treatment or procedure, the risks or dangers involved, and the prospects for success," as well as "alternative methods of treatment, the risks and benefits of such treatment and, if applicable, that the proposed treatment or procedure is experimental").

<sup>40</sup> Compare, e.g., Tex. Civ. Prac. & Rem. Code Ann. § 74.101 and 104 (requiring disclosure of the "risks or hazards" involved in a procedure); N.Y. Pub. Health Law § 2805-d (requiring disclosure of "alternatives" and "reasonably foreseeable risks and benefits"); 40 Pa. Cons. Stat. Ann. § 1303.504 (requiring "a description of a procedure" as well as disclosure of "risks and alternatives"); Ga. Code Ann. § 31-9-6.1 (West) (requiring disclosure of (1) diagnosis, (2) the proposed procedure's "nature and purpose", (3) the material risks of "infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death." (4) the procedure's likelihood of success; (5) alternative treatments; (6) prognosis if the proposed treatment is rejected).

<sup>41</sup> Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972).

<sup>42</sup> See, e.g., Tajchman v. Giller, 938 S.W.2d 95 (Tex. App. 1996) (holding that Texas' informed consent statute did not require disclosure of the particular steps involved in a procedure, only the "risks or hazards" associated with the procedure); Valles v. Albert Einstein Medical Center, 805 A.2d 1232, at 1240 (Pa. 2002) (holding that "the manner or method in which the surgeon performs the proposed procedure is not encompassed within the purview of the informed consent doctrine.").

<sup>43</sup> See, e.g., Gilmartin v. Weinreb, 735 A.2d 620, at 627 (N.J. Super. 1999) (in a case

disclosure duty even further, limiting the types of procedures for which informed consent is required,<sup>44</sup> or identifying a limited set of risks that need to be disclosed.<sup>45</sup>

### C. Understanding Materiality in Informed Consent

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where medication was negligently administered at a higher dose than indicated, holding that advising a patient “of the general risk of negligence ... is inadequate to the purposes of the informed consent rule[.]”); Mull v. Emory University, 150 S.E.2d 276, 292 (Ga. 1966) (holding that the informed consent rule “applies only to the duty to warn of the hazards of a correct and proper procedure of diagnosis or treatment, and has no relation to the failure to inform of the hazards of an improper procedure”); Mallett v. Pirkey, 466 P.2d 466, 470 (Colo. 1970) (“A doctor does not have a duty to disclose the risks of the improper performance of an appropriate procedure.”); Binur v. Jacobo, 135 S.W.3d 646, 655 (Tex. 2004) (holding that “failing to disclose that a diagnosis or prognosis may be or is erroneous when that diagnosis or prognosis supports a recommendation to undergo a surgical procedure is not a risk that is “inherent to” and “inseparable from” the surgical procedure itself”); Felton v. Lovett, 388 S.W.3d 656, at 661-62 (Tex. 2012) (defining the “inherent risks of treatment” as those “which are directly related to the treatment and occur without negligence,” excluding information about “eventualities or non-treatment-specific injuries, such as the possibility of hospital infections, or complications which occur without particular regard to the treatment the patient receives.”).

<sup>44</sup> See, e.g., Morgan v. MacPhail, 704 A.2d 617 (Pa. 1997) (limiting informed consent liability to “surgical or operative” procedures); Karlsons v. Guerinot, 57 A.D.2d 73 (N.Y.S.2d 1977) (limiting informed consent liability to cases involving “some affirmative violation of the patient's physical integrity such as surgical procedures, injections or invasive diagnostic tests”). Courts in states like Pennsylvania and Louisiana have found that physicians cannot be sued for breach of informed consent when they fail to provide information in connection with setting a broken bone, administering a flu shot, performing a blood test, performing a blood transfusion, administering radiation treatment, performing chiropractic manipulation, administering IV drugs, and treating a patient post-operatively eye drops. Most states justifiably reject this limitation, however. As explained by the New Jersey Supreme Court, “The critical consideration is not the invasiveness of the procedure, but the patient's need for information to make a reasonable decision about the appropriate course of medical treatment, whether invasive or noninvasive.” Matthies v. Mastromonaco, 733 A.2d 456, 464 (N.J. 1999)

<sup>45</sup> For example, Iowa and Louisiana’s informed consent statutes limit required disclosures to “the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, of disfiguring scars associated with such procedure or procedures,” Iowa Code Ann. § 147.137; La. Rev. Stat. Ann. 40:1299.39.5; (upheld in LaCaze v. Collier, 416 So. 2d 619, 622 (La. Ct. App.) writ granted, 420 So. 2d 440 (La. 1982) and *aff’d*, 434 So. 2d 1039 (La. 1983)). See also Ga. Code Ann. § 31-9-6.1 (limiting disclosure to the material risks of “infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death”).

Perhaps because there has been widespread agreement since the 1960's that the standard risk-and-benefit disclosure satisfies both the patient-based and physician-based standards of informed consent, there has been little comprehensive discussion of what materiality to patient decision-making means in a broader sense. As recognized by many commentators, legal definitions of "materiality" in the context of informed consent tend to be somewhat vague.<sup>46</sup> The few courts that have attempted to provide a definition have held that material facts are those that a reasonable patient would find "significant" in making a medical decision.<sup>47</sup> And with the exception of cases analyzing the therapeutic privilege, no court has considered the secondary question of whether informed consent requires disclosure of *all* facts a patient would consider material, or whether policy considerations or other factors might limit legally required disclosures to only some material facts.

It is problematic that the concept of materiality has, to date, been so under-theorized. While most courts and commentators have historically agreed that the physician's legal duty of disclosure only pertains to medical facts (under the standard risk-and-benefit disclosure), lay definitions of materiality – and understandings of materiality from an ethical perspective – are far broader.

## 1. Medical Materiality: Common Law Limitations

Legal scholars interpreting the common law history of informed consent have concluded that, with very rare exceptions,<sup>48</sup> the physician's duty only extends to disclosure of *medically material* facts – not other types of information that may nevertheless be relevant to a patient's choice.<sup>49</sup>

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<sup>46</sup> Waltz & Scheuneman, *supra* note 34 (noting that informed consent case law "ha[s] not clearly articulated standards of materiality"); BERG *et al*, *supra* note 17, at 64-65 (noting a "lack of clear definition of the scope" of required informed consent disclosure). According to some commentators, "the law can tolerate a vague definition of materiality" because of the strict causation requirements for informed consent cases – that is, the success or failure of an informed consent action depends on whether the plaintiff demonstrated that a reasonable patient in her position would have made a different decision had she been properly informed. Margaret A. Berger and Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking Daubert*, 104 MICH. L. REV. 257, 275 (2005). As noted in Part IV-D, however, these two issues are intertwined.

<sup>47</sup> See *supra*, notes 34-36.

<sup>48</sup> Most notably, required disclosures of some financial conflicts of interest (see Part III-A-2, *infra*).

<sup>49</sup> See generally, Marjorie M. Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 Yale L.J. 219, 284-285 (1985).

William McNichols describes cases about the withholding of non-medical “collateral” information as “at the boundary of the theory” of informed consent.<sup>50</sup> Similarly, Judith Daar (while ultimately arguing for a more nuanced view of disclosure obligations) describes cases involving disclosure of non-medical information as reaching “beyond traditional doctrine requiring disclosure of treatment risks and alternatives.”<sup>51</sup> She describes this “therapeutic limitation” on informed consent disclosure as effectively “tell[ing] physicians that they need not look beyond the medical needs of their patients in disclosing information about treatment. The physician need not be concerned with his patient as an investor, a business manager, a father, or a spouse.”<sup>52</sup> These interpretations are consistent with the practice of medical professionals and their understanding of their ethical obligations. The American Medical Association’s ethical guidance on informed consent, for example, describes the physician’s obligation as “present[ing] the medical facts ... and mak[ing] medical recommendations,” and does not speak to other facts the physician might disclose

## 2. Broader Lay Understandings of Materiality

It is widely understood that a variety of different factors can affect patient decisionmaking. Medically material facts, such as information about the medical efficacy of a procedure and its likelihood of improving the patient’s physiological well-being (“Will this procedure be successful in easing my symptoms?”), are obviously essential to a patient’s decision. However, a patient choosing to pursue one avenue of treatment may have a variety of different reasons for doing so, some of them falling outside the scope of medical fact. “How much will this procedure cost? How will I feel about my body after this procedure? Will I be subject to discrimination after this treatment? Does the hospital look like a luxury hotel? Do I trust my doctor?” A patient’s choice of whether to undergo a procedure (or where or by whom to have the procedure) may change depending on the answers to any of these questions. As noted by Judith Daar, “the realities of human decision-making will inevitably blur [the] line [between medical and nonmedical interests].”<sup>53</sup>

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<sup>50</sup> William J. McNichols, *Informed Consent Liability in a Material Information Jurisdiction: What Does the Future Portend*, 48 OKLA. L. REV. 711, 713 (1995)

<sup>51</sup> Daar, *supra* note 15, at 188-189.

<sup>52</sup> *Id.* at 195.

<sup>53</sup> Daar, *supra* note 15, at 196. See also BERG *et al.*, *supra* note 17, at 179 (“[T]o encourage patients’ reflections on what selection of a course of treatment is likely to mean

Moreover, the principles of decisional autonomy that underlie both the ethical and legal doctrines of informed consent would support a broader interpretation of materiality. If the goal of autonomous choice in the medical context is decision-making in accordance with a patient's personal goals and values, then non-medical factors are surely material under a lay definition.<sup>54</sup> And the breadth of debate about the possible expansion of informed consent in the contexts mentioned in Part III provides further support for the idea that materiality might be interpreted to include non-medical information.

### 3. Relevance of Materiality Regardless of Jurisdiction

Understanding what type of information is material to patient decision-making is important regardless of whether a jurisdiction adopts a physician-based, patient-based, or mixed standard of care. While only those jurisdictions adopting a patient-based standard of disclosure explicitly look to materiality to define the contours of informed consent, patient-centered language about the “facts ... necessary to form the basis of an intelligent consent by the patient” is prevalent even in physician-based jurisdictions.<sup>55</sup> Moreover, the causation requirement for informed consent means that even physician-centered jurisdictions must look to the relevance of an undisclosed fact to the patient's decision-making process when analyzing informed consent claims.

Modern scholars recognize that while the distinction between patient- and provider-based disclosure standards may be helpful as a theoretical matter, “in practice the boundary between these two standards is often blurred.”<sup>56</sup> Many courts, while purporting to adopt a single standard, often adopt something closer to a mixed model, incorporating aspects of physicians' usual practices while at the same time recognizing the importance of the patient's informational needs.<sup>57</sup> For example, the decision of the Kansas Supreme Court in *Natanson v. Kline* is widely cited as an example of the physician-based standard; there, the court framed the liability issue in terms of whether the physician's disclosures were “in

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to their lives, physicians may have to go beyond the narrow requirements of the law.”)

<sup>54</sup> See *Largey v. Rothman*, 540 A.2d 504, 508-509 (N.J. 1988) (arguing that “that the physician's duty of disclosure ‘arises from phenomena apart from medical custom and practice’: the patient's right of self-determination,” which defines “the direction in which [the patient's] interests seem to lie.”).

<sup>55</sup> *Natanson v. Kline*, 354 P.2d 670, 672-673 (1960)

<sup>56</sup> *BERG et al*, *supra* note 17, at 51.

<sup>57</sup> *Id.* at 51-52.



accordance with those which a reasonable medical practitioner would make under the same or similar circumstances.”<sup>58</sup> However, the court also emphasized that the physician’s duty includes a duty to disclose “significant facts within [the physician’s] knowledge which are necessary to form the basis of an *intelligent consent* by the patient to the proposed form of treatment,” a determination which necessarily relies on the patient’s needs and expectations.<sup>59</sup> Other courts are more explicit in recognizing that both professional standards and patient expectations are relevant to determining the scope of disclosure. The Wisconsin Supreme Court in Scaria v. St. Paul Fire & Marine Ins. Co., for example, held that “[t]he disclosures which would be made by doctors of good standing, under the same or similar circumstances, are certainly relevant and material and we surmise would be adequate to fulfill the doctor’s duty of disclosure in most instances,” but emphasized that “the duty to disclose or inform cannot be summarily limited to a professional standard that may be nonexistent or inadequate to meet the informational needs of a patient.”<sup>60</sup>

Moreover, many courts that purport to adopt a physician-based standard have arguably done so on the basis of a misinterpretation of the foundational physician-standard cases. The earliest cases that relied on professional custom to define the duties of disclosure did so in an era when physicians would regularly shield patients from troubling information (such as a cancer diagnosis) on the basis of the “therapeutic privilege” – the idea that sometimes, disclosure of medical facts may do more harm than good for some patients prone to emotional trauma.<sup>61</sup> In Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, for example, the disputed jury instruction

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<sup>58</sup> Natanson v. Kline, 354 P.2d 670, 673 (1960)

<sup>59</sup> *Id.* at 672-673 (emphasis added). See also ZeBarth v. Swedish Hosp. Med. Ctr., 499 P.2d 1, 10 (Wash. 1972) (holding that informed consent requires disclosure of “information which a reasonably prudent physician or medical specialist of that medical community should or would know to be essential to enable a patient of ordinary understanding to intelligently decide whether to incur the risk by accepting the proposed treatment or avoid that risk by foregoing it”); Salgo v. Leland Stanford Jr. University Board of Trustees, 317 P.2d 170, at 181 (Cal. App.) (defining the informed consent obligation as the duty to disclose “any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment,” but recognizing the need for physician discretion in determining the precise contours of disclosure).

<sup>60</sup> Scaria v. St. Paul Fire & Marine Ins. Co., 227 N.W.2d 647, 653 (Wisc. 1975). See also Winkjer v. Herr, 277 N.W.2d 579, 587-88 (N.D. 1979) (holding that even if a physician’s “disclosure conforms to accepted medical practice,” expert testimony about medical practice “does not define the legal duty to inform which exists as a matter of law,” and which requires the physician to “inform the patient of a significant risk of treatment or of an alternative treatment.”).

<sup>61</sup> See generally, FURROW *et al*, *supra* note 17, at 336-337.

established a patient-based standard: “A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.”<sup>62</sup> The court, however, noted that disclosure of *all risks* might be dangerous in light of “the patient's mental and emotional condition,” and that therefore a “certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent.”<sup>63</sup> The court ordered that the jury instruction be modified to reflect that “the physician has such discretion consistent, of course, with the full disclosure of facts necessary to an informed consent.”<sup>64</sup>

The fact that a physician maintains discretion to limit the scope of disclosure in exceptional circumstances by no means establishes a physician-custom-based standard of care. A better interpretation, and one recognized in more recent cases,<sup>65</sup> is that while the scope of disclosure depends on those facts necessary for a patient to make an informed judgment (from the patient's perspective), the therapeutic privilege allows physicians to limit disclosure if in their professional opinion such disclosure would be detrimental to the patient.

Finally, even in jurisdictions that adopt a physician-based standard, courts still need to evaluate materiality for the purposes of causation. The causation standard for an informed consent suit (regardless of jurisdictional definitions of scope of duty) requires a patient to prove that a reasonable patient would have opted for a different medical course of action had the physician satisfied her duty to disclosure. The patient needs to demonstrate that the undisclosed fact would have been material to the reasonable patient – that is, that the reasonable patient would have been likely to “attach

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<sup>62</sup> Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170, 181 (Cal. App. 1957).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> See, e.g., Carr v. Strode, 904 P.2d 489, 500 (Haw. 1995) (adopting the patient-based standard, but recognizing that expert testimony may be necessary “where privileges are asserted, as to the existence of any emergency claimed and the nature and seriousness of any impact upon the patient from risk-disclosure”); Bernard v. Char., 903 P.2d 676, 686-7 (Haw. Ct. App. 1995) aff'd, 79 Haw. 362, 903 P.2d 667 (Haw. 1995) (saying that proponents of the MD standard do so on the basis that “only a physician is capable of estimating the potential psychological impact that risk disclosure would have on a particular patient”; finding that “the application of the physician standard in nondisclosure cases based on the therapeutic privilege exception and the patient standard in cases where the duty of disclosure clearly applies is consistent with the underlying foundation upon which the doctrine of informed consent is premised.”).

significance” to the fact to such a degree that it would more likely than not affected her decision.

Thus, questions about what types of information are relevant to patient decision-making are important regardless of jurisdictional differences in determining the standard of care for disclosure.

## II. EXPANDING THE BOUNDARIES OF MATERIALITY

The common law informed consent standards established in the 1960’s and 1970’s still define the scope of physician liability. Courts continue to hold that physicians have a duty to disclose information “material” to a patient’s medical decision-making – including the patient’s diagnosis and prognosis, the risks and benefits of the recommended treatment, and the risks and benefits of any alternative treatments.

Today, however, it is increasingly obvious that what counts as “material” information for the average patient may not captured by the common law disclosure duty. A patient choosing whether or not to go forward with a medical intervention may base her decision on a variety of non-medical factors, including information about the physician, his disease status, experience, and conflicts of interest; the cost of treatment; or the social or legal implications of treatment.

This Part categorizes the types of non-medical information that patients might reasonably consider relevant to their medical decisions (and therefore suitable for discussion as part of the informed consent conversation). Some of these categories have already been thoroughly explored in the literature, while others are of more recent vintage, proposed in response to changes in the modern health care climate. Whether offered by policymakers, patient advocates, or academic commentators, these expanded understandings of what constitutes material information, if adopted, would revolutionize the doctrine of informed consent.

### *A. Provider-Specific Characteristics*

Every health care provider is an individual with unique characteristics; patients choosing between providers recognize this fact. The average patient might choose a treating physician based on her gender, her ethnicity, her age, the university from which she graduated, her reputation

in the community, or any number of other factors. Likewise, a patient deciding between multiple treatment options might consider information about the physician's degree of skill with these treatments (particularly in the context of surgery), her success rates, and her motivations for recommending one treatment over another.

The number of prominent lawsuits filed by patients claiming to have suffered injury as a result of not having access to provider-specific information is proof that patients consider such information material to their health care decisions. But with few exceptions, American courts have not recognized provider-specific disclosures as integral to the common law of informed consent. While their justifications vary, most courts ground their decisions in the principle that because "material information" is limited to information about the risks of a particular medical procedure, information about a provider's personal characteristics does not fall within the scope of materiality.

### 1. Physician Experience and Qualifications

One of the few cases requiring disclosure of provider-specific risk information is Johnson v. Kokemoor, in which a patient who was rendered quadriplegic after surgery brought an informed consent claim on the grounds that her physician "failed ... to divulge the extent of his experience in performing this type of operation."<sup>66</sup> The jury found for the patient after the trial court admitted evidence that Dr. Kokemoor failed to accurately disclose how often he had performed basilar bifurcation aneurysm surgery, and that he did not discuss the comparative risks of having such a surgery performed by a relatively inexperienced surgeon.<sup>67</sup> The Wisconsin Supreme Court upheld the trial court's decision, holding that "a reasonable person in the plaintiff's position would have considered such information material in making an intelligent and informed decision about the surgery."<sup>68</sup> The court emphasized that Wisconsin's informed consent law requires disclosure of

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<sup>66</sup> Johnson v. Kokemoor, 545 N.W.2d 495, 497 (Wis. 1996). The plaintiff in Kokemoor testified that she asked Dr. Kokemoor a direct question about his experience, to which he gave an allegedly misleading response. However, because the plaintiff framed her claim as one grounded in failure of informed consent rather than negligent misrepresentation, the Wisconsin court analyzed it by reference to affirmative disclosure obligations under the law of informed consent. *Id.* at 504, n. 29.

<sup>67</sup> *Id.* at 497.

<sup>68</sup> *Id.* at 505.

“all of the viable [treatment] alternatives,” and framed the issue of physician experience as relevant to the patient’s evaluation of alternative treatments.<sup>69</sup>

A handful of courts in other states have also held that information about a provider’s credentials or experience with a given procedure may need to be disclosed where those facts suggest there might be an increased risk of injury.<sup>70</sup> While most courts are unwilling to impose an affirmative duty of disclosure of provider qualifications, some have held that providers who misrepresent their credentials in response to patient inquiries might nonetheless be liable under the doctrine of informed consent.<sup>71</sup> In Howard v. University of Medicine and Dentistry of New Jersey, for example, the New Jersey Supreme Court found that “personal credentials and experience may not be a required part of an informed consent disclosure under the current standard of care” because that information doesn’t directly relate to the procedure itself.<sup>72</sup> Nevertheless, it held that where a physician actively misrepresents his qualifications, and those qualifications in fact substantially increase the risk of the injury the patient suffered, the patient may have a claim based on informed consent.<sup>73</sup>

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<sup>69</sup> *Id.* at 498.

<sup>70</sup> DeGenarro v. Tandon, 873 A.2d 191, 197 (Conn. App. 2005) (holding that provider’s lack of experience with the dental equipment used on the patient must be disclosed if it adds to the risk of the patient’s procedure). *See also* Goldberg v. Boone, 912 A.2d 698, 717 (MD 2006) (holding that it was an issue for the jury to determine whether the availability of a more experienced surgeon was material for the purposes of informed consent); Barriocanal v. Gibbs, 697 A.2d 1169, 1172 (Del.1997) (holding that the trial court erred in excluding evidence the physician’s failure to inform his patient of his lack of recent aneurysm surgery, and of the option of having the surgery at a teaching hospital instead). *Cf.* Wlosinski v. Cohn, 713 N.W. 2d 16, 20, n. 1 (Ct. App. Mich. 2005) (rejecting an expanded disclosure duty in a case of prior transplant failures, but limiting its holding to “statistical data regarding past treatment and other background information that has no concrete bearing on the actual risks of a given procedure.”).

<sup>71</sup> Howard v. University of Medicine and Dentistry of New Jersey, 800 A.2d 73 (N.J. 2002) (discussed below); Willis v. Bender, 596 F.3d 1244, 1260 (10th Cir. 2010) (predicting that “the Wyoming Supreme Court would allow an informed consent claim where a physician lies to a patient as to physician-specific information in direct response to a patient’s questions concerning the same in the course of obtaining the patient’s consent and the questions seek concrete verifiable facts, not the doctor’s subjective opinion or judgment as to the quality of his performance or abilities.”). *See also* Paulos v. Johnson, 597 N.W.2d 316, 320 (Minn.Ct.App. 1999) (stating that the physician’s misrepresentation while obtaining patient’s consent to surgery that he was board-certified in response to patient’s question presents “a pure informed consent issue” subject to a two-year statute of limitations).

<sup>72</sup> Howard v. University of Medicine and Dentistry of New Jersey, 800 A.2d 73, 83-84 (N.J. 2002)

<sup>73</sup> *Id.* at 84 (“If defendant’s true level of experience had the capacity to enhance substantially the risk of paralysis from undergoing a corpectomy, a jury could find that a

The vast majority of courts, however, reject the notion that informed consent requires affirmative disclosure of physician experience or qualifications, on the grounds that only information about the proposed treatment itself qualifies as material.<sup>74</sup> In Whiteside v. Lukson, for example, a Washington appellate court held that the state's informed consent statute requires disclosure only of "treatment-related facts, expressly excluding the physician's qualifications."<sup>75</sup> The court justified its refusal to expand the doctrine by citing the potentially significant burdens of disclosure on physicians – imposing a broader duty, according to the court, might require disclosure of "the physician's own health, financial situation, even medical school grades[.]"<sup>76</sup>

Finally, some courts have gone even further in maintaining a narrow view of disclosure duties, holding that even in cases where physicians actively misrepresent their experience, no informed consent action will lie. For example, the Pennsylvania Supreme Court in Duttry v. Patterson held that information about a surgeon's personal qualifications and experience is not material for the purposes of informed consent, *even if* the patient specifically requested this information and was misled.<sup>77</sup> The court justified its holding on the grounds that the materiality of the information "does not shift depending on how inquisitive or passive the particular patient is."<sup>78</sup> Duttry also held that while physicians ought not misrepresent their credentials, this issue is best addressed through a cause of action for fraud or misrepresentation, not informed consent.<sup>79</sup>

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reasonably prudent patient would not have consented to that procedure had the misrepresentation been revealed.").

<sup>74</sup> See, e.g., Ditto v. McCurdy, 947 P.2d 952 (Hawaii 1997); Duttry v. Patterson, 771 A.2d 1255 (Pa. 2001); Wlosinski v. Cohn, 713 N.W. 2d 16 (Ct. App. Mich. 2005); Duffy v. Flagg, 905 A.2d 15 (Conn. 2006); Kaskie v. Wright, 589 A.2d 213 (Pa. 1991); Shock v. United States, 689 F. Supp. 1424 (D. Md. 1988); Zimmerman v. NYC Health and Hospital Corp., 458 NYS2d 552 (Ny. App. 1983); Johnson v. Jacobowitz (NY App. 2009); Thomas v. Wilcaf, 828 P.2d 597 (Wash. App. 1992); Foard v. Jarman, 326 N.C. 24 (1990); Avila v. Flangas, 1996 WL 63036 (Ct. App. Tx. 1996) (unpublished).

<sup>75</sup> Whiteside v. Lukson, 947 P.2d 1263, 1265 (Wash. App. Div. 3 1997).

<sup>76</sup> *Id.* at 1265. Accord Willis v. Bender, 596 F. Rep. 3d 1244, 1256 (2010). See also Kaskie v. Wright, 589 A.2d 213, 217 (Pa. 1991) ("Are patients to be informed of every fact which might conceivably affect performance in the surgical suite?"); Heinemann, *supra* note 8, at 1103 ("Such disclosure may be welcome to patient advocates, but Johnson provides little basis for drawing the line against disclosures that implicate important issues of physician privacy.").

<sup>77</sup> Duttry v. Patterson, 771 A.2d 1255 (Pa. 2001)

<sup>78</sup> *Id.* at 1259.

<sup>79</sup> *Id.* See also Duffy v. Flagg, 905 A.2d 15, 23 (Conn. 2006) ("Nothing in our ruling today suggests that a physician who misleads or misinforms his or her patient about the

Thus, at least as a matter of common law, the overarching sentiment seems to be that information about a provider's experience or credentials is not material information that needs to be disclosed as part of the informed consent process. The few courts that have imposed more stringent disclosure duties have limited them to a duty not to misrepresent credentials when asked by the patient, or a duty to disclose physician experience only if it is significantly likely to increase the risk associated with the procedure the patient is about to undergo.

Despite courts' reluctance to mandate disclosure of information relating to provider experience, some legal commentators have argued that there is no reason to exclude it from the doctrine of informed consent. Information about the risks of a procedure as performed by a particular provider, according to these authors, relates directly to the probability of a procedure's success as compared to its alternatives; and a procedure's probability of success is surely material, even under the most traditional understandings of informed consent.<sup>80</sup>

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physician's skills, qualifications, or experience may not be liable in damages for misrepresentation.”). *But see Willis v. Bender*, 596 F.3d 1244, 1258-59 (10th Cir. 2010) (“[W]hen the misrepresentation occurs ... in the course of a physician obtaining the patient's consent to a proposed treatment or procedure, we see no reason why Wyoming would limit the patient's claim to the more generic negligent misrepresentation tort[.]”); *Johnson v. Kokemoor*, 545 N.W.2d 495, 504 n. 29 (1996) (noting that an “overlap between negligent misrepresentation and informed consent ... does not preclude the plaintiff from making allegations and introducing evidence in an informed consent case which might also have been pled in a negligent misrepresentation case.”).

<sup>80</sup> See, e.g., Twerski and Cohen, *supra* note 8, at 6 (arguing that “‘comparative provider’ cases, although new and revolutionary, are in fact theoretically more sound and practically easier to resolve than traditional informed consent cases that focus on comparing the risks of alternative modes of treatment,” because they avoid the problems of decision causation inherent in traditional informed consent suits); Douglas Sharrott, *Provider-Specific Quality of Care Data: A Proposal for Limited Mandatory Disclosure*, 58 Brooklyn L. Rev. 85, 142 (1992) (arguing that traditional informed consent tests “can be extended to provider-specific risk information if one views the treatment as not just the procedure itself, but instead as the procedure *as performed by* a specific provider.”); Iheukwumere, *supra* note 8, at 413 (noting that “it defies logic to assert that the experience of a physician is immaterial to a patient's informed consent.”); Ashley H. Wiltbank, *Informed Consent and Physician Inexperience: A Prescription for Liability?* 42 WILLAMETTE L. REV. 563, 565 (2006) (citing empirical evidence that patients want to know if they are being treated by a medical student, and arguing “it would follow that most patient-driven informed consent jurisdictions would include physician's experience as a factor in informed consent.”). *But see* Heinemann, *supra* note 8 (arguing that “the doctrinal foundation of the [Kokemoor] decision is ambiguous,” and raising policy arguments against the expansion of informed consent to include information about physician experience).

## 2. Physicians' Financial Conflicts of Interest

The rise of managed care in the 1980's and 1990's brought increased public attention to the financial relationships between health care providers and payers. Under managed care, physicians are frequently offered financial incentives – like capitation, bonuses, and withholds – to provide cost effective care. Patients and policymakers expressed concern that these financial incentives might lead physicians to limit their use of diagnostic testing, specialists, and expensive procedures in an effort to boost their own earnings.<sup>81</sup>

Legal commentators throughout this era began to consider the idea that informed consent might be interpreted to encompass disclosures of physicians' financial incentives and conflicts of interest.<sup>82</sup> If informed consent law had not yet embraced economic disclosures, they argued, it was only because “until very recently, economics has not been a serious concern for most patients.”<sup>83</sup> Under the modern system of managed care, however, many argued that information about financial pressures to direct or limit care would surely be material to patient decisionmaking. “Although the concept of ‘materiality’ can be vague,” wrote one commentator, “an incentive system strong enough to prompt significant alterations in care can reasonably be considered material.”<sup>84</sup> The American Medical Association, similarly concerned, adopted an ethical opinion requiring physicians to disclose “any financial incentives that may limit appropriate diagnostic and therapeutic alternatives that are offered to patients or that may limit patients' overall access to care” (but noting that these obligations could be satisfied if the health plan itself made the disclosure).<sup>85</sup>

Some courts were amenable to these concerns. In a series of well-publicized lawsuits against HMOs and physicians, patients alleged that they were harmed by being denied or dissuaded from costly treatment. In a few cases, courts recognized the validity of claims that a physician's failure to

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<sup>81</sup> Legislators at the time also banned “gag clauses” in payer contracts that prohibited physicians from discussing managed care payment practices or treatments that would not be covered under the plan.

<sup>82</sup> See, e.g., Morreim, *Economic Disclosure and Economic Advocacy*, *supra* note 4; Haavi Morreim, *To Tell the Truth: Disclosing the Incentives and Limits of Managed Care*, 3(1) AM. J. MANAGED CARE 35 (1997); Wolf, *supra* note 4; Mark Hall, *Informed Consent to Rationing Decisions*, 71 MILBANK QUARTERLY 645 (1993)

<sup>83</sup> Morreim, *Economic Disclosure and Economic Advocacy*, *supra* note 4, at 291.

<sup>84</sup> Morreim, *To Tell the Truth*, *supra* note 82, at 36. See also BERG *et al*, *supra* note 17, at 212 (it would be “fundamentally unfair to deprive patients of information concerning the financial pressures that may influence their physicians' treatment decisions.”).

<sup>85</sup> AMA CEJA Opinion 8.132: Referral of Patients: Disclosure of Limitations



disclose financial incentives constituted a breach of duty, allowing them to proceed under theories of informed consent or malpractice.<sup>86</sup> A Minnesota appellate court in 1997, for example, stated that a physician's failure to disclose a kickback scheme "presents a classic informed consent issue."<sup>87</sup>

Finally, no discussion of physician conflict of interest would be complete without mentioning Moore v. Regents, University of California, in which the California Supreme Court held that "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."<sup>88</sup> While that case dealt with financial incentives to develop and sell a patient's cell line, rather than economic incentives associated with participation in managed care, the California court's recognition of the materiality of information about "interest[s] extraneous to the patient's health [that have] affected the physician's judgment" continues to be cited today.<sup>89</sup>

Information about physicians' financial conflicts of interest, while not medically material under the traditional model, has thus been recognized some courts and commentators as relevant to the informed consent process.<sup>90</sup> This is probably the clearest case of common law legal

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<sup>86</sup> In most of these cases, the legal issue for resolution was whether a fiduciary duty claim for non-disclosure would be duplicative of a malpractice/informed consent claim. *Explain Neade more carefully. See, e.g., DAB v. Brown*, 570 N.W.2d 168 (Minn. Ct App 1997) (holding that plaintiff's claim that MD failed to disclose kickbacks was a malpractice claim, not a fiduciary duty claim); *Neade v. Portes*, 739 N.E.2d. 496 (Ill. 2000) (rejecting a fiduciary duty claim for failure to disclose financial incentives on the grounds that it was duplicative of the medical malpractice claim); *Shea v. Esensten*, 208 F.3d 712 (8<sup>th</sup> Cir 2000) (holding that a jury could find MDs liable for negligent misrepresentation for failing to disclose a financial incentive to avoid referrals, where this failure to disclose prevented the plaintiff "from making an informed choice of whether to seek what might have been a life-saving referral at his own expense").

<sup>87</sup> *DAB v. Brown*, 570 N.W.2d 168, 171 (Minn. Ct App 1997)

<sup>88</sup> *Moore v. Regents of Univ. of California*, 793 P.2d 479, 485 (Cal. 1990)

<sup>89</sup> *Id.* at 484.

<sup>90</sup> It is worth noting that while the existence of a financial conflict of interest is not a medically material risk in itself, it arguably increases the likelihood of medical malpractice. That is, the reason a patient might want to know if her physician has a financial conflict is because she worries that this will lead the physician to recommend treatment that is not medically indicated (as in the case of a physician who receives money from a pharmaceutical company) or decline to recommend treatment that would be medically indicated (in the case of MCO incentives to limit costs of care). Were a physician to deviate from the standard of care, the patient would surely have a claim for medical malpractice; the existence of the financial motivation would be, in a sense, irrelevant. *See, e.g., Brannan v. Nw. Permanente, P.C.*, 2006 WL 2794881 (W.D. Wash. 2006) (in a

informed consent duties extending beyond the bounds of medical materiality.

### 3. Other Physician-Specific Characteristics

Beyond personal experience and financial conflicts of interest, there is a host of other information that patients might consider material to their treatment decisions – either in deciding between different treatment alternatives, or in deciding between different health care providers. This might include information about the physician’s medical history, sleep patterns, substance abuse, disciplinary history, malpractice liability, criminal history, and even religious or political beliefs. However, while factors such as these are arguably relevant to some patients, courts considering common law informed consent claims on these grounds have generally been unreceptive, except occasionally where there is concrete evidence of increased medical risk associated with the physician characteristic.

The reason that a physician’s personal characteristics might be relevant to a patient’s decision-making is because they may suggest a greater propensity for negligent or otherwise harmful treatment. For example, a surgeon who is sleep-deprived or suffers from carpal tunnel syndrome might be less precise in the operating room. The fact that a physician has been sued for malpractice or subject to professional discipline numerous times might suggest a propensity for negligent treatment. A patient operated on by a surgeon with a communicable disease may have a risk of contracting this disease during surgery. In that sense, these factors might reasonably be treated as medically material, because they might affect the physiological outcome of a given treatment by a particular physician.

Some courts addressing these types of claims have therefore concluded that a physician has a duty to disclose personal information only to the extent it currently affects the physician’s performance and actually increases a risk associated with treatment. Where, for example, a surgeon has a health condition that does not actually affect her performance in the operating room, that information would not qualify as material and subject to disclosure.<sup>91</sup> Likewise, numerous courts have held that a physician’s

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malpractice claim, denying plaintiff’s motion to compel production of physician’s employment contract; holding that motive is not an element of a malpractice claim and that evidence of financial incentives is irrelevant).

<sup>91</sup> See Slutzki v. Grabenstetter, 2002 WL 31114657 (Iowa Ct. App. 2002)

history of substance abuse does not need to be disclosed,<sup>92</sup> expect perhaps where the physician's treatment of the patient actually occurs under the influence of drugs or alcohol or translates into conduct falling below the standard of care.<sup>93</sup> Even the context of HIV disclosure, where early informed consent claims were sometimes successful, falls within this categorization of medical risk.<sup>94</sup> While early courts that acknowledged a

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(unpublished) (finding that surgeon has no duty to disclose that she suffered from a herniated disc where the condition only caused pain when the physician was using her arms above shoulder level, and during operations "the operating table was adjusted to the surgeon's level of comfort, and when in a position to operate her arms are always down"); May v. Cusick, 630 N.W.2d 277 (Wisc. App. 2001) (unpublished) (finding no duty to disclose history of two minor strokes where there was no evidence that physician suffered residual effects from the strokes that would constitute a material risk). Compare Hawk v. Chattanooga Orthopaedic Group, 45 S.W.3d 24 (Tenn. Ct. App. 2000) (allowing informed consent claim under Tennessee statute to proceed where surgeon failed to inform patient that he had a disabling hand condition that may have impaired his performance).

<sup>92</sup> See, e.g., Kaskie v. Wright, 589 A.2d 213 (Pa. 1991) (refusing to expand the doctrine of informed consent to cases where the plaintiffs were actually informed of the "particular procedures," but were not informed of "facts personal to the treating physician," like alcoholism); Williams v. Booker, 310 Ga. App. 209 (Ga. App. 2012) (holding that neither physician nor hospital had a duty to disclose physician's alcohol abuse); Mau v. Wisconsin Patients Compensation Fund, 668 N.W.2d 562 (Wisc. App. 2003) (unpublished) (denying an informed consent claim where a doctor with a history of substance abuse had not been using drugs in the months before treating the patient, and was not operating under the influence at the time of the operation); Albany Urology Clinic PC v. Cleveland, 528 S.E.2d. 777 (Ga. 2000) (denying informed consent, fraud, and battery claims grounded in a physician's failure to disclose "negative personal life factor [history of cocaine use] that, although not directly related to the professional relationship, may, depending upon a patient's subjectively held beliefs, impact upon the patient's consent" where there was no evidence that the physician was under the influence of cocaine at the time of treatment); Hidding v. Williams, 578 So.2d 1192 (La. App. 1991) (upholding trial court finding that failure to disclose chronic alcohol use was a breach of the duty to obtain informed consent, where the trial judge found as a matter of fact that the physician "abused alcohol at the time of [plaintiff's] surgery," and expert testified that performing surgery under the influence of alcohol would be a breach of the standard of care and that a physician suffering from alcohol dependence should inform his patient of this fact).

<sup>93</sup> Williams v. Booker, 310 Ga. App. 209, 211-212 (Ga. App. 2012) ("The mere fact of a physician's drug or alcohol addiction or use at the time of the alleged malpractice does not create, in and of itself, a separate issue or claim of medical malpractice. Rather, 'it is only when that alcoholism translates into conduct falling below the applicable standard of care that it has any relevance.'").

<sup>94</sup> During the development of the AIDS crisis in the late 1980's, many patients who learned that they were treated by HIV-positive physicians brought claims of negligent infliction of emotional distress. Health care institutions, in turn, struggled with the issue of whether to require that HIV-positive health care providers should be treating patients, and, if so, whether they should be required to disclose their health status. Some hospitals required their physicians to disclose their HIV status; and the physicians challenged these actions as discriminatory. See Estate of Behringer v. Medical Center at Princeton, 592

physician's duty to disclose her HIV status recognized that the probability of HIV transmission from doctor to patient is quite low, they grounded their findings of possible duty in the fact that the consequences of transmission effectively constitute a death sentence.<sup>95</sup> As noted by the Maryland Supreme Court in *Faya v. Almaraz*, the existence of a duty is based on both the probability and seriousness of harm, and "[w]hile it may be unlikely that an infected doctor will transmit the AIDS virus to a patient during surgery, the patient will almost surely die if the virus is transmitted."<sup>96</sup>

However, most courts hold that no disclosure of a physician's personal characteristics is required, *even where* those characteristics arguably increase the medical risk to the patient. Courts adopting this view base it on a narrow vision of medical materiality -- the idea that doctors only need to disclose risks "inherent in the treatment," and not risks that are dependent on who is performing the procedure.<sup>97</sup> As recognized by the Pennsylvania Superior Court in *Kaskie v. Wright*, expanding informed consent to include "facts personal to the treating physician ... extends the doctrine into realms well beyond its original boundaries."<sup>98</sup>

Some physician-specific characteristics, however, may be of interest to patients despite their having absolutely no connection with the medical

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A.2d. 1251 (N.J. Super. Ct. 1991); *Scoles v. Mercy Health Corp.*, 1994 WL 686623 (ED Pa 1994).

<sup>95</sup> *Estate of Behringer v. Medical Center at Princeton*, 592 A.2d. 1251 (N.J. Super. Ct. 1991) (in a discrimination claim by a physician against a hospital that required him to disclose his HIV status, holding that the risk of HIV transmission would be a legitimate concern to reasonable patients, warranting disclosure, because the risk, while low, is not negligible, and the potential harm is severe); *Faya v. Almaraz*, 620 A.2d 327 (MD 1993) (finding a viable informed consent claim by patients of an HIV-positive surgeon because the risk of transmission, while "extremely low," was foreseeable, and the consequences of transmission are dire). However, given the dramatic advances in medical care for HIV-positive patients in the past decades, and the fact that many HIV-positive patients go on to lead long and fulfilling lives, it is unclear whether these legal conclusions would still stand today.

<sup>96</sup> *Faya v. Almaraz*, 620 A.2d at 333.

<sup>97</sup> See discussion at *supra* notes 41-45. See, e.g., *Kaskie v. Wright*, 589 A.2d 213 (Pa. 1991) (refusing to expand informed consent to require disclosure of physician's alcoholism and lack of license to practice, noting that in this case the patient was indeed informed of the risks of the "particular procedures ... irrespective of the surgeon performing them."); *Curran v. Buser*, 711 N.W.2d 562 (Neb. 2006) (finding that the standard of care did not require disclosure of physician's disciplinary history); *Cipriano v. Ho*, 29 Misc. 3d 952 (N.Y. Sup. Ct. 2010) (noting lack of common law to support an informed consent claim based on failure to disclose prior restriction of physician's surgical privileges). These cases adopt similar reasoning to those cases rejecting disclosure of information about physician experience and qualifications. See *supra*, Part III-A-1.

<sup>98</sup> *Kaskie v. Wright*, 589 A.2d 213, 217 (Pa. Super. 1991).

risks of treatment. Some patients might prefer not to be treated by a physician who is a Democrat, a woman, or belongs to particular religion. Others might opt not to seek treatment from a physician with a criminal history unrelated to her medical practice. Under broad standards of materiality, a patient who could demonstrate that she would not have pursued treatment by that person (decision causation) might be able to recover – but only if she could also prove that the injury she suffered was caused by the undisclosed fact (injury causation). Injury causation, however, will be extraordinarily difficult to prove – a point discussed in greater detail in Part IV-D. In any event, no serious proposals have been made to expand informed consent to this arena. Moreover, while anecdotal evidence suggests that some patients care about these types of issues,<sup>99</sup> there is no evidence that any disgruntled patient has brought suit on this basis.

### *B. Patients' Non-Medical Interests*

A patient's decision about whether or not to proceed with a particular treatment may be driven by the treatment's impact on her non-medical interests. That is, the precise physiological consequences of a medical intervention may be less important to the patient than its satisfaction of her non-medical goals. These can include financial goals (avoiding medical bankruptcy), legal goals (obtaining favorable medical testimony in a civil or criminal trial), social goals (being able to meaningfully participate in a family member's wedding; maintaining privacy), and cosmetic goals (being able to wear high heels<sup>100</sup>). While courts have almost uniformly rejected the idea that medical providers might have a common law duty to disclose factors affecting non-medical interests, a number of legal and medical commentators have recently proposed expanding consent disclosures in this way. Moreover, legislatures, in the context of informed consent to abortion, have expanded physicians' disclosure duties to include information about the non-medical implications of the procedure.

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<sup>99</sup> See Benjy Sarlin, *Herman Cain: Thank God My Arab Doctor Wasn't Muslim!* (2011), available at

<http://talkingpointsmemo.com/election2012/herman-cain-thank-god-my-arab-doctor-wasn-t-muslim>.

<sup>100</sup> See *Hartman v. D'Ambrosia*, 665 So. 2d 1206 (La. App. 1995) (upholding a trial court's judgment for a patient whose goal in having bunion surgery was to have a "normal" foot and be able to wear high heels, where the physician failed to inform the patient that the surgery would not achieve this goal).

Generally, courts are in agreement that physicians have no common law duty to inform patients about the non-medical consequences of a procedure. In Arato v. Avedon, for example, a patient's family argued that his physician had breached his duty to obtain informed consent by failing to disclose "all material facts that might affect" the patient's "rights and interests," including his financial interests in estate planning.<sup>101</sup> The California Supreme Court firmly rejected this argument, citing its own admonition in Moore that a "physician is not the patient's financial advisor."<sup>102</sup> It held that California law does not impose on physicians an "undefined [duty] to disclose every contingency that might affect the patient's *nonmedical* 'rights and interests.'"<sup>103</sup>

Other courts have used similar reasoning to reject informed consent claims based on a physician's failure to inform a patient of facts affecting her non-medical interests. In State v. Presidential Woman's Center, the Florida Supreme Court rejected the plaintiff's claim that an abortion informed consent statute was unconstitutionally vague because it did not explicitly limit the scope of required disclosure to medical risks.<sup>104</sup> "Physicians are not sociologists, economists, theologians, or philosophers," the court noted, "and it is implausible to conclude that the Legislature intended that physicians be required to venture far beyond their professional specialty and expertise to advise patients of nonmedical matters" such as the social or economic risks of abortion.<sup>105</sup> Similarly, in a case where a psychiatric evaluation requested by a patient's attorney resulted in adverse testimony in a criminal trial, a Texas court rejected a claim grounded in non-disclosure of the legal risks associated with medical care.<sup>106</sup> The court held that the possibility of adverse testimony based on a psychiatric diagnosis was a "risk concern[ing] the legal, rather than the medical, consequences of the diagnosis," and that the patient's attorney (rather than his psychiatrist) was the person best suited to advise the patient of this legal risk.<sup>107</sup>

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<sup>101</sup> Arato v. Avedon, 858 P.2d 598, 608 (Cal. 1993)

<sup>102</sup> *Id.* (citing Moore v. Regents, University of California, 793 P.2d 479, 486, note 10 (Cal. 1990)). While Moore ultimately held that a physician's fiduciary duty to his patient includes a duty to disclose his own conflicts of interest, the court noted that the basis of this obligation is "not because he has a duty to protect his patient's financial interests, but because certain personal interests may affect professional judgment." Moore, 793 P.2d at 486, note 10.

<sup>103</sup> *Id.* at 609 (emphasis in original).

<sup>104</sup> State v. Presidential Woman's Center, 937 So.2d 114 (Fla. 2006).

<sup>105</sup> *Id.* at 119-120.

<sup>106</sup> Clark v. Grigson, 579 S.W.2d 263 (Tex. Civ. App. 1978)

<sup>107</sup> *Id.* at 265

Legal scholars refer to the principle established in these cases as reflecting a “therapeutic limitation” to informed consent disclosure.<sup>108</sup> According to Judith Daar, cases like *Arato* “tell[] physicians that they need not look beyond the medical needs of their patients in disclosing information about treatment. The physician need not be concerned with his patient as an investor, a business manager, a father, or a spouse.”<sup>109</sup> Robert Gatter, likewise, acknowledges that the common law of informed consent “generally permits physicians to remain ignorant of a patient’s non-medical characteristics” (like the desire to “participate in daughter’s wedding rather than maximize chances of cure”) despite the fact that these non-medical characteristics are extremely relevant to a patient’s treatment preferences.<sup>110</sup>

However, many commentators seem troubled by the common law limitation on the scope of disclosure to medical interests. Judith Daar notes that “the realities of human decision-making will inevitably blur [the] line [between medical and nonmedical interests],” and contends that a requirement that physicians only disclose information relevant to the patient’s medical interests “defies the nature of communication.”<sup>111</sup> Robert Gatter, while stopping short of advocating for affirmative disclosure duties, recommends a broader duty of physician inquiry as part of the informed consent process – physicians, he argues, ought to be obligated to inquire about the patient’s subjective and non-medical goals of treatment before providing treatment recommendations.<sup>112</sup>

This Part will provide an overview of a number of contexts in which legal and medical scholars, and sometimes even policymakers, have suggested broadening the scope of informed consent disclosure to reach patients’ personal interests.

## 1. Financial Interests: Cost of Treatment

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<sup>108</sup> The term “therapeutic limitation” was first used by the Supreme Court of California in *Arato v. Avedon*, 858 P.2d 598, at 609.

<sup>109</sup> Daar, *supra* note 15, at 195. See also Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOYOLA U. CHICAGO L. J. 557 (2000). (interpreting *Arato* as “indirectly” defining the scope of inquiry to patient’s medical characteristics only); Richard M. Alderman, *The Business of Medicine-Health Care Providers, Physicians, and the Deceptive Trade Practices Act*, 26 HOUS. L. REV. 109 (1989) (concluding that the doctrine of informed consent does not extend to “nonmedical information” like the business or financial aspects of medical care).

<sup>110</sup> Gatter, *supra* note 109, at 567-568.

<sup>111</sup> Daar, *supra* note 15, at 195.

<sup>112</sup> Gatter, *supra* note 109, at 579.

The concern that informed consent doctrine is insufficiently protective of patients' non-medical interests has drawn attention most recently in the context of the dramatic shift in the landscape of health care financing. Consumers have been shocked by recent empirical studies and news reports publicizing the dramatic variability among the costs of different treatments (or the cost of the same treatment in different institutions).<sup>113</sup> Consequently, in the past two years, three articles in major medical journals and journals of medical ethics have argued that physicians ought to have a legal or ethical duty to protect their patient's financial interests by informing them about the cost of treatment.<sup>114</sup>

Because of the catastrophic impact medical bills can have on a patient's financial situation, Kevin Riggs and Peter Ubel argue that physicians have an ethical duty to initiate conversations about the financial burdens of care on a patient "in the same way they would discuss the adverse effects of a treatment."<sup>115</sup> Ubel and others ground this claim, at least in part, in the link between financial well-being and medical well-being – arguing, for example, that financial insecurity can cause people to "cut corners in ways that may affect their health and well-being," like spending less on food, clothing, or prescriptions.<sup>116</sup> In a prescient article published almost twenty years ago, Michael Wilkes and David Schriger noted that "financial well-being is certainly within the boundaries of most peoples' concept of health."<sup>117</sup>

While it is certainly true that financial security implicates health outcomes, so do a host of other factors – including housing status, job stability, food insecurity, discrimination, and the availability of social support networks. And while progressive medical providers are learning about the importance of inquiring about these social determinants of health

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<sup>113</sup> See references at *supra* note 12.

<sup>114</sup> Hall, *Financial Side Effects*, *supra* note 13; Riggs and Ubel, *supra* note 13; Ubel, Abernethy, and Zafar, *supra* note 13.

<sup>115</sup> Riggs and Ubel, *supra* note 13, at 849. See also Ubel, Abernethy, and Zafar, *supra* note 13, at 1486 (noting that "given the distress created by out-of-pocket costs, it is well within physicians' traditional duties to discuss such matters with our patients.")

<sup>116</sup> Ubel, Abernethy, and Zafar, *supra* note 13, at 1485 (also referring to the discussion of costs tradeoffs as "mak[ing] clinical sense").

<sup>117</sup> Michael S. Wilkes and David L. Schriger, *Caution: The Meter is Running: Informing Patients About Health Care Costs*, 165 WESTERN J. MED. 74, 78 (1996) (noting that "discussions about the cost of care are an important part of the physician-patient relationship").



during routine medical visits,<sup>118</sup> they may be not be prepared to predict the impact of a given medical intervention on these social factors.

A more justifiable argument for including disclosure of costs as part of informed consent is made by Alicia Hall, who grounds her position in theories of patient autonomy. Since the purpose of informed consent is to facilitate autonomous decisionmaking about medical treatment, and since “what counts as a benefit for a patient cannot be determined by the physician from an objective medical standpoint,” information about financial risks is essential for patients to make appropriate trade-offs – particularly in an environment where “health care providers are also health care vendors, and patients are also consumers, medical providers take on the additional obligations associated with business owners and managers.”<sup>119</sup>

Critics of this argument worry that including a discussion of costs as part of informed consent will transform the doctor-patient relationship into a mercantile model driven by cost containment, where patients will no longer trust their physicians to provide the best clinical advice.<sup>120</sup> However, as Hall recognizes, not every medical option is available to patients even under our current system, and at least disclosure of cost information would make this more transparent.<sup>121</sup>

The most significant concern about proposals to incorporate costs discussions into informed consent is that physicians typically lack accurate information about the cost of treatment.<sup>122</sup> Proponents of cost disclosure recognize this fact, but argue that the ethical duty to disclose costs requires physicians to educate themselves about treatment costs under various insurance policies, and make inquiries about the patients’ financial

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<sup>118</sup> Medical-legal partnerships like Loyola University Chicago School of Law’s Health Justice Project (<http://luc.edu/law/centers/healthlaw/hjp/index.html>) aim to educate health care providers about these considerations.

<sup>119</sup> Hall, *Financial Side Effects*, *supra* note 13, at 42, 44.

<sup>120</sup> As noted by Joseph Fins, “If some treatment options are out of a patient’s ‘price range,’ ... [w]ould providers simply exclude the more expensive options from the alternatives available to other customers with coverage or better insurance? So much for the notion of informed consent as the conveyance of risk, benefits, and alternatives. Put an asterisk on that and revise the construct as ‘some’ alternatives.” Joseph J. Fins, *Fee Disclosure at a Cost*, 44(6) HASTINGS CTR. REP. 3 (Nov.-Dec. 2014) (commentary on Hall, *Financial Side Effects*, *supra* note 13).

<sup>121</sup> Alicia Hall, *The Author Replies*, 44(6) HASTINGS CTR. REP. 4 (Nov.-Dec. 2014) (commentary on Finn, *supra* note 120).

<sup>122</sup> See, e.g. Giridhar Mallya, Craig Evan Pollack, and Daniel Polsky, *Are Primary Care Physicians Ready to Practice in a Consumer-Driven Environment?* 14 AM. J. MANAG. CARE 661, 665 (2008) (noting that PCPs “may not have the requisite knowledge to help patients ... make such decisions.”).

circumstances in order to satisfy this duty.<sup>123</sup> It would be unjust, many argue, for vulnerable patients to bear the burden of discovery and inquiry when providers are likely have greater ease of access to this information.<sup>124</sup>

## 2. Social and Ethical Arguments

Not all factors that might impact a patient's choice of medical treatment are as concrete as its financial impact. Some controversial treatments may also have social and ethical implications that some have argued ought to be considered as part of the informed consent process. Notable examples include abortion, surrogacy, end-of-life care, and genetic testing – medical interventions that pro-life advocates, disability advocates, and others have challenged as potentially demeaning to human dignity. Accordingly, some commentators have suggested that physicians seeking informed consent to these types of medical care be required to first inform the patient of the ethical arguments and social implications surrounding their choice.

This concern is most prominent in the context of abortion. Some state legislatures have recently adopted laws requiring physicians to present women seeking abortions with information that critics say reflects ethical perspectives on abortion rather than its medical consequences. For example, a South Dakota law passed in 2005 requires physicians to disclose that abortion “will terminate the life of a whole, separate, unique, living human being” with whom a woman enjoys a constitutionally protected relationship.<sup>125</sup> The U.S. District Court for the District of South Dakota initially enjoined enforcement of this provision, holding that it “requires abortion doctors to enunciate the State's viewpoint on an unsettled medical, philosophical, theological, and scientific issue, that is, whether a fetus is a

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<sup>123</sup> Hall, *Financial Side Effects*, *supra* note 13, at 44-45; Riggs and Ubel, *supra* note 13, at 849; Ubel at al 1486; C. Alexander, M. A. Hall, and J. D. Lantos, *Rethinking Professional Ethics in the Cost-Sharing Era*, 6 AM. J. BIOETHICS W17, at W20-21 (2006).

<sup>124</sup> Hall, *Financial Side Effects*, *supra* note 13, at 45. Essentially, Hall's argument boils down to the idea that informed consent obligations should be based on physicians' special expertise, and that in the modern American health care system, physicians' expertise extends to the non-medical arena of cost. This is a hotly-debated empirical question.

<sup>125</sup> S.D.C.L. 34-23A-10.1 (upheld in Planned Parenthood Minn. v. Rounds, 653 F.3d 662 (8th Cir. 2011) opinion vacated in part on reh'g en banc sub nom. Planned Parenthood Minnesota, N. Dakota, S. Dakota v. Rounds, 662 F.3d 1072 (8th Cir. 2011) and on reh'g en banc in part sub nom. Planned Parenthood Minnesota, N. Dakota, S. Dakota v. Rounds, 686 F.3d 889 (8th Cir. 2012)). Identical language is included in the abortion informed consent laws of North Dakota, and Kansas. N.D. Cent. Code Ann. § 14-02.1-02 (West); Kan. Stat. Ann. § 65-6709(b)(5), 65-6710 (West).

human being.”<sup>126</sup> The statute was ultimately upheld on appeal by the Eighth Circuit sitting en banc – but even then, a strongly worded dissent by four judges argued that the statute was unconstitutional because it required physicians to “advise their patients on metaphysical matters about which there is no medical consensus” and which are “unrelated to the intended medical procedure.”<sup>127</sup>

As a matter of common law, however, the two states that have considered the issue both held that the law of informed consent does not require doctors to tell their pregnant patients that aborting a fetus constitutes the killing of a “human being.” In *Acuna v. Turkish*, the Supreme Court of New Jersey considered a malpractice action by a woman who claimed that her OB/GYN “breached a duty owed to her by failing to inform her of ‘the scientific and medical fact that [her six- to eight-week-old embryo] was a complete, separate, unique and irreplaceable human being’ and that an abortion would result in ‘killing an existing human being.’”<sup>128</sup> The court roundly rejected the plaintiff’s claim, noting that the common law duty of informed consent only requires disclosure of “material information concerning the medical risks of a procedure.”<sup>129</sup> The court contrasted the disclosures requested by the plaintiff, noting that there was no medical or social consensus that these statements were medical facts, “as opposed to firmly held moral, philosophical, and religious beliefs.”<sup>130</sup> In 2011, an Illinois appellate court reached the same conclusion, holding that health

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<sup>126</sup> *Planned Parenthood Minnesota v. Rounds*, 375 F. Supp. 2d 881, 887 (D.S.D. 2005) vacated and remanded sub nom. *Planned Parenthood Minnesota, N. Dakota, S. Dakota v. Rounds*, 530 F.3d 724 (8th Cir. 2008)

<sup>127</sup> *Planned Parenthood Minnesota, N. Dakota, S. Dakota v. Rounds*, 530 F.3d 724, 741 (8th Cir. 2008) (J. Murphy, Wollman, Bye, Melloy dissenting).

However, another South Dakota law aimed at ensuring that women seeking abortions are exposed to pro-life arguments prior to consenting to the procedure has recently failed. The 2011 law would have required every woman seeking an abortion, one day prior to the procedure, to obtain a consultation at a crisis pregnancy center whose “principal mission” is “to provide education, counseling, and other assistance to help a pregnant mother maintain her relationship with her unborn child and care for her unborn child.” The law was preliminarily enjoined on First and Fourteenth Amendment grounds. *Planned Parenthood Minnesota, N. Dakota, S. Dakota v. Daugaard*, 799 F. Supp. 2d 1048, 1053 (D.S.D. 2011).

<sup>128</sup> *Acuna v. Turkish*, 930 A.2d 416, 418 (2007). The plaintiff also argued that “every physician, before performing an abortion, must advise the patient in clear and understandable language that ‘the family member [the embryo] is already in existence and that the procedure—indeed the central purpose of the procedure—is intended to kill that family member.’” *Id.*

<sup>129</sup> *Id.* at 418.

<sup>130</sup> *Id.*

care providers at Planned Parenthood did not breach their common law duty of informed consent when they informed the pregnant plaintiff that the fetus she was carrying was not a “human being.”<sup>131</sup> According to the court, nothing in Illinois common law requires providers to disclose “something other than [their own] scientific, moral, or philosophical viewpoint [on the issue of when life begins].”<sup>132</sup>

Prenatal genetic testing is another context where critics have challenged the standard informed consent regime. Typically used to screen for disabilities like Down syndrome, prenatal genetic testing offers prospective parents the opportunity to make informed decisions about whether to procreate naturally, whether to procreate at all, or whether to terminate a pregnancy. However, as recognized by Elizabeth Emens and other scholars, “at some level, the message from the doctors urging amniocentesis ... is that having a disabled child is worse than not having a child.”<sup>133</sup> This message, according to many disability advocates, reflects a one-sided and inaccurate perspective on disability.<sup>134</sup> Instead, Emens suggests, parents undergoing prenatal genetic testing should be presented with accurate information about life opportunities for children with disabilities, as well as other resources that might help correct for internal biases and misconceptions about disability.<sup>135</sup> The hope is that providing appropriate framing for information about disability would help remove social stigma about disability and improve societal attitudes towards those living with disabilities.

Similarly, in an article about growth attenuation for minors with profound disabilities, a group of physicians, philosophers, and attorneys (the Seattle Growth Attenuation and Ethics Working Group) recognized the profound social implications of this controversial treatment.<sup>136</sup> The Working Group ultimately recommended that parents considering growth attenuation “be made aware of the objections to growth attenuation expressed by organizations and individual members of disability communities”<sup>137</sup> by being provided with “information summarizing arguments for and against

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<sup>131</sup> *Doe v. Planned Parenthood/Chicago Area*, 956 N.E.2d 564 (Ill. App. Ct. 1st Dist. 2011).

<sup>132</sup> *Id.* at 573 (referring to this as “a contention that we find borders on contrivance”).

<sup>133</sup> Elizabeth F. Emens, *Framing Disability*, 2012 U. ILL. L. REV. 1383, 1412-1413 (2012).

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at 1417.

<sup>136</sup> Benjamin S. Wilfond *et al*, *Navigating Growth Attenuation in Children With Profound Disabilities*, 40(6) HASTINGS CTR. REP. 27 (2010).

<sup>137</sup> *Id.* at 37.

this controversial intervention.”<sup>138</sup> However, one member of the Working Group criticized this recommendation as a “remarkable intrusion into private medical decisions,” noting that it would similarly require that “parents seeking cochlear implants for a deaf child, surgical correction for club feet or scoliosis, or a do-not-resuscitate order for a terminally ill child ... be reminded that their decisions may be offensive to others and should be given literature on the reasons for those disagreements.”<sup>139</sup>

As a legal matter, however, no court or legislature has even approached the issue of including information recommended by disability advocates as part of the informed consent process for genetic testing or growth attenuation.

### 3. Impact on Third Parties

Closely related to the suggestion that patients be informed of the ethical implications of their treatment choices is the argument that, when third parties are affected by a patient’s treatment decision, the patient ought to be told about those effects.

Again, this argument arises most commonly in the abortion context, where some state informed consent laws require that physicians perform an ultrasound, display the image to the patient, and inform her of the age and size of the fetus, which could arguably be considered a third party for the purposes of this discussion.<sup>140</sup> Even in states without ultrasound laws, state informed consent brochures frequently include images and descriptions of fetuses at various stage of development so that a woman considering abortion understands the consequences of the procedure on the fetus.<sup>141</sup> The Supreme Court in Planned Parenthood v. Casey expressly permitted such disclosures during the informed consent process, noting that “most women considering an abortion would deem the impact on the fetus relevant, if not dispositive, to the decision.”<sup>142</sup> While recognizing that

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<sup>138</sup> *Id.* at 30.

<sup>139</sup> *Id.*

<sup>140</sup> This author takes no position on the issue of fetal status. It is worth noting, however, that in the context of diagnostic and therapeutic prenatal interventions, women are routinely told about the risks to the fetus of such interventions (such as amniocentesis, for example).

<sup>141</sup> Nadia N. Sawicki, *The Abortion Informed Consent Debate: More Light, Less Heat*, 21 CORNELL J. L. & PUB. POL’Y, 7 (2011).

<sup>142</sup> Planned Parenthood of Se. Pennsylvania v. Casey, 505 U.S. 833, 882 (1992)

information about the consequences to the fetus “have no direct relation to [the woman’s] health,” the Court found no constitutional barrier to state laws requiring disclosure of such information.<sup>143</sup>

In *Casey*, the Court analogized to the context of organ donation, writing, “We would think it constitutional for the State to require that in order for there to be informed consent to a kidney transplant operation the recipient must be supplied with information about risks to the donor as well as risks to himself or herself.”<sup>144</sup> Indeed, it seems clear that a live kidney donor would want to know about the impact his donation will have on the recipient. For example, he might not go through the procedure if he were informed that the chances of rejection were very high, or if the recipient were likely to die from other causes post-transplant. Likewise, the prospective recipient of a live kidney donation (particularly by a close friend or family member) might not consent to the procedure if he had concerns about the health implications of kidney removal on the donor.

Surrogate pregnancy is another situation where a treatment’s physiological impact on third parties might be relevant to patient’s decision. Part of the reason many people feel uncomfortable with surrogates bearing intentional parents’ children is because surrogate pregnancy imposes significant physical and emotional risks on the surrogate. It seems reasonable to conclude that some people who are unable to bear children on their own reject surrogacy in favor of other options (like adoption) in part due to concerns about the impact on the surrogate.

While some medical procedures (like abortion, organ donation, and surrogacy) have a clear physiological impact on third parties, others may have third-party consequences that are less tangible. The context of genetic testing provides one such example. Empirical research demonstrates that many patients who choose to undergo diagnostic genetic testing do so in large part “to generate information about other family members’ risks, most frequently their offspring.”<sup>145</sup> Based on this evidence, Nina Hallowell has argued that health care providers obtaining informed consent to genetic testing “need to give [patients] the opportunity to reflect upon the impact

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<sup>143</sup> *Id.* While the *Casey* decision was one about the constitutional validity of state abortion restrictions, and not about the common law standard for informed consent, the language used by the court is instructive.

<sup>144</sup> *Id.* at 882-883.

<sup>145</sup> Nina Hallowell, *Consent to Genetic Testing: A Family Affair*, in OONAGH CORRIGAN *ET AL*, *THE LIMITS OF CONSENT: A SOCIO-ETHICAL APPROACH TO HUMAN SUBJECT RESEARCH IN MEDICINE* (Oxford, 2009), at 189.

that any decision may have upon their relationships with particular others.”<sup>146</sup>

Incorporating facts about a treatment’s non-physiological effects on third parties has also been suggested in the context of limiting healthcare costs. In an article about the financial impact of medical choices on the healthcare system as a whole, M. A. Graber and J. F. Tansey note that many patients are “unaware of the social impact of their medical options,” like the economic impact of choosing a brand name medication over a generic.<sup>147</sup> Thus, they suggest that doctors should initiate “dialogue about social justice as part of ... the informed consent process.”<sup>148</sup> For example, they offer the following proposed consent form for patients requesting high-cost prescriptions:

I, as the patient, am requesting that my provider prescribe drug \_\_\_\_\_ for me. I understand there are less expensive medications that are also effective. I understand that by requesting this more expensive medication I am increasing healthcare costs to others, increasing the cost of insurance, using resources that could be used elsewhere in the healthcare system and may be taking an additional risk to my health as all of the side effects of new drugs may be not known. The reason that I am asking for this medication is \_\_\_\_\_. I believe that the benefit to me outweighs the potential risks and resultant harms to others.<sup>149</sup>

Perhaps unsurprisingly, no court or legislature has followed these suggestions to incorporate social justice discussions into the legal obligation of informed consent.

#### 4. Privacy Implications

Some commentators have suggested that where medical diagnosis or treatment poses a risk of violating a patients’ privacy, physicians affirmatively disclose this fact. While federal laws like HIPAA and HITECH as well as state privacy laws provide a great deal of protection for

<sup>146</sup> *Id.* at 195 (“Consent procedures need to emphasize these things, not sweep them under a carpet of information about abstract risks and benefits.”).

<sup>147</sup> M. A. Graber and J. F. Tansey, *Autonomy, Consent, and Limiting Healthcare Costs*, 31 J. MED. ETHICS 424, 425 (2005).

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

patients' medical information, there are some contexts that these laws do not cover and that patients might not recognize as potentially risky from a privacy perspective. Genetic testing and storage of blood and tissue samples are two such contexts.<sup>150</sup>

Sheldon Kurtz has argued that in the context of genetic testing, patient's privacy interests are so important that the law should require physicians to disclose of "the consequences of having information about the person stored in data banks" as part of the informed consent process.<sup>151</sup> These include the risk that stored genetic information might be shared with insurers, employers, or others in ways that might disadvantage patients.<sup>152</sup>

Likewise, many patients do not recognize that blood and tissue samples extracted for diagnostic purposes may be stored by health care facilities for extended periods of time and may even be used for other purposes to which the patients did not initially consent. Examples of cases where patients have subsequently learned about and objected to the storage and/or use of their bodily materials abound – from John Moore's suit against the University of California for the commercialization of a cell line based on his leukemia cells;<sup>153</sup> to the development of the extremely lucrative HeLa cell line without the knowledge or consent of Henrietta Lacks or her family;<sup>154</sup> to the more recent controversy surrounding Minnesota's storage of newborn blood spots.<sup>155</sup> One could therefore argue

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<sup>150</sup> Another example can be found in the context of unusual procedures that likely to be reported in the media. In an article about facial transplants, one author mentions a consent form for facial transplants includes disclosure of the potential for media intrusions in their personal lives. AP, *Facing Up to Ultimate Transplant*, WIRED (2005), available at <http://archive.wired.com/medtech/health/news/2005/09/68907?currentPage=all>

<sup>151</sup> Sheldon F. Kurtz, *The Law of Informed Consent: From 'Doctor is Right' to 'Patient Has Rights'*, 50 SYRACUSE L. REV. 1243, at 1258 (2000).

<sup>152</sup> *Id.* While the 2008 Genetic Information Nondiscrimination Act protects against genetic discrimination in employment and health insurance, it offers no such protection for discrimination in other spheres, such as life, disability, and long-term care insurance. 42 U.S.C.A. § 2000ff *et seq.*

<sup>153</sup> *Moore v. Regents, University of California*, 793 P.2d 479 (Cal. 1990).

<sup>154</sup> REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* (Crown, 2010).

<sup>155</sup> Challengers to Minnesota's blood spot law obtained a victory in 2011, when the Minnesota Supreme Court held that the state's storage and dissemination of blood samples violated the state's genetic privacy law. *Bearden v. State*, 806 N.W.2d 766 (Minn. 2011). Over 1 million blood spots were destroyed pursuant to a subsequent settlement. Lorna Benson, *After Settlement, Minn. To Destroy 1.1M Newborn Blood Samples* (Jan. 13, 2014), available at <http://www.mprnews.org/story/2014/01/13/health/newborn-genetic-material-storage-settlement>. A 2014 law later authorized the state department of health to store new blood spots indefinitely starting in August 2014 with parental consent. 2014 Minn. Sess. Law Serv. Ch. 203 (S.F. 2047) (WEST).



that if the privacy risks associated with the extraction of bodily material are substantial enough that they would cause patients to decline a diagnostic or therapeutic procedure, those risks ought to be disclosed.<sup>156</sup>

## 5. Availability of Support and Resources

A final category of information that might be material to a patients' medical decisions (but would not fall within the category of medical materiality) is information about financial and social support resources available to the patient depending on her health care decision.

In the abortion context, legislatures have taken the lead on incorporating such information into the informed consent process. Many states require that patients seeking abortions be provided with information about adoption agencies, crisis pregnancy centers, state financial assistance, medical assistance, and social support services available to mothers and children.<sup>157</sup> In 1986, the Supreme Court in Thornburgh v. Am. Coll. of Obstetricians & Gynecologists rejected as unconstitutional a requirement that women seeking abortions be advised of the availability of medical assistance benefits and paternal financial support, noting that the required information was "nonmedical information beyond the physician's area of expertise," "irrelevant and inappropriate" for many patients, and ultimately "not relevant to [informed] consent."<sup>158</sup> In 1992, however, the Supreme Court's decision in Casey rendered such arguments invalid. In Casey, Court

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<sup>156</sup> But this result can be avoided, because there is often a second opportunity for conversation and consent after the procedure is complete. That is, it is possible to disentangle a patient's consent to diagnostic testing from her subsequent consent to storage or research use of the samples. Indeed, it may be better to split the consent process in this way. Disclosing a risk of privacy breach when asking for consent to diagnostic testing may cause patients to decline testing if they believe the privacy risk is unavoidable. However, splitting the consent process into two consent conversations – one for the procedure and one for subsequent use of blood or tissue – makes it clear that the patient can reap the benefits of diagnostic testing without suffering its attendant privacy risks.

<sup>157</sup> Rachel Benson Gold and Elizabeth Nash, *State Abortion Counseling Policies and the Fundamental Principles of Informed Consent*, 10(4) GUTTMACHER POL'Y REV. (Fall 2007).

<sup>158</sup> Thornburgh v. Am. Coll. of Obstetricians & Gynecologists, 476 U.S. 747, 763-64, 106 S. Ct. 2169, 2180, 90 L. Ed. 2d 779 (1986) overruled by Planned Parenthood of Se. Pennsylvania v. Casey, 505 U.S. 833, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992). *See also* Planned Parenthood League of Massachusetts v. Bellotti, 641 F.2d 1006 (1st Cir. 1981) (noting that while information about the availability of adoption and public benefits does not "bear[] directly on any medically relevant factor" and so does not "fit[] easily within the traditional ambit of informed consent," it may be material to a woman's decision and therefore bears a reasonable relation to the state's interest).

found that “information relating to fetal development and the assistance available” to women who choose to carry their pregnancies to term is relevant to a woman’s abortion decision, and therefore that a statutory requirement requiring disclosure of opportunities to review such information is a “reasonable measure to ensure an informed choice.”<sup>159</sup>

Another context in which information about social support resources might reasonably be offered is in the context of prenatal genetic testing for disability. As noted in Part III-B-2 above, some commentators have suggested that patients be offered information about disability-related support resources even before they are tested for genetic anomalies.<sup>160</sup> However, such proposals have not been implemented.

#### IV. ADDRESSING CONCERNS AND PROPOSING LIMITATIONS

From the perspective of medical ethics, the informed consent process ought to be designed in a way that furthers patients’ autonomy in the sphere of medical decision-making. Furthering autonomy requires recognizing the patient’s goals and values, and providing the patient with the information needed to make a coherent decision in accordance with these goals and values. And because patients’ treatment preferences are influenced not only by medical factors, but also by social, financial, and other factors, an ethically-sound doctrine of informed consent ought, in theory, to incorporate these types of disclosures as well.

Achieving this ethical ideal is challenging, however. It is for this reason that neither legal standards nor standards of medical practice typically require physicians to satisfy this ambitious goal. Even the staunchest supporters of patient autonomy recognize that pragmatic and policy considerations may necessitate a narrowing of informed consent from its broadest possible scope<sup>161</sup> – particularly given that expanding the

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<sup>159</sup> *Casey*, 505 U.S. at 883. See also Thomas L. Jipping, *Informed Consent to Abortion: A Refinement*, 38 CASE W. RES. L. REV. 329, at 384-85 (1987) (noting that the heart of the informed consent requirement is materiality to a woman’s decision, and arguing that states should have the freedom to require disclosure of “[n]on-medical information, or medical information relating to non-medical factors” because such information may “be highly relevant, even vitally important” to a woman’s decision). Again, while the *Casey* decision was decided on constitutional grounds, it effectively set broader boundaries on what is permissible as part of the informed consent process.

<sup>160</sup> Emens, *supra* note 133, at 1416-17.

<sup>161</sup> Jay Katz notes that there are “sharp distinctions between the *legal* doctrine, as promulgated by judges, and the *idea* of informed consent, based on a commitment to individual self-determination.” KATZ, *supra* note 1, at xliii. In discussing the court’s

scope of informed consent would in turn expose physicians to broader tort liability risk. It is, however, possible to construct a disclosure obligation that strikes a fair balance between recognizing patients' needs and ensuring that health care providers are not unduly burdened. This section seeks to achieve that goal.

*A. Identifying Material Information for the Individual Patient*

One challenge of the idealized informed consent process is that, if its goal is to further individual patients' autonomy, a physician must know what would be material to each individual patient. Legal requirements, however, dispense with this consideration, turning instead to the standard of what a "reasonable patient" would find material, rather than any individual patient's subjective perspective. Many commentators have criticized the law's approach here, arguing that it effectively negates the right of individual self-determination.<sup>162</sup> As noted by Evelyn Tenenbaum in an article about the objective causation element of informed consent, requiring patients to prove that the undisclosed information would have caused a reasonable patient to pursue a different course of treatment is "unfaithful" to the underlying autonomy-based ideals of informed consent.<sup>163</sup>

While this criticism may be correct from an ethical perspective, legal and practical principles (out of necessity) require something more easily applicable. One concern with allowing breach (and, per Tenenbaum, causation) to be defined by reference to the needs and expectations of each individual patient is that patients' subsequent legal claims would be subject

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opinion in *Canterbury*, for example, he comments that "[t]he strong commitment to self-determination at the beginning of the opinion gets weaker as the opinion moves from jurisprudential theory to the realities of hospital and courtroom life." *Id.* at 71-72. *See also* Schuck, *supra* note 28 (revisiting the "informed consent gap" between informed consent idealists and realists).

<sup>162</sup> *See, e.g.,* KATZ, *supra* note 1, at 76-77 (noting that *Canterbury*'s adoption of a reasonable patient standard set aside issues of subjective self-determination); FADEN AND BEAUCHAMP, *supra* note 1, at 305-306 (noting that standards that may be appropriate for legal and institutional policies will omit some information relevant to patients; suggesting that a subjective standard is more in line with the principles underlying informed consent).

<sup>163</sup> Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, at 717-19 (2011). *See also* *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979) ("To the extent the plaintiff, given an adequate disclosure, would have declined the proposed treatment, and a reasonable person in similar circumstances would have consented, a patient's right of self-determination is irrevocably lost. This basic right to know and decide is the reason for the full-disclosure rule.").

to self-serving hindsight bias. A second concern is one of judicial economy, which looks with skepticism on evaluating each informed consent case on the basis of each individual patient's needs. Finally, from a practical perspective, modern medical care today does not allow physicians the years needed to form extensive relationships with patients that allow them to tailor disclosure to the patient's particular needs. It seems reasonable that, if some narrowing of the doctrine of disclosure is necessary, the objective patient standard may be a good place to start. And indeed, because most of tort law is based on the expectations and obligations of the "reasonable person," narrowing disclosures to information that is material to the reasonable patient would be entirely consistent with existing tort law principles.<sup>164</sup>

### *B. Limitations of Physicians' Knowledge and Expertise*

A second potential limitation on a broadened understanding of informed consent is that some of the information that patients might consider material may be beyond the scope of the physician's expertise or knowledge. For example, physicians often do not know how much a procedure will cost – either as a general matter, or how much it will cost out-of-pocket to a particular patient after taking into account insurance coverage. Likewise, discussing the legal or social implications of a treatment, as discussed in Part III-B-2, is likely outside the average physician's scope of expertise, and certainly far beyond what most physicians learn in medical school.

One of the primary goals of the informed consent obligation is to correct an information asymmetry between physician and patient, an asymmetry that is made even starker by the physician's position of power.<sup>165</sup> It is precisely because physicians are uniquely qualified to

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<sup>164</sup> Limiting disclosures to those considered material by the reasonable patient, however, still leaves open the question of whether the "reasonable patient" should be narrowed to "reasonable female patient," the "reasonable Jehovah's Witness patient," the "reasonable Hispanic patient." See generally, Dayna Bowen Matthew, *Race, Religion, and Informed Consent – Lessons from Social Science*, 36 J. L. MED. & ETHICS 150, 161-162 (2008) (noting that minority patients may want different types of information disclosed than white patients).

<sup>165</sup> FADEN AND BEAUCHAMP, *supra* note 1, at 305 ("[T]he reality of informed consent in clinical medicine and research is that a patient or subject cannot usually achieve substantial understanding without the aid of the professional(s) seeking consent. [It is the] 'most efficient – and, often, the only – way for the person to achieve an adequate understanding.'"); Franklin G. Miller and Alan Wertheimer, *Preface to a Theory of Consent Transactions: Beyond Valid Consent*, in MILLER AND WERTHEIMER, EDS., *supra* note 20, at

provide some types of information relevant to a patient's decision that we impose upon them a legal and ethical duty to provide it.<sup>166</sup> As noted in Canterbury, "The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible."<sup>167</sup> If the doctrine of informed consent is premised on physician knowledge and expertise, then it seems difficult to justify the expansion of this doctrine to require a physician to disclose information she does not have and cannot easily obtain.

Limiting legally required informed consent disclosures to information that is both material to patients and within the physician's unique expertise might result in a set of disclosure requirements quite different from the ones set by modern common law and legislation. In many ways, the range of required disclosures may become *broad*er.

Most notably, many of the physician-specific disclosures highlighted in Part III-A would be captured by a rule requiring disclosure of matters within the physician's unique qualifications and knowledge. Only the physician knows about her financial conflicts of interest, her level of experience with a procedure, her substance abuse problems, and her religious affiliation. If a reasonable patient considers this information material to a medical decision, she simply has no other choice but to rely on the physician's voluntary disclosure.<sup>168</sup> However, with the exception of

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95 (noting that the asymmetry of information exists in medical contexts is such that patients have no fair opportunity to self-inform at a reasonable cost). *But see* Schuck, *supra* note 28, at 928-931 (comparing patients and consumers; noting that while sometimes there are greater inequalities between physicians and patients than between sellers and consumers, the argument from information and power disparity is not as strong as many believe).

<sup>166</sup> This is especially so given that the informed consent obligation is one that is imposed on the medical provider himself, not the health care institution that employs or contracts with the provider.

<sup>167</sup> Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972). *See also* Cobbs v. Grant, 502 P.2d 1, 9 (Cal. 1972) (offering as a rationale for informed consent doctrine the fact that "patients are generally persons unlearned in the medical sciences and therefore, except in rare cases, courts may safely assume the knowledge of patient and physician are not in parity").

<sup>168</sup> Of course, a well-informed patient could affirmatively ask for the information she deems material. However, putting the burden of request on patients runs the risk of strating disclosures among patient populations based on their prior experience with the health care system and their understanding of what kind of question should be asked. *See* Duttry v. Patterson, 771 A.2d 1255, 1259 (PA 2001) (noting that materiality of the information

some information about physicians' financial conflicts of interests,<sup>169</sup> American law does not require disclosure of physician-specific characteristics as part of the informed consent process.

Another category of disclosures that might be captured by this view of informed consent might be information about the (non-physiological) social implications of a procedure.

For example, a patient with kidney failure who is learning about long-term dialysis would certainly want to know that it requires a commitment to be treated in a dialysis center three times a week for three to four hours per treatment. This information is material, in part, because the patient needs to understand that her work schedule will likely need to be adjusted if she chooses to pursue long-term dialysis. That said, this information might not be required under an interpretation of medical materiality that is limited to physiological risks and benefits. Rather, it tells her about the likely implications of the treatment on her lifestyle – essential information, to be sure, but unrelated to the treatment's physiological consequences.

For another example, consider patients whose prognosis or treatment is likely to result in a physical disability – i.e., amputation, blindness, living with a colostomy bag. A host of empirical research demonstrates that people are notoriously bad at predicting what life with a disability would be like; most people overestimate the amount of discomfort, anxiety, and lifestyle changes that come with a disability.<sup>170</sup> Physicians who treat such patients, however, often have a better understanding of how people with disabilities live their lives, and may be uniquely situated to share this kind of information with patients with inaccurate perspectives on disability. In an article arguing for “framing changes” in the context of disability, law professor Elizabeth Emens suggests that parents undergoing prenatal genetic testing also be presented with accurate information about how a child's disability might affect their lives.<sup>171</sup> Providing “up-to-date information on the life opportunities and life expectancy for various disabilities,”<sup>172</sup> for example, “could help dispel misconceptions about living with these disabilities and help prospective parents contextualize medical

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disclosed “does not shift depending on how inquisitive or passive the particular patient is.”).

<sup>169</sup> *Moore v. Regents, University of California*, 793 P.2d 479 (Cal. 1990).

<sup>170</sup> See, e.g., Jodi Halpern and Robert M. Arnold, *Affective Forecasting: An Unrecognized Challenge in Making Serious Health Decisions*, 23(10) J. GEN. INT. MED. 1708 (2008).

<sup>171</sup> Emens, *supra* note 133.

<sup>172</sup> *Id.* at 1417.

information, which tends to focus exclusively on the particular problems associated with a disability.”<sup>173</sup>

That said, some disclosures that have been advocated by commentators or have been imposed legislatively would *fall outside* the scope of informed consent under this interpretation. Most notably, information about the cost of medical treatment would be excluded, except in those exceptional circumstances where physicians do have access to cost information.<sup>174</sup> Likewise, while some commentators have suggested that physicians disclose information about the social, ethical, legal, and privacy implications of medical treatment, these too would not be required (perhaps with the exception of information about the consequences of living with a disability or the impact of a treatment on third parties, when offered by physicians with experience in these matters). Finally, physicians would not be obligated to disclose information about social support resources (like information about the availability of adoption resources, crisis pregnancy centers, and financial assistance) that some legislatures have adopted in the abortion context. Essentially, any information beyond what the physician learned in medical school, in practice, or concerns her personal characteristics would be excluded under a physician-knowledge-based standard of informed consent.

### C. Policy Limitations

If we accept the physician-expertise based disclosure model, critics are likely to argue that the expansive nature of this principle, particularly with respect to physicians’ personal characteristics, renders it too broad. For example, the average patient might wish to know how much sleep a surgeon has had before consenting to an operation – but few commentators have argued that these kinds of facts ought to be required as part of informed consent. Indeed, while an idealized version of patient autonomy would

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<sup>173</sup> *Id.* 1415. As an example of this, Emens cites the 2008 Prenatally and Postnatally Diagnosed Conditions Awareness Act, which “aims to help provide prospective parents who receive a positive prenatal (or postnatal) diagnosis of Down syndrome or other conditions with “up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes.” However, as Emens notes, the Act would require disclosure after the point of diagnosis, not before testing. *Id.* at 1415 (citing Prenatally and Postnatally Diagnosed Conditions Awareness Act, Pub. L. No. 110-374, 122 Stat. 4051 (2008)).

<sup>174</sup> Practice areas where physicians are more likely to know the cost of treatment include psychiatry and cosmetic surgery.

require such disclosures, there are legitimate policy reasons why we might not want to extend the legal requirement of informed consent that far.<sup>175</sup>

### 1. Physician Privacy

Some facts that are uniquely known to the physician may be deemed to be too personal, or too private, for disclosure.<sup>176</sup> These may include the physician's disability status, her personal habits, her religious beliefs, and recent personal trauma. Such information, it could be argued, falls within the private sphere of a physician's life, and even patients ought not have access to it without the physician's consent. In contrast, information about experience levels or success rates with a particular procedure may be understood as more directly related to the physician's medical practice; likewise, information about financial conflicts of interest might be deemed publicly-accessible enough that it ought to be disclosed. Many would argue that physicians entering medical practice should be entitled to a reasonable expectation of privacy with respect to their personal affairs – or at the very least, should not be required to disclose their private information as a matter of law. Even politicians and other public figures, whose personal lives often end up in the news, are not required by law to share deeply personal information, despite its potential relevance to voters.<sup>177</sup>

That said, the boundaries of what physician-specific information should be deemed too private for mandatory disclosure are unclear; a more careful and nuanced analysis of this issue is surely necessary.<sup>178</sup> However,

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<sup>175</sup> In limited cases, there might also be constitutional limitations on extending the doctrine too broadly. *See* Bobinski, *supra* note 11, at 333-337 (discussing First Amendment limitations); Albany Urology Clinic, P.C. v. Cleveland, 528 S.E.2d 777, 782, FN 19 (Ga. 2000) (discussing vagueness concerns).

<sup>176</sup> *See* Heinemann, *supra* note 8, at 1003-06 (discussing privacy concerns); Whiteside v. Lukson, 947 P.2d 1263, 1265 (Wash. App. Div. 3 1997) (expressing concern that broadening the informed consent duty would require disclosure of “the physician's own health, financial situation, even medical school grades[.]”)

<sup>177</sup> One exception to this relates to disclosures of financial conflicts of interest by political figures and elected officials.

<sup>178</sup> Some might argue that it is not necessary to include information about physician characteristics within the informed consent disclosure duty. Much physician-specific information (about their habits, their disability, their financial conflicts) is material to patients only because of the concern that these physician-specific characteristics will lead to poor medical outcomes – for example, a physician who is paid as a consultant to a pharmaceutical company might prescribe that drug rather than a more appropriate one. If this is the case, critics argue, then it's not clear why the informed consent cause of action is even necessary. Patients who are injured by physician error will be able to sue for malpractice regardless of the reason for the error; the non-disclosure of a characteristic that



for the purposes of this Article, it will suffice to recognize that some limitations ought to be placed on physician-specific disclosure in light of reasonable concerns about personal privacy.

## 2. Long-Term Impact on Patient Care

In addition to privacy concerns likely to be expressed by physicians, there are a host of utilitarian concerns about the long-term implications of sharing certain types of information, particularly relating to physician experience. As many commentators have already recognized, requiring physicians to affirmatively disclose their level of expertise or their success rates with a given treatment will likely result in shifting patient loads.<sup>179</sup> That is, patients with the ability to choose among different providers may flock to more experienced physicians. Those physicians will have heavy patient loads, while less experienced providers may find themselves without enough patients to develop the experience they need to advance in their fields. Thus, affirmative disclosure of experience levels will make it difficult for newer providers (or those hoping to learn how to perform new procedures) to develop their knowledge, and ultimately may result in fewer experienced physicians overall. A related concern is that the distribution of patients among providers is likely to be stratified in unjust ways. For example, patients of low socio-economic status, patients with serious illness requiring immediate treatment, and those whose insurance limits their access to providers may find themselves with less access to more-favored physicians, and might in turn have worse outcomes.

Another concern about requiring disclosure of success rates in particular is that this may lead providers to select patients in a way that disfavors the most critical cases.<sup>180</sup> A physician who currently takes on

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one might reasonably expect to impair physician performance alone should not be enough to impose liability. However, I would counter that the informed consent cause of action is indeed important for patients who are unable to succeed on a traditional malpractice claim. Perhaps the patient suffered an adverse outcome because her physician prescribed a medication that she had financial ties to, but a jury is unconvinced that this prescription actually fell outside the standard of care. The patient, while ultimately unsuccessful in her malpractice claim, may nevertheless have a reason to pursue an informed consent claim, and this claim may be more successful.

<sup>179</sup> See, e.g., Heinemann, *supra* note 8, at 1003-1106; Bobinski, *supra* note 11, at 333-335; William Nelson and Paul B. Hoffman, Commentary, *Physician Experience as a Measure of Competency: Implications for Informed Consent*, 5 CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 458, at 460 (1996).

<sup>180</sup> See generally, Kristin Madison, *The Law and Policy of Health Care Quality Reporting*, 31 CAMPBELL L. REV. 215 (2008) (noting similar risks associated with public

specialty patients with significant risk factors, for example, may choose to limit her practice to “easier” patients if her statistical outcomes in treating a high-risk population are lower than those of her peers who choose less risky patients. This, again, raises justice concerns about the impact on patients.

It is not clear to what extent these risks would actually manifest themselves if informed consent disclosure duties were expanded to include information about experience and success rates. But any proposal to expand disclosure obligations should certainly consider these risks, and ideally monitor the impact of the new disclosures on patient care in the long term.

### 3. Patient Understanding

Another common argument for limiting some types of disclosures (particularly with respect to success rates) is that the average patient may not be qualified to understand and logically make use of this information.<sup>181</sup> This concern has been raised in the context of websites and public reporting mechanisms, like *Hospital Compare*, that provide empirical data about quality measures like readmission rates, surgical complications, and healthcare-associated infections.<sup>182</sup> Some critics have argued that the empirical information provided is simply not useful to patients, in part because patients don’t understand the information or can’t interpret it in useful ways. For those who (rightly) view an ethical informed consent doctrine as requiring not just mere disclosure, but also understanding, this concern is certainly important.

A significant problem with this line of argument, however, is that it has been uniformly rejected as a matter of law. Regardless of ethical obligations, American law emphasizes disclosure and not understanding – in part because of how difficult it is for adjudicators to evaluate whether a patient has substantially understood a disclosure, and in part because of the belief that more information is always valuable to consumers. In Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, for

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reporting of provider and institutional quality information).

<sup>181</sup> Jay Katz notes that “[f]rom doctors’ point of view, since patients cannot be trusted to comprehend medicine’s esoteric knowledge sufficiently well, [inviting their participation in medical decisionmaking] does not make sense.” KATZ, *supra* note 1, at 91. However, Katz rejects this argument. “All professions possess esoteric knowledge ... [but that] does not necessarily suggest, however, that this knowledge cannot be communicated to, or understood by, patients.” *Id.* at 92.

<sup>182</sup> See Madison, *supra* note 180.

example, a First Amendment case about a Virginia law that prohibited pharmacists from advertising drug prices, the Supreme Court held that keeping the public in ignorance based on the fear that they will make poor choices is not a valid reason for suppressing speech.<sup>183</sup> While state actors' suppression of speech is clearly different from the establishment of informed consent requirements, cases like Virginia State Board of Pharmacy are instructive because they demonstrate that even if a recipient of information doesn't respond to it in the thoughtful way envisioned by the speaker, that information still has value. This principle is also reflected in the lengthy disclosures required by law for financial transactions, product sales, and the like. An entire body of American regulatory law has developed to identify the information that needs to be shared with consumers before they enter into a transaction, with almost no consideration for whether the average consumer is likely to understand this information, let alone read it.<sup>184</sup>

#### 4. Injury Causation as Mediating Concerns about Excessive Liability

A final point of debate about expanding physicians' informed consent disclosure obligation beyond medical materiality is what practical effect, if any, this will have. Critics may worry that expanding physician's disclosure duties to include material non-medical information would broaden the scope of physician liability too far. These concerns are unwarranted, however, as the doctrine of injury causation sets a reasonable limit on liability in such contexts.

As noted above, a patient who demonstrates that her physician breached a duty to disclose cannot prevail on an informed consent claim unless she satisfies a two-pronged standard of causation unique in the world of negligence. *Decision causation* requires a plaintiff to prove that, had a reasonable patient been informed of the undisclosed fact, she more likely than not would have made a different treatment decision. In a sense, the decision causation requirement is closely tied (if not identical) to the materiality standard for identifying duty and breach – information is material and needs to be disclosed if it would be likely to affect a

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<sup>183</sup> Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976). See also 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, at 503 (1996) (“The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”).

<sup>184</sup> But see, for example, Senator Elizabeth Warren's push to make credit card and loan agreements more readable.

reasonable patient's decision. However, even if a plaintiff demonstrates that the reasonable patient would have undergone a different medical treatment had she known of the undisclosed fact, she will only be successful in her claim if she also proves that the undisclosed fact more likely than not caused the injury. This requirement is commonly referred to as *injury causation*. The secondary requirement of injury causation is closely tied to the doctrine of proximate causation (also known as legal causation), which allows recovery only if a negligent act's causal connection to an injury is close enough to justify liability.

Notably, many of the expanded disclosures described above – cost, impact on third parties, physician characteristics, etc. – involve risks that do not manifest themselves as clearly as traditional medical risks. For example, even if a court were willing to find that a physician has a duty to disclose her history of professional discipline, it is unclear how this risk would manifest itself in a compensable injury. Any injury the patient suffers as a result of treatment would have to be closely tied enough to the physician's undisclosed disciplinary history to satisfy injury causation. This determination would be highly context-specific, and in many cases might be difficult to prove. If the physician had previously been disciplined for sexually assaulting patients during invasive procedures, then a patient who was sexually assaulted during such a procedure might be able to recover under informed consent (again, assuming a court is willing to accept a broadened disclosure duty). But if the patient suffered another, more common, kind of injury – like a physical complication associated the procedure – her claim would be unsuccessful for want of injury causation. Likewise, a patient who successfully argued that her physician had a duty to disclose the cost of a procedure would conceivably be able to recover if she suffers medical bankruptcy, but wouldn't be able to recover for any physical harms caused by the performance of the procedure. Similarly, a physician who suffers from alcohol abuse may have a duty to disclose this fact, but the patient will not be able to recover under informed consent unless a harm actually arose that is causally related to the alcohol abuse. Thus, because the category of injuries for which patients might be able to recover under a doctrine of expanded informed consent would likely be narrow, concerns about excessive liability for physicians are unwarranted.

That said, critics of expanded disclosure duties would be justified in their opposition if they could show that some of the disclosures proposed in Part III would *never* lead to an associated injury. If a physician fails to disclose that she is a Democrat, for example, what causally-related and legally-compensable injury could a patient possibly suffer?<sup>185</sup> Tort law

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<sup>185</sup> Certainly, a patient would not suffer any physical harm as a result of being treated

defines duty by reference to foreseeable risk and the precautions that need to be taken to avoid it. If there is no foreseeable risk from failing to disclose a particular fact, then there can be no duty and no breach. Consequently, some of the categories of disclosure described above, while arguably material to some reasonable patients, would be excluded from disclosure on the grounds that they will never cause a compensable harm.

## CONCLUSION

Revitalizing informed consent to require disclosure of information that falls outside the scope of medical materiality, while better reflecting modern understandings of how patients actually make medical decisions, would represent a dramatic shift. Although few practicing physicians would advocate for the expansion of informed consent liability beyond traditional models, policymakers, scholars, and patient advocates have signaled that such an expansion may be necessary. Thus, it is essential to develop an ethically sound, legally justifiable, and practically feasible doctrine of informed consent that incorporates some non-medical disclosures that patients consider relevant to their medical choices.

This Article argues that an ideal model would require physicians to disclose any information they are uniquely qualified to provide that would be material to a reasonable patient's decision about what kind of medical treatment to pursue. Disclosures based on the physician's unique knowledge and expertise would thus include not only information about the physiological consequences of treatment and non-treatment, but also information known to the physician personally about her own characteristics (such as her experience, conflicts of interest, health status, etc.). Physicians' specialized knowledge might also include information about the practical implications of living with a disability; medical implications for third parties; and, in some areas of practice where this information is readily known (like psychiatry and plastic surgery), the cost of treatment.

That said, this broadened body of knowledge subject to disclosure may need to be limited for pragmatic and policy reasons. For example, some physician-specific information might be deemed too personal for disclosure. Disclosure of information about provider's quality statistics

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by a physician with an opposing political perspective. And any claim for emotional distress on these grounds would fail given the narrowness of the tort doctrine of negligent infliction of emotional distress.

might lead to patient cherry-picking and have a negative impact on the health care system overall. Discussion of the precise boundaries of these potential limitations, however, is beyond the scope of this article.

The model of expanded disclosure proposed herein would, notably, exclude many categories of information that some commentators believe ought to be disclosed. These include privacy-infringing physician-specific disclosures; disclosures about the cost of most treatments; information about the social, ethical, legal, and privacy implications of treatment; and information about social services and other supportive resources that are currently required in the abortion context.

If advocates for such disclosures are correct that the information is material to patients' medical decision-making, how do we ensure that we strike the appropriate balance between supporting patient autonomy and not imposing undue liability on providers?

Consider the cost of treatment, for example. Because most physicians do not know the price of the treatments they provide – either as a general matter or as applied to a particular patient's insurance plan – this information would fall outside the scope of required disclosures described above, and would not subject a non-disclosing physician to tort liability. That said, patients have very legitimate reasons for wanting to know cost information before making medical decisions, and excluding cost information from the realm of informed consent disclosure would put patients at a disadvantage. But if our goal is to get cost information into the hands of patients so that they can make better-informed treatment decisions, we must recognize that there are ways of accomplishing this goal without imposing additional liability burdens on individual physicians. For example, some states have established institutional disclosure mandates requiring hospitals to provide transparent information to patients about the costs of common treatments.<sup>186</sup> Alternatively, states could themselves collect cost information from insurers and share it with consumers via all-payer claims databases.<sup>187</sup> Both of these options would achieve the goal of informing

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<sup>186</sup> Catalyst for Payment Reform and Health Care Incentives Institute, *Report Card on State Price Transparency Laws* (Mar. 2014). In 2013, Congress proposed a health care price transparency law that would require such state mandates; however, it has not been passed. Health Care Price Transparency Promotion Act, H.R. 1326. The Patient Protection and Affordable Care Act takes a similar approach at the federal level, requiring hospitals to provide the public with access to information about standard charges for certain services. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, §2718 (2010). *See also* Medicare Inpatient Prospective Payment System, 42 C.F.R. §405 *et seq* (2014).

<sup>187</sup> *See* Catalyst for Payment Reform, *supra* note 186, at 1-2.

patients without subjecting individual physicians to liability for non-disclosure of information that is outside their knowledge.

As in many other consumer protection contexts, states may have valid and compelling reasons for requiring service providers (here, physicians) to disclose various types of information to consumers (here, consumers of medical care). But these reasons are different in kind than the reasons behind traditional ethical and legal doctrines of informed consent. Informed consent is a common law doctrine grounded in the ethical obligations of medical professionals to correct for the information imbalance between patients and physicians. In contrast, state-mandated disclosure requirements may be aimed at achieving goals extrinsic to medical profession. Disentangling these two sources of disclosure duties is important for making sure that patients have access to information that may be material to their treatment decisions, while ensuring that physicians are not unduly burdened by the threat of civil liability for failure to disclose information that is not central to the practice of medicine.

The doctrine of informed consent was originally developed as a means for furthering patients' decisional autonomy. However, the type of information that is available to patients and relevant to their informed decisions in the 21<sup>st</sup> century is dramatically different than the information that was available and relevant a half-century ago. Recognizing these changes at a broader level promises revitalize the doctrine of informed consent; and expanding tort law's understanding of materiality is central to this mission.

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