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# THE VAGARIES OF INFORMED CONSENT

George P. Smith, II\*

## INTRODUCTION AND OVERVIEW

Within the phrase informed consent, both manipulative and coercive vectors of force can be found. First, the health care provider

[M]ust gain the 'consent' of the patient to prove that she was not physically or psychologically forced into a procedure. We then insist that this consent be 'informed,' recognizing that if a patient readily agrees to something about which she understands little or about which she has a false understanding, we have somehow or other abrogated or sidestepped her autonomous decision-making rights.<sup>1</sup>

The patient-physician relationship is central to the foundations of medical morality. From it emerge normative guidelines that effectuate ideally the end of medicine—to render “a right and good healing action in the interests of a particular patient.”<sup>2</sup> Technical competence, then, is shaped by this goal and, indeed, the very acts of the medical profession are to be considered unauthentic if they neglect to fulfill the real expectation of technical competence.<sup>3</sup> It is upon both the patient-physician relationship and the acknowledged technical competence built by a “participatory moral agency” that forces disclosure of all levels of information necessary for the patient’s valid choice or genuine consent to medical treatments.<sup>4</sup>

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1. WILLARD GAYLIN & BRUCE JENNINGS, *THE PERVERSION OF AUTONOMY* 159 (1996). See generally Edmund D. Pellegrino, *Patient & Physician Autonomy: Conflicting Rights and Obligations in the Physician-Patient Relationship*, 10 *J. CONTEMP. HEALTH L. & POL'Y* 47 (1994) [hereinafter Pellegrino, *Autonomy*]; Edmund D. Pellegrino, *The Human Person, the Physician and the Physician's Ethics*, 62 *LINACRE Q.* 74 (1995) [hereinafter Pellegrino, *Human Person*].

2. Edmund D. Pellegrino, *Toward a Reconstruction of Medical Morality: The Primacy of the Act of Profession and the Fact of Illness*, 4 *J. MED. & PHIL.* 32, 47 (1979) [hereinafter Pellegrino, *Reconstruction*].

3. *Id.* at 49.

4. *Id.* See generally DANIEL P. SULMASY, *THE HEALER'S CALLING: A SPIRITUALITY FOR PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS* (1997); THOMAS SZASZ, *THE THEOLOGY OF MEDICINE* ch. 1 (1977).

While the desire for obtaining information may be seen as stronger than the one for actually making the determinative health care decision itself, not every patient welcomes such information.<sup>5</sup> Indeed, realizing that most individuals make decisions rather badly forces many to choose to delegate medical decision-making to others.<sup>6</sup> For those declining to make their own decisions, it is quite simply psychologically attractive to pass responsibility for hard choices to others.<sup>7</sup> When this delegation occurs, it might be wise to consider developing a "full social impact calculus" which in turn considers all the people affected by it<sup>8</sup>—immediate family members, close friends, social workers as well as spiritual and health care providers. This calculus could be taken when the initial decision for obtaining treatments or accessing them are made. A full social impact calculus would result in some cases even arising where the sum of the social, economic, and medical consequences "on others may outweigh the impact on the person most affected."<sup>9</sup>

Patient information deficits must be remedied by the physician to the fullest extent possible.<sup>10</sup> The information disclosed must be complete, clear, and understandable in the patient's own language so that the patient knows not only the nature of his or her illness, its prognosis, and the alternative modes of treatment, together with their cost and probable effectiveness, but also the degrees of discomfort and the ultimate side effects on the quality of life. This duty of disclosure cannot be exercised by the physician on the grounds of patient ignorance or harm. To do so would underscore the inequality in information between patient and doctor and obstruct the goal of a morally valid consent that in turn is the memorialization of the patient's individual moral agency.<sup>11</sup>

The physician must always guard against manipulating patient choice and consent in order to simply accommodate his own personal or social philosophy. Setting valid limits on the degree to which manipulated consent is morally permissible is difficult. Two major situations are commonly recognized in which a physician can, and indeed should, exert moral agency for the patient and make the value choice on his behalf. The most common

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5. CARLE SCHNEIDER, *THE PRACTICE OF AUTONOMY, PATIENTS, DOCTORS & MEDICAL DECISIONS* 110 (1998). See TERRANCE MCCONNELL, *INALIENABLE RIGHTS: THE LIMITS OF CONSENT IN MEDICINE AND THE LAW* 77, 78 (2000) (maintaining the position that physicians are *not* obligated to comply with such patient wishes because such a waiver is valid only if it is both voluntary and informed).

6. SCHNEIDER, *supra* note 5, at 99. See also MARK A. HALLET AL., *HEALTH CARE LAW AND ETHICS* 208 (6th ed. 2003).

7. SCHNEIDER, *supra* note 5, at 175.

8. Roger B. Dworkin, *Medical Law and Ethics in the Post-Autonomy Age*, 68 *IND. L.J.* 727, 737 (1993).

9. *Id.* See generally ROGER B. DWORKIN, *LIMITS: THE ROLE OF THE LAW IN BIOETHICAL DECISION MAKING* ch. 7 (1996).

10. Pellegrino, *Reconstruction*, *supra* note 2, at 50. But see VEATCH, *infra* note 47 (discussing the therapeutic privilege to withhold information).

11. Pellegrino, *Reconstruction*, *supra* note 2, at 50.

case is where the patient and/or family request the physician to act according to their wishes—because of their emotional unwillingness or intellectual inability to deal with the immediate situation. In cases of this nature, it would be a failure of the authenticity of his act of profession for the physician not to assume moral agency and decide what course of action should be taken. When dealing with surrogate decision makers, it is even more important for the physician to ascertain with certainty that the surrogate is being guided by the best interests of the patient.<sup>12</sup>

The second situation in which a physician should exert moral agency for the patient occurs in emergency cases, in an intensive care or coronary care unit, or in an operating or emergency room. Because of the urgency of the situation, it is impossible for the physician to consult the patient; therefore, he must consult the patient's immediate family or a designated surrogate decision maker. In both of these situations, the physician's Golden Rule should be to act in such a manner as to "accord the patient the same opportunity to express or actualize his own view of what he considers worthwhile," as would be desired by the physician himself.<sup>13</sup> This rule, then, reinforces the mandate not only to bring compassion to the patient's illness, but exhibit the mandate as a "conscious advertence" in the act of profession and the act of medicine as well.<sup>14</sup>

The other party to informed decision-making is obviously the patient. Thus, the ethics of the good patient require truthfulness in the information given to the physician; avoidance of manipulation; faithful following of mutually agreed upon recommendations; self-education for comprehension of the facts disclosed by the physician; promise not to consult another physician (absent suspicion of either dishonesty or malpractice); and acknowledgment of a partial obligation to participate in reasonable therapeutic experiments designed to promote a healing of the patient's disease or those directed toward the discovery of possible cures for his or her own disease for others (non therapeutic), provided the other rules for professional behavior are followed.<sup>15</sup>

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12. *Id.* at 51.

13. *Id.*

14. *Id.*

15. *Id.* at 52, 54-55. See Len Doyal, *The Moral Importance of Informed Consent in Medical Research: Concluding Reflections*, in *INFORMED CONSENT IN MEDICAL RESEARCH* 313 (Len Doyal & Jeffrey S. Tobias eds., 2001) (arguing that certain types of medical research—epidemiological, for example—should be exempted from the informed consent requirement and, further, that in certain other cases where the research subject is incompetent, as with children having the consent of their parents, or in trauma cases where there is an acceptable risk-benefit ratio). See DANIEL CALLAHAN, *WHAT PRICE BETTER HEALTH?: HAZARDS OF THE RESEARCH IMPERATIVE* (2003) (arguing the therapeutic/non-therapeutic distinction gives rise to "therapeutic misconception" which arises when "a clinician researcher carries out research of no expected or intended benefit to a patient but which the patient believes will offer a chance of benefit"). See also Guido Calabresi, *Reflections on Medical Experimentations in Humans*, 98 *DAEDALUS* 387, 401 (1964) (advocating some form of consent should always be required which seeks to strike a balance between present and future lives). See generally Jonathan Montgomery, *Inform-*

What is seen in totality, then, between the patient and the physician is a set of mutually binding obligations that, if met, assure informed decision-making in health care services.<sup>16</sup>

The ongoing debate regarding the efficacy and integrity of the doctrine of informed consent and its application has been termed "oblique and inconclusive,"<sup>17</sup> and indeed a little more than a "fairy tale."<sup>18</sup> The reason for this state of affairs is attributed to a structural weakness reflecting not only a rapacious health care delivery system that is increasingly cost-conscious,<sup>19</sup> complex, and sophisticated,<sup>20</sup> but also by constraints imposed by the tort law system, human psychology, and the physician-patient relationship,<sup>21</sup> all of which are largely intractable.<sup>22</sup> Coupled with these foundational issues is the recognition that the adequate levels of both empirical research and analysis, together with comparative risk evaluation necessary to resolve the uncertainties, is not being pursued.<sup>23</sup>

Yet, for all of the weaknesses, the doctrine of informed consent and its offspring in elder care, negotiated consent,<sup>24</sup> serves a significant purpose in contemporary society—both as a construct and often a template for establishing an interdependent relationship, if not therapeutic partnership, between the patient and his or her physician where truth-telling becomes the crux of the doctrine and a true moral relationship between both parties is recognized.<sup>25</sup>

The purpose of this Article, then, is to probe the foundations and applications of informed consent in a variety of situations and thereby test its validity. The conclusion to be drawn from this analysis is that while the doctrine has yet to become an integral part of the ethos of medicine,<sup>26</sup> it still provides an important mechanism for maintaining a purposeful discourse

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*ed Consent in Clinical Research with Children*, in *INFORMED CONSENT IN MEDICAL RESEARCH*, *supra* note 15, at 173.

16. See Arthur L. Caplan, *Informed Consent and Provider-Patient Relationships in Rehabilitation*, 69 *ARCHIVES PHYSICAL MED. & REHABILITATION* 312 (1988); Dan W. Brock, *The Ideal of Shared Decision Making Between Physicians and Patients*, 1 *KENNEDY INST. ETHICS J.* 28 (1991).

17. Peter H. Schuck, *Rethinking Informed Consent*, 103 *YALE L.J.* 899, 904-05 (1994).

18. Jay Katz, *Informed Consent—Must It Remain a Fairy Tale?*, 10 *J. CONTEMP. HEALTH L. & POL'Y* 69 (1993).

19. See generally TIMOTHY S. JOST, *DISENTITLEMENT: THE THREATS FACING OUR PUBLIC HEALTHCARE PROGRAMS AND RIGHTS-BASED RESPONSE* (2003); ELEANOR D. KINNEY, *PROTECTING AMERICAN HEALTH CARE CONSUMERS* (2002); George P. Smith, II, *Distributive Justice and Health Care*, 18 *J. CONTEMP. HEALTH L. & POL'Y* 421 (2002).

20. See generally SCHNEIDER, *supra* note 5.

21. Pellegrino, *Autonomy*, *supra* note 1; Pellegrino, *Human Person*, *supra* note 1; SCHNEIDER, *supra* note 5, at 205; Schuck, *supra* note 17, at 905.

22. Schuck, *supra* note 17, at 905.

23. *Id.*

24. See generally Harry R. Moody, *From Informed Consent to Negotiated Consent*, 28 *GERONTOLOGIST* 64 (Supp. 1988).

25. GAYLIN & JENNINGS, *supra* note 1, at 55.

26. Katz, *supra* note 18, at 91.

between physician and patient and, as such, nurturing and preserving their essential partnership of healing and trust.<sup>27</sup>

## I. MALPRACTICE AND INFORMED CONSENT

### A. *Professional or Lay Standards*

A claim for malpractice is recognized essentially when a patient, as a direct result of a physician's failure to render that level of care consistent with what would have been given by other practicing physicians in the community in question, is injured.<sup>28</sup> Thus, the standard of conduct against which the defending physician's behavior is measured is tied to the conduct other similarly situated professionals in the field would have followed under the same or similar circumstances. The end result of this evaluation process is that the objective standard of reasonableness is thereby excluded totally from the evaluation.<sup>29</sup>

As to the elements of establishing a cause of action for failure to obtain informed consent for either a medical treatment or procedure, there is less uniformity of view.<sup>30</sup> Indeed, under older case law, the duty to obtain informed consent for a medical intervention was inherent in the essential idea that nonconsensual touching was, and is, a legal battery.<sup>31</sup> Modern case law, however, now takes one of two approaches to the duty to obtain informed consent,<sup>32</sup> yet treats the central issue as one of negligence.<sup>33</sup>

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27. See generally Pellegrino, *Autonomy*, *supra* note 1; Pellegrino, *Human Person*, *supra* note 1; Edmund D. Pellegrino, *Rationing Health Care: The Ethics of Medical Gatekeeping*, 2 J. CONTEMP. HEALTH L. & POL'Y 23 (1986) [hereinafter Pellegrino, *Gatekeeping*]. See also Mark A. Hall, *Law, Medicine and Trust*, 55 STAN. L. REV. 463, 478 (2002) (maintaining that without a minimal level of trust, patients will neither disclose information to the physician nor follow medical recommendations made to him or her).

28. Laura Hunter Dietz, Annotation, *Physicians, Surgeons, and Other Healers*, 61 AM. JUR. 2D *Physicians* § 202 (1981). See also HALL ET AL., *supra* note 6, at 201, 203, 210.

29. Dietz, *supra* note 28.

30. *Id.* See Aaron D. Twerski & Neil B. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. ILL. L. REV. 607 (1988).

31. Dietz, *supra* note 28, §§ 150-52. See FOWLER V. HARPER ET AL., LAW OF TORTS § 3.2 (2d ed. 1986).

32. Hunter L. Prillaman, *A Physician's Duty to Inform of Newly Developed Therapy*, 6 J. CONTEMP. HEALTH L. & POL'Y 43, 44 (1990).

33. Dworkin, *supra* note 8, at 729. Since the 1957 decision in *Salgo v. Leland Stanford Jr. University Board of Trustees*, the courts have been emphasizing and developing a negligence of failure to use due care theory of liability. 317 P.2d 170, 181 (Cal. Ct. App. 1959). This theory in turn places the physician in default for failing to educate adequately his patient to the collateral risks involved in the treatment. Indeed, *Salgo* provided the groundwork for the explosion of cases dealing with informed consent. In *Salgo*, as now, the physician is confronted with a perplexing problem: namely, how to balance the patient's need to know the risks and alternatives to treatment in order to give an informed consent with the individual patient's mental and emotional condition to accept and understand the medical information. *Id.* See also

Some states require a professional standard to be followed that in turn imposes a duty upon all physicians to inform their patients of not only the risks, but also the alternatives to any proposed medical treatment in the same manner as other physicians would practicing in the community.<sup>34</sup> Accordingly, in a 1981 Illinois case,<sup>35</sup> the court held that applying the reasonable medical practitioner standard of informed consent meant that there must indeed be specific expert medical testimony “of the necessity to inform patients of possible alternatives.”<sup>36</sup> Consequently, adherence to that level of care given in the relevant community by other practitioners applies both to malpractice actions and the separate action of failure to obtain informed consent.<sup>37</sup>

Other states choose to apply the *lay* or *prudent patient* standard of informed consent, thereby requiring a physician to inform his patient of all sources and degrees of information which an average, ordinary, and reasonable patient should and would require in order to make an informed decision regarding the need to submit to a proposed treatment therapy.<sup>38</sup> Under this standard of informed consent:

[A] physician is liable to his or her patient if (1) the physician fails to disclose any risk in the recommended treatment, or the existence of any alternative method of treatment, that a reasonable person would deem material in deciding whether to undergo the recommended treatment; (2) the patient would have foregone the recommended treatment had he or she known of the undisclosed information; and (3) as a result of

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David Thomsma & Edmund D. Pellegrino, *Medicine, Science, Self-Interest: Value Sets in Conflict in Human Experimentation*, in RESEARCH ON HUMAN SUBJECTS: ETHICS, LAW AND SOCIAL POLICY xvii *passim* (David N. Weisstub ed., 1998). Therefore, under *Salgo*, a physician owes a duty to his patient to disclose facts necessary to the formation of an intelligent consent and, further, subjects himself to liability for violation of that duty. *Salgo*, 317 P.2d at 181. At best confusing, the *Salgo* rule allows plaintiff's counsel to argue that there must be full disclosure because of the established duty to disclose. However, a court may use *Salgo* as justification for holding in favor of a defendant on the issue of the adequacy of disclosure—sustaining the proposition that the amount of information the physician gave the patient was sufficient for him to understand the risks and alternatives of the proposed treatment. Myers, *infra* note 44, at 1399. The discretion allowed to physicians has tended to subject them to liability in cases involving high risk and to exonerate them when a court considers the risk to be light. *Id.*

34. *Hondroulis v. Schuhmacher* (Hondroulis II), 553 So. 2d 398 (La. 1988).

35. *Ziegert v. S. Chi. Cmty. Hosp.*, 425 N.E.2d 450 (Ill. App. Ct. 1981).

36. Prillaman, *supra* note 32, at 45.

37. *Id.*

38. *Id.* See generally INST. OF MED., RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS (Daniel D. Federman et al. eds., 2003); KENNETH GETZ & DEBORAH BORFITZ, INFORMED CONSENT: A GUIDE TO THE RISKS AND BENEFITS OF VOLUNTEERING FOR CLINICAL TRIALS (2002); 45 C.F.R. § 46.101 (2004); 21 C.F.R. § 50.1 (2004).



the recommended treatment, the patient actually suffers an injury the risk of which was undisclosed, or the patient actually suffers an injury that would not have occurred had the patient opted for one of the undisclosed methods of treatment.<sup>39</sup>

## II. THE FOUNDATIONAL PARADIGM

The 1972 case of *Canterbury v. Spence*<sup>40</sup> presents a modern, comprehensive, and focal paradigm of the legal concept of informed consent in application. In *Canterbury*, a young boy complaining of back pain submitted to a myelogram which revealed a filling defect. The boy's mother was contacted after the test and an operation was recommended by Dr. William T. Spence, the attending physician, stating that such an operation was "not anymore [serious] than any other operation."<sup>41</sup> The boy submitted to the operation without being informed that paralysis was a risk of the procedure. Mrs. Canterbury arrived at the hospital *after* the operation and signed a consent form. The boy fell from his bed a day after the operation while, without assistance, he attempted to void. He thereupon became paralyzed and was required to undergo a second surgery. This time, Mrs. Canterbury signed a consent form *before* the operation. Years later, the youth "hobbled about on crutches, a victim of paralysis of the bowels and urinary incontinence."<sup>42</sup> At trial, Dr. Spence testified that there was only a one percent risk of paralysis occurring after this type of surgery. The central issue of the case was the scope and application of the doctrine of informed consent.

Because there is a duty to disclose risks of a procedure, the scope of that duty should be known. Any standard set in terms of what is done in the medical profession will be at odds with the patient's prerogative to decide on prospective therapy. This "right of self-decision shapes the boundary of the duty to reveal."<sup>43</sup> In order that the patient's interest in achieving his own determination of treatment is fulfilled, it is the law which must set the standard for adequate disclosure.<sup>44</sup> The test enunciated in *Canterbury* is that a "risk is thus material when a reasonable person, in what the physician knows

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39. *Neal v. Lu*, 530 A.2d 103, 111 (Pa. Super. Ct. 1987). See also *Festa v. Greenberg*, 511 A.2d 1371 (Pa. Super. Ct. 1986); *Salis v. United States*, 522 F. Supp. 989 (Pa. D. 1981).

40. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972). Accord *Wilkinson v. Vesey*, 295 A.2d 676 (R.I. 1972). See also *Cobbs v. Grant*, 502 P.2d 1 (Cal. 1972); *Natanson v. Kline*, 350 P.2d 1093 (Kan. 1960), clarified by 354 P.2d 670 (Kan. 1960); *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92 (N.Y. 1914), overruled on other grounds by *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957).

41. *Canterbury*, 464 F.2d at 777.

42. *Id.* at 776.

43. *Id.* at 786.

44. See Michael Justin Myers, Comment, *Informed Consent in Medical Malpractice*, 55 CAL. L. REV. 1396, 1407-10 (1967).

or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."<sup>45</sup> This includes a discussion of the inherent and potential dangers of the proposed treatment, the alternatives to that treatment, and the likely results if the patient remains untreated.

The courts have noted two exceptions to the general rule of disclosure. The first is where the person is unconscious or otherwise incapable of consenting and there is imminent harm that would result from failure to treat, which in turn outweighs any harm threatened by the proposed treatment.<sup>46</sup> If possible, consent of relatives should then be obtained. The second exception arises when the disclosure itself threatens the patient and thus becomes infeasible from a medical point of view. The critical inquiry, then, would be whether the physician was guided by sound medical judgment.<sup>47</sup> This privilege does not carry with it the paternalistic notion that the physician may remain silent simply because diligence might prompt the patient to forego the physician's recommended therapy.<sup>48</sup>

The danger of this second exception is that it may be judged by a subjective, hindsight test. *Canterbury* speaks to this concern and resolves it by requiring a determination of whether a prudent person in the patient's position would have decided to undergo treatment "if suitably informed of all perils bearing significance."<sup>49</sup> This affords opportunity for medical testimony regarding the relevance of certain risks, as well as other testimony by anyone

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45. *Canterbury*, 464 F.2d at 787.

46. See *Dunham v. Wright*, 423 F.2d 940, 941-42 (3d Cir. 1970).

47. See *Roberts v. Wood*, 206 F. Supp. 579, 583 (S.D. Ala. 1962). See also THOMAS BEAUCHAMP & JAMES CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* ch. 3 (1979). A therapeutic privilege exists to withhold information from a patient if it is either considered potentially harmful or it would cause any counter-therapeutic deterioration—no matter how slight—in either the patient's physical, psychological, or emotional well being. ROBERT M. VEATCH, *MEDICAL ETHICS* 203-04 (2d ed. 1997). The "urgency of the situation" justifies this exception to the doctrine of informed consent. JAY KATZ, *EXPERIMENTATION WITH HUMAN BEINGS: THE AUTHORITY OF THE INVESTIGATOR, SUBJECT, PROFESSION AND STATE IN THE HUMAN EXPERIMENTATION PROCESS* 37, 84 (1972). See also Kathleen M. Boozang, *The Therapeutic Placebo: The Case for Patient Deception*, 54 FLA. L. REV. 687, 746 (2002) (arguing, for example, that if viewed as effective treatment, with a therapeutic effect being achieved by its prescription and use, the representation that placebo use is therapy or medicine is neither untrue nor unethical); HALL ET AL., *supra* note 6, at 207; George J. Annas, *Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research*, 12 J. CONTEMP. HEALTH L. & POL'Y 297, 300, 314 (1996) (asserting that the very concept of therapeutic research should be eliminated altogether since it confuses the ideology of medicine with the ideology of science).

48. Myers, *supra* note 44, at 1409-10. See generally Allan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413.

49. *Canterbury*, 464 F.2d at 791.

having sufficient knowledge and capacity to testify. The courts thus assume a determinative role in assessing liability.<sup>50</sup>

In the pre-*Canterbury* period, courts sought to enforce a narrower objective test for materiality (reasonable doctor) and a broad-based test for causation (subjective patient). With *Canterbury*, a broad test for materiality is advanced (reasonable patient) and a narrower objective test for causation (what a reasonable patient would have chosen) preferred.<sup>51</sup> Criticism has been maintained that with *Canterbury* the courts are incorrectly treating informed consent as yet another branch of negligent medical practice instead of recognizing the patient's interest in autonomy and his or her right to make an informed choice about medical care. This right is the key interest protected by the informed consent doctrine. However, these criticisms are muted when hard questions are raised regarding how to value the protected interest and determine damages for interference thereto.<sup>52</sup>

### A. *Alternative Treatment*

Utilizing either the professional standard or the lay standard of informed consent, a physician is under a duty not only to inform his patient of appropriate alternative treatments, in addition to the alternative of no treatment at all, but also to describe and evaluate the benefits and the risks of those treatments to his at-risk patient.<sup>53</sup> Not every "conceivable alternative to every detail of treatment" need be provided, however.<sup>54</sup> Setting the limits of a physician's duty to inform patients of alternative treatments continues to be a struggle for the courts. If a professional standard of informed consent is adhered to, much difficulty in application is alleviated, since a jury panel will seek to decide the issue in conflict by comparing the testimony of competing medical experts.<sup>55</sup> If, however, the lay standard is followed, the jury determination is more complex because an evaluation must be made of what an ordinary, reasonable patient would both want and need to know under similar circumstances.<sup>56</sup>

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50. Landmark examples of the way in which courts have treated the application of informed consent include: *Corn v. French*, 331 P.2d 850 (Nev. 1958) (physician held liable where mastectomy was performed with a signed consent form, but patient had told physician that she did not want anything removed); *DiRosse v. Wein*, 24 A.D.2d 510 (N.Y. 1965) (failure to tell of the danger of exfoliative dermatitis from *gold* treatment for rheumatoid arthritis, resulting in exfoliative dermatitis, imposed liability on the physician); and *Darrah v. Kite*, 32 A.D.2d 208 (N.Y. App. Div. 1969) (failure to give adequate and timely explanation of the risks of ventriculograms, imposed liability on a neurologist).

51. Twerski & Cohen, *supra* note 30, at 615 n.30.

52. *Id.* at 620 n.47.

53. Prillaman, *supra* note 32, at 47.

54. *Id.*

55. *Id.* at 48.

56. *Id.*

Obviously, a decision reached according to this standard requires considerable and complex analysis of the credibility of opinions of opposing experts on varying community standards. Of additional complexity is the court's need to comprehensively instruct a jury on the elements of a medically acceptable alternative before the jury can be allowed to decide whether the average reasonable patient would indeed have wanted to know of the alternative.<sup>57</sup>

Medical acceptability is the criterion by which a fact finder determines whether an alternative treatment is to be disclosed.<sup>58</sup> The obvious difficulty here is fully comprehending those components or elements of a particular treatment, especially a new one, that make it acceptable and determine to whom it must be found acceptable.<sup>59</sup> "In terms of a doctor's duty to disclose, this issue can be broken down into two parts. First, what criteria, objective or subjective, make a particular treatment acceptable? Second, are there additional factors which create (or excuse) the particular physician's duty to know about the treatment?"<sup>60</sup> Every new medical treatment, whether it be surgery, drug therapy or an exotic technique, is initially experimental.<sup>61</sup>

In those cases where a *lay* approach to informed consent is followed, it must be first recognized that it cannot be extended effectively to determine what specific alternative treatments are medically acceptable, although it may well indeed be used as a mechanism through which acceptable treatments are revealed.<sup>62</sup> The juries applying the *lay* standard or approach to determine what a reasonable patient would have considered medically valid and acceptable leads to an interesting quandary for the concerned physician: the physician would never be in a position to know precisely which alternatives he or she must describe. This in turn could drive the physician to describe even *quack* treatments for fear that a future jury could find that a reasonable patient might have wished to be informed of such treatments.<sup>63</sup>

A wiser approach acknowledges the standard for medical acceptability is based solely on the perception of the reasonable practitioner.<sup>64</sup> Here, the pivotal inquiry would not necessarily be whether a reasonable practitioner would inform a patient of the particular alternative. Rather, the question to be raised would be simply whether an average, reasonable practitioner would

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57. *Id.*

58. *Id.* at 52.

59. Prillaman, *supra* note 32, at 52.

60. *Id.*

61. *Id.* In a landmark 1990 case in California, it was determined that an individual patient must first give an informed consent to a surgical procedure that would in turn yield tissues which would be transformed, subsequently, through genetic engineering, into commercial products of considerable value. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 749 (Cal. 1990).

62. Prillaman, *supra* note 32, at 57.

63. *Id.*

64. *Id.*

believe the treatment was a viable, *medically acceptable* alternative; or stated otherwise, whether it was recognized as an appropriate modality of treatment by a significant number of acknowledged experts in the field.<sup>65</sup> The role of expert testimony then would essentially be to explore both the number and the respectability of those accepting the treatment.<sup>66</sup> Developing and following this standard would allow a physician to:

[A]void the danger of having to describe the theories of quacks or to explain treatments too new to have a track record, but could still be held to have a duty to keep up with the relevant literature and other sources of information, and to inform patients of new treatments as they met the criteria of acceptance.<sup>67</sup>

### *B. Future Treatment*

It is often maintained that if a particular medical treatment were to be classified as futile, an attending physician is under no obligation to provide it to his or her patient. Indeed, the assertion goes even further: namely, that the physician needs not even advise a patient of the existence of such treatment.<sup>68</sup> Judging the futility of any treatment is, arguably and correctly, a medical matter.<sup>69</sup> No input from the patient is thus required.<sup>70</sup> Since a futile treatment offers no benefit to the patient, it can be argued that a physician has neither obligation to render treatment of a non-beneficent nature nor—for that matter—does a patient have a right to demand it.<sup>71</sup>

Without knowledge of a medical or surgical alternative and without having access to information regarding the pros and cons of each, a patient obviously has few if any tools with which to form a therapeutic alliance with a physician or even enter into a meaningful treatment dialogue with that physician.<sup>72</sup> While the physician avoids conflicts with his or her patient, this veil of silence often robs the patient of the right to self-determination, all under the guise of medical paternalism.<sup>73</sup> Whenever a treatment is labeled futile, it is exempted from the requirement of discussion. Thus the label itself “becomes a very powerful tool for relieving physicians of the requirement to

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65. *Id.*

66. *Id.* at 58.

67. *Id.*

68. Susan M. Wolf, *Conflict Between Doctor and Patient*, 161 L. MED. & HEALTH CARE 197, 198 (1988).

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.* at 198. See generally JOSEPH M. JACOB, *DOCTORS AND RULES* (1988).

73. See generally ALLEN E. BUCHANAN & DAN W. BROCK, *DECIDING FOR OTHERS: THE ETHICS OF SURROGATE DECISIONMAKING* (1989).

talk with their patient. The label marks off a realm in which it is argued that the requirement does not apply.”<sup>74</sup>

### C. *Uninsurable Treatment Options*

The results of an interesting and disturbing 1988 survey, supported by the American Medical Association’s Institute for Ethics and drawn from a random sample of 1,124 licensed United States physicians, were published recently.<sup>75</sup> Sixty-four percent responded (720 physicians).<sup>76</sup> Respondent physicians empirically validated the belief that physicians are uneasy in describing medically indicated care not covered by insurance.<sup>77</sup>

Because of restrictions in various health plans, useful patient care was sometimes not offered by thirty-one percent of the reporting physicians in the survey.<sup>78</sup> Within this group thirty-five percent reported, additionally, that this course of action is more common today than it was five years ago.<sup>79</sup> On the other hand, sixty-nine percent of the physician-respondents stated that they *rarely or never* followed this practice.<sup>80</sup>

One ethical rationale for not offering useful services not covered by insurance is physician discomfort over requests by patients to *game the system*, or, in other words, manipulate and deceive third party payers in their health plans.<sup>81</sup> Inasmuch as the vast majority of physicians believe such patient requests are unethical, some might avoid such tense encounters by electing not to offer useful but uncovered services.<sup>82</sup>

Other reasons proffered for refusing health care information include, rather paternistically, the compassionate desire not to raise levels of expectation, especially for Medicaid or other economically impoverished patients who have medical coverage restrictions. In other words, “why offer a useful medical service to someone who cannot afford it?”<sup>83</sup>

Financial pressures on physicians are also seen as a significant determinant in decisions to withhold treatment information. For physicians

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74. Wolf, *supra* note 68, at 199. See generally George P. Smith, II, *Utility and the Principle of Medical Futility: Safeguarding Autonomy and the Prohibition Against Cruel and Unusual Punishment*, 12 J. CONTEMP. HEALTH L. & POL’Y 1 (1996).

75. Matthew K. Wynia et al., *Do Physicians Not Offer Useful Services Because of Coverage Restrictions*, 22 HEALTH AFF. 190, 191 (2003).

76. *Id.*

77. *Id.* at 194.

78. *Id.* at 193.

79. *Id.*

80. *Id.*

81. Wynia et al., *supra* note 75, at 194.

82. *Id.*

83. *Id.* at 194–95. See also HALL ET AL., *supra* note 6, at 191.

with "more than 25 percent of income at risk" for patient care costs, the trend is to neglect to offer patients optimal but uncovered services.<sup>84</sup>

Sadly, the results of this study parallel—and, indeed, revive—earlier institutional concerns over *gag clauses* in managed care programs. In the late 1990s, these provisions were thought of as prohibiting physicians, by contract, from discussing with their patients medical service options which were not covered in their health plans.<sup>85</sup>

Adding significantly to present patient mistrust of the medical profession, this 1998 survey confirms the fact that *gagging* continues, not by contract, necessarily, but for other reasons as noted, all of which have the ultimate effect of compromising the very doctrine of informed consent.<sup>86</sup> The pivotal ethical concern, then, is: "to what degree is it possible, and a professional obligation, for physicians to try to explain to their patients why some useful services are not covered?"<sup>87</sup>

### III. INFORMED DECISION-MAKING AND NEGOTIATED CONSENT

Although it is seen that the foundation of informed consent is now well embedded in both the legal and medical arenas, negotiated consent is far from being as widely accepted. In fact, the ideal of negotiated consent is only beginning to emerge as a viable alternative to the traditional informed consent standard, particularly with application to healthcare for the elderly.

The informed consent standard, which is based upon autonomy, emerged from the acute care environment and from a narrowly conceived view of the relationship between professional caregivers (physicians) and those dependent upon them (patients).<sup>88</sup> Similarly, the concept of negotiated consent recognizes the ideal of autonomy, yet in a more limited fashion.<sup>89</sup> Negotiated consent recognizes the need for some version of "autonomy respecting paternalism" in the environment of long-term care, particularly involving elderly patients.<sup>90</sup> Fundamentally, paternalistic interventions that serve to

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84. Wynia et al., *supra* note 75, at 194-95.

85. *Id.* at 196.

86. *Id.*

87. *Id.*

88. Moody, *supra* note 24, at 64. See Brian F. Hofland, *Autonomy in Long Term Care: Background Issues and a Programmatic Response*, 28 GERONTOLOGIST 3, 4 (1988) (observing that "patient . . . autonomy is not a value indigenous to medical contexts, but one imported into medicine from extrinsic social agendas such as that of constitutional law and the evolution of individual rights"). See also Dworkin, *supra* note 8, at 737 (challenging the view that autonomy should be the dominant value in medical law and ethics).

89. Moody, *supra* note 24, at 64.

90. *Id.* (quoting DONALD VANDEVEER, *PATERNALISTIC INTERVENTION: THE MORAL BOUNDS ON BENEVOLENCE* (1986)). See generally VANDEVEER *supra*.

enhance autonomy and allow patients to decide and act in keeping with their own values compose the underpinnings of negotiated consent.<sup>91</sup>

### A. Working Principles

In light of the unique issues and moral dilemmas involved in long-term care for the elderly, the interactions between patients and practitioners are primarily acute transactions.<sup>92</sup> As such, enhancing the autonomy among patients of long-term care facilities is an extraordinarily difficult task.<sup>93</sup> The conditions at hand are very different from those encountered outside of residential care facilities, where informed consent is the prevalent model.<sup>94</sup> Recognizing these differences, negotiated consent attempts to address the various concerns involved and balance the involved parties' competing interests.<sup>95</sup> Under the negotiated consent standard, many legitimate views must be considered involving the patient, family, and institution.<sup>96</sup> The results are shared or dispersed authority for decision-making in which no single party has the exclusive power of decision<sup>97</sup> and a nonalgorithmic process whereby negotiation is not governed by strict deductive rules.<sup>98</sup> Instead, negotiation is "more heuristic in its cognitive style, implying less reliance on codes of ethics and more attention to opportunities for discussion . . . ."<sup>99</sup> Even in those instances in which the ideal outcome is not attainable, a common situation among the frail elderly, negotiation serves to make the best of a bad situation."<sup>100</sup>

In order to implement effectively negotiated consent, there must be active participation by the patient or the patient's surrogate and consultation with all parties holding an interest in the decision.<sup>101</sup> Furthermore, the patient must have at least a cursory knowledge of legal and ethical rights and the

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91. Moody, *supra* note 24, at 64.

92. *Id.*

93. See Harry R. Moody, *Ethical Dilemmas of Nursing Home Placement*, 11 GENERATIONS 16-23 (1987). The difficulties are heightened by professional interventions that verge on being more social than medical (e.g., eating, bathing, exercise), the patients' need for a degree of regimentation in their lifestyles, and the continuous fluctuation in competency or decisional capacity of the patients. See also Moody, *supra* note 24, at 64-65.

94. Moody, *supra* note 24, at 65.

95. *Id.*

96. *Id.* at 67.

97. *Id.* Instead, negotiated consent proposes the structure of a team decision-making process, allowing for greater influence and more effective communication. *Id.*

98. *Id.*

99. Moody, *supra* note 24, at 67.

100. *Id.*

101. *Id.* The notion exists, particularly with elderly patients, that a patient ought to be aware that negotiations are underway. Furthermore, the patient should know which parties are active participants in the negotiation process, and, ultimately, any decision derived should be presented in such a manner as to be publicly defensible on a wide-scale basis. *Id.* at 68.



“opportunity for scrutiny and enforcement of those rights through some outside, higher authority . . .”<sup>102</sup> In addition, the element of power in the deliberative process plays an integral part of the negotiated consent formula.<sup>103</sup> Obviously, little chance for negotiation exists if one party has such superior power as to leave the other party with no chance for deliberation.<sup>104</sup> By the same token, negotiated consent does not insist on absolute equality between the parties, either.<sup>105</sup> Instead, the doctrine essentially supports the concept of “shared decision-making” between the physician and patient in those situations in which it is possible.<sup>106</sup>

Although the ideals of virtue and compassion called for in negotiated consent may be sophistic, they are by no means quixotic. The introduction of negotiated consent in health care for the elderly is designed primarily to urge a different set of ideals and emphasize that practitioners must demonstrate virtues alongside the purported rights a patient is assumed to possess.<sup>107</sup>

### B. *New Directions*

In American society, individuals who reach the age of majority are permitted a broad range of choice.<sup>108</sup> They may choose their jobs, their relationships, and the patterns by which they live.<sup>109</sup> These rights of choice, however, are often denied to elderly persons because they are unable to effectuate preference without assistance.<sup>110</sup>

On November 1, 2002, the United States Census Bureau estimated one in every eight Americans (roughly, 12.3% of the total population) was sixty-five years of age and over—drawn as such from a total figure of 34.9 million in this age group.<sup>111</sup> The American Hospital Association has determined that a 7.9% increase in hospitalization occurs whenever there is a 10% increase in

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102. *Id.* at 67.

103. *Id.*

104. Moody, *supra* note 24, at 68.

105. *Id.* Although the physician’s base of experience endows physicians with greater facilities to reason more accurately about medical issues than can their patients, the patient has the option of non-compliance and thereby retains an element of power for himself. *Id.* See also SCHNEIDER, *supra* note 5, at 110.

106. See Moody, *supra* note 24, at 68 (citing UNITED STATES, PRESIDENT’S COMM. FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMEDICAL & BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: A REPORT ON THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP (1982)).

107. Moody, *supra* note 24, at 69.

108. Nancy N. Dubler, *The Dependent Elderly: Legal Rights and Responsibilities in Agent Custody*, in ETHICAL DIMENSIONS OF GERIATRIC CARE 137 (Stuart F. Spicker et al. eds., 1987).

109. *Id.*

110. *Id.*

111. U.S. CENSUS BUREAU, *Resident Population Estimates of the United States by Age and Sex: April 1, 1990 to July 1, 1999, with Short-Term Projections to November 1, 2000*, available at <http://www.census.gov/population/estimates/nation/intfile2-1.txt> (last visited Feb. 1, 2004).

the number of seniors.<sup>112</sup> Thus, it is predicted that a majority of hospital services, 51% of inpatient admissions and 59% of beds, will be given over to the elderly by 2027.<sup>113</sup> By 2030, it is predicted this very group will top seventy million people, meaning about one out of every five Americans will be included.<sup>114</sup>

As the population of aging citizens grows, so does the need for such citizens to make pivotal decisions regarding their medical treatment.<sup>115</sup> Reality dictates that the capacity of elderly patients to make such decisions is often impaired by a higher incidence and prevalence of chronic brain disease,<sup>116</sup> coupled with the burden of coping with numerous other medical afflictions. Moreover, the risk for elderly patients may be compounded because they are more likely to be excluded from the medical decision-making process as a result of reduced physician contact, ageism, and paternalism.<sup>117</sup>

Even for the elderly patient, informed consent for medical decision-making has been the standard consent practice in the medical community for a number of years.<sup>118</sup> However, for the elderly, this process has failed in a number of areas, one of which is the issue of a patient's competence to consent to treatment.<sup>119</sup> Thus, with the doctrine of negotiated consent as an alternative to the traditional model of informed consent, the needs and desires of elderly patients ideally have a greater chance of being addressed adequately and equitably.

Dependent elderly persons pose a special problem for healthcare professionals in that their decisions often require the involvement of helpers and facilitators.<sup>120</sup> Such involvement may result in differing standards of judgment and measures of worth being applied to an elder's individual choice.<sup>121</sup> The results are conflicting value systems that often reflect the competing concerns of institutional and individual self-protection and

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112. Laura B. Benko, *Boomer Bust?*, MODERN HEALTHCARE, July 28, 2003, at 24.

113. *Id.* See also L.J. Fitten & M.S. Waite, *Impact of Medical Hospitalization on Treatment Decision-Making in the Elderly*, 150 ARCHIVES INTERNAL MED. 1717 (1990). See generally James Lubitz et al., *Health, Life Expectancy, and Health Care Spending Among the Elderly*, 349 NEW ENG. J. MED. 1048 (2003).

114. Betty Booker, *Nursing-Home Costs Soar; Local Prices Average \$64,000 Annually*, RICH. TIMES DISPATCH, Aug. 7, 2003, at A1.

115. Fitten & Waite, *supra* note 113, at 1717.

116. See *id.* See also Emre Kokmen et al., *Epidemiologic Patterns and Clinical Features of Dementia in a Defined U.S. Population*, 105 TRANSACTIONS. AM. NEUROLOGICAL ASS'N. 334-36 (1980); W.A. Rocco et al., *The Epidemiology of Dementia*, 19 ANN. NEUROLOGY 415, 415-24 (1986).

117. Fitten & Waite, *supra* note 113, at 1717.

118. See *id.*

119. See *id.*

120. Dubler, *supra* note 108, at 137. See generally L.J. Fitten et al., *Assessing Treatment Decision-Making Capacity in Elderly Nursing Home Residents*, 38 J. AM. GERIATRICS SOC'Y 1097 (1990).

121. Dubler, *supra* note 108, at 137.

convenience.<sup>122</sup> In the end, the elderly person is at a great risk of losing the right to decide the course and conduct of his or her life.<sup>123</sup>

In such a scenario, the model of negotiated consent provides a realistic and viable means by which the interests of all parties involved may be represented. Negotiated consent allows for the interaction of all affected parties, including the patient, family, clergy, and physicians.<sup>124</sup> This process assures the presentation of a multitude of differing views while, ideally, preserving the values of the patient.

The process of negotiated consent also combats another weakness of the traditional informed consent doctrine. Commonly, informed consent can provoke anxiety and evoke previous experiences, fantasies, and associations for a patient, triggering an occasional primitive defense response.<sup>125</sup> With negotiated consent, the interaction of the parties and the commitment to shared dialogue should reduce the likelihood of such a response, if not completely eliminate it.

A further deficiency of the informed consent model, as applied to older patients, is their inability to comprehend the specific elements of informed consent information.<sup>126</sup> Thus, as a group, geriatric patients may have some impairment in providing their informed consent with regard to medical procedures.<sup>127</sup> Because the process of negotiated consent involves, among other things, the friends and family of the patient, it is likely that a greater sense of trust exists among the parties, particularly if the patient needs assistance to comprehend fully the intricacies of the specific consent.

However, the doctrine of negotiated consent is certainly not without its shortcomings. First of all, self-determination for long-term care residents is a valid ideal; however, it requires opportunity, capacity, and motivation on their part.<sup>128</sup> Although the opportunity and capacity factors receive a majority of the attention within the medical community, the motivational factor must be addressed seriously, particularly with elderly persons.<sup>129</sup> If elderly patients

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122. *Id.*

123. *Id.*

124. Moody, *supra* note 24, at 67. See also Dworkin, *supra* note 8, at 737 (arguing for a "full social impact calculus" in the decision-making process).

125. J.P. Hess et al., *Some Psychological and Legal Considerations in the Determination of Incompetence in the Elderly*, 7 MED. L. 151, 153 (1988).

126. B. Stanley et al., *The Elderly Patient and Informed Consent*, 252 JAMA 1302, 1305 (1984).

127. *Id.* The study revealed that, in comparison to their younger counterparts, older patients did show poorer comprehension, yet, generally seemed to make equally reasonable decisions. *Id.* Thus, significant adverse effects were not noted until the ability to comprehend was considered severely impaired, as in the case of severe senile dementia. *Id.*

128. Moody, *supra* note 24, at 69.

129. *Id.* Moody points out that, especially with elder patients, it is possible to provide opportunities and to safeguard rights, but without motivation, patients will derive no benefits from these acts. *Id.* It is essentially a patient's own liberty that he or she must exercise in order to take advantage of the opportunities that are available. *Id.*

are not sufficiently motivated to exercise the rights being secured for them, the doctrine of negotiated consent serves no additional benefit for the patients. Moreover, entertaining the multitude of opinions necessary for negotiated consent may require an overly burdensome and time-consuming recording process, and could even result in an invitation to litigation should the parties to the negotiation decide later that they are dissatisfied with the outcome.<sup>130</sup> Although perhaps a valid criticism, recording the outcome of the negotiation is obligatory for the process of negotiated consent to remain valid.<sup>131</sup>

#### IV. CONCLUSIONS

Perhaps it is a correct assessment that no meaningful collaboration or hoped-for therapeutic alliance can be achieved between doctor and patient until physicians treat patients as adults and not children; learn that there is a real distinction between the physician's ideas of best treatment and those which are seen as *best* by their patients; and, furthermore, learn how to acknowledge their own ignorance in diagnosis, as well as treatment and prognosis. Acting in such a manner will allow the patients to better understand the inherent uncertainties in both the art and science of medicine which, in turn, give rise to valid differences of belief based upon clinical experience.<sup>132</sup> Sadly, all too often, the quest for diagnosis and cure, or what has been termed "The Riddle," seduces many physicians and forces them to ignore the realities of pathological processes.<sup>133</sup>

In projecting the future of health care for the elderly, the standard of negotiated consent is undoubtedly a more desirable standard to implement for all parties involved than the traditional informed consent. Despite the assault on its viability, the imperative of negotiated consent focuses ultimately on the concept of "keep listening" as opposed to "keep talking."<sup>134</sup> This goal, even though often times difficult to achieve, may provide the elderly patient with a stronger sense of participation in the direction of his or her medical treatment and, hopefully, with a greater sense of trust and confidence, allow the "ethics of intimacy rather than the ethics of strangers [to] . . . take root and flourish."<sup>135</sup>

Seen as a normative value rather than an empirical constant,<sup>136</sup> perhaps, in reality, the consequences of the doctrine of informed consent are of less

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130. *Id.* at 68.

131. *See id.* A basic example of what should be recorded is as follows: "Family talked it over and decided in favor of trying the new treatment. Patient agreed it was best." Moody, *supra* note 24, at 68.

132. JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* xi (1986).

133. SHERWIN B. NULAND, *HOW WE DIE: REFLECTIONS ON LIFE'S FINAL CHAPTER* 249, 265 (1994).

134. Moody, *supra* note 24, at 70.

135. *Id.* at 69. *See generally* HARRY R. MOODY, *ETHICS IN AN AGING SOCIETY* (1992).

136. Schuck, *supra* note 17, at 932.

importance than the values it seeks to promote.<sup>137</sup> To be sure, the doctrine needs to be contextualized both procedurally and substantively in legal doctrine.<sup>138</sup> Setting new dialogic responsibilities for physicians, however, may not succeed in strengthening the process.<sup>139</sup> Indeed, in the present cost-conscious health care environment, such an imposition may only serve to further complicate its simple and direct mandate: namely, to provide a knowledgeable atmosphere for a therapeutic partnership or moral agency between physician and patient to occur.<sup>140</sup> In addition, without the doctrine of informed consent, there would be little opportunity to create an atmosphere in which—in health care delivery systems—both interdependence and interrelationship are acknowledged, professionally and legally, as practical normative values.<sup>141</sup>

Although the doctrine of informed consent will always remain a relative term, “with the degree of completeness resting on so many variables including, of course, the nature and reliability of the source,” it should be seen as more than an aspirational goal.<sup>142</sup> Rather, it can and indeed should serve as a useful construct for embedding the doctrine as an integral part of the ethos of medicine;<sup>143</sup> an ethos tied to a recognition of patient trust and partnership with the physician as the cornerstone of the healing enterprise<sup>144</sup> which must always seek to provide “a right and good healing action in the interests of a particular patient.”<sup>145</sup>

In the final analysis, however, it remains for the medical profession, not the legal profession, to formulate and effect a truly contemporary doctrine of informed consent, one, to be sure, that is responsive to the “proddings of the law,” but, more importantly, one that is cognizant of the very complex and nuanced interactions between patients and their physicians.<sup>146</sup>

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137. *Id.* at 939.

138. *Id.* at 951.

139. *Id.* at 935.

140. Pellegrino, *Human Person*, *supra* note 1; Pellegrino, *Autonomy*, *supra* note 1; Pellegrino, *Reconstruction*, *supra* note 2, at 74.

141. GAYLIN & JENNINGS, *supra* note 1, at 243.

142. Jeffrey S. Tobias, *Contemporary Challenges in Clinical Research: Paying Lip Service to Informed Consent, or a Genuine Shift of Gear?*, in *INFORMED CONSENT IN MEDICAL RESEARCH*, *supra* note 15, at 318-19.

143. Katz, *supra* note 18, at 91 (arguing that until the doctrine becomes an integral aspect of the ethos of medicine, it is condemned to remain a fairy tale).

144. See generally Edmund D. Pellegrino & John L. Harvey, *Whom Should the Patient Trust?*, *AM.*, Oct. 1, 2001, at 19.

145. Pellegrino, *Reconstruction*, *supra* note 2, at 47.

146. Katz, *supra* note 18, at 71. See generally KATZ, *supra* note 132.

