

2002

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### Recommended Citation

Barry Rosenfeld, *The Psychology of Competence and Informed Consent: Understanding Decision-Making with Regard to Clinical Research*, 30 Fordham Urb. L.J. 173 (2002).

Available at: <https://ir.lawnet.fordham.edu/ulj/vol30/iss1/10>

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# The Psychology of Competence and Informed Consent: Understanding Decision-Making with Regard to Clinical Research

## **Cover Page Footnote**

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# THE PSYCHOLOGY OF COMPETENCE AND INFORMED CONSENT: UNDERSTANDING DECISION-MAKING WITH REGARD TO CLINICAL RESEARCH

*Barry Rosenfeld\**

## INTRODUCTION

The role of psychology and related mental health disciplines in the informed consent process has gradually evolved from an essentially non-existent role into a central and important one. The importance of informed consent as a mechanism for protecting patient autonomy cannot be overstated. Both the ethical principals of psychologists as well as countless legal decisions have emphasized the importance of patient autonomy.<sup>1</sup> Rooted in the constitutional right to privacy, the importance of autonomy as a guiding principal in medical decision making (as in other forms of decision making) has been well established and is essentially unchallenged.<sup>2</sup>

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1. For example, Ethical Principal D in the American Psychological Association's Code of Conduct reads, "[p]sychologists accord appropriate respect to the fundamental rights, dignity, and worth of all people. They respect the rights of individuals to privacy, confidentiality, self-determination, and autonomy, mindful that legal and other obligations may lead to inconsistency and conflict with the exercise of these rights." AMERICAN PSYCHOLOGICAL ASSOCIATION OF PSYCHOLOGISTS ON ETHICAL PRINCIPLES AND CODE OF CONDUCT § 2.08, at 1599-1600 (1992).

2. Ruth Faden and Tom Beauchamp write, "[t]he constitutional right to privacy serves to protect individual autonomy; it has been invoked to prevent governmental interference with various areas of personal health care decisionmaking from abortion and contraception to treatment refusal." RUTH R. FADEN ET AL., A HISTORY AND THEORY OF INFORMED CONSENT 38 (1986). Although Faden and Beauchamp distinguish the constitutional protection of autonomy from the common law informed consent doctrine, they emphasize the concordance between these two paths, both of which serve to protect an individual's right to make independent treatment decisions. *Id.* at 39.

## I. INFORMED CONSENT

As is perhaps common knowledge for many clinicians and legal scholars, the doctrine of informed consent requires three elements to be present in order to validate medical treatment decisions.<sup>3</sup> The decision must be knowledgeable (i.e., the treatment provider must have disclosed relevant information to the prospective patient), voluntary (i.e., a decision made of the patient's own free will), and competent (i.e., by an individual with an adequate level of decision making ability). Although psychologists have been involved in providing research and clinical expertise to virtually all aspects of the informed consent process, psychology's role is most important in determining whether the patient is competent to make a treatment decision.<sup>4</sup>

The burden of the first element of informed consent, the "knowledge" element, rests with the treating clinicians. Specifically, the doctor must provide a reasonable amount of information regarding the known risks and benefits of a recommended treatment, as well as the risks and benefits of treatment alternatives. Not surprisingly, the volume of information necessary to make an informed decision varies depending on the nature and complexity of the decision at hand. Furthermore, different patients will certainly differ in the amount of information they desire. In general, however, a standard has emerged that is consistent with numerous other areas of the law: the "reasonable person" standard, or that amount of information that the typical person would find adequate and/or necessary to make such a decision.<sup>5</sup> Although psychologists have begun to use research tools to clarify the boundaries of the reasonable person standard, literature has not yet focused squarely on

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3. The essential elements of informed consent have emerged through a series of civil law decisions beginning with the seminal New York case of *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) ("[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."). See PAUL S. APPELBAUM ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 211-28 (1987); FADEN ET AL., *supra* note 2, at 22-43.

4. Although the terms "psychologists" and "psychology" are used throughout this Essay, it should be noted that these terms are intended to encompass all mental health professionals including psychiatrists and, to a lesser extent, social workers.

5. Early case law defined "reasonable" from the perspective of a typical clinician. Namely, whether a typical clinician would have made essentially the same disclosure. Since the seminal case of *Canterbury v. Spence*, 464 F.2d 772, 773 (D.C. Cir. 1972), however, courts increasingly look to the perspective of the patient to define what a "reasonable" amount of disclosure includes. Courts increasingly ask whether a typical patient would want additional information disclosed.

informed consent.<sup>6</sup> Instead, most mental health research has addressed the impact of disclosed information on treatment decisions or methods to improve comprehension and retention of disclosed information.<sup>7</sup>

Voluntariness, the second element of informed consent, pertains to the patient's decision making process. Individuals must be free to make their own decisions without undue coercion from others. Although studies of the patient's perceptions of coercion and the factors that influence this perception have begun to emerge in the psychology literature, this issue remains largely outside the domain of psychology.<sup>8</sup> Instead, defining the contours of voluntariness occurs primarily in the courts. Even so, no clear definitions or standards have been forthcoming.<sup>9</sup>

Competence, the final aspect of informed consent, is arguably the most important element of consent. Although only recently identified as a topic worthy of scientific scrutiny, the competence question has increasingly attracted the attention of the psychological sciences.<sup>10</sup> While the burden of competence falls primarily upon the decision maker, the clinician or researcher is responsible for ensuring that this requirement has been satisfied.<sup>11</sup> Importantly, the law presumes that every adult is competent to make decisions for themselves unless proven otherwise; for many individuals the burden of demonstrating competence may shift as a practical matter, if not a legal one. Mentally ill, mentally retarded, severely medically ill, and even healthy elderly adults share this burden, in that many individuals perceive their competence to be questionable.<sup>12</sup> This discussion focuses on three scenarios in which

6. See, e.g., Richard L. Wiener et al., *Social Analytic Investigation of Hostile Work Environments: A Test of the Reasonable Woman Standard*, 19 LAW & HUM. BEHAV. 263, 263 (1995).

7. See GARY B. MELTON ET AL., *PSYCHOLOGICAL EVALUATION FOR THE COURTS: A HANDBOOK FOR MENTAL HEALTH PROFESSIONALS AND LAWYERS* 352 (2d ed. 1997).

8. E.g., Steven K. Hoge et al., *Perceptions of Coercion in the Admission of Voluntary and Involuntary Psychiatric Patients*, 20 INT'L J.L. & PSYCHIATRY 167, 167-74 (1997).

9. See MELTON ET AL., *supra* note 7, at 352.

10. See generally TOM GRISSO & PAUL S. APPELBAUM, *ASSESSING COMPETENCE TO CONSENT TO TREATMENT: A GUIDE FOR PHYSICIANS AND OTHER HEALTH PROFESSIONALS* 1-11 (1998).

11. Some writers, such as Celia Fisher, in this Volume, have suggested that this standard places an unreasonable burden on patients in order to maintain their autonomy. Celia B. Fisher, *A Goodness-of-Fit Ethic for Informed Consent*, 30 FORDHAM URB. L.J. 159, 160 (2002). Such criticisms, however, have not been widely recognized.

12. See GRISSO & APPELBAUM, *supra* note 10, at 61-99.

questions of competence, and the role of the mental health professional, play a central role.

## II. LEGAL STANDARDS, CLINICAL ASSESSMENTS

Separating legal theory and clinical decision-making is necessary to any discussion of legal and ethical principals guiding real-world situations. Among the many crucial distinctions, few are as important as the distinction between law and clinical practice.<sup>13</sup> Although the decision-making capacity is clinical, determinations of competence are legal conclusions that are based only partially on clinical input.<sup>14</sup> Until a judge has declared an individual incompetent, the law's presumption of competence remains.<sup>15</sup> Moreover, when determinations of incompetence are rendered, they are typically situation-specific, pertaining to only a single issue or decision (although some individuals might be declared incompetent for a broad range of purposes).<sup>16</sup> Third, although the responsibility for determining whether an individual is competent or incompetent rests with a judge, formal proceedings to determine competence are relatively rare. Instead, most questions about competence are handled in a more informal manner.<sup>17</sup> For example, the treating clinician may simply defer to the wishes of an available family member whenever a patient's competence is deemed inadequate.<sup>18</sup> Finally, decisions regarding a patient's decision-making capacity are often heavily influenced by the input and opinions of a psychologist or psychiatrist.<sup>19</sup> Most judges look toward mental health professionals for guidance to determine when an impairment exists and the extent of such an impairment.<sup>20</sup> With these facts in mind, exploring the role of psychologists in resolving what appears to be complex ethical dilemmas becomes somewhat clearer.

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13. See MELTON ET AL., *supra* note 7, at 3-25 (detailing the vastly differing world views of lawyers as clinicians).

14. See *id.* at 129 ("The determination of a legal competency is a legal, not a clinical, decision.").

15. See Bruce J. Winick, *The MacArthur Treatment Competence Study: Legal and Therapeutic Implications*, 2 PSYCHOL. PUB. POL'Y & LAW 137, 152 (Mar. 1996) ("Modern legal approaches generally presume that people are competent to make decisions unless they have adjudicated incompetent to do so.").

16. See, e.g., APPELBAUM ET AL., *supra* note 3, at 82-83.

17. See *id.* at 90-93, 101-02.

18. See GRISSE & APPELBAUM, *supra* note 10, at 157 ("When patients have not completed advanced directives, the usual recourse is to ask family members to make decisions on their behalf.").

19. See, e.g., APPELBAUM ET AL., *supra* note 3, at 83-84.

20. MELTON ET AL., *supra* note 7, at 129; see APPELBAUM ET AL., *supra* note 3, at 104.

The hypothetical cases that serve as the focal point for this analysis have been previously described by Celia Fisher in this Volume and are only summarized in brief here.<sup>21</sup> These cases highlight several of the issues noted above. The cases outline the parameters of “competence” by illustrating the methodologies used in making these determinations, distinguishing between ethical and legal issues in the assessment of competence, and reviewing the procedures for surrogate decision making when competence is deemed impaired.

### A. Case One—Deteriorating Competence Over the Course of Study Participation

The first case described concerns a mentally ill woman, (whom we refer to as “Alice”), who has agreed to participate in a research study in which the standard treatment for her disorder, antipsychotic medications, are being withheld. In this scenario, the participant’s parents have requested that her participation be terminated because of their fears that her condition has deteriorated. The dilemma facing the study’s investigators is whether or not to accede to the parents’ wishes, or to respect Alice’s initial consent (which, conveniently, furthers their own research interests). This case is based on an actual study that generated significant scrutiny in the public press and academic community,<sup>22</sup> yet the ethical and legal issues are somewhat more complex than the media accounts suggested. The primary issue in this case pertains to the decision making competence of Alice, the schizophrenic woman described in the vignette. As noted earlier, valid informed consent requires that a decision maker be competent when they provide consent.<sup>23</sup> Assuming that Alice was informed of the nature of this research study, or the risks and benefits of study participation, and was allowed to make the decision voluntarily, the issue

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21. The order of presentation differs from that contained in Fisher, *supra* note 11, at 167-70, but the essential “facts” of these cases remains identical. These same cases have also been discussed elsewhere, although the focus of that discussion was different. See generally Barry Rosenfeld, *Competence to Consent to Research: Where Psychology, Ethics and the Law Intersect*, in *The Forum*, 12 ETHICS & BEHAV. 284, 284-87 (2002).

22. The study was entitled *Developmental Processes in Schizophrenic Disorders* and was directed by Keith H. Nuechterlein and Michael Gitlin at U.C.L.A. Medical Center. For an account and critic of this study, see Jay Horowitz, *For the Sake of Science*, L.A. TIMES, Sept. 11, 1994, (magazine), at 16; see also James Willwerth, *Did a UCLA Experiment Deliberately Allow a Schizophrenic to Fall Into a Severe Relapse?*, TIME, Aug. 30, 1993, at 40.

23. See *supra* notes 10-12 and accompanying text.

of her competence at the time she made the decision becomes central. Although the research investigators are legally required to assess Alice's decision making competence only when her competence is in question,<sup>24</sup> the requirement is ambiguous in practice.<sup>25</sup> Given the importance of Alice's decision to participate, permitting a woman with a severe mental disorder to consent to a potentially risky experiment *without* first assessing her capacity to make a rational decision in this matter is clearly problematic. Thus, it is probably (or hopefully, at least) reasonable to assume that Alice's decision to consent to this study, at the time she agreed, was a competent one.

Assuming Alice's consent was valid, the request on her parents' part to discontinue their daughter's participation in the study has no legal standing.<sup>26</sup> Furthermore, an assessment of her competence to *continue participating* is not necessary. Although her parents are certainly free to convey their concerns to the study personnel, their challenge to Alice's consent is not justified since Alice's initial decision to participate was a competent one. First, competence to consent to treatment is typically at issue only at the outset of a study (or course of treatment), not an ongoing requirement of study participation.<sup>27</sup> Alice was no doubt aware that she might begin to show renewed psychotic symptoms, and she was presumably aware of the risks and benefits of this outcome. Moreover, as a competent adult, Alice has the right to consent to or refuse whatever medical treatments or research studies she chooses.<sup>28</sup> Thus, even if the research investigators fear repercussions from public scrutiny or legal action brought by Alice's parents, they are actually obligated to follow Alice's request to participate in the study as long as she continues to agree to participate.<sup>29</sup>

On the other hand, if Alice changes her mind and requests that the study be discontinued, the situation becomes far more complex. Although ethicists generally agree that even an incompetent per-

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24. Special requirements are included in the regulations regarding competency to consent to research. See MELTON ET AL., *supra* note 7, at 357; see also 45 C.F.R. § 46.111(b) (2001).

25. Most investigators would routinely assess the prospective patient's capacity to consent in this situation. See generally MELTON ET AL., *supra* note 7, at 357.

26. *In re K.K.B.*, 609 P.2d 747, 752 (Okla. 1980) (upholding autonomous decision-making capacity of mentally ill person).

27. *Id.*

28. *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

29. *In re Storar*, 420 N.E.2d 64, 70 (N.Y. 1981).

son should have to *assent* to participate in any research study offered, even if they are not capable of providing valid informed consent, the nature of this situation complicates this issue considerably.<sup>30</sup> Assuming Alice is now more symptomatic, perhaps even to the point of incompetence, her decision to withdraw might plausibly be viewed as an *incompetent* decision and should perhaps be ignored by study personnel. If the investigators were to accede to Alice's now-incompetent request to terminate study participation, they would essentially be overriding the preferences of a competent decision maker (Alice at the time she provided consent), in favor of an incompetent one (Alice in her present, symptomatic state). Hence, while ethics might dictate that Alice be allowed to withdraw, the law could very well be interpreted to require the opposite. In the present case, the parents' request that Alice's participation in the study be terminated should be respected. Even though Alice herself may not be competent to decide whether to terminate her participation, her parents would probably be the parties seeking legal remedies for malpractice or mistreatment on her behalf.

The conflict between the previously expressed wishes of a competent individual and the current wishes of an incompetent one are even clearer in a situation where the consent issues have been reversed, although the likely outcome is quite different. Imagine that Alice, while competent, had refused to participate in the research study after being informed of the risks and benefits of the study. Then, after her condition had deteriorated, and with the continued pressure from either her family or the research investigators, Alice changed her mind and agreed to participate in the study that she had previously refused. It is hard to imagine any clinician, lawyer, or ethicist accepting this consent as a valid change of heart. Instead, the investigators would be seen as highly unethical for having manipulated an incompetent individual into agreeing to

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30. The National Bioethics Advisory Council ("NBAC"), convened by President Clinton, specifically recommended that any incompetent person be given the opportunity to refuse research participation even if she have been deemed incompetent and a legally-appointed surrogate has consented. This recommendation emphasizes the importance of "assent," whereby even incompetent persons must be willing to participate in research. The recommendations of the NBAC, while influential for many ethicists, have no formal legal standard and have not been adopted by any agency. The NBAC was a purely advisory committee whose commission ended on October 3, 2001. See Nat'l Bioethics Advisory Comm'n, (Oct. 20, 1999), available at <http://www.georgetown.edu/research/nrcbl/nbac/about/nbaccharter.pdf>; see also <http://www.georgetown.edu/research/nrcbl/nbac/> (announcing Commission's and the charter's expiration date).

participate in a research study.<sup>31</sup> In sum, although this vignette has a number of elements that would concern most ethicists, the essential elements of this case are relatively clear. Although competence is a variable quality that often waxes and wanes with the symptoms of a mental disorder, a competent individual's consent is typically considered to be lasting, even after an individual's mental state has deteriorated to the point where she is no longer able to make rational treatment decisions.<sup>32</sup>

### B. Case Two—Coercion and Competence

The second vignette is in many ways clearer, but nevertheless raises a number of important psycho-legal issues. To begin with, it is important to reiterate the distinction between a clinical assessment of incapacity and a legal determination of incompetence.<sup>33</sup> This vignette describes a man, John, with mild mental retardation who has refused to participate in a research trial of a new anti-aggressive drug. The issue of whether John's refusal is legally valid hinges on his competence to make medical treatment decisions.<sup>34</sup> Since competence to make treatment decisions is a legal determination, John either *is* or *is not* legally authorized to make this decision for himself.<sup>35</sup> However, it is more likely that the issue of John's competence has never been adjudicated and he is simply permitted to make decisions for himself, provided he agrees with the recommendations of his doctors.<sup>36</sup> If the latter scenario applies, then presumably the first step in this process would entail a clinical evaluation of John's decision making capacity. The specific methods for conducting this analysis are beyond the scope of this commentary. The methods essentially involve assessing the extent to which he understands the relevant risks and potential benefits of

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31. The investigators may also be legally liable for any damages caused by Alice's subsequent participation in the research study if they accept Alice's "change of heart" when she is clearly not competent to make such a decision.

32. Some prominent writers have suggested that an ongoing assessment of competence is appropriate whenever decisional capacity is likely to fluctuate (Nat'l Inst. of Health, Research Involving Individuals with Questionable Capacity to Consent: Points to Consider, at <http://grants.nih.gov/grants/policy/questionablecapacity.htm>, (last visited Oct. 7, 2002)), but this suggestion is neither supported by case law, nor generally accepted by medical ethicists or legal scholars.

33. See *supra* note 14 and accompanying text.

34. MELTON ET AL., *supra* note 7, at 308 (citing Zinermon v. Burch, 494 U.S. 113, 135-36 (1990)).

35. John's competence to make such decisions depends on whether he is found legally competent in a civil proceeding. MELTON ET AL., *supra* note 7, at 350.

36. See *id.* at 347.

the proposed treatment, as well as the risks and benefits of alternatives, whether he appreciates the implications of the decision, and is able to make a reasoned choice that is logically consistent with his values and goals.<sup>37</sup> Although the ultimate determination will be made by a judge, the legal decision will undoubtedly be heavily influenced by the opinion of a clinical psychologist or psychiatrist who has evaluated John's decision making capacity. However, once a decision has been reached as to John's competence, the legal issues become much simpler.

If John is not found competent, *his* consent is really not the central issue.<sup>38</sup> The decision as to whether he can be enrolled in the study would rest with his appointed surrogate decision maker (typically a family member or independent third party). If the surrogate decision maker gave their consent despite John's objection,<sup>39</sup> then yet another dilemma would emerge whereby the refusal of the incompetent patient was being overruled. Arguably, despite the frequent deference given to the wishes of even incompetent individuals, this situation might be one in which John's objection could be overruled simply because of the "stakes" involved in this decision.<sup>40</sup>

However, assuming that John is considered competent to make this treatment decision, his refusal would have to be considered valid despite the possible negative repercussions from continued aggressive behavior.<sup>41</sup> Further, in this scenario, the intimation that John would lose his placement in a residential facility *because* he refused to consider unproven, possibly unhelpful, research medications raises obvious ethical issues. Although John can certainly be removed from a residence because of inappropriate behaviors, framing a research study in this context suggests a clear use of coercion to influence this decision process which is obviously in violation of the informed consent standard.<sup>42</sup>

37. See GRISSE & APPELBAUM, *supra* note 10, at 7; see also PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBS. IN MED. & BIOMED. & BEHAV. RES., MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 17-23 (1982).

38. *But see supra* note 31 and accompanying text (discussing the importance of *assent* in situations where an incompetent person is participating in experimental research).

39. Hopefully, the surrogate decision-maker would be influenced, although not absolutely limited by, John's opinions.

40. See FADEN ET AL., *supra* note 2, at 16-20.

41. See MELTON ET AL., *supra* note 7, at 357.

42. See FADEN ET AL., *supra* note 2, at 337-73 (discussing coercion, manipulation, and persuasion).

Although legal responses to John's decisions according to his competence or incompetence seem relatively simple, the reality of these dilemmas are somewhat more complex. Despite John's mental retardation, it is quite likely that his competence to make medical treatment decisions has never been adjudicated. More likely, John has been allowed to make decisions for himself whenever he agreed with the recommendations of his doctors. His competence is only now being questioned because he is refusing his doctors' recommendations. If John's condition (mild mental retardation) has been essentially stable throughout his lifetime, the fact that his decisions have previously been accepted arguably creates *de facto* evidence of his competence. In other words, he should be considered competent to make decisions that do not conform to his doctors' recommendations because his treating clinicians have always presumed him to be competent. Nevertheless, regardless of the history behind John's prior decisions, if his competence has not been previously adjudicated and is now being questioned legally, the starting point must be with a clinical evaluation of his decision-making capacity, and only after this evaluation has been completed will the outcome of the situation be clear.<sup>43</sup> Importantly, under no circumstance does the residence supervisor have any authority to make decisions on John's behalf.<sup>44</sup>

### C. Case Three—Advance Directives for Research

The third vignette is perhaps the most complex, in part because of the legal ambiguity of the advance directives<sup>45</sup> for research. In this scenario, Nina, an elderly woman with Alzheimer's disease has specified in her "living will" that she prefers to participate in any research study that might offer some hope of benefit. Although advance directives for treatment (or the refusal of treatment) are

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43. See GRISSE & APPELBAUM, *supra* note 10; see also MELTON ET AL., *supra* note 7, at 356-58.

44. See GRISSE & APPELBAUM, *supra* note 10; see also MELTON ET AL., *supra* note 7, at 356-58.

45. Advanced directives are documents signed by a competent person giving direction to health care providers about treatment choices in certain circumstances. There are two types of advanced directives. The first type, the durable power of attorney for health care ("durable power"), allows the patient to name a "patient advocate" to act for her and carry out her wishes. The second type, a living will, allows the patient to state her wishes in writing, but does not name a patient advocate. Univ. of Mich. Health Care Sys., *Legal Concerns: Advance Directives/Living Wills*, available at <http://www.med.umich.edu/1libr/topics/legal06.htm> (last visited Sept. 15, 2002).

well established and widely utilized,<sup>46</sup> the status of advance directives for research is more equivocal. Whereas advance directives for treatment can specify with some degree of clarity what the treatment in question entails, few research studies are known far enough in advance to enable a prospective subject to provide informed consent to a specific study. Instead, advance directives for research typically provide somewhat ambiguous guidance for a surrogate decision-maker, informing them merely of the disabled person's willingness to participate in research in general or a particular type of research. Although the vignette does not indicate whether Nina's advance directive specified her interest in participating in the type of research currently at issue, the legitimacy of her advance directive is, at best, questionable. As a result, Nina's children are certainly within their authority to challenge Nina's advance directive.

However, Nina's advance directive would not likely be at issue until after her condition had deteriorated to the point of incompetence. At that time, a surrogate decision-maker would have to be appointed to make decisions on Nina's behalf.<sup>47</sup> In most instances, Nina's children would be appointed as surrogate decision-makers, but the possibility also exists that a third party might be appointed. In either case, the standard for guiding the proxy's decisions will differ depending on the jurisdiction. Some states apply the "best interest" standard, in which decisions are supposed to reflect the patient's best interest.<sup>48</sup> Other states apply a "substitute judgment" standard in which decisions are intended to replicate the decision the patient would have made.<sup>49</sup> Although judges in a jurisdiction following the substitute judgment standard would give Nina's advance directive considerable weight, her wishes might also be influential in a jurisdiction following a best interest standard.

It is also possible that a judge could consider Nina's advance directive to be valid. Even so, her children might still challenge the appropriateness of any particular research study by arguing that

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46. Seventy-five percent of Americans are in favor of advanced directives. In fact, twenty-five to thirty percent of Americans have actually prepared an advanced directive. US Living Will Registry, *U.S. Living Will Registry Fact Sheets*, available at <http://www.uslivingwillregistry.com/factsheet.shtm> (last visited Oct. 30, 2002).

47. ALAN MEISEL, *THE RIGHT TO DIE* § 10.7 (2d ed. 1989).

48. See *Conservatorship of Drabick*, 245 Cal. Rptr. 840, 852-53 (Cal. Ct. App. 1988).

49. For further discussion and analysis on the "substitute judgment" standard, see *In re Fiori*, 652 A.2d 1350, 1371 (Pa. Super. Ct. 1995).

their mother would not have consented to that particular study were she still competent. Again, as the individuals most familiar with Nina's personal preferences and values, her children's opinions would weigh heavily in any decision regarding what Nina would have wanted were she still competent. Ultimately, however, the preferences of Nina's children have relatively little legal authority unless they are formally appointed as surrogate decision-makers.<sup>50</sup> Thus, knowing that her children are opposed to her advance directive, Nina would probably be better served by specifying a health care proxy in advance. A health care proxy would most likely insure that her wishes are carried out after her mental state has declined.<sup>51</sup>

However, even in a scenario in which Nina's children have essentially no legal standing, their opinions might nevertheless dictate treatment simply because of their presence and vocal opposition. Physicians and researchers are often reluctant to challenge family members who are adamantly opposed to a course of action because of the fear of possible litigation. Clinicians are often more beholden to individuals who are present and vocal (and potentially litigious if ignored) than they are to written dictates of questionable authority. Thus, although the legal authority of Nina's children may be questionable or non-existent in the present scenario, their influence might nevertheless be substantial.

#### SUMMARY

The scenarios described above highlight a number of important issues in which psychology, ethics, and the law intersect. First, all three scenarios illustrate the difference between legal authority and practical reality. Family members often have less legal standing than they would like, and are often unhappy with the limitations of their authority. Furthermore, their influence is often far more substantial than their legal standing would suggest. Fear of litigation or claims of unethical practice can dwarf the privileges of legal authority. In addition, although the principals of autonomy guide many of the decisions made on behalf of incompetent individuals, balancing the need to preserve autonomy with the desire to protect incompetent decision-makers is fraught with difficulties. Researchers studying individuals of questionable competence have both an ethical and legal obligation to insure that their subjects

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50. See *supra* notes 46-49 and accompanying text.

51. See *supra* notes 46-49 and accompanying text.

have received adequate protection. Researchers must support the decision making authority of a competent individual and protect that individual against abuses when they are not.

