Bioethics and Law: The Second Stage – Balancing Intelligent Consent and Individual Autonomy

Judith C. Areen
Georgetown University Law Center, areen@law.georgetown.edu

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Essays


Judith C. Areen

In 1758, David Hume pointed to a curious feature of government: Nothing is more surprising to those, who consider human affairs with a philosophical eye, than to see the easiness with which the many are governed by the few; and to observe the implicit submission with which men resign their own sentiments and passions to those of their rulers. When we enquire by what means this wonder is brought about, we shall find, that as Force is always on the side of the governed, the governors have nothing to support them but opinion. 'Tis therefore, on opinion only that government is founded; and this maxim extends to the most despotic and most military governments, as well as to the most free and most popular.

The opinions or fictions that sustain governments are not fixed for all time. When the American colonies were founded, most Englishmen believed that men were created unequal and that they owed obedience to government because God had authorized the king to rule. It was as unthinkable in the sixteenth and early seventeenth century for a subject to challenge the author-

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1. Professor of Law and Dean, Georgetown University Law Center. A.B. Cornell University 1966; J.D. Yale Law School 1969. This article is a revised version of the Marks Memorial Lecture delivered by the author on March 7, 1989.

ity of the king as it would be for an arm or a leg to challenge the head for control of a person’s body.3 By the end of the seventeenth century, however, the principle that government depends on the consent of the governed was overtaking belief in the divine right of kings. Its most forceful defender was John Locke in his *Second Treatise on Government.*4

The nature and timing of the transition from divine right to popular sovereignty is a subject that continues to divide historians.5 Lawrence Stone points to the quiet abandonment by the English state in 1641 of the officially sanctioned use of torture to extract information from political suspects as evidence of the widening acceptance of the idea that individuals have certain rights that a sovereign should not violate.6 Yet as late as July 21, 1683, the University of Oxford adopted a decree condemning certain “damnable doctrines,” including the proposition that “all civil authority is derived originally from the people.”7 In the unanimous view of the faculty and administration of Oxford, this was one of several doctrines “repugnant to the Holy Scriptures, . . . destructive of the kingly government, the safety of his Majesty’s person, the public peace, the laws of nature and bonds of human society.”8 Nonetheless, by the eighteenth century, the damnable doctrine was so widely accepted that Hume could simply assume that no one continued to support the divine right of kings9, and the revolutionaries in America enshrined the doctrine in the founding documents of our nation.

Americans soon moved on to the more practical problem of how to make the concept of popular sovereignty work. With the extension of the franchise in this country10, elections became the primary method, albeit an imperfect one, of determining the will of the people. The declining propor-

3. “The king towards his people is rightly compared to a father of children, and to a head of a body composed of divers members . . . .” JAMES VI AND I, THE TREW LAW OF FREE MONARCHIES (1598), reprinted in, DIVINE RIGHT AND DEMOCRACY: AN ANTHOLOGY OF POLITICAL WRITINGS IN STUART ENGLAND 99 (D. Wootton ed. 1986) [hereinafter DIVINE RIGHT].


5. For example, historians still debate whether Locke was the first to enunciate a true theory of popular sovereignty. Some have pointed to the *Defensor Pacis* of Marsilius of Padua, one of the conciliarist opponents of papal power, as an earlier source, but others argue that Marsilius did not support true popular sovereignty. See, e.g., Introduction to DIVINE RIGHT, supra note 3, at 50. Julian Franklin believes no comparable theory can be found prior to George Lawson’s *Politica of 1657.* J. FRANKLIN, JOHN LOCKE AND THE THEORY OF SOVEREIGNTY (1978). K. Thompson, by contrast, points to Maximilian Petty, who spoke on behalf of the Levellers during the Putney Debates. *THE LEVELERS AND THE FRANCHISE, reprinted in, THE INTERREGNUM: THE QUEST FOR SETTLEMENT 1646-1660* 57-78 (G. Aylmer ed. 1972).


7. DIVINE RIGHT, supra note 3 at 120.

8. *Id.*

9. In 1741 Hume wrote “the mere name of king commands little respect; and to talk of a king as GOD’s viceroyent upon earth, or to give him any of those magnificent title 5, which formerly dazzled mankind, would but excite laughter in everyone.” Whether the British government inclines more to Absolute Monarchy, or to a Republic, in ESSAYS AND TREATISES ON SEVERAL SUBJECTS 35 (London, 1758), cited in E. MORGAN, supra note 2 at 151.

tion of the citizenry that bothered to vote in our national elections in the 1980's is one sign of just how imperfect a principle popular sovereignty is. But the power of the principle should not be discounted simply because it has not been fully realized. In Professor Morgan's words, popular sovereignty is "a goal to be sought, never attainable, always receding, but approachable and worth approaching." It is an ideal that has captured the imagination not only of this country, but of growing numbers of peoples around the globe.

The principle that government rests on the consent of the governed eventually spread beyond the political arena to alter such private behavior as the relationship between physician and patient. This Article examines the successive transformations of the principle of consent as it has developed in the field of law and bioethics from bare consent to informed consent, and then, more strikingly, to beyond informed consent. This most recent form of the principle may prove to be every bit as revolutionary as the idea of popular sovereignty in 17th century England.

I. THE FIRST STAGE: INFORMED CONSENT

Before this century, the idea of a physician obtaining consent from a patient was as novel in the practice of medicine as was consent by the governed in politics in the early seventeenth century. In the treatise Decorum that accompanied the Hippocratic Oath, for example, physicians were advised to "perform all things calmly and adroitly, concealing most things from the patient while you are attending him." Further on, physicians were counseled to treat the patient with solicitude, "revealing nothing of the patient's present and future condition."

Not until the early 1900's, in Mohr v. Williams did American courts explicitly adopt the principle of lay consent. The opinions suggest that the developing doctrine of consent in the political realm influenced the courts when they tackled the relationship of physician and patient. In Mohr, for

11. E. MORGAN, supra note 2 at 306.
12. Pernick has pointed to the eighteenth century pronouncements of Benjamin Rush and his teacher, John Gregory of the University of Edinburgh as evidence of early consent practices. Pernick, The Patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy, in President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 3 MAKING HEALTH CARE DECISIONS 5 (1982). Katz has persuasively challenged this claim, however, explaining "Like Gregory, though somewhat more inconsistently, Rush too favored deception whenever enlightenment was not equal to the task of managing the physician-patient relationship." J. KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 16 (1984).
14. 95 Minn. 261, 104 N.W. 12 (1905), overruled on other grounds Bang v. Charles T. Miller, 251 Minn. 427, 88 N.W.2d 186 (1958) and Genzel v. Halvorson, 248 Minn. 527, 80 N.W.2d 854 (1957).
example, the court used the term “citizen” to identify the source of a patient’s autonomy:

The free citizen’s first and greatest right, which underlies all others—the right to himself—is the subject of universal acquiescence and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise and prescribe (which are at least necessary first steps in treatment and care), to violate without permission the bodily integrity of his patient by a major or capital operation, placing him under anaesthetic for that purpose, and operating on him without his consent or knowledge.16

By 1957, however, mere consent was held to be inadequate by a court in *Salgo v. Leland Stanford Jr. University Board of Trustees.*17 Martin Salgo was a 55-year-old man who suffered from leg cramps. The physician recommended aortography to see whether he had occlusion of the abdominal aorta, and Salgo consented to it. When Salgo awoke the morning after the procedure, he could not move his legs. He claimed that his paralysis, which proved to be permanent, was caused by negligent performance of the aortography.18 He also claimed that the physicians had negligently failed to warn him of the risk of paralysis, and that, if he had been fully informed, he would not have consented to undergoing the procedure.19

The opinion of the California District Court of Appeal in *Salgo* launched the attack on bare consent with these words: “[a] physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an *intelligent consent* by the patient to the proposed treatment.”20 In the court’s discussion this more stringent requirement of “intelligent consent” was also expressed as a requirement of “informed consent.”21 It was this later formulation that has since been enthroned in the pantheon of immortal, albeit vague, legal doctrines.

Jay Katz has traced the origin of the adoption of the principle of informed consent. Ironically, it was submitted to the *Salgo* court in an *amicus curiae* brief prepared on behalf of the American College of Surgeons. Thus the concept that some physicians consider to be a kind of plague visited on them by the legal profession was first proposed to the courts by a medical group.22

The potential implications of the call for “informed” or “intelligent consent” were and are simply staggering. Franz Ingelfinger, in his classic essay “Informed (But Uneducated) Consent,”23 first elucidated the difficul-

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18. *Id.*
19. *Id.* at 578, 317 P.2d at 181.
20. *Id.* at 578, 317 P.2d at 181.
21. *Id.*
22. J. KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT 60 (1984). According to one of the brief’s authors, Paul Gebbard of Vedder, Price, Kaufmann and Kammholz, a Chicago law firm, the “broad-brush duty implied by the language of the brief was fully endorsed by the College at the time.” R. FADEN AND T. BEAUCHAMP, supra note 15 at 145 n.37.
ties of achieving intelligent consent:

Chances are remote that a [volunteer in a medical experiment] really understands what he has consented to—in the sense that the responsible medical investigator understands the goals, nature, and hazards of his study. . . . How can he appreciate the sensation of living for days with a multi-lumen intestinal tube passing through his mouth and pharynx? How can he interpret the information that an intravascular catheter and radiopaque dye injection have an 0.01 per cent probability of leading to a dangerous thrombosis or cardiac arrhythmia?”

It is not surprising, therefore, that courts began to focus almost exclusively on disclosure of information as the key to judging whether the consent obtained by a physician was “informed” or “intelligent” and leaving to one side the much more elusive matter of the patient’s actual subjective understanding.

To underscore the potentially revolutionary nature of the California court’s conclusion that it is not sufficient simply to obtain the consent of a patient to treatment, but that the consent must be preceded by appropriately full disclosure, consider what would happen if citizens were required to give “intelligent” or “informed consent” in elections. It might prove necessary to provide formal written disclosures of the risks posed by a particular candidate, and detailed discussion of alternative candidates and their views, and then to ask voters to sign a form indicating that they had read the information.

More than fifty years passed between the adoption of a consent requirement in *Mohr* and the rejection of mere consent in *Salgo*, the decision that inaugurated the first stage of the interaction between bioethics and law. In only seventeen more years, *Salgo*, itself, was eclipsed by an even more powerful principle: informed consent is also not enough.

II. THE SECOND STAGE: BEYOND INFORMED CONSENT

In 1974, the Department of Health, Education and Welfare (since reorganized into the Department of Health and Human Services or “HHS”) issued the first comprehensive federal regulations governing research involving human subjects. They marked the beginning of the second stage of the development of bioethics and law, for the regulations require researchers who are working with human subjects to do more than obtain informed consent.

The heart of the regulations is the establishment of Institutional Review Boards (IRBs). Each institution that sponsors research funded by HHS is required to establish its own IRB. Each IRB must have at least five members, and the members must represent both genders and more than one profession. At least one member must be a nonscientist, such as a lawyer, ethicist, or member of the clergy, and at least one must be affiliated outside

24. *Id.* at 465-66.
25. 39 Fed. Reg. 18,914 (1974). The regulations have been amended several times since. All references are to the most current form of the regulations which are set forth in 45 C.F.R. § 46 (1988). The regulations apply only to research funded or conducted by the Department.
the institution sponsoring the research.26

Each research project that is subject to the regulations must be approved in advance by the appropriate IRB. In granting approval, an IRB is required to determine that "informed consent will be sought from each prospective subject or the subject's legally authorized representative."27 The IRB is required to do more than ensure that informed consent will be obtained, however. First, it must determine that risks to the subjects have been minimized "by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes."28 Second, the IRB is required to determine that the risks to the subjects are "reasonable" when considered in relation to the anticipated benefits to the subjects, if any, and the importance of the knowledge that may reasonably be expected to result.29 Thus even if a researcher is able to find willing subjects who give their informed consent to participation in research, before the researcher can proceed the IRB is required to make an independent determination that (i) the research design has reduced risk to the extent reasonably possible in view of the purpose of the research, and (ii) that the research is worth the remaining risk it poses to the subjects.

Unfortunately, there is little systematic information available about how well the IRBs are performing their duties.30 My experience serving on the IRBs of a private research university and of a public agency, however, is that the very process of presenting a protocol for advance review to a committee assembled for the purpose of avoiding undue risk to the subjects has done more to raise the consciousness of both researchers and IRB members about these issues than might be expected from a regulatory process that vests so much discretion in each local institution.

There is a clear need for a comprehensive review of how IRBs are performing their regulatory duties. There is also a need to develop an on-going mechanism for IRBs to share their experience. Ideally, a national system should be established for collecting and reporting significant IRB decisions, thereby facilitating the development of a kind of common law of IRB decisions. The system should include appropriate incentives for each IRB to supply its fair share of reports to the common pool. The principle embodied in the federal regulations that informed consent is not enough soon spread beyond medical research. There are any number of examples that could be

27. 45 C.F.R. § 46.111(a)(4). There are a few narrow exceptions set forth in 45 C.F.R. § 46.116(d), but they need not detain us here.
29. 45 C.F.R. § 46.111(a)(2).
30. The best data available is now quite old. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978), that was established by Congress to investigate the ethics of research, sponsored a study of IRBs that was conducted by the Survey Research Center at the University of Michigan. Their findings are discussed in Gray, Cooke, and Tannenbaum, Research Involving Human Subjects: The Performance of Institutional Review Boards in Assessing This Empirical Study, 201 SCIENCE 1094 (1978).
used to illustrate this change. I will focus on two: (1) contracts for surro-
gacy and (2) decisions to withdraw or withhold life-saving treatment.

(a) Contracts for Surrogacy

On February 6, 1985, Mary Beth Whitehead and William Stern entered
into a surrogacy contract in which he agreed to pay her $10,000 after the
birth and delivery to him of a child conceived via artificial insemination us-
ing his sperm. The parties were brought together after both responded to
advertisements placed by the Infertility Center of New York. Baby M was
born March 27, 1986. Mrs. Whitehead realized, almost from the moment of
birth, that she could not bear to part with Baby M. She refused to give the
baby to the Stems and rejected the agreed upon fee. Mr. Stern and his wife
sued in the New Jersey courts for delivery of the child and obtained an ex
parte order requiring Mrs. Whitehead to hand over the baby.\(^\text{31}\) Mrs. White-
head and her husband fled to Florida with the baby, but were eventually
tracked down. The trial court, after a 32 day trial, held that the surrogacy
contract was valid, gave custody of Baby M to Mr. Stern and his wife, and
terminated Mrs. Whitehead’s parental rights.\(^\text{32}\) Polls at the time indicated
that almost 70% of Americans agreed with the lower court that surrogate
mothers should have to abide by their agreements.\(^\text{33}\) After all, a contract is
a contract. Marybeth Whitehead had given her consent, and that consent
should be enforced by the courts.

Mrs. Whitehead appealed to the New Jersey Supreme Court, which on
February 3, 1988, reversed the lower court and held the contract invalid and
unenforceable.\(^\text{34}\) The higher court declared explicitly that consent was not
enough:

The point is made that Mrs. Whitehead agreed to the surrogacy
arrangement, supposedly fully understanding the consequences. . . .
[W]e suggest that her consent is irrelevant. There are, in a civilized
society, some things that money cannot buy. In America, we decided
long ago that merely because conduct purchased by money was “vol-
untary” did not mean that it was good or beyond regulation and prohi-
bition. Employers can no longer buy labor at the lowest price they can
bargain for, even though that labor is “voluntary,” or buy women’s
labor for less money than paid to men for the same job, or purchase the
agreement of children to perform oppressive labor, or purchase the
agreement of workers to subject themselves to unsafe or unhealthful
working conditions. There are, in short, values that society deems
more important than granting to wealth whatever it can buy, be it la-
bor, love or life.\(^\text{35}\)

I think the court was right to refuse to recognize the surrogacy con-

\(^{31}\) In re Baby M, 109 N.J. at 416, 537 A.2d at 1237.
\(^{32}\) Id. at 417, 537 A.2d at 1237-38.
\(^{33}\) Sixty-nine percent of the 1,045 adults interviewed by phone said surrogate mothers should
have to abide by the agreements they had signed. Poll Shows Most in U.S. Back Baby M Ruling,
\(^{34}\) In re Baby M, 109 N.J. 396, 537 A.2d 1227 (1988).
\(^{35}\) Id. at 440-41 (citations omitted).
tract, although not because it is analogous to a contract for child labor or unsafe working conditions. It is true that moving reproduction out of the family and into the marketplace may lead to economic exploitation of some women because women as a group in our country remain economically more vulnerable than men. In fact, concern with such exploitation led to the condemnation of surrogacy by a majority of a committee established to examine the implications of human assisted reproduction developments, known as the Warnock Committee. The Committee explained: "[e]ven in compelling medical circumstances the danger of exploitation of one human being by another appears to the majority of us far to outweigh the potential benefits, in almost every case. That people should treat others as a means to their own ends, however desirable the consequences, must always be liable to moral objection."

But the argument that women should be denied freedom to contract to provide surrogacy services is a risky one to advance. It raises the specter of a return to past centuries when the common law denied married women the authority to make any contracts. Arguments about economic exploitation imply that all potential surrogates, individually and collectively, lack the capacity to pursue their own legitimate objectives through contract, and thus carry the risk of perpetuating negative stereotypes. A better alternative would be to prohibit only those surrogacy contracts that are exploitative. A state might decide, for example, to honor only contracts that paid the surrogate at least the minimum wage for her services, whether or not the child was born alive.

There is a second risk that results from moving procreation from the family to the marketplace—the risk that surrogacy poses to the most vulnerable participant in a surrogacy agreement—the anticipated child. The child conceived in surrogacy who best illustrates my point is not Baby M, but Christopher Ray Stiver, born six years ago in Michigan with a strep infection and suffering from microcephaly, a congenital disorder that commonly is accompanied by mental retardation. When Alexander Malahoff, the surrogate father, ordered the hospital not to treat or care for the child, the physicians in attendance at the birth were forced to obtain a court order in order to treat the child's infection. Later, Malahoff denied paternity and responsibility for the child. Judith Stiver, the surrogate mother, also disclaimed any parental responsibility, presumably because she believed she was simply delivering a product pursuant to a contract.

In 1986, a similar problem arose in the District of Columbia when a 32-year-old woman contracted to become a surrogate mother for her sister. The surrogate had a history of drug abuse that was not known to her family. After she was successfully artificially inseminated with her brother-in-law's...
sperm, she was tested for HIV antibody to detect the presence of the AIDS virus. The test was positive. The contracting couple was not told. At birth, the child tested positive for the HIV antibody. Both the surrogate mother and the contracting couple refused to take custody of the child.\footnote{40. The facts are set forth in a letter from four physicians to the New England Journal of Medicine. 317 New Eng. J. Med. 1351 (1987).}

I do not mean to suggest that problems never arise when a handicapped child is born in an intact family. Disappointment and grief can make it difficult for any parent to respond adequately. Emotional or custodial abandonment, however, is generally not considered an option when a handicapped infant is born into a family.\footnote{41. The Stiver-Malahoff dispute supports this point. When the Stivers discovered that Mr. Stiver, and not Alexander Malahoff, was the biological father of the baby, the Stivers assumed responsibility for the child. Peterson, supra note 39, at A10, col.1.} The existence of an intact relationship between the parents induces both to feel jointly responsible for the future of the child, and precludes either from feeling that the responsibility belongs to someone else. But as the two cases just described suggest, surrogacy arrangements increase the risk that biological parents will feel that it is acceptable to abandon less-than-perfect infants at least emotionally, and, if permitted to do so, physically and financially. The surrogate mother will do so because that is what she is supposed to do; the father and his spouse, if any, because he is likely to feel that as a purchaser he has the right to reject “damaged goods.” Treating children as commodities, as surrogacy necessarily does, thus poses real risks to the children conceived.

The problem of adults abandoning surrogate children who are less than “perfect” is not one easily cured by state regulation. Some purposes simply cannot be legislated, and good parenting is one of them. Even if a legislature passed a rule, for example, that surrogate fathers must accept and retain custody of any child delivered pursuant to a surrogacy contract, it is not clear how the law could be enforced. The law could require the surrogate father to pay money; but, as every parent knows, paying money is a small part of the burdens of raising a child. Would the law demand that the father physically keep a child he clearly does not want? The law does not force even married, biological parents to do that. If a parent does not want a child, it is impossible to create a caring family relationship by force of law, or even a relationship in which the child will be safe from physical or emotional harm.

The arguments against court recognition of surrogacy contracts have prompted some to conclude that surrogacy should be a criminal offense. Surrogacy can be done at home, however, without sophisticated medical technology. Therefore, banning it altogether would require the state to police intimate conduct in a way that would be unacceptably intrusive.

An intermediate step, which would discourage surrogacy, particularly when it involves the economic exploitation of poor women, would be to limit the fees that could be paid to surrogates to reimbursement for medical and other expenses of pregnancy and to forbid third parties to promote surrogacy arrangements for financial gain. The role of the third party in the Baby M case suggests there is a need to regulate the intermediaries.
Center was warned by its own psychologist that Mrs. Whitehead "exhibited certain traits that might make surrender of the child difficult," but the Center proceeded without telling either Mrs. Whitehead or the Sterns of the risk. Such callousness should be penalized.

Under this approach, private surrogacy arrangements would be permitted subject to the limitation on fees described above. If one of these private arrangements broke down, however, custody of the child would be decided—as it was in the Baby M case—according to the principles of family law rather than contract law. In family law, the guiding principle is designed to protect the most vulnerable party—the child. Custody is decided, therefore, on the basis of what is in the best interests of the child, not on the basis of who had more bargaining power in the period prior to conception when a contract was drafted, that is not on the basis of contract alone.

There would be little surrogacy under this approach because few women would proceed without the lure of large fees, and few couples would take it upon themselves to find a surrogate without the services of a commercial service. But given the risks surrogacy poses to the most vulnerable—such as the Michigan baby with microcephaly, the D.C. baby with AIDS, or any other less than "perfect" baby—discouraging surrogacy seems the best choice.42

The decision of the Supreme Court of New Jersey in Baby M that informed consent is not enough to justify surrogacy contracts is analogous to the policy embodied in the federal regulations governing research with human subjects that informed consent is insufficient. But recent case decisions concerning the withholding and withdrawing of life-saving treatment demonstrate that the trend toward requiring more than informed consent will not always be used to protect the interests of vulnerable individuals.

(b) Decisions to Withdraw Life-Saving Treatment

In the past decade, a growing body of legal, medical, and ethical authorities have concluded that the same principle of consent that applies to ordinary medical treatment should apply when the treatment at issue is necessary to sustain life. Competent, adult patients should have the right to consent to—or to refuse—life-saving treatment. Opinion polls show that three of every four American adults agree.43

A majority of states extend this principle of respect for individual determination to formerly competent patients. Thirty-eight states and the District of Columbia adopted living will statutes, or natural death acts, that empower competent adults to prepare written directions for health care to be followed


if they become terminally ill and unable to direct their own care. Because most of the living will statutes do not apply to patients in irreversible comas, and many impose rigorous procedural hurdles, the use of durable power of attorney statutes to designate a proxy for health care decisions has also grown. In 1988, however, it became evident that assertions claiming a consensus about termination of life-saving treatment were premature.

In In re O'Connor, the New York Court of Appeals reviewed a dispute between a hospital and the two daughters of Mary O'Connor, a 77-year old widow who was a patient in the hospital. As a result of several strokes, Mary O'Connor became mentally incompetent and unable to ingest food or water without medical assistance. Prior to becoming incompetent, Mrs. O'Connor made several statements to the effect that she would not want to live or to be kept alive by artificial means if she were unable to care for herself. For example, she told a friend and co-worker whose father was dying of cancer that she believed in letting nature take its course and not using artificial means. On another occasion she termed it “monstrous” to keep people alive by using “machinery, things like that,” when they are “not going to get better.” When she was caring for her dying husband, she told her daughter that she would not want to go on living if she could not “take care of herself and make her own decisions.”

When the hospital sought permission to insert a nasal gastric tube to provide nutrition and hydration, her daughters refused on the ground that such a step would be contrary to their mother’s wishes. Although the trial and intermediate appellate courts agreed with the family, the New York Court of Appeals overturned the lower court decision and granted the request of the hospital on the ground that there was not “clear and convincing proof that the patient had made a firm and settled commitment, while competent, to decline this type of medical treatment under circumstances such as these.” The court added: “[t]he ideal situation is one in which the patient’s wishes were expressed in some form of a writing, perhaps a ‘living will’, while he or she was still competent.” The court concluded:

It is true, of course, that in her present condition she cannot care for herself or survive without medical assistance and that she has stated that she never wanted to be a burden and would not want to live, or be kept alive “artificially” if she could not care for herself. But no one contends, and it should not be assumed, that she contemplated declining medical assistance when her prognosis was uncertain. Here both medical experts agreed that she will never regain sufficient mental ability to care for herself, but it is not clear from the record that the loss of

45. For example, a requirement that the patient reaffirm a will after being declared terminally ill by two physicians.
46. These statutes enable a competent adult to designate a proxy decisionmaker who is authorized to make health care decisions if the declarant is unable to do so.
48. Id. at 526-27, 531 N.E.2d at 611, 534 N.Y.S.2d at 890.
49. Id. at 527, 531 N.E.2d at 611, 534 N.Y.S.2d at 890.
50. Id. at 522, 531 N.E.2d at 608, 534 N.Y.S.2d at 887.
51. Id. at 531, 531 N.E.2d at 613, 534 N.Y.S.2d at 892.
her gag reflex is permanent and that she will never be able to obtain food and drink without medical assistance.\textsuperscript{52} Surely the possibility that Mary O'Connor may recover her gag reflex does not outweigh the concession that she will never regain sufficient mental ability to care for herself. Thus the majority admits in this passage that it is violating the essence of Mrs. O'Connor's expressed wishes. As Judge Simon noted in his dissent, the majority's test reduces the right of self determination to a "hollow premise."\textsuperscript{53}

Judge Simon, also questioned the majority's use of the evidence in the record. Mrs. O'Connor was undoubtedly aware of the gravity of the problem she was addressing and the significance of her statements because she worked in the emergency room and pathology laboratory of a hospital for 20 years "confronting the problems of life and death daily."\textsuperscript{54} She suffered through the long illnesses of her husband, father and two brothers, and had, herself, been hospitalized for congestive heart failure.\textsuperscript{55} Judge Simon also echoed Franz Ingelfinger's concern with the "disparity in knowledge between lay persons and doctors."\textsuperscript{56} He warned that medical personnel will undoubtedly be reluctant to honor a patient's instructions if they are less than complete or unclear in any way, and thus the inevitable result of the court's decision is that courts will be asked to intervene in an increasing number of cases. "Decisions under such circumstances will necessarily reflect the value choice of the judge rather than those of the patient, and are nothing short of arbitrary intrusions into the personal life of the patient."\textsuperscript{57} Thus, the principle of requiring more than informed consent was used in O'Connor to undercut the self-determination of a patient who no longer could defend her decision to withdraw treatment or consent to treatment.

III. CONCLUSIONS

This article has traced the transformation of the principle of informed consent in medical care and research, a principle that mirrors the principle of popular sovereignty on which this country was founded. Beginning in 1957, courts in this country rejected the principle of mere consent to medical care in favor of the more rigorous requirement of obtaining informed or intelligent consent, a principle that places a burden on health care professionals to disclose the "facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment."\textsuperscript{58}

By 1974, even the more rigorous principle of intelligent or informed consent in medical care and research, a principle that mirrors the principle of popular sovereignty on which this country was founded. Beginning in 1957, courts in this country rejected the principle of mere consent to medical care in favor of the more rigorous requirement of obtaining informed or intelligent consent, a principle that places a burden on health care professionals to disclose the "facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment."\textsuperscript{58}
consent was increasingly seen to be inadequate. Thus, federal regulations governing research with human subjects require that, in addition to obtaining informed consent from subjects, researchers persuade an institutional review board that the benefits of the research outweigh its risks. In another example of the "second stage" of the interaction of law and bioethics, the Supreme Court of New Jersey in *Baby M* held that the consent of Mary Beth Whitehead to turn over the child she conceived pursuant to a surrogacy arrangement was not sufficient to sustain the contract. The court decided that the risks surrogacy posed not only to Baby M, but also to future surrogate mothers or children, outweighed its benefits.

The second stage has the potential to bring us closer to the ideal of decisionmaking by the people embodied in that noble fiction, popular sovereignty. But it could also move us toward a society in which individual choice is ignored in a misguided quest for proof that the individual totally comprehends all aspects of a particular decision and that there is no possibility that the person might change his or her mind. That risk became manifest this past fall, when the New York Court of Appeals authorized a hospital to insert a nasal gastric tube in Mary O'Connor despite her repeated previous statements that she did not ever want to be maintained by machines. Such second-guessing of autonomy has the potential to fatally undermine its exercise. Consider, for example, what might happen if the procedural and substantive standards imposed by the New York Court of Appeals on Mrs. O'Connor were invoked in the political realm. Voters might be required to demonstrate a detailed knowledge of all candidates and issues before they would be permitted into the voting booth. Surely such a requirement would do more to undermine popular sovereignty in the long run than to foster it.

Lawmakers and judges who wrestle with the elusive goal of respect for autonomy in the context of medical care or research need to temper their zeal for certainty with a realistic sense of human nature. We all understand that there are times when talking another person into making an agreement in some way takes advantage of the other. Just as caveat emptor has been rejected for many important decisions in life, from buying a house to participation in medical research, contract theories of government need to move beyond bare consent—to foster informed intelligent choice through education of the electorate and disclosure of relevant information. But the goal must always be to enhance choice, not to discourage it by erecting unduly onerous procedural barriers. Intelligent consent, like popular sovereignty, is a "goal to be sought, never attainable, always receding, but approachable and worth approaching."