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DEATH AND THE MAGIC MACHINE: INFORMED CONSENT TO THE ARTIFICIAL HEART†

GEORGE J. ANNAS*

INTRODUCTION

Jay Katz introduces his remarkable and insightful book, *The Silent World of Doctor and Patient*,¹ by recounting a portion of Solzhenitsyn's *Cancer Ward*.² He describes an encounter between a patient, Oleg Kostoglotov, and his doctor, Dr. Ludmilla Afanasyevna. The doctor wanted to use experimental hormone treatment, but the patient refused. Katz argues that what made conversation impossible between them was the patient's undisclosed intention of leaving the hospital to treat himself with "a secret medicine, a mandrake root from Issyk Kul." He could not trust the doctor with this information because the doctor would make the decision for the patient in any event, because the doctor believed, "doctors *are* entitled to that right . . . without that right there'd be no such thing as medicine."³

Katz objects to this notion, pointing out that "if doctors are 'entitled to that right,' then patients must continue to trust them silently." But he also chastises "proponents of informed consent and patient self-determination" (among whom I number myself),⁴ who "have insufficiently appreciated that trusting oneself and others to become aware of the certainties and uncertainties that surround the practice of medicine, and to integrate them with one's hopes, fears, and realistic expectations, are inordinately difficult tasks" (p. xv). His purpose in this book, he tells us, is not to explore informed consent in great depth,

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1. J. KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* (1984) [hereinafter KATZ].

2. A. I. SOLZHENITSYN, *THE CANCER WARD* (1968).

3. *Id.*, quoted in KATZ, *supra* note 1, at xv.

4. G. J. ANNAS, *THE RIGHTS OF HOSPITAL PATIENTS* 57-91 (1975).

but to "identify as many issues as possible and to pursue them for some distance" (p. xx).

My own purpose is to explore one of the many "leads" Professor Katz offers in a bit more depth: the application of informed consent to artificial heart experimentation. Using this extreme example, I will argue that Katz is certainly correct in proposing more in-depth, informed and trusting conversation between doctor-researcher and patient-subject. But much more than conversation is required to promote and protect the rights *and* welfare of individual subjects. Solzhenitsyn's fictional patient, Oleg, *knows* about his folk remedy, and so satisfies the informational requirements of informed consent:

When I get back to Ush-Terek I'll use the issyk-kul root to keep the tumor from producing metastases. There is something noble in curing with strong poison. Poison doesn't pretend to be innocent medicine. *It says plainly: I am poison. Watch out! Or else. And we know what risk we're taking.*⁵

Suppose that it was not Oleg, but Dr. Afanasyevna who was proposing to use the issyk-kul root; and suppose doctor and patient had discussed this "experimental treatment" at length, and that Oleg understood the risks perfectly. Under these conditions would we or should we conclude that it is perfectly acceptable for the issyk-kul root to be administered to Oleg? This commentary argues that while such informed consent is a necessary precondition to lawful human experimentation, it is not a sufficient one. Prior to the conversation and offer of an experimental intervention, an *independent judgment* must be made that the proposed therapy, be it surgery, radiation, or an issyk-kul root, is a reasonable medical experiment from both a scientific and public policy perspective. This is necessary to protect the patient's *welfare*; to prevent patients from being demeaned and dehumanized by accepting offers they are in no position to refuse.

Medical ethicist John Fletcher of the National Institutes of Health (NIH), for example, correctly argues that "the major ethical question in research is whether the experiment ought to be done at all."⁶ The law, as embodied in the Nuremberg Code⁷ and current

5. A. I. SOLZHENITSYN, *supra* note 2, at 347 (emphasis added).

6. Fletcher, *The Evolution of the Ethics of Informed Consent*, in RESEARCH ETHICS 211 (K. Berg & K. Teanoy eds. 1983).

7. Reprinted in J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS 305-06 (1972) [hereinafter EXPERIMENTATION WITH HUMAN BEINGS]. The Declaration of Helsinki is similar, but has been described as "less legalistic." E.g., Refshauge, *The Place for International Standards in Conducting Research on Humans*, 55 BULL. WORLD HEALTH ORG. 135 (1977).

NIH regulations,⁸ is consistent with this view. The Nuremberg Code, formulated on the basis of international criminal law by American judges sitting in the Nazi War Crimes Trials, sets forth ten prerequisites for *legal* human experimentation. The first principle deals with the informed consent of the research subject, or what may be termed the subject's rights. The other nine principles have primarily to do with protecting the subject's welfare: they set forth actions that must be taken *prior to* seeking subject enrollment in the experiment. These actions include a determination that the experiment is designed properly to yield fruitful results "unprocurable by other methods"; that its "anticipated results" will justify performance of the experiment; that all "unnecessary physical and mental suffering and injury" is avoided; that there is no "*a priori* reason to believe that death or disabling injury will occur"; that the project has "humanitarian importance" that outweighs the degree of risk; that "adequate preparation" is taken to "protect the experimental subject against even the remote possibilities of injury, disability, or death"; that only "scientifically qualified" persons conduct the experiment; that the subject can terminate participation at any time; and that the experimenter is prepared to terminate the experiment if "continuation is likely to result in injury, disability, or death to the experimental subject."⁹

NIH and FDA have codified these general preconditions in their regulations, and local committees, called Institutional Review Boards (IRBs) are mandated to review research protocols prior to subject recruitment to see to it that these preconditions have been observed.¹⁰ Our initial experience with heart transplantation, and our current experience with the artificial heart, illustrate how informed consent can be used improperly as an excuse to justify massive assaults on the welfare of human subjects, even though the quality of the consent is highly questionable, and the quality of the experiment itself does not meet the welfare requirements of the Nuremberg Code.

I. INFORMED CONSENT TO HEART TRANSPLANTATION

Professor Katz's casebook *Experimentation with Human Beings*,¹¹ has had a profound impact on my own thinking, and I used it as a text in more than a dozen courses during the 1970s. It is the finest

8. Protection of Human Subjects, FDA, HHS, 46 Fed. Reg. 8942 (1981). See also Proposed Model Federal Policy for Protection of Human Subjects, Office of Science and Technology, 51 Fed. Reg. 20,204 (1986).

9. See EXPERIMENTATION WITH HUMAN BEINGS, *supra* note 7, at 305-06.

10. R. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH (2d ed. 1986).

11. EXPERIMENTATION WITH HUMAN BEINGS, *supra* note 7.

collection of materials ever assembled on this subject. One of my favorite readings from the casebook is the excerpt from Philip Blaiberg's *Looking at My Heart*,¹² portions of which Jay Katz also reproduces in his powerful chapter VI, "Respecting Autonomy: The Obligation for Conversation" in *The Silent World of Doctor and Patient* (pp. 130-39). In this chapter, Katz persuasively demonstrates that Philip Blaiberg, the recipient of the world's second human-to-human heart transplant, regressed when in the presence of Dr. Christiaan Barnard. He saw him as an "omnipotent parent and hero . . . Barnard became General Smuts, under whom Blaiberg had served and admired greatly . . . Barnard also became Christ, the powerful protector" (p. 132). But in identifying Barnard as Christ, Blaiberg may have "confused his own identity with that of the surgeon" (pp. 132-33). He actually said he wanted to go through with the operation "not only for my sake but for you [Barnard] and your team who put so much into your effort to save Louis Washkansky" (p. 132). Barnard himself seemed unaware of this confusion on the part of his patient, and of his own conflict of interest between wanting to perform the world's second human heart transplant for himself, and attempting to convince Blaiberg that the operation was in Blaiberg's best interests. Indeed, Barnard even began talking about the operation as fulfilling not his own goals, but "Washkansky's dream." This, as Professor Katz notes, "is startling and suggests that he was as confused about his identity as Blaiberg was about his own" (pp. 139-40).

Louis Washkansky, the recipient of the world's *first* human-to-human heart transplant, it turned out, also was not particularly interested in discussing the details of heart transplantation. Barnard did not press the issue, deciding "no words were needed." But were they? Katz argues that more words (conversation) may not have changed the ultimate decision, but could have improved "the nature and quality of Barnard's and Washkansky's thinking about available choices" (p. 137).

Both, at best, had reflected on the forthcoming operation in isolation, and neither had any idea what had transpired in the other's mind. At the least, respect for Washkansky's psychological autonomy required Barnard to challenge his patient's silent acquiescence. . . . *If Washkansky wanted a new heart, he also had to have the heart to learn more about the operation* (pp. 140-41).¹³

Katz continues by noting that since the first heart transplant op-

12. *Id.* at 640-42.

13. (emphasis added).

erations were "extraordinary" procedures, candidates should be *required* to learn about them, and not permitted to give disclosure and consent. "Barnard should have insisted they talk for a while" (p. 141). Katz concludes his discussion of this case by noting the common clinical controversy over whether to respect the patient's "rights" or "needs" (p. 141). I shall restate this "conflict" by attempting to construct a system that protects both the "rights" and "welfare" of subjects of "extraordinary" human experimentation.

Katz presents a psychoanalytic explanation of the dynamics of the doctor-patient relationship in the dramatic human experimentation context, and suggests conversation to help elucidate issues of transference and countertransference. He argues powerfully that "[m]agical and hopeful expectations exist side by side with expectations of cruel disappointment" (p. 144). And later, he notes that when medical knowledge and skill prove impotent against the claims of nature, "all kinds of senseless interventions are tried in an unconscious effort to cure the incurable magically through a 'wonder drug,' a novel surgical procedure, or a penetrating psychological interpretation" (p. 151). He hopes that through education,

[a]t least medical students can learn to appreciate that *it may be their magical hopes that cause them to intervene*, rather than believing that they are responding to the *magical expectations of their patients*. Thus doctors' heroic attempts to try anything may not necessarily be responsive to patients' needs but may turn out to be a *projection of their own needs onto patients* (p. 151).¹⁴

This powerful insight is descriptive not only of the behavior of human heart transplant pioneers, but also seems to have set the standard for the behavior of surgeons involved in artificial heart experimentation. In his autobiography, *One Life*,¹⁵ Christiaan Barnard has a conversation with himself in which he tries to explain why he did not have further discussions with Louis Washkansky about the risks and likely outcomes of the first human-to-human heart transplant:

I offered a chance, and he grabbed it, without asking any questions. *At the South Pole, the wind can blow in one direction only - north. At the point of death, any promise of help can go in one direction only - toward hope.* So I offered him hope, believing this was my duty. To have refused it would be a betrayal of myself and my profession. In a way, *we share the same hope. We're in this together.*¹⁶

14. (emphasis added).

15. C. BARNARD, *ONE LIFE* (1969).

16. *Id.* at 293 (emphasis added).

This rationalization, of course, is consistent with Katz's notion that Barnard had confused himself with his patient. It also is consistent with Dr. Afanasyevna's view that "doctors *are* entitled." It takes this view even further, however, by arguing that doctors have a *duty*: "to have refused it would be a betrayal of myself *and my profession*." But it also indicates that Dr. Barnard believed that for Washkansky *there really is no choice*; that since he was dying he *must* accept a heart transplant. It was his only hope, and some hope is always better than none. Later, Dr. Barnard refined the analogy, and the rationale for action in the absence of full discussion, by arguing that for Washkansky the alternatives were so obvious that the choice was trivial:

For a dying man, it is not a difficult decision because he knows he is at the end. If a lion chases you to the bank of a river filled with crocodiles, you will leap into the water convinced you have a chance to swim to the other side. But you would never accept such odds if there were no lion.¹⁷

This "lion and the crocodiles" analogy has become the standard by which artificial heart experimenters discuss the decisions of their patient-subjects to this day. For example, when Dr. Denton Cooley implanted the world's first total *artificial* heart into the chest of Haskell Karp, in 1969, he initially argued that his own skill and the patient's consent were the only justification needed:

I have done more heart surgery than anyone else in the world. . . . Based on this experience, I believe I am qualified to judge what is right and proper for my patients. *The permission I receive to do what I do, I receive from my patients*. It is not received from a government agency or from one of my seniors.¹⁸

17. *Id.* (emphasis added). Recently, Dr. Barnard has moved to the United States, "discovered" Glycosphingolipids, a compound he believes rejuvenates the skin, and has begun arguing that physicians should be legally granted "the right of active euthanasia [Because] [t]here is no point in using medical technology to prolong a painful death or an empty life." In discussing his own past heart transplant work he says individuals inevitably and wrongly asked him "how long" his patients had survived. "They should have asked whether surgery had improved the patient's life. If so, it was a success, even if he survived only a few months. If not, it had failed, no matter how long he lived. . . ." He argues that "patients usually understand this better than the rest of us":

They are seldom obsessed with surviving at all costs, and they grow less so in proportion to their illness. *In contrast, it is the healthy who need to cling even to the bitterest life.*

Barnard, *First Word*, OMNI, Mar. 1986, at 6 (emphasis added). These words, of course, have direct application to Dr. Barnard's conversations with both Washkansky and Blaiberg. They also indicate how radically his own thinking about death has changed over the past twenty years.

18. T. THOMPSON, HEARTS 216 (1971) (emphasis added).

Later, however, he restated the issue of the patient's consent in "lion and crocodile" terms: "He was a drowning man. *A drowning man can't be too particular what he's going to use as a possible life preserver.* It was a desperate thing, and he knew it."¹⁹

More recently we have witnessed the advent of "permanent" artificial hearts, and renewed interest in using artificial hearts on a temporary basis as a "bridge" (or "tollgate") to a human heart transplant. The informed consent issues explicated by Katz remain relegated to matters of secondary concern and unaddressed in any but crude and primitive manners.

II. PERMANENT ARTIFICIAL HEARTS AND INFORMED CONSENT

Prior to performing the world's first *permanent* artificial heart implant, Dr. William DeVries, like Dr. Cooley, underlined his view of the importance of informed consent as the primary justification for performing the procedure. One major problem was that the only power source available was an approximately 400 pound drive cart, which had to be attached to both a power source and a source of compressed air, that made ambulation almost impossible. Many, including one of the device's designers, Dr. Robert Jarvik, believed the device shouldn't be used on humans until it was easily portable or entirely implantable. Dr. DeVries disagreed:

Many people have asked us the question as to—it's not fully implantable, why then would you do it? Why don't you wait ten years, when it's implantable, and then do it? *But the key is informed consent. Why should I let people die,* when I can give them a chance to live—if they're willing to accept the limitations of the external pumping system?²⁰

19. J. THORWALD, *THE PATIENTS* 402 (1971) (emphasis added). The Karp implant led to a lawsuit by his widow against Dr. Cooley primarily alleging lack of informed consent. Both the trial court and the appeals court summarily dismissed the notion that more than the patient's consent was needed to justify this experiment. They concluded that the implant was therapy for a dying man: "[T]he record contains no evidence that Mr. Karp's treatment was other than therapeutic and we agree that in this context an action for experimentation must be measured by traditional evidentiary malpractice standards." *Karp v. Cooley*, 493 F.2d 408, 423-24 (5th Cir. 1974), *aff'g* *Karp v. Cooley*, 349 F. Supp. 827 (S.D. Tex. 1972). This conclusion is untenable. Either the judge was not presented with sufficient evidence at trial about the nature of this first-of-its-kind human experiment, or the judge viewed the risks involved as irrelevant. For a fuller discussion of this case, see G. J. ANNAS, L. H. GLANTZ & B. F. KATZ, *INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA* 11-14 (1977).

20. *Nova, Artificial Heart* (Time-Life Video 1984) at 3 (transcript). The other major problem was and remains the incompatibility of human blood and the device's surface that leads to clotting.

Dr. DeVries is certainly correct insofar as he asserts that the informed consent of his subject is a *necessary* prerequisite to acceptable human experimentation: if the subject's competent, voluntary, informed and understanding consent cannot be obtained, the experiment cannot be performed lawfully or ethically.²¹ Even in this regard, however, it can be argued persuasively that although the consent form and process used by Dr. DeVries in the Barney Clark case is a *vast* improvement over the consent process used by Dr. Christiaan Barnard, and a considerable improvement over the consent form and process used by Dr. Denton Cooley, it was still seriously deficient.

Specifically, Dr. Clark signed an eleven page consent form that is more notable for its length than its content. It was incomplete, internally inconsistent, and confusing. It assumed, as his physicians then believed, that Dr. Clark would either die on the table, or go home in about ten days and continue to be mentally competent for the rest of his life. It took no account at all of a "halfway success"; survival coupled with severe confusion, mental incompetence, or coma. The consent form made no provisions for proxy consent to additional procedures or experiments in the event of incompetence, for a mechanism to terminate the experiment, or for how Dr. Clark would die. These and other shortcomings are serious and evidence a lack of clear thinking and planning on the part of Dr. DeVries and the Utah IRB.²² But one can argue that it is easy to be critical of *any* initial attempt, and that no local IRB could have done better. As Professor Al Jonsen has put it, the Utah IRB, in devising a consent form and process with Dr. DeVries, was asked "to build a Boeing 747 with Wright Brothers parts."²³ What about changes that have been made over the past four years in the consent form and process?

Disturbingly, there have been very few changes, and most have

21. See G. J. ANNAS, L. H. GLANTZ & B. F. KATZ, *supra* note 19, at 27-61.

22. For a fuller discussion of this form, see Annas, *Consent to the Artificial Heart: The Lion and the Crocodiles*, HASTINGS CENTER REP., Apr. 1983, at 20-22. For arguments that the form and process was reasonable, see AFTER BARNEY CLARK 22-24 (M. Shaw ed. 1984) ("I believe that Barney Clark's consent was autonomous, voluntary, and fully informed.") [hereinafter AFTER BARNEY CLARK]; Galetti, *Replacement of the Heart with a Mechanical Device: The Case of Dr. Barney Clark*, 310 NEW ENG. J. MED. 312 (1984); Levine, *Total Artificial Heart Implantation—Eligibility Criteria*, 252 J. A.M.A. 1458 (1984) ("Considering the alternatives . . . I think he made an easily understandable choice . . ."). For a discussion of Dr. Clark's psychiatric history before and during the experiment, see Berenson & Grosser, *Total Artificial Heart Implantation*, 41 ARCH. GEN. PSYCHIATRY 910 (1984).

23. On the role of the IRB, see Eichwald, Woolley, Cole & Beamer, *Insertion of the Total Artificial Heart*, IRB, Aug./Sept., 1981 at 6; Woolley, *Ethical Issues in the Implantation of the Total Artificial Heart*, 310 NEW ENG. J. MED. 292 (1984).

been for the worse. Since Dr. DeVries moved to Humana Audubon in Louisville, Kentucky, to conduct his permanent artificial heart implants, he has done three more as of December, 1986. In May, 1985, after completing all four of his implants, he discussed the issue of informed consent to the artificial heart with *New York Times* medical writer, Dr. Lawrence K. Altman. Dr. Altman reports:

Dr. DeVries has repeatedly said that the four men in whom he has implanted artificial hearts were so coerced by their diseases that they felt that death was their only alternative. In signing the 17-page consent form, each recipient, Dr. DeVries has said, "told me in their own way that they didn't care" if they read it or not, and had signed it primarily because they had to [in order] to get the device.²⁴

This is a devastating admission from a surgeon who uses informed consent as *the* primary justification for permanent artificial heart implants in humans. Was it the patients or Dr. DeVries who believed in every case that "death was their only alternative?" And what would it take to persuade Dr. DeVries either that there were other alternatives, or that death could be preferable to the "magic machine?"²⁵ Professor Katz's concern with requiring conversation,

24. Altman, *The Ordeal of a "Human Experiment,"* N.Y. Times, May 14, 1985, at C3, col. 2.

25. After performing his second implant, on William Schroeder, Dr. DeVries had this to say on when he might consider calling a halt to the experiment: "[I]t's impractical on the basis of two patients to determine whether or not these questions [whether society can afford artificial heart implants] can be answered. The third patient may have a stroke, the fourth patient may have a stroke, the fifth patient may have a stroke. In that case the question is not going to be can society pay for it. The question will be: *is it proper to even do this? Should it even be done anymore?*" Q&A: Dr. William C. DeVries, Louisville Courier J., Feb. 3, 1985, at 13, col. 2 (emphasis added).

And after the first four permanent artificial heart implants, the director of the Humana Heart Institute was asked how Humana could argue that any progress was being made given the severe problems suffered by the recipients. Dr. Lansing replied: "Yes, there is progress. [William] Schroeder is improving and showing signs of recovery; [Murray] Haydon will soon be off the respirator and beginning to make a recovery; and yes, [Jack] Burcham has required dialysis for a pre-op condition, but we hope it is temporary. All the patients are living, and at this time *none of the three has a condition that is either irreversible or immediately life-threatening.*" AM. MED. NEWS, May 10, 1985, at 58 (emphasis added). This statement, made on April 24, 1985, unfortunately turned out to be wishful thinking. Within hours, Mr. Burcham was dead. Also, prior to their deaths, Mr. Schroeder suffered subsequent devastating strokes, and Mr. Haydon was not able to leave his intensive care room for more than brief periods. The only other patient in the world to receive the Jarvik-7 as a permanent implant, Leif Stenberg, suffered a stroke and died, and the Swedish surgeon who did the implant, Bjarne Semb, has said publicly that he will not do any more implants because the device is simply too crude and causes such terrible effects in its recipients. Of Mr. Stenberg, Dr. Semb said, "[h]e might as well have died." Kolata, *Surgeons Disagree on Artificial Heart*, 230 SCIENCE 786 (1985).

It is possible to make an argument that the initial implant in Barney Clark was justifi-

and exploring what myths or beliefs the surgeons and their patients are harboring that permit them to accept silence seems especially critical when dealing with the most highly publicized experiment in the history of the world.

The primary rationale for accepting silence seems to be the same one that comforted Drs. Barnard and Cooley: the patient was dying and so had no choice. In Dr. DeVries' words concerning Dr. Barney Clark: "He was too old for a transplant, there were no drugs that would help; the only thing that he could look forward to was dying."²⁶

These experiences raise the question as to whether we can ever justify experimentation on very sick, terminally ill patients. Doesn't their disease, Solzhenitsyn's story of Oleg notwithstanding, inevitably coerce them into "volunteering" for something they necessarily will see as hopeful? And won't parents inevitably volunteer their children for even bizarre and unprecedented experiments, like xenografts, if they are led to believe the experiment might prevent death?²⁷ Here

able in that it was not known "*a priori*" that it would cause such devastating results. It is no longer possible reasonably to make this argument. Recipients have died and/or suffered devastating problems. It would seem that there is simply not enough known about anticoagulation therapy to prevent either bleeding or strokes, for this device to be used in humans at this time. More animal and laboratory research is required before human experimentation can ethically recommence.

It should also be emphasized that while the inventor and researcher may believe in the Jarvik-7, almost no one else does. The NIH Working Group, for example, while endorsing research on fully implantable electrical artificial hearts, noted that "pneumatically actuated . . . systems that do not permit substantial levels of ambulation and relatively normal activity are *importantly suboptimal*." WORKING GROUP ON MECHANICAL CIRCULATORY SUPPORT OF THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, ARTIFICIAL HEART AND ASSIST DEVICES: DIRECTIONS, NEEDS, COSTS, SOCIETAL AND ETHICAL ISSUES 33 (1985) (emphasis added).

26. Clark, *An Incredible Affair of the Heart*, NEWSWEEK, Dec. 13, 1982, at 71-72. See also *supra* note 17.

27. Perhaps the example of the most "magical thinking" in recent history is provided by Dr. Leonard Bailey and his transplant of a baboon's heart into a dying infant known as "Baby Fae." Of course this infant herself could not consent to this first-of-its-kind human experiment, and since one of the primary hypotheses being tested (the effectiveness of cyclosporin on xenografts) could have been tested on an adult, I believe this experiment should not have been tried first on a child who could not agree to it. The case was made even worse because the infant's parents were separated, and the family impoverished. But Dr. Bailey's belief in himself and his procedure is remarkable. Within ten days after the transplant he said, "[i]n the best scenario, Baby Fae will celebrate her 21st birthday without the need of further surgery. That possibility exists." Breo, *Interview with "Baby Fae's" Surgeon: Therapeutic Intent was Topmost*, AM. MED. NEWS, Nov. 16, 1984, at 1.

In fact, this was never a realistic or reasonable expectation, and it raises serious questions both about Dr. Bailey's ability to separate science from emotion (or to distinguish medicine from magic), and what exactly he led the parents of Baby Fae to expect. I have said flatly that this transplant was an "inadequately reviewed, inappropriately consented to, premature experiment on an impoverished, terminally ill newborn that cannot be justified";

Katz helps us again, by insisting on explicit recognition of the limits of interventions at the end of life. Of course, we can justify experimentation on such individuals *only* if we can obtain their voluntary and informed consent.

But informed consent *alone* is an insufficient justification for radical human experimentation. Proper attention to the other nine precepts of the Nuremberg Code, for example, would have required us to address the question of whether there isn't an "*a priori*" reason to believe that "death or disabling injury" will necessarily follow from this experiment; whether such a "halfway success" of continued life in a severely compromised state doesn't amount to "unnecessary physical and mental suffering and injury"; and whether the "anticipated results" justify the performance of this experiment. The welfare of the subject of this experiment does not seem to have been addressed adequately, and until it was, consent for the experiment should not have been sought.

Dr. DeVries sometimes seemed to justify this experimental shortcoming by acting as if he believed he was engaged in therapy, not experimentation at all. At times, for example, he suggested that his goal was to get his patient to go home, or to "play a round of golf." In fact, this scenario never seems to have been realistic. Dr. Clark realized,

and that "therapy was never a realistic goal." Annas, *Baby Fae: The "Anything Goes" School of Human Experimentation*, HASTINGS CENTER REP., Feb. 1985, at 15-17. Others have been somewhat kinder, but consistent with Katz's "magical thinking" hypothesis. The experiment, for example, has been described as a "leap of faith." Dr. Jack Provonsa, Director of Loma Linda's Center for Christian Bioethics, has even asserted that such "leaps of faith" are more likely to occur at religious institutions like Loma Linda (predominately Seventh Day Adventists): "The person who is part of a supportive, communal religion can 'become more secure' in the atmosphere, and then may be willing to take chances that a less secure, less religiously committed individual is willing to take." Colen, *Ethics and Baby Fae*, *Newsday*, Nov. 2, 1984, Part II, at 2, col. 1. This seems more "faith healing" than science. Cf. Fox, *It's the Same, but Different: A Sociological Perspective on the Case of the Utah Artificial Heart*, in AFTER BARNEY CLARK, *supra* note 22, at 68-90 (discussion of the role for Mormonism in the Barney Clark case).

Medical-scientific commentators on Dr. Bailey's published paper on Baby Fae, Bailey, Nehlsen-Cannarella, Concepcion & Jolley, *Baboon-to-Human Cardiac Xenotransplantation in a Neonate*, 254 J. A.M.A. 3321 (1985), used words like "essentially irrelevant" to describe the tissue typing done on the baboon, and "wishful thinking" to describe the "belief that the infant's immune system was immature and thus more readily immunosuppressed" Jonasson & Hardy, *The Case of Baby Fae*, 254 J. A.M.A. 3358, 3359 (1985). Bailey later accused these authorities of "representing dated, historical thinking" Breo, *Precise Cause of Death Eludes "Baby Fae" Team*, AM. MED. NEWS, Dec. 20, 1985, at 18. On the other hand, his immunologist, Dr. Nehlsen-Cannarella, admitted that with "dying babies . . . it's difficult to separate strong desires and wishes from scientific truth" *Id.* at 16. See also Caplan, *Ethical Issues Raised by Research Involving Xenografts*, 254 J. A.M.A. 3339 (1985).

shortly before his death, that although he also had hoped for some therapeutic gain, he had become involved in "pure non-therapeutic experimentation" for others. Asked by Dr. DeVries in his only publicly shown videotaped interview if the experience had been hard, Dr. Clark replied, "[y]es, it's been hard, but the heart itself has pumped right all along and *I think it's doing well.*"²⁸ Clark, it seems, fully realized what DeVries could not admit openly: the subject, who at the outset was a patient seen as an end with the artificial heart used as a means to sustain him, had become simply a means to the end of sustaining the artificial heart. Dr. Clark nonetheless might have agreed to this experiment in advance even if he had known that he would spend most of his 112 remaining days on earth in an intensive care unit, extremely debilitated and depressed, and mentally incompetent at most times. But if this had been known, the IRB should not have approved the experiment since it would have violated most of the basic precepts of subject protection set forth in the Nuremberg Code.

Consent, even informed consent, cannot convert an otherwise unacceptable experiment into an acceptable one. *Before* patients are asked to consent to experimental procedures, the procedure itself must be judged *independently* to be a reasonable one to perform on a human being. Using informed consent in a vacuum without such independent review, makes desperate, dying patients targets for quackery, because an offer of "life" from a physician (whom patients are likely to mistake and misidentify as Christ or God) is an offer dying patients are in no reasonable position to refuse. Use of informed consent in this context converts it from a shield designed to protect the patient into a sword designed to attack the patient's vulnerability. There is an element of paternalism in this suggestion, of course, but no more than that involved in licensing physicians, including these experimenters, and regulating prescription drugs. But we are unlikely to succeed at protecting subject welfare unless we provide terminally ill patients with more procedural protections than we provide healthy volunteers. Much more imaginative work needs to be done on informed consent to permanent implants (and more experimentation with animal models as well) before additional implants can be justified. IRBs have been unable to contribute much to protecting patients in this setting, and although their prior review is legally and ethically required, it has been superficial to date and remains insufficient to protect potential subjects

28. Altman, *Recipient of Artificial Heart Calls the Ordeal Worthwhile*, N.Y. Times, Mar. 3, 1983, at A1, col. 2 (emphasis added).

adequately.²⁹

29. See Williams, *Why IRB's Falter in Reviewing Risks and Benefits*, IRB, May/June 1984, at 1-5. On December 20, 1985 the FDA held a hearing to determine if Dr. DeVries should be permitted to complete his "series of seven" permanent implants that had originally been approved, or whether such research should be suspended in view of the devastating effects it had had on the first four recipients. The FDA decided to permit Dr. DeVries to continue, but only if additional information was supplied to the FDA, and future implants were reviewed on a case-by-case basis. See Clark, *Stiffer Rules for the Heart*, NEWSWEEK, Dec. 30, 1985, at 68; Boffey, *More Implants of Artificial Hearts Are Urged by U.S. Health Panel*, N.Y. Times, Dec. 22, 1985, at 34, col. 1. No major problems were seen by the agency in the consent form or process, although Dr. DeVries reported to a U.S. Congressional committee on February 5, 1986, that modifications were planned for both.

Following a three day visit to Dr. DeVries in August, 1985, I suggested further exploration of a number of problem areas in informed consent:

[L]et me outline some of the major areas of concern I have about the protocol review and consent process, and suggestions that might help to improve it in the event further implants are done.

1. *Correspondence between the protocol and the consent form*

* * *

As we discussed, a review of the protocol indicates that the lack of correspondence between the studies you are conducting and those actually consented to is substantial and serious and should be corrected. Specifically: (a) The assertion in the protocol that the primary goal is therapy cannot stand scrutiny, the protocol itself needs to be amended to place experimental goals first, and therapeutic goals (if any) in a clearly secondary position. (b) As to the experimental studies, *none* of the ones that are so clearly described in the protocol are detailed at all in the consent form, and this is, of course, the primary purpose of the consent form, i.e., to spell out what experimental things will be done, including their risks to the patient. Specifically, you need to at least describe the non-invasive studies (e.g., circulatory response studies; nutritional studies; and exercise studies); and to both describe in detail, and list the risks of the invasive studies (e.g., the hemodynamics studies; the pharmacological studies, including Isoproterenol, Dopamine, Sodium Nitroprusside, Nitroglycerin, and, unless it has been deleted, Ephedrine; and the studies with the Heimes driver). Since many of these studies are designed to take place at three different times (at the time of the implant; one week after the implant; and 6-8 weeks after the implant), each occasion should have a separate consent form (the original master consent form should describe those studies that will be done at the time of the implant, and indicate what followup studies are planned and that a separate consent form and process will be employed for the followup studies).

2. *Defining the role of the Subject's "Advocate" and that of the IRB "monitor"*
The role of each of these separate individuals is unclear and needs clarification if they are to contribute to making the consent process a meaningful one for the subject and his family.

* * *

3. *The Role of the IRB*

My own impression is that the Humana IRB has done both you and your subjects a disservice by permitting use of the current consent form (for the reasons outlined both above, and *infra*), and by failing to either understand or support the basic functions of an IRB. Specifically, the three members of the IRB I met with argued vigorously for such propositions as: (1) the implant procedure was not experimental at all, but "the whole thing is primarily therapeutic" and we should treat these research subjects "like any other patient;" (2) informed consent is

III. ARTIFICIAL HEARTS FOR "TEMPORARY" USE

Dr. Denton Cooley implanted the world's first two mechanical

"just a parade of horrors" to the patient and so serves only to scare them; and (3) withdrawal from the experiment by the research subject would be "murder" if the researcher permitted it and turned off the artificial heart. . . . If the Humana IRB actually believes the propositions these possibly non-representative members put to me on August 27, 1985, it should come as no surprise to anyone that they found their task so simple that they were able to adopt the Utah form almost verbatim, changing primarily only the identity of the hospital in the submitted consent form.

* * *

4. *The Publicity Clause*

As I discussed with you, members of the IRB, and your attorneys, this clause is unprecedented and unacceptable. Subjects have never before in the history of human experimentation had to sign away all rights to privacy regarding every possible mode of communication, and should not have to in their case. It should be separated from the "master form" and rewritten in a manner which more closely mirrors a reasonable attempt to protect privacy. [*Humana's publicity clause provides*: "I am fully aware of the considerable public interest anticipated in my story as a recipient of a Total Artificial Heart. I am also aware that Humana Hospital Audubon has an obligation to disseminate medical information concerning my hospital course as deemed appropriate in the judgment of my physician. In addition to those materials identified in paragraph 13 [regarding medical professionals and the FDA] Humana Hospital Audubon, as approved by my physician, is authorized to make, or permit to be made, photographs, slides, films, video tapes, recordings and other means of recording and/or communicating hereinafter referred to as "material(s)," that may be used in newspapers, magazine articles, television, radio broadcasts, movies or any other media or means of dissemination. I consent to the use of my name, likeness, or voice for such purposes. I agree that Humana Hospital-Audubon or Humana, Inc. will be the sole and exclusive owner of such materials, and I release the Humana Heart Institute, International, Humana, Inc., Humana Hospital Audubon, their officers, agents and employees from all claims of liability with respect to the showing, use or dissemination of such material(s). I understand that the materials which are made public, as described in this paragraph, will protect my modesty and be within generally accepted bounds of good taste.]

5. *Deletion of the Right to Withdraw Clause*

(a) This is, as we discussed at length, a profound and serious omission, since it seems to indicate that all involved have adopted the view of the IRB Chairman that terminating the experiment by turning off the artificial heart, even at the express demand of the patient, is a crime of some sort, perhaps murder. This conclusion indicates that very little thought has gone into this. I can understand the reasons for not overly-dramatizing this issue with the promise of a "key" to turn off the driver; but to swing entirely the other way and imply that under no circumstances can the patient or his doctor turn off or disconnect the artificial heart is to transform the subject entirely into a means of preserving the "life" of the artificial heart, instead of a willing volunteer in an experiment that concludes when he decides he has had enough. If this really is what is intended, at the very least subjects should be informed in advance that the artificial heart will be kept in place and running as long as possible no matter what the patient, his family and doctor wants, and no matter what his physical condition. Even if the artificial heart was therapeutic (which I think we agree it is not) a patient would still

have the right to order its use disconnected, as patients can now discontinue kidney dialysis or mechanical ventilator support, or even artificial feeding, although all are necessary to maintain their lives. When the artificial heart becomes totally implantable and reliable enough to be therapeutic, we may have debating issues here; but at the current time arguments that turning off the Utah drive with the patient's consent is "murder" is simply uniformed hysteria, that has the result of making the patient a servant of the artificial heart itself. (b) Related to this is the problem of what to do if the patient is incompetent to make a decision. This eventuality should be planned for in advance (since it is very predictable) and the prospective subject asked to (1) spell out as best he can the circumstances under which he wants the heart turned off if he cannot communicate; and (2) designate a proxy with the authority to make the decision for him under the criteria he outlines.

* * *

6. *The Consent Process*

We all believe that consent is a process, not a form, and that the form is merely evidence that the process actually took place . . . I think it would be useful to devise a question or two to ask the subject regarding every major point made in the consent form. The question should not, of course, be one that can simply be answered "yes" even if "yes" does not reflect the patient's actual understanding, e.g., "Do you understand all of the risks?" Instead, the question should demand use of specific information about the experiment that you believe it is critical that they understand in order to give their "informed consent" to it. (e.g., Can you describe the types of studies I am going to perform on you and the artificial heart shortly after it is implanted?; What happened to the last five individuals who had permanent artificial hearts implanted in them?, etc.). If the subject cannot adequately answer the questions, he is incapable of giving informed consent, and cannot be accepted as a suitable candidate until the information needed to answer the questions is mastered. Such a procedure may help both the researcher and the subject to take the informed consent process more seriously.

Realistic answers probably will not be found in simply trying to apply rules and regulations developed primarily for routine drug studies. What is involved in the artificial heart experiment is nothing short of transforming a life, and with it all previous interrelationships with the environment and with one's family. Indeed, your experiments will probably teach as much about these transformations and interactions than about the interaction of the artificial heart with the human body. Accordingly, what is needed is much more relevant (as opposed to simply more detailed) information about the impact of the artificial heart on one's lifestyle, mobility, psychology, and relationships to one's family. Indeed, if as now appears to be the case, the artificial heart utterly transforms not only the patient, but also the patient's family (at least the entire life of the patient's spouse) a good deal more attention needs to be given to this aspect of the experiment. Much, if not all, of this information should be supplied to prospective subjects *before* they even come to Louisville to be formally screened for the program. Consent forms themselves are clearly inadequate. What is needed is a book-length treatment on the program and the experiences of the first subjects, together with appropriate illustrations. This could probably be usefully supplemented by videotapes of past and current recipients, as well as telephone conversations with their family members. These should be mastered *before* a potential recipient is on site since the trip to Louisville itself represents a decision to seek the artificial heart and individuals are likely to arrive at Louisville with misperceptions of what is likely to occur if the artificial heart is implanted in them. It is, of course, much harder to dispel misperceptions that have been acted on than it is to present information to an

hearts for temporary use in 1969 and 1981.³⁰ After these two implants, Dr. DeVries performed four permanent implants and Dr. Bjarne Semb performed one in Sweden. After these seven implants, "temporary" mechanical implants, used to sustain the patient until a human heart for transplant becomes available, have dominated the field. This use is controversial for many reasons, not the least of which is that as long as there is a shortage of human hearts for transplant, temporary artificial hearts are unlikely to save any net lives; they will only change the identity of those who actually obtain the human hearts.³¹ Moreover, the way these devices change the recipient's identity is an inherently unfair one, by permitting those with artificial hearts to "jump the queue" and become first in line for the next available matching human heart.³²

But my quarry here is informed consent. Initially, note that temporary artificial hearts *always* have the possibility of becoming *de facto* permanent (e.g., if the patient suffers a complication, such as a stroke, that makes him or her ineligible for a human heart transplant). Since this risk is real,³³ we should require informed consent procedures to be at least as rigorous as those for permanent implantation.

But the historical record to date is one of almost indifference to informed consent. This highly experimental intervention has been justified consistently primarily on the basis that it is a therapeutic modality in an *emergency* setting. The third use of such a temporary device (after Dr. Denton Cooley's two) was perhaps the most clumsy and

uncommitted individual. Accordingly, as I think your own experience to date illustrates, by the time the subject is actually given the consent form to read (or reads it himself) it is too late for them to care about the consents or to "change their minds" and turn back from the course they seem to have inevitably embarked on

Letter from George J. Annas to Dr. William DeVries (Sept. 26, 1985).

30. Cooley, Liotta & Hallman, *Orthotopic Cardiac Prosthesis for Two-staged Cardiac Replacement*, 24 AM. J. CARDIOLOGY 723 (1969); Cooley, *Staged Cardiac Transplantation: Report of Three Cases*, 1 HEART TRANSPLANTION 145 (1982).

31. Annas, *No Cheers for Temporary Artificial Hearts*, HASTINGS CENTER REP., Oct., 1985, at 27-28 [hereinafter *No Cheers for Temporary Artificial Hearts*]. *Contra*, Hill, Farrar, Hershon, Compton, Avery, Levin & Brent, *Use of a Prosthetic Ventricle as a Bridge to Cardiac Transplantation for Postinfarction Cardiogenic Shock*, 314 NEW ENG. J. MED. 626 (1986).

32. See *No Cheers for Temporary Artificial Hearts*, *supra* note 31. See also, Annas, *The Prostitute, the Playboy, and the Poet: Rationing Schemes for Organ Transplantation*, 75 AM. J. PUB. HEALTH 187 (1985).

33. For example see the cases of Mary Lund, who waited more than 40 days on a "temporary" artificial heart before obtaining a human heart replacement; and Bernadette Chayrez, who has received *two* "temporary" artificial hearts and lived on her second one for more than 200 days before dying during her second human heart transplant. See *infra* notes 58-62 and accompanying text.

embarrassing since it involved a device that was not even designed or approved for use in human beings.³⁴ I describe the case in some detail because it has set the tone for a rash of "me-too" experiments similar to those that followed Christiaan Barnard's first human-to-human heart transplant,³⁵ and has directly caused the FDA to take a *laissez faire* attitude toward "temporary" implants that seems to be an abdication of the agency's responsibility to protect the public from unproven and untested medical devices.

IV. THE CASE OF THE PHOENIX HEART

On Tuesday morning, March 5, 1985, Dr. Jack Copeland, Chief of University Medical Center's Heart Transplant Team in Tucson, Arizona, performed a human heart transplant on Thomas Creighton, a thirty-three year old, divorced father of two. The procedure was not a success, as Mr. Creighton's body rejected the heart. At 3:00 a.m. Wednesday morning a search for another human heart began, and Dr. Copeland placed Mr. Creighton on a heart-lung machine. At 5:30 a.m. the medical team placed a call to Dr. Cecil Vaughn of Phoenix, asking if he had an artificial heart ready for human use. Dr. Vaughn was scheduled to implant an experimental model developed by dentist Kevin Cheng into a calf later that day, and had never considered use of the device in a human. Nonetheless, he called Dr. Cheng. Dr. Cheng told him, "It's designed for a calf and not ready for a human yet." Asked to think about it for ten minutes, Dr. Cheng recalls, "I knelt and prayed." When Vaughn called him back he said, "The pump is sterile, ready to go."³⁶ The two helicoptered from the hospital to the airport, chartered a jet to Tucson, and then took another helicopter to the Tucson hospital. They arrived at 9:30 a.m. Wednesday morning. The implant procedure began at noon. Designed for a

34. For a detailed description of the case of Thomas Creighton, see Annas, *The Phoenix Heart: What We Have to Lose*, HASTINGS CENTER REP., June 1985, at 15-16 [hereinafter *The Phoenix Heart*]; Copeland, Levinson, Smith, Icenogle, Vaughn, Cheng, Ott & Emery, *The Total Artificial Heart as a Bridge to Transplantation: A Report of Two Cases*, 256 J. A.M.A. 2991 (1986).

35. Following Dr. Barnard's initial human-to-human heart transplant, about 150 human heart transplants were done at 60 places around the world in the next two years. There were almost no long-term survivors in the unseemly rush to join the "me-too" club of heart transplant surgeons, and this episode stands as one of the blackest marks in the history of surgery. B. JENNETT, *HIGH TECHNOLOGY MEDICINE* 84-85 (1984).

36. Altman, *Anguish, Hope, a Moment of Fame: A Heart's Story is Told*, N.Y. Times, Mar. 19, 1985, at C1-2, col. 1; See also, Blakeslee, *Arizona Surgeon Defends Heart Implant*, N.Y. Times, Mar. 12, 1985, at C2, col. 1; Hubert & Ring, *Tucsonian Gets Mechanical Heart at UMC: New Device Doesn't Have FDA Sanction*, Arizona Daily Star, Mar. 7, 1985, at 2, col. 1.

calf, it was too large, and surgeons could not close the chest around the device. The implant maintained circulation until 11:00 p.m. that night when, in preparation for a second heart transplant, doctors turned it off and put Mr. Creighton back on the heart-lung machine. By 3:00 a.m. Thursday, Dr. Copeland completed a second human heart transplant. The next day Mr. Creighton died.

The press treated the story like a modern American melodrama. *USA Today* called the implantation of Dr. Chen's heart "the fulfillment of an American dream."³⁷ The *New York Times* editorialized that "the artificial heart has at last proved it has a useful role . . ."³⁸ *Time* headlined the event as a "bold gamble";³⁹ and *Newsweek* faulted the FDA, noting, "[i]t's hardly fair to doctors, or their patients, to make them break the law to save a life."⁴⁰ The FDA initially termed the unauthorized experiment a violation of the law, but by week's end had done an about face and was flailing itself as "part of the problem."⁴¹

Dr. Copeland relied upon the same two basic excuses his predecessors had used to justify the implant in the absence of the patient's consent: (1) the "only other option was just to let him die" so "we had nothing to lose"; and (2) in an emergency, a physician can do anything to save the patient's life.⁴² Neither of these assertions can stand scrutiny. The physician may have "nothing to lose," but the patient certainly does. The choice is *not*, as the five permanent implant patients have all demonstrated, simply one between "life and death." The much more likely scenario is life in a severely disabled and debilitated state; a risk to which *only the patient himself or herself* should be able to consent. The rationale that for a dying patient anything is justified, is an illustration of what Professor Katz has termed the "magical thinking"; that the doctor actually has the power to conquer death, and that prolonged life (or prolonging the dying process) is *always* a

37. Kuhn & Pesce, *Heartmaker: A Dentist with a Dream*, *USA Today*, Mar. 8, 1985, at 1A, col. 3.

38. *The Man with the Illegal Heart*, *N.Y. Times*, Mar. 9, 1985, at A22, col. 1. Even after having the benefit of another nine months to rethink the issue, and after concluding that the permanent artificial heart "in its present form . . . cannot be described as a success"; the *Times* continued to describe temporary implants as "useful." Editorial, *The Heart that Fizzled*, *N.Y. Times*, Jan. 10, 1986 at A26, col. 1.

39. Wallis, *A Bold Gamble in Tucson*, *TIME*, Mar. 18, 1985, at 63.

40. Adler, *When Life is on the Line*, *NEWSWEEK*, Mar. 18, 1985, at 88.

41. Altman, *Learning to Live with the Artificial Heart*, *N.Y. Times*, Mar. 17, 1985, § 4, at 7, col. 3.

42. Hubert & Rothenberg, *Patient has a 'long shot'*, *Arizona Daily Star*, Mar. 8, 1985, at 3, col. 2.

reasonable medical goal.⁴³

Likewise, the emergency argument is misplaced. *All* heart-diseased patients will encounter such an "emergency" before they die, and to use this as an excuse to experiment dehumanizes them, making them "fair game" for any experiment no matter how bizarre or extreme. This, of course, is not the law. "Emergencies" like this are anticipatable⁴⁴ and must be planned for, with the patient's consent, if risky and extreme experimental interventions are to be offered.⁴⁵

The FDA collapsed when Dr. Copeland asserted he was only trying to "save a life" and did not notify the agency of his plans because he did "not want to make the government his [Mr. Creighton's] executioner."⁴⁶ Professor Katz would probably see this assertion as another example of identity confusion on the part of the surgeon: Dr. Copeland seems to be projecting the role of "executioner" upon himself, and took objectively useless steps to try to prevent the death of his patient which he had (albeit in an attempt to save him), directly caused by his own interventions. Conversation with the patient might clarify this confusion, but more than conversation is required to prevent a recurrence of such well-intentioned but pointless "experimentation."

Instead of attempting to curtail and contain experimental temporary use, the FDA actually took steps that served to encourage and spread it, and did so in a way that almost guarantees that nothing scientifically useful will be learned from temporary implants. In October, 1985, the FDA released proposed guidelines that permit *any* sur-

43. Nor is it appropriate to permit physicians *even to offer* certain interventions to patients on the sole justification that the patients are "dying anyway." Taken to its logical extreme, this rationale can justify *any* intervention. This, of course, undercuts the entire rationale for an FDA or any other rules or regulations about human experimentation. Nor is it the law. As the U.S. Supreme Court noted in upholding the FDA's authority to forbid the use of Laetrile, even on terminally ill cancer patients: "the terminally ill deserve protection . . . from the vast range of self-styled panaceas that inventive minds can devise." U.S. v. Rutherford, 442 U.S. 544 (1979).

44. Mr. Creighton was actually Dr. Copeland's third patient to experience immediate rejection of a heart transplant. Since rejection is a "reasonable foreseeable risk," it should be planned for, not treated as an ad hoc "emergency." See *The Phoenix Heart*, *supra* note 34.

45. The use of proxy consent to "emergency" experimentation, when allowed at all, is generally permitted only for alternative therapies that pose little or no additional risk to the subject, and even then only after a careful research protocol has been developed and independently approved by an institutional review board. See, e.g., Brain Resuscitation Clinical Trial I Study Group, *Randomized Clinical Study of Thiopental Loading in Comatose Survivors of Cardiac Arrest*, 314 NEW ENG. J. MED. 397 (1986).

46. Copeland, *We Can't Sacrifice Lives to Risks*, USA Today, Mar. 11, 1985, at 10A, col. 2.

geon to use any artificial heart in an "emergency" like the one just described.⁴⁷ By February, 1986, the FDA had also given four centers approval to do ten such implants each and by the end of 1986, surgeons had performed at least fifteen additional "temporary" implants.⁴⁸ There was no master protocol, no uniform patient selection criteria, and, as the reader should be able to guess by now, we have seen no advancements in the area of informed consent.

Indeed, the informed consent forms and processes devised by the first four centers to use the artificial heart as a planned temporary measure are all different and all significantly inadequate, suffering from all or almost all of the shortcomings involved in obtaining consent for permanent use. It seems likely that the reason doctors have not taken consent seriously at all in the "temporary" setting is because the primary argument given for use of the temporary artificial heart is its alleged "emergency" nature. In fact, in at least two of the first five such implants, the patients themselves did not personally participate in any meaningful way in the consent process.⁴⁹ And in Europe's first "temporary" use, doctors did not even tell the patient of the planned procedure "because we wanted to prevent him from being disturbed."⁵⁰ This is unacceptable. The medical community should never view a patient who does not personally consent to its implantation as an appropriate subject for experimentation with the artificial heart since this is a profoundly radical experiment that can have predictable, devastating effects on the subject.

47. FDA, HHS, "Guidance for Emergency Use of Unapproved Medical Devices; Availability," 50 Fed. Reg. 42,866 (1985).

48. The original four hospitals to obtain FDA approval are: U. of Arizona at Tucson; Pennsylvania State U. at Hershey; Abbott-Northwestern Hospital, Minneapolis; and Presbyterian-University Hospital, Pittsburgh. The FDA (remarkably) has indicated it may approve up to ten or eleven more sites. Cole, *Four Years of Replacing Ailing Hearts: Surgeons Assess Data, Questions Remain*, 256 J. A.M.A. 2921, 2930 (1986).

49. Thomas Creighton at Tucson, and Mary Lund in Minneapolis. Michael Drummond's consent is also of questionable quality. See *The Phoenix Heart*, *supra* note 34.

50. The implant was done at the West Berlin Charlottenburg University Clinic by Dr. Emil Buecherl. *German Not Informed He Has Artificial Heart*, N.Y. Times, Mar. 10, 1986, at A17, col. 4. The case is reminiscent of another one collected by Professor Katz in his casebook, EXPERIMENTATION WITH HUMAN BEINGS, *supra* note 7, which concerned a twenty-three year old Brazilian cowboy who was the recipient of the first human-to-human heart transplant in South America. He was not told about the proposed transplant, and learned of it only when he heard a news broadcast about it in his hospital room a week later. He lived about three weeks: "[T]he Brazilian surgeons point out at the same time that no ethical questions are raised by da Cunha's [the patient] lack of informed consent. If a man is incapable of understanding an operation he vitally needs, they say, there is no choice but to proceed . . . Besides, add the surgeons, da Cunha was psychologically better off not knowing and worrying about his risks." MED. WORLD NEWS, July 12, 1968, at 9-10, quoted in EXPERIMENTATION WITH HUMAN BEINGS, *supra* note 7, 1098.

Indeed, Dr. Copeland's third "bridge" patient (his second was a spectacular success),⁵¹ endured perhaps the most brutal course of any of the permanent or temporary recipients to date, and it is impossible to argue reasonably that her personal consent should not have been required for each step of her experimental course. Mrs. Bernadette Chayrez became the second woman in the world to receive an artificial heart on February 3, 1986. Four days later Dr. Copeland removed it, and replaced it with a human heart. The transplant was unsuccessful. Subsequently, without the patient's consent, but with that of her family, she became the first person to receive a second artificial heart on February 9. The implant turned out to be permanent, and Mrs. Chayrez spent the rest of her life, 212 days, in the hospital on her "temporary" artificial heart. She died on October 11, 1986, shortly after an attempt to transplant another human heart into her body.⁵²

In commenting on the experience, Dr. Copeland has been unable to recognize the ethical issues, or properly separate his own identity from that of his patient. He has said, for example, "It was almost like we were married to her, we all felt so close to her after all these months."⁵³ In this spousal role, he could not envision terminating the experiment even when it was a clear failure. In his words, "[i]f you cannot transplant a patient, *the only option* is to maintain them the best you can on a total artificial heart."⁵⁴ He could not face the patient's death, and suggests that perhaps "a committee of bioethicists and critics who want to save a few bucks could turn the pump off . . . let them turn the *damned thing* off."⁵⁵ The "damned thing" Dr. Copeland was referring to was, of course, the artificial heart; but he may just as well have been describing his patient. As for ethical problems, Dr. Copeland is clear, "I don't see any ethical problems at all in what happened with Bernadette . . . I see the work that we are doing here in the same light as . . . sending up the spacecraft into outer space. Now what possible benefit can we derive from that? A tremendous benefit. *Our endeavors are the same.*"⁵⁶

With such a fantasyland view of one's activities, it should probably not be surprising that informed consent is a relatively trivial matter to the heart implanters. They should, however, recall that even at

51. See *supra* note 34.

52. Hubert, *Chayrez Dies*, Arizona Daily Star, Oct. 12, 1986, at 1, col. 1.

53. Epstein, *Heart Patient's Death: Sorrow, Lessons Endure*, AM. MED. NEWS, Nov. 7, 1986, at 3.

54. *Id.* at 45 (emphasis added).

55. *Id.* (emphasis added).

56. *Id.* (emphasis added).

the height of our competition with the Soviet Union to put the first man on the moon, the United States rejected a proposal to send a manned flight before we could insure its safe return. Even though volunteers could be obtained, it was thought to be *a priori* wrong to send a man to his death even for something clearly seen as in the national interest. Informed consent was simply an inadequate justification for the taking of a human life. It is also an inadequate justification for artificial heart experimentation.

Even if it were sufficient, however, we are not taking it seriously at all in the temporary setting. And informed consent must be taken seriously, at least seriously enough to establish *uniform minimal standards* that all American centers using "temporary" artificial hearts must meet regarding informed consent. Of course, these should be developed in conjunction with a uniform master protocol and patient selection criteria, so that some useful scientific information can be obtained from multicenter use.⁵⁷ The consent forms and processes from the four primary American centers currently doing temporary implants demonstrate major variations on significant issues that should be clarified and agreed upon before further implants are permitted.⁵⁸

57. See also Relman, *Artificial Hearts—Permanent and Temporary*, 314 NEW ENG. J. MED. 644 (1986).

58. Three of the four centers used the Jarvik-7 (a smaller model was used for Mary Lund at Abbott-Northwestern, where she became the first woman recipient), and at Hershey a substantially similar device, called the "Penn. State Heart," was used. The specific areas of disagreement or significant divergence in the consent forms include:

1. *The description of the nature of the experiment as contrasted with the artificial heart's past use.* One consent form, for example, describes it as having been "successfully implanted in five patients"; one says it "has supported life in growing calves for up to 260 days"; another that it has been subject to "extensive testing in experimental laboratory animals and humans"; and the fourth is silent on its past uses and results.

2. *The description of the risk/benefit ratio.* None mention two of the complications that all four of Dr. DeVries' patients have suffered: hemolytic anemia and immunosuppression; and only one mentions pulmonary insufficiency as a possible complication. One form says that all reasonable alternatives have been discussed, the other three allege that use of the artificial heart is the "only alternative" available to maintain life. But even among these three there are variations; one hedges with the phrase that it is "quite unlikely" that I will survive long enough to obtain a heart transplant without it, while another asserts there isn't "any possibility" of survival without use of the device.

3. *The ability to withdraw.* One form doesn't mention this issue at all; two others use boilerplate language common to most consent forms involving drug studies, and one uses somewhat reasonable language on the right to withdraw, "recognizing that such a decision after the total artificial heart is implanted will result in my death."

4. *Proxy consent.* None of the forms provide any mechanism for proxy consent; and one actually attempts to do away with the consent requirement altogether by providing: "If I am too sick to be consulted, I authorize such procedures as are *in the professional judgment of the medical staff necessary* and desirable for my life, safety or comfort." (emphasis added).

CONCLUSION

Artificial hearts did not create all the problems they have exposed in our informed consent procedures and IRB review. Nonetheless, these problems are real, and the advent of the artificial heart provides us with an opportunity to take meaningful action. This action should not only protect the rights and welfare of potential recipients of the artificial heart, but also should help set high standards for other controversial human experiments and develop fair and equitable allocation schemes for human organs. Work on informed consent is *necessary*, but not alone sufficient to permit artificial heart experimentation.

Because the issues of patient consent and quality medical research in the area of the artificial heart have not received sufficient attention and concern to adequately protect subjects of these experiments, there should be a moratorium on further artificial heart research with humans. This moratorium should continue until a joint review and oversight committee of the FDA and NIH⁵⁹ has developed and ap-

5. *Waivers*. Two forms have no waivers and three guarantee that confidentiality will be respected. One form, however, adopts the unacceptable publicity language of the Humana form (*see supra* note 25) (Abbott-Northwestern), and another uses boilerplate products liability waiver language: "I expressly understand that no warranties are made with respect to the implant and use of the temporary artificial heart, and all express or implied warranties are disclaimed, including without limitation any warranty of merchantability or warranty of fitness for a particular purpose."

6. *If a human heart transplant is not done*. Only one form discusses what will be done in this case, and says simply, "you will be supported by the artificial heart as long as possible."

All of these issues, as well as the issue of payment for the device and the procedure, are important enough and common enough to be dealt with in a uniform manner. It now seems apparent that neither the manufacturer nor the hospitals will voluntarily form a multicenter review panel to develop uniform standards related to the protocol, uniform patient selection criteria, and minimal standards for informed consent forms and processes.

59. I presented a proposal to this effect to the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives on February 5, 1986, *Status of the Artificial Heart Program: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong., 2nd Sess. 144-277 (1986) (testimony of Annas, G. J.). The two committee members present were not supportive, nor was the FDA. The hearing itself took place one week after the explosion of the space shuttle Challenger, and this disaster was commented on by almost all of the witnesses. Their point was that we should not let the disaster stop the space program. Of course no one had suggested that it should, any more than anyone would seriously suggest the disasters suffered by Barney Clark, William Schroeder, Murray Hayden, and Jack Burcham should end the quest for an effective, efficient and totally-implantable artificial heart. But just as reality has caught up with the private hope and public hype of the space program, so it has caught up with the hype of the artificial heart. Our reactions to disappointment should be basically the same in both programs. To reassess, move forward with more knowledge and more caution, "to liberate the space program, [artificial hearts] and technology in general from the mystique that we have placed on it. . . . Our

proved the scientific reasonableness, proper use, clear patient selection criteria, adequate informed consent procedures, and clear rules on stopping individual experiments. Permanent artificial heart implants should be suspended at least temporarily because of the devastating results they have had on subjects and their families, because their original justifications are no longer valid, and because the consent process used is too primitive to protect human subjects. Temporary artificial heart implants should be suspended for the same reasons, and additionally because there are no multicenter protocols, and the United States has yet to develop a fair and equitable method for allocating scarce human hearts.

Human experimentation is a public enterprise, and the use to which humans are put, as well as the mandatory minimum procedures used to protect their rights and welfare, are matters of serious public concern. As illustrated by the most public experiments in the history of the world, these issues are taking a back seat to the hype and glitz of what currently passes for "scientific medicine." It is imperative that we reassert the importance of human values implicit in the Nuremberg Code before the Code is quietly rewritten by well-meaning inventors and researchers.

I hope Professor Katz will find the following thoughts of another patient in the *Cancer Ward* a fitting conclusion to a discussion of "death-defying" magical heart implants and informed consent.

Of course he knew that since all people are mortal, some day he too would have to turn in his check. But *some day*, not now! It was not frightening to die right now. Why? Because: How would it be? Afterwards, what? And how would it be not to exist, how would it be without me? . . . [H]e could not even think about it, he could not decide or say anything.⁶⁰

technology is imperfect, because we are imperfect, so either worshipping or despising our technological age is just a neat shifting of blame." Walter McDougal (quoted by Wilford, *After the Challenger: America's Future in Space*, N.Y. Times, Mar. 16, 1986, (Magazine) at 38, 106).

60. A. I. SOLZHENITSYN, *supra* note 2, at 301 (emphasis in original).