9-1986

Made in the U.S.A.: Legal and Ethical Issues in Artificial Heart Experimentation

George J. Annas

2. Made in the U.S.A.: Legal and Ethical Issues in Artificial Heart Experimentation

by George J. Annas, J.D., M.P.H.

The death of William Schroeder in Louisville, Kentucky, on August 6, 1986, brought to a close a remarkable chapter in public human experimentation. Artificial heart implants represent the most public experiments in the history of the world. The manner in which they are conducted is a matter of utmost public and professional concern, since it graphically portrays the seriousness with which we take our laws and ethical rules regarding the protection of the rights and welfare of human subjects. Unfortunately, the brief history of artificial heart implants is neither a happy nor a proud one. Begun with high hopes and therapeutic intentions with the Barney Clark implant, the permanent procedures rapidly became little more than publicity stunts used to advertise Humana, Inc., a for-profit hospital chain. Indeed, on the night Mr. Schroeder died, Humana Hospital Audubon sent its public relations director to justify the experiment to a national television audience on *Nightline*, apparently because no physician at the hospital was willing or able to publicly defend the experiment.

In the United States, ethics and law have taken a distinctly back seat to notions of scientific advance; experimental artificial hearts are being implanted almost in a historic vacuum, with scant regard for existing norms and codes of human experimentation. The National Institutes of Health (NIH) and the Federal Drug Administration (FDA) have been unable or unwilling to supervise or control implant experimentation. Thus additional steps are needed to safeguard the rights and welfare of human subjects of future implant experiments.

I wish to emphasize at the outset that I don't question the motives of any of the players in the drama. Indeed, in the arena of human experimentation, all involved have different and appropriate social roles. It is Dr. Robert Jarvik's social role to improve the artificial heart. It is Dr. William DeVries' social role to attempt to use the artificial heart to benefit his patients. It is Dr. Jack Copeland's social role to try to save his patients' lives in extreme situations. But the roles of inventors, researchers, and surgeons do not exhaust the universe. Human experimentation is an area that crystallizes our view of the rights and welfare of individual humans. These values have been the subject of public discourse for at least the past forty years, from the enunciation of the Nuremberg Code by U.S. judges in 1946, to the promulgation of the Declaration of Helsinki in 1964 and its revisions in 1975, to the latest redraft of NIH's and FDA's regulations on human experimentation. It is the obligation of all health professionals to act in the best interests of their patients and to protect the welfare of their subjects. It is my social role, and that of others concerned with human rights in health care, to advocate for the rights and welfare of the subjects of human experimentation.

Because the rights and welfare of potential subjects of experimental artificial heart implants are not now adequately protected, I strongly believe there should be a moratorium on all such implants until scientific reasonableness, proper use, clear criteria for patient selection, adequate informed consent procedures, and clear rules on stopping individual experiments have been developed and approved by a joint review and oversight committee of FDA and NIH. Permanent artificial heart implants should be at least temporarily suspended 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 the United States has yet to develop a fair and equitable method for allocating scarce human hearts. Let me first deal with permanent implants,

All the recipients of permanent heart implants to date have died, and most suffered devastating and disabling strokes or seizures, as well as serious bleeding.

George J. Annas is Utley Professor of Law & Medicine at the Boston University School of Medicine and chief of the Health Law Section of the Boston University School of Public Health, Boston, Massachusetts.

and then address the somewhat more complicated issue of "temporary" use.

Permanent Artificial Implants

To be acceptable, human experimentation in the U.S. must be conducted in accordance with the principles of the Nuremberg Code and the relevant federal regulations. For an experiment to be legally and ethically acceptable, it must be reasonable and based on scientific knowledge and a weighing of the risk/benefit ratio; *and* thereafter the subject must give his or her informed, voluntary, competent, and understanding consent. Neither of these independent conditions is any longer satisfied by experimentation with the Jarvik-7 as a permanent device.

NOT A REASONABLE EXPERIMENT

Article 5 of the Nuremberg Code states: "No experiment should be conducted where there is *a priori* reason to believe that death or disabling injury will occur; except perhaps in those experiments where the experimental physicians also serve as subjects." Obviously this is not one of those "exceptional" experiments. The question thus is: Is there "*a priori* reason to believe that death or disabling injury will occur" as a result of permanent artificial heart implants?

This question can be answered only by examining the record of the experiment to date. Prior to the first implant, in Dr. Barney Clark, the researchers believed that their patient would either die on the operating table or go home within about ten days.[1] The catastrophic disabling condition that necessitated hospitalization for the rest of Dr. Clark's life (112 days) was completely unanticipated and unplanned for. Dr. DeVries has since done three additional implants. After his second implant patient suffered a stroke, Dr. DeVries was quoted as saying:

> [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?*[2]

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.*[3]

This statement, made on April 24, 1985, unfortunately turned out to be wishful thinking. Within hours, Mr. Burcham was dead. Mr. Schroeder subsequently suffered devastating strokes and died in the hospital on August 6, 1986; and Mr. Haydon was not able to leave his intensive care room for more than brief periods before he died on June 19, 1986. The only other patient in the world to receive the Jarvik-7 as a permanent implant, Leif Stenberg, suffered a stroke and died. The Swedish surgeon who did that implant, Dr. 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, "He might as well have died."[4]

One could argue that the initial implant in Barney Clark was justifiable in that it was not known "*a priori*" that it would cause such devastating results. It is no longer possible to reasonably make this argument. All permanent recipients have died, and most suffered devastating and disabling strokes or seizures, as well as serious bleeding. 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.

While the inventor and researcher may still believe in the Jarvik-7, almost no one else now does. The NIH Working Group, for example, though it endorsed 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.*"[5] It is also noted that "[n]one of the [pneumatic] devices had proven durability in animals according to a rigorous formal protocol."[6]

As Dr. Claude Lenfant, the director of the National Heart, Lung and Blood Institute, put it shortly after the death of Mr. Schroeder: "It is time now to pause and reflect [upon the four implants and what has been learned] and do more research and work on the design of the equipment." He went on to note that all the implants had the same kinds of problems—strokes and blood-clotting—and added, "I would really be astounded to see the same program continue without a radical change."[7]

Two primary justifications are nonetheless offered as arguments to continue experimentation with the Jarvik-7 as a permanent implant: the patients are dying, so there is nothing to lose; and as long as adult patients consent, they should not be deprived of a possible benefit. Neither argument justifies continuation of the experiment.

DYING PATIENTS DESERVE PROTECTION

The law has recognized that certain populations are especially vulnerable to exploitation in the human experimentation arena. Special protections have been devised for children, prisoners, and mental patients.[8] But perhaps the most vulnerable population of all is that comprised of the terminally ill. The FDA and the United States Supreme Court have recognized this by insisting that the protection of the Food, Drug and Cosmetic laws apply to the terminally ill. The Court has stated unequivocally, "For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." And later in the same opinion, "To accept the proposition that the Food, Drug and Cosmetic Act has no relevance for terminal patients is to deny the Commissioners' authority over all drugs, however toxic or ineffectual, for such individuals. . . . [T]he terminally ill no less than other patients [deserve protection] from the vast range of self-styled panaceas that inventive minds can devise."[9] The worldwide "death with dignity" movement and the right-to-refuse-treatment movement likewise insist that we honor the liberty interests of the terminally ill. Terminal illness alone can never be an adequate justification for experimenting on human beings.

The terminally ill retain all rights as citizens until their death, and deserve the full protection of the law. Terminal illness alone can never be an adequate justification for experimenting on human beings.

There are many reasons for this. First, the terminally ill retain all their rights as citizens until their death, and deserve the full protection of the law. Second, although we may know that they *are* dying, there is no scientific way to tell exactly *when* they will die.[10] Third, the terminally ill are especially vulnerable to manipulation and exploitation. The notion that anything can be done that "saves a patient's life" embodies what Yale Law School psychiatrist Jay Katz has described as the "magical myth": that the physician actually has the power to conquer death. As he has noted, "at such times all kinds of senseless interventions are tried."[11] Fourth, as Harvard Medical School surgeon Dr. Francis Moore has noted, this type of innovation will actively be sought by "desperate patients" who want to be subjects, and the procedure will be seen by them as their only "hope for survival."[12] Fifth, the choice is not between life and death. As history has illustrated, the choice is between two different ways of dying. Under congressional mandate, NIH has devised special regulations and protections for prisoners, children, fetuses, and mental patients. It may be time to devise special procedures to protect the terminally ill as well.

INFORMED CONSENT

As Article One of the Nuremberg Code, as well as the FDA and NIH regulations, make clear, informed consent is a *necessary* precondition to acceptable human experimentation, but it alone is *not sufficient*. The most important ethical question is whether the experiment should be performed at all. The existence of the FDA itself is based on the premise that the consent of the public to quackery and unapproved drugs and medical devices is not sufficient justification to permit their marketing. We do not permit certain items even to be offered to patients, because we *know* they will accept them since they are in no position to be able to refuse them. Laetrile is one infamous example. Dying cancer patients are often desperate, and desperate individuals will often "consent" to treatments that are dangerous and/or ineffective. This raises two issues. The first is that certain things should simply not be offered to desperate patients even if they will accept them, because all the evidence we have indicates that they are dangerous and cannot help the patient. A patient agreeing to have his heart removed and replaced by a mechanical pump that is dependent upon a 300-pound drive cart may be the most extreme example of this. But there are others. We would surely not permit researchers working on a cure for AIDS to do *anything* to AIDS patients that these patients consented to. We would want the protocols carefully reviewed, the risk/benefit ratio worked out, and a solid scientific basis for the experiment articulated. Even then, if the experiment presented an *a priori* likelihood of death or serious disability, we would not (or at least should not) permit it even though we could recruit subjects for it.

Dr. William DeVries asserted, prior to the Barney Clark implant: "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?"[13] The implication is that informed consent alone justifies the experiment. But this is incorrect. Indeed, it perverts the very essence of informed consent, converting a doctrine designed as a shield, to protect patients from procedures they don't understand or want, into a sword to justify doing otherwise unacceptable procedures on them. The subject's "informed consent" cannot make an otherwise unacceptable procedure acceptable. Dr. DeVries simply begs the relevant (and difficult) question: When is it reasonable to offer a permanent artificial heart to a human being?

On the other hand, Dr. DeVries is certainly correct to insist that informed consent is a *necessary* prerequisite to acceptable human experimentation; and if it cannot be obtained, the experiment cannot be lawfully or ethically performed. In this regard, the current consent process at Humana Audubon is far too primitive to give a neutral observer any confidence that informed consent is actually being obtained. On this we have, first, Dr. DeVries' own assessment, made in May 1985 after performing his four implants. Dr. Lawrence K. Altman reports that "Dr. DeVries has repeatedly said that the four men in whom he has implanted artificial hearts were so coerced by their disease that they felt that death was their only alternative. In signing the 17-page informed consent forms, 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 to get the device."[14]

Dr. DeVries here raises the question of whether we can *ever* justify experimentation on very sick, terminally ill patients. The answer is that we can *only* justify experimentation on such individuals, individuals who we know *a priori* are severely coerced by their diseases, if we provide them with more protection than we would healthy volunteers. One thing we cannot justify in this group of patients is to put the burden on them to decide if the research project itself is scientifically reasonable and if the risk/benefit ratio is socially acceptable. By refusing to resolve this central ethical issue itself, and by putting the burden of its resolution on Dr. Clark, the Utah institutional review board (IRB) abdicated its responsibility to determine if it is reasonable to implant in a human being an artificial heart that requires lifetime tethering to a clumsy drive cart.

But this is just the beginning. There were major problems with the Utah consent form used for Barney Clark. Specifically, Dr. Clark signed an eleven-page consent form 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 operating 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. No provisions were made 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.[15] But one can argue that it is easy to be critical of *any* initial attempt. What about changes that have been made over the past four years in the consent form and process used at Humana for permanent implants number 2, 3, and 4? Disturbingly, there have been very few changes, and most have been for the worse. There remain a series of crucial protocol and consent process issues that are unresolved at Humana and that individually and collectively demand resolution before it will even be possible to obtain the informed consent of a potential candidate. These can be briefly outlined:

The Humana publicity clause is unprecedented and unacceptable. Subjects have never before in the history of human experimentation been required to sign away all rights to privacy regarding their case.

1) The assertion in the protocol that the primary goal is therapy (rather than experimentation) cannot stand scrutiny. This inaccurate assertion has confused both members of the Humana IRB and patients, and must accordingly be changed.

2) None of the experimental studies so clearly described in the protocol are detailed at all in the consent form (including invasive studies like the hemodynamics studies; the studies with the Heimes driver; and the pharmacological studies, including isoproterenol, dopamine, sodium nitroprusside, nitroglycerin, and ephedrine). This must be corrected.

3) The "right to withdraw" clause has been omitted, and there is no discussion of or plan for how the patient will die and how the decision to terminate the experiment will be made. If the patient is competent, the patient has a legal right to discontinue the experiment. This right must be explicitly preserved, and provisions made for its exercise. Without this clause, death may seem escapable and deniable to all concerned.

4) No provision is made for decision-making regarding the experiment after the patient becomes incom-

petent or otherwise unable to communicate his desires. Appointment of a proxy by the patient should be part of the standard consent procedure.

5) The Humana publicity clause[16] is unprecedented and unacceptable. Subjects have never before in the history of human experimentation been required to sign away all rights to privacy over every mode of public communication regarding their case. This clause should be deleted and a fairer confidentiality statement substituted for it.

6) Much more serious attention must be devoted to the role of the patient's spouse and family members. It has become evident that permanent artificial heart implantation is in large measure a family affair. Indeed, the wives of the patients to date devoted all or much of their lives to caring for their husbands while they were alive, and much of their time to discussing and explaining the experience after their husbands' deaths. The notion that some of the recipients had, that they wanted to make the decision on their own and not "burden" their spouse and family members, is a fantasy. The Humana protocol requires the patient to have a supportive family; the family's role in the consent process, and in follow-up care and termination of the experiment, needs to be highlighted and articulated. Spouses should have clear veto power over the experiment, and subjects should understand the severe burden this experiment will put on their family.

7) The Humana Institutional Review Board seems unable to come to grips with any of these issues. In my discussions with members of the Humana Audubon IRB in August 1985, for example, members vigorously defended such propositions as: (1) the implant procedure is not experimental at all, but "the whole thing is therapeutic"; (2) informed consent is "just a parade of horribles" that serves only to scare patients; and (3) withdrawal from the experiment by the research subject would be "murder" if the researcher permitted it and turned off the artificial heart.

REVIEW BOARDS

On the other hand, it is probably unfair to single out the Humana IRB for its shortcomings in reviewing a protocol and designing a consent form and process for permanent artificial heart implantation. As Professor Albert Jonsen has observed about the Utah IRB and its work on the Barney Clark consent form and process, "It was like asking them to design a Boeing 747 with Wright Brothers parts." No local IRB can be expected to do anything but a poor to miserable job of reviewing an artificial heart protocol and designing a consent process for it.

IRBs, originally thought of as adding an extra layer of protection for the subjects of human experiments, may have become more a part of the problem than the solution. At least in the cases of artificial heart and xenograft research, they have tended to be viewed as procedurally legitimizing experimentation that is extremely difficult, if not impossible, to accept on the basis of substantive guidelines, like the Nuremberg Code and the federal regulations. In fact, they are often much more true to their name than to their intended function: protecting their institution from outside criticism as a first priority, and only worrying about protecting the patient if this protection seems consistent with the interests of the institution.

What we need in the United States is a joint FDA-NIH national review and oversight panel composed primarily of non-physicians and non-scientists to review and monitor protocols and patient selection criteria, and to design consent forms and processes for highly controversial and complex human experiments, including artificial heart implants (permanent and temporary), xenografts, human embryo research, genetic engineering, and any other contemplated human experiment deemed to warrant such review by FDA or NIH. In conducting such review and monitoring, all information made available to the review committee should be public information, and panel deliberations should be public as well.

In the meantime, FDA should respond to the following question: If the first four artificial heart implants were not sufficiently disabling and debilitating to their subjects to warrant suspension of further experimentation with permanent implantation of the Jarvik-7, what consequences to subjects would warrant such a suspension or moratorium?

Temporary Artificial Heart Implants

Regulation of temporary heart implants has more urgency than that of permanent implants, for a number of reasons. First, there has been a de facto moratorium on permanent artificial implants for almost a year and a half because of Humana's inability to locate another suitable candidate. Much of this can be explained by the fact that all four of the recipients of permanent artificial hearts would today be candidates for human heart transplantation, because patient selection criteria have expanded rapidly in many centers over the past year to include patients over sixty years of age. Second, FDA has agreed on the need to review each additional implant separately, and retains the ability to terminate the projected "series of seven" implants at any time it deems this action warranted. Third, Dr. DeVries has been working on and thinking about both the technical and the ethical issues in artificial heart implantation for more than five years,

and has demonstrated that he is sensitive to the issues and open to suggestions to improve both the technical and ethical aspects of the procedure.

On the other hand, temporary implants have consistently been justified by their implanters on untena-

The potential recipient's choice is not simply 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 should be able to consent.

ble grounds, have no master scientific protocol, have no standard consent protocol or patient selection criteria, and utilize wildly varying consent forms and procedures. Temporary heart implantation in the United States is almost completely out of control, and a real possibility exists that the tragic "me too" orgy of heart transplants that followed Christiaan Barnard's human heart transplantation in 1968 could be repeated with temporary implants worldwide. Such transplants have been done in Sweden and Germany, and are under consideration in Canada and Australia, among other countries.

As the number of heart transplant centers grows, patient selection criteria will loosen, and the number of candidates waiting for human hearts will increase. Since the number of human hearts is not likely to increase substantially, more and more individuals will die on the waiting list. This has encouraged experimentation with "temporary" artificial hearts, but shouldn't permit us to ignore the ethical and legal constraints that help define acceptable human experimentation.

The first and foremost problem with "temporary use" is that there can be no reasonable certainty that the "temporary" artificial heart will not turn out to be permanent. A suitable heart donor may never be found or, much more likely, the recipient may suffer a severe complication (such as stroke or kidney failure) that makes him or her ineligible for a human heart transplant. Accordingly, temporary artificial implants should be at least as well thought out, planned for, and consented to as permanent artificial hearts, and all the issues outlined regarding permanent artificial hearts must be addressed by those contemplating use of that heart as a temporary device.

INADEQUATE JUSTIFICATIONS

There have been about twenty planned temporary implants in the U.S., using five different devices. The first two implants were performed by Dr. Denton Cooley, in 1969[17] and 1981.[18] Dr. Cooley had neither of these implants reviewed or approved by the FDA, an IRB, or any other review method. He argued that they were both therapeutic, not experimental, and were done in emergency conditions to save the patient's life. Both patients died shortly after receiving a human heart transplant. No further temporary implants were attempted until March 1985, when Dr. Jack Copeland inserted an artificial heart, developed by a dentist for use in animal experimentation, into the chest of Thomas Creighton. He also died shortly after receiving a human heart transplant.[19] This implant occasioned a public debate about the role of the FDA in such experimentation, and the FDA has since declared that it will not attempt to regulate individual "emergency" uses of such experimental devices. Since then Jarvik-7 artificial hearts have been used as temporary devices at at least four centers. In addition, in a separate and more carefully conducted study, Dr. William Pierce implanted another device, called the "Penn State" heart, which was approved by the FDA for temporary use. Dr. Pierce's first patient died eighteen days after a human heart transplant, and a second remains alive as of today on a de facto permanent Penn State heart.

In most of these cases, two primary justifications have been advanced for using a temporary artificial heart: the patient was dying, so there was "nothing to lose"; and it was an emergency. Neither justification is sufficient to permit use of an experimental device of this nature in an unconsenting patient.

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 "magical thinking": that the doctor actually has the power to conquer death, and that prolonging life (or prolonging the dying process) is *always* a reasonable medical goal.

The emergency argument is likewise 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 anticipatable and must be planned for, with the patient's consent, if risky and extreme experimental interventions are offered.

INFORMED CONSENT FLAWS

Since the primary arguments given for use of the temporary artificial heart have involved its alleged "emergency" nature, the constant process has not been taken very seriously. Indeed, in at least two of the first five 1985 implants, the patients themselves did not participate in any meaningful way in the consent process.[20] This should be unacceptable. No patient who does not personally consent to implantation is an appropriate subject for experimentation with the artificial heart, since this radical experiment can have such devastating effects on the subject.

Informed consent must be taken seriously, at least seriously enough that all centers using "temporary" artificial hearts should meet certain uniform minimal standards regarding informed consent. Of course, these should be developed in conjunction with a uniform master protocol, so that some useful scientific information can be obtained from multicenter use. The consent forms and processes employed by the first four centers demonstrate major variations on significant issues. These should be clarified and resolved before further implants are permitted. Three of the four centers used the Jarvik-7 (in one case a smaller version), and the other a substantially similar device (the Penn State heart). The specific areas of disagreement or significant divergence include:

1) *The description of the risk/benefit ratio.* None mentions two of the complications that all four of Dr. DeVries' patients suffered: hemolytic anemia and immunosuppression. Only one mentions pulmonary insufficiency as a possible complication. One form asserts 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 that it is "quite unlikely" that the patient will survive long enough to obtain a heart transplant without the artificial heart, while another asserts there isn't "any possibility" of survival without use of the device.

2) *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."

3) *Proxy consent.* None of the forms provide any mechanism for proxy consent. 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 supplied).

4) *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[21] (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."

5) *If a human heart transplant is not done.* Only one form discusses what will be done in this case. It 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 both important enough and common enough to be dealt with in a uniform manner. It now seems apparent that neither the manufacturers nor the hospitals involved 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. Accordingly, NIH and FDA should establish a joint national review and oversight panel, made up primarily of non-physicians and non-scientists, to review the protocols, patient selection criteria, and consent forms and processes with the charge of developing uniform minimal standards and monitoring the actual experiments.

NEED FOR A FAIR ALLOCATION SCHEME

As long as there is a shortage of human hearts for transplantation, use of temporary artificial hearts cannot save lives, since the total number of heart transplants that can be done is limited by the total number of transplantable human hearts available. The use of temporary artificial hearts can only change the *identity* of those who will receive heart transplants. As long as there remains a shortage of human hearts, it can reasonably be argued that even if the technical and consent problems can be resolved, temporary artificial hearts should still not be implanted because they are useless to the health care system (since they save no net lives) and are extremely expensive, adding significantly to the already high cost of heart transplantation. I personally believe this; but even if I did not, I would still oppose use of the temporary artificial heart until an equitable and agreed-upon method to allocate human hearts is developed. Otherwise, use of these devices merely changes the identity of those who will

receive the limited number of hearts available, in a way that is intrinsically unfair.

It does this because surgeons are currently able to put patients who have temporary artificial hearts in the front of the line for the next available human heart. Thus they gain priority over other individuals who may have been on the waiting list longer, may be better suited for the available heart, may be in better physical condition to benefit from the available heart, etc., and who may well die because of this reallocation. Perhaps society will decide that this is a proper thing to do; but it certainly has not made this decision yet, and until it does, prioritizing hearts in this fashion is arbitrary and unfair to all the patients in the United States waiting for human hearts.[22]

Conclusion

Permanent artificial hearts did not create all the problems they have exposed in our informed consent and IRB review procedures, and temporary artificial hearts did not create the problems they have exposed in the allocation of human hearts for transplant. Nonetheless, these problems are real, and the advent of the artificial heart provides us with an opportunity to take meaningful action that will not only protect potential recipients of the artificial heart but also help set high standards for other controversial human experiments, and develop fair and equitable allocation schemes for human organs.

Human experimentation is a public enterprise, and the uses to which we put humans, as well as the mandatory minimum procedures used to protect their rights and welfare, are matters of serious public concern. We are not taking these issues seriously enough today. It is imperative that we reassert the importance of human values implicit in the Nuremberg Code before it is quietly rewritten by well-meaning inventors and researchers.

References

1. New York Times, April 17, 1983, at 44.
2. Louisville Courier Journal, Feb. 3, 1985, at 13 (emphasis supplied).
3. *Surgeon DeVries' Dream: "Forgettable" Heart Implant*, AMERICAN MEDICAL NEWS, May 10, 1985, at 1, 58 (emphasis supplied).
4. *Surgeons Disagree on Artificial Heart*, SCIENCE 230: 786 (Nov. 15, 1985).
5. Working Group on Mechanical Circulatory Support, National Heart, Lung, and Blood Institute, *Artificial Heart and Assist Devices: Directions, Needs, Costs, Societal and Ethical Issues* (May 1985) at 33 (emphasis supplied).
6. *Id.* at 15.
7. *Let's Reevaluate Jarvik-7, Critics Say*, AMERICAN MEDICAL NEWS, Aug. 22/29, 1986, at 7.
8. G.J. ANNAS, L.H. GLANTZ, B.F. KATZ, INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA (Cambridge: Ballinger, 1977).
9. *U.S. v. Rutherford*, 544 U.S. 442 (1979).
10. Ward Casscells, Testimony before the FDA Circulatory System Advisory Panel on Artificial Heart Implants, Dec. 20, 1985, Wash., D.C., citing J.R. Wilson et al., JOURNAL OF THE COLLEGE OF CARDIOLOGY, 2: 403 (1983).
11. J. KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT (N.Y.: Free Press, 1984), at 151.
12. F. Moore, in *Ethical Aspects of Experimentation with Human Subjects*, DAEDALUS, Spring 1969, at 509.
13. "Artificial Heart," *Nova* (transcript, p. 3).
14. L.K. Altman, *The Ordeal of a "Human Experiment,"* New York Times, May 14, 1985.
15. G.J. Annas, *Consent to the Artificial Heart: The Lion and the Crocodiles*, HASTINGS CENTER REPORT, April 1983, at 20–22.
16. The clause reads:

> 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 [relating to professional, scientific, and FDA use of information] Humana Hospital–Audubon, as approved by my physician, is authorized to make, or permit to be made, photographs, slides, films, video tapes, recordings or other means of recording and/or communicating hereinafter referred to as "material(s)" that may be used in newspaper, 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, 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. (Aug. 8, 1985 revision)

17. Annas et al., *supra* note 8, at 11–14.
18. A. Caplan, *The Artificial Heart*, HASTINGS CENTER REPORT, February 1982, at 22–24.
19. G.J. Annas, *The Phoenix Heart: What We Have to Lose*, HASTINGS CENTER REPORT, June 1985, at 15–16.
20. *See, e.g.*, G.J. Annas, *No Cheers for Temporary Artificial Hearts*, HASTINGS CENTER REPORT, October 1985, at 27–28.
21. See *supra*, note 16.
22. G.J. Annas, *The Prostitute, the Playboy, and the Poet: Rationing Schemes for Organ Transplantation*, AMERICAN JOURNAL OF PUBLIC HEALTH 75: 187–89 (1985).