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Loma Linda University Center for Christian Bioethics

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Update

The Compleat Physician

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This article is drawn from a presentation Dr. Provonsha made to medical students at Loma Linda University.

I have carefully chosen the title of this paper. (Isaac Walton's *The Compleat Angler* was obviously in mind as the source of the words.) The word compleat is an archaic form of the word complete—and that's a point I wish to make. There isn't anyone around these days who is a complete physician—the knowledge explosion of our times has changed all that. One has to reach back into the past even for the label.

But there are many people who feel a touch of sadness at his passing including quite a few patients—mostly older people who knew him and a few middle-aged folk who were his patients as children. Some of us around a medical school feel a touch of nostalgia too, mostly for the idealistic students the old figure inspired. They still come to us once in a while, dreamers who will be brought down out of the clouds—some with a resounding thud—before we are through with them. Some who formerly had stars in their eyes will be transmuted into materialistic cynics by the trauma of it, and that's a pity. But the majority of students who come to us these days are generally more or less realistic about medicine, particularly those who come from medical homes. You know that the scientific age has dawned in medicine, as well as elsewhere, and are ready to face up to the fact. (If you had any illusions they are dispelled by the flood of didactic material with which you are inundated). The burgeoning laboratory facilities, the space-age gadgetry which has become a daily necessity for the practice of good medicine, the increasingly limited amount of time one has available for broad reading, all very quickly orient today's student toward specialization and the team approach to practice. If along the way he does happen to run into a compleat physician, mostly in one- or two-doctor hospitals in primitive mission surroundings, he is likely to be simply appalled rather than inspired. (Perhaps appalled is not the word, maybe we should say overwhelmed, by what has to be done and how poorly equipped he is to do it.) The fact is that an increasing number of physicians simply could not practice medicine today at any distance from large city facilities.

Yes, the compleat physician has almost passed from the scene. In some ways there should be tears shed at his passing. The often colossal ignorance that he carried in his scruffy black bag is in retrospect not nearly as great a source of reassurance as it was when he used to carry it in through the door on that dead dodo bird, the house call. How he ever managed to maintain that almost reverential

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stature he enjoyed is, from this vantage point, difficult to imagine. By present standards he was often but a step from medical disaster, medically he was far from compleat, yet he was genuinely respected, often even loved, and almost never sued (though infrequently paid). What has replaced him will never quite fill his niche in the hearts of grateful patients.

But I am shedding a tear, nonetheless. Not for his lack of information and meager equipment (though he sometimes surprisingly compensated for both with his skill as an observer. There weren't many of his replacements who could tell as much about a patient with a stethoscope, looking in a patient's mouth, or simply using their nose, as he could). What I am shedding a tear for is not that the compleat physician is gone, but that that other thing he was, for which we've not found many replacements, is also in danger of passing with him—he was also often a complete human being.

Inadequate information can be supplemented, scientific equipment can be developed and supplied, but it is difficult to fill the empty shoes of a complete man.

What does it mean to accept the inevitability of practicing incomplete medicine and yet be a complete person?

First, it has to do with self image. Specialization—even the newer possibility of specializing in family medicine (which is what I engaged in), a considerably more realistic and competent kind of general practice—requires above all a maturity and self-acceptance that permits one to trust other people. Only insecure people have compulsive needs to be omnicompetent. Emotionally secure physicians can freely admit that someone else knows more about something than they do, and are willing to sacrifice something of their own personal prestige for the good of patients. The complete person does not specialize in order to achieve status. He does so out of realism, (the knowledge explosion) in terms of his own interests and gifts, and for the good of patients. Medicine is shot through with incomplete physicians who are also incomplete persons; there is a frightful display of envy, competition, status, and economic skullduggery going on in medicine as elsewhere—to it's shame (and its generally tarnished public image). "Freedom of enterprise" is often a catchword for freedom from ethical restraint and control that has permitted some in medicine to behave like economic jackals behind the scenery, and how artfully that scenery can be placed.

Second, the complete person has a way of looking at other persons who are the patients. The incomplete physician knows that his patient is a person who does not have incomplete needs. It is the physician who specializes, not the patient. He assumes responsibility for the whole patient in the sense that where the problem exceeds his own competence he sees to it that other incomplete physicians become involved, in whose areas of training the difficulty lies. But as the complete person, he knows that the patient also has needs that are human rather than merely technical. The complete physician knows about and ministers to human needs, be they emotional, social, or spiritual. These of course may also have their technical requirements, and then the incomplete physician calls for assistance from the appropriate professions or agencies. It is no shirking of the physician's task to say what he can to the patient in areas of the spirit and then to add, "but I have a friend who can help you more than I in these matters. May I call him?" But the complete physician also knows and understands deeply about such things—it is a part of his own humanity and personal walk with God.

Finally, being an incomplete physician but a complete person says something about the physician's consciousness of his profession—something about the relation of the part to the whole—not just to the whole of medicine but the whole of existence. Herein lies the difference between a mere technician and one who has a profession. The technician knows everything to be known about his own line of work, except its relation to every other line of work. If ever there was a time for the medical profession to resist the forces

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turning physicians into glorified technicians it is now. That means that it is necessary as never before for the physician to rediscover his proper place in the larger scheme of things. He must redefine, as it were, the philosophy of medical practice, not merely sharpen its technique. What is forced upon us by the technical explosion is a reexamination of the philosophical, even metaphysical undergirdings of the task of medicine.

For several centuries medicine has suffered, along with a number of other aspects of social life, from one of the oldest of Christianity's dichotomies, that of a categorical separation between the sacred and secular.

The gulf between these two areas of life was borrowed from another—spirit and matter, supernatural and the natural. The ancients knew a two-story universe in which the upper floor was reserved for spiritual beings and the lower for material beings whose proper sphere was nature. The Greeks were the main source of this separation. The Hebrews and the Bible knew quite a different scheme of things. In it there was no radical disjunction between the supernatural and natural. God dwelt on both floors and was active in each. Thus the incomplete physician who is a complete person stands with due humility before the wisdom of the body—God's wisdom. He knows that God is at work in every normal physiologic process.

Physicians are sometimes accused of playing God in the decisions they are forced to make. It is true that medical decisions sometimes have enormous consequences for life, death, happiness, or misery, even for the quality of life to be lived; but the physician who sees God at work accepts his role with humility born of his incomplete knowledge, and with the courage derived from awareness that God may also be at work in his decisions and what a closeness to God that phrase suggests. It calls to mind a statement by Ellen G. White. "If we consent, He will so identify Himself with our thoughts and aims, so blend our hearts and minds into conformity to His will that when we obey Him we shall be but carrying out our own impulses" (DA, 668). Being a complete person while an incomplete physician implies just such closeness and dependence on the Great Physician. The complete person does not fear to make necessary decisions—he only makes them humbly, with the sense that in being the medium through which God makes decisions he does not thereby become God. The God-complex is not an unknown posture of physicians who are incomplete persons. Some of my medical colleagues manipulate the bodies of patients who serve their ego needs. Note well that phrase, for the man who has to play God has some very deep-seated needs for which he is compensating. Men and women often go into medicine for personal ego reasons that are unrecognized. Few professions give as much opportunity for the exercise of personal power. A man, for example, who enjoys little power at home may find the pecking order reversed in the operating room and behave like a tyrant. There is also the occasional opportunity to medically humiliate persons who would in other circumstances be socially their superiors. Such physicians play with bodies, even with personal lives, as if they were objects to be arranged at will. This is the God-complex as expressed in medicine, even in the way drugs are used. The complete person who accepts the fact of his incompleteness in medicine has no such needs, and enormously respects the body and its processes. All of his therapeutic actions are designed to assist and cooperate with the body's (God's) own wisdom, not merely to control or rearrange it with his chemicals and other agents.

"Men and women often go into medicine for personal ego reasons that are unrecognized."

The physician who is sensitive to God at work is also aware, however, that nature as now observed is not only a picture of the divine activity—there is a snake in the garden too. He sees the great controversy between good and evil also expressing itself at the level of natural process as disease, and joins the battle against this evil as one who fights on the side of God. Whenever such a physician encounters this evil at work in the body and personality of his patients he says in effect, "surely an enemy hath done this" (Matthew 13:28). The physician who cooperates with the Great Physician is engaged in no casual struggle—but against the enemies of God. As Jesus Himself pointed out when He said, "whether is it easier to say thy sins be forgiven thee or to take up thy bed and walk" (Mark 2:9). There is no semantic gulf between sickness and sin.

The statement, "In God we live and move and have our being. Every breath, every throb of the heart, is a continual evidence of the power of an ever-present God," shows that the proper posture of the true physician is with head bowed and shoes placed from off his feet, because this is holy ground. The physician standing before the human body and its processes is standing before the handiwork of the most high God. The anatomist, whether macro or micro, is looking at God's workmanship. The physiologist is seeing God in action. It is a mixed

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picture, of course, because of the conflict we just referred to (and that's why medical students begin their studies with the normal, so that they recognize where it departs from the pattern and thus know the enemy when they see him), but nevertheless, insofar as the body operates in it's normal fashion it obeys the creative will of God. It is the physician's task to assist God in bringing this part of creation back into obedience to its Creator. This is a holy, sacred task. The true physician will know that the ancient dichotomy between the sacred and secular was a perversion of reality, not its true expression; God dwells on all floors! Insofar as men cooperate with what God is doing in the world there are no such divisions as sacred and secular, or sacred and profane professions! There are only sacred and profane men in them! All of life lived out in harmony with God, all human activity carried out in obedience to the will of God, and God's will involves the whole of creation—nature's laws are also God's laws–is a sacred thing. And what a lot of human tragedy and ineffectiveness has been traceable to the failure to recognize that fact. The physician, whether in the laboratory or at the bedside, is doing a sacred work and should bring to it the sense of reverence and respect that term conveys. (Sacred as used here is not synonymous with gloom or gravity, but with respect.)

A practical consequence of this failure is seen in the image pre-medical students sometimes have of themselves and their future professions, even the reasons why they choose medicine as a career. Even worse is the image others sometimes have of the profession, and the reason some choose to go elsewhere than where they belong—in medicine. When I was a student at Pacific Union College there was an interesting tension between pre-meds and the pre-ministerial colleagues—including administrators. One of my former classmates, a minister, threw up his hands in horror. "But, Jack, you are a minister!" Frank apostasy couldn't have been much worse. Even my mother could never quite get over introducing her son—who was now also a doctor—as her minister son, failing to include the medical aspects of that ministry. During my freshman year at Loma Linda, Alfred Shryock received a letter from a student who had been accepted for medicine but then had second thoughts. Dr. Shryock put the letter on the bulletin board for us all to read. It stated, in effect, that since he had applied for admission to the medical school he had been converted and now decided to go into the ministry, presumably where converted people belong.

That is a false image based on a gross misunderstanding of God and his work. I suppose what bothers me most is that even medical people often view themselves and their profession in this way, and a sacred calling becomes profaned when entered into by profane people.

A true picture of God redemptively at work will enable us to see that all have ultimately the same call to share with God in that redemption. The complete person who is also a physician shares this call with other complete persons, whether they are ministers, educators, or whatever. But they all share in another fact; they are all incomplete in their professions. The clergyman these days is also an incomplete minister, the educator is an incomplete teacher, and so on down the line. All have the same call, but each answers it through the medium of his own partial profession or work, based on his own peculiar but limited skills, talents, and opportunities. Only together do we perform with God a complete ministry to the needs of humankind.

I repeat, there are no intrinsically sacred and profane professions. There are only sacred and profane people in them.

Which brings me to a final important point having to do with the special function of this school and the Christian physicians who graduate from it. This has to do with the nature and function of symbols. Let me take a moment to define my words. A symbol is an object or action that has a pointing function. It points beyond itself to another thing or value rather than to itself. Symbols may be quite arbitrary—such as signs that point the way to certain places or that bear some kind of necessary relation to the thing to which they point. A father, (not the word, but the relation) may be a symbol of God, as Jesus told us. There is something about the parent-child relation that is like, and thus belongs to the Divine-human relation. We thus see in the father-child relationship something about God—it points to Him and is thus a symbol.

A symbol analogous to the one I wish to consider is the Sabbath. God set apart a portion of time to point to a certain quality of all time, and thus in a sense to existence and Himself as the Creator. The Sabbath as a sacred symbol was to point to the sacredness of the whole week. It was to call attention to the fact that the Creator was at work during the week. It was set apart, because it is the nature of symbols that they must stand out. They cannot function as symbols unless they are noticed. Of what value is a sign if nobody can see or read it?

Just as a sacred day symbolically calls attention to the presence of the Creator in all the days, so the Christian physician is called to symbolize the sanctity of the healing vocation. There are no intrinsically sacred or profane professions, but some serve as more effective symbols than others. Medicine is one of these precisely because it is so deeply involved in the human situation. Within the practice of medicine itself there is need of physicians who recognize the sacred quality of the profession. This school and its graduates does and should stand for something in the world of medicine. That there is a sanctity about persons, and life, and that God is concerned about the quality of human existence. In short it should stand for the sacred quality

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of medical practice. It does stand for this, though not always, nor to the degree that it ought. Some of you may not know how your school is thought of by people in the world of medicine—even in the communities and hospitals where its graduates practice. I've watched operating rooms become better places because Loma Linda surgeons were operating. I've seen doctors' meetings take on a much more wholesome atmosphere because of a Loma Linda physician's presence. I've seen communities take on a different character because Christian physicians were influential in them. And I've been proud. But, I've also been ashamed on occasion, and I'd rather not talk about that.

You who are taking your places in the world of medicine are called to stand for something, and don't you ever forget it! Remind yourselves of it daily. The question is, what will you stand for? Will your life and work point to the sacredness of all life and work, or will you profane the highest privilege that can be granted to any human being?

The compleat physician is gone, shed a tear, but also thank God for the information that sped his passing. We need each other now as never before. What the world is calling for is the pooling of the incomplete talents of all of us, in medicine and beyond.

But what the world needs even more is complete individuals who, because of the wholeness and integrity of their personal witness, can become symbols of what God is trying to do in the world and thus channels of His divine healing. God is in need of such to dress the world's wounds so that He can heal them. ■

Jack W. Provonsha, MD, PhD, *was influential in the establishment of the Center for Chrisitan Bioethics and is director emeritus of the Center. Currently, Dr. Provonsha is retired and living in Loma Linda, California.*

Informed Consent Documentation For Total Artificial Heart Technology

Katrina A. Bramstedt, PhD

The supply of human donor hearts is very small. According to the United Network for Organ Sharing (www.UNOS.org) there are approximately 4,100 patients waiting for a human donor heart in the United States at any point in time, yet only approximately 2,200 human hearts are donated each year. While clinically effective, bridging devices such as left ventricular assist systems actually cause the UNOS waiting list to swell.[1] Various educational efforts have been implemented in an attempt to expand the donor pool, yet the allograft shortfall continues. Total artificial heart (TAH) implantation has been attempted in the past; however, technical and ethical complexities abounded.[2,3,4] Nonetheless, endeavors to address the ongoing deficit of human donor hearts continue and new designs of total artificial heart technology are in the early stages of human clinical trials.[5,6] Because this technology is beginning to reemerge, clinical investigators need to be prepared to deal with the ethical complexities of informed consent for these trials. Reflecting on the past and looking to the future, guidance is offered in preparing informed consent documentation for human clinical trials of artificial replacement heart technology.

The shift from animal studies using total artificial heart technology to human clinical trials is not without risk, and it is not enough to argue that these devices might save lives. While several years' usage of mechanical cardiac bridging devices has given scientists and clinicians much empirical data,[7,8] the known and potential risks of a total artificial heart must be carefully weighed in light of the potential harm to study participants. Thus said, it is critical to emphasize that informed consent is not achieved by the participant's mere signing of an "official" form. There are two key components of informed consent: 1) participation must be voluntary, and 2) trial information (including risks and benefits) must be provided at a level commensurate with the individual's level of understanding. The autonomy and welfare of participants, and the integrity of science and medicine as professions rely on both components of informed consent.[9]

In the United States, Federal law (45 CFR 46.116) regulates informed consent for research studies involving human participants. The law requires that the informed consent process must include advising participants that the study involves research, as opposed to standard clinical therapy. The purposes of the research must also be explained, as well as the expected duration of the subject's participation, a description of the procedures to be followed, and identification of which procedures are experimental as opposed to standard clinical practice. The reasonably foreseeable risks and discomforts (physical, psychological, psychosocial) of study participation must be

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disclosed, as well as the reasonably expected benefits to the subjects themselves or to future patients. In the case of TAH technology, trial participants must be informed if the act of receiving a TAH will preclude them from receiving an allograft if the artificial implant fails or other complications ensue. Participants also need to be informed if they will be permitted multiple TAH implants in cases of malfunction.

Many Americans lack health insurance and many more have only marginal insurance coverage. Because of this, some patients seek out research studies as a way of accessing therapies at low or no cost.[10,11] Some individuals may view a TAH clinical trial as their "health plan," if in fact they are unable to pay for an allograft procedure. Nonetheless, this situation does not preclude clinical investigators from informing these participants that TAH technology is experimental medicine, not a replacement for standard of practice medicine (allografts) at this point in time. Individuals lacking health insurance are vulnerable to clinical trial recruitment and their objectivity in decision-making may be impaired; thus it is the responsibility of the clinical investigator to look out for the subject's welfare and best interests. These goals are paramount to study recruitment, enrollment deadlines, and data collection.

Federal law requires that appropriate alternative procedures or courses of treatment, if any, must be disclosed to potential research participants. Depending on the clinical criteria chosen for study inclusion, these options may range from medical management of symptoms to surgical management such as mechanical assist bridging (with continued waiting on the UNOS list). For those who are morally opposed to allografts, medical management of symptoms or a permanent mechanical assist device would be their only options other than receipt of a TAH. Also, while the presence of the device's external battery pack will likely identify the subject as a TAH recipient, hospitals must nonetheless inform participants of the procedures that will be used to maintain confidentiality of their personal clinical information. Patients should be counseled that if they choose to interact with the media following implantation, their privacy might be severely affected.

Because total artificial heart technology entails more than "minimal risk" (defined by the FDA as having the probability and magnitude of harm or discomfort as not greater than those ordinarily encountered in daily life or during routine medical or psychological exams and tests), trial participants must be informed whether or not any compensation or medical treatments are available if injury occurs and, if so, what they consist of, and how to obtain further information. The financial arrangements for both the medical and surgical expenses associated with TAH technology should be delineated during the informed consent process, and subjects should be advised of the long-term care requirements of their implant. No guarantees (implicit or explicit) should be made about device performance. Participants must be informed of whom to contact for answers to pertinent questions about the research itself and the rights of research subjects.

Clinical investigators must specify that study enrollment is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled. Further, the subject must be informed that he/she may discontinue participation at any time without penalty. This involves the requirement to instruct participants on the consequences of device inactivation, as well as the process of device inactivation. Therapy withdrawal in situations other than futility is ethically troublesome because there is no ethical consensus as to equating the concept of withdrawal of TAH therapy with the concept of the subject's disease state taking its natural course when in fact the diseased heart is no longer present and the TAH is functioning normally. Requests to withdraw TAH therapy should be carefully reflected upon with the aid of a psychiatric consultation in an effort to determine the status of the subject's decision-making capacity as well as the root cause of the subject's request to abandon therapy.

There is no ethical requirement to provide futile therapy.[12] In situations of futility TAH therapy can be withdrawn via device inactivation. While this is ethically permissible, the potential of a futile outcome should be discussed with potential research subjects as part of the informed consent process. It is suggested that the research subject complete an Advance Directive that would specifically state their treatment preferences in the event of clinical complications that render the lack of functional capacity to make decisions. If the research subject already has an Advance Directive, the subject should review it to ensure that their stated preferences reflect their values in light of TAH implantation. Even if a research subject refuses to complete an Advance Directive, he/she should be required to appoint two surrogate decision-makers (one primary, one alternate) as part of the informed consent process in the event that post-surgical complications result in temporary or permanent loss of decision-making capacity.[13] These surrogates (usually close friends or relatives) will likely know the values of the research subject and could be able to assist clinicians in decisions about continuation or withdrawal of TAH therapy, as well as general clinical matters. If these surrogates are unable or unwilling to function as proxy decision-makers when the time arises, the hospital should defer to their clinical ethics service or ethics committee to assume the surrogate role.

In addition to the Federal requirements discussed above, institutions are not prohibited from requiring their investigators to make further disclosures to participants. In this age of

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biotechnology it is not uncommon for the materials or products of research to become commercialized. Because of this, institutions should inform research subjects that their tissues or other biological specimens might be used in a commercial product such as a cell line.[14] Institutions should decide in advance whether or not subjects will be entitled to financial royalties or other payments as a result of the use of their specimens, and this policy should be disclosed to research subjects as part of the informed consent process.

Conflict of interest, whether actual or perceived, can effect the integrity of scientific research, as well as science as a profession. There may be situations in which the individual's treating cardiologist may also be an investigator in the artificial heart clinical trial. In this case, the patient should be informed of this duality of interest and given the opportunity to seek a second opinion from a physician who is not associated with the clinical trial. The patient should be reassured that they are under no obligation to participate in the trial and that deciding against trial participation will not adversely effect the existing doctor-patient relationship. Clinicians involved in the research study should disclose any potential conflicts of interest to the institutional review board/human subjects protection committee of the hospital conducting the trial, as well as the research subjects.

Informed consent should be documented by the use of a written consent signed by the research subject. The consent form must be written in simple, nontechnical language so as to facilitate comprehension. Novel tools to assist the informed consent process include videos, question and answer workbooks, photos, sketches, and diagrams. The use of bold face font, underlined font, and simple paragraph structures can also aid the effort to calibrate informed consent to a participant's level of educational sophistication.[15,16] Language that is too complex or technical might intimidate potential participants to indicate that they comprehend the information when in fact they do not. This of course does not imply that simple language be allowed to dilute the potential risks of the study. It is suggested that subjects be allowed to examine an actual TAH device and interact with other TAH recipients as part of the informed consent process. In addition, potential participants need to be given adequate time to review and contemplate the study before they actually enroll. This can be accomplished by requiring a defined time delay between the recruitment interview and the signing of the consent form.

Participants who cannot give informed consent should be excluded from TAH clinical trials because these individuals are very vulnerable. As a patient's time on the UNOS waiting list lengthens they experience increasing physical and mental challenges. Their capacity to comprehend clinical information, as well as risks and benefits, may become impaired due to physical and emotional stress. Due to the risk level of experimental TAH technology, the inability to give informed consent should preclude trial enrollment. Determination of a patient's best interests can be confounded by the fact that there is no way to determine how long a patient will wait before getting an allograft (if in fact they get one), and patients may feel that a TAH is their "only hope." Similarly, if a patient's cardiac surgery goes awry, vulnerable family members should not be put in the position of trying to make a hasty determination of whether or not their loved one would want a TAH. Thus, avoiding this ethically troublesome category of patients is appropriate at this stage of the technology.

Before proceeding from animal studies to human clinical trials, scientists and clinicians should reflect on the ethical and technical complexities of TAH technology, including how a subject's personal values and vulnerability can impact decision-making for trial enrollment. Participation should not be the result of social or financial pressures; rather participants should understand that the nature of clinical trials, in general, is that they normally benefit the lives of future patients (as data accumulates and technologies are optimized) and any incidental benefits to themselves are altruistic bonuses. ■

• *This article is reprinted with permission from the* Japanese Society for Artificial Organs, *(2001) 4:273–277.*

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Ralph J. and Carolyn Thompson Endowment Established in 2001

The Center for Christian Bioethics was recently pleased to receive notification of another generous financial contribution from the Ralph J. and Carolyn Thompson Foundation. In 2001, the Thompsons formally established an endowment fund for the Thompson Library located in the Center for Christian Bioethics. This year the Foundation doubled the principle balance of the endowment. In addition to building the endowment, the Thompsons donated sufficient funds for the routine needs of the library. These funds will allow the Center to keep up to date with the rapid expansion in bioethics publications. If you are in the vicinity of Loma Linda University, you owe it to yourself to come by and experience our library!

Editor's note: We apologize to Ralph J. and Carolyn Thompson for the absence of their names on the list of 2001 Contributors in the previous issue of UPDATE (17.3).

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