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SCOPE NOTE 5

Baby Fae: Ethical Issues Surrounding Cross- Species Organ Transplantation

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On October 26, 1984, Dr. Leonard L. Bailey and his associates at the Loma Linda University Medical Center in California implanted a heart from a seven-month-old baboon in a human infant born with hypoplastic left heart syndrome. Baby Fae, as the newborn child has become known in an effort to preserve anonymity, lived for twenty days with her new heart succumbing on the evening of November 15 to heart and kidney failure resulting from rejection of the foreign tissue.

While media attention to this event has been intense, established journalists and broadcast commentators have eschewed the tendency toward sensationalism and have instead focused on the ethical and social issues generated by this medical event. As a result, the general public has been afforded a greater than usual opportunity to participate in the scrutiny of scientific experimentation, a role generally reserved for the academic and research communities.

Spokespersons, including prominent physicians, leading ethicists, and respected social-commentators, have given voice to a still growing list of concerns which includes the following

The SCOPE NOTE SERIES is intended to present a current overview of issues and viewpoints related to a specific topic in biomedical ethics. It is not designed as a comprehensive review, but rather it offers immediate reference to facts, opinion, and legal precedents (if applicable) for scholars, journalists, medical and legal practitioners, students, and interested laypersons.

- * The experimental rather than therapeutic nature of the transplant.
- * Doubts that the procedure offered a greater chance of survival than any less radical alternative, such as the surgical treatment developed by Dr. William I. Norwood and performed at the Children's Hospitals in Boston and Philadelphia.
- * The lack of prior peer review of the research base for the procedure.
- * The quality of life for Baby Fae, in both physical and social contexts.
- * The hospital's refusal to release the institution's research protocol as well as the consent forms signed by the parents.
- * The quality and extent of information provided to the parents regarding other treatment options, the risks of the procedure, and prognosis for their child.
- * The confusing nature of the account of the events leading up to the surgery and the occasional misstatements of fact provided to the public by the hospital.
- * The allocation of substantial economic resources for transplants and artificial organs which benefit relatively few individuals.
- * The "grandstand" or "adventurist" nature of initially presenting research as a "fait accompli," and the resulting media attention accorded to an institution and physician.
- * The adequacy of reliance on internal review procedures for research involving human-subjects when external review policies do not pertain.
- * Religious and societal response to the implantation of an animal organ in a human being thus violating the integrity of natural species.

* The use and sacrifice of animals in research. Xenografts, or transplants between animals of different species, have been performed with little success for the last twenty years. One of the pioneers in such research involving humans is Dr. Keith Reemtsma who, in 1963, transplanted chimpanzee kidneys into six human patients, one of whom lived as long as nine months. In 1964 James Hardy placed a chimpanzee heart in a 68-year-old man, and in 1977 Christiaan Barnard attempted two such simian-human procedures. These patients lived only hours or days. A search of recent literature in the clinical medicine database, MEDLINE, provides little basis for the hope of success in such ventures. Complications are reported regarding wolf-dog kidney xenografts despite the use of the immune suppressant drug cyclosporin-A, implants of calf-bone for spinal fusion in humans, as well as bovine carotid heterografts utilized for vascular access in humans.

RESEARCH INVOLVING HUMAN SUBJECTS

The federal government has developed and published extensive, regulation. for experimentation involving human subjects with studied attention to problems related to the participation of children and other individuals who lack the capacity for informed consent (see attached bibliography for citations to these regulations). The research on xenografts performed at Loma Linda University has been conducted without the utilization of public funds; therefore, the institution is not legally subject to governmental oversight by the National Institutes of Health (NIH). While the cost of the research and Baby Fae's treatment has not been revealed, hospital officials have declared, that substantial funding has been acquired through staff contributions and support by the Seventh-Day Adventist Church, which sponsors the University. Since Baby Fae's transplant did not involve the use of new drugs or a novel mechanical device, the procedure was also exempt from review by the Food and Drug Administration.

Loma Linda University, including its medical complex, does receive federal funds for other research projects. Thus, it has established an internal Institutional Review Board (IRB) which approves research proposals, and the University also houses a Center for Christian Bioethics. Dr. Charles R. McCarthy, Director of NIH's Office of Protection from Research Risks has stated that Loma Linda "made a commitment to follow the same policies and procedures at that institution no matter what the source of funding," and he concluded that "they have procedurally done what is required and exceeded what is required" (Washington Post, 11/18/84, p. A15. Name and title of NIH official printed incorrectly by Post). It has been revealed that Dr. Bailey's request to perform baboon to human heart transplants underwent a review procedure by the Institutional Review Board which lasted fourteen months. The Board's final decision to allow such surgery to be performed came during the week preceding Baby Fae's admittance to Loma Linda University Medical Center.

In an emotional response to the infant's death, Dr. Bailey saluted his tiny patient with the words "Baby Fae has opened new vistas for all." Since he has vowed to continue his research and has been granted permission for several more baboon to human transplants, it has been suggested by several commentators that there is a need for careful discussion in the scientific and policy-making communities regarding whether such experiments should be subject to more than internal review.

An editorial in the Washington Post (11/20/84, p. A14) contends it would be wise to refrain from any further such transplants involving infants at Loma Linda until "knowledge and consensus" has been achieved in the medical community, and until the procedure has proved successful for a "fully consenting adult." This comment underlines the special considerations that become evident when experimentation is conducted with children or others, such as the institutionalized mentally infirm, who do not have the ability to achieve

informed consent. In an editorial, the journal Nature has summed up Baby Fae's fate with the assertion that "the serious difficulty over the operation . . . is that it may have catered to the researchers' needs first and to the patient's only second" (Nature 312(5990): 88, 8 November 1984). Charles Krauthammer, senior editor of The New Republic, shares this opinion of the procedure stating that for the Loma Linda doctors the motive was the research imperative: "Priority was accorded the claims of the future, of children . . . not yet born." If Baby Fae could have been a consenting volunteer to such research, "the ethical questions would evaporate." As it was, she served as "a conscripted means to a noble end" (Time 24(23): 87-88, 3 December 1984).

Recent government regulations pertaining to protections for children in research impose added responsibilities on Institutional Review Boards depending on the degree of risk and the extent to which the research may benefit the subject. Requirements are also placed on IRBs to monitor the obtaining of permission from parents or guardians. The regulations specifically recommend that "research involving risk should be conducted first on animals and adult humans in order to ascertain the degree of risk" (48 FR 9816). In this context, it must be noted that the rationale for the first experiment, namely that the underdeveloped immune systems, of newborns say at present make them the most appropriate human subjects for xenograft research, seems no longer to be viable.

For Baby Fae., the responsibility for consent for the experimental surgery necessarily was transferred to her parents. In her case, the process of informed consent has been questioned by observers because of the hospital's refusal to release the consent forms signed by the parents, the uncertainty about the efficacy of the alternative Norwood procedure evident in statements made by Dr. Bailey, and the instability apparent in the parents' financial situation and personal lives which could have increased their vulnerability to manipulation or coercion. In addition, newspaper accounts of the idolization

accorded Dr. Bailey by the infant's young mother raise concern about excessive paternalism.

The Judicial Council of the American Medical Association has responded to the Baby Fae xenograft experiment and the implantation of an artificial heart into William Schroeder by suggesting the following guidelines for such research:

- * Experimental or clinical investigation should be conducted as part of a systematic program under accepted standards of scientific research.
- * Physicians conducting such investigations should demonstrate the same concern for people involved as for their patients.
- * Voluntary written consent must be obtained from the patient or from a legally authorized representative if the patient lacks capacity for consent. The physician must disclose the use of an experimental procedure, the nature of the procedure, risks and benefits, alternative procedures.
- * Adequate safeguards should be provided for the welfare, safety, and comfort of the patient. The medical profession recognizes that the advancement of science must be secondary to primary concern for the individual. The physician must never deny the best possible therapeutic modality in favor of an experimental treatment.
- * Physicians should cooperate with the media, with the approval of the patient or patient's lawful representative, to ensure the availability of medical news. However, practices which are designed to create fanfare or sensationalism are not approved.
- * The objective disclosure to the media of pertinent information is encouraged. (American Medical News 27(46): 8-14 December 1984.)

RESOURCE ALLOCATION

In the spirit of Garrett Hardin's concept of "Promethean Ethics," it is necessary to consider

the, long-term consequences of the case of Baby Fae. The growing use of transplanted and artificial organs has exacerbated the necessity for society to make critical choices regarding the allocation of economic resources devoted to health care. Several commentators remind us that it is painful to adopt or even contemplate a national policy that would allow some to die, especially cuddly infants who unconsciously invoke tremendous sympathy. However, we will have to ask, sooner or later, as does Barry Vinocur, whether the interests of justice are served by the investing of enormous sums on such approaches as xenografts and the artificial heart which may extend the lives of relatively few individuals while less spectacularly newsworthy programs of potential benefit to large numbers are jeopardized (see Vinocur, New York Times, 11/9/84, p. A30; and Washington Post, 12/1/84, p. A.19).

Our technological wizardry has clearly outpaced our willingness or ability to grapple with social, political, and economic realities. High-tech medicine has engendered a glamorous, extensive industry which is well on its way to becoming, as Langdon Winner would say, "autonomous" since its complexity and degree of integration in social systems take it out of the public's control. Winner credibly explains that the massive systems required to support modern technology are no longer guided or molded by the goals of society at large. Instead, their ultimate purpose is insular: self-preservation and stability. (See Autonomous Technology: Technics Out-Of-Control as a Theme in Political Thought. MIT, 1977.)

Hardin and Gerald Winslow both warn of the necessity of triage in the coming era of increased: scarcity of resources. If we, as a humane people in a nation built on democratic principles, prefer to adopt egalitarian rather than utilitarian goals, then we must be prepared to support access to new medical advances for everyone who could potentially benefit from them. In the case of heart replacement by transplantation or artificial device, it has been estimated by the American Council on Transplantation that at present in the U.S. there

are approximately 50,000 candidates who could benefit from these procedures. A conservative estimate of government expense for inclusive, non-selective treatment, at an average per patient cost of \$150,000, is \$7.5 billion annually. The decision of Congress in 1972 to pay for kidney transplants and dialysis for all those requiring such care has set a precedent for universal treatment. Expecting to support approximately 5000 patients at a cost of \$140 million, the Medicare system is now faced with 85,000 patients and a staggering bill of \$2 billion (see Friedrich, Time, 10 December 1984, and Reiss, 1982).

When resources clearly cannot satisfy all needs, justice-based triage is often placed in confrontation with public sentiment. Recently passed legislation which attempts to regularize the procurement and distribution of organs for transplantation, Public Law 98-507, has as its goal a just and efficient system of allocation of these scarce resources. But established policy and ideals of distributive justice fade into the background when television brings us face to face with a big-eyed, bravely smiling child clinging to a precarious life.

ANIMAL RIGHTS

Immediate response to Baby Fae's transplant centered on the criticism generated by antivivisectionists who picketed the Loma Linda University Medical Center. Since most people would agree that animals have certain rights, such as the right not to be subjected to pain, we must deal with the dilemma that necessarily occurs when rights conflict. William Raspberry's commentary, appearing only a few days following the historic operation, cavalierly dismisses the concerns of animal rights advocates with the statement "when it comes down to a clear choice of sacrificing an animal to save a human . . . the choice seems ridiculously easy. Maybe it's nothing more than my pro-human prejudice, but I don't see what all the fuss is about" (Washington Post, 10/31/84, p. A17). As Donald J. Barnes,

Washington Director of the National Anti-Vivisection Society responds, "the 'fuss' is about respect for life and alternatives to violence and inequality" (Washington Post, 11/8/84, p. A26).

In Animal Liberation, Peter Singer finds fault with a complacently accepted pro-human attitude toward other species. He argues that at its root is a "selfish desire to preserve the privileges, of the exploiting group" and he asks us to recognize that our "attitudes to members of other species are a form of prejudice no less objectionable than prejudice about a person's race or sex." (p. xi). During an Interview with American Medical News, Dr. Bailey offers another arguable and thoughtful point of view in his response to animal rights demonstrators outside the medical center. Their "sensitivity," he contends, is "born of a luxurious society. . . . when it gets down to a human living or dying, there shouldn't be any question." (Am. Med News, 11/16/84, p. 18). Most participants in the controversy over the use of animals in research now support the concepts of reduction in number of animals utilized, especially regarding the replication of results, and replacement of animals by use of computer simulation.

MAJOR NEWS ACCOUNTS AND EDITORIALS

(Listed Chronologically)

Altman, Lawrence K. "**Baboon's heart implanted in infant on coast.**" *New York Times*, 10/28/84: 1, 38.

Altman, Lawrence K. "**Doctors say baby with baboon heart is doing 'remarkably well.'**" *New York Times*, 10/29/84: A15.

Mathews, Jay. "**Baboon heart transplant in baby defended.**" *Washington Post*, 10/29/84: A1, A13.

Altman, Lawrence K. "**Baby with baboon heart better; surgeons defend the experiment.**" *New York Times*, 10/30/84: A1, C3.

- Mathews, Jay. "**Baboon's heart seen as not sole option for baby.**" *Washington Post*, 10/30/84: A1, A8.
- Raspberry, William. "**Baby Fae's life.**" *Washington Post*, 10/31/84: A17.
- Altman, Lawrence K. "**Confusion surrounds Baby Fae.**" *New York Times*, 11/6/84: C1, C11.
- Altman, Lawrence K. "**Baby Fae's mother asks privacy and repeats support of surgery.**" *New York Times*, 11/9/84: A1, A23.
- Breo, Dennis L. "**Is 'Baby Fae' transplant worth it? Experts mixed.**" *American Medical News* 27(42): 1, 41-43, 9 November 1984.
- Vinocur, Barry. "**Less dramatic remedy for Baby Fae cases.**" *New York Times*, 11/9/84: A30.
- Boffey, Philip N. "**Baby Fae appears well after first sign of rejecting baboon heart.**" *New York Times*, 11/12/84: B14.
- Clark, Matt, et al. "**A Breakthrough transplant?**" *Newsweek* 104(20): 114-116, 118, 12 November 1984.
- Wallis, Claudia. "**Baby Fae stuns the world.**" *Time* 124(20): 70-72, 12 November 1984.
- Altman, Lawrence K. "**Survival record is set by heart-implant baby.**" *New York Times*, 11/13/84: A18.
- Altman, Lawrence K. "**Baby Fae put back on respirator: heart and kidneys begin to fail.**" *New York Times*, 11/14/84: A1, A23.
- Preston, Thomas A. "**Baby Fae: the ethics of medical adventurism.**" *Washington Post*, 11/14/84: D7.
- Altman Lawrence K. "**Baby Fae rallying with two new drugs.**" *New York Times*, 11/15/84: A27.
- Altman, Lawrence K. "**Two reports give new details on baboon heart decision.**" *New York Times*, 11/16/84: A14.
- Breo, Dennis L. "**Interview with Baby Fae's surgeon: therapeutic intent was topmost.**" *American Medical News* 27(43): 1, 13-19, 16 November 1984.
- Dolan, Maura. "**Baby Fae's mother: on a seesaw of optimism and fright.**" *Washington Post*, 11/16/84: A3.
- Altman, Lawrence K. "**Baby Fae dies, but doctor sees gain for science.**" *New York Times*, 11/17/84: 1, 9.
- "**The Life and death of Baby Fae.**" *New York Times*, 11/17/84: 22.
- Mathews, Jay. "**Surgeon hails infant's legacy.**" *Washington Post*, 11/17/84: A1, A5.
- Russell, Cristine, and Rensberger, Boyce. "**Baby Fae case leaves tremors: heart specialists find fault with transplants.**" *Washington Post*, 11/17/84: A1, A4.
- Altman, Lawrence K. "**Learning from Baby Fae: few answers and many questions result from baboon-to-human heart transplant.**" *New York Times*, 11/18/84: 1, 30.
- Russell, Cristine. "**Lack of scrutiny fueled Baby Fae controversy.**" *Washington Post*, 11/18/84: A15.
- Altman, Lawrence K. "**A Deadly battle between medicine and the power of the body.**" *New York Times*, 11/20/84: C2.
- "**Baby Fae.**" *Washington Post*, 11/20/84: A14.

Boffey, Philip K. "**Medicine under scrutiny: Baby Fae case underscores new pressure on researchers at the frontiers of science.**" *New York Times*, 11/20/84: A1, C2.

Dart, John. "**The Adventists and Baby Fae.**" *Washington Post*, 11/24/84: C10.

Goodman, Ellen. "**No more Baby Faes.**" *Washington Post*, 11/24/84: A19.

Adler, Jerry; Huck, Janet; and McAlevey, Peter. "**Baby Fae's heart gives out.**" *Newsweek* 104(23): 94, 26 November 1984.

"**Baboon heart transplant stirs professional debate over efficacy.**" *Medical World News* 25(22): 6-7, 26 November 1984.

Wallis, Claudia. "**Baby Fae loses her battle.**" *Time* 124(22): 88-89, 26 November 1984.

Losman, Jacques G. "**The Research road to Baby Fae and beyond.**" *New York Times*, 11/27/84: A30.

Redfern, Martin. "**Why Baby Fae never stood a chance.**" *New Scientist* 104(1432): 7, 29 November 1984.

Vinocur, Barry (incorrectly printed as Vanocur). "**Baby Fae: a double standard and a needed investigation.**" *Washington Post*, 12/1/84: A19.

Yoder, Edwin M., Jr. "**Life-and-death spectacles.**" *Washington Post* 12/2/84: D7.

Breo, Dennis. "**Medical team thinks Baby Fae procedure will help save lives.**" *American Medical News* 27(48): 8, 7 December 1984.

Altman, Lawrence K. "**Two A.M.A. officials deplore publicity in heart surgery experiments.**" *New York Times*, 12/6/84: A18.

"**Judicial Council offers new research guidelines.**" *American Medical News* 27 (46): 8,

14 December 1984.

LEGISLATION AND REGULATIONS

U. S. Congress. House. Committee on Energy and Commerce. Subcommittee on Health and the Environment. **NATIONAL ORGAN TRANSPLANT ACT.** Washington, D.C.: Government Printing Office, 1984. Serial, no. 98-70.

Hearings to consider proposed legislation, the National Organ Transplant Act. Among witnesses and those presenting statements are Albert Gore; Oscar Salvatierra, President of the American Society of Transplant Surgeons; Jeffrey Prottas, Senior Research Associate of the Health Policy Center at Brandeis University; James Young, Director of Medical Affairs, Blue Cross-Blue Shield; several transplant surgeons; and transplant recipients and family members. A study authored by Lisa Potetz of the Congressional Budget Office, titled "Potential Costs of Organ Transplant Options," is also reprinted.

NATIONAL ORGAN TRANSPLANT ACT. Public Law 98-507. 1984.

Monies are made available for the planning, establishment, and operation of regional organ procurement organizations. The functions of such non-profit organizations are to identify potential organ donors and communicate information to hospitals in each service area; conduct education efforts to acquire organs and tissues from potential donors; arrange for acquisition, preservation, and tissue typing of donated organs; establish criteria for allocation of donated organs among transplant centers. Each organization must have a Board of Directors composed of members representing hospital administrators, neurosurgeons or neurologists, nurses, tissue banks, and the general public. The legislation also mandates the establishment of a United States Transplantation Network which will oversee the functions of regional procurement organizations, maintain a national registry of individuals needing organs, provide a computerized system for

matching organs and individuals, staff a round-the-clock telephone service to facilitate organ matching, facilitate matching donors and recipients by distributing blood sera from individuals in the registry, establish standards and coordinate transportation of donated organs. An advisory council will prepare comprehensive analyses of the medical, ethical, legal, economic, and social issues presented by organ procurement and transplantation. The fifteen member council will include six physicians; two non-physicians representing the field of human organ procurement; four experts from the fields of law, ethics, theology, health care financing and the social and behavioral sciences; three members of the general public. The purchasing of organs is prohibited.

U. S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. **RESEARCH INVOLVING CHILDREN: REPORT AND RECOMMENDATIONS, AND APPENDIX.** Washington D.C.: Government Printing Office, 1977. DHEW Publications Nos. (OS)77-0004 and (OS)77-0005. 2 vols.

The Commission presents recommendations which delineate the roles of Institutional Review Boards, as well as stipulate the necessity of prior research on animals and older children, the protection of privacy, equitable subject selection, adequate provision for informed consent of subjects and parents, the weighing of benefit against risk when procedures involve more than minimal risk, the involvement of a parent or guardian in the research, restrictions on inclusion of children who are wards of the state. The report also provides legal and ethical discussions, reviews of the necessity for and extent of research involving children, along with a survey of institutional review and consent procedures. The extensive appendix volume reprints papers and reports reviewed by the Commission, including a legal analysis of consent for experimentation on children, reports of the National Minority Conference on Human Experimentation, a lengthy

report on a survey of research investigators, and regulations and guidelines for research with children from HEW the British Medical Research Council, Society for Research in Child Development, American Academy of Pediatrics.

U. S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. **IMPLEMENTING HUMAN RESEARCH REGULATIONS: THE ADEQUACY AND UNIFORMITY OF FEDERAL RULES AND OF THEIR IMPLEMENTATION.** Washington, D.C.: Government Printing Office, 1983.

The second biennial report of the Commission on the adequacy of federal regulations and policies for the protection of human subjects of biomedical and behavioral research addresses the problem of evaluating the performance of Institutional Review Boards which oversee local research activities and attempt to insure adherence to federal policies. The procedure for assessing the effectiveness of an institution's IRB by site visit is presented in detail with attention to IRB composition, administrative support, efficiency, performance. Recommendations for improvements in federal regulations for the protection of research subjects center on the reestablishment of an Ethics Advisory Board within HHS, clarification of certain requirements particularly the meaning of "IRB review," establishment of a uniform system for the implementation of federal rules within a single office. Policy statements on the proper conduct of research developed by the American Association of Medical Colleges and Yale University are reprinted.

"Protection of Human Subjects." *CODE OF FEDERAL REGULATIONS*, Title 45, Part 46: 98-117, 1984.

Regulations apply to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or part by a government grant, contract, cooperative

agreement, or fellowship. Guidelines for the establishment of Institutional Review Boards are presented with attention to membership, functions, and procedures for review and approval of proposed research. Requirements for “legally effective” informed consent are prescribed. Additional protections for research involving specific groups including fetuses, pregnant women, prisoners, and children are delineated. In regard to children, HHS limits funding to research involving only minimum risk, or research which presents direct benefit to individual subjects, or presents an opportunity to alleviate a “serious problem affecting the health or welfare of children.” Specific requirements for informed consent by parents or guardians are provided.

BABY FAE, ORGAN TRANSPLANT-ATION, AND RESOURCE ALLOCATION

“**Celebrity Surgery.**” *NEW REPUBLIC* 191(25): 6, 42, 17 December 1984.

Media “hype” has become central to medicine. The baboon transplant and William Schroeder’s artificial heart implant are considered to be what Daniel Boorstin calls “pseudo-events.” They exist “only for the purpose of being publicized.” The \$35 million Humana, Inc. has pledged for their artificial heart project, and the \$1 million cost (as estimated by this author) of the research and Baby Fae’s transplant at Loma Linda are willingly spent because the publicity is valued. Media attention plays a central role in the allocation of donor organs with publicity often determining who will live and who will die. While one concern of ethicists about the Baby Fae case is that other therapeutic options were not offered for consideration to the parents, realistically, the real option for Baby Fae, until the Loma Linda team came along, was the “conventional therapy . . . to place the babies in a corner and let them die.” “Celebrity” patients participate in a process that is “more religious than medical.” It is a public sacrament designed to celebrate our society’s respect for the value of human life. This noble premise, however, is false and hinders the

development of sensible social policy.

Fox, Renee C., and Swazey, Judith P. **THE COURAGE TO FAIL: A SOCIAL VIEW OF ORGAN TRANSPLANTS AND DIALYSIS.** 2nd ed. Chicago: University of Chicago Press, 1978.

Working together at the Harvard University Program on Technology and Society, Fox, a sociologist, and Swazey, a biologist and historian of science, produce an examination, of the “medical, ethical, and social implications of the ‘de- democratization of dialysis,’” and also a conceptual analysis of “the process of therapeutic innovation” with emphasis on cultural ramifications. Focusing on the research physicians engaged in these biomedical innovations, the authors spent extensive periods of time at major transplantation and dialysis centers observing surgical procedures, out-patient clinics, medical team conferences, and research laboratories in addition to conducting interviews with patients and families, and with members of transplant teams. Emerging themes are the dynamics of the gift-exchange relationship including the gatekeeping role of the medical team that decides who will receive treatment; as well as the problems of uncertainty inherent in therapeutic innovation. Case studies of Houston’s artificial heart program and Seattle’s dialysis treatment center assist in the construction of a sociological portrait of the transplant surgeon which exemplifies the “courage to fail” ethos of such physicians, and exhibit the complexity and seriousness of the resource allocation issue. Seattle’s adoption of “social worth” criteria for treatment selection is carefully considered. The text demonstrates that these medical innovations are both causing reformulations of societal value systems and are themselves shaped by the culture surrounding them.

Friedrich, Otto. “**One Miracle, Many Doubts: A Feat of Heart Surgery Sharpens the Debate Over Benefits and Costs.**” *TIME* 124(24): 70-73, 77, 10 December 1984.

In light of the second implantation of an artificial heart and the increase in organ transplantations, many medical experts are beginning to voice doubts about the “course of high-technology medicine, doubts about cost, ethics, efficiency and simple justice.” The cost of such medicine is staggering: \$100,000-200,000 for heart transplants, \$20,000 a year for a kidney patient on dialysis. Congress’s decision to pay for kidney transplants and dialysis for all who need them has resulted in a cost of \$2 billion for 82,000 patients. It has been estimated that at least 50,000 people could benefit from artificial or transplanted hearts. At an average cost of \$150,000 per operation, the cost of merely initial treatment is conservatively estimated at \$7.5 billion annually. In a trillion-dollar economy, such costs are feasible, representing only 3 percent of the budget deficit or the price of three Trident submarines. The question, however, is how resources for medicine should be allocated. Observers have recognized that our spending of \$1 billion every day on health care has not generally improved the health of the citizenry or extended the life span. Instead the expenditures have created a large industry. Health care for the poor and preventive medicine, which would greatly improve the lives of thousands, receives little funding while priority is given to experiments on individuals. Since demand exceeds resources in high-technology medicine, rationing or triage is now commonly practiced. Few scientists see any retreat from high-tech medicine since its “glamour attracts talent, money and publicity,” and since spin-offs from such research will continue to be invaluable.

Gorovitz, Samuel. **“Will We Still Be ‘Human’ If We Have Engineered Genes and Animal Organs?”** *WASHINGTON POST*, 9 December 1984: C1, C4.

In an attempt to explore the boundaries of possible biological futures for man, Gorovitz constructs two hypothetical cases involving transplantation of animal parts to humans and the modification of “germlines” through genetic engineering. He rejects the “slippery slope” approach which

argues that once first steps are allowed, placing limitations will be arbitrary and controversial. Instead, reliance rests on “our capacity to exercise judgment.” In regard to the use of animal parts in humans, we agree that certain procedures are unproblematic, such as the utilization of pig heart valves. Our actions are guided by the realization that we would respond in a “fundamentally different way” to a body visibly constructed of parts of other animals since “participation in the human social order is deeply rooted in having a human body.” Gorovitz believes we will resist victimizing others by “increasing their separation from their fellow human beings, thus diminishing their humanity.” We can proceed with interspecies transplants and gene transfer because we can and will “exercise discretion, change direction, and say ‘this is far enough.’”

“Grandstand Medicine.” *NATURE* 312(5990): 88, 8 November 1984.

The “serious difficulty” of the baboon heart transplant operation is stated to be its catering to “the researchers’ needs first and the patient’s only second.” Fault is found with the failure to search for a suitable human heart, and the highly experimental status of the procedure. Loma Linda Medical Center is called on to release protocols for the operation and consent forms signed by Baby Fae’s parents. Since more such transplants have been approved, the hospital and personnel have “an obligation to the scientific community if not to the public as a whole” to provide reassurance as to the viability of the procedure and the information provided to parents. “Otherwise suspicions will arise that its researchers are playing to the grandstands.”

Hardin, Garrett J. **PROMETHEAN ETHICS: LIVING WITH DEATH, COMPETITION AND TRIAGE.** Seattle: University of Washington Press, 1980.

The name Prometheus means “fore-thinker,” thus a Promethean perspective on ethics weighs present actions against potential future

consequences. Always, the ecologist's question, "And then what?" must be posed. To illustrate this approach to ethics, Hardin considers three topics that are often shunned in our culture: death, competition, and triage. With the premise that there can be an excess of a good thing, Hardin concludes that there must be limits on research aimed at staving off death at any cost. Death, Hardin contends, "will always fulfill an important, even essential, role in human society." Physicians have generally been unwilling to think rationally about death, and their bias toward life forces prolonged dying on their patients rather than a quick death. The purpose of triage, from the French "sort" or "choose," is to maximize the number of lives saved when resources are scarce. The word, however, is perceived to be negative because of the implied abandonment of the unchosen. The appearance of compassion is stimulated by injudicious rescue efforts which cannot stand the test of the Promethean question "And then what?" The compassionate Promethean renounces some present good for the sake of the future.

Iglehart, John K. "Transplantation: The Problem of Limited Resources." *NEW ENGLAND JOURNAL OF MEDICINE* 309(2): 123-128, 14 July 1983.

A Congressional inquiry launched by Albert Gore, uncovered dilemmas facing policy makers surrounding the availability of organs and the cost of transplantation procedures. Such questions as "Who shall live?" "Who shall pay?" and "Who shall decide?" raise social, economic, medical, political, and ethical questions in a humanitarian society where resources are limited. Hearings underscored the need to develop a mere rational organ procurement system and an adequate mechanism to evaluate emerging technologies. The shortage of organs will be exacerbated by improvements in medical techniques and the use of the new drug, cyclosporin, which suppresses rejection of foreign tissue. Experts agreed that many transplantation procedures are no longer experimental but are still classified as such by

third-party payers as an excuse for not financing such operations. Dr. Norman Shumway described heart transplantation as a "proven therapeutic intervention with a five-year survival rate of at least 50 percent." Media attention appears to substantially influence resource allocation priorities. Publicity has given more urgency to liver transplants required by a few individuals than to the mere widespread need for donor kidneys. Although the Surgeon General recommended that the federal government participate but not assume a "leadership position" in the procurement process, Gore's report will recommend a strong federal role in a "cohesive national program."

JUSTICE AND HEALTH CARE. Edited by Earl E. Shelp. Dordrecht, Holland: D. Reidel 1981.

The collection of fifteen essays by eminent scholars critically examines the issues surrounding the allocation of healthcare resources. The volume opens with conceptual and historical analyses of theories of justice, including Allen Buchanan's review of utilitarianism, libertarianism, and Rawls's "Justice as Fairness." Eric Cassell opens the second section devoted to micro-allocation issues on a pragmatic note by arguing that abstract theories of justice are not appropriate as a basis for decision making at the bedside. He finds concepts of love, compassion, and mercy to be more adequate guideposts for treatment decisions. Other essays provide considerations of justice in programs for prenatal care, care of defective infants, and the dying patient. The most extensive section, that devoted to macro-allocation, includes James Childress's discussion of priorities in health care in which he finds that current emphasis favors rescue or crisis medicine rather than preventive care. Karen Lebacqz sees the concern of justice to be as important an element in selection of subjects for research as informed consent and risk-benefit ratio.

Katz, Jay, and Capron, Alexander Morgan.

CATASTROPHIC DISEASES: WHO DECIDES WHAT? A PSYCHOSOCIAL AND LEGAL ANALYSIS OF THE PROBLEMS POSED BY HEMODIALYSIS AND ORGAN TRANSPLANTATION. New York: Russell Sage, 1975.

Guided by the question “Who should have the authority to make the decisions which have such far-reaching consequences for those affected by catastrophic diseases and for society as a whole?” Katz and Capron identify the problems raised by such diseases, specifically kidney and heart failure, and construct a detailed model for assessment of the issues, formulation of policy, and oversight of major medical interventions. Since decisions regarding treatment of these diseases exemplify the “tragic choices” necessitated by scarce resources and the fact that all victims cannot be saved, the authors advocate an open decisionmaking process which includes voices from outside the biomedical establishment at the formulation and review stages, while administration of research and therapy is placed in the hands of professionals in the field. A review of innovative treatments for heart and kidney diseases, which explores the goals and values served by a commitment to treat these diseases, is followed by attention to the authority and decisionmaking capacity of the participants—patients, families, physician-investigators, institutional review boards, and government agencies. The work then turns to a recommended framework for development of regulations to govern investigation and treatment with attention to resource allocation decisions, donor selection, administration at local and national levels, and review through scientific publication, professional bodies, and the courts.

Krauthammer, Charles. “**The Using of Baby Fae.**” *TIME* 24(23): 87-88, 1984.

While the case of Baby Fae brought out defenders of beast, the integrity of man, and the right of the press to information, Krauthammer asks “Who was defending Baby Fae?” The motive for the

procedure is considered to have been the “research imperative” rather than the “therapeutic imperative.” Baby Fae was a means to a “noble end . . . priority was accorded to the claims of the future, of children not yet stricken, not yet even born.” The Nuremberg Code on human experimentation prohibits the participation of subjects without their consent. Baby Fae could not give consent and whether her parents were truly informed of the prognosis, risks, and treatment options is open to question. A society that grants the future some claims gives a “moral imperative” to some research on non-consenting children. As Paul Ramsey argues, those involved must “sin bravely.” In this case, bravery was “fatuously ascribed to Baby Fae,” an infant as incapable of bravery as awareness of her role.

Levine, Carol; Randal, Judith; Christopherson Lois K.; and Caplan Arthur L. “**To Mend the Heart: Ethics and High Technology.**” *HASTINGS CENTER REPORT* 12(1): 13-24, February 1982.

Articles on coronary artery bypass surgery, heart transplants, and the artificial heart pose issues of equity of access, just allocation of health care resources, efficacy of treatment, and the distinction between research and therapy. Randal considers factors which may influence the patient population for bypass surgery which is predominantly middle-class, white and male. This skewing raises serious questions of equity. She explains that this type of surgery is collectively the most costly procedure performed in this country and the condition it treats could often be avoided or managed by changes in life style. The patient selection criteria used for heart transplants at Stanford University is examined by Christopherson. She questions whether it is fair to restrict treatment to those who have the greatest probability of survival or to those with strong family support. At present, another implicit criterion is the ability to pay. However, “societal indignation over economic barriers to health care has not been matched by willingness to assume the costs for those who are otherwise excluded.”

Caplan analyzes the quixotic regulatory process which governs the introduction of novel medical devices. In a discussion of Denton Cooley's implantation of an artificial heart in 1981, Caplan explains that Cooley had not applied for review by the FDA or a local institutional review board. This violation received little attention since the government's program for development of a totally implantable artificial heart has been less than successful and is criticized for targeting massive funds for a "half-way" technology which may not be as efficacious as more simplistic approaches to heart disease. As with Baby Fae's radical transplant, Cooley's use of an artificial heart appears to "cross over the borderline from desperate medical therapy to research, but the distinction may seem trivial when the surgery can be depicted as concrete evidence of technological advance in a field lacking empirical examples of success."

Reiss, John B.; Burckhardt, John; and Hellinger, Fred. "**Cost and Regulation of New Medical Technologies: Heart Transplants as a Case Study.**" *In: CRITICAL ISSUES IN MEDICAL TECHNOLOGY*, ed. by Barbara J. McNeil and Ernest C. Cravalho. Boston: Auburn House, 1982, pp. 399-417.

Government funding of heart transplants, in a manner analogous to the End Stage Renal Disease program, is analyzed in regard to the identification and estimation of potential budget outlays, and the recognition of attendant social, ethical, and legal concerns. Components of costs are carefully rendered with a total per-patient cost for recipients surviving five years placed at \$177,000. While in 1980 the Department of Health and Human Services estimated that 1000 hearts could be made available for transplantation, potential candidates are numbered at 30,000. Thus, total government costs range from \$146.8 million for 1000 patients to \$4401 million for 30,000 patients. Beyond funding, regulatory issues which must be addressed are patient selection criteria, accountability measures, the lack of incentives for efficiency and diffusion of technology in a

cost-based payment system, macro-resource allocation policies.

Teresa and Howard, as told the Eleanor Hoover. "**Baby Fae: A Child Loved and Lost.**" *PEOPLE* 22(23): 48-58, 63, 3 December 1984; and 22(24): 151-154, 157, 160-161, 10 December 1984.

Baby Fae's parents discuss their insecure personal lives, the baby's birth, their short time with their daughter, and their reactions to the diagnosis and operation. From their story, it appears that initial treatment of their baby was rather callous. Baby Fae was sent home to die without support or assistance offered to the young parents. Teresa and Howard voice their conviction that the transplant was the "best shot at giving her life." Although the Norwood operation was discussed with the parents, Teresa dismissed it quickly since she believed "it was only temporary." She explains that she read unpublished papers on the procedure and watched films of transplant operations in her attempt to make the right decision. The anxiety and attachment of the parents for their child is communicated, and reactions to the course of treatment and Fae's decline are detailed.

Vaux, Kenneth. "**Baby Fae and Human Wholeness.**" *CHRISTIAN CENTURY* 101(38): 1144-1145, 5 December 1984.

The most pertinent ethical consideration regarding Baby Fae's transplant is whether the procedure was morally justifiable. According to Vatican theologian Gino Concetti, conditions which would make an interspecies transfer "licit . . . had not been met" in this case. These conditions include the certainty that no human or artificial organ was available and a foreseeable "broadly positive outcome." Seventh-Day Adventists believe we should strive to make an impaired body whole and sound. Vaux feels the implant "was not ethically justified." He argues that the Nuremberg Code stipulates that benefit to the subject must clearly override danger, and Christian ethics demands that abstract goals of future benefit do not

legitimize the harm or sacrifice of lives entrusted to our care. Also at issue is the “ultimate nature and destiny of the human person.” A view of the human person as objectifiable and “amenable to scientific discernment,” as propagated by early modern science, has helped to generate a belief that a person is malleable and imperfection should be assaulted by any means. This technological, utopian attitude which attempts to ameliorate nature’s inadequacies “may be abolishing our true being.”

Winslow, Gerald H. **TRIAGE AND JUSTICE: THE ETHICS OF RATIONING LIFE-SAVING MEDICAL RESOURCES.** Berkeley: University of California Press, 1982.

The development of just criteria for triage decisions is explored by weighing utilitarian and egalitarian approaches on the basis of Rawls’s theory of justice as fairness. There is now an emerging awareness that our ability to create new technology-dependent costly medical therapies forces us to ration these life-saving resources. Winslow utilizes two scenarios which necessitate triage decisions: planning for a major earthquake and allocation of the artificial heart. Now that technical problems associated with the totally implantable artificial heart are being solved, attention is shifting to social considerations of scarcity and adequate funding. Since potential beneficiaries have been estimated at ten times as large as those requiring hemodialysis, it is questionable that society would be willing to pay the bill for all who need treatment. Winslow is careful to point out that triage decisions are not limited to selection of patients for treatment but also extend to policy considerations regarding allocation of resources for medical care. Decisions on which diseases or problems will take precedence “deserve scrutiny from the perspective of distributive justice.” Winslow does develop a framework for triage decisionmaking which favors a view of equal access to scarce medical resources instituted by a system of random selection among medically eligible candidates.

ANIMALS IN RESEARCH

ANIMAL RIGHTS AND HUMAN OBLIGATIONS. Edited by Tom Regan and Peter Singer. Englewood Cliffs, N.J.: Prentice-Hall, 1976.

An anthology of writings ranging from Aristotle and Aquinas to Schweitzer and Singer explores three questions: distinctions in animal and human nature, whether humans have obligations to other species, and the assignment of rights to animals. Considerably distinct points of view are evident throughout the collection. For Aristotle, man is the only “rational animal,” and Descartes views animals as “machines.” Darwin, however, contends that there is not an “enormous gulf” separating man and the lower animals. Many commentators agree that we have obligations to all beings possessing sentience (the ability to experience pain and pleasure), rationality, or autonomy. Bentham, Mill, Plutarch, Singer, and Schweitzer agree that the quality of sentience alone is enough to obligate us not to cause unnecessary pain to animals. While Kant does not attribute free will or ego to animals, Schopenhauer contends that animals do possess self-consciousness. Rickaby feels animals cannot have natural or legal rights since, they are not rational. Feinberg counters this view by pointing out that infants and mental defectives are not rational yet we would not strip them of rights. As to what rights animals have, Feinberg feels they have a right not to be treated cruelly, Salt thinks they may exercise emotional and cognitive capacities, Regan argues for a right to life, and Rachels sees a right to liberty.

ANIMALS IN RESEARCH: NEW PERSPECTIVES IN ANIMAL EXPERIMENTATION. Edited by David Sperlinger. Chichester/New York: John Wiley, 1981.

Legislation to control animal experimentation in England, other European countries, and the United States is documented in the first section of this volume with attention to implementation of

regulations in practice and recent proposals for reform. The second part looks at the main fields where animals play a major role in research, with chapters devoted to medicine, biological sciences, cancer research, behavioral sciences, and ethnology. The final section on general concerns includes an interesting theoretical piece by Don Bannister which links the use of animals in psychology with a particular and limited definition of the field. This convergence of methodology and theory is given wider application in the author's contention that the use of animals in medical research is also tied to a particular approach which emphasizes cure rather than prevention.

Regan, Tom. **THE CASE FOR ANIMAL RIGHTS**. Berkeley: University of California Press, 1983.

Regan attempts to present an approach which strikes a balance between the demands of academic philosophers and the practical concerns of veterinarians and laboratory scientists. In carefully elucidating his case for animals, the author is scrupulously not "against humanity." His rights thesis is also not "anti-science." The requirement to treat animals justly is considered part of, not opposed to, the human rights movement. Animals are held to be sophisticated creatures with mental capacities for desires, expectations, the ability to feel pleasure, pain, and emotions. They have an intrinsic value which is independent of their potential usefulness to higher creatures and therefore possess the moral right to be treated with respect. Regan demonstrates that moral questions concerning the degree of animal awareness and autonomy, views of duty, justice, equality, and rights can be rationally addressed. He presents a well-supported argument that those who would deny basic rights to animals have a "morally impoverished vision" of the duties of humanity.

THE ROLE OF ANIMALS IN BIOMEDICAL RESEARCH. Edited by Jeri A. Sechzer. *ANNALS OF THE NEW YORK ACADEMY OF*

SCIENCES 406: 1-229, 1983.

The proceedings of a workshop sponsored by the Animal Research Committee of the New York Academy of Sciences addresses the use of animals in various scientific disciplines, evolving research methodologies especially the development of statistical strategies which lessen the number of animals utilized, and the effect of ethical concerns on regulatory policy. Contributors examine the contributions and use of animals in toxicology, pharmacology, behavioral research, neuroscience, psychiatry, nutrition, and pain research. Ethical discussions center on evidence of animal self-awareness and a social climate which values individual rights. Considerable attention throughout the volume is given to the utilitarian ratio of animal sacrifice and pain to the amount of benefit to humans or other animals. Arthur Caplan provides a concise overview of the major areas of contention regarding the legitimacy of animal research and the moral worth of animals.

SCIENTIFIC PERSPECTIVES ON ANIMAL WELFARE. Edited by W. Jean Dodds and F. Barbara Orlans. New York: Academic Press, 1982.

The contributions in this collection, resulting from the First Conference on Scientific Perspectives on Animal Welfare, sponsored by the Scientists Center for Animal Welfare, represent a concerted effort by scientists to take the initiative toward responsible use of animals in research. The volume's purpose is to show that "the advancement of science and of humane ethics are consonant and complementary." Accountability for the proper use of animals is accorded to four distinct groups: investigators, institutions, funding agencies, and publication editorial boards. Responsibilities of each of these groups in the development of review procedures are detailed and discussed in a separate series of papers with a summary statement for each group. The volume concludes with twelve major recommendations on animal experimentation developed by the conference. These include the elimination of

unnecessary pain, the establishment of institutional animal care and use committees, public awareness programs, use of consultants with expertise in animal issues to review funding proposals, training courses to increase scientists' empathy with animals, inspection procedures, the establishment of "codes of practice" regarding humane animal care in journal editorial policies, additional funds for upgrading animal facilities. Also provided are an historical review of animal experimentation, and a discussion of the three classic tenets of humane experimentation, namely, refinement, replacement, and reduction.

Singer, Peter. **ANIMAL LIBERATION: A NEW ETHICS FOR OUR TREATMENT OF ANIMALS**. New York: Random House, 1975.

Pro-human "speciesism" is considered to be a form of prejudice as morally objectionable as racial or sexual bias. Singer's arguments for the interests of animals are based on a utilitarian viewpoint. Since animals are sentient creatures, their degree of suffering cannot be calculated to be outweighed by goods to be obtained by human society through animal experimentation or intensive agricultural production methods. Neither can our attitudes be justified by a presumed lack of intelligence in animals since we would not subject infants or mentally defective humans to harmful experimentation the purpose of which is to serve the ends of others. However, Singer rejects the notion that animal rights should never be violated, rather he argues for elimination of trivial use and needlessly harmful practices. One chapter documents unnecessary, redundant, and useless yet harmful experimentation on animals. He advocates vegetarianism and provides an

extensive exploration of "factory farms."

BIOETHICSLINE, a database in the MEDLARS system of the National Library of Medicine, and produced by the Information Retrieval Project of the Kennedy Institute of Ethics, may be searched for publications dealing with ethical, moral, and public policy issues related to the case of Baby Fae. the following subject terms are suggested. They may be combined to limit retrieval to specific aspects of the case:

(KW) BABY FAE
(KW) ORGAN TRANSPLANTATION
(KW) HUMAN EXPERIMENTATION
(KW) ANIMAL ORGANS
(KW) PARENTAL CONSENT
(KW) HEARTS
(KW) RESOURCE ALLOCATION
(KW) SELECTION FOR TREATMENT

The annual volumes of the BIBLIOGRAPHY OF BIOETHICS also may be consulted for materials related to these topics. The BIBLIOGRAPHY includes chapters devoted to "Human Experimentation," "Informed Consent," "Organ Donation," "Organ Transplantation," "Resource Allocation." Volume 10 of the BIBLIOGRAPHY OF BIOETHICS, produced and published by the Kennedy Institute, of Ethics, is available for \$25 (\$15 to members of the Kennedy Institute) from the Kennedy Institute of Ethics, Georgetown University.

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