

Approved _____

Date 3-27-86

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by Marvin L. Littlejohn at _____
Chairperson

1:30 a.m./p.m. on March 17, 1986 in room 423-S of the Capitol.

All members were present except:

Rep. Bideau, excused.

Committee staff present:

Emalene Correll, Research
Norman Furse, Revisor
Sue Hill, Secy. to Committee

Conferees appearing before the committee:

Rep. Dale Sprague
Senator Jack Steineger
Ms. Rita Wolf, Director of Policy & Planning, Dept. of Health & Environment
Ms. Carmen Koch, Mid-West Organ Bank, Wichita, Ks.
Bob Randall, Mid-West Organ Bank, Wichita, Ks.
Steve Vogelsang, American Red Cross, Wichita, Ks.

Visitor's register, (no one registered this date).

Chairman called meeting to order, and thanked Rep. Elaine Hassler for stepping in on very short notice last week to take over for the Chairman in carrying 3 bills to the House Floor that were to be debated. He appreciated her help. Also stated that he was happy to be back to work after being in the hospital for a few days last week. Thanked all for their kind words.

Chairman asked wishes of members in regard to minutes in need of approval. Rep. Williams moved to approve minutes of February 27, March 3,4,5, and 6th as written, motion seconded by Rep. Cribbs Motion carried.

Chair noted that SB 179 will not be discussed as noted on agenda as the finished version of the balloon of that bill is not yet ready. Committee will discuss it tomorrow.

Chair stated hearings will begin on HCR 5049, and invited Rep. Sprague to speak to committee in this regard.

HCR 5049:--

Rep. Sprague asked members to recall when he had earlier asked for this legislation in HCR 5049, he suggested that it might be a vehicle to be studied during Interim. This is a bill that would deal with payment of liver transplants through the SRS. Since he spoke to committee on February 24th, he has learned from Ms. Correll in Research that there are 9 other states reviewing such procedures. Currently, he stated, Medicaid under Kansas plan does not pay for heart/lung/pancreas/liver. He stressed he feels it appropriate at this time to ask the LCC to accept this legislation for Interim Study. He answered questions, i.e., about expanding the study to encompass a broad scope of study, insurance to cover transplants, availability of organs, where such surgeries to take place, educating public. His request this date he said, is not to ask for immediate action on HCR 5049 by this committee since there are too many unknowns, i.e., fiscal note, priorities of donors.

Hearings closed on HCR 5049.

Chair asked Ms. Correll to give brief overview on SB 532.

Ms. Correll stated the Senate had found the bill difficult, and had appointed a sub-committee to study it. SB 532 was heavily amended by this sub-committee, and she

CONTINUATION SHEET

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE

room 423-S, Statehouse, at 1:30 A.M./p.m. on March 17, 1986

explained the bill section by section as amended by the Senate. This bill creates new legislation, but would be made a part of the Anatomical Gift Act. She then said, this amended version passed the Senate 39-1.

Hearings began on SB 532:--

Senator Steininger stated through SB 532, families faced with tragedy with members of their families can still help someone else. It is a bill to inform Kansans they can donate organs to help others to live. It has been a source of great help to many to know they can salvage something out of the great tragedy they are facing, and give life to others. Kansas has been a very progressive state in health issues, and presently there is a very active group working for organ procurement, and this legislation will serve to strengthen the organ procurement process. He answered questions, i.e., no, organs are not purchased, not autioned off.

Ms. Rita Wolf, Director of Policy and Planning in the Department of Health and Environment gave hand-out to members, (see attachment No.1), for details. She stated SB 532 would require hospital administrators or their designees to request anatomical gifts from families of potential donors and obtain their permission in order to procure organs for donation. The introduction of immuno suppressive drugs, such as cyclosporine, which prevent rejection of transplanted organs combined with increasing sophistication of surgical care have greatly contributed to and increased the success of organ transplantation. With increased need for donation of organs is widely acknowledged and the scarcity of organs is a problem. Efforts to educate the public in this regard should be made. Further, she said identification of potential organ donors is best done in the hospital. Brain-dead patients, victims of severe head injury or strokes are usually determined in the critical care unit of a hospital. It is estimated that in the United States only 15% of families of these potential donors are asked for organ donations. This bill, if passed, should increase those numbers. Yes, the issue is highly sensitive. Intrusion of requesting organ donations at a time when a family is suffering with a tragically ill family member is difficult, and protocol developed by the hospital should address this situation. Their Department recognizes the need for organ donation and because of that, supports SB 532, however, it might be appropriate at this time to ask that a Task Force be established by the Kansas Legislature to study the medical, legal, ethical, economic and social issues presented by organ procurement and transplantation, and its recommendations hopefully should meet with the government policy questions.

Ms. Wolf answered questions, i.e., "Are you saying you don't want the bill passed until you have this study?" She answered, "That is my feeling. I think there are so many issues involved in organ donation and I think that a study should be made. There are other states that have done that. Maryland has done that. I think that all issues should be explored. The concept is adaptable and something that we support, but there are so many questions that need decisions." A committee member then asked, "Is that the Department's decision or your decision?" She answered, "I'm speaking for the Department. The reason I said my decision, is that Ms. Sabol isn't here, and I don't know exactly how she feels about that. I produced the testimony and this whole thing is mine, and so this is the way I feel. As I said, Ms. Sabol is in Wichita, and I tried to get some answers before I got here, but couldn't because she wasn't available. Preliminary discussion when I started preparing testimony earlier in the year, I told her at the time that I thought that there are so many other issues involved and I think she has a certain amount of agreement to that".

Ms. Carmen Koch, Mid-West Organ Bank, Wichita, Kansas, gave hand-out to members, (see Attachment No.2). (Attachment was packet of information including her printed testimony and several articles about organ donations.) She stated she is a Registered Nurse, and presently the Program Coordinator for the Mid-West Organ Bank of Kansas City, Missouri. Their organization is a non-profit organ procurement agency serving the state of Kansas and the Western two-thirds of Missouri. A large part of their work goes to education programs for medical and nursing staff in hospitals in the area. How to identify and medically maintain potential organ donors and how to approach families of these donors is included in their educational program. The importance of the participation of health care professional cannot be over emphasized. They are the gatekeeper of the donor process, and without their participation, the family

CONTINUATION SHEET

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE

room 423-S, Statehouse, at 1:30 /a/m./p.m. on March 17, 1986

Hearings continue on SB 532:--

cannot be given the opportunity to donate the organs of a loved one. Midwest Organ Bank supports the concept of required request in Kansas, but cannot support SB 532 as it has been amended. They have grave concerns about certain aspects of this bill, i.e., taking the opportunity of approaching the family away from the attending physician. He is the one who is best qualified to approach the family in regard to organ donation, and may wish to do so. Also the bill does not say the donor hospital shall notify an organ procurement organization, but does say, notify an organization which procures anatomical gifts. The distinction is most important. Also, reporting requirements stated could place an unnecessary burden on the hospitals. We urge reporting of this information be kept as simple as possible. Our concerns, she said, are also shared by the University of Kansas Medical center. We urge this committee to consider our concerns and amend SB 532 to reflect these concerns. She then answered numerous questions from members, i.e., they are a procurement organization, and no they cannot contact all hospitals. It is their hope that hospitals will contact them when appropriate. Yes, we do have staff to go to procure the organs, and often it is the same surgeons who will do the transplant operation as well.

Ms. Koch continued to answer questions, i.e., legislation signed by President Reagan in 1984 made it illegal to buy and sell organs. Mid-West Organ bank does give first priority to Mid-West patients, and the urgency of need, compatibility, not social-economic status is criteria for transplants.

Bob Randall, Mid-West Organ bank spoke to members on HB 532, saying he was in full support of Ms. Koch's comments. He stated required requests should be viewed from a medical point of view if it is to be effective, similar to informed consent when a patient goes to surgery. Donor families have the right to know all available options, regardless of their religious beliefs, or if someone in the family might have objections to organ donations or transplants. It is our job as professionals to make this information available to families he said. There is no hospital that cannot support organ donors. This legislation could make sure all hospitals could approach all families in the respect to organ donations. He answered questions, i.e., small hospitals in the rural parts of Kansas might have problems in regard to having proper facilities and some disagreement on this subject was discussed at this point. Further, he stated, he hopes that potential donors in these rural areas will not be ignored and he is hopeful this legislation will speak to this problem as well.

Steve Vogelsang, American Chapter of REd Cross, Wichita, Kansas spoke to HB 532. His concerns were with language in line 24, if it were changed to "based on hospital accepted policy and procedures", this would potentially eliminate need for language in bill on lines 83-88 which would also eliminate confusion since every hospital does have the potential to support tissue or eye donations. Lines 72-77 place too heavy a burden on already overburdened hospitals record keeping. Yes, it is vital that proper documentation be done, but unless this information is readily made available to organ-tissue banks, it will do no good. Original language in line 79 is better than new language in line 80. This would better provide for better and fair distribution of organs. This legislation will provide on-going programs and their organization feels that continuing education is necessary to keep hospital staff stimulated in these procedures. The need for organ donors will continue to grow, if proper methods are used. He then answered questions, i.e., currently there is no FDA licensing required for organ-tissue banks, however regulations will most likely be forthcoming in the next couple of years. Any hospital in the state of Kansas can support an organ-tissue donor. Hospitals that do not have a ventilator or ICU cannot support a solid organ donor. Yes, the cost is picked up the the procurement organization. There are no costs to the hospital or the donor. The processing fee is picked up by the third party carrier.

Chairman at this point asked if 2 conferees scheduled yet to speak could return to meeting tomorrow, and they agreed to.

Meeting adjourned at 3:15 p.m.

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

Testimony on Senate Bill 532

Presented to House Public Health and Welfare
March 17, 1986

Presented by Barbara J. Sabol

*Attn. #1
3-17-86*

This is the official position taken by the Kansas Department of Health and Environment on Senate Bill 532.

BACKGROUND INFORMATION

Senate Bill 532 requires hospital administrators or their designees to request anatomical gifts from families of potential donors and obtain their permission in order to procure organs for donation. The introduction of new immuno suppressive drugs such as cyclosporine which prevent the rejection of transplanted organs combined with the ever-increasing sophistication of surgical care have greatly contributed to and significantly increased the success of organ transplantation. Transplant procedures now provide life-saving treatment for a small number of patients dying from end-stage cardiac and liver diseases. Survival rates for heart transplant recipients for one-year survival are at 80%, 65% for liver transplant recipients. Heart and liver transplants are widely recognized as acceptable medical treatments and no longer experimental procedures. With increased success we can predict increased transplantation. With increased transplantation, the greater will be the demand for donated organs. Currently across the nation there are not enough donations of any type of organ to meet the demands of potential recipients. Organ transplantations have also attracted significant public attention. The search for organs by eagerly awaiting recipients is often publicized by the national media. Even our own local newspapers and television recently have publicized cases in our own community. Funding assistance to obtain these high technology, very costly yet often life-saving procedures is often addressed. The need for donation of organs is widely aknowledged and the scarcity of these organs present a problem. Efforts to educate the public about the need for organ and tissue donation should be made. Individuals should be encouraged to indicate their willingness to become organ and tissue donors.

STRENGTHS

Identification of potential organ donors is best done in the hospital. Brain-dead patients, victims of severe head injury or strokes are usually determined in the critical care unit of a hospital. It is estimated that in the United States only 15% of families of potential donors are asked for organ donations. The provisions of this bill should increase these numbers.

WEAKNESSES

This issue is highly sensitive because of the perceived intrusion of requesting organ donation at the time a family is suffering the loss of a member. The protocol developed by the hospital should address this area. Some firm mechanism that ensures the request from every potential donor should be developed to guarantee consistency in policy implementation.

*Attn. #1
3-17-86
Hs. PHW*

DEPARTMENT'S POSITION

The Department recognizes the need for organ donation and supports Senate Bill 532.



Midwest Organ Bank

4006 Central

• Kansas City, Missouri 64111

• Phone: 816-531-3763

Attn # 2
3-17-86

March 17, 1986

Representative Littlejohn and Members of the Committee:

I am a Program Coordinator for the Midwest Organ Bank in Kansas City, Missouri. The Midwest Organ Bank is a non-profit organ procurement agency serving the state of Kansas and the western two-thirds of Missouri.

One of the responsibilities of the Midwest Organ Bank is the development and implementation of Professional Education programs for medical and nursing staffs in hospitals within this area.

This education includes how to identify and medically maintain potential organ donors, and how to approach the family in a sensitive manner. The importance of the participation of the health care professional cannot be over-emphasized. They are the gatekeeper of the donor process. Without their participation, the family cannot be given the opportunity to donate the organs of a loved one.

The Midwest Organ Bank strongly supports the concept of required request in Kansas, but we cannot support Senate Bill 532 as amended. We testified earlier at the Senate hearings for this Bill and expressed our concerns regarding it at that time. Senate Bill 532 has been amended, however, we still have grave concerns about certain aspects of this Bill.

Our concerns regarding the amended Senate Bill 532 are as follows:

- 1) As written, this bill takes the opportunity of approaching the family away from the attending physician. In many small hospitals, the attending physician may also pronounce death. He may be the most qualified person to talk to the family and may wish to do so. In addition, in no way is there a conflict of interest in the attending physician pronouncing death and then speaking to the family regarding organ donation, in fact, this is the most desired situation.

Attn # 2
3-17-86
Hs. PHW

Representative Littlejohn and Members of the Committee
March 17, 1986
Page Two

2) As written, this bill does not say that the donor hospital shall notify "an organ or tissue procurement organization" but rather says, "an organization which procures anatomical gifts." The distinction is important since "organ procurement organizations" is the accepted, recognized terminology by the Department of Health and Human Services, and the National Office of Transplantation.

3) Section (e) of the unamended Bill and Section (f) of the amended version both deal with a hospital that would not have the facilities to participate in the donation of organs and tissues. While we fully concur that not all hospitals in Kansas will have the ability to maintain and procure organs, any hospital in the state has the ability to procure eyes. This exclusion would not allow many families the opportunity to donate eyes.

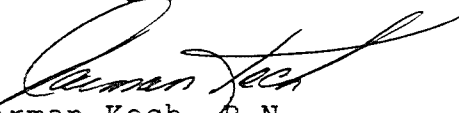
4) The reporting requirements stated in the amended version of Senate Bill 532 could place an unnecessary burden on the hospitals. We would urge that the reporting of this information be kept as simple as possible.

These concerns are also shared by the University of Kansas Medical Center, and we are authorized to indicate this to you.

We urge you to consider these concerns and amend Senate Bill 532 to reflect them. Working together, the Kansas Hospital Association and the organ and tissue organizations can protect the rights of the donor families, and provide desperately needed organs and tissues for the many hundreds of Kansans who are awaiting a transplant.

Thank you for your time and careful consideration of this bill.

Sincerely,


Carman Koch, R.N.
Program Coordinator
MIDWEST ORGAN BANK

Take the time to think about organ donation. Someone did for Greg.

Dear Family
My name is Greg Massey. I am 10 years old. I have been sick all my life. I have had to go to the doctor a lot but I like my doctor. I never did feel good but I do now. I've had to miss a lot of school. I never could play like other boys because I got tired easy and sometimes I would get sick. I want to thank you very much for the new kidney. It makes me feel better and now I can eat all I want to. Now maybe I can start growing and be like other boys.

Thank you very much.
Greg Massey

Signed by the donor and the following two witnesses in the presence of each other:

Signature of Donor Date of Birth of Donor

Date Signed City & State

Witness Witness

This is a legal document under the Uniform Anatomical Gift Act or similar laws.

Midwest Organ Bank/Kansas City
4006 Central
Kansas City, Missouri 64111
816/531-3763

Midwest Organ Bank/Wichita
1035 North Emporia, Suite 100
Wichita, Kansas 67214
316/262-6225

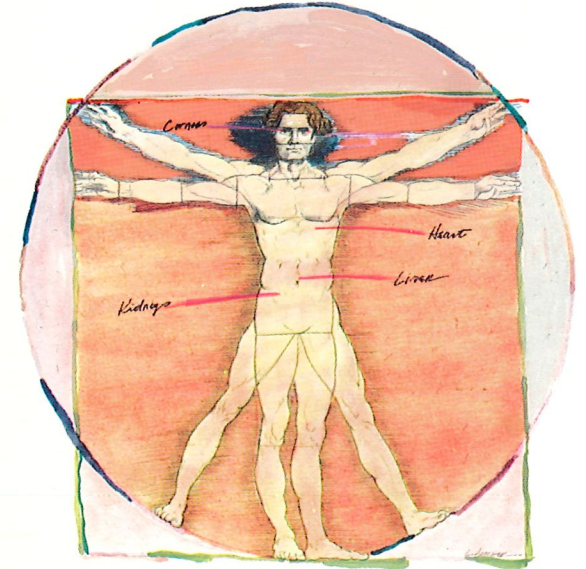
Midwest Organ Bank

Kansas City

4006 Central
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816/531-3763

Wichita

1035 North Emporia, Suite 100
Wichita, Kansas 67214
316/262-6225



**HOW
TO SAVE
A LIFE**

Saving lives begins with you.

Every person has the potential to save another person's life because everyone can donate a part of themselves when they die.

The first step toward saving another life is to know what to do. It's being aware and educated about your choices. It's being concerned about human life.

Now is the time to think about organ donation.

Discuss it with your family now. Let them know your wishes so in the event that you should die, they will know what to do.

No technology can replace vital organs in the way transplants do. Today we can fight terminal and debilitating illness with organ transplantation. Indeed, thousands of people with kidney, heart, liver, and vision failure can live normal lives because of the generosity of others who donated their organs for transplantation after death.

Many tissues and organs can be transplanted—kidneys, corneas, heart, heart/lung, liver, pancreas, skin, bone, bone marrow, and heart valves. And with high success rates: Cornea transplants are 90% successful, kidney transplants 60%, heart and liver transplants more than 70%.

But sadly enough, thousands of people die because there just aren't enough organs donated, even though more than 20,000 potential donors die each year. Why does this problem occur? Most families find it difficult to make the decision to donate organs at the time of their loved one's death *if they have never talked about it before*.

By talking about it now, you can let your family and friends know how you feel. And you can find out what they would want if the question arises. You can sign a donor card expressing your desire to save a life and carry it with you in your wallet.

Questions you may have about organ donation.

How do you obtain organs for transplants?

They are donated by individuals at the time of death. The cause of death will determine which organs can be donated.

Is there any conflict between saving my life and using my organs for transplantation?

No. A dedication to saving your life is the utmost objective of all health professionals. Organ donation occurs only after all efforts to save your life have been exhausted and death has been legally certified.

How are organ transplants coordinated?

After certification of death, the hospital notifies the transplant team. They remove the organs and take them to the hospital where the transplantation will take place.

Who will receive the organs for transplantation?

The recipients are determined by urgency of need and blood and tissue type. First priority is always given to suitably matched recipients from our own area. We also participate in a national computerized organ sharing network.

Can I be sure my donation will be used?

Yes. The organs will be used to benefit the health and life expectancy of critically ill people. This will be done through transplantation or medical research.

Is the body disfigured when the organs are donated?

No. The body is treated with respect and is not disfigured. The surgery to remove the organs is done under sterile conditions in a hospital operating room by a qualified surgeon.

Will the funeral be delayed?

Every effort will be made to schedule the surgery to remove the organs as soon as possible so there is no unnecessary delay in funeral arrangements.

Will it cost my family anything?

Absolutely not. All costs for organ donation are paid by the Midwest Organ Bank.

What about my religious beliefs?

Religious leaders all over the world support organ donation on the basis that this is the highest expression of humanitarian ideals. If you have questions about your faith's beliefs, consult your minister, priest, or rabbi.

How can I become a donor?

Simply sign the attached card in the presence of two witnesses, preferably your next of kin, who also sign. Notify your family of your decision to be a donor and carry your donor card with you at all times.

Saving lives begins with you. Please help others by signing this donor card.

UNIFORM DONOR CARD

OF _____

Print or type name of donor

In the hope that I may help others, I hereby make this anatomical gift, if medically acceptable, to take effect upon my death. The words and marks below indicate my desires.

I give: (a) _____ any needed organs or parts

(b) _____ only the following organs or parts

_____ Specify the organ(s) or part(s)

for the purpose of transplantation, therapy, medical research or education;

(c) _____ my body for anatomical study if needed.

Limitations or special wishes, if any: _____

UNIFORM ANATOMICAL GIFT ACT

Final Draft

Approved by the National
Conference of Commissioners
on Uniform State Laws on
July 30, 1968

*KANSAS STATUTE ATTACHED

UNIFORM ANATOMICAL GIFT ACT

An act authorizing the gift of all or part of a human body after death for specified purposes.

SECTION I Definitions

(a) "Bank or storage facility" means a facility licensed, accredited or approved under the laws of any state for storage of human bodies or parts thereof.

(b) "Decedent" means a deceased individual and includes a stillborn infant or fetus.

(c) "Donor" means an individual who makes a gift of all or part of his body.

(d) "Hospital" means a hospital licensed, accredited or approved under the laws of any state and includes a hospital operated by the United States government, a state, or a subdivision thereof, although not required to be licensed under state laws.

(e) "Part" includes organs, tissues, eyes, bones, arteries, blood, other fluids and other portions of a human body, and "part" includes "parts."

(f) "Person" means an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association or any other legal entity.

(g) "Physician" or "surgeon" means a physician or surgeon licensed or authorized to practice under the laws of any state.

(h) "State" includes any state, district, commonwealth, territory, insular possession, and any other area subject to the legislative authority of the United States of America.

(2) any accredited medical or dental school, college or university for education, research, advancement of medical or dental science or therapy; or

(3) any bank or storage facility, for medical or dental education, research, advancement of medical or dental science, therapy or transplantation; or

(4) any specified individual for therapy or transplantation needed by him.

SECTION 4 Manner of Executing Anatomical Gifts

(a) A gift of all or part of the body under Section 2 (a) may be made by will. The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated, or if it is declared invalid for testamentary purposes, the gift, to the extent that it has been acted upon in good faith, is nevertheless valid and effective.

(b) A gift of all or part of the body under Section 2 (a) may also be made by document other than a will. The gift becomes effective upon the death of the donor. The document, which may be a card designed to be carried on the person, must be signed by the donor, in the presence of 2 witnesses who must sign the document in his presence. If the donor cannot sign, the document may be signed for him at his direction and in his presence, and in the presence of 2 witnesses who must sign the document in his presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the gift valid.

(c) The gift may be made to a specified donee or without specifying a donee. If the latter, the gift may be accepted by the attending physician as donee upon or following death. If the gift is made to a specified donee who is not available at the time and place of death, the attending physician upon or following death, in the absence of any expressed indication that the donor desired otherwise, may accept the gift as donee. The physician who becomes a donee under this subsection shall not participate in the procedures for removing or transplanting a part.

(d) Notwithstanding Section 7 (b), the donor may designate in his will, card or other document of gift the surgeon or physician to carry out the appropriate procedures. In the absence of a designation, or if the designee is not available, the donee or other person authorized to accept the gift may employ or authorize any surgeon or physician for the purpose.

SECTION 7 /Rights and Duties at Death/

(a) The donee may accept or reject the gift. If the donee accepts a gift of the entire body, he may, subject to the terms of the gift, authorize embalming and the use of the body in funeral services. If the gift is of a part of the body, the donee, upon the death of the donor and prior to embalming, shall cause the part to be removed without unnecessary mutilation. After removal of the part, custody of the remainder of the body vests in the surviving spouse, next of kin or other persons under obligation to dispose of the body.

(b) The time of death shall be determined by a physician who attends the donor at his death, or, if none, the physician who certifies the death. This physician shall not participate in the procedures for removing or transplanting a part.

(c) A person who acts in good faith in accord with the terms of this Act, or under the anatomical gift laws of another state /or a foreign country/ is not liable for damages in any civil action or subject to prosecution in any criminal proceeding his act.

(d) The provisions of this Act are subject to the laws of this state prescribing powers and duties with respect to autopsies.

SECTION 8 /Uniformity of Interpretation/ This Act shall be so construed as to effectuate its general purpose to make uniform the law of those states which enact it.

SECTION 9 /Short title/ This Act may be cited as the Uniform Anatomical Gift Act.

SECTION 10 /Repeal/ The following acts and parts of acts are repealed:

- (1)
- (2)
- (3)

SECTION 11 /Time of Taking Effect/ This Act shall take effect...

KANSAS

Kansas Statutes Annotated

UAGA Sec. 65-309 - 65-3217

I. DEFINITIONS

Section 65-3209 (1969) - same as UAGA.

II. PERSONS WHO MAY EXECUTE AN ANATOMICAL GIFT (DONOR)

Section 65-3210 (1969) - same as UAGA

III. PERSONS WHO MAY RECEIVE AN ANATOMICAL GIFT (DONEES)

Section 65-3211 (1969) - same as UAGA.

IV. MANNER OF EXECUTING AN ANATOMICAL GIFT

Section 65-3212 (a-e) (1969)

1. By Will: Sec. 65-3212 (a) - same as UAGA.
2. By Document of Gift (card): Sec. 65-3212 (b) - same as UAGA.
3. To a Specified or Unspecified Donee: Sec. 65-3212 (c) - same as UAGA.
4. Donor designating Physician: Sec. 65-3212 (d) - same as UAGA.
5. Gift Noted on License: None as of 1977 legislative session.

V. DELIVERY OF DOCUMENT OF GIFT

Section 65-3213 (1969) - same as UAGA.

VI. AMENDMENT AND REVOCATION OF GIFT

Section 65-3214 (1969) - same as UAGA.

VII. RIGHTS AND DUTIES AT DEATH

Section 65-3215 (a-d) (1969)

1. Responsibilities to Body: Sec. 65-3215 (a) - same as UAGA.



Photos by Enrico Ferrelli—Wheeler Pictures

A critical moment in the saga of a transplant: In Fairfield, Ohio, surgeons remove heart of a brain-dead accident victim

MEDICINE

The New Era of Transplants

After many setbacks the art of replacing the body's organs has come of age.

At 10:30 a.m. the phone rings on the desk of Donald W. Denny, coordinator of organ transplants at the University of Pittsburgh School of Medicine. The caller on the other end, Burt Mattice, Denny's counterpart at Miami Valley Hospital in Dayton, Ohio, wants to know if surgeons at Pittsburgh can use the liver of a local five-year-old boy who has been struck by a car, suffering irreversible brain injury. He has been pronounced legally dead, but is being maintained on a mechanical respirator. Denny knows that 1,100 miles away in San Antonio, Texas, another five-year-old boy is dying of an incurable liver disease and has been waiting for just such a donor. Denny goes into action, triggering a precisely timed plan for saving the child's life.

Denny alerts the parents of the San Antonio boy and they immediately arrange to fly with their son to Pittsburgh. Then Denny, Dr. Thomas Starzl, the country's leading liver-transplant surgeon, and a surgical assistant, Dr. Shin Yang, take a hospital van to Allegheny County Airport where they board a chartered jet for Dayton. Arriving at the Dayton hospital, the surgeons don scrub suits and perform a two-hour operation to remove

the dead child's liver. Denny, meanwhile, calls Starzl's team at Pittsburgh Children's Hospital and signals them to start removing the San Antonio boy's diseased liver the minute he arrives.

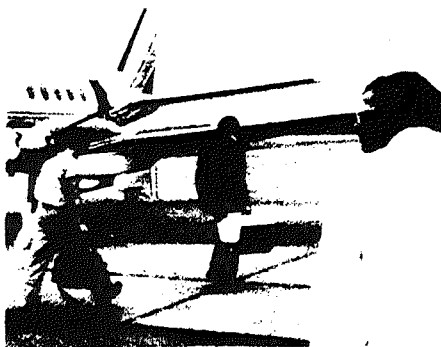
After removing the donor liver in Dayton, Starzl chills the organ with a salt solution and places it in an Igloo picnic cooler for the return trip to Pittsburgh. On the plane back, Starzl, Denny and Shin relax with a few beers. When they arrive at Children's Hospital, their patient is fully prepped and, over the next four hours, Starzl and surgeon Byers Shaw install the new liver. A week later their young patient is doing fine.

For most people, the drama that unfolded earlier this month could only be described as a miracle of modern medicine. For Donald Denny, 48, it was a routine day's work. So far, this year has been even busier than last when he and his associate, Brian Broznick, 30, traveled 77,000 miles to obtain 102 kidneys, 80 livers, 22 hearts and three sets of hearts and lungs for transplantation. "Calls come in at 2 in the morning, on Christmas Day," says Denny. "I had to leave before dinner on

my daughter's 16th birthday." And transplant coordinators at many of the nation's 156 medical centers where such surgery is performed are leading similarly hectic lives.

The reason is quite simple. After years of disappointing failures, organ transplantation has suddenly burgeoned anew. Eminent surgeons who had long since given up transplants are moving back into the field. Dr. Denton A. Cooley, who gave up transplanting hearts more than a decade ago, has taken it up again and plans to perform at least 32 operations by the end of next year. The trustees of Boston's prestigious Massachusetts General Hospital are under pressure to reconsider the ban they placed on cardiac transplants nine years ago on the ground that they were "experimental." Last year in the United States, surgeons performed 103 heart transplants, compared with only 24 in 1976. The number of liver transplants jumped from 14 to 62 during the same period, and the number of kidney grafts from fewer than 4,000 to 5,358.

The resurgence in transplants can be attributed to better surgical techniques, greater understanding of the body's immune sys-



6 p.m.: Pittsburgh team rushes to Ohio



9:57 p.m.: Heart placed in solution

tem and, especially, the recent development of cyclosporine (page 41), a new drug to combat rejection, the major cause of transplant failures in the past. "We are crossing that magic threshold," says Dr. Calvin R. Stiller of University Hospital, London, Ont. "We have reached the point at which most organ transplants have survival rates in excess of 50 percent, and with kidneys, the rate is 80 to 90 percent."

Traffic Accidents: But the new era of the transplant has brought with it serious—even tragic—problems. Most important is that there aren't enough organs for all who need them. About 20,000 people who die each year, mostly in traffic accidents, are potential donors, yet organs were obtained from only a tenth of them last year. Only half of the 10,000 Americans who could have benefited from kidney transplants actually received them. At the University of Pittsburgh, 71 patients have died during the past two years while waiting for donor livers.

Waiting for a donor is actually a race against death. In Washington, D.C., Pat and Mike Lewis have spent an agonizing four months hoping that a liver will be found for their five-year-old daughter Monica. Mike even wears a phone beeper so that he won't miss the call from Pittsburgh. "We have a lifesaving surgical technique with a horse-and-buggy delivery system," he says. In Woburn, Mass., Pat Ronan lies nearly bedridden and breathless for lack of a new heart and a healthy set of lungs. "It's frustrating to know that potential donors don't even know there's somebody like me who needs help," says the 35-year-old housewife. "I can't afford to wait too long."



7:40 p.m.: At work on Ohio donor



10:00 p.m.: Ready for transport

In desperation, some people have gone public to make their need known. Last fall, Charles Fiske, a Boston hospital administrator, took the podium at the annual meeting of the American Academy of Pediatrics and asked for help in finding a liver for his dying daughter, Jamie. The ensuing nationwide attention helped get Jamie her liver and encouraged a succession of well-orchestrated public appeals from parents of children in similar straits. A few weeks ago President Reagan joined the running media event during his regular Saturday radio broadcast when he mentioned three families who are searching for transplants.

Understandable as they are, appeals that call attention to specific cases can be unfair and misleading. "There are 40 to 50 children every day who need liver transplants," says Denny. "The media circus that focuses on just one child at a time doesn't help the public understand the situation." But ironically, it was as much Charles Fiske's understanding of the media as it was a medical procedure that saved his daughter's life. "Certainly, there has to be a better way than relying on bursts of media publicity," Rep. Albert Gore Jr. of Tennessee said last spring during congressional hearings on the issue of finding donor organs.

Taped Message: There are 110 organ-procurement agencies around the country trying to fill the demand for transplants. The North American Transplant Coordinators Organization (NATCO) operates two 800 numbers that give callers a taped message listing the organs sought by various transplant centers. A transplant coordinator dialing the East Coast number one day last



9:55 p.m.: The heart is removed



12:10 a.m.: At Pittsburgh operating room



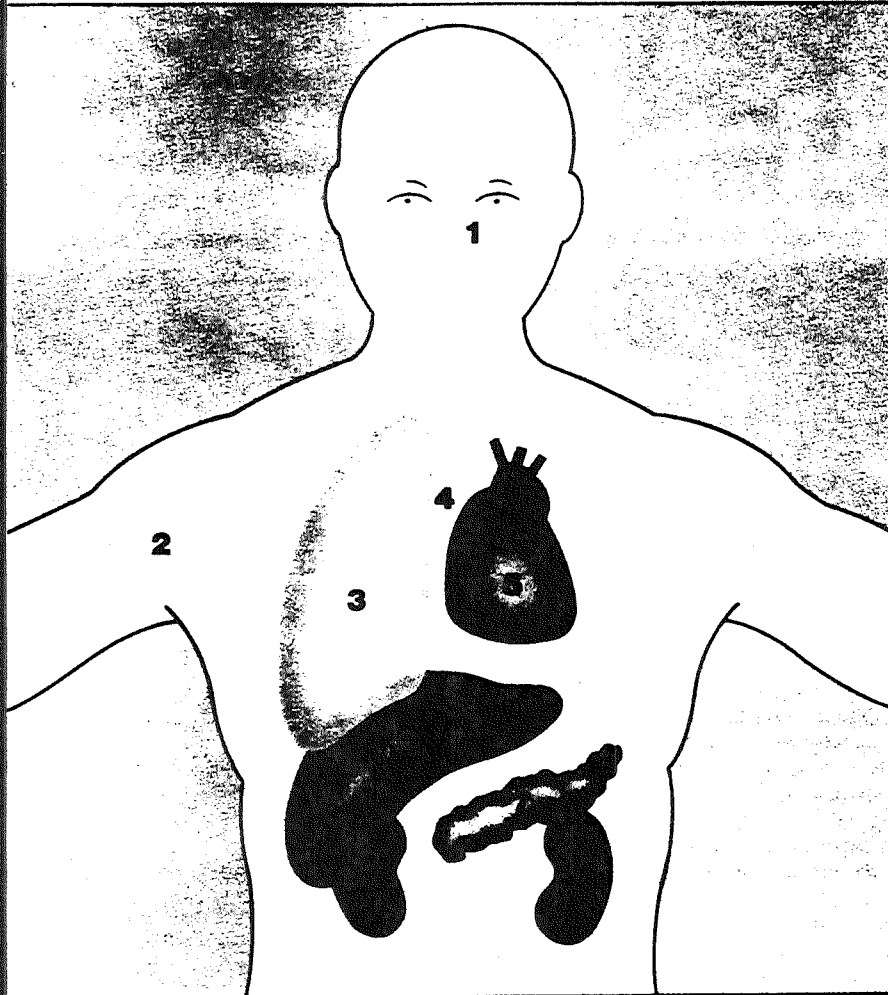
12:17 a.m.: Preparing for implantation



Surgeon with old heart (left) and new

REPLACING THE BODY'S PARTS

Using sophisticated new drugs that help prevent rejection of donated organs and more meticulous techniques for splicing the replacements, surgeons have been able to improve dramatically the success rates of transplants for a variety of organs.



1. CORNEA

TOTAL TRANSPLANTS: 128,000

SUCCESS RATE:
90% of patients have improved vision.

COST: \$2,500-\$5,000

2. BONE MARROW

TOTAL TRANSPLANTS: 2,049

SUCCESS RATE:
Terminal leukemia, 15% cured;
aplastic anemia, 80% cured;
acute leukemia in first remission, 60% cured (children), 40% cured (adults).

COST: \$60,000-\$150,000

3. LUNG

TOTAL TRANSPLANTS: 38

SUCCESS RATE:
Longest surviving patient lived 10 months.

COST: \$50,000-\$150,000
(Data are worldwide.)

4. HEART-LUNG

TOTAL TRANSPLANTS: 22

SUCCESS RATE:
13 patients are still living.

COST: \$78,000-\$92,000

5. HEART

TOTAL TRANSPLANTS: 500

SUCCESS RATE:
78% patient survival after one year, 58% after three years, 42% after five years.

COST: \$57,000-\$110,000

6. LIVER

TOTAL TRANSPLANTS: 540

SUCCESS RATE:
Liver cancer, 26% patient survival after one year; noncancerous liver disease, 39% patient survival after one year.

COST: \$54,000-\$238,000

(Data for U.S. and Western Europe. University of Pittsburgh reports a 66% one-year survival rate after 139 liver transplants.)

7. PANCREAS

TOTAL TRANSPLANTS: 334

SUCCESS RATE:
25% of the grafts function.
Patient can survive on insulin if transplant fails.

COST: \$18,000-\$50,000

(Data are worldwide.)

8. KIDNEY

TOTAL TRANSPLANTS:
No total figures available; 23,076 transplants done in the last five years

SUCCESS RATE:
51% graft survival after one year, 40% after three years, 31% after five years.
Patient can survive on dialysis if transplant fails.

COST: \$25,000-\$35,000

The number of transplants are U.S. totals unless otherwise noted. Sources: Battelle Human Affairs Research Centers; The Fred Hutchinson Cancer Research Center; University of Minnesota Medical School; Eye Bank Association of America.

MEDICINE

week, for example, would have learned that New York's Presbyterian Hospital has two patients, one critical, in need of hearts. Unfortunately, the logistical problems of distributing organs sometimes lead to waste. Five additional livers were offered to Starzl the day he operated on the San Antonio youngster, but his team was too busy to use them. One was sent to the University of Minnesota, but the rest never found recipients.

Physicians and hospitals share some of the blame for the shortage of organs. It doesn't occur to doctors that the organs of an accident victim might be useful, or they may be reluctant to suggest donation to a grief-stricken family. Moreover, Denny says, many physicians have trouble explaining to the family the concept of brain death, the total absence of neurological function in which respiration and blood pressure can be maintained only by mechanical devices. "The patient doesn't appear dead," notes Denny. "His chest is moving up and down, his kidneys are making urine, his heart is pumping. The family needs time to understand."

Formidable Burden: Another part of the problem is the extraordinary cost of transplantation. The price of a heart transplant ranges from \$57,000 to \$110,000 the first year. For livers the cost can run as high as \$238,000 and kidneys average \$35,000. Such costs place a formidable burden on patients since most insurers, including the federal Medicare and Medicaid programs, regard heart and liver transplants as experimental and refuse to pay for them. "The transplants look expensive," says Roger Evans of the Battelle Human Affairs Research Centers in Seattle. "But you've got to look at what it would cost if the patients didn't get a transplant. It might cost \$80,000 to care for a person with end-stage cardiac disease."

The ability to replace diseased organs with healthy ones has long been one of medicine's highest goals. But it has also been one of the most frustrating to achieve. In 1950 Dr. Richard Lawler of the Little Company of Mary Hospital, Chicago, transplanted a kidney from a cadaver into Ruth Tucker, a 49-year-old housewife dying from chronic uremia. Gradually, the transplant ceased functioning, and when Lawler operated again to see what had happened, he was horrified to find, in place of the new kidney, a shriveled mass of dead tissue. What he was looking at was the result of immunological rejection, the single biggest roadblock to successful transplantation.

Gradually, immunologists began to unravel the mysteries of rejection. It was already known that the white blood cells that are designed to protect the body against invading bacteria and viruses would also attack and destroy a graft of "foreign" tissue. Researchers discovered the reason when they found that the response was triggered by antigens, protein

Bob Conrad



Hank Morgan

Waiting for a kidney: A race against death

molecules on the surface of all cells, which in the presence of genetically different antigens alert the immune system and command the white blood cells to attack. In identical twins the antigens are the same. Siblings have a one-in-four chance of sharing the crucial antigens. But in unrelated individuals, the chances of a good match are only 1 in 1,000.

To narrow those odds and make possible transplants from cadavers as well as living donors, researchers developed ways to type tissue. In one method, perfected by Dr. Paul Terasaki of the University of California, Los Angeles, lymphocytes—the white cells involved in rejection—from both the prospective donor and the recipient are placed on separate glass plates and exposed to various sera containing antibodies that attack different tissue antigens. When a set of lym-

phocytes is killed by the antibodies in the sera, it indicates that the corresponding antigen is present on the cell. By comparing results, doctors can tell how many antigens the donor and recipient do or do not have in common before deciding whether to perform a transplant.

Transplanters also use a more direct method called a mixed lymphocyte culture. They mix white blood cells from donor and recipient in a tissue culture; if the cells start to provoke each other and grow it signifies that the tissues are a poor match.

Immune Responses: Tissue typing does not guarantee success, however, because not all of the genes that determine lymphocyte antigens have been identified. As a result, surgeons have looked for ways to prevent rejection by suppressing the recipient's immune responses. One of the first methods was to destroy the patient's white blood cells by exposing the body to massive doses of radiation, but it was abandoned as both risky and ineffective. Some of the drugs used to treat cancer also kill lymphocytes, and in 1962 Dr. Roy Calne of Cambridge, England, reported improved survival of patients getting kidney transplants using one such drug, Imuran. Subsequently, the steroid, prednisone, which also attacks lymphocytes, and a serum containing antibodies to lymphocytes, were added to Imuran as the standard course of rejection treatment.

Armed with typing and the three-drug regimen, surgeons boldly forged ahead during the 1960s and early 1970s, transplanting not only kidneys but also hearts and livers from unrelated donors. In the end, the results were grievously disappointing. While a 70 percent success rate after one year was achieved with related kidney donors, most of the patients receiving other organs died from serious infections brought on by the

Cyclosporine: The Breakthrough Drug

Like many pharmaceutical companies, the Sandoz corporation asks employees traveling abroad to bring back rather unusual souvenirs: handfuls of dirt. The Switzerland-based firm knows that such valuable drugs as the antibiotic streptomycin often come from fungi, bacteria and other microbes living in various types of soil, and in 1970 the company's policy struck paydirt. As Sandoz microbiologists screened soils collected in Wisconsin and Norway, they discovered two kinds of fungus that exuded a substance now known as cyclosporine. It wasn't a particularly good antibiotic, but Sandoz researcher Jean Borel found that it did suppress the immune reaction in the human body that is responsible for rejecting foreign tissues such as transplants. And even more important, the drug still kept the immune system on alert to prevent infection—a leading cause of death among transplant patients.

Since experimental use of cyclosporine began in the United States in 1979, some 2,000 patients in 11 major transplant centers have received it. One year's supply of the drug, taken in daily oral doses, costs \$4,000 to \$6,000, but in some cases may pay for itself by shortening the time patients spend in the hospital. The drug is mixed with olive oil, which carries it across the intestine and into the bloodstream. Although cyclosporine must be taken for life, that is a small inconvenience in exchange for a greater chance of surviving. According to Sandoz, kidney-transplant patients given cyclosporine have more than an 80 percent chance of living through their first year, compared to a 50 percent chance without the drug; for livers, survival zoomed from 35 to 70 percent. And as Stanford University surgeon Norman Shumway told a recent congressional hearing, "there has not been a single instance of clinically diagnosable rejection" of a transplanted heart since he began using cyclosporine in 1980.

Today cyclosporine is awaiting approval by the Food and Drug Administration for general use. As University of Pittsburgh surgeon Thomas Starzl told the congressional hearings, his liver-transplant patients survive so much better with cyclosporine that the operation "is now considered a service as opposed to an experimental procedure."

SHARON BEGLEY

Pat Ronan, with her family, seeks a heart and lung: 'I can't afford to wait too long'

Ira Wyman



MEDICINE

lack of disease-preventing lymphocytes in the body. "It was a hideously difficult enterprise," recalls Starzl. "There was a terrible mortality with organs from nonrelated donors—more than 50 percent were dying."

The introduction of cyclosporine in 1979 turned the situation around. The drug, fortuitously discovered in a fungus, doesn't wipe out the body's immune defenses as do the other drugs such as Imuran. Rather, it appears to inhibit the hormone that controls the action of the T cells specifically involved in tissue rejection but not those that combat infection. "There is a central core of T helper cells," explains Dr. Richard Simmons, a surgeon at the University of Minnesota School of Medicine. "If you can keep that core from expanding [to reject the tissue], you have a remarkably effective drug."

Cyclosporine has been the single most important factor in stimulating the renaissance of organ transplants and promises to make the next decade far more successful than the previous one. The current status of the most important transplant procedures:

■ **Heart.** As cardiac surgery goes, heart transplantation is relatively simple. The surgeon removes the lower chambers of the patient's heart, leaving intact the blood vessels to the lungs and the rest of the body, and replaces them with the left and right ventricles of the donor. But rejection has been a formidable problem from the start. Following Dr. Christiaan Barnard's "Miracle in Cape Town" in 1967, surgeons around the world took up the procedure in an almost cavalier abandon, performing more than 100 in the first year. But only a quarter of the patients lived for more than a few months, and by the end of 1970, most



Hank Morgan

Success story: Najarian with recipients

heart surgeons had abandoned transplants.

But at a few centers, surgeons persisted with slow and steady caution, among them Dr. Norman E. Shumway of Stanford University in Palo Alto, Calif., who devised the original operation. Of the 275 transplants he and his colleagues have performed since 1968, 114 are still alive and one has survived for 13 years. With the advent of cyclosporine, a number of heart surgeons have come back into the heart-transplant arena, and Shumway expects to increase the number he'll perform at Stanford. "This year," he

says, "we'll be doing twice as many as we've ever done, close to 50."

■ **Lung.** This organ presents special problems for transplanters and only 38 single-lung grafts have been done since 1963. Dr. Frank J. Veith of New York's Montefiore Medical Center, who has performed seven of them, notes that it is hard to find a donor lung that is free of infection. Moreover, a potential donor lung is often damaged in the intensive-care unit. "From the time that an injury occurs, and brain death is pronounced," says Veith, "the organ that suffers the most is the lung." Finally, a lung must be almost exactly the right size in order to meet the specific respiratory requirements of the recipient. The longest survivor of a lung transplant has been only 10 months.

Although cyclosporine may improve the outlook for single-lung transplants, many surgeons believe the better choice is a transplant of both heart and lungs as a unit. Almost always, says Dr. William A. Baumgartner of Johns Hopkins, a patient with emphysema or other severe lung disorders will have suffered heart damage as well. The heart-lung procedure was pioneered at Stanford by Dr. Bruce Reitz and Shumway in 1981, and their first patient is still alive. Of 22 patients who have received heart-lung transplants since the advent of cyclosporine, 13 have survived.

Steve Stark, a 33-year-old teacher from Mission, Texas, with severe pulmonary hypertension, received a heart-lung combination at Stanford in June. Although he suffered a brief episode of kidney failure after surgery, he was able to leave the hospital within a month. Now he swims, lifts weights and jogs. "It's a little weird to think that I've got somebody else's heart and lungs inside of me, but I take it in stride," says Stark.

The First Transplants

The first mention of human-organ transplantation is found in ancient Egyptian manuscripts, but it wasn't until the 1950s that whole human organs were successfully transplanted. Since then, research has focused on ways to combat rejection of the grafts. A history of the first transplants:

■ **1905:** Austrian ophthalmologist Eduard Zirm restored the sight of a workman, Alois Glogar, blinded when his corneas were burned by lime. Dr. Zirm took sections from the cornea of an 11-year-old boy whose eye had been removed following an accident and attached them to his patient's damaged eyes. Glogar's right eye was lost to secondary glaucoma, but the left cornea remained transparent until his death three years later.

■ **1954:** At Boston's Peter Bent Brigham Hospital, Drs. John P. Merrill, Joseph E. Murray and J. Hartwell Harrison trans-

planted a kidney to Richard Herrick, a 24-year-old former Coast Guardsman with terminal nephritis. Although previous transplants had lasted only a short time, the doctors hoped for greater success with Herrick because his twin brother had agreed to donate the kidney. The genetic similarity of identical twins, the doctors anticipated, would eliminate the key obstacle to surgery, the rejection reaction. The operation resulted in the first successful transplant of a healthy kidney and opened the way to other transplants between identical twins. Herrick died of a heart condition a little more than eight years after his operation.

■ **1963:** At the Gustave Roussy Institute near Paris, Dr. Georges Mathé decided to try

a radical treatment to save a 26-year-old man dying of acute leukemia—the total replacement of his bone marrow. Mathé administered a massive dose of radiation to suppress the young man's immunological defenses and then injected marrow extracted from the patient's father, mother, sister and three brothers. Initially, the patient became violently ill, but he recovered and was released from the hospital less than three months following the operation.

■ **1963:** Although a human-lung transplant had never before been attempted, Dr. James D. Hardy at the University of Mississippi Medical Center had experimented with the procedure on dogs and felt the time was right for "cautious clinical application" with a suitable candidate. John R. Russell, a 58-year-old prisoner serving a life sentence for murder, was deteriorating

Starzl

Ferorelli—Wheeler Pictures





Photos by Hank Morgan

All in the family: Billy Nickels of River Forest, Ill., before getting a kidney from his mother, reunited with his parents after surgery

■ **Liver.** From a surgical standpoint, this is the most challenging transplant. Surgeons take as long as four hours just to remove the donor liver in order to assure that the blood vessels and bile duct aren't damaged. In extracting the diseased liver from the recipient, they must take care to tie off literally thousands of tiny "collateral" blood vessels that have sprouted around the abdominal cavity as a consequence of disease. In performing the transplant, the surgeon has to make five key connections—the upper and lower portions of the vena cava, the portal vein, the hepatic artery and the delicate bile duct. By comparison, a kidney transplant requires only three much smaller suturing jobs.

A complex organ with many functions, the liver must work when it's installed or the patient dies. "With the liver, there's nothing

like dialysis to back you up," says Dr. John S. Najarian of the University of Minnesota Medical School. "If it doesn't work, that's it." Two weeks ago one of Najarian's patients bled to death because the new liver had been slightly damaged in transit and failed to provide essential clotting factors.

Despite the technical difficulties, liver transplantation is one of the more dramatic medical success stories. At the University of Pittsburgh, one-year survival rates have risen since the introduction of cyclosporine from 33 percent before 1979 to 66 percent today, and Starzl plans to perform about 100 of the operations in the next year.

■ **Pancreas.** In victims of severe diabetes, transplantation of the pancreas eliminates the need for regular insulin injections and may well prevent the eye damage and circulatory complications common to the dis-

ease. First tried in 1966, doctors abandoned the operation because of high rejection rates. But the new antirejection techniques have revived their interest. At the University of Minnesota, Dr. David Sutherland and Najarian have done transplants on 80 patients, 24 of whom are completely off insulin.

■ **Kidney.** Of all organs, the kidney has the best transplantation track record. Even without cyclosporine, Najarian's team at Minnesota reports 80 percent of grafts from cadaver donors are still working after a year, and the survival rate for kidneys from living, related donors is 90 percent. Patients getting cyclosporine, Najarian notes, are half as likely to suffer infections or rejection episodes. "The bottom line is that the drug may decrease hospital stays," he says.

To most kidney-disease sufferers, a transplant is far preferable to periodic renal dial-

steadily with progressive cancer of his left lung and emphysema of his right as well as advanced kidney disease. Using a lung from a man who had died of a heart attack, Dr. Hardy replaced Russell's left lung. Although the lung graft appeared to take, other organs failed, and the patient died 18 days later. Because of a low success rate with this operation, the combined heart-lung transplant is now a preferred procedure.

■ **1963:** William Grigsby, a 47-year-old janitor, became the first human to receive what was considered a successful liver transplant. Drs. William R. Waddell and Thomas E. Starzl at Denver's Veterans Administration Hospital and the University of Colorado Medical Center replaced Grigsby's cancerous liver with a normal organ from a patient who had died of an inoperable brain tumor. Grigsby lived for 22 days after the operation and then succumbed to a surgical complication, blood clots in the lungs.

■ **1968:** Dr. Richard C. Lillehei at the Uni-

versity of Minnesota Medical School transplanted both a kidney and a pancreas into a 32-year-old woman suffering from kidney failure and diabetes. The operation was considered the first successful pancreas transplant. But the patient, whose identity was never revealed, died 114 days later of pneumonia, a complication of immunosuppressive therapy.

■ **1967:** Using a procedure pioneered by Drs. Norman E. Shumway and Richard R.

Lower at Stanford University Medical Center, Dr. Christiaan Barnard performed the first heart transplant. At Groote Schuur Hospital in Cape Town, South Africa, Barnard replaced the diseased heart of Louis Washkansky, a 55-year-old grocer, with that of a 25-year-old woman killed in an auto accident. After the surgery, Washkansky commented: "I am a new Frankenstein." Although the patient's new

heart continued to function, Washkansky died of pneumonia after 18 days.

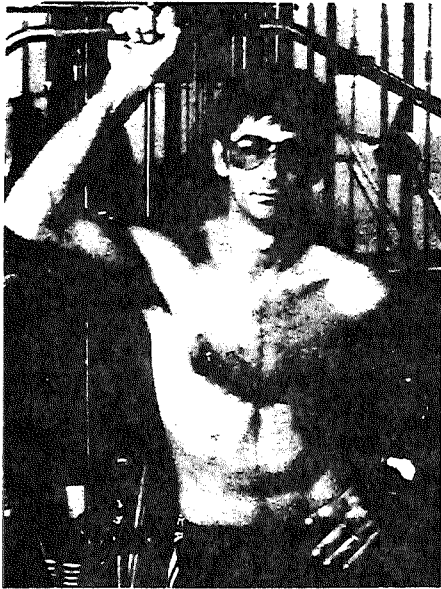
■ **1981:** For more than a year, the condition of 45-year-old Mary Gohlke had deteriorated. Severe pulmonary hypertension in both lungs had damaged her heart and was making breathing increasingly difficult. Drs. Norman E. Shumway and Bruce A. Reitz at Stanford University Medical Center decided to perform a dramatic and risky operation: a combined

heart-and-lung transplant. In three previous attempts at the tandem transplant, the longest survival had been 23 days. The Stanford team's surgery was the first heart-lung operation in 10 years, but they had a new weapon in their arsenal: the immunosuppressive drug cyclosporine. Today, Mary Gohlke is back at her job as a newspaper executive in Arizona.

NANCY STADTMAN

Shumway
James D. Wilson—NEWSWEEK





John McDermott



Jeff Lowenthal—NEWSWEEK

Fully recovered: Steve Stark works out; Alverston Connor (standing) returns to hospital as a visitor

ysis. Alverston Connor, a 54-year-old Chicago woman, recalls that as a result of dialysis she had to follow a rigid diet and could drink only one cup of water a day. Her weight dropped to 83 pounds and she had to use a wheelchair. One day her son, Melvin, presented her with a certificate that read: "Good for one kidney, left or right." "Parents don't like to take things from their children, but I was feeling so bad I was willing to do anything," Connor says. She had the transplant four years ago and has been enjoying life ever since: "For the first three months, I ate three banana puddings a week and had hot chocolate three times a day."

■ **Bone Marrow.** Dr. E. Donnell Thomas and his colleagues at the University of Washington have performed 1,700 marrow transplants since 1969, on patients with leukemia—a cancer involving the marrow—certain forms of anemia and other diseases. About half their patients with acute lymphocytic leukemia—the most common form of the disease in children—are alive two years after transplantation. Thomas has achieved the same long-term survivals in three quarters of patients with aplastic anemia, a highly lethal disease.

Bone marrow is by far the easiest tissue to transplant, but it poses the greatest risk for a patient. A donor's marrow is removed with a syringe from the pelvic bone and then infused into the recipient's arm, like a unit of blood. But bone marrow contains the "stem" cells from which red and white blood cells develop, including the lymphocytes that cause rejection. The recipient faces a double-barreled danger if there isn't a close tissue match: not only might he reject the transplant, but the transplant might reject him, a potentially fatal condition called graft vs. host disease (GVHD).

Researchers at several U.S. centers are now testing ways of performing marrow transplants between poorly matched indi-

viduals without causing GVHD. In one method, developed in Israel and now under trial in New York's Memorial Sloan-Kettering Cancer Center, physicians mix marrow with a soybean protein that isolates the mature lymphocytes so that they can be removed. The remaining immature lymphocytes can theoretically be given to the recipient because the cells will acquire a tolerance for his tissues and function normally. The technique has been tried successfully on 25 patients, mostly children with inherited immune deficiencies.

■ **Intestine.** Transplants of intestinal tissue have been virtually impossible. The high bacterial content of the intestine simply posed too great a risk of infection for a

patient with a depressed immune system. But using cyclosporine, Drs. Graham Craddock and Zane Cohen of the University of Toronto have performed intestinal grafts in dogs with a 60 percent success rate. Some experts predict that the operation will be ready for humans within a year.

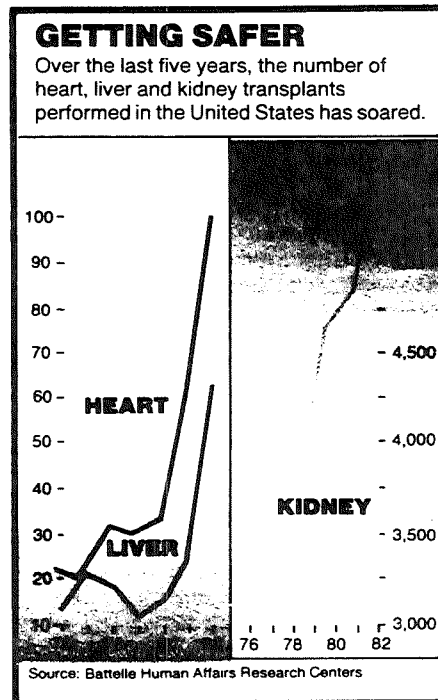
As is the case with the artificial heart, the transplantation field has its skeptics. Some of them warn that the transplantation enterprise might consume more of the nation's increasingly scarce health-care dollars than the results warrant. "It is a big mistake to put too much emphasis on transplants," says Dr. Arnold Relman, editor of the *New England Journal of Medicine*. "The real drama lies in conquering the disease, not in a technological tour de force that prolongs

life a bit for a relative few." The transplanters steadfastly disagree. "Replacing a diseased organ is beneficial, even if the results are only 10 percent," says Stiller, "since the alternative for these people is death."

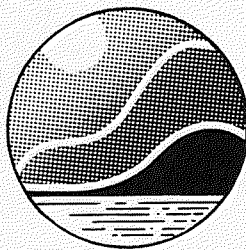
For the time being at least, some of the nation's policymakers seem to agree, and are slowly coming to grips with the problem of finding organs and paying for their transplantation. The administration, however, would leave organ procurement in the private sector. Assistant Secretary of Health and Human Services Dr. Edward Brandt points out blood-donor programs have long been a local responsibility. "I don't see why we shouldn't explore the same kind of approach for solid organs." But there is strong opposition. "The gap in terms of supply and demand is serious enough that a strong federal role is required," says an aide to Representative Gore. Gore is drafting legislation that would, among other things, set up a nationwide computerized clearing house for organs, establish a National Center of Health Care Technology to determine when transplant procedures should be paid for by Medicare and Medicaid programs, and restrict transplant surgery to regional centers to make more efficient use of organs.

After many a disappointing false start, the era of the transplant may have finally arrived. Researchers view cyclosporine as only the first of a new family of drugs to combat rejection with greater effectiveness and safety. Even better, the new technology of genetic engineering may make possible perfect tissue matching by gene alteration. "I don't think there is any transplant that won't be possible," says Stiller. "Within a decade, people won't be dying because of the failure of an organ."

MATT CLARK with DEBORAH WITHERSPOON, MARIANA GOSNELL and JOHN CAREY in New York, DANIEL SHAPIRO in Houston, PAMELA ABRAMSON in Palo Alto, MADLYN RESENER in Chicago, JERRY BUCKLEY in Boston and AMY WALLACE in Washington



Bob Conrad



AT THE CENTER

Midwest Bioethics Center has received a good response to its first newsletter. Our membership is growing and so is the community's interest in the topic of medical ethics. If you have not joined, I would encourage you to do so to keep up with the medical ethical issues which face persons in the Midwest.

This issue of **Midwest Medical Ethics** is of special interest to all persons involved in organ transplantation. Clergy from a wide variety of religious denominations describe their positions on transplantation. This should be a helpful resource to those who deal with recipients and the families of donors, as well as those considering whether they would be willing to be a donor.

Our thanks to Helen Gray of the **Kansas City Times** and Dr. Robert Meneilly for their assistance with this issue.

The Board of Directors, at its first annual meeting, developed the following mission statement:

The mission of the Midwest Bioethics Center is to assist individuals and society in responding to the ethical dilemmas of modern medicine and biomedical technology.

We believe this statement succinctly sets forth what the center is about in this community.

In furtherance of our mission, the Center has provided inservice programs and consulting services for health care providers in this region. If your group is interested in the educational and consulting services of the Center, please contact us at:

1200 East 104th Street,
Suite 217
Kansas City, Missouri 64131
816/942-1992

Mary Beth Blake J.D.

Religious Views of Organ Transplantation

We asked a variety of Kansas City area clergy, "What is your denomination's belief about organ transplantation? or, if there is no specific belief, what is your personal belief about organ transplantation?"

ISLAM

"If any one slay a person, unless it be for murder or for spreading mischief in the land, it would be as if he slew the whole people. And if any one saved a life it would be as if he saved the life of the whole people." (Holy Quran 5-35).

"Help ye one another in righteousness and piety, but help ye not one another in sin and rancor." (Holy Quran 5-03)

In these verses Allah the almighty commands us to help each other in that which is good and promises to reward whoever saves a life from danger as if he saved all humanity.

The higher council of the religious scholars of Saudi Arabia issued a ruling (*afatwa*) on the subject of organ transplantation in light of Islam. In decision No. 99, the Council ruled "The Board unanimously resolves the permissibility of removing an organ or a part thereof from a living person and grafting an organ onto him, should the need arise, should there be no risk in the removal, and should the transplant seem likely to be successful."

The Board also resolved, by majority, the following:
1. The permissibility of removing an organ, or a part thereof, from

Continued on pg. 4

PRESBYTERIAN

As Presbyterians we believe in the faithful use of everything God gives us. We call it "stewardship". Because of this we believe in making available our physical organs when we no longer have need for this body. The final and ultimate stewardship we can practice in this life is the donating of any parts of our body which God can use to sustain productive life and better health for another person. To think that some blind person might have sight through my corneas when my body expires and I am resurrected not only gives me great joy but will give real comfort and satisfaction to my grieving family. To know that my kidneys, heart, lung, liver, bone or skin could contribute toward the wholeness of a young father or mother being able to

Continued on pg. 4

ON THE INSIDE

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a dead person for the benefit of a life, should the need arise, should the removal cause no dissatisfaction, and should the transplantation seem likely to be successful.

2. The permissibility of a living person donating organs or a part thereof for the benefit of a living person in need.

Imam Mohamed, President, The Islamic Society of Greater Kansas City.

PRESBYTERIAN

Continued from pg. 1

raise their children makes the very thought of my own death acceptable. Why should what I no longer need not be made available to a neighbor who has a desperate need?

The fact that we donate our organs is not going to make us somehow incomplete in our new state of resurrection life. The fact that certain of our organs will be respectfully removed is not to affect the appearance of my body should my family desire a viewing when I am deceased. To the steward who entrusts his or her body to God, making any parts of it available for the use of the Great Physician for the life of another, God is sure to say, "Well done good and faithful...enter into the joy of your Lord."

Robert H. Meneilly, D.D. is pastor of the Village Presbyterian Church in Prairie Village, Kansas.

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Midwest Bioethics Center
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CHRISTIAN SCIENCE

Continued from pg. 2

one regards health itself as fundamentally physiological or spiritual. While they respect the humanitarian motives of physicians involved in transplant programs as well as other areas of medicine, they feel in general that their own best contribution to society's search for well-being can be made by striving to demonstrate in their lives the abiding healing power of a spiritual understanding of God.

This kind of healing is not simply the equivalent of "faith healing." Christian Scientists approach and practice, as a part of a way of life, a religious discipline rather than a test of belief or will. They view prayer as much more than petitioning God for miracles. Their experience as a denomination over the past century has convinced them that spiritual healing is both real and practical — a resource for humanity that is only beginning to be understood.

Dale W. Ferguson, C.S.B., is a public practitioner and teacher of Christian Science. He also serves as the Christian Science Committee on Publication for the State of Missouri, an office of the church for those desiring information regarding Christian Science.

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JEHOVAH'S WITNESSES

Continued from pg. 3

this reason, each individual faced with making a decision on this matter should carefully and prayerfully weigh matters and then decide conscientiously what he or she could or could not do before God. It is a matter for personal decision."

Reprinted from *The Watchtower*, March 15, 1980, p. 31. Used by permission. Provided by *Larry Stogsdill*, elder, Old Pike Congregation of Jehovah's Witnesses, Kansas City, Missouri.

COMING EVENTS

March 7, 1986

"... a time to die: from Caring to Caring" Cosponsored by the Midwest Bioethics Center, KU Medical Center, Southwest Clinical Society and the Academy of Health Professions. For information, call (816) 942-1992

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FOREWORD

The Midwest Organ Bank is independent of any hospital or transplant unit and serves as the central coordinator for organ recovery and distribution in Kansas and the western half of Missouri.

Through the 24-hour emergency telephone number, (816) 931-6353, the Midwest Organ Bank team is on call for the evaluation of donors and the retrieval, preservation and distribution of cadaveric organs.

The Professional Education Department of the Midwest Organ Bank offers informative programs pertaining to organ donation which may be scheduled upon request.



MIDWEST ORGAN BANK, INC.

**Professional Education and Business Office
4006 Central
Kansas City, Missouri 64111
(816) 531-3763**

**Laboratory
305 West 43rd Street
Kansas City, Missouri 64111
(816) 931-6353**

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INTRODUCTION

The need for cadaveric organs for transplantation today continues to exceed donations in all areas of the country. Thousands of chronically ill people are awaiting transplantation of a kidney, cornea, liver, heart, or other tissue. Organs obtained by the transplant hospitals alone will not meet this need. Community hospital participation in organ recovery is essential if we are to be able to offer transplantation to all of these patients.

A substantial number of all potential organ donors are cared for in community hospitals. Usually they are patients who have had irreversible brain damage and death is imminent. Head trauma, cerebrovascular accidents, cerebral anoxia, brain stem herniation from cerebral edema and primary brain tumors are chief causes of cerebral death. In these circumstances, grieving families may find comfort in giving a "Gift of Life" through organ donation.

Transplantation is becoming a common mode of therapy for many chronically ill people; and as public education continues, more families will be initiating organ donations. However, there still is a severe shortage of cadaveric organs for transplant. Only through your participation in the organ donor program will we be able to provide these people the chance for a better life through transplantation.

The following information has been provided to assist you in the identification and evaluation of a potential organ donor and in the coordination of a retrieval.

EARLY IDENTIFICATION AND EVALUATION OF THE DONOR IS ESSENTIAL. MIDWEST ORGAN BANK PERSONNEL CAN BE REACHED 24 HOURS A DAY AT (816) 931-6353 FOR ASSISTANCE IN DONOR EVALUATION AND MEDICAL MAINTENANCE.

A POTENTIAL KIDNEY DONOR

- Is between the ages of 1 and 55 years.
- Has irreversible brain damage and death is imminent.
- Is on a respirator and has effective circulation.
- Has no history of chronic hypertension, long-standing diabetes or kidney disease.
- Has no systemic infection or malignancy other than a primary brain tumor.
- Has normal kidney function at time of admission.

Contact the Midwest Organ Bank for any donor evaluation **BEFORE** proceeding further. Some variations in the above criteria may be acceptable but must be evaluated by the Midwest Organ Bank.

CARDINAL POINTS OF KIDNEY DONOR MANAGEMENT

- Vigorous expansion with IV fluids.
- Maintenance of adequate blood pressure.
- Maintenance of good urine output.

For additional information, see Comprehensive Medical Management, p. 13.

Kidney Donor Checklist and Worksheet

In an attempt to insure that recovered organs are viable for transplant, please wait until the Midwest Organ Bank has evaluated the donor **BEFORE** approaching the family for consent. The kidney donor checklist and potential donor information worksheet which should be completed prior to contacting the Midwest Organ Bank follow.

Identification

1. Identify potential kidney donor.
2. Request permission from attending physician to proceed with organ donor evaluation.

Notification

1. Notify Midwest Organ Bank (use potential donor worksheet for initial information).
2. Notify in-house coordinator, if appropriate.
3. Notify coroner or medical examiner, if appropriate.
4. Notify OR and retrieval surgeon of possible retrieval.
5. Notify pastoral care or social services, if appropriate.

Evaluation

1. Use Midwest Organ Bank and your staff nephrologist (if available) to assist in thorough donor evaluation.
2. Obtain the following lab work STAT:
 - a. Serum creatinine
 - b. BUN
 - c. ABO
 - d. Serum electrolytes
 - e. Urinalysis
 - f. Urine and blood cultures*
 - g. HAA and VDRL*
 - h. CBC

*Although the results of these tests may not be back by the time of the retrieval, they are still necessary for complete donor evaluation.

Institution of Medical Management

1. Obtain written consent for donation from next of kin.
2. Institute medical management (see p. 13).
3. Obtain blood samples (as per Midwest Organ Bank) for tissue-typing.

VERIFY THAT PRONOUNCEMENT OF DEATH IS WRITTEN ON THE DONOR'S CHART.

POTENTIAL DONOR INFORMATION WORKSHEET

Name: _____ Age: _____ Sex: _____ Race: _____

Hospital/Unit: _____ Attending Physician: _____

Admission Date/Time: _____ Diagnosis: _____

Next of kin consent obtained? _____ By whom? _____

Organs/tissues to be donated: _____

If Coroner's case, Coroner notified? _____ Name: _____

Neurological Status: _____

Brain Death Pronounced? _____ By whom? _____

Current BP: _____ Hypotensive periods? _____

Dopamine? _____ Dosage: _____ Hypertension? _____

Urine Output last 24 hours: _____ Current: _____ Oliguria? _____

Infections? _____ Febrile Periods: _____ Antibiotics: _____

Past Medical History: _____

LAB WORK

ABO _____	Admit	Present		Admit	Present
Creatinine _____	_____	_____	Urinalysis:		
BUN _____	_____	_____	pH _____	_____	_____
Electrolytes _____	_____	_____	Sp. Grav. _____	_____	_____
Cultures:			Protein _____	_____	_____
Blood _____			Blood _____	_____	_____
Urine _____			Glucose _____	_____	_____
Other _____			Micro _____	_____	_____
				_____	_____
HAA _____					
VDRL _____					

NOTE: Additional lab tests may be requested by the Midwest Organ Bank if other organs are to be donated.

COMPREHENSIVE MEDICAL MANAGEMENT

Until death has been pronounced, all changes in the patient's regimen must be made with prior approval of the attending physician or his designee. Even after pronouncement of death, supportive care **MUST** be continued and charted through the time of surgery to ensure the viability of the kidneys.

Below are some specific suggestions:

I VOLUME EXPANSION

In head trauma cases, the patient is often dehydrated to reduce cerebral edema. Therefore, aggressive volume expansion is necessary as part of good donor management to ensure adequate renal function. Rapid infusion of large quantities of IV fluids (i.e., $\frac{1}{2}$ normal saline, Ringers, D5W) are often needed to balance fluid and electrolyte levels.

Creatinine and BUN, which may be elevated secondary to dehydration, should return to within normal levels with this volume expansion.

Note: The type of fluid used for volume expansion should be dictated by the patient's electrolyte status (i.e., the use of $\frac{1}{2}$ normal saline or D5W in patients who have high sodium levels).

II BLOOD PRESSURE SUPPORT

Head trauma patients are frequently treated with Dopamine to support blood pressure. With volume expansion, Dopamine can usually be reduced and preferably discontinued as long as systolic blood pressure is maintained at 100mm/Hg.

ARAMINE AND LEVOPHED SHOULD NEVER BE USED TO SUPPORT BLOOD PRESSURE IN AN ORGAN DONOR.

III ESTABLISH DIURESIS

Adequate blood pressure and hydration with IV fluids should promote increased urine output. 12.5-25 gms. of Mannitol should be given initially and as needed until the kidneys are retrieved in order to maintain adequate diuresis. It can be added to the IV fluids or may be given as a bolus.

Urine outputs over 200 ml/hour are considered optimal. When urine output is high, careful volume replacement is essential to maintain a sustained diuresis. Serum electrolytes, BUN and creatinine should be monitored. When the donor has diabetes insipidus, urine output may continue in spite of severe dehydration.

An elevated serum creatinine and hypernatremia may result from dehydration. Good renal function should be seen with brisk diuresis and decreasing serum creatinine in response to a fluid challenge.

Lasix 20-40 mg. IV should be given immediately prior to the transfer of the donor to the operating room. The IV fluids should be wide open at this time.

OBTAINING CONSENT FOR ORGAN DONATION

Timing is essential in requesting donation from the family. It is best if the family can be approached for donation after they have had an opportunity to begin to adjust to the inevitable death of their family member.

If given time to accept the loss of their family member they should be able to perceive the donation as an opportunity to make some meaning out of an otherwise meaningless death. If approached too soon, the family may perceive this as showing more concern for the organs than for their loved one, and may be unwilling to donate.

Before making the request, the attending physician and the Midwest Organ Bank should ALWAYS be consulted. It can then be decided as to who will approach the family. It is usually the attending physician by himself or with a nurse from the unit, who approaches the family to obtain consent. The hospital chaplain or a representative from social services may also be involved in this capacity.

Apprehension about approaching the family has been expressed by many medical professionals. However, it can be helpful to keep in mind that as medical professionals we have an obligation to the family to make them aware of organ donation. The final decision rests with the family, but it is our responsibility to offer this option to them.

According to the Uniform Anatomical Gift Act, any person has the legal right to donate all or part of his body after death for medical research, education, or therapy. A consent form (see pg. 16) must be signed and witnessed. Consent may be obtained by telephone if recorded or witnessed by two people, although it is required that oral consent also be confirmed later in writing or by telegram. In all cases, family consent should be obtained in coordination with the potential donor's attending physician. It is standard medical practice to also obtain consent from the next of kin. This is to avoid any conflict that might arise concerning the donation of the organs. Both Kansas and Missouri have enacted legislation defining brain death.

The following persons, in order of priority, may consent to donation of the organs for transplantation:

1. Spouse
2. Adult son/daughter
3. Either parent
4. Adult brother/sister
5. Guardian of the deceased at time of death
6. Person authorized for disposition of the deceased.

Anyone discussing organ donation with the family must be knowledgeable of the critical need for organs and all aspects of the donation process to ensure informed consent. They should also be prepared to answer questions asked by the family in a manner in which they are capable of understanding.

The Professional Education Department of the Midwest Organ Bank is available to provide hospitals with in-service education in the areas of donor evaluation, medical management and emotional factors surrounding an organ retrieval. For more information on these in-service programs, call (816) 531-3763.

ORGAN DONATION CONSENT*

I _____ wish to donate the following organ(s)
name of next of kin
of _____ for the purposes of transplantation or
donor's name

medical research:

- | | |
|-------------------------------------|---|
| <input type="checkbox"/> kidneys | <input type="checkbox"/> skin |
| <input type="checkbox"/> eyes | <input type="checkbox"/> pancreas |
| <input type="checkbox"/> heart/lung | <input type="checkbox"/> bone/bone marrow |
| <input type="checkbox"/> liver | <input type="checkbox"/> any needed organ |

This donation is a gift for the benefit of mankind and is made in accordance with the Uniform Anatomical Gift Act.

I hereby authorize the physicians of _____ after
hospital name
the death of _____ to perform the necessary surgery
donor's name
to remove these organs and to perform a postmortem examination should it be required.

witness signature

signature next of kin

witness signature

signature next of kin

address next of kin

Order of Priority of Next of Kin

1. Spouse
2. Adult son/daughter
3. Either parent
4. Adult brother/sister
5. Guardian of the deceased at time of death
6. Person authorized for disposition of the deceased

*This is a suggested form. Your institution may have its own form for use in obtaining consent.

DETERMINATION OF DEATH

The pronouncement of death must be made by a physician or his associate in consultation. Death must be pronounced and recorded in the chart prior to surgery for organ removal. To avoid a conflict of interest, the physician who removes the organs should not pronounce death.

When brain death has been diagnosed, the body must be maintained by artificial respiration to maintain cardiac function. This allows for removal of the organs with minimal ischemic damage and increases the probability of good function after transplantation.

If cardiac arrest occurs, most organs (except skin and eyes) cannot be retrieved due to ischemic time of greater than 30 minutes prior to removal.

SURGERY

I. SUPPLIES FOR NEPHRECTOMY

- A. Major laparotomy set
- B. Vascular instruments
- C. 30,000 units heparin and 10 mg. Regitine, to be given 5 minutes before cross-clamping of the aorta.

II. SUPPLIES FOR INITIAL FLUSHING AND CANNULATION

- A. Back table
 - Sterile waterproof drapes
 - Gown and gloves for preservation technicians
- B. Ring stand
 - One (1) basin containing ice, covered with waterproof drape
 - One (1) sterile basin to be available for sterile iced saline
- C. I.V. pole
- D. Portable surgical lamp
- E. Instruments
 - Three (3) Mosquito hemostats
 - Three (3) Kelly hemostats
 - Two (2) Metzenbaum scissors
 - One (1) Suture scissors
 - Three (3) Vascular forceps (DeBakey)
- F. Suture: 0 silk ties
- G. 3 or 4 liters of lactated Ringer's (or if unavailable, saline) solution should be kept in the O.R. refrigerator for immersion and surface cooling of the kidneys once removed.

III. TISSUE TYPING

It is essential to obtain:

- A. At least 15 to 20 lymph nodes in a tube of nutrient lymph node medium. If no medium is available, place lymph nodes in a sterile container on ice.
- B. The spleen, wrapped in two surgeon's gloves and placed on ice.
- C. 60-100 ml. of blood placed in at least five 10 ml. green-stoppered (heparinized) vacutainer tubes, with the remainder placed in red-stoppered (clot) tubes.

These materials are needed for tissue typing and cross-matching procedures.

ORGAN DONOR NEPHRECTOMY

En Bloc Nephrectomy with In Situ Perfusion (A Suggested Protocol)

1. A bilateral subcostal incision is made, using electrocautery to control bleeding, table to table. The lower flap is reflected inferiorly and towel clipped in place. (Figure 1)
2. Expose the aorta and inferior vena cava by incising posterior peritoneum over the great vessels. Access to the entire retroperitoneum is achieved.
3. Have available a Smith ring or similar fixed retractor to elevate the structures overlying the great vessels and kidneys after the superior mesenteric artery is divided.
4. Expose the distal aorta and place two umbilical tapes around it just above the aortic bifurcation. If the patient is hypotensive, tie down the distal ligature and tag it. Ligate and divide the inferior mesenteric artery near its origin. Isolate and divide the inferior mesenteric vein at the point it disappears below the pancreas. (Figure 2)
5. Expose the superior mesenteric artery by elevation of the pancreas. Ligate and divide the superior mesenteric artery. Isolate and divide the celiac axis. Sharply take down the diaphragmatic attachments to the spine. This allows total exposure of the aorta into the chest and inferior vena cava to the hepatic veins. Isolate aorta above the celiac axis and place umbilical tapes around the aorta for proximal control later. (Figure 3)
6. Incise anterior Gerota's fascia via a midline retroperitoneal incision and expose the anterior surface of both kidneys. Do not dissect into the renal hilum. Remember not to disturb the triangle of tissue between the ureter and the lower pole of the kidney. Exposure is facilitated with deaver retractors to hold the retroperitoneal contents. All dissection is performed sharply.
7. Expose and divide the ureters as close to the bladder as possible. A narrow deaver beneath the retroperitoneum exposes the ureters to the bladder. It is important to use sharp dissection to free the ureters, incising retroperitoneal tissue at least 1cm away from the ureter. This prevents devascularization so easily caused by blunt finger stripping. Tag the open cut end of the ureter with 3-0 silk for easy identification. Retract the ureters laterally to prevent accidental injury. Good urine output should be noticeable from the ureters. Samples should be taken for culture and sensitivities from each ureter. Dissect the ureters to the mid-aorta at this point. (Figure 4)



Figure 1

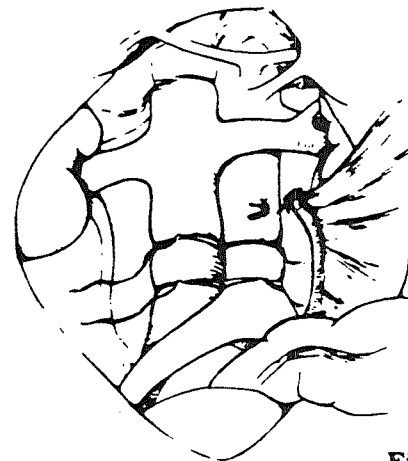


Figure 2

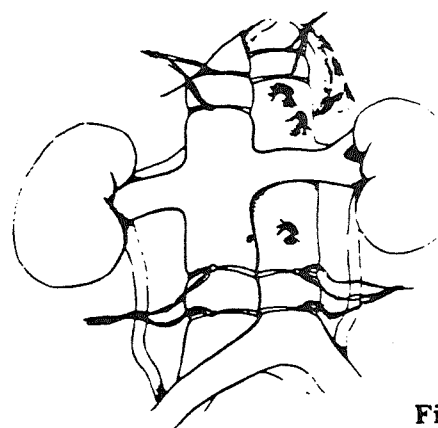


Figure 3

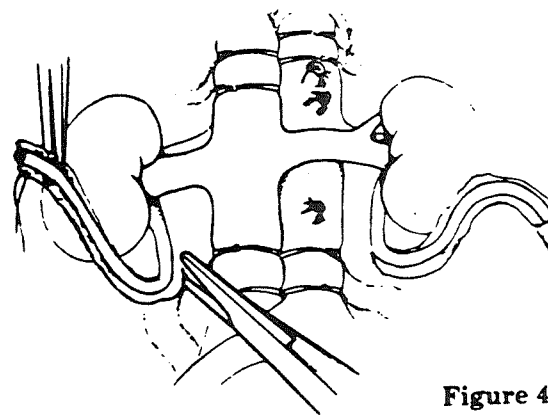


Figure 4

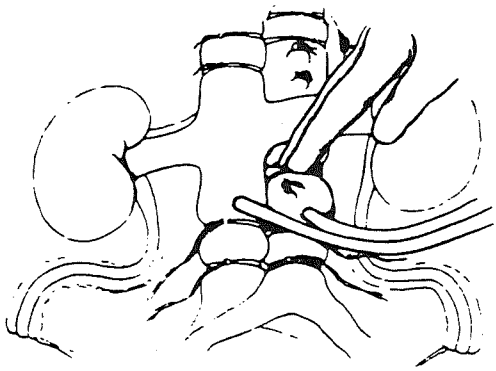


Figure 5

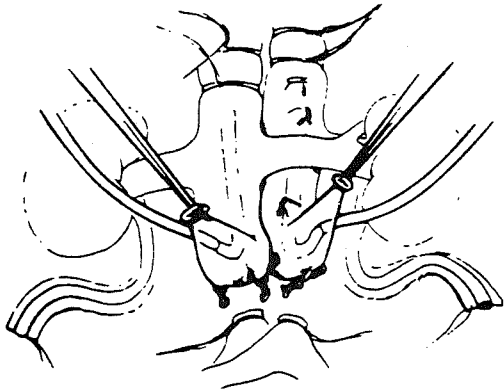


Figure 6

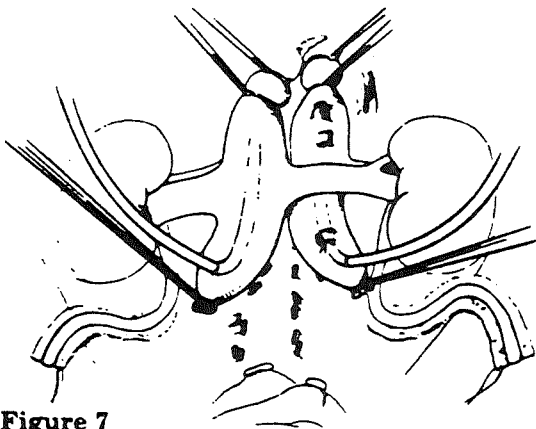


Figure 7



Figure 8

8. Using the proximal aortic umbilical tape as a tourniquet to temporarily stop blood flow, place the perfusion catheter or tubing into the aorta. Make a small hole in the aorta just above the iliac bifurcation, insert the tubing and tie firmly into place. Insert a Saratoga sump into the vena cava via a small incision and tie firmly in place. Divide the aorta and vena cava between the previously placed tapes. If blood pressure is stable, mobilize the aorta and vena cava, Weck clipping the lumbar veins and arteries. Continue up to the level of the renal arteries if BP is stable. (Figures 5 & 6)
9. Use large syringe to obtain at least 60cc of blood from vena cava. Administer 30,000 units of heparin followed by 10mg Weck and allow 2-3 minutes for circulation.
10. Ligate proximal aorta (note time) with umbilical tape. Open Saratoga sump for drainage. Immediately begin cold flush solution. The monitor and respirator can be discontinued at this point. (Figure 7)
11. Tie down the proximal vena cava and carefully inspect the kidneys for uniform cooling and pale cortex color. If not, check for occluded or ligated renal arteries.
12. Free the kidneys and ureters. Be sure adequate tissue is removed with the ureters and that the capsule of the kidney is not torn. Retract ureters laterally and cephalad at all times to prevent injury. Be sure tubing remains in place for continuing flush solution. Retract the great vessels cephalad and carefully resume dissection and division of the remaining lumbar vessels along the vertebral column. Clip the lumbar vessels on the great vessel side before dividing.
13. By hugging the vertebral fascia, one will avoid injuring the right renal artery as it passes posterior to the vena cava. Free the kidneys from the posterior body wall and remaining Gerota's fascia. (Figure 8)
14. When the proximal ties are reached, divide the aorta and vena cava between ties. Pass the en bloc specimen to an ice slush basin. Be sure to tie off aorta, if necessary, to prevent loss of flush solution.
15. Excise at least 15 to 20 lymph nodes and place in solution provided by the Midwest Organ Bank personnel. If solution is not available, place lymph nodes in sterile container and cool on ice. Remove the spleen, place in double sterile gloves, and place on ice.

POINTS TO REMEMBER

1. Notify Midwest Organ Bank as soon as you have identified an organ donor. This allows our perfusion team to prepare for the retrieval. It also enables you to thoroughly evaluate the viability of the kidneys, thus eliminating further pursuit if the kidneys do not appear viable.
2. Use the enclosed donor worksheet to gather donor information.
3. Use appropriate timing and sensitivity when approaching the family for consent.
4. If cardiac arrest occurs requiring CPR, organs such as kidneys, heart and liver will not be suitable for transplantation. Tissue such as eyes and skin can still be donated however.
5. Expenses incurred in the kidney retrieval process are **NEVER** billed to the donor's family. The costs are billed to the Midwest Organ Bank and paid for by Medicare. Charges from the time the donor is pronounced dead are billed to the Midwest Organ Bank.
6. **THE MIDWEST ORGAN BANK IS STAFFED 24 HOURS A DAY TO ASSIST WITH EVALUATION AND MEDICAL MANAGEMENT OF A DONOR.**

(816) 931-6353

INTRODUCTION

Heart and liver transplants are no longer experimental but therapeutic. With the use of a new immunosuppressive drug called Cyclosporine, these transplants now have 60% (and greater) success rates.

There are hundreds—possibly thousands—of people whose lives could be saved by a heart, heart/lung, or liver transplant.

In order to help provide organs for those in need, the Midwest Organ Bank now evaluates every potential donor for the possibility of multiple organ donation.

Unlike kidneys, there is no effective way to preserve the liver, heart, etc., for more than a few hours. This shortage of time may be the most critical factor in a multi-organ donation. Currently, there are only a few centers in the United States that are transplanting the liver, heart, or heart/lung. Therefore, a team of surgeons from one of these centers will travel to the donor hospital, retrieve the organs, and then transport them back to the transplant center.

Hospitals must have policies and procedures for granting these out-of-state teams temporary privileges so that no time is lost. Please make sure your institution has a mechanism for granting these privileges.

GENERAL CRITERIA

Initial information needed by the Midwest Organ Bank regarding a potential multi-organ donor is: age, weight, and blood type. Weight and size is a major factor since the heart and liver are transplanted orthotopically. The contra-indications for a multi-organ donor include those for a kidney donor. Additional contra-indications are listed on the following pages.

A multi-organ donation usually refers to a kidney, heart, heart/lung, and liver donor, but can also include eyes, skin and bone. As a rule, the Midwest Organ Bank coordinates the donation of all organs unless it is **exclusively** for eyes, skin, or bone. We have included the phone numbers of the institutions retrieving these organs so that you may contact them directly.

As always, contact the Midwest Organ Bank for donor evaluation **prior** to approaching the family for consent. We must determine the suitability of each organ prior to activating the process and calling in the retrieval teams.

LIVER DONATION

Age: 3 months to 50 years

Weight: Must closely approximate weight of potential recipient.

Physical Exam: Liver should be normal size, no major abdominal trauma.

Blood Pressure: The liver is very susceptible to damage from anoxia or hypoxia. Blood pressure and blood gases must be within normal limits.

Lab Studies: ABO, total and direct bilirubin, SGOT, SGPT, LDH

Contra-indications:

- Drug and/or alcohol abuse
- Hepatitis
- Liver dysfunction (such as gall bladder surgery)

Surgical Requirements:

OR privileges for retrieval team

Type and crossmatch 5 units whole blood or packed red cells for donor

Heating blanket and esophageal temperature probe

Back table with waterproof drape

Two sterile splash basins

Two IV poles

Refrigerate 4 liters lactated Ringer's

Sternal saw

1 bucket crushed non-sterile ice

Shave and prep skin, neck to pubis

Photocopy of patient's chart

Anesthesia Requirements:

Maintain blood pressure and hydration

Maintain temperature >95° F

Maintain hematocrit >35%

Maintain respirator, 100% O₂

Administer standard Midwest Organ Bank medications (Mannitol, Heparin, Regitine)

HEART DONATION

Age: Male 10-35 years; Female 10-40 years.

Weight: Must closely approximate weight of potential recipient.

Blood Pressure: The heart is very susceptible to damage from anoxia or hypoxia. Blood pressure and blood gases should be within normal limits. Dopamine support should be minimal (<10mcg/kg/min). Cardiac arrest during hospitalization will usually rule out heart donation. Consult the Midwest Organ Bank if this has occurred.

Lab Studies: ABO, blood gases, cardiac enzymes, EKG, chest x-ray, echo-cardiogram, cardiology consultation.

Contra-indications:

- Cardiac irregularities or disease
- Cardiac trauma
- Drug abuse
- Hepatitis

Surgical Requirements:

OR privileges for retrieval team

Type and crossmatch 5 units whole blood or packed red cells

Heating blanket, esophageal temperature probe

Back table with waterproof drape

Two sterile splash basins; two IV poles

Refrigerate 4 liters lactated Ringer's

Sternal saw

Shave and prep skin, neck to pubis

Photocopy of patient's chart

2 Suctions

1 bucket crushed non-sterile ice

An escort out of building for retrieval team

Anesthesia requirements:

Maintain blood pressure, preferably with hydration

If Dopamine is required, maximum dosage is 10 mcg/kg/min

Maintain hematocrit >35%

Maintain temperature >95° C

Maintain respirator, O₂ set at 100%

LUNG DONATION
FOR HEART/LUNG DONATION
BOTH HEART AND LUNG CRITERIA MUST BE MET

Age: 10-50 years

Height and Weight: Critical factors required to closely match donor and recipient.

Blood Pressure: A systolic blood pressure of 100mm Hg is required. Dopamine support is acceptable up to 10 mcg/kg/min. The central venous pressure should be maintained at 10-16 cm H₂O. Blood gases should be within normal limits.

Lab Studies: ABO, blood gases, sputum gram stain or culture, chest x-ray, CBC, SMA-12, blood cultures.

History: Short hospitalization, absence of pulmonary disease, absence of infiltrates on chest x-ray.

Special Requirements: At the present time, lack of adequate preservation techniques makes it necessary to transport the donor to the transplant center. These arrangements are made by the Midwest Organ Bank at no cost to the donating family. The body will be returned to the family, usually within 24 hours.

BONE DONATION

**Bone Bank
Overland Park, Kansas
(913) 649-9609**

The need for bone is not constant. The Bone Bank or the Midwest Organ Bank will contact hospitals as needs arise.

Age: 15-65 years

Contra-indications:

- Systemic bacterial infection
- History of cancer
- Hepatitis or positive Australia antigen
- Positive VDRL
- History of RB

Time Limit: Bone must be retrieved within 12 hours after death.

Surgical Requirements:

OR privileges for retrieval surgeons.

Procedures are completely sterile with routine prepping and draping.

EYE DONATION

**Kansas City Eye Bank
Kansas City, Missouri
(816) 531-1066**

**Kansas Oddfellow's Eye Bank, Inc.
Kansas City, Kansas
(913) 588-6658**

Age: No age restrictions.

Contra-indications:

- Hepatitis
- Viral diseases
- Active tuberculosis
- AIDS
- Herpes
- Rabies
- Syphilis
- A disease requiring isolation of patient

Medical Management:

- Retrieve eyes within 6 hours after death
- Apply Lacri-lube or artificial tears to keep the corneas moist
- Close eyelids, papertape shut and apply ice

Surgical Requirements: None

The Eye Bank coordinator will provide all enucleation materials.

SKIN DONATION

Gene and Barbara Burnett Burn Center
Kansas City, Kansas
(913) 588-6142

Age: 2 and up

Time Limit: Skin must be retrieved within 8 hours after death.

Contra-indications:

Always rule out donation:

- Treponemal diseases
- Hepatitis-viral or toxic
- Poisoning
- Disseminated malignancy
- Cancer chemotherapy
- Exanthematous infections

May rule out donation:

- Autoimmune diseases
- Collagen diseases
- Recent transfusion
- Infections with history of septicemia

Surgical Requirements:

OR privileges for retrieval surgeons

Skin prep: Shave donor areas

Betadine scrub for 10 minutes

Sterile drape

Skin grafts are taken from thighs, legs above the ankles, anterior and posterior trunk, upper arms above the elbow

PANCREAS DONATION

Pancreas transplantation is still in its experimental stages. Most pancreas donations, at this time, will be used for research only. Family members need to be made aware of this when approached for consent.

Age: 10-40 years

History: Family history negative for diabetes.

Lab: Blood glucose on admission.

POINTS TO REMEMBER

1. The Midwest Organ Bank is responsible for coordinating all arrangements with the out-of-state transplant centers.
2. Contact the Midwest Organ Bank (816) 931-6353 before approaching the family for consent.
3. Blood type, age, and weight of the donor is needed to determine suitability of recipients.
4. Extra time is needed to coordinate a multi-organ donation (6-24 hours).
5. Lung and heart/lung donations require transportation of the donor to the transplant institution.
6. The Skin, Bone, and Eye Bank may be called directly by your institution if no solid organs are to be donated.
7. The donor family never pays any costs related to organ donation. All costs are billed to the Midwest Organ Bank.

ORGAN TRANSPLANT AND PROCUREMENT ACT OF 1984

APRIL 6 (legislative day, MARCH 26), 1984.—Ordered to be printed

Filed under authority of the order of the Senate of APRIL 5 (legislative day, MARCH 26), 1984

Mr. HATCH, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2048]

The Committee on Labor and Human Resources to which was referred the bill (S. 2048) having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

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I. SUMMARY OF THE BILL

The Organ Procurement and Transplantation Act, S. 2048, amends the Public Health Service Act (PHSA) and makes additional provisions, as follows:

(1) Provides for the establishment by the Secretary of Health and Human Services of a Task Force on Organ Procurement and Transplantation. Sets forth the duties of the Task Force in assessing the

Nation's organ procurement system and in developing a plan for further coordinated efforts in organ procurement. Describes the membership of the Task Force. Directs the Task Force to submit a final report within nine months.

(2) Provides that the Secretary shall assure the establishment and operation in the private sector of an Organ Procurement and Transplantation Registry, and authorizes \$2,000,000 per year for grants and contracts. Provides that the Registry shall include potential organ recipients, potential organ donors who have volunteered to be listed, and a matching system to link available organs with potential recipients. Sets forth other duties of the Registry in facilitating and coordinating organ procurement activities.

(3) Provides that the Secretary may make grants to organ procurement organizations after the Task Force has submitted its report (provided the grants are not in a manner inconsistent with recommendations of the Task Force concerning Federal assistance for organ procurement agencies). Defines, solely for the purpose of receiving assistance under this section, an organ procurement organization. Authorizes for these grants \$5,000,000 for fiscal year 1985 and for each of the two succeeding fiscal years.

(4) Requires that the Secretary publish an annual report on the scientific and clinical status of organ transplantation.

(5) Prohibits the interstate buying and selling of human organs for transplantation.

II. BACKGROUND AND NEED FOR LEGISLATION

In the last 15 to 20 years, major advances have been made in the science of human organ transplantation. Surgical techniques have been improved, knowledge of transplantation immunology and tissue-typing has grown, the ability to preserve solid organs outside the body has increased, and, most recently, the use of a new anti-rejection drug called cyclosporine has dramatically improved the survival rates of transplant recipients. Kidney transplant patients, for example, now have better than an 80 percent chance of surviving for at least a year, compared to a 50 percent chance before cyclosporine. For liver transplants, cyclosporine has doubled the one-year survival rate, from 35 percent to 70 percent.

These advances have brought new hope to thousands of people suffering from diseases of the heart, liver, kidneys, lungs, and other organs. While kidney-failure patients can frequently maintain a normal, if restricted, lifestyle through dialysis, end-stage failure of other organs leads inevitably to total disability and death. The prospect of successful organ transplantation has led many people to hope for a restoration of their health.

However, as a result of several factors transplants remain difficult to obtain for many patients. The number of donated organs that become available falls far short of the number of people on waiting lists at any given time. Although it is estimated that in this country up to 20,000 people die annually under circumstances that would make them suitable organ donors, organs are actually recovered from fewer than 15 percent. Another limiting factor, especially for liver and heart transplants, is the small number of medical centers that are equipped to carry out organ transplants.

Highly trained teams of surgeons and extensive hospital resources are required. Finally, the enormous cost of transplant procedures is a major hurdle for many potential organ recipients. While kidney transplants are covered under Medicare, most insurers, including the Federal Government, have until recently regarded heart and liver transplants as experimental and therefore not covered. Some changes in these policies are beginning to be made, but most patients needing organs other than kidneys are still faced with formidable financial burdens.

These issues have recently been brought to public awareness by media coverage of desperate families seeking organs and funds for transplants. Several of these appeals have been for young children needing livers, and some have received nationwide publicity. In addition, President Reagan made the plight of such families the subject of one of his Saturday radio broadcasts. The increased public awareness of the need for organs has brought an upsurge in donations and in people requesting organ donor cards. Obviously, however, such ad hoc efforts cannot fully achieve long-term solutions to the problem of increasing organ availability.

Congressional attention has also been focused on the dilemma of transplantation. As a result of the realization that a more comprehensive solution to the problems associated with organ transplantation and transplant reimbursement, approximately 17 pieces of legislation were introduced to address various aspects of organ transplantation. In order to bring more information to the Congress to aid in the decisionmaking on the transplant issue, Senator Edward Kennedy introduced S. 1728, the National Task Force on Organ Procurement and Transplant Reimbursement Act on August 2, 1983; this bill was referred to the Committee on Labor and Human Resources, which held hearings on the subject of organ transplantation on October 20, 1983. As a result of the hearings held by the Committee, Senator Orrin Hatch introduced S. 2048, The Organ Procurement and Transplantation Act. Since, S. 2048 included the task force provision required in S. 1728 and other provisions thought to be critical to the transplant issue, S. 2048 was acted upon and reported out of the Committee on Labor and Human Resources with amendments favorably. Efforts have been made in both the Senate and the House of Representatives to explore the complex medical, ethical, legal, and financial problems related to organ donation and transplantation. In particular, the existing system for organ procurement has come under scrutiny as policymakers have sought to understand where improvements may be made.

The present system is a mixture of private sector initiatives and governmental involvement on both the State and Federal levels. There are some 120 organ procurement agencies of various sizes around the country, whose operations relating to kidney procurement are funded by Medicare. A number of these agencies are organized into networks, such as the Southeastern Organ Procurement Foundation, to coordinate their activities and facilitate sharing of donated organs. Nationally, procurement agencies can access a central computer registry of potential kidney recipients (the United Network for Organ Sharing, or UNOS) and can call a national telephone hotline established by the North American Trans-

plant Coordinators Organization which lists transplant centers needing nonrenal organs. Organ donation is encouraged by a number of voluntary health organizations and by the laws in all 50 States and the District of Columbia recognizing the Uniform Donor Document (organ donor card) established under the Uniform Anatomical Gift Act. Computerized registries of potential organ donors, such as the Living Bank in Houston, also exist. In addition, a new private sector organization, the American Council on Transplantation, has been formed with support from the Department of Health and Human Services. This organization is commencing work on efforts to educate the public and health professionals about organ transplantation, and to enhance organ availability and patient access to organs.

Despite all these efforts, more needs to be done to encourage organ donation and to improve procedures for efficient organ procurement leading to successful transplantation. The Organ Procurement and Transplantation Act seeks to support development of a rational and fair national health policy regarding organ transplantation. The work of the proposed Task Force on Organ Procurement and Transplantation will provide the basis for creating an effective organ procurement system and for determining the appropriate roles of the private and public sectors in that system. The computerized registries of potential recipients and donors, and the matching system to link available organs with recipients, will provide a truly national, coordinated mechanism for efficient distribution of all available organs. The proposed grants to new and existing organ procurement organizations will enable them to act quickly on the recommendations of the Task Force. The annual report on the scientific and clinical status of organ transplantation will provide an up-to-date summary of advances in the field, and will be especially valuable to health insurers in assessing the development of transplant procedures. Finally, the prohibition on the buying and selling of human organs is directed at preventing the for-profit marketing of kidneys and other organs.

III. HISTORY OF S. 2048

A bill, S. 2048, to provide for the establishment of a Task Force on Organ Procurement and Transplantation and an Organ Procurement and Transplantation Registry, and for other purposes was introduced by Senator Hatch on November 3, 1983, and was referred to the Committee on Labor and Human Resources.

A public hearing on organ transplantation issues had been held on October 20, 1983. On March 21, 1984, the Committee met in open executive session to consider an amended version of the bill which incorporated the recommendations and comments of members of the committee, professional societies, the Administration, and interested individuals. By roll call vote, the Committee unanimously approved the bill and ordered that it be reported favorably to the Senate.

IV. TEXT OF S. 2048 AS REPORTED

A BILL To provide for the establishment of a Task Force on Organ Procurement and Transplantation and an Organ Procurement and Transplantation Registry, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
That this Act may be cited as the "Organ Procurement and Transplantation Act".

FINDINGS

SEC. 2. The Congress finds and declares that—

(1) the lack of suitable donor organs for patients awaiting surgery is a major obstacle to all organ transplant programs;

(2) a number of patients waiting for donor organs face certain death within a predictable time period;

(3) the absence of coordinated and effective systems to solicit, identify, and match organ donors with transplant patients has forced such patients and their families to resort to public appeals through the mass media in order to procure the organs needed for transplantation;

(4) a cooperative relationship between an informed public and a receptive medical community is necessary for the identification and procurement of organs for transplantation; and

(5) there is a need for additional medical centers which are capable of performing human organ transplant surgery.

TITLE I—TASK FORCE ON ORGAN PROCUREMENT AND TRANSPLANTATION

ESTABLISHMENT

SEC. 101. Within thirty days after the date of enactment of this Act, the Secretary of Health and Human Services shall, under the authority of section 301 of the Public Health Service Act, establish a Task Force on Organ Procurement and Transplantation.

DUTIES OF THE TASK FORCE

SEC. 102. (a) The Task Force shall assess the nature and extent of public and private efforts that are needed to create a widely known, well defined, and effective organ procurement system, and shall develop a plan to assure the establishment of a national organ donor network and organ procurement system which emphasizes involvement by the private sector and provides for the coordination of existing organ procurement programs and services.

(b) The plan developed under subsection (a) shall include—

- (1) an analysis of the factors that affect and determine the availability of organs for transplantation;
- (2) a specification and clarification of mechanisms that exist or can be developed in the private sector to identify potential organ donors, encourage health care providers to promptly notify appropriate organizations of the availability of organs for transplant, provide for rapid matching of donors with appropriate organ recipients, facilitate the removal of organs, maintain the viability of organs, and transport organs to appropriate organ recipients, including mechanisms such as a national donor identification system;
- (3) provisions for the education and training of health professionals, including physicians, nurses, and hospital and emergency care personnel;
- (4) provisions for the education of the general public, the clergy, law enforcement officers, members of local fire departments, and other agencies and individuals that may be instrumental in effecting organ procurement;
- (5) an identification of barriers to the donation of organs to pediatric patients, including an assessment of—
 - (A) barriers to the improved identification of pediatric organ donors and their families and pediatric organ recipients;
 - (B) current health care services provided for pediatric patients who need organ transplantation and organ procurement procedures, systems, and programs which affect such patients;
 - (C) cultural factors affecting the family with respect to the donation of the organs of a minor; and
 - (D) ethical and economic issues relating to organ transplantation needed by chronically ill pediatric patients;
- (6) recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of organs;
- (7) an analysis of barriers to the interstate transportation of organs for transplantation;
- (8) an analysis of the factors involved in insurance reimbursement for transplant procedures by private insurers and the public sector;
- (9) an analysis of the factors relating to insurance reimbursement for long-term immunosuppressive drug therapy for organ transplant patients by private insurers and the public sector; and
- (10) an assessment of need for additional medical centers which are capable of performing human organ transplant surgery and recommendations for the expeditious establishment of such centers.

MEMBERSHIP

SEC. 103. (a) The Task Force shall be composed of nineteen members as follows:

(1) The Secretary of Health and Human Services (or the designee of the Secretary).

(2) The Surgeon General of the United States (or the designee of the Surgeon General).

(3) The Director of the National Institutes of Health (or the designee of the Director).

(4) The Administrator of the Health Care Financing Administration (or the designee of the Administrator).

(5) Seven individuals appointed by the Secretary who are not officers or employees of the United States and who represent health professionals with expertise in the field of organ transplantation, including physicians, nurses, and hospital and emergency care personnel.

(6) Two individuals appointed by the Secretary who are not officers or employees of the United States and who represent private health insurers.

(7) Four individuals appointed by the Secretary who are not officers or employees of the United States and who represent the clergy, patient advocacy organizations, and voluntary organizations.

(8) Two individuals appointed by the Secretary who are not officers or employees of the United States and who have experience with respect to organ procurement.

(b) A vacancy in the Task Force shall be filled in the same manner as the original appointment was made. A vacancy in the Task Force shall not affect its powers.

(c) Members shall be appointed for the life of the Task Force.

(d) The Secretary shall select a Chairman from among the members of the Task Force who are not officers or employees of the United States.

(e) Eleven members of the Task Force shall constitute a quorum, but a lesser number may hold hearings.

(f) The Task Force shall hold its first meeting on a date specified by the Secretary which is not later than thirty days after the date on which the Secretary establishes the Task Force under section 101. Thereafter, the Task Force shall meet at the call of the Chairman or a majority of its members, but shall meet at least three times during the life of the Task Force.

(g)(1) Each member of the Task Force who is not an officer or employee of the United States shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for grade GS-18 of the General Schedule under section 5332 of title 5, United States Code, for each day (including traveltime) during which such member is engaged in the actual performance of duties or a member of the Task Force. Each member of the Task

Force who is an officer or employee of the United States shall receive no additional compensation.

(2) While away from their homes or regular places of business in the performance of duties for the Task Force, all members of the Task Force shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under sections 5702 and 5703 of title 5, United States Code.

DIRECTOR AND STAFF OF TASK FORCE

SEC. 104. (a) The Secretary shall appoint an Executive Director who shall be compensated at a rate not to exceed the rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of title 5, United States Code.

(b) With the approval of the Task Force, the Executive Director may appoint and fix the compensation of such additional personnel as the Task Force considers necessary to carry out its duties.

(c) The Executive Director and the additional personnel of the Task Force referred to in subsection (b) may be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and may be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(d) Subject to such rules as may be prescribed by the Task Force, the Executive Director may produce temporary or intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals not to exceed \$100 per day.

(e) Upon request of the Task Force, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Task Force to assist the Task Force in carrying out its duties under this Act.

(f) The Secretary shall provide the Task Force with such administrative and support services as the Task Force may request.

REPORT

SEC. 105. (a) The Task Force may transmit to the President, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives such interim reports as the Task Force considers appropriate.

(b) Not later than nine months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a final report to the President, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives. The final report of the Task Force shall contain a detailed statement

of the findings and conclusions of the Task Force and such recommendations as the Task Force considers appropriate.

DEFINITIONS

SEC. 106. For purposes of this title—

(1) the term "Federal agency" has the meaning given to the term "agency" in section 551(1) of title 5, United States Code;

(2) the term "Secretary" means the Secretary of Health and Human Services; and

(3) the term "Task Force" means the Task Force on Organ Procurement and Transplantation established under section 101.

TERMINATION

SEC. 107. The Task Force shall terminate one month after the date on which the Task Force transmits the final report required under section 105 to the President, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

TITLE II—FACILITATION OF ORGAN PROCUREMENT AND TRANSPLANTATION

ESTABLISHMENT OF PROGRAM

SEC. 201. Title III of the Public Health Service Act is amended by adding at the end thereof the following new part:

"PART K—ORGAN TRANSPLANTS

"ESTABLISHMENT OF ORGAN PROCUREMENT AND TRANSPLANTATION REGISTRY

"SEC. 399A. (a) Under the authority of section 301, the Secretary shall assure the establishment and operation in the private sector of an Organ Procurement and Transplantation Registry which meets the requirements of subsection (b). To the extent necessary to carry out this section, the Secretary may make grants and enter into contracts in a total amount not in excess of \$2,000,000 in any fiscal year.

"(b) The Organ Procurement and Transplantation Registry shall—

"(1) promote the establishment, in one location or by coordinating regional centers, of—

"(A) a national registry of individuals who need organs for transplantation;

"(B) a national registry of individuals who, prior to their death, have voluntarily made commitments to donate organs for transplantation and be

listed in the registry, which shall include provisions to—

“(i) permit any such individual, prior to death, to rescind any commitment made by such individual to donate organs and be listed in the registry;

“(ii) require a health care provider who cared for any such individual at the time of death of such individual to, prior to releasing any organ of such individual for donation, verify through the registry the commitment of such individual to donate such organ; and

“(iii) ensure, in accordance with Federal and State laws and criteria established by health care providers governing the confidentiality of medical records, access to the registry for physicians and other health care professionals; and

“(C) a national system to match organs available for donation with individuals listed in the registry described in subparagraph (A);

“(2) assure the operation of a twenty-four-hour telephone service to facilitate the matching of organs with individuals included in the registry described in paragraph (1)(A);

“(3) establish and maintain standards of quality for the acquisition and transportation of donated organs;

“(4) promote the coordination, as appropriate, of the transportation of donated organs to transplant centers;

“(5) provide information to the public and to physicians and other health professionals regarding organ donation; and

“(6) develop, prepare, and distribute, in conjunction with appropriate governmental and private entities, model uniform national organ donor cards in order to—

“(A) assure participation in the national registry described in paragraph (1)(B); and

“(B) assure the continuation of a system of organ donor cards under which individuals may agree to donate organs for transplantation without participation in such registry.

“(c) For purposes of this section, the term ‘organ’ means the human kidney, liver, heart, lung, bone marrow, and any other human organ or tissue included by the Secretary by regulation.

“ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

“Sec. 399B. (a)(1) Subject to paragraph (2), the Secretary may make grants for the planning, establishment, and initial operation of organ procurement organizations described in subsection (b).

"(2)(A) No grant authorized under paragraph (1) shall be made by the Secretary until 30 days after the Task Force on Organ Procurement and Transplantation transmits the final report required under section 105(b) of the Organ Procurement and Transplantation Act.

"(B) The Secretary may make grants authorized under paragraph (1) only if such grants are made in a manner that is not inconsistent with any recommendation of the Task Force on Organ Procurement and Transplantation contained in the report referred to in subparagraph (A) that addresses the issue of Federal assistance for organ procurement agencies.

"(b)(1) An organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

"(A) is a nonprofit entity;

"(B) has the capability of becoming self-supporting;

"(C) is not an organization which provides health care services or carries out other activities not related to the procurement of organs, except that it may be an organization which provides health care services or carries out other activities not related to the procurement of organs if it was being reimbursed for organ procurement activities under title XVIII of the Social Security Act before the date of the enactment of this part;

"(D) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization;

"(E) has a defined service area which—

"(i) includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget); or

"(ii) does not include any part of such an area and is of sufficient size which will include at least fifty potential organ donors each year; and

"(F) has sufficient staff to effectively obtain organs from donors in its service area.

"(2) An organ procurement organization shall—

"(A) have agreements with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations;

"(B) conduct systematic efforts, including professional education, to acquire organs from potential donors;

"(C) arrange for the acquisition and preservation of donated organs;

"(D) arrange for the appropriate tissue typing of donated organs;

"(E) have a system to allocate donated organs among transplant centers according to established criteria;

"(F) provide for the transportation of donated organs to transplant centers;

"(G) have arrangements to coordinate its activities with transplant centers in its service area;

"(H) participate in the Organ Procurement and Transplantation Registry established under section 399A;

"(I) have arrangements with tissue banks for the preservation and storage of tissues as may be appropriate; and

"(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs.

"(c) For grants under subsection (a) there are authorized to be appropriated \$5,000,000 for fiscal year 1985 and for each of the two succeeding fiscal years."

TITLE III—ANNUAL REPORT ON ORGAN TRANSPLANTATION

REPORT REQUIRED

SEC. 301. Title IV of the Public Health Service Act is amended by adding at the end thereof the following new section:

"ANNUAL REPORT ON ORGAN TRANSPLANTATION

"SEC. 480. The Secretary shall publish an annual report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institute of Health and the Commissioner of the Food and Drug Administration in the preparation of the report."

TITLE IV—PROHIBITION OF ORGAN PURCHASES

PROHIBITED ACTS

SEC. 401. (a) Subpart 1 of part F of the Public Health Service Act is amended by adding at the end thereof the following new section:

"PURCHASE OF HUMAN ORGANS PROHIBITED

"SEC. 352A. (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer for valuable consideration any human organ for use in human transplantation if the transfer affects interstate commerce.

"(b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.

"(c) For purposes of this section:

"(1) The term 'interstate commerce' has the same meaning as in section 201(b) of the Federal Food, Drug, and Cosmetic Act.

"(2) The term 'human organ' means the human kidney, liver, heart, lung, bone marrow, and any other

human organ or tissue included by the Secretary by regulation.

"(3) The term 'valuable consideration' does not include the reasonable costs associated with the removal, storage, processing, preservation, quality control, and transportation of a human organ."

(b) Such subpart is further amended by adding at the end of the heading for such subpart "and Human Organs".

(c) The heading for part F of such Act is amended—

(1) by inserting a comma and "Human Organs," after "Products"; and

(2) by inserting a comma after "Laboratories".

V. HEARING

A public hearing on organ transplantation issues was conducted by the Committee on October 20, 1983, with the following individuals providing testimony:

Dr. Edward M. Brandt, Assistant Secretary for Health, Department of Health and Human Services; Dr. C. Everett Koop, Surgeon General of the Public Health Service; Dr.Carolyn K. Davis, Administrator, Health Care Financing Administration.

Rick and June Brooks, Laurinburg, North Carolina; Charles Fiske, Bridgewater, Massachusetts; Gary Coleman (on videotape), Los Angeles, California, representing the National Kidney Foundation; Jim and Patty Stannis, Union Grove, Wisconsin.

Dr. Oscar Salvatierra, American Society of Transplant Surgeons; Dr. Nancy Ascher, Liver Transplant Program, University of Minnesota Hospital, Minneapolis; Dr. Clive O. Callender, Howard University Transplant Center, Washington, D.C.

Dr. Anthony Monaco, New England Organ Bank, Inc., Boston, Massachusetts; Dr. Gary Friedlander, American Council on Transplantation; Lawrence C. Morris, Blue Cross/Blue Shield, Chicago, Illinois; The Honorable Judy Baar Topinka, Representative to Illinois State Legislature, District 43, Chicago.

VI. COMMITTEE VIEW

The issue of human organ transplantation became one of the most widely discussed and publicized health issues during 1983 and 1984. There are several reasons for this prominence, but the most important factor is increasing media attention paid to the plight of individuals whose lives were in jeopardy because of difficulties and delays in obtaining an organ transplant. Associated factors in the growing interest in organ transplantation have been remarkable improvements in morbidity and mortality of patients undergoing organ transplantation, due to improved techniques and the development of immunosuppressive medications which reduce the incidence of rejection of the transplanted organs. As surgical and medical techniques improve, rendering transplantation safer and more efficacious, the gap between available resources and demand will increasingly widen. Therefore, the Committee believes it is timely to direct the development of a national policy regarding the appropriate federal and private sector roles in organ transplantation. An equitable policy and system is necessary so that individuals

throughout our country can have access to organ transplantation when appropriate and necessary. In contrast, the committee believes that individual pleas through television and newspaper articles, while commendable in bringing to public attention the urgent circumstance of one person's need, may be counterproductive to the needs of many others requiring organ transplantation.

As the Committee studied this issue, it became apparent that significant activities are already being undertaken in the private sector to promote organ donation and to facilitate individuals in need of receiving life savings organ transplantation. The National Kidney Foundation, and the American Red Cross have all developed laudable efforts to encourage our citizens to become voluntary organ donors. The American Academy of Ophthalmology and the Eye Bank Association of America have for years encouraged individuals to become eye donors, providing sight saving corneal transplants. The American Association of Blood Banks has been a leader in facilitating bone marrow transplantation, the American Association of Tissue Banks has been instrumental in facilitating skin transplantation for tens of thousands of burn victims, and the American Academy of Orthopedic Surgeons has promoted bone and cartilage allografts which can improve the function and vitality of many individuals previously disabled from injury or disease.

Further, the Committee is impressed and encouraged by some new developments in the private sector related to organ transplantation. One example of a laudable initiative is the establishment of Oil Flights, a charitable program developed by a group of individuals in the oil industry. Oil Flights provides a nationwide emergency transportation program to assist individuals in need of an organ transplants to be flown to the surgical teams who will perform the surgery. This program is underwritten by a cross-section of petroleum industry companies to assist individuals in critical need of organ transplantation, and is a praiseworthy effort of private sector involvement in a national health program. Another exemplary program is Life Page, developed by Telocator Network of America, a trade association representing electronic paging and mobile phone manufacturers. This organization has made available to individuals awaiting organ transplantation the free use of electronic pagers, this gives them freedom to be away from phone communication and not risk missing contact with the surgical transplantation centers.

The Committee has also learned of equally impressive work being performed by hundreds of professionals who serve as transplant coordinators, and are represented by North American Transplant Coordinators Organization (NATCO). These individuals include physicians, nurses, and allied health professionals who work with organ recipients and whose main objective is to obtain and distribute valuable human organs and tissues which are desperately needed by the waiting victims of endstage organ failure. They assist with recovery of viable organs for transplantation and have helped develop a network of hospitals within geographic areas which will refer donors to the appropriate place for organ and tissue recovery. These professionals have been instrumental in establishing a 24-hour hot line (the NATCO 24-Alert System), serving individuals in need of liver, heart and heart-lung transplants

from the 15 transplant centers which perform these operations across the United States and Canada. This complements the United Network for Organ Sharing (UNOS) computer system which serves individuals nationwide needing kidney transplantation, and the 56 Donor Program, another computer registry serving the West Coast. The Committee appreciates that within the private sector the independent organ procurement agencies and the hospital based organ procurement agencies have made a substantial and effective contribution to individuals in need of organ transplantations throughout the country.

In short, a great deal of effort is being extended by professionals and voluntary health organizations to enable those in need to benefit from developments in human organ and tissue transplantation. The Committee applauds each and every one of these efforts and has found in them good and sufficient cause to believe that the national coordinating effort, while stimulated by the federal government and this legislation, should nonetheless be located in the private sector rather than in government.

In this regard the Committee is aware and encourages the very worthwhile effort, established in the private sector with the assistance of the federal government through the office of the Surgeon General of the United States, to provide a cohesive and united policy for organ transplantation. The American Council on Transplantation (Act) was established in 1983 and includes highly respected individuals from the health professions, hospital administration, and organ procurement organizations. The goals of this organization are to motivate the public to become organ donors, to encourage health professionals to identify in a timely manner, to promote equitable access to and effective use of multiple organs and tissues, and to address technical, ethical and financial issues involved in organ transplantation. The Committee hope that the information and accomplishments of Act will be shared with the task force established by this legislation. To prevent redundant and unnecessary work, the federal task force is directed to consult with the American Council on Transplantation and utilize their work to the extent practicable.

It is the sense of the Committee that the task force established by this legislation is essential to determine complex and challenging issues related to reimbursement for transplantation surgery, ethical, social, and cultural issues. There is great concern among the public and private sector that developing technologies in organ transplantation will become increasingly more costly and impose large financial burdens on already strained national health resources. However, it is felt that with careful analysis, recommendations can be made to develop policies ensuring: fair access to transplant surgery for individuals who without such surgery would be at risk of losing their lives; and a means of public and private insurance to pay for such procedures. However, before legislative changes in reimbursement policy for public insurance is considered, the Committee believes that the task force must evaluate the current status of the Medicare trust fund, states, policies regarding Medicaid payments for transplantation surgery, recent changes in private sector reimbursement policies for transplantation, and past experience with the endstage renal disease program (ESRD). Alter-

natives to traditional reimbursement policies should be considered, including prospective payment for organ transplantation procedures, creation of a separate trust fund for payment of such procedures, and reimbursement only at designated regional transplantation centers, to be determined in cooperation with private sector, health professional, and voluntary organizations.

One critical aspect of the transplantation policy is reimbursement for immunosuppressive medications such as cyclosporin. A recent Office of Technology Assessment (O.T.A.) study found that the success rate of kidney transplantation with cyclosporin has been substantially higher than with other methods of treatment, and individuals receiving this medication had shorter hospital stays and lower inpatient costs. Legislative proposals have been made to provide federal reimbursement for this medication, based on projected cost savings. However, the same OTA study found that patients on cyclosporin had poorer kidney function and higher outpatient costs than those on other treatment regimens. Therefore, given somewhat conflicting data regarding this medication, but the potential for significant cost savings, the task force should carefully consider the cost benefit and health benefits of reimbursement for immunosuppressive medication. The task force is advised to consider the efforts of these private sector organizations and determines if federal activities are necessary to complement current efforts, or to improve and expand voluntary organ procurement and transplantation procedures. It is hoped that policy recommendations will carefully consider their successes and benefit from their experience. Grants authorized by this legislation to organ procurement agencies are to be based on recommendations of the task force and are to be made only if deemed necessary to improve their capacity to arrange for individuals suffering from end organ failure receiving the life saving transplantation.

The Committee believes that one important and appropriate new activity to include in the national computer registry is to provide a centralized list of individuals who have voluntarily agreed to donate organs to aid matching available organs with recipients in need of such organs—guaranteeing the donors rights of recission and the confidentiality of medical records. These provisions are intended to augment and do not replace the current donor card system, nor do they vitiate traditional state law and common law protections against improper or unconsented use of organs.

The Committee is aware that some individuals and organizations have expressed concern that the legislation prohibiting sale for "voluntary consideration" of human organs, may inadvertently make it illegal to reimburse individuals for reasonable costs incurred in the process of organ donation. At present, a person donating a kidney may sustain expenses from travel, housing, and lost wages, which are now appropriately and fairly reimbursed by voluntary organizations of federal programs. It is not the intent of the Committee that any such reasonable costs be considered part of valuable consideration.

It is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation. This is not meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health

of the donor. The current state of the law is uncertain with regard to the sale of organs, and the Committee believes that legislation is necessary to clarify this issue. The Committee believes that human body parts should not be viewed as commodities; however, recognizing that laws governing medical treatment, consent, definition of death, autopsy, burial, and the disposition of dead bodies is exclusively state law, the proscription in this legislation relates only to interstate commerce.

VII. TABULATION OF VOTES CAST IN COMMITTEE

In Executive Session of the Committee on Labor and Human Services on Wednesday, March 21, S. 2048 passed 18-0 on a rollcall vote.

VIII. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., April 5, 1984.

HON. ORRIN G. HATCH,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for S. 2048, a bill to facilitate organ procurement and transplantation, as ordered reported by the Senate Committee on Labor and Human Resources on March 21, 1984.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

Rudolph G. Penner.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 2048.
2. Bill title: A bill to facilitate organ procurement and transplantation.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on March 21, 1984.
4. Bill purpose: This bill would establish a task force to plan a national organ donor network and organ procurement system and to coordinate existing services. The bill would also establish an organ procurement registry and provide financial assistance for the planning and initial operation of organ procurement organizations.
5. Estimated cost to the Federal Government:

(By fiscal year, in millions of dollars)

	1985	1986	1987	1988	1989
Amounts subject to appropriations action:					
Authorization level:					
Task force	(1)	(1)			
Organ Procurement and Transplantation Registry	2	2	2	2	2
Assistance for organ procurement organizations	5	5	5		

	1985	1986	1987	1988	1989
Estimated outlays:					
Task force.....	(¹)	(¹)			
Organ Procurement and Transplantation Registry.....	2	2	2	2	2
Assistance for organ procurement organizations.....	5	5	5		
Appropriations action totals:					
Authorization levels.....	7	7	7	2	2
Estimated outlays.....	7	7	7	2	2
Direct spending provision:					
Budget authority:					
Hospital insurance.....	0	-2	-5	-9	-16
Supplementary medical insurance.....	-4	-7	-10	-14	-17
Medicaid.....	(¹)	(¹)	(¹)	(¹)	(¹)
Estimated outlays:					
Hospital insurance.....	7	18	33	52	78
Supplementary medical insurance.....	-3	-6	-9	-13	-16
Medicaid.....	(¹)	(¹)	(¹)	(¹)	(¹)
Direct spending totals:					
Budget authority.....	-4	-9	-15	-23	-33
Estimated outlays.....	4	12	24	39	62
Total authorization level/budget authority.....	3	-2	-8	-21	-31
Total outlays.....	11	19	31	41	64

¹ Less than \$500,000

The costs of this bill fall within budget functions 550 and 570.

Basis of estimate: The bill authorizes appropriations for grants for organ procurement organizations for planning, establishment and initial operation. Authorization levels are stated in the bill. Authorized amounts are assumed to be fully appropriated and spent in the year of appropriation.

The bill also provides funding of up to \$2 million each fiscal year for an Organ Procurement and Transplantation Registry. CBO assumed that the full \$2 million would be utilized for the network. Furthermore, CBO assumed that the number of transplants would increase with improved information on matching donors and recipients. This would also reduce the number of unused donor organs, as kidneys must be transplanted within a short time after they became available. Over the five year period from 1985 to 1989, an estimated total of almost 2,200 additional transplants could occur as a result of the expanded networking authorized by this bill.

The effects of this bill on the Hospital Insurance (HI) program would be to increase costs as a larger number of transplants would be made possible under the network. The Supplementary Medical Insurance (SMI) program would show savings starting in the second year, increasing in the outyears. The additional patients who receive and retain kidney grafts would no longer require renal dialysis, a procedure currently covered under SMI.

Over the long run, successful transplants are less expensive per patient than dialysis. While the transplant costs more initially than one year of dialysis, dialysis must be continued indefinitely. During the projection period, the increased costs would outweigh savings because of the assumed increases in transplants. Once the number of transplants leveled off, after 1989, federal outlays would decline.

The budgetary impact on the Medicaid program for the dual Medicare-Medicaid beneficiaries is \$100,000 or less each year. The assumed enactment date of this bill is April 1, 1984.

6. Estimated cost to State and local governments: The budgetary impact on state and local governments would be \$100,000 or less each year. The state and local change represents the state and local share of Medicaid outlays.

7. Estimate comparison: CBO has previously completed an estimate of H.R. 4080, the National Organ Transplant Act, as amended and ordered reported by the House Subcommittee on Health, Committee on Ways and Means, March 9, 1984. The previous estimate assumed appropriations would be made in fiscal years 1984 through 1989. The funding for the registry or network in that bill would come from the Hospital Insurance Trust Fund. H.R. 4080 also provided higher levels of funding for organ procurement organizations.

8. Previous CBO estimate: None.

9. Estimate prepared by: Marianne S. Deignan.

10. Estimate approved by:

C. G. NUCKOL
(For James L. Blum,
Assistant Director for Budget Analysis Division).

IX. REGULATORY IMPACT STATEMENT

The Committee has determined there will be little increase in regulatory burden and paper work imposed by this bill. Creation of the Task Force on Organ Procurement and Transplantation, and the annual report on clinical and scientific aspects of organ transplantation will require transmission of data for Congress to utilize in developing related national health policy. However, no new regulations are required.

X. FAMILY FAIRNESS STATEMENT—S. 2048

The Committee has determined that this bill does not have a direct impact on family functions but will likely result in support for families in which there is a member in need of organ transplant surgery. It is estimated that with recent improvements in transplantation surgery and medical management that as many as ten percent of our population at some time may be candidates for transplantation surgery in the future. This legislation will likely reduce current problems and barriers to securing organ transplantation by offering more coordinated and comprehensive services. These organ transplant services will also facilitate an individual returning home more quickly and in better health, both of which will contribute to family stability. The creation of the Task Force to study transplantation may result in recommendations which will provide additional support to families in the future.

XI. SECTION-BY-SECTION ANALYSIS

S. 2048—ORGAN PROCUREMENT AND TRANSPLANTATION ACT AS REPORTED BY THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

Section 1 of the bill cites the Act as the "Organ Procurement and Transplantation Act."

Section 2 of the bill sets forth the findings of the Congress with respect to the shortage of donor organs, the absence of a coordinated system for organ procurement, and the need for additional transplant centers.

TITLE I—TASK FORCE ON ORGAN PROCUREMENT AND TRANSPLANTATION

Section 101 of the bill requires the Secretary of Health and Human Services to establish a Task Force on Organ Procurement and Transplantation.

Section 102 of the bill sets forth the duties of the Task Force. These include the charge to assess the nature and extent of public and private efforts that are needed to create an effective organ procurement system, and to develop a plan to assure the establishment of such a system, emphasizing private sector involvement and the coordination of existing organ procurement programs. Highlights of the plan to be developed include consideration of organ availability, donor identification, education of health professionals and the public, barriers to pediatric organ donation, transplantation research, barriers to interstate transportation of organs, insurance reimbursement for transplants and for immunosuppressive drugs, and the need for additional transplant centers.

Section 103 of the bill describes the membership of the Task Force. The 19 members will include four government officials from the Department of Health and Human Services; seven individuals representing health professionals; two individuals representing private health insurers; four individuals representing the clergy, patient advocacy organizations, and voluntary organizations; and two individuals experienced in organ procurement. The Secretary will appoint one of the non-government members as Chairman.

Section 104 of the bill provides for an Executive Director and staff for the Task Force.

Section 105 of the bill requires that, within nine months of its establishment, the Task Force transmit a final report to the President and to the Senate Committee on Labor and Human Resources and the House Committee on Energy and Commerce. The report is to detail the findings and conclusions of the Task Force and any recommendations they wish to make. Interim reports may also be transmitted.

Section 106 of the bill defines the terms "Federal agency," "Secretary," and "Task Force."

Section 107 of the bill provides that the Task Force will terminate one month after transmitting its final report.

TITLE II—FACILITATION OF ORGAN PROCUREMENT AND
TRANSPLANTATION

Section 201 of the bill amends Title III of the Public Health Service Act (PHSA) by adding a new Part K, consisting of two new sections. New section 399A of the PHSA provides for the establishment in the private sector of an Organ Procurement and Transplantation Registry, and new section 399B provides for start-up grants for organ procurement organizations. Section 399A describes the purposes of the Organ Procurement and Transplantation Registry, and, to assure its operation, authorizes the Secretary to enter into grants and contracts not exceeding \$2,000,000 in any fiscal year. The functions of the Registry are to include the establishment, in one location or by coordinating regional centers, of (1) a national registry of potential organ recipients; (2) a national registry of individuals who have volunteered to be organ donors upon their death (with provisions for rescinding the commitment to donate, for requiring health care providers to verify the commitment through the registry, and for ensuring access to the registry by health care providers); and (3) a national system to match available organs with individuals listed in the registry of potential organ recipients. Other functions of the Organ Procurement and Transplantation Registry include operating a twenty-four-hour telephone service for matching available organs with recipients; establishing standards of quality for the acquisition and transportation of donated organs; promoting the coordination of the transportation of donated organs to transplant centers; providing information to the public and to health professionals about organ donation; and coordinating the distribution of model uniform national organ donor cards to assure participation in the national donor registry and to assure continuation of the existing donor card system for individuals wishing to be an organ donor but who do not wish to be listed in the national registry. The term "organ" is defined to mean the human kidney, liver, heart, lung, bone marrow, and any other human organ or tissue included by the Secretary by regulation.

Under the new section 399B of the PHSA, the Secretary is authorized to make grants for the planning, establishment, and initial operation of organ procurement organizations, except that such grants may not be made until 30 days after the Task Force has submitted its final report, and then only if the grants are made in a manner that is consistent with any recommendation of the Task Force which addresses the issue of Federal assistance for organ procurement agencies. For purposes of receiving assistance under this section, an eligible organ procurement organization is defined and its functions described. It must be a non-profit entity, capable of becoming self-supporting; must carry on only organ procurement activities, not health care services (unless it was already being reimbursed for organ procurement activities under Medicare); must have necessary accounting procedures to assure fiscal stability; must have a defined service area meeting certain criteria; and must have sufficient staff to obtain organs from donors in its service area. The functions of such an eligible organ procurement organization are to have agreements with local hospitals which have

facilities for organ donations; to conduct systematic efforts, including professional education, to acquire organs from potential donors; to arrange for the acquisition, preservation, tissue typing, allocation, and transportation of donated organs; to coordinate its activities with its local transplant centers; to participate in the Organ Procurement and Transplantation Registry; to have arrangements with tissue banks for the preservation and storage of tissues; and to evaluate annually the effectiveness of the organization in acquiring potentially available organs. Appropriations for the start-up grants are authorized at \$5,000,000 for each of the fiscal years 1985, 1986, and 1987.

TITLE III—ANNUAL REPORT ON ORGAN TRANSPLANTATION

Section 301 of the bill amends Title IV of the Public Health Service Act by adding a new section 480, requiring the Secretary to publish an annual report on the scientific and clinical status of organ transplantation.

TITLE IV—PROHIBITION OF ORGAN PURCHASES

Section 401 of the bill amends Title III of the Public Health Service Act by adding a new section 352A to subpart 1 of part F. The new section makes unlawful the purchase of any human organ for use in human transplantation if the transfer affects interstate commerce. Penalties for violation are a fine of not more than \$50,000 or imprisonment of not more than five years, or both. The terms "interstate commerce", "human organ", and "valuable consideration" are defined, and do not include the reasonable costs associated with the removal, storage, and transportation of a human organ.

XII. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standard Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE

SECTION 1. This Act may be cited as the "Public Health Service Act."

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART F—LICENSING—BIOLOGICAL PRODUCTS, HUMAN ORGANS, [AND]
CLINICAL LABORATORIES, AND CONTROL OF RADIATION

Subpart 1—Biological Products and Human Organs

PURCHASE OF HUMAN ORGANS PROHIBITED

SEC. 352A. (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer for valuable consideration any human organ for use in human transplantation if the transfer affects interstate commerce.

(b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.

(c) For purposes of subsection (a):

(1) The term "interstate commerce" has the same meaning as in section 201(b) of the Federal Food, Drug, and Cosmetic Act.

(2) The term "human organ" means the human kidney, liver, heart, lung, bone marrow, and any other human organ or tissue included by the Secretary by regulation.

(3) The term "valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human organ.

PART K—ORGAN TRANSPLANTS

ESTABLISHMENT OF ORGAN PROCUREMENT AND TRANSPLANTATION
REGISTRY

SEC. 399A. (a) Under the authority of section 301, the Secretary shall assure the establishment and operation in the private sector of an Organ Procurement and Transplantation Registry which meets the requirements of subsection (b). To the extent necessary to carry out this section, the Secretary may make grants and enter into contracts in a total amount not in excess of \$2,000,000 in any fiscal year.

(b) The Organ Procurement and Transplantation Registry shall—

(1) promote the establishment, in one location or by coordinating regional centers, of—

(A) a national registry of individuals who need organs for transplantation;

(B) a national registry of individuals who, prior to their death, have voluntarily made commitments to donate organs for transplantation and be listed in the registry, which shall include provisions to—

(i) permit any such individual, prior to death, to rescind any commitment made by such individual to donate organs and be listed in the registry;

(ii) require a health care provider who cared for any such individual at the time of death of such individual to, prior to releasing any organ of such individual for donation, verify through the registry the commitment of such individual to donate such organs and

(iii) ensure in accordance with Federal and State laws and criteria established by health care providers governing the confidentiality of medical records, access to the registry for physicians and other health professionals; and

(C) a national system to match organs available for donation with individuals listed in the registry described in subparagraph (A);

(2) assure the operation of a twenty-four-hour telephone service to facilitate the matching of organs with individuals included in the registry described in paragraph (1)(A);

(3) establish and maintain standards of quality for the acquisition and transportation of donated organs;

(4) promote the coordination, as appropriate, of the transportation of donated organs to transplant centers;

(5) provide information to the public and to physicians and other health professionals regarding organ donation; and

(6) develop, prepare, and distribute, in conjunction with appropriate governmental and private entities, model uniform national organ donor cards in order to—

(A) assure participation in the national registry described in paragraph (1)(B); and

(B) assure the continuation of a system of organ donor cards under which individuals may agree to donate organs for transplantation without participation in such registry.

(c) For purposes of this section, the term "organ" means the human kidney, liver, heart, lung, bone marrow, and any other human organ or tissue included by the Secretary by regulation.

ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

SEC. 399B. (a)(1) Subject to paragraph (2), the Secretary may make grants for the planning, establishment, and initial operation of organ procurement organizations described in subsection (b).

(2)(A) No grant authorized under paragraph (1) shall be made by the Secretary until 30 days after the Task Force on Organ Procurement and Transplantation transmits the final report required under section 105(b) of the Organ Procurement and Transplantation Act.

(B) The Secretary may make grants authorized under paragraph (1) only if such grants are made in a manner that is not inconsistent with any recommendation of the Task Force on Organ Procurement and Transplantation contained in the report referred to in subparagraph (A) that addresses the issue of Federal assistance for organ procurement agencies.

(b)(1) An organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

(A) is a nonprofit entity;

(B) has the capability of becoming self-supporting;

(C) is not an organization which provides health care services or carries out other activities not related to the procurement of organs, except that it may be an organization which provides health care services or carries out other activities not related to

the procurement of organs if it was being reimbursed for organ procurement activities under title XVIII of the Social Security Act before the date of the enactment of this part;

(D) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization;

(E) has defined service area which—

(i) includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget); or

(ii) does not include any part of such an area and is of sufficient size which will include at least fifty potential organ donors each year; and

(F) has sufficient staff to effectively obtain organs from donors in its service area.

(2) An organ procurement organization shall—

(A) have agreements with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations;

(B) conduct systematic efforts, including professional education, to acquire organs from potential donors;

(C) arrange for the acquisition and preservation of donated organs;

(D) arrange for the appropriate tissue typing of donated organs;

(E) have a system to allocate donated organs among transplant centers according to established criteria;

(F) provide for the transportation of donated organs to transplant centers;

(G) have arrangements to coordinate its activities with transplant centers in its service area;

(H) participate in the Organ Procurement and Transplantation Registry established under section 399A;

(I) have arrangements with tissue banks for the preservation and storage of tissues as may be appropriate; and

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs.

(c) For grants under subsection (a) there are authorized to be appropriated \$5,000,000 for fiscal year 1985 and for each of the two succeeding fiscal years.

TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART I—GENERAL PROVISIONS

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ANNUAL REPORT ON ORGAN TRANSPLANTATION

Sec. 480. The Secretary shall publish an annual report on the scientific and clinical status of organ transplatation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.