NATIONAL ORGAN TRANSPLANT ACT

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

NINETY-EIGHTH CONGRESS

FIRST SESSION

ON

H.R. 4080

A BILL TO AMEND THE PUBLIC HEALTH SERVICE ACT TO AUTHORIZE FINANCIAL ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS, AND FOR OTHER PURPOSES

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NATIONAL ORGAN TRANSPLANT ACT

FRIDAY, JULY 29, 1983

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:45 a.m., in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will please come to order.

This morning the subcommittee will explore the transplantation of human organs. It is one of the most promising and rapidly evolving areas of medicine. It is fast revolutionizing both medical practice and human existence.

Organ transplantation is now a viable medical procedure. One of our first witnesses this morning is living proof of how transplantation saves lives.

Transplantation has been a matter of intense interest in scientific circles for many years. Public interest has mushroomed. Parental pleas for young Jamie Fish and Brandon Hall raised public consciousness, Presidential pleas have aided in generating an outpouring of public sympathy.

This morning we will hear from several people who will tell us about their agonizing wait for organs that could save the lives of their loved ones.

Although the major problem has been perceived to be a shortage of willing donors, this is, in fact, not the case. Each year there are some 20,000 potential donors, but less than 3,000 are actually available to help those waiting for transplant operations.

Just last year one transplant program was unable to make use of over 300 livers offered for transplant, despite a waiting list of patients. Those livers, in effect, were discarded.

This situation shows we have come to a point where our health care delivery system is incapable of effectively allocating and distributing available organs for transplantation. As this new field of medicine rapidly grows, it is doing so without adequate planning or financing.

There are victims of this uncontrolled, topsy-turvy growth. They are those who fall into the cracks, who must wait, often in vain, for the call that a donor has been found. This Nation's current system works at less than 15 percent of capacity. We must do better.

We know the overwhelming majority of Americans are willing to donate. Unfortunately, when tragedy strikes they are unaware of the opportunity which enables life to be given from death.

Several issues are of concern to me and must be addressed by this subcommittee.

One. Can we do a better job of assuring that available donors and recipients are efficiently matched?

Two. Is there a more effective means of locating potential donors than nationwide television pleas?

Three. How can the high cost of transplant technology best be financed? Heart and liver transplants are lifesaving therapies but present enormous costs to individuals and the health care delivery system.

We must find answers to these questions if we are to end what is becoming a national tragedy resulting from the lack of a system for procuring organs and matching them swiftly with waiting recipients.

We must also avoid the chaos and bitterness that inevitably will arise if transplants are available only to the very rich or to those fortunate enough to be singled out by the media for special attention.

The thousands of people who will need organ transplants this year cannot count on the media, or the Air Force, or the President. We face the awesome challenge of devising a delivery system for transplanting organs on a systematic, equitable, and routine basis.

Before we call upon our first witness, I would like to recognize the very distinguished member of the subcommittee, Congressman Tom Luken from the State of Ohio, who has urged us to hold this hearing, for which we are indeed grateful and appreciate his leadership.

Mr. LUKEN. Thank you, Mr. Chairman, Mr. Gore.

I congratulate the chairman on moving forward with this hearing on organ transplants. I am very pleased to be a participant in it.

I think there are two questions. Can we afford the cost in dollars of a national transplant policy? And the other question, Can we afford the cost in lives and suffering of not having a transplant policy as a Nation?

It is indeed unfortunate that it takes a tragedy, such as the death of a young husband, father, child, or other loved one to bring home to us the gaps and shortcomings in our national policy.

Today we will hear from families who have lost a loved one who might have been saved if an organ transplant had been available to them, families whose every hour is consumed with hope and anxiety, awaiting the possibility of an organ transplant.

In his radio talk last Saturday, President Reagan appealed for a liver donor for an 11-month-old, Ashley Bailey. We can all identify with the President's desire to help this suffering child. However, his action points to a marked discrepancy between his personal view and the more universal views of the Government he leads.

Our experts would tell us today that American people are generous and willing to donate organs. However, dealing on a case-by-case basis presents a question of fairness to all, all the others

whose problems do not happen to catch the attention of the President.

We live in an organized society. Therefore, we create institutions and establish policies to deal with human problems on a level that individuals cannot possibly manage individually.

To sum it up, Air Force I isn't a national policy.

Mr. Chairman, there are steps we can immediately take in the development of a comprehensive policy on transplants, as you have indicated so well. We can improve and standardize the operation and effectiveness of the over 100 organ procurement agencies which are operating in the United States.

Second, and most importantly, we can prod, or push, or encourage, or legislate actions that will expedite a national policy for transplants of livers and hearts, and to change these from an experimental classification to one that is more routine. This will make them available to the people who need them.

Medical science is advancing. We will hear testimony making the point these operations are becoming more feasible. And I think it is certainly time.

I congratulate the chairman—that this subcommittee, where the responsibility lies of making recommendations to the Congress, is taking action at this time.

Thank you, Mr. Chairman.

[The radio address of President Reagan and attachment follows:]

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release July 23, 1983

RADIO ADDRESS
BY THE PRESIDENT
TO THE NATION

The Oval Office

THE PRESIDENT: My fellow Americans, before I get to the heart of my remarks today, I want to mention some important legislation currently before the Congress. I'm sure you're all aware of the difficulties some countries are having in meeting payments on their debts. Their problem touches all of us in a very real way and, indeed, poses a threat to the stability of the world financial order. For that reason, something called the International Monetary Fund was created some years ago. It's better known as the IMF and that's how I'll refer to it.

Nations, including our own, contribute to IMF and countries with temporary balance-of-payment problems borrow from it on a short-term basis. In order to get a loan, they have to agree to terms the fund managers lay down with regard to correcting the practices and policies that contribute to their financial difficulties.

I've asked the Congress to approve an $8.5 billion contribution to the fund. Some in the Congress and a great many citizens think this is a giveaway which will increase our deficit. The IMF is not foreign aid and the $8.5 billion is not being given away. We will have additional drawing rights in that amount from the IMF. In fact, in its entire history, the two countries that have borrowed the greatest amounts from the fund have been the United Kingdom and the United States. The sum we're asking Congress to approve does not increase our budget and is returned with interest as loans are repaid.

In addition, it creates jobs because it keeps the wheels of world commerce turning. Exports account for one out of five manufacturing jobs in the United States. The IMF and its programs help keep Americans at work. This is important legislation for international economic stability and I hope you'll support it.

But today, I want to speak only of -- or not speak, I should say, of great national issues. Instead, I'm taking to the airwaves in hopes we can save one little eleven-month-old girl from Texas and many others like her. The young girl from Texas is Ashley Bailey. And all eleven pounds of her are in critical condition at the University of Minnesota Hospital in Minneapolis. She is now fed intravenously and has but two or three weeks to live unless she receives a liver transplant.

Back in May, Congressman Charlie Stenholm of Texas wrote me of the plight of this baby girl who must receive a transplant to survive. The surgery was estimated to cost $140,000. The Congressman said there'd been a tremendous outpouring of community and business support in the Abilene, Texas area and about $75,000 already had been raised.

A week or so after I received the letter, the Texas and federal Medicaid programs contributed $82,000 toward the operation and medical expenses were no longer a problem for little Ashley.

MORE

What she needed then, and needs now, is a donor. Time is running out. I'm issuing a plea to the nation to find Ashley a donor.

Once one is found, an Air Force jet is standing ready in case immediate commercial transportation is not available. Have a pencil ready -- I'll give you a phone number in just a few seconds.

Right now, somewhere in America, there might be a pair of stunned and grief-stricken parents whose own baby has died in an accident or is sadly near death. I know if these parents were aware their baby could make it possible for Ashley to live, they would have no hesitation in saying: "Save that little girl."

I urge any of you who know of a possible liver donor for Ashley to call The Living Bank in Houston. The number is 800-528-2971. I'll repeat the number: 800-528-2971. Please call.

There are many other children like Ashley. We're looking for donors for them as well. Right here in the White House we have an electrician, Stuart Thomas, whose daughter Candi -- another eleven-month-old girl -- is waiting for a transplant. The helicopter squadron at Andrews Air Force Base is alerted to transport Candi and her mother to Pittsburgh as soon as a suitable liver is found.

In the last few days we lost little Courtney Davis from Beaumont, Texas and Michelle Heckerd from Shenandoah Heights, Pennsylvania because we couldn't find livers to save their lives.

Nancy and I receive so many requests from families in need of organ donors, that I directed the Surgeon General to conduct a conference on organ transplants. The major recommendation was to develop a public awareness program on organ donorship. This is underway and I hope my broadcast today adds to the momentum. The project will stress education for doctors, state highway police, hospital officials, and others on the need to consider organ donorship when accidental death occurs.

America has faced shortage in the past of everything from nylons during World War II to oil in the 1970's. But modern medical science has provided us with a new shortage -- a shortage of living organs: livers, hearts, lungs, eyes, kidneys. I urge all Americans to fill out donor cards -- little cards you carry in your wallet or purse that, in the event of your death, offer the hope of life to others. You can obtain these cards by simply calling your local kidney, heart or lung associations.

Americans are giving people. In many of the cases where these very expensive operations are essential, local citizens have raised money to help the families in need. I've already mentioned the community support given to Ashley. Well, not far from Washington, Morningside, Maryland raised over $100,000 for the Goode family, whose little Nicky needs a transplant.

That kind of caring should make us all proud to be American. We can save more of our children and adults through organ donorship. Organ donors offer the greatest gift of all -- the gift of life. Right now Ashley Bailey, as well as other desperately ill children, are waiting for that gift. Please help us find donors for these children.

Until next week, thanks for listening, and God bless you.

END

THE WASHINGTON POST
July 28, 1983

Hardship Cases

PRESIDENT REAGAN has frequently used his high office to demonstrate concern for some person whose unfortunate circumstances have come to his attention. In his radio talk last Saturday, for example, he appealed for a liver donation for an 11-month-old girl whose life depends on a transplant operation. The appeal brought hundreds of calls—though not, as yet, a suitable donation—and it served the additional purpose of encouraging people to carry donor cards indicating that their organs can be used for transplants if they should die suddenly.

The desire to intervene in an individual hardship case—especially one as poignant as that of a small child facing death—is an impulse that most people can readily respond to and applaud. But the president's fondness for personal intervention points to a curious disconnection between his personal view of himself and his more general view of the responsibilities of the government he leads.

The point is that there are practical limits to the ability of any one person, even a president, to dispense enough favors to make a small dent in the mass of troubles afflicting the citizens of this country. And dealing on a case-by-case basis raises questions of fairness to all the other troubled people whose problems don't happen to catch the president's eye. Organized societies and the institutions they create are there precisely to deal with human troubles on a scale and on a basis that individuals cannot possibly manage on their own.

It would be nice to imagine that this assistance could depend solely on voluntary acts of generosity for their maintenance. But it has never been so in any large society. There are many skilled and caring people who have devoted their lives to charitable works and others who have found satisfaction in contributing to the support of such people. But the simple fact is that until government got involved in the business of social service, most of this nation's more unfortunate and afflicted people lived lives of misery—as such people still do throughout the world.

Removing the personal element from charity by having government or other large institutions take over tends, however, to reduce public support for these functions. Like the president, most people are ready enough to do a kind act when the situation forcefully presents itself. But no one takes personal satisfaction from paying his taxes. That's where presidential leadership could be *really* helpful—in reminding people that their taxes make possible not one or two, but literally millions of acts of day-to-day kindness of the most essential sort.

Mr. WAXMAN. Thank you very much.

Our first witness is a colleague of ours, and a good friend. Congressman Gore is chairman of the Subcommittee on Investigations and Oversight of the Committee on Science and Technology. In that capacity he has held a number of days of hearings on this subject and developed an expertise which we are pleased to have him share with us.

STATEMENT OF HON. ALBERT GORE, JR.

Mr. GORE. Thank you very much, Mr. Chairman.

I am pleased to join you today as the Health and Environment Subcommittee examines the status of organ transplant surgery and the problems that accompany the rapid medical progress that has occurred in this field.

As we meet here this morning, young Candy Thomas is fighting for her life, having just received a liver transplant. She and her mother, Penny Thomas, and Stuart Thomas, her father, have our thoughts and prayers this morning. Candy and her mother attended our hearings last April.

Also, as we meet here, many other Americans, including a constituent of mine, Mrs. Lorene White, whose husband will testify soon, are awaiting transplants that offer the only hope to save their lives.

Last April we had 3 days of hearings on this subject. We have been conducting an extensive investigation of these issues for several months. I will be submitting for your consideration a more extensive statement and would ask unanimous consent that it be included in the record, and that more extensive statement will outline in detail the conclusions and recommendations of our investigation.

This morning I would like to highlight for your subcommittee the major findings and proposed recommendations including an outline of comprehensive legislation which I will introduce shortly after Congress reconvenes from the August recess. And I appreciate the consultation that we have had, Mr. Chairman, between our staffs on the development of this legislation.

Mr. WAXMAN. Without objection, the record will be held open to include the further statements you wish to add to this testimony.

Mr. GORE. All of us have been touched by the sight of little children such as those who are here today who suffer from biliary atresia, a fatal liver disease. There is no more compelling plight than that of their parents who must mount nationwide media campaigns to plead for an organ donation or for funds to save the lives of their children.

As you and other members have been approached by families in your districts, I have been approached by families from Tennessee to help locate organs to be transplanted. In fact, it was just such instances involving the cases of Brandon Hall and Carlisle Beall that first led me to question the ability of the present system to provide for those chilren and others.

Although we are all immensely grateful that pleas such as that made by the President last Saturday, or as I myself have made and others have made on a number of occasions, have helped these fam-

ilies, surely there must be a better way to provide transplants for those in need.

In other words, the time has come to move from an ad hoc case-by-case publicity campaign to a nationwide system for solving this problem as well as it can be solved for all those who need transplants.

The problems faced by people seeking transplants are numerous. However, during our hearings three general problems stood out:

No. 1, there is a shortage of available transplantable organs. Of the 20,000 Americans who suffered brain death in hospitals each year, and could be potential organ donors, only 2,500 are actual donors. Procedures used by most States such as driver's license checkoffs, and those used by hospitals and independent organ procurement networks, are valiant efforts and have resulted in some strides being made. But as the statistics show irrefutably, the job of obtaining enough organs for transplant patients is just not being done.

For example, the current gap between supply and demand for transplantable kidneys alone is in excess of 5,000. Recent advances in transplant surgery and particularly the discovery of cyclosporine, a new drug which inhibits the body's natural tendency to reject transplanted organs, have dramatically improved surgery survival rates. Liver transplant survival rates have doubled. Heart transplants are now considered almost routine with an 80-percent chance of success. Heart/lung transplants, pancreas, and small intestine transplants, almost in the realm of science fiction a short time ago, can now be offered seriously as therapeutic alternatives for selected patients.

Additional scientific success will continue to increase survival rates and thereby further widen the organ gap unless strong efforts are undertaken. We need a nationwide strategy that will stimulate donor awareness of the need for transplantable organs. The single most identified reason for the shortage of organs for transplantation is the lack of awareness of the need for organs on the part of potential donors, and on the part of health care and emergency professionals.

Efforts to stimulate donor awareness must involve both the private and public sectors.

Second is the need for coordination of organ procurement and distribution systems. The present process of organ acquisition is fragmented. This has occurred despite the outstanding and heroic efforts of many individuals and organizations. Even though there has been widespread Federal funding, a national strategy has not emerged. A central guiding mechanism is essential to the development of a cohesive and rational strategy to provide an effective national system of organ acquisition and distribution.

It has been suggested that this can be accomplished by a coalition of interested voluntary health organizations and the professional medical and surgical societies.

I do not wish to discount the value of these efforts, and I believe that these groups have a key role to play. However, the current gap between supply and demand is likely to grow rapidly with the advances in transplant surgery. This gap and the inevitable inequi-

ties it fosters in organ availability for transplant recipients demand forceful direction and action.

I believe only the Federal Government can best provide the glue and the conscience from which a national system can be formed.

Last, there is a need to insure equitable and timely access to lifesaving and medically effective technologies. For most families this means correcting the uneven reimbursement policies that deny coverage for these procedures because they are labeled experimental by the Federal Government for the purpose of medicare reimbursement.

Ironically, only a tiny minority of potential recipients are actually seeking coverage under medicare, since medicare is a program primarily designed to assist the elderly. However, the medicare pronouncement has directly inhibited coverage of these procedures by other federally supported programs, such as CHAMPUS, by many Blue Cross-Blue Shield plans, and by many private insurers.

The refusal of CHAMPUS to pay for liver transplants was particularly disappointing as it left several families in the armed services without the means to save the lives of their children.

Fortunately, an amendment that I sponsored was passed on the floor of the Congress earlier this week which will correct this problem by providing CHAMPUS with explicit authority to cover liver transplants.

However, we cannot continue to resolve these problems in an ad hoc basis. The experimental label now assigned to liver and heart transplants is a reflection of an outdated system that only sees two categories, black and white, viable and experimental.

Emerging technologies exist on a continuum, with experimental on one end and widely accepted medical practice on the other.

There must be a system of evaluation by which newly developed procedures and technologies can rationally progress in stepwise fashion from experimental to routine practice.

Clearly, a nationwide strategy is necessary if we are to overcome these problems. The bill I will shortly introduce provides just such a strategy, and is crafted to achieve three primary goals:

No. 1, to increase voluntary donations of organs;

No. 2, to improve coordination of organ procurement and distribution; and

No. 3, to insure equitable and timely access to lifesaving and medically effective technologies of which liver transplants offer only one example.

The main features of the bill are as follows:

No. 1, formation of a National Center for Human Organ Acquisition. This Center will be responsible for developing and implementing a national program for acquisition and distribution of organs. The proposed Center would be located within the Department of Health and Human Services as an agency of the Public Health Service.

This program would enhance the existing system of organ procurement. Frontline organizations would serve specific geographic areas with a population base sufficient to generate approximately 100 organs per year. These organizations would operate under uniform guidelines developed by the national center and would be linked to regional coordinating networks. A national clearinghouse,

to be established by the center, would provide a uniform registry of potential recipients for various transplant procedures.

Using computer and communications technology now available, such a central clearinghouse could be expected to provide ongoing communication with procurement agencies and transplant centers. They would also provide for equitable distribution of available organs based on medically determined urgency of need, size, blood and tissue typing, proximity to a transplant center, and other characteristics.

No. 2, development of a program to promote organ donation. It seems most appropriate for voluntary organ donation to be promoted by voluntary health organizations and professional oganizations already active in this area. The proper role of the Government in this case would be that of a facilitator.

Therefore, the bill will provide for the development of a national federation of interested groups under the auspices of the proposed National Center for Human Organ Acquisition. This federation would also be an appropriate entity to work with States and municipalities to effect standard procedures in areas such as identification of potential donor status and adoption of uniform brain death standards.

No. 3, provide for the development of an aggressive acquisition program. The National Center for Human Organ Acquisition would report annually on the status of voluntary organ donation. If the center judges efforts to improve voluntary donation are unsuccessful, consideration in progressing fashion would be given to the following:

First, provision of incentives, such as a voucher sytem or tax credit for a donor's estate;

Second, a system of mandated choice such as requiring selection of donor status, yes or no, at time of driver's license issuance. In other words, it would remain completely and totally voluntary, but the choice would have to be made yes or no.

Third, adoption of a system of presumed consent unless objection is registered in advance.

No. 4, reestablishment of the National Center of Health Care Technology. A vigorous and broadly based health care technology process must be put in place as soon as possible. This should include the Federal and the private sector and would be separated from reimbursement decisions.

We must have a better capacity to evaluate the progress of this new technology.

No. 5, restriction of organ transplantation to designated regional centers. The requirements for conducting organ transplantation programs are formidable. To promote maximum use of scarce resources and insure the highest quality of care, the bill restricts organ transplantation to designated regional centers. These facilities will be chosen based on geography, peer review of experience, commitment of institutional resources, and linkage with organ retrieval programs.

Efforts should be made to encourage concentration of reasonable transplant services into these centers. Creation of regional centers permits a logical transfer of transplant procedures from the category of experimental into a mechanism that permits the controlled

diffusion of new technologies in a manner that should make reimbursement more workable.

Mr. Chairman, during the past several months we have witnessed the recurring spectacle of families forced to mount these nationwide media campaigns in order to save the lives of their children or family members. It does not require a great deal of insight to discern that there is something wrong when families are compelled to endure this additional burden at a time of such unprecedented stress.

I am pleased to have the opportunity to share the work of my subcommittee with yours, and look forward to working closely with this committee as we endeavor to establish a truly rational, responsive and effective national system to redress this wrong.

Thank you.

Mr. WAXMAN. Thank you very much, Mr. Gore, for your testimony.

We appreciate the work that you have done in your subcommittee in looking into this problem. We will want to join you in supporting legislation at the Federal level to make sure that we do the job that must be done to match those donors who want to give a gift of life to those recipients who are so desperately in need of an organ for transplantation purposes.

I am very disturbed by some of the figures I have seen.

The statistics show about 20,000 potential donors each year, but only 3,000 actually make a donation. Why is it that out of 20,000 potential, we end up with only 3,000? About 25 percent of the kidneys donated are wasted even after we find so much of the potential is not realized.

Mr. GORE. That is a key question. Our figures are actually even lower. Out of 20,000 brain deaths each year, only 2,500 of them result in organ donation. These decisions must be made by families and if every family in America aware of this problem sat down together and had a conversation that went along roughly the following lines:

> Look, we want to have a policy as a family; we hope a tragedy never occurs. If, in the unlikely event a tragedy should strike our family, we want to have a family policy that if other lives can be saved as a result of that tragedy, we don't want to hesitate; we don't want to compound the tragedy by burying the organs that could sustain life for one, two or many others.

That decision and that family conversation has not taken place yet across this country. It is beginning to take place. Attitudes are beginning to change.

But that conversation has to take place.

Mr. WAXMAN. We need people to become aware that if an unforeseen tragedy strikes them or members of their family, they may contribute their organs to someone whose life would be saved by virtue of that donation.

Mr. GORE. That is precisely it. There has to be a change in one other place also.

Doctors and critical care nurses and other hospital personnel face a very difficult human problem. When a patient dies under the circumstances so frequently associated with brain death, it is an extremely emotional experience, and the role of the doctor and health care professional is to, in part, comfort the family of the

person who has died, and be with them, and to shift gears psychologically and inform them that an opportunity to save lives has been created out of this terrible tragedy.

It is very difficult for them to shift gears. They haven't traditionally done it. It is a new mandate arising out of the new technology. Doctors and health care professionals have to become more aware of the mandate so that they accomplish that difficult shifting of gears and speak with the family in very sensitive terms about what can be done to avoid compounding the tragedy that has happened.

Mr. WAXMAN. On the one hand, many people who could be potential donors don't ever see themselves in that kind of situation, so they haven't thought through in advance the donation they may make or members of their family may make, and the health care professionals are not attuned to giving them the guidance to make that donation.

But the problem can be seen from another perspective; the statistic that—in one program—300 livers were offered, but then were discarded because they were not made available to the people who needed those livers. It is a very disturbing statistic to me.

How do you explain that?

Mr. GORE. Well, the first part of the problem is awareness of the need for organ donation. That dwarfs the rest of the problem.

The second part of the problem, which absolutely has to be attacked aggressively, is better coordination of the organ acquisition, procurement, and distribution system.

We now have 110 separate organ procurement networks across the country. We have three different national hotlines. We heard about two at our hearing in April, and the President gave out yet a third in his radio address last Saturday.

All of the people in those 110 networks and the people manning those hotlines and the others that are operating, really make heroic efforts on a daily basis, and they have also made some very helpful efforts to coordinate on their own these different systems, and there is a working relationship between all of them now.

It is just not quite good enough because the instances you cite still occur. They occur even now, and we need to have better coordination.

For example, there is one major liver transplant center, Pittsburgh. It is not humanly possible for people to use all of the organs there. So distribution is a difficult problem, and the same donor may make it possible for several other people to live by donating several organs.

And the coordinating of that process with the blood and tissue typing, the ranking of the priority on the list, and the geographic proximity, as well as other considerations, are very difficult for these heroic and terrific people who are working these systems solely on their own. They need some help.

Mr. WAXMAN. Assuming we can do a better job, and I think you are right, the Federal Government must take a leadership role to coordinate what is an increasingly valuable medical procedure that can save lives that would otherwise be lost.

Thank you very much.

Mr. Luken.

Mr. LUKEN. Mr. Gore, you are to be congratulated for the leadership that you have shown in developing these matters.

One additional area I would like to get into with you, because you are obviously an expert on this subject, is the development of the national policy to make these procedures affordable.

This question is very important in the individual cases, and this question is a very serious one because—and I would ask you about this—do you find that the traditional providers, the doctors groups, sometimes, the hospital administrations, are reluctant to push ahead to make a national policy that operations, the transplants would be feasible, affordable, and paid for by the insurance companies, medicare, and so on?

Mr. GORE. Well, there has been some reluctance primarily because the advances in this lifesaving procedure have occurred much more swiftly than is usually the case.

We had a watershed event where transplants are concerned, and that was the development of a more effective, new immuno-suppressive drug, cyclosporine.

You remember in the early days of transplants, one of the major concerns was, will rejection take place? When Christian Barnard did his first transplants, that is what all of the concern was all about, and it continued that way until quite recently.

This new drug almost makes rejection a thing of the past. They regulate the levels of the drug that are needed and monitor the rejection process. What I am saying is, this advance occurred swiftly, all at once, and it took these health care providers by surprise. They didn't shift gears as quickly as they should have. It is a problem not unique to liver transplants. It is just most starkly seen here.

The Congress actually addressed this problem a few years ago and set up a national center to evaluate the progress of new technology to help us shift gears more quickly.

This was, unfortunately, abolished a couple of years ago—or 1½ years ago, and it should be reestablished, and that is one of the steps that I am asking be taken in my legislation.

Mr. LUKEN. Well, as far as those families that are faced with the need of the heart and liver transplants, if they are under medicaid coverage, the decisions are made by the States, as I understand it.

If they are covered under medicare or under private insurance, they are still faced with the fact that they will not be covered, generally speaking, except in very few cases—the insurance doesn't cover it, therefore they cannot afford the operation.

That is what we have to look at as national legislators, it seems to me. How do we push along, how do we produce, how do we facilitate?—obviously the steps you have suggested will provide a momentum toward developing a policy. But aren't we at a stage now where we could urge HCFA, where we could urge the appropriate agencies under medicare, change the classification of heart and liver transplants from experimental to routine, so that they can be paid for.

Mr. GORE. Well, as I tried to say in my statement, it really is a continuum. We need a system that will help us see these procedures in more than two categories. They are not just experimental

on the one hand or routine on the other. They progress as they go along.

Liver transplants, for example, are clearly no longer experimental, nor are they——

Mr. LUKEN. Medicare considers them experimental.

Mr. GORE. I am getting to that. Your question is on target, but this is an important point.

They are not yet routine, but we need an ability to say, look, they have progressed far enough; they can save enough lives at this point that we ought to pay for them in selected centers that have demonstrated their ability to kick up the survival rate into really a good level and for patients that are on the priority list.

Now, let me tell you how the funding problem breaks down now.

Some private insurance companies are actually ahead of the Federal Government in funding these procedures. Medicare, however, will not fund it.

Medicaid programs, as you say, are controlled by States in this respect. More than a quarter of the medicaid programs are now funding these procedures. CHAMPUS refused to fund the procedure, but we just passed an amendment that I referred to in my statement which overturns the CHAMPUS decision and requires them to go ahead and fund it.

The private insurers that are currently not funding liver transplants and heart transplants are in many cases taking their cue from the Federal Government decision.

If the Federal Government decision can be changed, then that will open the door.

Let me make one other point.

The biggest irony in this whole issue is that the studies indicate that the cost of terminal care for the long period of time these children and other patients, survive up until the point of their death—the cost of that terminal care—exceeds the cost of the transplant which would save their lives and avoid the cost of the terminal care.

Mr. LUKEN. Does your legislation that you propose provide for medicare changing its policy, which is an impediment to granting these procedures?

Mr. GORE. It avoids——

Mr. LUKEN. I realize the total effect of what you are doing is moving in that direction, and that may be the only way we can go at the present time.

Mr. GORE. In spite of the facts that are so clear in this case, as a general policy I think decisions on the assessment of health care technology should be made by professionals. It is clear to me that in this instance the technology has progressed to a sufficient degree that it should be funded without any question whatsoever, but we need to address—just as we don't need to continue addressing liver cases on an ad hoc basis, neither can we address technology assessment questions on an ad hoc basis.

We have to address the generic problem, and solve that generic problem and at the same time solve this problem, and it can be done quickly.

Mr. LUKEN. It seems to me that the most important question for us—as you say, the scientists, the experts in the field, are those

best qualified to make the individual decisions, but it seems to me that there is eventually a collective judgment that has to be made by an agency or through legislation to deal with the basic problem which you have outlined in your testimony, which is "The medicare pronouncement has directly inhibited coverage of these procedures" by the private insurance companies, which is where the important decisions lie, with the private insurance companies, as the families who will testify here today will indicate to us.

It seems to me that we have to grapple with facilitating that decision by HCFA, by the agencies involved, whether it is direct legislative injunction or direction or not, it seems to me that is the most important decision we have to make.

Mr. GORE. I agree with that, and that is why I offered the amendment that I offered a few days ago, to forcibly change by legislation a decision on the part of CHAMPUS. If they will not speed up their decisions on technology assessment, we must wrest that decision from them and make it for them.

I am convinced, however, that we can at the same time improve the way they make those decisions, so that instances like this don't recur.

You know, a pancreatic transplant, for example—in a few years, as the technology progresses further, that may present very similar problems. We don't need to be making that decision on an ad hoc basis. We need to put into place now a decision that insures the Government addresses it rationally and quickly.

Mr. LUKEN. Well, Mr. Chairman, Mr. Gore, I think that your efforts are moving this process along. I hope that our efforts today will produce and facilitate that collective judgment that the Congress can use its influence, either through legislation or through the efforts you are making in defining of the procedures that we are working on, to get liver and heart transplants made, in effect, routine.

Mr. GORE. Well, my subcommittee and this subcommittee have worked together very effectively and productively in the past to put into law a number of changes which we believe have been helpful, and this is going to be another one.

Mr. LUKEN. Thank you.

Mr. WAXMAN. Thank you, Mr. Luken.

Mr. Gore, we appreciate your testimony very much. We have worked well together in the past. I think this is an issue that calls upon us both to join with all of our colleagues in the Congress in deciding that we have to do a better job than what we see around the country.

Thank you for being with us.

While we are meeting here today, there is a session taking place on the House Floor. There is a vote for which we have to recess the meeting to respond to. We are going to recess for 10 minutes while we vote, and then come back.

[Brief recess.]

Mr. WAXMAN. The meeting of the subcommittee will come to order.

Our next panel includes a number of individuals who will share with us their personal experiences with the organ transplant system in this country.

Mrs. Deborah Montgomery comes from Cincinnati, Ohio. Mr. and Mrs. James Richardson live in Charlotte, N.C. Mrs. Marian Turpin is from Baltimore, Md. Mr. Raymond White, from Brentwood, Tenn. And Mrs. Hope Walden from Cedar Grove, N.J.

Mr. WAXMAN. We want to welcome you to this hearing. I know it is sometimes difficult, certainly unusual, to be talking to a congressional committee, but I want you to relax.

What we want to know from you is, what experiences you have had. Just tell us your story. We want to know. We want to be helpful.

Why don't we start with Mr. and Mrs. Richardson.

STATEMENTS OF MR. AND MRS. JAMES RICHARDSON, CHARLOTTE, N.C.; DEBORAH MONTGOMERY, CINCINNATI, OHIO; RAYMOND D. WHITE, BRENTWOOD, TENN.; HOPE WALDEN ON BEHALF OF THE AMERICAN LIVER FOUNDATION; AND MARIAN TURPIN, BALTIMORE, MD.

Mrs. RICHARDSON. Mr. Chairman, ladies and gentlemen, my name is Ernestine Richardson. I come to you from Charlotte, N.C. I have a daughter 2 years old by the name of Chicika Richardson with biliary atresia, a very chronic liver disease that will kill her unless we find a donor for her liver transplant.

Chicika was hospitalized at 4 months old. It was then Dr. Morton performed a kasai, hoping that that would correct the blockage of the bowel ducts. However, it wasn't a complete success. So Dr. Morton then came to us and told us eventually we would lose Chicika. There was something on the inside of us that kept telling us that it had to be another way. We just could not accept the fact that God would just let us lose her like that.

It was when Chicika was in intensive care that I read in a medical journal about Dr. Starzell and liver transplants. At that particular time he was in Colorado.

I consulted Dr. Moore about it and I told him that I wanted Chicika to have a liver transplant. He then told me that it was experimental and he would look into it for me.

Dr. Starzell then moved to Pittsburgh, which made it possible for us to take our daughter there. She went on the computer there October 23. We have been constantly waiting ever since.

Since then it has been stress, pressure, strain. Words just cannot describe what we have gone through with Chicika. We love her so much and she is our only child. We just cannot accept the fact that unless we find a donor we will lose her.

We consulted the White House. We didn't have any other place to turn. We tried every agency, everybody was turning us down left and right. There was no place to go. So, a White House aide returned the call back to me and he directed me to the crippled children program, which they will pay some of her liver transplant but not all of it.

The amount has not yet been determined, but, as parents, how can you sit back and see your child sick, not knowing when her liver just may fail completely, and, as a parent, you are willing to do anything in the world for her, and yet there is nothing because it is like your hands are tied and nothing at all that you can do.

I feel like, and I pray to God that some way, somehow that we can come up with some solution to get parents to donate these parts. I know it is a very tragic moment for parents. I can understand, because I am a parent myself, but your body is so precious. It is like a store with very expensive parts, and if you could only say I have lost my child, my wife, my husband, or whoever, but I would like to benefit another—please think of our daughter and the little ones that are waiting.

It is no point for a child, or no one to have to suffer. But, please, think of donating these parts. It is very precious to not only my child, but others.

Mr. WAXMAN. Thank you very much.

Mr. Richardson, anything you wanted to add?

Mr. RICHARDSON. Well, she mostly covered what we have been going through for the past 1½ years. It really has been disgusting to a certain point, to where we haven't been able to get a donor. Chicika has been on the computer for 10 months now awaiting the transplant. During the 10 months we have been through some things that only if it were your child you could understand how we feel.

I have been through it so much—I don't know—I get stopped up when I start to speak or even try to think or talk about this.

I think I will just leave it at that.

Mr. WAXMAN. Thank you very much.

Mrs. Montgomery.

STATEMENT OF DEBORAH MONTGOMERY

Mrs. MONTGOMERY. Mr. Chairman, I want to thank you for inviting me here today to testify before this committee.

My name is Debbie Montgomery; my husband's name was Joseph Montgomery. He was a 35-year-old man with 3 children. They are 16, 14, and 6. My husband died May 3 of this year. He died of a heart disease known as cardiomyopathy. We learned of his disease in January of this year. The doctors told us that he would only have 3 to 6 months to live.

Cardiomyopathy is a heart disease that progressively deteriorates the muscles of the heart. This causes the heart to become so enlarged that the muscles cannot keep the heart pumping, which will eventually cause the heart to stop.

The only operation known that could have been done to save my husband's life was a heart transplant. This he was denied because we did not have $60,000 in advance. My husband was forced to go on social security disability and, as you know, you do not receive any medical benefits for 2 years after you are on disability.

I went to my insurance company in January. They, knowing the importance of this operation, did not give us an answer until the end of March.

Blue Cross told us that heart transplants are still on the experimental list and they would not be able to pay for such an operation.

What bothers me most is how can a procedure that has been done in this country alone for 15 years still be considered experimental?

We were told by our physician that this is how long the operation has been done at Stanford University.

After the insurance company refused to pay for the heart transplant, we tried other agencies to see if they could help.

The Heart Association told us the money they have is for research. I do not understand, or fail to see the difference.

United Appeal told us they had no assistance for heart transplants.

We were going into the third month while finding out all of this. During this time my husband was getting worse. Between the time that we first found out how sick my husband was in January until the day he died in May, he had been in the hospital four times, staying anywhere from 4 days to 2 weeks.

My husband was in a great deal of pain during this time. He had a lot of shortness of breath and had to be put on oxygen most of his stays in the hospital. He took on the average of 13 to 15 pills a day. Most of these helped pump the heart; some were for the pain he was having, and others helped rid the body of fluids that would build up around the heart area.

If my husband would have been able to have the heart transplant, there was a 70-percent chance that he would be alive today sitting here instead of me, a 50-percent chance of living another 5 years or most probably longer.

How do we put a price on a human life?

The one thing that bothers me and a lot of other people is, if the procedure, the heart transplant or any other type of transplant, is a good one to do, why not do more of these operations?

If it is not, why are we bothering to do them at all and building up hope in patients that are sitting around waiting for someone to call them in hopes of a new life?

I sat with my husband many times and saw him go through some very rough times. There would be times that he was so sick that he wouldn't even be able to get out of bed. He kept hoping that something would happen to help him have a new life. During the times that my husband was very sick, he would be totally drained of any energy that he had built up.

The night of my husband's death, knowing the shortage of organs, we donated my husband's eyes so someone would be helped. This was the only organ of my husband's that the doctors were able to use.

The day before my husband died, he told me that if anything went wrong in the future to donate any part of his body the doctors would be able to use.

A heart transplant is one of the operations which is literally a life-saving operation which, without it, a person will die like my husband. There is no other way to keep them alive.

People should be made aware of the importance of donating organs. You never know if this or something similar could happen to your famliy. I hope it never does. I know I was shocked when the doctors told me that my husband needed to have a new heart. You don't realize how fast it can happen. There is really no set number of people that are known that need a transplant because most of the time you are not even put on the waiting list unless you have the money for the operation.

Although there are cards on the back of everyone's driver's license to donate any part of your body you want, most people don't even realize what these are for.

I know for a fact when I got my driver's license, they did not ask me or most people that I know: Do you want to donate your organs if something would happen? The people who work at the Driver's License Bureau should be either explaining to the people or something should be done. That is the only way I know that could help donate organs that might be helpful. It could save someone's life.

Mr. WAXMAN. Thank you very much, Mrs. Montgomery.

Mr. White.

STATEMENT OF RAYMOND D. WHITE

Mr. WHITE. Thank you, Mr. Chairman.

I am Raymond White of Nashville, Tenn., and Menlo Park, Calif. We have two addresses because my wife, Lorene (Renie) White, is waiting in Menlo Park near Stanford Medical Center, to be available when an appropriate organ donor is found so she can have a heart/lung transplant that represents her only hope to live for more than a few months.

My wife has a condition that destroys both the heart and lungs. She has had this problem over 20 years. We have always known there was no cure for it, and that someday it would end her life.

In June 1981 what had been a chronic problem for so long became an acute one, and death that had been a distant prospect became a near term certainty and an immediate possibility.

Since that time, she has been in the hospital for 5 months, very near to death at times, has been and is on numerous medications.

She requires oxygen 24 hours a day. She has been bedridden much of the time and housebound, barely able to walk around, almost all of that time. She is constantly exhausted, both physically and mentally, and is unable to take care of herself, so she requires constant attendance.

When this final stage of Renie's illness began, we were unaware that a successful heart/lung transplant had ever been accomplished. Although we frequently had been told if only that could be done, that is what could save her.

Since we didn't know there had been a successful transplant, we just settled down to wait for her to die. That was all we could do. We wanted to make her last days as comfortable and useful and filled with love as we could.

In October 1981, shortly after she entered the hospital for her second and longest stay, and at a time when it appeared that death might come any hour, we were told that Stanford had done heart/lung transplants, and it was suggested that we apply. Even though it was an astonishing concept in the abstract, and is incredible to consider for yourself, Renie immediately decided, let's try it, and the whole family said, let's do it. We had no other option.

For the first time, we actually had hope. It was really a reprieve from death at the 11th hour. Twenty-one months later, we still have hope, but that is all, because after 18 months of searching, it has not been possible to find a suitable donor, and she is still in

limbo between life and death, with death as an everyday possibility.

During this long siege, I have learned at firsthand about a great many of the problems associated with organ transplantation. The science and technology of organ transplantation has made enormous advances in recent years, and tremendously effective life-enhancing and life-extending therapy is possible.

Unfortunately, the system for delivering this therapy has not kept pace, and the result is that the delivery of the benefits of transplantation is just marginally effective.

There are two choke points in the delivery system, as I see it. One is financing the operation and the other is in finding donor organs and matching them to the recipients.

I estimate that if my wife were to have her transplant today and proceeded to a normal recovery, the total cost of her illness would be about $375,000.

Amazingly enough, this is not a problem for us. The transplant itself is paid for under Federal grant because Stanford has a grant to do this surgery in an experimental way. We have two good health insurance policies that are paying everything medical up to the transplant. We can take care of the living and transportation expenses, which I estimate will be $50,000 by the time this is finished.

But if any one of these three parts of the equation were missing, she would be denied the therapy, just as you have heard, and most people are not in the fortunate position that we are in. Everything clicked right for us financially.

But it has not clicked right in getting a donor. That is the other choke point.

I do believe that the problem of financing these operations must be addressed and that some kind of a national health insurance program or at the very least changing the government's pronouncement, so that private insurance can be available, is necessary.

I do think it is not a program whose cost potential is unlimited because the limit is always going to be the number of donors. There is a fixed top on that. We are never going to get above it, and this problem, this donor part, is going to be the death of my wife unless something happens soon.

The fact that she, as of yesterday, has been in California waiting 18 months for a donor, and that nowhere in this whole country has it been possible in 18 months to find a donor for her clearly indicates the system for obtaining donors is just marginally effective.

There are so many other evidences of this deficiency that I could not name them all, but let me tell you a few.

One-third of all those at Stanford who come for heart transplants that are accepted die before a donor can be found.

The death of infants awaiting liver transplants happens regularly. We just don't hear about it, but they are happening all the time.

People needing kidney transplants who can live to wait frequently wait for years to find a donor, even though in a given year there are enough unused donors to transplant every one of them.

And people like myself, like the other folks here who realize that the system is not going to produce unless they are just lucky, are

driven to doing anything they can, making public appeals, writing letters, calling people on the phone, anything to try to make it happen.

People should not have to die unnecessarily like this, and they shouldn't have to wait years, and they shouldn't be pushed into a corner of knowing that they have to try to do it themselves.

I think that my wife has now waited longer than anyone else ever has for a major organ, one without which she will die.

We waited about 6 months before we started to try to do things to help get a donor. I have a list that is attached which I will give to you of things we have done. But we have made literally thousands of contacts with individual doctors, with hospital administrators, and had many public notices on TV and in newspapers. All of it, 547 days of trying, has produced no donor, not one.

There are some things that I think are susceptible to legislative solution, and I would like to just mention a few things, and I will be finished.

One is, I think regularizing brain death law throughout the country is a valuable thing. I think coroners and medical examiners should be required to release brain dead persons with family consent for service as organ donors. I think that all hospitals that are large enough to have the potential for donors should be required to have an organ donor program, an active one. If they receive medicare or medicaid funds, that is one handle to use, if it is not done voluntarily, which it may be, and certainly is in many cases.

I think that research into transplantation and immune therapy should be funded at a useful level.

And finally, I do believe that funding to produce a viable truly nationwide organ donor program is valuable. We have lots of little wheels all around the country—people have done a wonderful job of inventing the wheel individually everywhere. But the trouble is the gears don't all mesh. They don't move as one, and they need to.

Thank you.

Mr. WAXMAN. Thank you very much, Mr. White.

Mrs. Walden.

STATEMENT OF HOPE WALDEN

Mrs. WALDEN. Ladies and gentlemen, look at me. I have just discoverd a joy in my life that you have known all along. It's the joy of waking up in the morning full of energy and the joy of seeing a rosy-cheeked woman in my mirror.

That's the same mirror that once had a pain-ridden woman staring back at me. She was jaundiced with yellow eyes and never had relief from overwhelming fatigue, and was tormented by unrelenting itching. That woman was me.

I was a victim of primary biliary cirrhosis, a rare and fatal liver disease. It is an insidious disease that robs you of your life, little by little. You know you are dying. You can feel the changes in your body. You lose a piece of your life every day.

I suffered from PBC most of my adult life, but was not diagnosed until 1978. I was given medication, but it didn't cure the illness or even relieve the symptoms. Its side effects made me feel worse.

In addition to my physical problems, there was also the social stigma to cope with. Most people associate liver problems with alcoholics. You and I know that liver disease can strike anyone, even children. But until people learn more about liver diseases, people who are suffering from them will continue to be suspect.

There is even a more serious problem that results from a lack of awareness. I was suffering from a fatal liver disease and I didn't know that liver transplants were being performed. I found out by accident. Imagine how many others would not have to die or how many more donors there would be if people were aware that liver transplants were possible?

By the time I went to Pittsburgh to be evaluated for a transplant in January 1982, I had developed osteoporosis. My vertebrae were collapsing and the pain was like nothing I had ever experienced. I had begun to have blackouts and in April, I was hospitalized. I couldn't walk. I waited 10 interminable days before the decision was made to accept me into the transplant program.

The waiting continued—the next 4 months were agonizing. I knew I was dying and there was still no donor for me. Finally, on May 5, the call came. I had only 6 hours to get to Pittsburgh, but I made it. My transplant was done, but 3 months later, I needed another transplant and that was the turning point for me after years of suffering. Four months later, I was released from the hospital and 5 weeks after that, I returned to work.

No one recognized me at the office and I felt like I had just come out of a time machine.

I was 4 inches shorter. My osteoporosis had turned me into the incredible shrinking woman. My newfound energy more than makes up for my loss of height. As a manager of a major airline, I have a stressful job but handle it with ease.

I'd like to mention one other major problem liver transplant patients must endure. That is the financial burden. I was lucky my insurance coverage paid for my operation. Most others are not so fortunate. It's heartbreaking to see families watch their loved ones suffer while they must struggle to raise the funds needed to pay for this lifesaving surgery.

I wouldn't be here today if I had not been given a new lease on life through liver transplantation. This was the only treatment available for my condition. I am a shining example of one of the many success stories. I implore you, please give others who have no hope for survival a chance to live. You hold their lives in the palm of your hand. Time is running out for many. They need your help.

Mr. WAXMAN. Thank you very much for your testimony.

Mrs. Turpin.

STATEMENT OF MARIAN TURPIN

Mrs. TURPIN. I am Marian Turpin. I am here with my husband and family from Baltimore, Md.

I would like to introduce my son, John Turpin. He has a liver disease called biliary atresia. John is 23 months old; in another few days he will be 2 years old.

Biliary atresia is a disease where John was born without bowel ducts. He had surgery performed when he was about 3 months old to try to correct this.

However, after the surgery and a few months later it was determined that the surgery was unsuccesful at that time; my husband and I were told that the only alternative to save his life would be a liver transplant.

John has developed cirrhosis and inflammation of the liver, which is associated with this type of disease.

At that time, we were referred to the Children's Hospital in Pittsburgh to determine whether he was a candidate for a liver transplant. It has been determined and established and at this point we are on a waiting list for children awaiting liver transplants.

That took place in September 1982. And it has almost been 1 year since we have been waiting for a liver donor.

That year of waiting has been a very depressing, frustrating, and agonizing period of our lives. I think my husband and I, with the support of our friends and family, have done everything possible that we can do to help in making people aware, and doing what we can as a family to find a donor for our son. We have established a trust fund in his name where donations have come in from different organizations and from community groups to help raise funds which will cover the cost for the medical and surgical procedure. And we were told that that procedure would cost us anywhere from $60,000 to $150,000. And having to go through a period where you know that your child may not have a long life to live, it is enough pain for us to have suffered without having to go through trying to raise money to help with the surgical costs.

We also understand that usually children with this type of disease are not expected to live beyond their third birthday. As I said before, my son will be 2 years old in a few more days. And we feel that our time is running short, and we took this opportunity to come before you now and to ask people to help us in any way possible to try to locate a donor for him, because our worst fear is waiting until the last minute, and living with the thought that the possibility may come where he may die because we did not extend our efforts as far as we could to help him.

Thank you.

Mr. WAXMAN. Thank you, Mrs. Turpin.

Mr. Turpin.

Mr. TURPIN. It is silly, in my opinion, for a government of this magnitude and power not to recognize and address itself to this problem.

Please, don't wait until it touches your life personally to do something about it. As has been shown here today among these witnesses, our loved ones cannot wait. Please let's cut the bureaucracy and get to work.

Mr. WAXMAN. Thank you very much.

Let me thank each of you. I think you have challenged our emotions as citizens and our responsibilities as public officials. I wish I could wave my gavel and create a system of organ donation to meet the needs of all those patients that wait. We wish we could help.

I think we are going to have to think through exactly what must be done. Congressman Gore talked about legislation that he will be asking us to consider.

I am asking my subcommittee staff to work with him and his staff, because I think it is essential that we get some kind of coordinated system in this country to educate those who can donate organs, to make them available to those who are waiting so desperately for a lifegiving organ that can be used for transplantation.

Mr. White, you pointed out there are a couple of roadblocks. One is to coordinate the donation of an organ for transplant, and the other is paying for this very, very expensive medical procedure.

In your situation, Stanford has a grant of money, is that correct?

Mr. WHITE. That is correct. And that is a very rare and unusual situation too.

Mr. WAXMAN. For the Turpin family, you are asking people to contribute to a trust fund in order to pay for the surgery, is that right?

Mrs. TURPIN. It is.

Mr. WAXMAN. And Mrs. Montgomery, your husband was turned away because you didn't have the $60,000 up front to assure—who—the doctor, the hospital, all the people involved—that they would get paid for their medical services?

Mrs. MONTGOMERY. Pittsburgh told us that we had to have the money ahead of time before they would even put him on a list or look at him.

Mr. WAXMAN. The costs of a transplant operation are really staggering—$100,000 or $200,000 means nothing. They are beyond the means and imagination of so many people. Yet we have insurance companies refusing to pay—even the Federal Government under medicare refusing to pay for this service because it is called experimental.

We are going to hear from some doctors later in our hearing. But we know the new advances that are far beyond the experimental stage. We ought to at least ask those insurance agencies that pay for care to pay for this lifesaving medical procedure. And I think we need to go forward and do more.

Mr. Turpin, I very much appreciate the comments you made. It is our responsibility. A government of this magnitude that just yesterday voted in the House to spend billions of dollars for defense, ought to be able to figure out how to save the lives of our citizens; and at least coordinate the donation of organs for those who are willing to make the contribution, to have that contribution made available to those who are in need of that donation.

Thank you very much.

Let me call on my colleagues.

Mr. LUKEN. Mr. Chairman, there are many aspects that have been brought out by the victims here of the failure of a national policy.

I think the most graphic demonstration is in the description of our insurance policies.

Mrs. Montgomery, you had a policy that would pay up to $500,000 for hospital expenses but it didn't make the $60,000 you needed in order to get in line, just to get in line to be available if you could then find a transplant donor, is that right?

Mrs. MONTGOMERY. Right.

Mr. LUKEN. Do you have any particular thoughts about that?

You have indicated, I believe, that your husband donated his eyes because he was very conscious of the need for donors. You are here, not because you need anything now, but because you want to carry on that fight?

Mrs. MONTGOMERY. Right. There are so many people out there that need help. I know what I went through with all the expenses. And I don't think you should have to go through that. It is shocking to begin with, when you find out that you have to have $60,000. Then you have to wait for an organ. It is hard to even realize—there are so many—people just aren't donating the organs when they should to help preserve lives.

My husband was totally a healthy man. He was completely healthy, except——

Mr. LUKEN. Thirty-five years old, working?

Mrs. MONTGOMERY. He was working up until 1 year ago January.

Mr. LUKEN. And then he went eventually—before he died, on social security disability, a 35-year-old person, and would have been, in a short time, eligible for medicare because of that.

Mrs. MONTGOMERY. Yes.

Mr. LUKEN. But even if he were eligible for medicare, you could not have provided the finances to get in line?

So you had every advantage, every resource that anyone could have. Yet he was not eligible for the funding. And of course there are others here who have had community drives to provide the funding. But in your case, that community drive just didn't have time to get started, isn't that right?

Mrs. MONTGOMERY. Right. It started 1 week before my husband died. His heart had deteriorated faster than they expected.

Mr. LUKEN. I think that demonstrates the fact that we need not only put attention to these individual aspects, but we need to develop a national policy, and we need to influence the formulation of a policy by medicare, which will in turn force the insurance companies to adopt a similar policy. And I think that is the only way that people can have available to them the necessary financing, the necessary resources for the transplant centers and so on.

I believe that is the most important thing we can do.

The other things are necessary, but I think we have to keep our eye on the ball, and that is a development of policy which, in your case, graphically demonstrates, if everything else were available—transplant centers, availability of organs—if all of that were present, your husband, a 35-year-old productive person, still would not have had the lifegiving operation available.

Thank you very much.

Mr. WAXMAN. Mr. Sikorski.

Mr. SIKORSKI. Thank you, Mr. Chairman. I commend you for putting this together today so that we can educate ourselves and the world to a serious problem.

Thank you for coming. I have a 2-year-old and share personally each of your stories. I am not only touched personally but officially.

The problems you bring to us today are major problems, as you know and experience. The costs we are talking about are gigantic. They are more than the largest single purchase you ever make,

your house. The problems with coordination and the fact that there are not enough donors are serious problems. But we are a great nation, and what you are doing is—that you are testing us, you are testing us as a society.

In my office is a saying from Hubert Humphrey, from my State, that the true test of a society's greatness is how it treats those in the dawn of life, the children, and those in the shadows of life, the ill.

You are posing that concept to America, which has accomplished great things. We have fought wars that have protected societies, and we have gone out beyond our planet to the Moon and other planets, and gone into elements and particulates of elements way beyond the human comprehension. And now, because of our curiosity, because of our scientific advancement, medical achievements, we are now posed with the issue of applying that to make American and other lives better.

Hopefully we are capable still as a great nation to respond to that test. I am convinced we are, and am joining with you in meeting that test.

Thank you for your willingness to come this morning.

Mr. WAXMAN. Thank you, Mr. Sikorsi.

We do very much appreciate your being with us. We want to wish you, each of you personally, our very best wishes, and to tell you that we hope your being here today will be the beginning of an effort by Congress to address this very difficult and important problem.

Thank you very much for being here.

Our next panel consists of two distinguished transplant surgeons, Dr. Oscar Salvatierra, chief of the Transplant Services of the University of California, San Francisco; Dr. Folkert Belzer, chairman of the Department of Surgery at the University of Wisconsin.

I would like to ask these two gentlemen to come forward. I welcome you to this hearing. We would like you to proceed with your testimony.

STATEMENTS OF OSCAR K. SALVATIERRA, M.D., PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS; AND FOLKERT BELZER, M.D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF SURGERY, UNIVERSITY OF WISCONSIN

Dr. SALVATIERRA. Thank you, Mr. Chairman.

Mr. Chairman, I am Oscar Salvatierra, M.D., professor of surgery and urology, and chief of the Transplant Service at the University of California at San Francisco.

I am here today representing the American Society of Transplant Surgeons. The society appreciates your invitation to participate in these hearings, and we are anxious to join with you in examining ways to improve the availability of transplants for those patients who need them.

We believe these hearings are especially timely in light of recent and forthcoming advances in organ transplantation. The field of transplantation has entered a new era—an era charaterized by substantial increases in the survival rates for a variety of transplantable organs.

Our purpose today is first to share with your our perspective on the state of the art in organ transplantation and to affirm the likely continued success of this form of therapy.

In my written testimony, I have offered an analysis of some of the constraints on this therapy and made some recommendations regarding these constraints. I will briefly summarize some pertinent areas from this written testimony.

Advances in the field of organ transplantation have been rapid and profound. In the kidney area, we now see survival with kidneys from related donors in the 95-percent range, and this because of a new protocol utilizing transfusion of blood from the prospective kidney donor to the prospective kidney recipient.

Among cadaver graft recipients, we are seeing graft survival rates in the range of 80 percent or greater due to the new immunosuppressive agent, discussed earlier, cyclosporine.

Although our experience with kidney transplants is the most extensive, the available evidence on other organ transplants, heart, heart/lung, liver and pancreas, is equally encouraging.

Of course, in these latter cases, only cadaveric organs can be used. With heart transplantation and with the use of cyclosporine, we are now seeing patient survival rates of 80 percent, and without these transplants, none of these patients would have survived.

The University of Pittsburgh liver transplant program is presently reporting 1 year survival rates of 60 to 70 percent, up from only 30 percent before 1980.

Most importantly, heart and liver recipients have excellent rehabilitation. Kidney transplantation is no longer considered experimental, and it is clear now that transplants of livers, hearts and pancreas in carefully selected patients at qualified centers should no longer be considered experimental, either.

The recent NIH concensus conference on liver transplantation supports this view. These procedures are and should be viewed as state of the art medical care delivery.

We are all excited about this progress in transplantation for a number of reasons. First, and most important, it makes possible the survival and rehabilitation of many patients who would formerly have died or have been severely disabled.

But perhaps equally important in this time of constrained resources is the cost effectiveness of organ transplantation, whether heart, kidney, liver, when compared to alternative therapies or costs of terminal care.

Despite the potential for significantly expanding the application of transplantation therapy, there are also some very real constraints, constraints which have brought us to these discussions today.

First, there is the very critical shortage of suitable organs. In spite of the advancements in transplantation described, the number of kidney transplants, for example, has remained relatively stable.

Improved transplantation results will definitely decrease the number of patients on dialysis and at a subsequent cost savings, but a much greater decrease in the number of patients being maintained on dialysis and further cost reduction in the end-stage renal

disease program can be obtained by also substantially increasing the number of transplants performed.

In other words, the greatest impact on decreasing the number of patients on maintenance dialysis will be achieved by a combination of improved results and increased utilization of transplantation.

If 10,000, instead of 5,000, transplants could be performed annually with, for example, 40 percent from related donor sources and 60 percent from cadaver sources, and with current optimum results, then an estimated almost $500 million would be saved over a similar 10,000 patients that would be maintained on dialysis alone for a 4-year period.

Just maintaining this transplant level of 10,000 each year would ultimately produce enormous savings, and many more patients would be returned to normal or near-normal lives.

The imbalance in the supply of, and demand for, organs is an extremely critical problem that needs to be solved if we are to achieve a 10,000-per-year level in kidney transplantation, and to also increase the availability of organs to patients who require a heart or liver transplant to maintain life.

I would now like to share with you some of our views about promising approaches to solving some of our problems in providing optimum opportunities for organ transplantation to those patients in need of this therapy, whether kidney, heart, liver, or pancreas.

These suggestions involve four areas, and essentially parallel the suggestions in the proposed legislation that we heard this morning from Representative Gore.

First, improvement in organ availability and donation is paramount.

Second, development of an assessment program for evaluating emergent organ transplant therapies is essential.

Third, development of a national data collection system and a national coordinated organ-sharing effort, as has been alluded to this morning is very much needed.

Fourth, assurance that policies and performance of Federal reimbursement mechanisms and third-party payers do not act as disincentives to organ transplantation which can be much more cost effective than conventional alternative therapies usually available to these patients.

It is, of course, proper to ask what specific role the Federal Government should play in these areas. I would just expand on one of these areas, and that is the area of organ procurement.

Incentives for organ retrieval must be provided. The most important of these is an assurance to the family of the donor that all hospital costs related to the untimely death will be covered.

We, additionally, recommend that Federal and private health insurance programs continue to pay their fair share of reasonable procurement and distribution costs.

We would also recommend as a means to improve and increase organ donation that hospitals be required to establish and develop donor identification procedures and protocols within their own institutions.

This might be a requirement of certification or a requirement of hospitals receiving medicare reimbursement.

In summary, I have tried to outline in my written testimony the current improved status of organ transplantation and to indicate the role that the Federal Government might play, not only in making this therapy available to more patients who need organ transplants, but also in removing impediments which might hinder the advancement of the field of transplantation.

The Federal Government has a unique opportunity to help many desperate people survive and live better lives. Extremely important at this time of cost containment is that organ transplantation, whether kidney, heart, heart/lung, liver, provides a definite cost savings when compared to alternative therapies under which patients in need of transplants live, and which alternative therapies are all reimbursed by third party payers compared to the reimbursement problems faced with some areas of transplantation.

I would, again, like to thank the chairman and members of the committee for this opportunity to share some of our views on organ transplantation.

[Testimony resumes on p. 41.]

[Dr. Salvatierra's prepared statement follows:]

TESTIMONY BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
HOUSE ENERGY AND COMMERCE COMMITTEE,
BY OSCAR SALVATIERRA, JR., M.D.,
PRESIDENT OF THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS,
JULY 29, 1983

Mr. Chairman, I am Oscar Salvatierra, M.D., Professor of Surgery and Urology, and Chief of the Transplant Service at the University of California at San Francisco. I am here today representing the American Society of Transplant Surgeons. The Society appreciates your invitation to participate in these hearings, and we are anxious to join with you in examining ways to improve the availability of transplants for those patients who need them. We believe these hearings are especially timely in light of recent and forthcoming advances in organ transplantation. The field of transplantation has entered a new era -- an era characterized by substantial increases in the survival rates for a variety of transplantable organs.

Our purpose today is first to share with you our perspective on the state of the art in organ transplantation and to affirm the likely continued success of this form of therapy. We would then like to offer our analysis of some of the constraints on this therapy and conclude with our recommendations regarding these constraints.

Advancements in the field of organ transplantation have been rapid and profound. As an example, two recent advances that have greatly improved the survival of kidney organ grafts are the

advent of a new immunosuppressive agent, Cyclosporine, and the introduction of donor-specific blood transfusions prior to living donor kidney transplantation. Cyclosporine is expected to be approved for general use later this year. Data from the four transplant centers currently approved for Cyclosporine use show one-year cadaveric kidney graft survival rates of over 80 percent and patient survival rates of 95 percent. In my own center as well as others where donor-specific blood transfusions are employed, live donor graft and patient survival rates without Cyclosporine have reached 95 percent and 98 percent, respectively, at one year. Because of such developments as these, kidney graft survival has markedly improved over the results that were being obtained just three years ago.

In connection with end-stage renal disease, it is important to note that comparison of dialysis patients and transplant patients shows that transplant recipients ultimately have significantly higher patient survival rates and obtain greater rehabilitation. Unfortunately, more than 10,000 patients are currently on lists awaiting transplantation, and many of the 65,000 patients presently on dialysis would also consider this therapy, if organs were more readily available.

Although our experience with kidney transplants is the most extensive, the available evidence on other organ transplants -- heart, heart-lung, liver and pancreas -- is equally encouraging. Of course, in these latter cases, only cadaveric organs can be used. Since 1967, more than 500 heart transplants have been performed and since 1963, over 600 liver transplants have been

performed. The most recent data from the heart transplant program at Stanford University show patient survival rates of 80 percent at one year and 50 percent at five years. Without these transplants, none of these patients would have survived. The University of Pittsburg's liver transplant program is presently reporting one-year survival rates of 65 percent -- up from only 30 percent before 1980. Most importantly, heart and liver recipients have excellent rehabilitation.

Certainly, we have not witnessed the end of advancements in organ transplantation. There are other promising innovations now being tried that may yield further general improvements, such as the use of monoclonal antibodies.

Kidney transplantation is no longer considered experimental, and it is clear now that transplants of livers, hearts, and pancreas in carefully selected patients at qualified centers should no longer be considered experimental either. The recent NIH consensus conference on liver transplantation supports this view. These procedures are and should be viewed as state-of-the-art medical care delivery. With the expected FDA approval later this year of Cyclosporine, which will make this drug more widely available, the number of transplant procedures will likely increase significantly.

We are excited about this progress in transplantation for a number of reasons. First and most important, it makes possible the survival and rehabilitation of many individuals who would formerly have died or have been severely disabled. In the specific case of end-stage renal disease, the quality of life of

the many thousands of patients who are tied to some form of chronic dialysis can be greatly enhanced.

But perhaps equally important in this time of constrained resources is the cost effectiveness of organ transplantation, whether kidney, heart, liver or pancreas. For example, the average cost of a renal transplant in the first year is approximately $25,000 to $35,000, and this figure decreases significantly in subsequent years to a minimal maintenance cost for medication. In contrast, the cost of chronic center-based dialysis, without even considering hospitalization for associated illnesses, is estimated to exceed $25,000 per year, every year a patient remains on dialysis. Yet when the cost of hospitalization for associated dialysis-related illness is also taken into account, the yearly cost of dialysis for a child at our center exceeds $70,000 per year. The medical costs of transplantation can be expected to decline further as new and better use of immunosuppressive drugs reduces re-hospitalization for the management of rejection episodes and complications. Obviously, the value of rehabilitation must also be taken into account as successful transplantation returns more individuals to productive lives, removing the obstacles faced by individuals on dialysis.

There is capacity at our transplant centers to do more. A gradual, planned expansion of the capacity of these transplant centers is possible. However, at the same time, strict professional standards and protocols must be applied to the approval of new centers, and we must assure that an adequate

volume of services is provided at each site. In order to enhance the quality and cost effectiveness of transplant services, the American Society of Transplant Surgeons has supported continuation of a system of careful planning and approval for the establishment of transplant centers.

Despite the potential for significantly expanding the application of transplantation therapy, there are also some very real constraints -- constraints which have brought us to these discussions today. First, there is a very critical shortage of suitable organs. In spite of the advancements in transplantation I have described, the number of kidney transplants has remained relatively stable. Improved transplantation results will definitely decrease the number of patients on dialysis and at a subsequent cost savings. But a much greater decrease in the number of patients being maintained on dialysis and further cost reduction in the end-stage renal disease program can be obtained by substantially increasing the number of transplants performed.

In 1979, 4,721 kidney transplants were performed; by 1982, this figure had increased only slightly to 5,350 for that year, and yet most estimates of need are more than double this number. If 10,000 instead of 5,000 transplants could be performed annually, with 40 percent from related donor sources and 60 percent from cadaver sources, and with current optimum results, then $500 million would be saved over a similar 10,000 patients maintained on dialysis alone for a four-year period. Just maintaining this transplant level of 10,000 each year would

ultimately produce enormous savings, and many more patients would be returned to normal or near-normal lives. The imbalance in the supply of and demand for organs is an extremely critical problem that needs to be solved if we are to achieve a 10,000 per year level in kidney transplantation, and to increase the availability of organs to patients who require heart or liver transplants to maintain life.

I would now like to share with you some of our views about promising approches to solving some of our problems in providing optimum opportunities for organ transplantation to those patients in need of this therapy, whether kidney, heart, liver, or pancreas. These suggestions involve four major areas: (1) improvement in organ availability and donation; (2) development of an assessment program for evaluating emerging organ transplant therapies; (3) development of a national data collection system and a national coordinated organ-sharing effort; and (4) assurance that policies and performance of federal reimbursement mechanisms and third party payers do not act as disincentives to organ transplantation, which can be much more cost effective than conventional alternative therapies.

At the center of efforts to increase the utilization of transplantation must be strategies for the promotion of organ donation. There must be greater focus on educational campaigns. We must continue broad appeals to our fellow citizens which heighten their awareness of the need for organs, and we must take practical steps to insure that their intention to donate is recorded. But these special educational efforts must also be

extended to physicians, nurses, and health professionals involved in specialized care units like emergency rooms, shock-trauma centers, and ICUs. These individuals need to be trained to identify potential donors and to deal effectively with family members in emotional turmoil. We believe the progress being made in organ transplanttion will itself be an important factor in the promotion of organ donation. We appreciate and believe the efforts of the Surgeon General, through his workshop on "Solid Organ Procurement for Transplantation," are appropriate and will greatly enhance educational efforts.

It is, of course, proper to ask what specific role the federal government should play in organ donation. There are, in fact, several very important and needed ways in which the federal government can participate in the effort to increase organ procurement. Incentives for organ retrieval must be provided, the most important of these being an assurance to the family of the donor that all hospital costs related to the untimely death will be covered. We additionally recommend that federal and private health insurance programs continue to pay their fair share of reasonable procurement and distribution costs. The American Society of Transplant Surgeons is committed to supporting the DRG prospective reimbursement system in order to achieve better containment of the health care costs that have eluded us. However, the DRG system as applied to kidney transplantation may result in inadequate funding of organ procurement efforts which are paramount to any transplantation effort and therefore prove a disincentive. Organ procurement is

included as part of the clinical renal transplantation DRG, but organ procurement is an entirely different process and should not be considered as part of kidney transplant recipient care. The failure to have a separate DRG (or other mechanism) for organ procurement may inhibit procurement because it competes for the same dollars used for patient care. It is important that we be assured of a reasonable organ procurement reimbursement rate that falls within the guidelines of the DRG system and that reimbursement procedures in this area be better elucidated. We would also recommend, as a means to improve and increase organ donation, that hospitals be required to establish and develop donor identification procedures and protocols within their own institutions. This might be a requirement of certification or a requirement of hospitals receiving Medicare reimbursement.

Our second major suggestion involves the important role which the federal government might play in acting as a catalyst for the development of an assessment program for evaluating emerging transplant therapies. At present, this process is quite fragmented. The Medicare program has been given much of the responsibility, but other responsibility has been assigned to such agencies as the NIH. Similar fragmentation of responsibility exists amongst private purchasers of care. A major impediment to the growth of organ transplantation may well be the unwillingness of third party payers to cover costs for services they continue to regard as experimental. We have and are continuing to experience funding difficulties in heart, heart-lung, and pancreas transplantation. New successful

therapeutic approaches in kidney transplantation may go unfunded for unreasonably long periods of time. The recent NIH concensus conference on liver transplantation finally reaffirmed that liver transplantation was therapeutic, a fact that was already recognized by some private insurance carriers. We therefore need a credible peer-review process for making judgments concerning whether a service is state-of-the-art medical care or experimental, as well as a way to pay for services that need to be performed at a small number of testing sites. In the absence of such a process, we will surely have inequities and access limitations, which are not appropriate or defensible.

Our third major suggestion is the following: in order to assist with the major areas of organ procurement and emerging transplant technology assessment already enumerated, we would strongly support the development of a national data-collection system and organ-sharing program. These are two separate areas, but efficiency would be maximized by joining operation. We believe it would be appropriate for the federal government to provide funding assistance for this activity. The program could be administered under the auspices of a board of directors whose membership would be nonsalaried and appointed by the groups most involved in these areas, for example, the American Society of Transplant Surgeons and the NIH. A national coordinated organ-sharing system would maximize the placement and utilization of organs that cannot be transplanted regionally.

A better data-collection system for all transplantable organs -- kidney, heart, heart-lung, liver, and pancreas -- is

also essential. Before the advent of the end-stage renal disease program ten years ago, data regarding outcomes of transplanted organs were maintained through the joint efforts of the American College of Surgeons and the NIH. However, this role was assumed by others in the administration of the ESRD program and for the past ten years, despite well-intentioned efforts, there has been no timely and reliable reporting of the collective transplantation efforts in this country. The American Society of Transplant Surgeons represents all organ transplantation efforts in this country, and it would be willing to join with the NIH and other interested parties in the re-establishment of a reliable data-collection system. This would not only be important as a quality control and assurance system, but it would allow transplant surgeons and patients to be fully informed of transplantation outcomes and would foster the application of the more successful transplantation strategies. Most importantly, it would also provide valuable information to a transplant technology assessment program which would evaluate emerging transplantation therapies.

Last but not least, some comments should be made about additional potential problems for kidney transplantation under the DRG prospective reimbursement system. As indicated before, we support this type of system as a means of achieving cost containment. We have pointed out a possible disincentive for organ procurement through this system. But further consideration must be given to the fact that whereas most disease processes and therapies have undergone extensive medical and surgical

partitioning to reach a specific DRG, kidney transplantation with its many forms and many types of patients has not undergone such a partitioning and is uniquely considered under a single global DRG. In other words, hospital reimbursement will be an average price for the average transplant patient, without regard for risk category, living-related or cadaver transplantation, or other considerations. This may very well provide a disincentive for hospitals to transplant those patients who might be most in need of such transplants, for example, diabetic patients who tend to do so poorly on dialysis. In addition, this Medicare prospective reimbursement system makes no allowance for an outpatient drug such as Cyclosporine, which most patients will probably not be able to afford, and yet, might singly be most responsible for improved results from transplanted cadaver organs.

In summary, I have tried to outline the current improved status of organ transplantation and to indicate the role that the federal government might play, not only in making this therapy available to more patients who need organ transplants, but also in removing impediments which might hinder the advancement of the field of transplantation. The federal government has a unique opportunity to help many desperate people survive and live better lives. Extremely important at this time of cost containment is that organ transplantation -- kidney, heart, heart-lung, liver and pancreas -- provides a definite cost savings when compared to alternative therapies under which patients in need of transplants live.

I would again like to thank the chairman and members of the committee for this opportunity to share some of our views on organ transplantation.

Mr. WAXMAN. Thank you very much.

STATEMENT OF FOLKER O. BELZER, M.D.

Dr. BELZER. Mr. Chairman, I do not have a prepared statement.

I would just like to address a few points as a physician. I personally have been involved in liver, pancreas and kidney transplantation for the last 15 years.

I know as a physician that the results at the present time of transplantation of extra-renal organs, although not perfect, are far better than to be called experimental. You have heard some of the frustrations of some of the patients.

Perhaps you can hear some of the frustrations of the physician. We heard that heart transplantation now carries an 80-percent, 1-year survival and a 50-percent, 5-year survival, which is better than we can obtain at the present time for most cancers.

We, in my department, started heart transplantation 8 years ago. We have several long-term survivors. We had to stop heart transplantation 3 years ago because of the absence of funding.

This was funding only for the hospital, as physician fees were never charged for these patients. We had a 27-year-old husband of an X-ray technician die of cardiomyopathy, which is a treatable disease, as we heard, and as is known, by heart transplantation.

Mr. Waxman, you asked why 300 livers could not be used. Dr. Stazell is doing a superhuman job, and works about 24 hours a day in the operating room.

But he cannot do it alone. I did my first liver transplants more than 10 years ago for biliary atresia. If I wanted to start a liver transplant program in my department at the present time, I could not do this because of inability to get it funded.

My final point is to Mr. Luken. He asked a very important question—can we afford transplantation. But nobody looks at hidden costs outside transplantation.

We recently looked at a young patient with juvenile diabetes who died at about the age of 28, and we looked over his hospital bills over the last 5 years while he was admitted for insulin comma, for stroke, for major amputations of his extremities, all secondary to his juvenile diabetes, and his total hospital bills over the last 5 years were over $300,000.

It would have been cheaper to transplant this patient prior to his complications, with a pancreatic transplant, and have him live and be cured. So I believe strongly the Government should be looking at ways to fund extra-rental transplants.

If medicare will not pay for it, insurance companies will call it experimental. We hear the same frustrations of the patients, but also the frustrations of physicians who are able to provide this care, but cannot at this time.

Thank you very kindly.

Mr. WAXMAN. Thank you very much, Dr. Belzer.

Is it fair to say the primary reason we have seen an increase of interest in organ transplants and success in surgery is due to the development of cyclosporine?

Dr. SALVATIERRA. In good part, yes, sir, Mr. Waxman.

Mr. WAXMAN. For those who do not know, this is a drug that allows the body to have a transplant without rejecting the transplanted organ.

Now that we have this procedure and have much improved chances for success, I am interested in how many transplants you anticipate to be performed 5 years from now, let's say, in 1988—kidneys, hearts, and livers.

Do you have any idea what we are looking at down the road?

Dr. BELZER. I think there are different estimates. I don't think the numbers will be astronomical. We are looking at about 10 to 15,000 kidney transplants a year, which is double or triple the number we have to do now.

Pancreatic transplantation will be actually for a few patients. Most diabetics can do extremely well with insulin. There are a small number of patients, however, where juvenile diabetes is more malignant than cancer.

Those patients can only have pancreatic transplantation. Liver transplantation, the numbers are not absolutely known.

It could be 4,000. It could be more than that. But the numbers are not going to be astronomical.

In heart transplantation, again, I don't believe these numbers will be astronomical. But for the 27- to 35-year-old patient with cardiomyopathy, or the young children growing up having had surgery at infancy for congenital heart diseases, who are now reaching end-stage heart diseases at age 16, those are the patients that should have heart transplantation.

Mr. WAXMAN. Why are there more kidney transplants than heart or liver?

Dr. BELZER. Probably because kidney failure was the fifth cause of death. Although heart disease is probably the first cause of death—most of these patients are elderly, die of coronary artery disease, and probably are not candidates for heart transplants.

Mr. WAXMAN. What about a national computer system to match organ donors and recipients? Do we need to have a national computer system to do more in this area?

Dr. SALVATIERRA. Yes, Mr. Waxman; I think we need a better coordinated national effort, not only in respect to organ sharing, particularly for those organs that cannot be placed regionally, but also perhaps this might be tied in with a data collection system that might provide us more information about the activity and outcomes in various areas of transplantation.

Certainly this would be of tremendous benefit to any technological assessment program that we might develop to assess these programs.

Mr. WAXMAN. Do we need Federal support for central, all-organ computer system?

Dr. SALVATIERRA. I think we do.

Just going back a bit, the major problem with transplantation really relates to the fact of its rapid development.

But with this rapid development of the field, we have found ours with fragmented services, particularly in the areas of organ procurement as was alluded to earlier despite the fact that individuals involved in a transplant effort are very committed to transplantation, and to their patients.

I think it would be of great benefit if we could bring this together in a more coordinated effort and we have tried, on a voluntary basis to effect this.

But I think we will need some assistance to better achieve the goals that we are all talking about.

Mr. WAXMAN. In your statement you suggest there should be a gradual, planned expansion of the capacity of transplant centers. I gather what you mean by that is not that we should have every hospital to the country doing transplant surgery, but that there should be centers that would have the primary responsibility so that they would, probably because they are busier transplant centers, provide better quality of care.

Is that a fair statement?

Dr. SALVATIERRA. Yes.

Mr. WAXMAN. How should the Nation insure that there is an orderly expansion of transplant centers? Does the primary burden rest with medicare or the private insurers as you see it?

Dr. SALVATIERRA. I think it is a combination. It must include a peer review group.

A peer review group that assures quality of care and adequate training of personnel that might be involved in that transplantation effort.

Mr. WAXMAN. Who should convene that peer review group?

Dr. SALVATIERRA. I think it should involve, if I may make the suggestion, the most interested parties—for example, the American Society of Transplant Surgeons, and the NIH, in a cooperative effort could work some of those problems out.

Mr. WAXMAN. You also indicated in your statement that you believe the Federal Government should play an important role in developing an assessment program for evaluating emerging transplant therapies. Why is Federal leadership important in this area? Why hasn't the private sector established such a peer review process, and could you support legislation to establish a strong Federal agency to conduct such reviews on an ongoing basis?

Dr. SALVATIERRA. In answer to your latter question, yes. To your other questions, one of the primary reasons we need such an assessment of technology relates to the distinction as to whether the therapy being practiced is experimental or therapeutic.

Certainly there will be various interested parties involved—the third-party payers and the practitioners involved in the therapy.

But I firmly believe that such a group, and I cannot indicate to you where it should be placed, but I thoroughly believe such a peer review group should exist.

Mr. WAXMAN. Thank you very much.

Mr. Luken.

Mr. LUKEN. Gentlemen, it seems to me that we need a breakthrough here. Let me suggest—I would like your comments on it as to where we are.

Dr. Salvatierra, in your testimony you say that kidney transplant is no longer considered experimental.

"It is clear now that transplants of hearts, livers, and pancreas for carefully selected patients at qualified centers should no longer be considered experimental either."

That is your testimony. That is not medicare policy. That is not Federal policy. That is not the policy of the big insurance companies.

Dr. SALVATIERRA. Right.

Mr. LUKEN. In other words, the only program we have is a pilot program, something like 15 patients that have been taken care of.

So there is a dichotomy; there is a big gap between what you are saying and what we think is the consensus of scientific medical opinion on the subject as to what our policy should be and what our policy actually is, is that right?

Dr. SALVATIERRA. Yes; there is a dichotomy, when these therapies can save lives, can alleviate suffering, in comparison to the more costly alternative therapies that are available, and in the nonrenal area, you are primarily dealing with terminal care.

In the renal area, yes, dialysis is helpful, does maintain life, but I don't think there is anyone who would disagree that renal transplantation would provide the best quality of life for these patients and at reduced cost.

Mr. LUKEN. Doctor, you can speak authoritatively with renal because you have so much experience with it, because it is covered; it is not considered experimental, isn't that right?

Dr. SALVATIERRA. That is right.

Mr. LUKEN. But we had the Montgomeries here who said they could not even look into the question of whether it would be a feasible thing. In his case, the 35-year-old man, with a heart condition. We will never know whether it would have been feasible, a viable thing for him to have a transplant because they had the disincentive of the $60,000 obstacle in front of them, even though they had $500,000 of medical coverage. They could not even get up to the starting point.

Dr. SALVATIERRA. Mr. Luken, one of the problems is that these decisions are primarily being made by the third-party carriers.

Mr. LUKEN. That is exactly right, and they are going to do it on a dollars-and-cents basis.

Dr. SALVATIERRA. That is right. To call something experimental, particularly in these areas, when you see the benefits that I think all of us have witnessed, to call something experimental in these areas I think is just an excuse not to provide payment.

But, what they don't realize is that it is actually cheaper to save lives in many instances.

Mr. LUKEN. We all know who makes policy in these cases. It is the third-party carriers, and they work with those who deliver the care, which is the hospitals, right?

The hospitals have a good deal today. They work very closely together.

Now, I am going to introduce a statement by the Greater Cincinnati Hospital Council. It wasn't my impression to set them up when asking them for the testimony, but their testimony, I assume, is typical of that which we would get from deliverers of health care across the country.

It is very negative on the subject of making these procedures, transplants, transforming them from experimental to regular or to routine.

As a matter of fact, one of the things that they point out is that the cost in the renal experience—they are very apprehensive, because they believe that the renal, end-stage renal experience, the policy was established by this Congress, I believe, in 1972, and since then, for example, one of the things they cite is that, in the medicare budget for renal procedures, 5 percent of the medicare budget next year, 1985, will be allotted for 0.2 percent of the patients.

They seem to think that is a disincentive. Is it?

Dr. BELZER. It is.

Mr. LUKEN. Is it one that should stop us?

Dr. BELZER. There are also 68,000 people alive on dialysis in the United States at the present time, and about 15,000 or 20,000 people with functioning transplants walking around. That is the other side.

I might just say that third parties are going to follow the advice of medicare, and if medicare or the Government calls it experimental, they will call it experimental and they will follow it right down to the line.

Mr. LUKEN. Dr. Salvatierra, what is going on in that area of advising HCFA, coming up with a decision on this policy?

Can you tell us anything much about that?

Dr. SALVATIERRA. It is difficult to comment on that. Most of the policies are made by that organization. I think they have sought good input. Somehow there are problems. I cannot give you a real explanation, Mr. Luken.

Mr. LUKEN. Well, there has been a great deal of good work done by Congressman Gore on the overall problem.

You address significantly, I think, four different points.

One of them was the disincentives, because of policies of Federal reimbursement. But in your discussion of it, you didn't get to the overall policy question, is that right?

You will agree that that is key to opening up a lot of solutions to all of the individual problems.

Dr. SALVATIERRA. And certainly I think very key—I think there are two major areas that probably are the most important of the number that we have discussed today, and one is organ availability and the other is reimbursment of extrarenal organ transplantation. Key to that, and following up from your comments, is that we have to assure that there are no disincentives to organ donation and that we accept organ transplantation that is life-saving and less costly than alternative therapies as therapeutic and nonexperimental.

Mr. LUKEN. If it is a dollars-and-cents proposition, as with the Montgomeries, they will never find out whether a donor is available.

Mr. WAXMAN. Thank you, gentlemen, very much, for being with us. We very much appreciate your testimony.

Our next panel this morning consists of three experts on organ transplant policy.

Jeffrey M. Prottas, Health Policy Center, Heller School, Brandeis University; Roger Evans, director, National Heart Transplantation Study, Battelle Research Center; and Dr. James M. Young, member, Massachusetts Task Force on Liver Transplantation and vice president, Blue Cross of Massachusetts.

Mr. WAXMAN. We would like to welcome you to our hearing today.

Dr. Prottas.

STATEMENTS OF DR. JEFFREY M. PROTTAS, SENIOR RESEARCH ASSOCIATE, HEALTH POLICY CENTER, BRANDEIS UNIVERSITY; JAMES M. YOUNG, M.D., VICE PRESIDENT AND MEDICAL DIRECTOR, BLUE CROSS AND BLUE SHIELD OF MASSACHUSETTS, INC.; AND ROGER W. EVANS, PH.D., RESEARCH SCIENTIST, HEALTH AND POPULATION STUDY CENTER, BATTELLE HUMAN AFFAIRS RESEARCH CENTERS

Mr. PROTTAS. Thank you, Mr. Chairman.

The United States has the largest and the most effective organ procurement system in the world. Despite this, it has never been able to meet the Nation's need for transplantable organs. This chronic shortfall is likely to increase because advances in medical techniques are improving the range and effectiveness of organ transplants.

This shortage of transplantable organs is not the result of a shortage of potential donors nor of an unwillingness on the part of the population to donate.

Conservative estimates put the number of suitable donors of cadaveric organs at 20,000 a year; other authoritative estimates go as high as 50,000. Last year, somewhat more than 2,600 kidney donors were found.

Nor is the willingness to donate a primary impediment to increases in available organs. Public opinion polls show that well over 70 percent of the population support organ donation. More importantly, when families of potential donors are approached a very high percentage give permission to proceed with the donation.

While improvement in this area is desirable, it is not lack of altruism among our people that limits the number of organs available for transplant. The problem lies in our organ procurement system. Fortunately improvement is obtainable.

There are approximately 110 organ procurement agencies in the United States. Under the end-stage renal disease program, these agencies are totally funded by the Federal Government. Last year they spent approximately $40 million to obtain about 6,000 kidneys, including kidneys obtained from a living donor.

This organ procurement system is, strictly speaking, a kidney procurement system as the end-stage renal disease program only pays for kidney retrieval.

In practice, all organs for transplant are obtained by this national network. These 110 agencies vary greatly in terms of organizational structure, size, and effectiveness. If the entire Nation were served as well as the most effective of these organizations serve their own regions, the number of available organs would double.

This improvement can be brought about if there are coordinated reforms in the national structure of the program and in the operating practices of the procurement agencies themselves.

The first issue is the regionalization of organ procurement. There are too many organ procurement agencies. As a result, many agencies are too small to operate effectively.

In addition, the distribution of agencies across the Nation conforms to no sensible pattern. While some areas are underserved, others have several competing agencies. A single agency services almost all of New England, another almost all of southern California; yet Washington, D.C., has four agencies, Chicago has six and Louisiana, four.

It may be that some OPA's have grown too large to effectively service their catchment areas, but it is certain that many OPA's are too small to do so.

Some programs do not, in practice, have a single full-time organ procurement coordinator; many have only one.

For a task that requires 24-hour-a-day availability, quick response to referrals and unrelenting efforts to insure the participation of hospitals, nurses, and doctors, there are clearly critical economies of scale.

Moreover, when several agencies attempt to operate in the same area, no amount of cooperation can avoid inefficiencies and, in some multiagency areas cooperation is not always a reality.

Multiple agencies often mean duplication of preservation and laboratory facilities and each agency faces artificial constraints on its choices of community hospitals in which to work.

The solution to this is a reduction of the number of organ procurement agencies and an increase in their average size. The Nation would be better served if there were only 40 or so large organ procurement agencies.

The second important issue is direction and oversight. Last year the Federal Government spent about $40 million on kidney acquisition, yet most organ procurement agencies receive neither direction nor assistance from the funding agency, the Health Care Financing Administration.

For HCFA, of course, organ procurement is the smallest part of one of its smaller programs. It is, moreover, a program quite unlike the others.

Finally, the majority of organ procurement agencies are embedded in transplant hospitals. I can say from experience that disentangling their activities and spending patterns from the parent hospital is time consuming and requires extensive familiarity with organ procurement issues.

Nevertheless, some better central oversight of organ procurement is needed.

The goal of such oversight would be twofold: To see to it that nationwide standards were applied as to what is and is not a proper function of an organ procurement agency and, second, to provide technical assistance to those agencies whose level of effectiveness could be improved.

With 110 agencies spread across the country, someone is always inventing the wheel and someone has always yet to invent it. From the point of view of effective oversight and assistance there are obvious advantages to a decrease in the number of agencies and to their location outside of hospitals.

Still there are real benefits to be had even if national direction should proceed without regionalization.

Last, there needs to be operational reforms within organ procurement agencies.

The changes already discussed would lay the groundwork for a greatly improved organ procurement system but, in the last analysis, only effectiveness at the local level can provide more organs for transplant.

Elsewhere, I have discussed many of the administrative and structural changes needed to improve the effectiveness of organ procurement agencies at the local level. I will not go into those details here.

For this committee's purposes, the important point is that changes at the national level are not only consistent with those needed at the local level but would actually reinforce needed local reforms.

Successful organ procurement is essentially an exercise in medical marketing. The cooperation of medical professionals in nontransplant hospitals is the key to success.

These professionals, primarily nurses in intensive care units and neurosurgeons, control access to potential donors. For a variety of reasons, an orientation toward nontransplant hospitals and medical marketing is easier to obtain if the OPA is large and operationally independent of the transplant hospital and team.

Organ procurement agencies do not work for their local transplant hospital or surgeon. They work for a national program designed to serve a national need. Agencies that recognize this and are able to act upon it are more professionalized and effective than are the others.

National direction and regional structure would make it easier for more agencies to take on that character. Those changes would not, by themselves, double the available organs, but they would provide a favorable environment for further improvement in local capacity.

Finally, these recommendations would also, as a byproduct, help alleviate some other difficulties facing our organ procurement system. In particular, it would increase the system's ability to deal with the thorny problem of meeting the rising demand for nonrenal organs.

It also might help reduce the high discard rate, 20 to 25 percent, of cadaveric kidneys.

Thank you very much.

Mr. WAXMAN. Thank you very much.

We have a vote on the House floor. I am trying to find out if this is going to be followed by a series of votes. If it is one vote, we will go and return. Let's wait a minute.

Why don't we do this. Dr. Young or Dr. Evans—why don't we take a break now for lunch and come back at 1:30. Would that be possible with your schedule?

Dr. YOUNG. Getting a little tight for me.

Mr. WAXMAN. Let's make it 1:15.

Dr. YOUNG. OK. Compromise.

Mr. WAXMAN. That is what we do here all the time.

We will now break and come back here at 1:15 and we will try to start promptly at 1:15.

[Whereupon, at 12:30 p.m., the subcommittee was recessed, to reconvene at 1:15 p.m., the same day.]

AFTER RECESS

Mr. WAXMAN. The subcommittee will come back to order.

Dr. Young, we would like to call on you at this time and hear your testimony.

STATEMENT OF JAMES YOUNG, M.D.

Dr. YOUNG. I am Dr. James Young, vice president and director of medical affairs for Blue Cross and Blue Shield of Massachusetts.

As you know, my State has begun to grapple with complex issues surrounding the expanding repertoire of expensive new surgical procedures which are technically feasible, yet are of high risk.

Recently, I served on an expert panel appointed by the commissioner of public health to assess one of these procedures, liver transplantation. Generalizing from the panel's work, I would recommend five guidelines for controlled introduction of costly, complex, and high-risk new procedures.

First, third-party payors should develop standard procedures for recognizing, on an interim basis, new, complex and costly procedures. The current practice of flatly accepting or rejecting procedures risks either quashing innovation or encouraging premature, wasteful proliferation of untested techniques.

Instead, we need the flexibility provided by provisional acceptance of procedures to be performed in a pilot study for limited numbers of patients. A competent medical technology assessment group should designate such procedures and set the terms for provisional acceptance.

I would like to digress a moment from my testimony here to urge your consideration for the support of section 309 of H.R. 2350, which will reinstate the funding of the National Center for Health Care Technology.

The terms and duration of provisional acceptance should allow for complete evaluation, followed by a decision point as to whether and for which conditions to recognize the procedure as generally accepted. If required to initiate the procedure, certificate of need approval should be limited to the duration of the pilot study.

Second, prudent planning suggests that these procedures be introduced at central sites in appropriately sized regions. Regionalization will assure geographic accessibility without wasteful rivalry and duplication of resources. It will also facilitate development of a national network for harvesting donor organs and matching patients to organs. Perhaps most importantly, by concentrating complex cases at one site, regionalization will increase the technical skill of surgical teams.

A regional center might well involve a consortium of hospitals and medical schools, but it should consist of two surgical support teams—for harvesting the donor organ and for implantation. It would be linked through a single access point to other regions in a national network; and the consortium should systematically evaluate, and take responsibility for, the cost and quality of all such procedures in its region.

The appropriate region may be a health services area, a State or group of States—depending on the capital intensity of the procedure—the availability of organs, the number of surgical candidates,

and the willingness of suitable facilities to participate. If it is a group of States, as seems likely for liver and heart transplantation, then national planning and Federal guidance would be advisable.

Third, complex procedures require adequate facilities. The regional center should consist of one or more tertiary-care general hospitals with experience in like procedures already in common practice. The center should be linked to organ procurement and other relevant national networks. Of course, the surgeons and support teams must be trained in the procedure and the hospital must commit adequate beds and ancillary resources. Finally, the hospital should make special efforts to control facility costs associated with the procedure.

Fourth, we must find a more impartial gatekeeper than the media. Each region should develop an equitable method of selecting candidates for the procedure. Eligibility should extend to all patients considered capable of gaining a substantial benefit from the procedures, as measured by longevity and quality of life. That is, eligibility should be based on widely accepted medical indicators. Again, this may require a Federal role in financing.

Fifth, controlled introduction of a new procedure provides a one-time opportunity to objectively address the issues surrounding its full acceptance. Systematic evaluation should be undertaken as early as is feasible in order to estimate, for various groups of patients, the risks, benefits, and costs associated with the procedure. Evaluation should encompass, at a minimum:

First, followup data on clinical outcomes for several years.

Second, annual costs for eligible patients who do and do not undergo the procedure.

Third, comparison of actual outcomes and costs against predicted values based on previous experience.

In closing, I would reiterate the need to closely scrutinize high-risk new procedures. Those who provide, reimburse, and regulate medical care share an obligation to foster innovation while protecting patients and controlling costs. This dual responsibility requires the flexibility of interim or provisional terms for reimbursing new procedures; it dictates prudent planning for regionalized access and national coordination; and it demands rigorous evaluation of costs, risks, and benefits.

In the end, we must weigh the medical and economic evidence against our social values. To facilitate that process, a representative national body should be established to consider the evidence collected by technical experts and to advise whether and on what terms society should support new procedures.

Thank you for the opportunity to testify. I will be happy to answer your questions.

Mr. WAXMAN. Thank you very much, Dr. Young, for your testimony.

We will hear from Dr. Evans.

STATEMENT OF ROGER W. EVANS, PH. D.

Dr. EVANS. Mr. Chairman, members of the committee, I would like to just note that the testimony that I will present will be somewhat abridged from that which I have submitted.

I have been asked today to consider the financing of organ transplant procedures in the United States.

While I intend to do this, I will also discuss several other issues which directly or indirectly impact upon the question of payment.

As you are probably aware, I am directing two major studies concerning organ transplantation—they are the national heart transplantation study and the national kidney dialysis and kidney transplantation study.

Both studies are funded by the Health Care Financing Administration. The major objective of the national heart transplant study is to examine the impact of a potential coverage decision on beneficiaries, the medicare program, and health care providers.

The major objective of the kidney study is to comparatively assess the quality of life of end-stage renal disease—ESRD—patients currently being treated by dialysis and transplantation.

In recent months, the financing of organ transplant procedures has been the subject of both considerable attention and concern. There have been several highly publicized cases where private insurers have refused payment for organ transplants and Federal or State programs have stepped in to assist the patient.

Donor organ procurement has been the subject of much discussion over the past several months, as it has been here today, but the financing of organ transplants was specifically excluded from consideration at both the Surgeon General's Workshop on Solid Organ Procurement and the National Institutes of Health Liver Consensus Development Conference.

Today, however, we must face this issue head on because, all things considered, payment of organ transplants, in my estimation, epitomizes the very questions of resource allocation and rationing which our society must face in the very near future.

We are here today because of the success of organ transplantation. The survival rates of the recipients of all organ transplants have improved considerably over the years.

Substantial gains have also been made in areas other than mere patient survival. In particular, the rehabilitation of most transplant recipients, a highly selected group, compares very favorably with those of persons who have undergone coronary revascularization, and is actually superior to that of renal dialysis patients.

With improvements in patient survival and rehabilitation has come a substantial increase in the number of transplants performed in the United States and abroad. In calendar year 1982, in the United States alone, 5,358 kidney transplants were performed, 103 heart transplants, 62 liver transplants, and 35 pancreas transplants.

As I have already noted, however, there is a tremendous disparity between the need for organ transplants and the availability of donor organs. Unfortunately, while the data on which estimates of need and supply have been based are woefully inadequate, I can at least provide you with some insight into this problem.

The Health Care Financing Administration now estimates that between 6,000 and 7,000 patients on renal dialysis are awaiting kidney transplants. Last year, 3,691 cadaveric kidney transplants were performed in the United States. Depending upon patient se-

lection criteria, it is now estimated that between 1,000 and 75,000 people are in need of heart transplants.

The American Liver Foundation currently estimates that between 4,000 and 5,000 people could benefit from liver transplantation, yet assuming all kidney donors could also have served as liver donors, only about 1,800 livers would have been retrieved last year.

Dr. David Sutherland estimates that between 5,000 and 10,000 people each year could benefit from pancreas transplants, although there are over 1 million insulin-dependent diabetics in the United States.

I think the conclusion that must be reached is clear: The supply of donor organs will never be sufficient to meet the need. Consequently, not everyone who could potentially benefit from a transplant will do so. Difficult decisions must inevitably be made about who will benefit. The legal and ethical implications of these decisions are the subject of research in the national heart transplantation study.

Now let me turn my attention to the cost of transplantation and the financing thereof. Computing the cost of a transplant procedure is far more complicated than it would first appear. Moreover, we should view the cost of a transplant procedure as only one part of the total cost of treating various end-stage diseases—renal, cardiac, and hepatic.

In short, we must recognize that even without a transplant, patients with end-stage disease are expensive to treat. In other words, traditional medical management of these patients is not without cost. In fact, I would argue that the cost of a transplant procedure must be viewed as the marginal added cost of treating the patient over and above what would be required to care for the patient otherwise.

Based on the available data I can, nonetheless, provide a range of costs for kidney, heart, liver, pancreas, and heart-lung transplants. A kidney transplant is estimated to cost between $25,000 and $35,000, a heart transplant between $37,000 and $110,000, a liver transplant between $54,600 and $238,000, a pancreas transplant between $18,000 and $50,000, and a heart-lung transplant between $78,000 and $92,000.

There are several factors that account for this rather extreme range of costs. They include: First, postoperative complications and length of hospital stay; second, hospital room charges; third, the assessment of surgical fees; and fourth, the availability and use of cyclosporine.

Room charges vary considerably from hospital to hospital; some transplant surgeons assess fees and others do not; and cyclosporine has been shown to reduce the cost of transplants.

Ultimately, I think we must recognize that a true cost savings can be realized only if a decision is made not to treat patients upon the diagnosis of an end-stage disease. Once the disease has been diagnosed, and palliative treatment efforts initiated, a certain cost is associated with the disease.

I doubt, however, that many physicians, patients, and families of patients are willing to sit idle once an end-stage disease is recognized, regardless of how dismal the prognosis. This underscores the

importance of my observation that the cost of a transplant procedure must not be separated from the cost of the disease, itself.

As I have already noted, payment for transplant procedures is by no means uniform or consistent. We heard that earlier today.

While heart, liver, and pancreas transplants are considered experimental under the medicare program, kidney transplants are paid for by medicare but are subject to a coinsurance deductible. Medicare is paying for 15 heart transplants under the national heart transplantation study.

Nevertheless, several heart and liver transplants have been covered under various State medicaid programs following denial of reimbursement by private insurers. Private insurers routinely pick up the coinsurance portion of kidney transplantation procedures, but most private insurers, following the lead of the medicare program, consider heart, liver, and pancreas transplants experimental.

Dr. David Sutherland, of Minnesota, has informed me that some private insurers have paid for pancreas transplants, subject to a 25-percent coinsurance. Also, some private insurers have paid for heart transplants subject to a 20-percent coinsurance, while others choose only to reimburse for a portion of the expenses associated with heart transplantation.

For example, a claim may be reviewed and the patient reimbursed for all expenses considered to be not specifically required for the transplant. In such instances, the insurer assumes that the patient would have been hospitalized, anyway, and, thus, for example, the room charges would be reimbursed. But, in the case of a heart transplant, a procedure such as an endomyocardial biopsy would not be covered since this would be considered a purely transplant-related expense.

To meet the expenses associated with a heart or liver transplant, many patients and families engage in public fundraising efforts. Many transplant centers now require up-front money or assurance from insurers that a preset amount will be paid before they perform a transplant. Thus, in some instances, patients and families who find the cost of transplant beyond their financial means have been forced to go public to derive the financial support they need to gain entry to a transplant program.

Some liver transplant programs require an assurance of as much as $140,000 up front before they will proceed with a transplant. A similar requirement is made by several heart transplant programs, where an expectation of $43,000 to $125,000 is not unreasonable.

While heart, liver, and pancreas transplants are not paid for under the medicare program, all of these procedures are currently under review by the Health Care Financing Administration or the Public Health Service's Office of Health Technology Assessment. The latter agency reviews health care technologies and makes coverage recommendations to the Health Care Financing Administration.

The tremendous disparity between the need for organ transplants and the availability of donor organs will certainly limit what might be called the total program expenditures associated with extrarenal organ transplant procedures. There are simply too few donor organs available, and people's attitudes toward donation, methods currently used to retrieve organs, and the criteria used to

select donors will continue to constrain the volume of transplant activity.

At this time, I fear, there is no reason to expect a sudden long-term increase in the availability of donor organs. Thus, while we are concerned about, and must continue to concern ourselves with, the cost of transplantation procedures per se, I doubt that the total economic burden imposed on the health care system by several hundred extrarenal organ transplants will be excessive. This is immediately obvious when we consider the fact that there are other very costly medical conditions that are routinely treated in this country and are reimbursed for by medicare, medicaid, and private insurers.

For example, there are numerous neoplastic diseases which are often treated at great expense and covered, even though the prognosis for patients with these conditions is very dismal.

While donors, financing, and access to care should all be matters that concern us today, I feel an equally compelling concern about the financial status of patients following transplantation. We can speak of medical treatment expenditures, but we should also keep in mind that not all transplant recipients are able to return to work and, consequently, become dependent upon various income maintenance programs such as the social security disability insurance benefits program.

Preliminary results from our research on end-stage renal disease reveals that 39.0 percent of the kidney transplant recipients in our study receive income support through the social security program—as compared with about 60 percent of the dialysis patients.

Excluding these benefits, about 26 percent of the kidney transplant recipients had family incomes below the one-person household poverty line. Once social security benefits are added to the total family income, this figure falls to 14 percent. In the general population, about 10 percent of all households have incomes below the one-person poverty line—$4,620.

In conclusion, if I were to stop today and reflect on my own testimony, I think several conclusions are obvious. First, we, as a society, and you, as concerned legislators, must be commended for our unparalleled compassion and our irreproachable intentions to satisfy basic health care needs. The problem, however, is that we must somehow make our compassion consistent with the constraints within which we live. Human life, indeed, is hypothetically priceless, but we cannot deny that significant costs, economic and social, are incurred to assure our very survival. Thus, we should recognize the generic nature of the issues we are confronting today.

[Testimony resumes on p. 68.]

[Dr. Evans' prepared statement follows:]

ORAL TESTIMONY PRESENTED BEFORE THE SUBCOMMITTEE
ON HEALTH AND THE ENVIRONMENT OF THE COMMITTEE
ON INTERSTATE AND FOREIGN COMMERCE
U.S. HOUSE OF REPRESENTATIVES

July 29, 1983

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The views expressed here are those of the presenter and do not necessarily represent the views of the Battelle Human Affairs Research Centers nor the Battelle Memorial Institute.

Mr. Chairman and Members of the Committee:

I have been asked today to consider the financing of organ transplant procedures in the U.S. While I intend to do this, I will also discuss several other issues which directly or indirectly impact upon the question of payment.

As you are probably aware, I am directing two major studies concerning organ transplantation--they are the National Heart Transplantation Study and the National Kidney Dialysis and Kidney Transplantation Study. Both studies are funded by the Health Care Financing Administration. The major objective of the heart transplant study is to examine the impact of a potential coverage decision on beneficiaries, the Medicare program, and health care providers. The major objective of the kidney study is to comparatively assess the quality of life of end-stage renal disease (ESRD) patients currently being treated by in-center hemodialysis, home hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation.

In recent months, the financing of organ transplant procedures has been the subject of both considerable attention and concern. There have been several highly publicized cases where private insurers have refused payment for organ transplants and federal or state programs have stepped in to assist the patient. This has proven to be very controversial and it has become evident that a uniform plan of action does not exist to deal adequately with the financing problem.

While the availability of cyclosporine has spurred much enthusiasm within the transplant community, and given much hope to patients with various end-stage diseases, this enthusiasm has been dampened by the lack of two vital resources--money and donor organs. Both, unfortunately, are likely to limit the number of persons who will benefit from organ transplantation.

Donor organ procurement has been the subject of much discussion over the past several months, as it has been here today, but the financing of organ transplants was specifically excluded from consideration at both the Surgeon General's Workshop on Solid Organ Procurement and the National Institutes of Health Liver Consensus Development Conference. Today, however, we must face this issue head-on because, all things considered, payment of organ transplants, in my estimation, epitomizes the very questions of resource allocation and rationing which our society must face in the very near future. Resources, economic and human, are limited and must be put to the wisest uses possible, thus, necessitating prudent decisions about how the health care dollar will be spent. I think we can all agree that individuals suffering from catastrophic diseases can no longer be placed at the mercy of the health care delivery system.

We are here today because of the success of organ transplantation. The survival rates of the recipients of all organ transplants have improved considerably over the years. Among patients receiving cadaveric kidney transplants, it is expected 59 percent will live at least five years. Among extrarenal transplant recipients, it is now expected that approximately 50 percent of all those receiving hearts will live five years or longer. A combined analysis of liver transplant recipients at four major centers in the world reveals that, of those with neoplastic disease, 12 percent will live three years, while 30 percent of those with non-neoplastic disease will do so. At Pittsburgh, where the best liver transplant results have been achieved, Dr. Thomas Starzl and his colleagues predict that, with the use of cyclosporine, 60% of all liver transplant recipients will live three years. Dr. David Sutherland and his colleagues at the University of Minnesota, the

most active pancreatic transplant center in the world, are reporting patient survival to be 84% at one year with graft survival at about 25%. Dr. Stuart Jamieson and his colleagues at Stanford University Medical Center have completed 14 heart-lung transplants, of which 11 are still living.

Substantial gains have also been made in areas other than mere patient survival. In particular, the rehabilitation of most transplant recipients, a highly selected group, compares very favorably with those of persons who have undergone coronary revascularization, and is actually superior to that of renal dialysis patients. The unspecified rate of rehabilitation among transplant recipients now approaches 85% for heart, liver, and pancreas patients, is about 89% for kidney transplant recipients, and is described as "most satisfactory" for heart-lung transplant recipients.

With improvements in patient survival and rehabilitation has come a substantial increase in the number of transplants performed in the U.S. and abroad. In calendar year 1982, in the U.S. alone, 5,358 kidney transplants were performed, 103 heart transplants, 62 liver transplants, and 35 pancreas transplants. Worldwide over 725 heart transplants, 540 liver transplants and 260 pancreas transplants have ever been performed. The bulk of these procedures have been performed in the U.S.

As I have already noted, however, there is a tremendous disparity between the need for organ transplants and the availability of donor organs. Unfortunately, while the data on which estimates of need and supply have been based are woefully inadequate, I can at least provide you with some insight into this problem. The Health Care Financing Administration now estimates that between 6,000 and 7,000 patients on renal dialysis are awaiting kidney transplants. Last year, 3,691 cadaveric kidney transplants were performed in

the U.S. Depending upon patient selection criteria, it is now estimated that between 1,000 and 75,000 people are in need of heart transplants, yet given last year's pool of kidney donors, only about 1,000 viable donor hearts would have been retrieved under the best of retrieval efforts. The American Liver Foundation currently estimates that between 4,000 and 5,000 people could benefit from liver transplantation, yet assuming all kidney donors could also have served as liver donors, only about 1,800 livers would have been retrieved last year. Dr. David Sutherland estimates that between 5,000 and 10,000 people each year could benefit from pancreas transplants, although there are over one million insulin-dependent diabetics in the U.S. Stringent patient selection criteria, of course, limits the number of diabetics that would benefit from pancreas transplants. Once again, however, the number of viable pancreata for transplantation is severely limited, perhaps, no more than 1,800 under the best of circumstances.

Based on the foregoing, I think the conclusion that must be reached is clear: the supply of donor organs will never be sufficient to meet the need. Consequently, not everyone who could potentially benefit from a transplant will do so. Difficult decisions must inevitably be made about who will benefit. The legal and ethical implications of these decisions are the subject of research in the National Heart Transplantation Study.

Now let me turn my attention to the cost of transplantation and the financing thereof. Computing the cost of a transplant procedure is far more complicated than it would first appear. Moreover, we should view the cost of a transplant procedure as only one part of the total cost of treating various end-stage diseases--renal, cardiac, and hepatic. In short, we must recognize that even without a transplant, patients with end-stage disease are expensive

to treat. In other words, traditional medical management of these patients is not without cost. In fact, I would argue that the cost of a transplant procedure must be viewed as the marginal added cost of treating the patient over and above what would be required to care for the patient otherwise. In this regard, a relatively simple cost model can be used to depict the cost of a transplant. This model would contain several elements of cost including the following: (1) pretransplantation costs, (2) transplant evaluation costs, (3) transplant procedure costs, (4) donor organ procurement costs, and (5) posttransplant costs. Within this scheme, the cost of the transplant is viewed as all transplant costs minus the pretransplantation costs. Unfortunately, no analysis of organ transplant costs sufficiently accounts for each of the elements of cost I have described. Thus, all transplantation cost analyses, to date, have been limited and do not accurately depict the cost of end-stage disease per se. In the National Heart Transplantation Study we intend to correct this deficiency by looking at patients who have end-stage cardiac disease but do not receive transplants.

Based on the available data I can, nonetheless, provide a range of costs for kidney, heart, liver, pancreas, and heart-lung transplants. A kidney transplant is estimated to cost between $25,000 and $35,000, a heart transplant between $37,000 and $110,000, a liver transplant between $54,600 and $238,000, a pancreas transplant between $18,000 and $50,000, and a heart-lung transplant between $78,000 and $92,000. There are several factors that account for this rather extreme range of costs. They include: (1) postoperative complications and length of hospital stay, (2) hospital room charges, (3) the assessment of surgical fees, and (4) the availability and use of cyclosporine. Room charges vary considerably from hospital to hospital,

some transplant surgeons assess fees and others do not, and cyclosporine has been shown to reduce the cost of transplants. At Stanford, for example, Dr. Edward Stinson and associates report a reduction of about $45,000 in the cost of a heart transplant.

Ultimately, I think we must recognize that a true cost savings can be realized only if a decision is made not to treat patients upon the diagnosis of an end-stage disease. Once the disease has been diagnosed, and palliative treatment efforts initiated, a certain cost is associated with the disease. I doubt, however, that many physicians, patients, and families of patients are willing to sit idle once an end-stage disease is recognized, regardless of how dismal the prognosis. This underscores the importance of my observation that the cost of a transplant procedure must not be separated from the cost of the disease itself.

As I have already noted, payment for transplant procedures is by no means uniform or consistent. While heart, liver, and pancreas transplants are considered experimental under the Medicare program, kidney transplants are paid for by Medicare but are subject to a coinsurance deductible. Medicare is paying for 15 heart transplants under the National Heart Transplantation Study. Nevertheless, several heart and liver transplants have been covered under various state Medicaid programs following denial of reimbursement by private insurers. Private insurers routinely pick up the coinsurance portion of kidney transplantation procedures, but most private insurers, following the lead of the Medicare program, consider heart, liver, and pancreas transplants experimental. Dr. David Sutherland has informed me that some private insurers have paid for pancreas transplants, subject to a 25% coinsurance. Also, some private insurers have paid for heart transplants subject to a 20% coinsurance,

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while others choose only to reimburse for a portion of the expenses associated with heart transplantation. For example, a claim may be reviewed and the patient reimbursed for all expenses considered to be not specifically required for the transplant. In such instances, the insurer assumes that the patient would have been hospitalized anyway and, thus, for example, the room charges would be reimbursed. But, in the case of a heart transplant, a procedure such as an endomyocardial biopsy would not be covered since this would be considered a purely transplant-related expense.

To meet the expenses associated with a heart or liver transplant, many patients and families engage in public fund raising efforts. Many transplant centers now require "up front" money or assurance from insurers that a preset amount will be paid before they perform a transplant. Thus, in some instances, patients and families who find the cost of transplant beyond their financial means have been forced to "go public" to derive the financial support they need to gain entry to a transplant program. Some liver transplant programs require an assurance of as much as $140,000 "up front" before they will proceed with a transplant. A similar requirement is made by several heart transplant programs, where an expectation of $43,000 to $125,000 is not unreasonable.

While heart, liver, and pancreas transplants are not paid for under the Medicare program, all of these procedures are currently under review by the Health Care Financing Administration or the Public Health Service's Office of Health Technology Assessment. The latter agency reviews health care technologies and makes reimbursement recommendations to the Health Care Financing Administration. Quite surprisingly, although the results of heart transplantation are superior to those of liver transplantation, the recent

National Institutes of Health Liver Transplantation Consensus Development Conference concluded that liver transplantation is therapeutic. This consensus statement does not imply that federal programs nor private insurers will necessarily reimburse for liver transplants. A separate Public Health Service report concerning reimbursement is to be submitted to the Health Care Financing Administration by August 31, 1983. Since a decision on heart transplantation is pending until the completion of the National Heart Transplantation Study, it is difficult to envision that a coverage determination on liver transplantation will be forthcoming until the heart transplantation issue is resolved although, I suppose, an interim decision could be made.

The tremendous disparity between the need for organ transplants and the availability of donor organs will certainly limit what might be called the total program expenditures associated with extrarenal organ transplant procedures. There are simply too few donor organs available, and people's attitudes toward donation, methods currently used to retrieve organs, and the criteria used to select donors will continue to constrain the volume of transplant activity. At this time, I fear, there is no reason to expect a sudden long-term increase in the availability of donor organs. Thus, while we are concerned about, and must continue to concern ourselves with the cost of transplantation procedures per se, I doubt that the total economic burden imposed on the health care system by several hundred extrarenal organ transplants will be excessive. This is immediately obvious when we consider the fact that there are other very costly medical conditions that are routinely treated in this country and are reimbursed for by Medicare, Medicaid, and private insurers. For example, there are numerous neoplastic

diseases which are often treated at great expense even though the prognosis for patients with these conditions is very dismal.

While the financing of organ transplant procedures should be a primary consideration in planning for the future of transplantation, another concern I have today that will truly impact upon the cost of transplantation is the potential proliferation of transplant programs across the U.S. There are now approximately 150 kidney transplant centers, 10 heart transplant centers, 4 heart-lung transplant centers, and 4 liver transplant centers. Last year about four medical centers in the U.S. performed one or more pancreas transplants. As you might expect, these centers are not mutually exclusive. While a large number of centers improves access to transplantation for patients in need, it may actually contribute to higher overall program costs because staff and facilities are duplicated at many locations across the country. Therefore, an appropriate question at this time may very well be, how many centers are necessary to optimally meet the need for transplantation while at the same time imposing the least economic burden on society?

The literature on the regionalization of medical care shows that there are certain benefits derived from limiting the number of locations at which particular types of specialized care are provided. For example, in the organ transplant field, we might expect to find higher survival rates, a better quality of care, lower costs, and increased patient satisfaction at transplant programs that, for the lack of a better term, could be called centers of excellence. These centers have appropriate and well-trained staff, excellent physical facilities, and a track record in organ transplantation. Constraining transplant activities to a smaller selected group of centers may ultimately limit access for some transplant candidates but, at the same time,

assure the patients who receive transplants the best possible outcomes at the lowest overall cost. As transplant procedures are perfected, and patient management becomes routine, then consideration might be given to increasing the number of centers involved in transplant activities.

There is still other reason to consider limiting the number of organ transplant programs. This has to do with the availability of donor organs and their acquisition. As I have already noted, the number of donor organs available, particularly extrarenal organs, is disconcertingly small. Thus, if there is a large number of extrarenal transplant programs, it will be exceedingly difficult to allocate the available organs. In effect, transplant centers, and indirectly patients, would be competing directly for organs. Since the matching of extrarenal organs to potential recipients is relatively unsophisticated at this time, unlike it is for kidneys, matching will not serve as a good basis for allocating organs to patients. Consequently, given a large number of transplant programs, complex procedures would have to be developed to distribute the available organs in some equitable and fair manner. Currently, these procedures remain undefined.

I am also concerned about the logistics of donor organ acquisition. Once excised from the human body, organs are viable for relatively short periods of time. The kidney is viable for the longest period--about 72 hours. Yet, for other organs such as the heart, what we call the mean ischemic time, that is, the time the organ can be out of the circulatory system and yet remain viable, is approximately 3.3 hours. This means that for extrarenal organs, the time period between the excision of the organ and transplantation into the recipient is extremely short and must be minimized to every extent possible. Yet when we consider the geographic distribution of extrarenal organ

transplant centers, it is likely that viable organs may be wasted unless the donor is transported to the transplant center. For example, there is not sufficient time to remove a heart from a brain dead cadaver in Missouri and transport it to the Stanford University Medical Center to be transplanted. Thus, the geographic distribution of transplant centers will necessarily affect the number of viable donor organs that can be used. In addition, the distribution of centers will necessarily affect the costs associated with organ retrieval.

Finally, while donors, financing, and access to care should all be matters that concern us today, I feel an equally compelling concern about the financial status of patients following transplantation. We can speak of medical treatment expenditures, but we should also keep in mind that not all transplant recipients are able to return to work and, consequently, become dependent upon various income maintenance programs such as the Social Security Disability Insurance Benefits Program. Preliminary results from our research on end-stage renal disease reveals that 39.0% of the kidney transplant recipients in our study receive income support through the Social Security Program (as compared with about 60% of the dialysis patients). Excluding these benefits, about 26% of the kidney transplant recipients had family incomes below the one-person poverty line. Once Social Security benefits are added to the total family income, this figure falls to 14%. In the general population, about 10% of all households have incomes below the one-person poverty line ($4,620).

In conclusion, if I were to stop today and reflect on my own testimony, I think several conclusions are obvious. First, we as a society, and you as concerned legislators, must be commended for our unparallelled compassion and our irreproachable intentions to satisfy basic health care needs. The problem,

however, is that we must somehow make our compassion consistent with the constraints within which we live. Human life, indeed, is hypothetically priceless, but we cannot deny that significant costs, economic and social, are incurred to assure our very survival. Thus, we should recognize the generic nature of the issues we are confronting today. Organ transplantation is but one technology available to treat a specifically defined subset of catastrophic diseases, but there are children, women, and men in medical facilities across the country with a variety of other medical conditions that could also benefit from increased economic allocations for health care. Do we not share the same compassion for them? Aren't we also concerned about their fate? With these thoughts in mind, I think the question is not whether or not transplants should be performed but, rather, the questions should be where and how many should be performed given competing health care needs.

Mr. WAXMAN. Thank you for your testimony.

CBO estimates that a Federal program to pay for a heart transplant program could equal $1.5 billion a year and a liver transplant program could cost $400 million a year.

How much of these costs will be assumed by private health insurers when and if transplants are accepted as routine medical care, and do you believe there is a need for Federal end-stage heart disease or end-stage liver disease programs?

Dr. EVANS. First of all, the estimates that they have are probably on the low side, given some other estimates that have been made available, projections based on transplant activity. For example, at Stanford, the figures they had were $212 million per year. Those figures are subject to a lot of interpretation because of the poor estimates we have of the number of people requiring the procedures, the number of donor organs available, and the number of procedures the center could perform in a given year.

The figures are not terribly realistic, but they could be higher than that.

One of the other questions you have asked is, is there some need for a Federal program in this area? I think there is a clear need for us to do something about the problem. If we are going to allow transplant activity to go on, then there ought to be some kind of support for it. Presently, that support is lacking.

If we were to regionalize programs, have selection criteria by which patients were admitted to those programs, we could constrain the level of that activity and perhaps both private insurers and the Federal Government would be able to cover the cost of those procedures, and perhaps Dr. Young could speak to that, but the problem has been that there has been an awful lot of public attention, people having to go to the public to raise funds.

The policies are terribly inconsistent and very difficult to deal with for the families of the patients, as well as the physicians.

Mr. WAXMAN. Dr. Young, I want to ask you specifically a question about the representative national body you think should advise whether and on what terms society should support new medical procedures.

How could such a body help you at Blue Cross in Massachusetts?

We used to have such an agency in the National Center for Health Care Technology and its National Advisory Council, and you have indicated your support for the reestablishment of the National Center, which we fully agree with you about.

Dr. YOUNG. From Massachusetts' point of view, we do have a rather complex, sophisticated method by which we evaluate these.

We have an assessment committee, some 38 physicians supported by 7 additional each, total of 265 from around the State.

We meet once a month and evaluate new procedures, such as heart, livers, et cetera.

We do that for Massachusetts, but my concern in addressing this issue to you is that we are one of the few that has such a sophisticated system set up. The National Center for Health Care Technology Assessment did have a mechanism by which they would bring together the broad scope for the entire country.

We can look to them for assistance for our local committees and still make local decisions that are appropriate for our own local

areas such as Massachusetts, but they could set the stage for a more broad issue.

I would like to address another issue. There is a bucket which the insurers have which contains benefits that they let out certain amounts for their particular subscribers.

The ones that are excluded are the experimental.

However, there is another group that I think, as far as procedures are concerned, that needs to be addressed, and that is the investigatory, and this is what we are talking about when we talk about heart, lung, heart and lung.

We have heard today Dr. Shumway has an NIH grant that supports his heart program. If a third-party payor began to get into that, for how much is the third-party payor responsible? The cost controls that are necessary do not permit unbridled growth in that particular area, and NIH has such grants and cost control.

As third parties, we are trying to address that issue, because we feel it is a responsible way to go to attempt to do something about the investigatory aspects, and we have a large commission in Massachusetts that is going to be addressing from the point of view of society this broad scope of issues.

We stand ready to go ahead and put our shoulder in and do whatever we have to in order to move the issue and try to get it accomplished to a satisfactory conclusion.

Mr. WAXMAN. Dr. Prottas, what should the Federal Government do to encourage the establishment of stronger local procurement agencies? Could Federal development grants help encourage local areas develop strong independent agencies?

Dr. PROTTAS. I don't think the first way to go is to try to make all of the 110 agencies we presently have, stronger. I think that they have inherent problems having to do with simply being on too small a scale to do the job properly.

Most of these agencies do not, in practice, operate under serious financial constraint, since they can be reimbursed 100 percent of their costs.

The problems they have are more questions of expertise, independence, and skill.

Certainly, the Federal Government, since the Federal Government is, in fact, supporting the system completely, as it stands, they certainly have a reason to be concerned if they get their money's worth.

Mr. WAXMAN. Thank you.

Mr. Luken.

Mr. LUKEN. Dr. Young, in Massachusetts, your organization, Blue Cross of Massachusetts, do you cover the cost of liver and heart transplants?

Dr. YOUNG. At this moment, we do not.

Mr. LUKEN. What would it require for your organization to cover heart and liver transplants? Could you say at this time?

Dr. YOUNG. I can make a good approach at it, I hope.

If you are talking in the area of insurance, and this is what we have to talk about with this, the problem has to be that Massachusetts Blue Cross and Blue Shield would have to have enough of a spread of all of the organizations that subscribe with them to spread the costs for the small catastrophic individual instances we

are talking about; namely, we have to have enough people in that large pool to be able to say $230,000, $110,000, could be withdrawn from that for individuals in that pool.

The freedom-of-choice issue is significant when it comes to certain of the major accounts, or even the minor accounts, the individuals.

They can choose not to pick that up.

Therefore, there is an uneasiness about the breadth of how you can cover the most number of people. This has been one of the problems, I think, of making third parties reluctant to get into this, because I have been told by the actuaries essentially it is not an insurable item unless you have a large huge group that you can amortize those costs across and, even so, they are rather expensive.

Mr. LUKEN. Your only consideration is financial? I believe that is all you have been talking about.

Dr. YOUNG. I think there are some significant areas. With that particular committee of doctors that we take our advice from, they have considered the issue of whether heart transplants or liver transplant is investigational.

Recently, there is an article that has come out in Groote Schur, Christiaan Barnhard, 10 percent have developed some type of malignancy within 3 years, and they were not on cyclosporine. Cyclosporine was used in England, and there were 4 cases that developed some malignancy out of 33 cases. There are issues with some of these suppressive drugs that are a problem.

The quality of life for some of the people, some articles indicate some people spend 50 percent of their next year in and out of the hospital.

There is a lot of issues that are not alone financial.

In children, you have transplanted them and put them on a——

Mr. LUKEN. If I can interrupt just a moment. When you were describing the considerations for your organization in changing its policy, defining it as experimental or routine or ordinary. You did not mention these, and how would you evaluate these quality-of-life issues? How would you weigh them?

Dr. YOUNG. That is where we are asking for help from a large group of people who are responsible to address that issue.

In other words, physicians alone are not capable. Insurers alone are not capable, and we are asking that perhaps revisiting the issue of renal transplant or renal dialysis that was done in Washington, where they had to have a group of individuals who choose which individuals were or were not on dialysis.

Mr. LUKEN. You mean reviewing it?

Dr. YOUNG. Yes, same issue.

Mr. LUKEN. Dr. Evans, I thought his material was especially good and comprehensive on these questions of national policy, and what he seemed to be saying, from a medical standpoint, at least heart and liver. He points out the contradiction, that heart seems to be further along, but the liver, the defining process, is further along. Maybe those two will catch up, but in any event, from a medical standpoint, as I heard his testimony and read it, he would say they are not experimental. But he did not say that, therefore, medicare should establish—a national policy; or we should pass legislation saying that it is not experimental. He did not say that, did he?

Dr. YOUNG. No; I didn't hear him say that.

Mr. LUKEN. Would you say that?

Dr. YOUNG. I don't think that legislative action should define experimental versus nonexperimental. I did make the comment previously that there are three different levels: experimental, acceptable, or standard, and the one in between, which is investigatory, and that is where heart and liver are.

Mr. LUKEN. Dr. Evans made a very good point: neoplastic diseases are just as cataclysmic, just as expensive, and just as precarious; right?

Dr. EVANS. Right.

Mr. LUKEN. Yet they are routinely covered.

Dr. EVANS. This is a point that was made, indeed.

Mr. LUKEN. Isn't this a contradiction?

Dr. EVANS. I don't think it is a contradiction. I think the question is that, if we are going to talk about paying for certain procedures, covering them, we have to compare it with something.

We happen to pay through the medicare program for kidney transplants. That is a benefit.

My question is, How do other procedures compare in terms of their benefits with other procedures that are currently covered, and what the testimony showed that in terms of heart transplant, the comparison is fairly equal, certainly less equal in the case of liver transplantation in terms of patient survival.

Mr. LUKEN. Equal to renal?

Dr. EVANS. Yes; if I happen to be a cardiovascular surgeon, and I was raising that issue, to make that comparison directly and say the medicare is paying for these procedures, but it is denying it to liver transplant patients, and the results are different.

Mr. LUKEN. Medicare has some catching up to do.

Dr. EVANS. One has to raise these concerns about payment for procedures, and when I talk about neoplastic disease, and take pancreatic cancer as a good example: A patient, their expected survival is about 6 months at the point of diagnosis, and it fits well with the diagnosis of end-stage cardiac disease, but that person would be covered under most insurance plans, in the medicare program.

Mr. LUKEN. Let me understand this. We should drop this objection because it is a transplant and just consider it as any other procedure on the medical questions which you have outlined; whether it is neoplastic disease or renal or heart, the same considerations should be applied, the medical considerations, survivability, quality of life; they all should be considered on the same basis?

Dr. EVANS. Right; and there should be some comparison across those.

The idea of health care technology assessments that allow us to make those comparisons and then make decisions about how to allocate funds to programs, is necessary, and what are we going to do about all people with catastrophic disorders?

Mr. LUKEN. I can't argue with that.

I have no more questions.

Dr. EVANS. Thank you.

Mr. WAXMAN. I might point out that the National Center for Health Care Technology was authorized by this committee originally, and we fought for it in 1981, but the Reagan administration

came to the Congress and provided no funds whatsoever for it. We are trying to have it be established under the National Institutes of Health legislation, which, by the way, will be on the floor next week, and, guess what, the Reagan administration has a different version which does not include funding for that.

Let me thank the three of you for your participation in this hearing.

Our final panel was to consist of three of our colleagues. Unfortunately, Dan Marriott, from the State of Utah, is not able to be with us, because he has an amendment on the House floor.

I ask unanimous consent to include CBO estimates and other relevant materials in the record. [See p. 80.]

We are pleased to welcome two of our colleagues, Congressman Dan Glickman and Congressman Charles W. Stenholm, to present their testimony.

STATEMENTS OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS; AND HON. DAN GLICKMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. STENHOLM. I am pleased to have this opportunity to testify before you and Mr. Luken today on the subject before you.

Listening to the previous panel, I found it very interesting with some of the problems that we have experienced in the past 2 months, and I don't envy you your job.

You have also heard from other witnesses today who have presented the need for a better coordinated national organ transplant system far more eloquently than I could ever do today.

To those families represented here who have lived with the fear, frustration, and financial problems that accompany the pain and suffering of patients waiting for organ transplants for a chance at life, I can only offer my own personal commitment to work in any way possible to improve methods of dealing with organ procurement.

I offer, as well, my very deep gratitude to the parents of five children whose deaths this week might have escaped public attention nationally had not those parents made the decision to offer the chance of life to other children. They are the very real, unheralded heroes. Their unselfish gift of life will be long remembered by all of us who have worked on behalf of those tiny transplant patients for the past few months.

I don't have any magic solution to the problems you have heard outlined here today. I can only share the experience of one congressional office and one family we have come to know well during the past 3 months. The family of 11-month-old Ashley Bailey contacted me in early May to assist them as they wandered through this complex maze that we currently have in organ procurement. Members of my staff and I worked as liaison between the Department of Health and Human Services, the Texas Department of Human Resources, the Texas Legislature, the Texas Governor's office, and the White House, as the first hurdle—funding problems—were overcome.

From that point until today, two members of my staff have worked extensively with the Baileys to try to bring national attention to Ashley's need, that of a liver. We have made that nationwide plea, ultimately carried by the President, himself, this past weekend, knowing that there has to be a better way for the future. The media and the American public tire quickly of the "same old story" or, as one television network told us, "we are about 'livered' out."

The families of these children, watching other children die as they wait for the traditional procurement system to work, are desperate to try anything that might possibly mean a chance at life for their child, just as I know I would be desperate in their place.

As Annette Bailey, Ashley's mother, has said,

> It is the waiting that is the hardest. To get over obstacle after obstacle and just see Ashley slipping away while there is nothing we can do.

As I said earlier, there is no simple answer to the many, many problems we face as transplant procedures improve. I commend the thorough work done by my colleagues on the Investigation and Oversight Subcommittee of the Science and Technology Committee. Their study of this complex area of medicine deserves recognition, and I look forward to that group's recommendations, as I know you do.

Knowing that this body will give the subject equal study, I would not presume to offer a premature legislative solution, but would look to you for the needed direction. If my office's personal experience can be of any help to you as you work toward a more viable national transplant network, we will certainly be pleased to share our experience with you.

I have only one other comment to make today. Many, many times over the past 3 months, I have been asked about the fairness of a Congressman or the President, working to draw attention to just one of these children, when there are many others of equal need.

I would point out that since the President's plea Saturday, there have been four or five liver transplants—news reports differ—for small children at the three major transplant centers in this country, and another is underway in Louisiana right at this moment; Ashley Bailey is not one of those children—yet.

I think the parents of each of those children, if they could be here today, would be the first to tell you that public attention desperately needs to be drawn to these children, whenever and by whomever it can be drawn. But our time is running out and the effectiveness of public appeals of any sort as the only means of dealing with this problem is not the answer.

I strongly believe we need a nationally coordinated procurement system; strong emphasis needs to continue to be placed on educational programs for physicians and others involved in emergency care; and most certainly, a voluntary national public awareness program needs to be undertaken that, in time—and it will take time—will make transplants an automatic consideration by parents and loved ones whenever there is a death in this country.

Again, I wish this committee every success in these deliberations. And I also hope you all find time to say a prayer for Ashley Bailey tonight.

I do offer my services, and that of my staff.

I would answer three questions you asked earlier today, Mr. Chairman.

First, can we do a better job of assuring that available donors and recipients are efficiently matched? I would have to answer, most definitely we can. Ashley, even though she was on the Minneapolis University Hospital priority list, and had two previous mentions by the President of the United States, Ashley Bailey was not included on one of the main computer donor lists until just about 2 weeks ago.

Whether or not this would have made any difference or not, we will never know, but, to the family, it made a big difference.

Second, is there a more effective means of locating effective donors from national television? There most certainly has to be.

Third, how can the high cost of transplant technology best be financed? That is one question which I do not have an immediate answer for you, but I was very interested in the testimony of the three previous panelists.

Mr. WAXMAN. I commend you for that very excellent statement. Thank you for being with us.

STATEMENT OF DAN GLICKMAN

Mr. GLICKMAN. My statement is very short. I have been interested in this issue, and not only because we had a young child in Kansas, Julie Borher, who needed a transplant. I drafted an amendment to the Justice Assistance Act, which was approved by the House approximately 2 months ago, which sought to see that to law enforcement officials are sensitive to and aware of procurement issues of organs, because often they are the first ones to come to the scene of an accident, a case of trauma, find the organs and have them part of the process, to identify organs for transplanting purposes, but I don't think the current situation can go on much longer.

We can't continue to rely on happenstance, nor the current policy of the possibility of an Air Force plane being made available. That is the current national organ bank, if the President gets interested and Air Force I or a Lockheed Jetstar becomes available, they help.

Your committee has a bill coming to the floor, H.R. 2350, the Health Research Extension Act, and this could be a timely opportunity which should not be passed up. It is a bill I support.

This bill provides all sorts of emergency medical services and treatment for cancer, heart, blood vessel, lung diseases and section 407(b)(1)(G) directs the NIH Director to cooperate with and assist the Federal and State agencies charged with protecting the public health.

We should knock heads and think about preparing some language to that bill to direct the NIH to establish within a set timeframe at least a Federal information network along the lines of

what Congress directed the Justice Department to do with regard to missing children.

I know there are certain things that we might do in this area, for example, grants to local communities, but there is absolutely no reason to delay on this simple step which all of us can agree needs to be taken.

I thought I would bring to the attention of the committee my views on the issue as well.

Mr. WAXMAN. What I think might be most appropriate for us to all work together to figure out legislation that must be passed this year, and in the short period of time we have between now and next week when the bill will be brought up, I am not sure we can address all the problems, and let's look at it between now and then, and if it does not seem feasible or reasonable to offer an amendment at that time, let's all get together and offer a bill and have our colleagues join us in doing something to address those problems that Mr. Stenholm so adequately pointed out that we must address.

Thank you for being with us.

That concludes the business of the subcommittee, and I wish to thank everybody for participating and for being with us.

We stand adjourned.

[Mr. Marriott's prepared statement follows:]

TESTIMONY OF HON. DAN MARRIOTT

Mr. Chairman: Thank you for the opportunity to appear before the committee today to testify on behalf of the thousands of persons seeking organ donations in order that they may lead fruitful, productive lives. It is on their behalf that I thank you for holding these hearings today.

In particular, I wanted to appear on behalf of young Clayton Conger of Rock Springs, Wyoming, a four year old hospitalized last week at the University of Utah Medical Center. Fortunately, Clayton is one of the lucky ones. He is the recipient of a liver donation and is now recovering from his operation performed just Wednesday, July 27th. I know that everyone in this room today, those of us who really care, and the millions of Americans pulling for Clayton and the other liver transplant patients, wish them a speedy recovery.

But this week made it even more evident that it is still time that we focus our attention on the plight of those still waiting for organ donations.

The bottom line, Mr. Chairman, is that our system of organ transplants is growing—growing every day. As medical technology advances, the remarkable organ transplant operations are becoming very successful and more numerous. But, while the medical and scientific communities have developed their techniques, it is apparent that the systematic organization of a "donor bank" is trailing far behind technologies.

Waiting for organ donations are thousand of individuals, who without the access to media publicity, do not have easy access to available organs for donation.

There are several problems confronting these patients today, and I would like to touch upon each one briefly.

First, as I am sure you know, the donor awareness program is very poor. Even medical technicans working in hospital emergency rooms across the United States, are not pushing the need for vital organ donations. I am pleased that Rep. Morrison of Washington has initiated "Organ Donor Awareness Week" and feel that this is a vital step towards the availability of organs for transplant. It is essential that the medical community make each and every American aware of the life he can save when he or one of his loved ones meets an untimely death. No one individual, in his period of grief, remembers that his relative may spare the death of another living being in a state geographically apart from his. I clearly remember seeing one television documentary of a mother whose daughter was killed in a motorcycle accident, and who agreed to have her daughter's kidney transplanted to save a critically ill individual. She visited that individual not too long after the death of her daughter, and felt a sense of relief knowing that in dying, her daughter was able to give some-

thing of herself to another life. This publicity must be fostered. It is not that people don't want to donate—they aren't aware of the need. Nor are they tactfully reminded of the need at the time of an accident and/or death. This is the responsibility of the medical community. They must, perhaps with our assistance, get an "on-line" awareness program, not unlike the National Red Cross blood banks. In this regard, I look forward to the enactment of organ donor awareness week. Unless organs are available, successful medical technologies are worthless.

The second problem facing individuals in need of transplants are the costs of these operations. We have witnessed many heart-rendering stories of communities that have held rallies to raise the funds for upcoming operations. I applaud their efforts. But, as technologies advance and these transplants become more numerous, something has to be done. Otherwise, it will be those who can afford the organ transplant operations, who will be the ones who can afford to live. Mr. Chairman, this is not democracy.

The cost of a heart-lung transplant at Stanford University Medical Center is an estimated $150,000. I understand that $80,000 of that must be "paid in advance." This is a critical question, Mr. Chairman—"who pays?"

The third problem facing individuals in need of transplants is the lack of coordination between donors and recipients. It is basically a frightful mess. Management has certainly not kept up with technology.

What we have, Mr. Chairman, is a hit-or-miss program based on luck. Without media publicity a transplant patient must wait for his local transplant center to notify him of an available donation. In turn, the transplant center must compete with other facilities throughout the United States to secure that necessary and vital organ donation.

This is indeed an inequitable situation—one that can be remedied.

There are some 30,000 Americans whose sight has been severely impaired by corneal disease or injury. That sight can be restored by means of a corneal transplant operation—an operation that can only be done following the donation at death of a human cornea. In addition to these number of people who could have their sight restored by donor tissue, tremendous contribution can be made in the field of research.

There is an Eye Bank Association of America in Houston, Texas. It is in the process of setting up a computerized system for eye donation referrals at Emory University in Atlanta. I applaud their efforts. There are currently 23 eye banks in the country. There is one at the University of Utah in Salt Lake City. But these banks do not have the dollars to hook up to the system.

At the University of Utah, alone, there are now 50 people awaiting corneas. And, the only way of securing one is to call the other 22 Eye Banks and hope for a hit-or-miss opportunity.

This is the closest central clearinghouse system that has been developed in the United States for donated organs. The rest of the story goes downhill.

There are many organ transplant centers. The University of Utah is the site of the Intermountain Transplant Center for Kidneys. While officials there hope to expand and can foresee transplants in the future of heart/lungs, livers, pancreas, etc., persons in this region must rely on one of the other transplant centers for these types of organs.

There is another organ transplant network started in Richmond, Virginia. This is called the united network for organ sharing. But right now, they are established only for kidney referrals.

There are no other central clearinghouses for any other organs!

Yes, there are three liver transplant centers—in Pennsylvania, Nashville, and at the University of Minnesota. These centers are the ones that compete for organ donations. As more and more hospitals throughout the country become efficient in liver transplant operations, more and more institutions will be competing for the limited number of organ donations. As technology advances, the demand will only increase.

The solution?

Mr. Chairman, we must build a central referral center. We must have a professional system of evaluating how organs can best be utilized. It must be computerized and every transplant center and hospital in the United States must be able to plug into it. As the system will already have on file a list of organ needs, when a donation is made, the institute can immediately contact the system and non-bias referrals can be made, based on a qualified match between donor and recipient. This referral center, or clearinghouse, not the transplant centers, will become the means for determining the supply/demand question.

This is the solution, Mr. Chairman, and it should be a high priority for the U.S. Congress to address.

What I advocate is that there should be a partnership between government and hospitals to get the central organ donor center established. Once it is established, the responsibility of its operation should be transferred to the private sector.

I will work with you, Mr. Chairman, and the members of your committee and the members of the Science and Technology Committee, Chairman Albert Gore, and the Surgeon General of the United States, Dr. Koop. We all realize the need for prompt action.

Today is a first step. But, Mr. Chairman, it is a great step and a vital one in meeting the needs of our expanding medical technology and a giant step in saving lives.

Thank you, Mr. Chairman.

[Whereupon, at 2:10 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

[The following statements were submitted for the record:]

Greater Cincinnati Hospital Council
1811 Losantiville Avenue, Suite 450, Cincinnati, Ohio 45237, Phone 513 631-0200

Statement of the Greater Cincinnati Hospital Council to the Health Subcommittee of the House Committee on Energy and Commerce concerning Medicare Coverage for Heart Transplants
Friday, July 29, 1983

Lynn R. Olman
President

On behalf of the Greater Cincinnati Hospital Council, which represents 34 hospitals in Southwest Ohio, Northern Kentucky, and Southeast Indiana, the following comments are submitted regarding Medicare reimbursement for heart transplants.

First, the Hospital Council is certainly not opposed to heart transplants. Our concern about this topic is related to the funding for heart transplantation, which is a question of public priorities. Although advances in medical practice and technology are encouraged in our society, the use of limited public resources for these advances is a public policy issue that requires extensive discussion. Recognizing the shrinkage in the Medicare Trust Fund, it is essential to understand that if a new treatment or procedure becomes eligible for coverage under Medicare, the resources to fund it will, in all likelihood, be taken from an existing program. It is estimated that 40 to 50 percent of our population--the aged, dependent poor, children, and those with chronic disabilities--require extensive medical services for which they are unable to pay. We must remember that the scope of services to these groups would be at risk in the trade-off for Medicare coverage of heart transplants.

It is impossible to allocate scarce resources without hurting someone. It is also impossible to ignore the emotional impact of a person dying when the medical technology is available but the dollars are not. Every medical

decision cannot be made on the basis of the "greatest good for the greatest number," but neither should these decisions ignore such factors as the possibility of success or the post-operative quality of life.

It is helpful to look at the experience of Medicare's End Stage Renal Disease (ESRD) program when considering adding coverage for heart transplants under Medicare. In 1973, Congress removed the financial barrier by making ESRD patients eligible for Medicare, regardless of age or financial condition. More than 50,000 Americans now receive hemodialysis, and lead otherwise normal lives. The problem is cost: it quadrupled in the first six years, and is expected to reach 2.68 billion in 1985. This amount is 5 percent of the Medicare budget for .2 percent of the patients. The Hospital Council is not in any way opposed to treatment for End Stage Renal Disease. What must be kept in mind, however, are the financial and societal choices. For example, 2.68 billion would pay for 82.3 million office visits to an internist, 425,000 fetal monitors, 81 million out patient radiation therapy treatments for cancer patients, or many other services. In an era of limited resources, every expenditure is an implicit rationing decision. If the federal government decided that Medicare should pay for heart transplants, one might question whether these dollars could be more wisely spent on reducing risk factors for heart disease or for preventing some other malady that is prevalent among our population.

The choice to use Medicare funds for heart transplants creates medical, ethical, social, and political dilemmas for which there are no easy solutions. It is the position of the Greater Cincinnat Hospital Council that these decisions must be made after careful consideration and debate, and with the public's full understanding of the choices, costs, and consequences.

CONGRESSIONAL BUDGET OFFICE
U.S. CONGRESS
WASHINGTON, D.C. 20515

Alice M. Rivlin
Director

July 27, 1983

MEMORANDUM

TO: Brian Biles
Mike Genel

FROM: Lisa Potet

SUBJECT: Potential Costs of Organ Transplant Options

This memorandum examines federal policy options related to organ transplantation. The first section discusses the current federal payment for kidney transplants and options to expand benefits to kidney transplant recipients. The second section considers options provide federal benefits for transplantation of other organs, particularly the heart and liver.

The cost estimates presented below are subject to a large degree of uncertainty. For one thing, transplant technology is changing rapidly. In addition, little definitive data is available concerning the number of possible transplant recipients, the potential supply of donor organs, and the costs of transplants. Because of this uncertainty, the estimates presented here are intended to be illustrative and should be used very cautiously. In some cases, where information from experts varies widely, a range of estimates is provided.

FEDERAL PAYMENTS FOR KIDNEY TRANSPLANTS

Medicare's End Stage Renal Disease (ESRD) program currently provides benefits--including coverage of kidney transplant surgery as well as dialysis treatments--to about 65,000 individuals, at a cost of $1.8 billion for fiscal year 1982. About 90 percent of all patients on dialysis are eligible for Medicare benefits, and most kidney transplants performed--in excess of 5,300 in 1981--are financed by ESRD. Under this program, Medicare benefits for all Medicare-covered health survices are provided indefinitely to patients undergoing kidney dialysis, and for three years after successful transplant surgery.

Given recently improved transplant outcomes--one-year survival rates up from 50 percent to over 80 percent--and the growing number of dialysis patients, the number of kidney transplants is expected to increase. Experts believe that a rate of 10,000 transplants annually--about twice the current level--could be achieved five years from now. This is based on estimates that nearly 40 percent of patients currently on dialysis, and 8,000 of the additional 20,000 new dialysis patients each year are potential candidates for transplantation. 1/

Budget Impact of Additional ESRD Transplants

Analysis indicates that substitution of kidney transplants for dialysis could lead to savings for the ESRD program. Although the first-year costs for transplant recipients are higher than annual dialysis costs, transplantation is less costly than continued dialysis over a period of years. One estimate compares the five year per-patient costs of transplantation (including the costs of failed transplants) in 1979 dollars to be $70,000, as opposed to $100,000 for dialysis. With this differential the 5-year savings from doubling the current number of transplants would be between $480 and $900 million in 1984 dollars, the higher estimate assuming an improved transplant success rate. 2/

Supply of Donor Organs

A shortage of donor organs is considered the major constraint to increasing the number of organ transplants today. Almost 6,000 individuals are currently awaiting donor kidneys. One recent estimate based on age and cause of death is that 20,000 potential donors are available each year. Others argue that the potential is lower, however, given technical constraints in organ donation. Some potential donors are rejected because of the condition of the organ. In other cases, death occurs quickly and

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1. Testimony of Richard A. Rettig, Ph.D. before the Investigations and Oversight Subcommittee, Committee on Science and Technology, April 27, 1983. The 20,000 new patients does not represent ESRD program growth, which is also affected by eligibility rules and deaths.

2. Estimates based on preliminary analysis done by Dr. Jerome Aroesty, of the Rand Corporation. Technological changes that lower inpatient costs of transplant surgery could further increase the savings, but only if reflected in future revisions of Diagnostic Related Group (DRG) rates.

enough time is not available to receive family consent and carry out the necessary medical preparation of the donor.

Some have argued that the federal government could take steps to improve the availability of donor organs. Activities suggested for federal funding include encouraging the development of organ procurement agencies in currently uncovered geographical areas, establishing a national computer network to improve matching between donors and recipients and reduce the number of unused donor organs, and funding educational programs for physicians and the public to encourage organ donation.

Options to Expand Kidney Transplant Benefits

Two options have been suggested that would expand benefits to kidney transplant recipients. The first would cover the outpatient costs of immunosuppressant drug therapy. The second option would eliminate the current benefit limit of three years after successful transplantation.

The growing use of cyclosporin A as immunosuppressant therapy in transplant recipients is expected to lower inpatient transplant costs, but raise out-of-pocket costs to recipients. Immunosuppressants are taken indefinitely by transplant recipients to prevent rejection of the donor organ. Cyclosporin A has been credited in the last three years with decreasing complications after transplant surgery, making the associated hospital stays shorter and less costly, and improving patient outcomes. The extent of the cost decrease has not yet been determined, but could be substantial. One transplant center reports a 50 percent decline in heart transplant costs, although some experts believe this is high.

Since Medicare does not cover outpatient drugs, the costs to patients of cyclosporin A may be quite high. Although prices have not yet been set (FDA approval of cyclosporin A is pending) and the typical long-run dosage not yet agreed upon, annual per-patient costs of cyclosporin A for outpatient use are estimated by the manufacturer to be $5,000-$6,000. While some experts believe that after the first post-transplant year, $2,000 in annual costs may be a more reasonable estimate, even this lower estimate indicates costs about twice as high as those for current immunosuppressant therapy.

Annual costs of covering outpatient cyclosporin A treatment for new transplant patients could be in the range of $30 to $60 million, the higher amount reflecting an annual number of 8,000 to 10,000 transplants. As the number of surviving recipients grew, cyclosporin A costs would

increase--perhaps to between $70 and $150 million a year. Since Medicare coverage of cyclosporin A is unlikely to affect whether it is used, there are no offsets from reduced inpatient costs.

Without limitations, Medicare coverage could raise the price of the drugs, however. With no competitors, and most users covered by Medicare, the manufacturer would have an incentive to set a high price. This could be avoided if the Health Care Financing Administration were given authority to set a maximum price for the drug and purchase it in bulk on behalf of the beneficiaries.

Coverage of cyclosporin A would lower out-of-pocket costs to some transplant recipients, but it may be perceived as unfair to dialysis patients, and other Medicare beneficiaries. ESRD benefits cover only 80 percent of dialysis costs, leaving substantial out-of-pocket payments for dialysis patients. Furthermore, costs of other outpatient drugs--some of which are very expensive--are not covered under Medicare. In addition, Medicare coverage of cyclosporin A may simply replace private insurance payments for some patients. The extent of supplemental insurance coverage by ESRD beneficiaries is not known, however.

A second possible option would be to eliminate the three-year limit on Medicare benefits to patients with a successful kidney transplant. Currently, although 78 percent of recipients who receive a kidney from an unrelated donor survive three years, the rate at which the graft is retained is lower--45 percent. 3/ Both these rates have been increasing, however, a trend that is expected to continue as a result of medical advances. The difference in the rates represents those who end up back on ESRD--either on dialysis or for re-transplantation.

The argument made in favor of removing the limit is that it is arbitrary and unfair. Establishment of the three-year limit was not based on studies of post-transplant costs or patient rehabilitation, but was set in 1978 amendments (P.L. 95-292) because the original one-year limit was thought to discourage patients from choosing transplantation. Although some argue that the three-year benefits limit may lead some patients to choose to remain on dialysis, this is not seen as a serious impediment to increasing the number of transplants, which are constrained more by the supply of organs than by patient demand. But, recipients may benefit to the extent that

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3. Henry Krakauer, et. al. "The Recent U.S. Experience in the Treatment of End-Stage Renal Disease By Dialysis and Transplantation", New England Journal of Medicine, June 30, 1983, p. 1558-1563.

employers are currently discouraged from hiring workers with high health care costs--annual Medicare costs for maintaining successful transplant patients were about $4,000 per patient in 1979.

On the other hand, extending benefits would raise ESRD program costs. Program costs could increase from perhaps $50 million a year in the short run to $200 million a year as the number of surviving recipients grew. Comparisons of quality of life under dialysis and transplant are being studied, but to the extent that patients with successful transplants return to work, extending benefits past the three-year limit could substitute Medicare for private insurance, without additional benefits to the transplant survivors.

OPTIONS TO PROVIDE FEDERAL BENEFITS FOR TRANSPLANTS OF HEARTS, LIVERS AND OTHER ORGANS

In recent years, medical advances have been improving survival rates for heart and liver transplant recipients. Although the number of such surgeries performed is small--about 100 of each are expected this year--many experts regard these procedures as valid treatments for patients who would otherwise die, and the number of each of these transplants is expected to increase in coming years.

In addition to saving lives, other benefits of transplant surgery have been noted. Follow-up studies have found most recipients able to work. For example, one study of heart transplant recipients surviving a year or more found 73 percent had returned to work, homemaking or school. 4/

Medicare currently does not finance heart or liver transplants on the basis that they are experimental. The policy on liver transplants is currently under review, and an extensive study of heart transplantation is underway, however. The federal share of Medicaid is reimbursed when state programs choose to cover transplant procedures. An informal telephone survey of state Medicaid programs indicates that although only one has an official policy of coverage, 16 of them have approved payments for a heart or liver transplant and others might have, had a request been made.

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4. Roger Evans, "Problems and Prospects In Heart Transplantation, 1983: The Need for Comprehensive Health Care Technology Assessment", Update Number 27, National Heart Transplant Study, March 31, 1983, p. 25.

Two major options exist for changing federal policy regarding heart and liver transplants. The first would provide coverage for these procedures under Medicare and require states to provide Medicaid coverage. The second would provide federal benefits for all heart and liver transplant recipients similar to those for kidney transplants under the ESRD program.

Two key factors in estimating the potential costs of these options are the number of likely transplants and the typical costs of the procedure. For each of these, a wide range of estimates exists.

In the short run, the number of heart and liver transplants is expected to grow significantly, but still remain very small compared to the number of kidney transplants. Transplant surgeons have estimated the annual number of transplants five years from now to reach about 500 for hearts and perhaps 300 for liver transplants.

The number of expected transplants does not reflect the number of potential recipients with end-stage cardiac or liver disease, however. Medical advances and a greater supply of donor organs could dramatically increase the number of heart and liver transplants.

Experience in projecting costs of the ESRD program indicates the difficulties in predicting utilization of new technologies. The size of the ESRD program has grown much more quickly than originally expected, primarily due to changes in patient selection criteria that increased the number of older patients on dialysis. Between 1970 and 1977, the average age of dialysis patients increased from 42 to 50. 5/ On the other hand, because the limited supply of organs poses a constraint not faced in dialysis, transplant programs might not grow as rapidly as did the ESRD program.

The number of potential heart transplant recipients is greater than that for livers. Estimates compiled by the National Heart Transplant Study of individuals with end-stage cardiac disease who would be suitable transplant candidates range from 12,000 to 75,000 a year. 6/ Although the supply of donor hearts could seriously constrain the number of transplants, technological advances to keep potential recipients alive while waiting for a donor organ--such as an artificial heart--could enable more patients to be transplanted in the future.

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5. See Katherine Jones, "Hemodialysis and Kidney Transplant Surgery", in Strategies for Medical Technology Assessment, Office of Technology Assessment, September 1982, pp. 175-184.

6. Roger Evans, "Defining the Need for Heart Transplantation", Update Number 5, National Heart Transplantation Study, April 22, 1982, pp. 10-12.

The number of potential annual liver transplant recipients has been estimated at about 4,600 nationally--roughly 12 percent of the population each year that dies with end-stage liver disease. 7/ This estimate is based on current criteria for choosing suitable transplant recipients.

Technological change could lead to an alteration of these criteria, however, and a possible large increase in the number of potential recipients. A question often raised is whether individuals suffering from alcohol-related cirrhosis of the liver--the most common end-stage liver disease--are appropriate candidates for transplant. Transplants have been performed on alcoholic patients who had been alcohol-free for some period of time prior to surgery. Usually, however, alcoholic patients are considered unsuitable candidates due to poor overall medical condition.

The estimates here use cost data from a major transplant center. Depending on the patients condition, costs in 1980 ranged from $30,000 to $120,000 for a heart transplant--averaging about $60,000. Costs for liver transplants in 1981 ranged from is $30,000 to $215,000, averaging $90,000.

Future costs, however, may be substantially different. For example, continued success with cyclosporin A or other medical advances to reduce the complications associated with transplant surgery could shorten hospital stays and reduce costs.

Costs of Providing Transplant Coverage for Medicare and Medicaid Beneficiaries

Federal costs of providing coverage for heart and liver transplants under Medicare and Medicaid would, in the short run, probably be less than $5 million a year. This low figure assumes both a small total number of heart and liver transplants, and patient selection criteria that would exclude most Medicare beneficiaries. With current criteria, patients aged 65 and over are almost always considered too old to be suitable transplant candidates. Disabled beneficiaries must wait two years for Medicare eligibility, a time period during which most patients with cardiac or liver disease severe enough to make them transplant candidates would not survive. Changes in typical patient selection criteria to include older patients, or those in earlier stages of the disease would allow more Medicare patients to benefit, and would also increase federal costs.

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7. Benjamin Barnes et. al. Final Report of the Task Force on Liver Transplantation in Massachusetts, May 1983.

A change in Medicare policy could be expected to expand coverage by other payers. Although many private payers have reimbursed for heart and liver transplants, other have denied payments on the basis of following Medicare policy. Even when payments have been made, they are often determined on a case-by-case basis rather than a policy of coverage.

Costs of Providing Federal Coverage for All Transplant Recipients

Available data indicate that the federal costs of providing three-year benefits for all heart tranplant recipients beginning at the time of transplant could range from $40 million to $135 million per year in 1984 dollars in the short run. This assumes there would be between 150 and 500 transplants each year. Given the large population with end-stage cardiac disease, however, annual costs could be substantially higher in the long run--$1.5 billion in 1984 dollars if 5,000 heart transplants were performed each year, for example. This number of transplants would require a very large increase in the availability of donor organs and transplant facilities, and may never be attained, however.

Costs of coverage for liver transplantation could range from $40 million to $100 million a year in the short run, but long-run costs could be much greater. If the supply of organs and number of transplant facilities increased, long-run annual costs could reach $400 million, for example, if 1,000 liver transplants were performed each year. Again, this number of transplants may never be feasible.

Finally, new developments in the transplantation of other organs could further increase federal costs if these were covered. In particular, due to recent success with donation by living relatives, growth in the number of pancreas transplants is expected by some surgeons in the near future. Currently, the major center for pancreas transplants performs about 25 surgeries a year. Surgeons predict as many as 500 procedures annually ten years from now.

Coverage of pancreas transplants in the short-run would be relatively less costly than for other organs--between $5 million and $75 million, assuming between 25 and 500 transplants annually. Transplant costs are lower than those for the heart or liver procedures--about $30,000 for the recipient and less than half that for a living donor. In the long run, however, the number of potential recipients--primarily individuals with severe complications from diabetes--may be as large as 5,000.

NATIONAL ORGAN TRANSPLANT ACT

MONDAY, OCTOBER 17, 1983

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:45 a.m., in room 2322, Rayburn House Office Building, the Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. This morning the subcommittee will receive testimony on H.R. 4080, the National Organ Transplant Act.

The transplant of human organs is one of medical science's most remarkable advances. Transplantation saves lives. It can dramatically improve the quality of life of patients on renal dialysis.

Last July, the subcommittee heard testimony from transplant patients and families whose loved ones were waiting for organ donations. We also heard from transplant surgeons and health policy experts. All agreed that the gap between those in need of transplants and available organs is great, and as transplant technology becomes more sophisticated, it will widen. They also agreed that this gap is unnecessary.

Today there is a genuine risk that without better systems of planning and financing, transplants may become a medical option available only to the rich or those clever enough to achieve media celebrity. Public pleas from the President—though heart rending—divert attention from the fact that our Nation's system of health care delivery is not prepared to efficiently utilize the miracle of transplantation.

Each year hundreds of donated organs—kidneys, livers, hearts—are discarded or exported overseas. Yet thousands of patients wait day after day in hope for the call that a donor organ has become available. For many this call will never come. Many on waiting lists will die before an organ becomes available.

Our task is motivated by a sense of urgency. H.R. 4080 was introduced on October 5 by Congressmen Albert Gore, Tom Luken, Joe Skeen, and myself. It is the product of an extensive investigation by this subcommittee and the Subcommittee on Investigations and Oversight of the Committee on Science and Technology. The legislation is intended to increase the number of organs available for donation and improve the process of matching donor organs with recipients.

It will do this without relying upon the sale of human organs, as some have suggested. In fact, the bill explicitly prohibits organ sales and imposes strict criminal penalties on those who would pro-

mote such practices. The specter of individuals coerced to sell their kidneys—placing their lives in jeopardy—represents a form of human exploitation foreign to our concepts of medical and social ethics.

Our first witness this morning, Congressman Albert Gore, deserves special praise for his tireless work on this issue. Through his efforts as chairman of the Investigations and Oversight Subcommittee, the public and medical community have become increasingly aware of the need for improvements in this area. I am pleased to say his legislation enjoys broad bipartisan support and has been cosponsored by 20 of our House colleagues.

Without objection, a copy of H.R. 4080, the National Organ Transplant Act, will be printed in the record at this point. And further, without objection, we would like to insert a statement by our colleague, Congressman Bliley, for the record, and leave the record open at this point for any other comments that members wish to have inserted.

[Testimony resumes on p. 109.]

[The text of H.R. 4080 and the statement of Mr. Bliley follows:]

98TH CONGRESS
1ST SESSION

H. R. 4080

To amend the Public Health Service Act to authorize financial assistance for organ procurement organizations, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 5, 1983

Mr. GORE (for himself, Mr. WAXMAN, Mr. LUKEN, and Mr. SKEEN) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce and Ways and Means

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A BILL

To amend the Public Health Service Act to authorize financial assistance for organ procurement organizations, 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 "National Organ Transplant Act".

TITLE I—AMENDMENT TO PUBLIC HEALTH SERVICE ACT

SEC. 101. Part H of title III of the Public Health Service Act is amended to read as follows:

"PART H—ORGAN TRANSPLANTS

"ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

"SEC. 371. (a) The Secretary may make grants for the planning, establishment, and initial operation of qualified organ procurement organizations described in subsection (b) and to expand the activities of such organizations.

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

"(A) is a nonprofit entity,

"(B) 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 and establishes an advisory board as required by subparagraph (G),

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

"(D) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys,

"(E) has procedures to obtain payment for non-renal organs provided to transplant centers,

"(F) has a defined service area which is a geographical area of sufficient size which will include at least fifty potential organ donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area, and

"(G)(i) in the case of an organization which is not an organization which provides health care services or carries out other activities not related to the procurement of organs, has a Board of Directors which includes—

"(I) members who represent hospital administrators, neurosurgeons or neurologists, intensive care or emergency room nurses, tissue banks, and voluntary health associations in its service area and the general public residing in such area, and

"(II) from each transplant center in its service area which has with the organization arrange-

ments described in paragraph (2)(G), a physician who has practicing privileges in such center,

"(ii) in the case of an organization which is an organization which provides health care services or carries out other activities not related to the procurement of organs, establishes an advisory board for organ procurement which will be an advisory board to its Board of Directors, which will include the representation prescribed by clause (i), which will have exclusive authority to establish policy for the procurement of organs and the other functions described in paragraph (2), and which will have no authority over any other activity of the organization, and

"(H) has a full-time director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area.

"(2) An organ procurement organization shall—

"(A) have effective agreements, to identify potential organ donors, 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 and tissues 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 United States Transplantation Network established under section 372,

"(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)(1) For grants under subsection (a) there are authorized to be appropriated $5,000,000 for fiscal year 1984, $10,000,000 for fiscal year 1985, $15,000,000 for fiscal year 1986, and $20,000,000 for fiscal year 1987.

"(2) There are authorized to be appropriated for fiscal years 1988 and 1989 such sums as may be necessary to continue grants for the initial operation or expansion of organ

procurement organizations which received inital grants for such purpose under subsection (a) in fiscal year 1986 or 1987.

"UNITED STATES TRANSPLANTATION NETWORK

"SEC. 372. The Secretary shall by contract provide for the establishment and operation of a United States Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed $2,000,000. Funds for such contracts shall be made available from the Federal Hospital Insurance Trust Fund established under title XVIII of the Social Security Act.

"(b)(1) A United States Transplantation Network shall carry out the functions described in paragraph (2) and shall—

"(A) be a private nonprofit entity which is not engaged in any activity unrelated to organ procurement, and

"(B) have a board of directors which includes representatives of organ procurement organizations described in section 371, transplant centers, voluntary health associations, and the general public.

"(2) A United States Transplantation Network shall—

"(A) maintain a national registry of individuals who need organs,

"(B) provide, through the use of computers and in accordance with established criteria, a national system to match organs and individuals included in the registry,

"(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the registry,

"(D) establish and maintain standards of quality for the acquisition and transportation of donated organs and for tissue typing centers,

"(E) prepare and distribute, on a regionalized basis, samples of blood sera from individuals, included in the registry, to facilitate matching the compatability of organ donors and organ recipients,

"(F) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

"(G) provide information to physicians and other health professionals regarding organ donation, and

"(H) collect, analyze, and publish data concerning organ donation and transplants.

"GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

"SEC. 373. (a) No grant may be made under section 371 or contract entered into under section 372 unless an ap-

plication therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

"(b)(1) In considering applications for grants under section 371, the Secretary shall give priority to any applicant which has a formal agreement of cooperation with all transplant centers in its proposed service area. The Secretary may not make a grant for more than one organ procurement organization which will serve the same geographical area.

"(2) A grant for planning under section 371 may be made for one year with respect to any organ procurement organization and may not exceed $100,000.

"(3) Grants under section 371 for the initial operation or expansion of organ procurement organizations may be made for three years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $1,000,000 for initial operation or expansion.

"(c)(1) The Secretary shall determine the amount of a grant made under section 371. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

"(2)(A) Each recipient of a grant under section 371 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

"(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant under section 371 that are pertinent to such grant.

"(d) No organ procurement organization which receives a grant under section 371 may use funds under such grant for expenses for which reimbursement may be made under title XVIII of the Social Security Act. No reimbursement of an organ procurement organization under title XVIII of the Social Security Act may be reduced because the organization received a grant under section 371.

"(e) For purposes of this part:

"(1) The term 'transplant center' means a health care facility in which transplants of organs are performed.

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

"ADMINISTRATION

"SEC. 374. (a) The Secretary shall establish in the office of the Assistant Secretary for Health a National Center for Organ Transplantation. The National Center shall—

"(1) administer this part and the organ procurement activities under title XVIII of the Social Security Act,

"(2) conduct a program of public information to inform the public of the need for organ donations,

"(3) provide technical assistance to organ procurement organizations receiving funds under section 371, the United States Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants, and

"(4) issue an annual report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.

"(b)(1) The Secretary shall establish an advisory council to advise the National Center. The advisory council shall conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation.

"(2) The advisory council shall be composed of fifteen members appointed by the Secretary as follows:

"(A) Six members shall be appointed from physicians who are eminent in the various specialties of medicine related to human organ transplantation. Of the physicians, at least three shall be transplant surgeons.

"(B) Two members shall be appointed from individuals who are not physicians and who represent the field of human organ procurement.

"(C) Four members shall be appointed from individuals who are not physicians or scientists and who as a group have expertise in the fields of law, theology, ethics, health care financing, and the social and behavioral sciences.

"(D) Three members shall be appointed from individuals who are not physicians or scientists and who are members of the general public.

No individual who is a full-time officer or employee of the Federal Government may be appointed to the advisory coun-

cil. A vacancy in the advisory council shall be filled in the manner in which the original appointment was made.

"(3) The advisory council shall, within eighteen months of the date of the enactment of this part, conduct a national conference to consider questions respecting—

"(A) the equitable access by patients to organ transplantation,

"(B) the allocation of donated organs among transplant centers and among patients equally medically qualified for an organ transplant, and

"(C) payment for nonrenal organ transplantation.

The Secretary shall publish the proceedings of the conference within three months of its completion.

"(c) The Secretary shall provide for a registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation.

"REPORT

"SEC. 375. 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 Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the

report. The Secretary shall make the report and other related information available to service benefit plans, health insurers, and other entities which are responsible for making payments for health care.".

TITLE II—MEDICARE AND MEDICAID AMENDMENTS

SEC. 201. (a) Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended by adding at the end the following new sentences: "The Secretary, after consultation with the Assistant Secretary for Health, may determine that items or services furnished with respect to a patient are 'reasonable and necessary' for purposes of paragraph (1) only if the patient, the person furnishing the items or services, and the conditions under which the items or services are furnished meet such medical criteria of general applicability as the Secretary may specify. If the Secretary so determines that payment for particular items or services will be made only if furnished at a designated center or centers, payment may be made under this title with respect to such items or services at such a center only if the center agrees not to deny a patient health care services on the grounds of race, color, national origin, creed, source of payment for the items or services, residence, or any other ground unrelated to the patient's need for the item or service or the availability of the item or service.".

(b) Section 1886(a)(4) of such Act (42 U.S.C. 1395ww(a)(4)) is amended by adding at the end the following new sentence: "Such term shall not include costs of organ transplant procurement services.".

SEC. 202. (a) Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended by striking out "and" at the end of paragraph (43), by striking out the period at the end of paragraph (44) and inserting in lieu thereof "; and", and by inserting after paragraph (44) the following new paragraph:

"(45) provide—

"(A) for written policies respecting the coverage under the plan of organ transplant procedures, except that in the absence of such policies the plan shall be deemed to provide for coverage of such procedures in the same manner and under the same conditions as such procedures are covered under title XVIII consistent with the second and third sentences of section 1862(a), and

"(B) notwithstanding any other provision of this title, that payment under the plan for such a procedure shall be in the amount determined (with respect to the diagnosis-related group described in section 1886(d)(4)(A) including the procedure) under section 1886 respecting payment for such procedure.".

(b) Section 1903(i) of such Act (42 U.S.C. 1396b(i)) is amended by striking out the period at the end of paragraph (6) and inserting in lieu thereof "; or" and by adding at the end the following new paragraph:

"(7) with respect to any amount expended for an organ transplant procedure for which the Secretary has designated a specific center or centers for that procedure under the second and third sentences of section 1862(a), if the procedure is not performed at such a center.".

(c)(1) Section 1902(a)(45)(A) of the Social Security Act (added by the amendment made by subsection (a)) and section 1903(i)(7) of such Act (added by the amendment made by subsection (b)) shall apply to a procedure performed more than thirty days after the date the Secretary of Health and Human Services establishes restrictions with respect to such procedure under the second sentence of section 1862(a) of such Act.

(2) Section 1902(a)(45)(B) of the Social Security Act (added by the amendment made by subsection (a)) shall apply to payment for procedures performed on or after the first calendar quarter that begins more than sixty days after the date of the enactment of this Act.

SEC. 203. Each hospital for which payment for organ transplantation is made under title XVII or XIX of the

Social Security Act shall provide to the Secretary of Health and Human Services for the registry under section 374(c) of the Public Health Service Act information on all patients undergoing organ transplantation in such hospital.

TITLE III—PROHIBITION OF ORGAN PURCHASES

SEC. 301. (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration if the transfer affects 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 "human organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ or tissue (including corneas, bone, and skin) included by the Secretary of Health and Human Services by regulation.

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

(3) The term "commerce" means trade, traffic, or transportation between a place in a State and any place outside thereof or which affects such trade, traffic, or transportation.

THOMAS J. BLILEY, Jr.
2d DISTRICT, VIRGINIA

MEMBER OF
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OPENING STATEMENT OF REP. THOMAS J. BLILEY, JR., HEARINGS ON H.R. 4080, THE NATIONAL ORGAN TRANSPLANT ACT

I regret that previous commitments prevent me from appearing personally this morning. I do want to commend the Chairman and the Subcommittee, as I believe the question of assisting in organ donation and transplantation is a most appropriate one for this Subcommittee to explore.

Attention has recently been drawn to the problem of the availability of livers and kidneys suitable for transplantation. President Reagan and others have made the search for livers for sick children a national issue. In a less helpful light, a proposal by a Washington area physician to buy and sell kidneys has drawn widespread objections from both the medical community and the general public.

Recent advances in medical technology and drug treatments such as Cyclosporin-A have greatly increased the liklihood of a successful organ transplant, and thus of the liklihood of happy and productive lives for patients with failing organs. But these advances also bring with them problems, such as the ill-advised organ sales proposal and similar questions of availability of suitable organs.

As the government begins to look into this area, I believe it is important for us to examine ways in which the public and the private sector have already begun to deal with organ transplantation problems. And, in this area as many others, we find that the people,

and their organizations in the private sector, are already way ahead of us. The Southeastern Organ Procurement Foundation, a private organization located in my hometown of Richmond, in particular has done a remarkable job of matching organs with patients. About a year ago they established a Kidney Center which is now manned 24 hours a day to help in organ donations. In just the first quarter of this year SEOPF's Kidney Center assisted in the location of 469 kidneys used in nearly 300 transplants in the region they serve, which includes nearly the entire eastern United States.

SEOPF is to be commended for thie work in this area, and I am pleased that we will be hearing from one of their representatives this morning. I believe the Subcommittee has an obligation to examine these remarkably successful efforts by SEOPF and other private sector organizations to see what the federal government can do to promote the availability of organs for transplan tion.

Mr. WAXMAN. Mr. Gore, we are delighted to have you here. It is through your efforts that this legislation is before us. You have worked very tirelessly on this whole problem trying to figure out what would be appropriate for Congress to do in this regard, and I am pleased to welcome you at this time to present your legislation to us.

STATEMENT OF HON. ALBERT GORE, JR.

Mr. GORE. Thank you, Mr. Chairman.

I would like to ask your permission and that the subcommittee to insert the full text of my rather lengthy prepared statement into the record.

Mr. WAXMAN. Without objection.

Mr. GORE. That being done, I will attempt to summarize my statement here. I want to begin though on a personal note, by thanking you very sincerely in this public forum for your friendship and your help in drafting this legislation, in the work we together have done over the past year in trying to focus attention on this problem, and now as we get to the stage of our common effort, and we have solutions coming into view, I want to thank you for working together to make this solution possible.

It really does help when you have oversight hearings and open up a problem and begin looking at it, to have a close friend and ally who is able to understand and see the nature of the problem and move quickly and expeditiously to solve it. That is what this meeting here today is all about and I just wanted to begin by telling you how much I appreciate it.

This problem is one which is quite urgent for many thousands of Americans. We can deal with it as an issue but for many thousands of Americans this is a life and death matter. I have constituents who are waiting right now, trying to get access to this lifesaving procedure, transplantation. Without it, there will be death; with it there will be life.

It is really a very dramatic and stark issue and it is new for the country. It has kind of taken us by surprise because of the rapidity with which medical sciences advances. When the first transplant procedures were done long ago, all of the news was about rejection. You may remember when Christian Barnard was transplanting the first heart and every night on the news there was some indication of whether or not the transplant was going to take or not, or whether the recipient was going to reject the donated area.

Well, the doctors heroically continued in the face of very long odds, but there came a time when heart transplant almost stopped in this country. Then with the discovery of the new miracle drug, cyclosporin, the problems of rejection were almost completely solved. There still has to be a close match of donor and recipient, but the problems of rejection are now able to be largely solved.

As a result of that and as a result of the increasing skill of our surgeons, the operations have become more and more common and, of course, the demand is just outstripping the supply. The best source of supply is from persons who tragically have become brain dead. There are some 20,000 brain deaths each year, but that trage-

dy is compounded by the fact that only 2,200 of them result in organ donations and lifesaving transplants.

There are many reasons why this is the case. This bill attempts to attack that problem and attempts to solve that problem. There have been enough studies of the problem, Mr. Chairman. We will hear from some who want to study the problem a long time. We know what needs to be done. We have had enough studies.

I mentioned the lengthy investigative hearings that my subcommittee has held over the past year, particularly this year. In July I presented to this subcommittee the major findings and recommendations from my subcommittee's investigation, and I want to say that in those hearings, and in the work we have done, we have all benefited from the work of the Health Care Financing Administration, the longstanding contracts like HCFA has had with Drs. Prottas and Evans, have proved invaluable to both of our subcommittees.

I am certain, Mr. Chairman, that you would agree that if it were not for the extensive work of these two distinguished gentlemen, and their colleagues over the past 2 years, we would not be in the position that we are in today, a position in which we can now take immediate steps to correct the shortcomings in the present system. As a result, many lives will be saved that would otherwise have been lost, if instead we had to undertake our own study.

Furthermore, had we needed to do such a study, it might have been done under the present emotionally charged circumstances, and because of public interest and impatience, there would have undoubtedly resulted a study of shorter duration under these significant pressures, and, therefore, one that was less thorough and less comprehensive than the excellent work we have had the benefit of using in drafting H.R. 4080.

These lengthy studies have shown some interesting things:

First, there is not a shortage of potential donors, as I indicated a moment ago.

Second, Americans are willing to donate. In fact, the recent rate of organ donations has been going up in the wake of the publicity about the problem. As Americans understand the opportunities to save lives, attitudes are changing, but there is a very significant problem in the organ procurement system nationwide. There are presently 110 separate organ procurement networks around the country. Many individuals who are dedicated have devoted their lives to making these networks operate well and they have tried heroically to coordinate these 110 networks, one with another, but much more needs to be done. They are doing a good job but a better job needs to be done.

Independent organ procurement agencies account for 18 percent of the organ procurement agencies around the country, but retrieve 40 percent of the kidneys. In other words, of the 110 separate networks, 36 of them are independent networks and they are getting 40 percent of the kidneys now that I am speaking of specifically here.

The independent agencies face cash flow problems. They need money to cover capitalization and permanent financing. As an example of that, presently $100 of the amount reimbursed by HCFA for each kidney retrieved, goes for paying interest on the loans that

these agencies have taken out. Reforms are also needed in the national structure of the organ procurement system itself. Legislative changes are necessary so that the system is for all organs and not just for kidneys.

What you have now is a national system loosely coordinated, with the Federal Government paying for all of the part of the system that retrieves kidneys, and then a completely separate, not ad hoc, but patchwork system that has grown up for the nonrenal organs. This effort obviously needs to be coordinated because the same donor is going to provide in many cases organs for several different recipients, different organs, kidneys, liver, heart, lungs, and so forth.

The problems of coordinating that have really got to be solved because the system that reimburses for the kidney retrieval is now telling people that they cannot reimburse for the retrieval of any of these other organs, and it is just really kind of a hectic situation at the present time and needs to be straightened out.

There are too many of these organ procurement agencies, Mr. Chairman. Many of them are too small to operate effectively. Some areas are underserved and others, such as New York, Chicago, and the District of Columbia have several competing agencies. There are six right here in the District of Columbia, while in some western parts of the country, there are none at all.

The present system then, is fragmented. We need a national coordinating mechanism. All potential organ recipients must be accessible to all organ retrieval organizations. We need a nationwide computer system, a manned 24-hour phone line. Now, some will say that we already have pieces of this in place. It is true for some purposes, but they are not coordinated. We have seen—I thought there were two nationwide hotlines until Reagan went on television and gave out yet a third nationwide hotline.

On the NAPCO system, you call up and you have to listen for 15 to 20 minutes to an oral tape recording of all of the patients around the country. Now, obviously we can do better with that because in some of these cases, 15 minutes is an important period of time and you might miss one of those names while sitting there listening to the droning on and on of these names and circumstances. We can do better than that.

We need a focal point in the Federal Government. After all, there is already widespread Federal funding. Thirty million dollars was spent last year to retrieve 6,000 kidneys, but no national strategy has emerged, and I want to ask this question if you agree with me it is an important question to ask, to those who say we ought to let a private network spring up and handle this: We are paying for it. The Federal Government is already paying for it. They are paying for these 110 separate organ-procuring networks, but they are just doing it in an uncoordinated fashion. It should be coordinated and the OPA should receive some direction and assistance from the funding agency.

Also, we need to assure timely and equitable access to new health care technologies. There is an important part of the problem. The unfortunate decision 2 years ago to dissolve the National Center for Health Care Technology was a very, very serious mistake.

I think most health care professionals agree that this was a very serious mistake on the part of the administration, and now we have to undo some of the damage that was done.

The fact is our social and political structure and support mechanisms have not responded to technological advances in a timely fashion. There was an NIH consensus conference in June, but as yet, there still has been no decision and this again underscores the fact we need a more timely mechanism to make these decisions.

I will recall for you some testimony that was presented in this regard in my subcommittee by Dr. David Banta when he was talking about heart transplants.

He says, and I quote:

> Perhaps the most distressing case is that of heart transplant. The NCHCT recommended that it be covered at selected centers in February 1980. It is still not covered. The rationale was that heart transplant raises many ethical and economic questions, as well as efficacy and safety questions that are being addressed in the Battelle study.
>
> The previous Secretary of HHS, Patricia Harris, decided that heart transplants should not be covered. However, I should note that HCFA does not have the authority to base payment decisions on such broader considerations as cost and ethical considerations. Under HCFA guidelines, I believe heart transplants should be provided already.
>
> I am sympathetic with the Administration's concerns about transplants. However, technology must be addressed in a consistent manner. If HCFA lacks the authority to limit transplants to certain centers, it could request that authority.
>
> If HCFA wishes the authority to base decisions on economic and social criteria, it can request Congress to give it that authority. And, by all means, HCFA should define "reasonable and necessary" by regulation.
>
> One is left with the impression, in the case of heart transplant, at least, that HCFA is delaying payment for cost containment reasons. If this is a true perception, this is a serious perversion of the process of technology assessment and its place in policymaking.

So, obviously, I think the bill's provisions to give more rationale to the system of providing time and equitable access to new life saving procedures is one that is definitely needed.

To address another point in our legislation, the buying and selling of human organs. You will be hearing a little more about this later.

Let me just say very briefly that I think the buying and selling of human organs is a very serious mistake. It ought to be prohibited, because it is inconsistent with our system of values to auction off life to the highest bidders.

We can be asking for very serious problems if we don't scotch this proposal before it gets going, because Americans understand there is a difference between things and people. Things are bought and sold. People are not, and parts of people shouldn't be, either.

One can speculate about a world that would be created with such a provision. Could someone put up his kidney as collateral for a car loan and what would the repossession procedure consist of?

If someone needed an appendectomy, and couldn't afford it, could he go and get the appendectomy and give a kidney in payment of the other operation? It just becomes bizarre to discuss these kinds of scenarios and what is bizarre about it is that you would be investing a property right in a part of a person, and that is just wrong, it is against our system of values and I am grateful that the medical and scientific communities have spoken up loudly and clearly with virtual unanimity in favor of this provision of the bill,

and I am also grateful that the spokespersons for the administration evidently are strongly in favor of this provision of the bill as well.

I am not as pleased with administration's response to other parts of the bill. I understand that there are mixed feelings within the administration. Having had a number of private conversations with people in the administration who have been wrestling with this problem, I know that they have mixed feelings, and I know that the official policy is one that concerns many individuals within the administration, but the administration must speak for itself and their response, their official response and formal response has been extremely slow.

They will tell you that this council they want, that they want, that they have set up, will solve the problem. Mr. Chairman, that council is not even going to meet again until next year.

Where is the sense of urgency? Where is the commitment to this problem? They want to spend $100,000 on the effort, $100,000—well, the opportunities to save millions of dollars in Federal money is just being missed.

Let's look at the facts of medicare costs for dialysis alone. We have heard that in the case of liver transplants, the cost of transplants is much cheaper than the cost of the lengthy and tragic terminal care that would be unnecessary if the transplant took place.

It is ironic you are saving not only lives but money. Let's look at the cost for dialysis. There was a rather lengthy study of the cost that can be saved with transplants and we are paying an awful lot of money for kidney dialysis in this country.

Let me give you the figures.

If you take 1,000 patients and put them on dialysis, then you take 1,000 patients and give them kidney transplants, then you compare the costs for each group of 1,000 patients, in the first year, the transplants are about twice as expensive as the dialysis.

More lives would be saved. Out of 1,000, 955 would remain alive at a cost of $34 million. With dialysis, 930 would remain alive at $17.6 million. In second year, if you add another 1,000 and continue each year after that, dialysis would still be more expensive.

However, within 3 years, Mr. Chairman, you would begin saving a substantial amount of money. In the third year, the cost would be $56.9 million for dialysis, and $51.7 million for transplants.

And in the fifth year, this is really the figure that I wanted to give you—in the fifth year, out of those 5,000 patients, 3,570 would be—excuse me, that is—that is 4,000, out of 4,000 patients, 3,570 would be alive on dialysis, at a cost of $67 million, 4,385 would be alive with transplants, at a cost of only $55.9 million.

So, you are saving a great deal of money at the same time that you are saving a lot of lives. Now, the time to act is now, during this session of Congress. We have agreement on what the problems are, and on what the solutions are. We have the support of the transplant surgeons, the organ transplant coordinators, the organ procurement people, we have spent hundreds of hours in thorough investigation, and in the drafting of the bill.

All of the key people involved in the effort toward procuring organs and transplanting organs across the country, the key people have been involved in drafting this bill. With your support, Mr.

Chairman, with your cooperation and hard work, we now are on the verge on bringing the country up to date in order to deal with this new era of organ transplantation that we have entered.

Let's pass this bill during this session of Congress.

Thank you.

[Testimony resumes on p. 127.]

[The statement of Mr. Gore follows:]

TESTIMONY OF THE HONORABLE

ALBERT GORE JR.

Mr. Chairman, I am pleased to join you this morning as the Subcommittee on Health and the Environment receives testimony on the bill H.R. 4080, the "National Organ Transplant Act," legislation to establish a national strategy to cope with the growing problems presented by the increasing need for transplantable organs.

As you know, the Science and Technology Subcommittee on Investigations and Oversight, which I chair, has conducted an extensive and thorough investigation of this issue for many months, including three days of hearings in April. In July, I presented to this subcommittee the major findings and recommendations from my subcommittee's investigation. At that time I also shared with you an outline of a bill that has become the bill we are here this morning to discuss. As you know Mr. Chairman, in drafting this legislation, our staffs have worked closely together, and with many of the distinguished witnesses who will testify before you. I am quite pleased to report that the result of this effort is a bill that enjoys broad support from Members on both sides of the aisle and from the various professional and voluntary health groups that work with organ procurement and transplantation.

Today, I would like to reflect back on the many months of my investigation of this issue, and share with you the reasons why this legislation is so crucial if we are to overcome the barriers that have prevented the largest and the most effective organ retrieval system in the world from being able to meet this nation's growing need for transplantable organs.

We have entered a new era in health care as a result of the miraculous improvement in organ transplantation. The medical community's surgical and medical prowess has given many individuals, who only recently would have faced certain death, the promise of renewed hope and a real chance of returning to a normal life. In addition, not only are lives saved, but organ transplants actually save money. In a cost study done by the Health Care Financing Administration (HCFA), of the various therapies provided by the End Stage Renal Disease (ESRD) program, patients receiving kidney transplants saved the program millions of dollars. For every increase of 1,000 patients transplanted per year, by five years, not only would $12 million be saved, but 800 lives as well.

With these facts in mind, it has been a deep disappointment to me that our nation is not better prepared to accept this new technology. As a result, thousands of patients remain on waiting lists. Tragically, many will die this year before an organ becomes available.

The Need for a National Network

The shortage of transplantable organs is not the result of a shortage of potential donors. At the April hearings, estimates put the number of suitable donors of cadaveric organs at ten to twenty thousand per year. Unfortunately, last year in over 80 percent of these cases the tragedy of these brain deaths was compounded by the lack of organ donation. The gift capable of saving the life or relieving the suffering of one of the thousands of Americans awaiting a transplant was never made available. Equally disturbing was the fact that

of the more than 6,000 organs that were donated, 20 percent went unused, partly because they were at the wrong place at the wrong time.

Americans are also willing to donate the needed organs. In testimony presented before our subcommittee by Dr. David Ogden, President of the National Kidney Foundation, Dr. Ogden shared with us the results of a survey conducted for his organization entitled "Attitudes and Opinions of the American Public Towards Kidney Donation." Among a nationally representative sample of 1,574 persons age eighteen and over, 93 percent were aware of the need for donor organs and of how the present organ donation system works. Of these individuals 75 percent stated they would be willing to donate the organ of a loved one who died. More importantly, we learned that when families of potential donors are approached a very high percentage do in fact give permission to proceed with the donation. Although the responses to other questions in the Kidney Foundation survey did indicate the importance of a program to improve public attitudes about organ donation, it remained clear that it is not a lack of a willingness to donate that keeps us from meeting the need for transplantable organs. The problem lies in the organ procurement system.

In examining the present system, we have all benefited from the work done through the Health Care Financing Administration. In particular the long standing contracts HCFA has had with Drs. Prottas and Evans have proved invaluable to both of our subcommittees. I am certain, Mr. Chairman, that you would agree, that if it were not for the extensive work of these two distinguished gentlemen and their colleagues over the last two years we would not be in the position we are in today to take immediate steps to correct the

shortcomings in the present system. As a result, many lives will be saved that would otherwise have been lost if instead we had to undertake our own study. Furthermore, had we needed to do such a study, it would have had to be done under the present emotionally charged circumstances. Because of public interest, there would have undoubtedly resulted a study of shorter duration under significant pressures, and therefore likely to be far less thorough than the comprehensive and excellent work we have had the benefit of using in drafting H.R. 4080.

The existing patchwork system consists of about 110 separate organ procurement agencies, staffed by dedicated and hard-working individuals. These agencies are totally funded by the federal government as part of the ESRD program. Last year they spent approximately $30 million to obtain about 6,000 kidneys. But the statistics show irrefutably that the job of obtaining enough organs for transplant patients is not being done. Clearly, there is room for much improvement. Despite the fine efforts of those working in the present system, the gap between the number of donors and those on waiting lists has continued to grow as scientific advances create even a greater demand for organs. In addition, the existing system is limited to the retrieval of kidneys. This is inconsistent with the growing need for all organs. Most of us will recall that it was the plight of the families in need of non-renal organs such as livers and hearts that stirred many of our interests. I have stated before that the problems families face as they work within the present system first caught my attention when a family sought my help in finding a liver for their two year old son. It was in helping them that I found that many thousands of others were in the same predicament.

Legislative changes are required if the existing system is to be expanded to include the retrieval of the other organs.

Other changes are also needed. In Dr. Prottas's testimony at our April hearing, he discussed the importance of the independent (IOPA) over the hospital based organ procurement agency (OPA). "...(IOPA's) are important out of proportion to their number...Although IOPA's represent only some 18 percent of the nation's procurement agencies, they actually obtain over 40 percent of the nation's transplantable kidneys." Dr. Prottas went on to explain the reasons for this important difference and concluded: "If the entire nation were serviced by procurement agencies as effective as the IOPA's, a 50 percent increase in the number of kidneys procured could be expected. If it (the nation) were covered by OPA's as effective as the most effective IOPA's, the number of organs retrieved would be doubled!" In drafting H.R. 4080 we have worked closely with Dr. Prottas to translate his findings into a framework for a nationwide network for organ procurement that will have deeeply rooted throughout it, those characteristics Dr. Prottas has found most responsible for the success of the IOPA's.

In arriving at our decision to use a system of Public Health Service grants, as a means to provide an incentive for OPA's to change in the ways Dr. Prottas has suggested, several key factors stand out.

First is a principle that underlies the entire bill: increase the immediate number of available transplantable organs. In our investigation, several of those we spoke with, including Dr. Prottas and others intimately involved in the management of the IOPA's, told the subcommittee that the only way we would be able to insure that

the necessary changes would be made, was to provide the authority to force OPA's to make the desired changes. Although that may indeed prove to be the necessary approach, our approach seeks only positive steps to increase the number of donor organs. It was our belief that even by shutting down only the ineffective OPA's organs otherwise retrieved would be lost. Therefore all OPA's are encouraged to remain in operation during implementation of a nationwide framework to improve and expand the existing system.

Second was the understanding of financing and cash flow problems faced by entirely free-standing IOPA's. The entirely free-standing IOPA is the desired model for organ procurement. In discussions the subcommittee had with HCFA, we learned that capitalization and permenant financing (costs such as the payment of salaries) force free-standing IOPA's to take out loans to cover these costs inbetween reimbursement payments. As a result, $100. of the amount reimbursed by HCFA for each kidney retrieved goes for the payment of interest on loans these agencies are forced to take out. Other IOPA's, that are not free-standing, have done so to avoid being forced into a position where it would be necessary for them to take out loans. The grants proposed in H.R. 4080 would provide the necessary capital for permenant financing and would help solve the cash flow problems making loans unnecessary. This would have the added benefit of making the IOPA a more attractive work setting. During our investigation we have learned of instances where IOPA's were unable to attract the high quality staff necessary because of

uncertainty in job security that resulted from the present financing schemes.

The Subcommittee also learned that improvement could be brought about not only through reforms in the operating practices of the procurement agencies themselves, but by coordinated reforms in the national structure of the organ procurement program itself. In testimony again from Dr. Prottas and supported by materials we received throughout the Subcommittee's investigation, there are too many organ procurement agencies. As a result many agencies are too small to operate effectively. In addition the distribution of the agencies across the country conforms to no sensible pattern. While some areas are underserved others have several competing agencies. There is also a need for coordination of organ retrieval and distribution systems. The present process is fragmented. Even though there has been widespread federal funding, a national strategy has not emerged. Most organ procurement agencies receive neither direction nor assistance from the funding agency. A guiding mechanism is essential to the development of a cohesive and rational strategy to provide an effective national system of organ retrieval and distribution.

For these reasons the bill proposes establishment of the United States Transplantation Network (USTN) and the National Center for Organ Transplantation (NCOT). These two organizations: USTN, to be a non-profit private entity contracted with by NCOT; and NCOT, a new office to be set up within the Public Health Service; together will serve to gather the patchwork of 110 organ procurement agencies into an efficient operating network. The goal in setting up such a system would be two-fold: first, to see to it that nationwide standards were applied to organ procurement; and second, to provide

technical assistance to those agencies whose level of effectiveness could be improved.

USTN-- will act primarily as a service orginization to assist the local procurement agencies as appropriate. They will maintain a national registry, similar to the existing United Network for Organ Sharing or UNOS system, but for all individuals who need an organ. The UNOS system is presently limited to those awaiting kidneys. USTN will operate a national computer system and a manned 24-hour telephone service to facilitate the matching of donated organs with potential recipients.

NCOT-- will administer the development grants to the organ procurement organizations (OPO's), assist in promoting public understanding of the organ donor system, oversee the activites of the USTN, and carry out the organ procurement activities of Medicare and Medicaid. NCOT will also have a multi-disciplinary advisory committee to examine medical, legal, social, and ethical issues raised by organ transplantation. Among its responsibilities, this committee is charged with examining the question of who should pay for the newly emerging transplant procedures.

The Payment for Organ Transplants

The payment for organ transplants has been a particular concern of the subcommittee throughout our investigation. It was as a result of the testimony of U.S. Army Captain John H. Broderick on behalf of his daughter Adriane, that the subcommittee expanded the original scope of our investigation, which had been primarily organ procurement, to include the

issue of reimbursement. As part of our expanded investigation, the subcommittee sought materials from a number of sources on how existing reimbursement mechanisms reached coverage decisions. In particular we sought to learn the reason for uneven reimbursement policies, in which many providers had chose not to pay for most organ transplant procedures, forcing families to use public fund raising appeals.

There is a need to insure equitable and timely access to life saving and medically effective technologies. It is ironic that, unlike those seeking kidney transplants, many of the other transplant recipients are not seeking coverage under Medicare. Yet, the Medicare pronouncement that these procedures are "experimental" has directly inhibited the coverage of these procedures by other entities which are responsible for making payments for health care. What is most disturbing about this is the process that Medicare uses for accessing new health care technologies.

In testimony before the subcommittee, Dr. H. David Banta, Assistant Director for Health and Life Sciences, Office of Technology Assessment, discussed Medicare's assessment of heart transplants. This assessment occurred while the National Center for Health Care Technology (NCHCT) was still operating. I would like to share some of his testimony regarding Medicare assessments with you:

> "Perhaps the most distressing case is that of heart transplant. The NCHCT recommended that it be covered at selected centers in February 1980. It is still not covered. The rationale was that heart transplant raises many ethical and economic questions, as well as efficacy and safety questions that are being addressed in the Battelle study.
>
> The previous Secretary of HHS, Patricia Harris, decided that heart transplants should not be covered. However, I should note

that HCFA does not have the authority to base payment decisions on such broader considerations as cost and ethical considerations. Under HCFA guidelines, I believe heart transplants should be provided already.

I am sympathetic with the administration's concerns about transplants. However, technology must be addressed in a consistent manner. If HCFA lacks the authority to limit transplants to certain centers, it could request that authority. If HCFA wishes the authority to base decisions on economic and social criteria, it can request Congress to give it that authority. And, by all means, HCFA should define "reasonable and necessary" by regulation.

One is left with the impression, in the case of heart transplant, at least, that HCFA is delaying payment for cost containment reasons. If this is a true perception, this is a serious perversion of the process of technology assessment and its place in policymaking."

The "experimental" label is a reflection of an outdated system that only recognizes two discrete points: "experimental" and "accepted medical practice." More accurately, emerging technologies exist on a continuum where these points are extreme endpoints. We must put in place a system by which newly developed procedures and technologies can rationally progress in a stepwise fashion from "experimental" to "accepted practice."

The bill addresses these concerns, particularly those raised by Dr. Banta. In Title One, the Secretary of the Department of Health and Human Services is required to report annually on the scientific and clinical status of organ transplantation. This report, and other related information, is to be provided annually to Blue Cross and other major health benefit providers. This will insure the timely assessment of new technologies and avoid the present problem where for example, decisions not to reimburse for liver transplants are based on a finding that is over three years old, in a field where quantum jumps have occurred in a period of one year.

In Title Two, there are additional provisions designed to facilitate timely and equitable access to emerging technologies. The bill provides the Secretary with new options in deciding what is "reasonable and necessary." This will provide the inbetween steps that exist between "experimental" and "accepted practice," and allow for the controlled difussion of new technologies in a way that is consistent with timely availability of new health care technologies. To accomplish this, the bill would allow the Secretary to permit payment for transplants and other procedures at specialized centers, or under other specialized circumstances.

The Buying and Selling of Organs

Finally, I believe it is necessary, if we are to provide a comprehensive national strategy, to address the recent proposals to buy and sell human organs. A number of witnesses at the April hearing suggested alternative systems for organ donation, should it be decided that the existing system is unsuccessful. In July, when I testified before this subcommittee, I mentioned some of these alternatives. I think it is important to note none of these proposals have been included in H.R. 4080. The most important step we as a nation can take to redress the present problems is to improve the present voluntary system. H.R. 4080 does this.

We have recently witnessed the most extreme form of incentives, the proposal to buy and sell organs. As Chairman of the Science and Technology Subcommittee on Investigations and Oversight, I have learned that care must be taken if we are to prevent technology from dehumanizing people. We will need

to make conscious choices to protect that which is uniquely human. This is a case where such a decision must be made.

In this case it is not a difficult decision. There is no need to risk the problems a for-profit organ procurement system conjurs up. The result of these proposals has not been to offer new hope to those awaiting transplants. In fact, patients awaiting kidney transplants were among the first to have publicly expressed their outrage that such a proposal had been made. These proposals have only served to exploit the desperation of Americans who are pressed by the serious economic troubles our nation is experiencing. Selling a part of their body is not the answer to their problems and it is not the answer for those awaiting transplants.

Conclusion

As I have explained, the problems posed by the rapid improvement in organ transplants, require the expansion and improvement of a system that has not kept pace with rapid scientific developments. There is no reason this system cannot be adapted to meet the growing demand. That is what H.R. 4080 does.

If the system does eventually fail us, it will be because individuals decide not to support it. A decision not to donate, is a vote cast against the day when organ transplants will be a technology that all of our families could benefit from.

Clearly the time is right to act. We have the means and the technology to prevent much suffering and many tragic deaths. We have all recognized the problems; now it is time for concrete steps to be taken. It has been suggested that this can be accomplished by coalitions of interested voluntary health organizations, the professional medical and surgical societies, and private sector financing. I do not wish to discount the value of these efforts, and I believe that these groups have a key role to play. However, at this time such a proposal is clearly inadequate. This bill will solve the problem.

Mr. WAXMAN. Thank you very much, Mr. Gore. You made an excellent presentation, and you have done a fantastic job spending hundreds of hours, you and your staff, working out this legislation.

You say that there is agreement as to what the problem is. Is the problem that we don't have enough organs, or is the problem that we are not getting organs that are donated to those who need them?

Mr. GORE. It is the latter. We are not getting the organs that are available for transplantation to the people who need those organs.

Now, part of that is because we don't have a good system for retrieving the organs. It is a terrible burden to put on the medical community, doctors and emergency care nurses, to approach a family at such a tragic time.

It is almost too much to ask. I say almost, because it isn't too much to ask in view of the tremendous opportunities to save lives. We need to do a better job, and we need to coordinate the distribution of the organs when they are retrieved.

At some centers around the country, we have tragically seen many of the organs discarded because they weren't in the right place at the right time. It is hard to coordinate these things nationwide if you have the same source of organs providing multiple donations and you have to tissue type each one and check different recipient lists and be in contact with different networks around the country and listen to a 15- or 20-minute tape recording for a while, and then go to another sort of network for the other organ.

We need a national computer registry.

Mr. WAXMAN. You have described the system that we now have in place as very fragmented, and even cited for us the fact that in one central location they were destroying organs that couldn't be used.

Are you critical of the people involved in this work that are doing what they can now, or are you saying that we ought to do something different?

Mr. GORE. Oh, absolutely not. The people involved in this work today are modern-day heroes. They save thousands of lives every year and they have put this system together on their own. I happen to think that they have almost worked miracles in making this thing work as well as it does today, and I want to compliment them and those Americans whose lives have been saved.

They stand in awe of these people. They have done a magnificent job. The present system has gone about as far as we can expect it to go without a national focus and without more coordination at the national level.

We are paying for it. It ought to be paid for and coordinated so that we build upon the work that these people have done.

We don't want to supplant or replace these networks that have been created. What we really want to do is to provide incentives for them to establish closer ties with the medical centers and medical community, in their geographic area on the one side, and closer ties with the U.S. transplantation networks that we are establishing at the national level.

So we want to build on the work of these heroic individuals and improve the work that they have started and try to coordinate it at the national level.

Mr. WAXMAN. You indicate there is a sense of urgency with people you have talked to—people who are waiting for organs and people who are working in this field. Do you get a sense from reading the administration's testimony and talking to them that they don't share that sense of urgency?

Mr. GORE. Well, there is an anomaly in the approach of the administration. On a personal level, they are extremely concerned and empathetic, and when individuals and families have called the White House or the Department of Health and Human Services, they get a very human response and they get some help, and that is good, but somehow there is an inability to see the national dimension of the problem.

Perhaps it is a reflective preference for keeping the Government out of everything it can be kept out of. I have had some sympathy with that view, but, gosh, this ought to be an exception.

Here is a national problem, national in scope, with national dimensions, with national payment for it. We are paying $30 million a year. Why not have a national response to the problem?

Building on the private networks, working with the regional networks that have sprung up, coordinate them at the national level. They don't see the problem that way. I must admit I don't quite understand why, unless it is this sort of reflective attitude of, don't let the Government do anything.

Mr. WAXMAN. Suppose we didn't have the Government do anything. There are people waiting for organs for transplantation. What would your response be should they say to you, let there be a private-sector commercial sale of organs? They are certainly willing to pay whatever price will be necessary to purchase an organ to save the life of a loved one.

Why not let someone go into the business of buying and selling organs?

Mr. GORE. It is very interesting that some of the first voices raised against the proposal to buy and sell organs were from recipients who were waiting for organs. Their statements have been very moving.

They have said, in effect, I know what a terrible thing it is to be left without a kidney or to be left without a normal, functioning organ, and I can't imagine someone wanting to, a healthy person wanting to give one up simply for money, and their statements have really been powerful and persuasive.

The answer to your question, however, is that it is just wrong. It is against our system of values to buy and sell parts of human beings. It is against our system of values to auction off life to the highest bidder. We have laws against other things that make certain kinds of contracts illegal.

The notion has perhaps a superficial attraction to some because we have all learned that the market system will solve lots of problems if we just stand out of the way and let it work. It is very true.

This ought to be an exception. It ought to be the exception because you don't want to invest property rights in human beings. It is just that we have laws against slavery for reasons that is not completely dissimilar.

It is just wrong.

Mr. WAXMAN. One time we allowed in many places in this country, I think we still do, the buying and selling of blood. How do you distinguish that?

Mr. GORE. Well, I distinguish it one important way. Blood is unusual, and once given, it is still retained. The individual who donates blood suffers no harm. A doctor who takes blood from someone isn't violating the Hippocratic oath by doing harm. The Hippocratic oath says, first, do no harm.

A doctor who carves into a healthy person to take a kidney simply for money is violating the Hippocratic oath. Now, the example of blood is interesting for another reason, however, Mr. Chairman.

I am not making the case that buying and selling blood ought to be outlawed, because I think the two cases are distinguishable, but you could make a pretty strong case, if you wanted to, less than 3 percent of the blood that is used in the country comes from buying and selling of blood.

More than 7 percent comes from voluntary donations. The blood that comes from the commercial operation is a poorer quality. There have been tremendous problems because of the nature of the donor population, and, when the commercial sale of blood began a few years ago, there was a dramatic decline in the rate of voluntary blood donations, and we haven't fully recovered from that.

Indeed, if you compare the rate of voluntary blood donations in the United States to the rate in other countries, such as England, which outlaw commercial blood sales, their rate of voluntary blood donations is far higher than ours.

Many have theorized, I think with some justification, that the reason the voluntary donation rate went down is because some said, well, if some are getting money, why should I give it for free?

What we are talking about here is the gift of life and the real problem is how to persuade people to give life, not how to purchase it.

Mr. WAXMAN. If we look then at the actual experience we had with blood, which you have very well distinguished from donating organs, we found that people were reluctant to donate if they knew there was buying and selling of blood.

As a consequence, the people who were donating blood were often people who had public health problems, infections that were passed on to the recipient of the blood. If we allow commercialization, the buying and selling of organs, we face the possibility of inferior quality and perhaps greater public health danger.

Mr. GORE. I think so, without any question, and I think that is yet another reason why the medical community has been so strong and vociferous to the proposal to buy and sell organs.

Mr. NIELSON. I have no questions. I congratulate you for introducing the legislation.

Mr. GORE. Thank you, and thanks to the subcommittee. I look forward to continuing our good, close working relationship to pass this bill in this session of Congress.

Mr. WAXMAN. Mr. Gore, I do want to commend you, again, and let me invite you to join us here. Even though you are not a member of the subcommittee, you are a member of the full com-

mittee and, as lead author of this legislation, we would certainly welcome your participating in the hearings.

Mr. GORE. I appreciate that, Mr. Chairman. Thank you.

Mr. WAXMAN. Our next witness will present the views of the administration on H.R. 4080. Dr. Edward Brandt is Assistant Secretary for Health and Dr. Carolyne Davis is Administrator of the Health Care Financing Administration.

I would like to welcome both of you to our meeting. Your prepared statements will be made part of the record in full, and we would like to ask you to summarize your statements.

STATEMENTS OF EDWARD N. BRANDT, JR., M.D., ASSISTANT SECRETARY FOR HEALTH, OFFICE OF ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND CAROLYNE K. DAVIS, PH. D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Dr. BRANDT. Thank you very much, Mr. Chairman, and members of the subcommittee. Dr. Davis and I both have statements and we will try to summarize them. My purpose is to discuss the activities of the Public Health Service in organ procurement transplantation as they relate to provisions in H.R. 4080, and Dr. Davis will discuss the activities of her agency.

There is a natural tendency to associate organ transplantation with children with end-stage live disease who await suitable donors to possibly save their lives. The tragedy occurs when the patient dies before a suitable donor organ is found. The Congress, the administration, including the President, the media, affected organizations in the private sector, and third-party payers have all become involved in this issue.

Factors that affect the number of transplants performed include a shortage of suitable donors, a lack of public awareness about organ donation, lack of trained specialists and facilities, and lack of knowledge on how to perserve organs. It is on these areas that I will focus my remarks this morning.

Much of the work of the PHS deals with the development of new knowledge in the biomedical sciences to improve our understanding of disease: its progression, its treatment, and its prevention. The National Institutes of Health has supported researech on organ transplantation for 20 years. In 1982, NIH supported 293 projects, totalling $36.5 million. The primary aims of this basic and clinical research is to develop procedures for the most effective selection of recipients of grafts, to develop optimal procedures to condition the recipient prior to transplantation in order to minimize the risk of rejection, to identify the factors that trigger the rejection of transplants and to develop ways in which to treat rejection. Many of the medical and surgical techniques that have improved organ transplantation were products of research supported by NIH.

Despite NIH investment in research on methods of perserving organs, no new approaches have yet been developed. Although significant advances have been made in this area, more research needs to be conducted on ways to preserve organs ex vivo. At the present time, a donor liver can only be preserved up to 10 hours, a

heart for up to 4 hours and a kidney for 72 hours. A lung cannot be preserved at all.

Since 1979, the Food and Drug Administration has made available for U.S. clinical trials cyclosporin A, a drug used along with adrenal glucocorticoids to prevent graft rejection. In September 1983, the FDA declared the new drug application approvable. Cyclosporin is not without problems—it is expensive and transplant recipients apparently have to take it for the rest of their lives. And, we still do not know what the long term side effects may be. Whether children with liver transplants will grow normally, what the long-term survival rates will be, what the long-term risks are with respect to cancer and repeated infections are all questions of the future.

The NIH convened a Consensus Development Conference in June 1983 on liver transplantation. The consensus of the participants was the liver transplantation offers an alternative therapeutic approach which may prolong life in some patients suffering from severe liver disease that has progressed beyond the reach of currently available treatment and consequently carries a predictably poor prognosis.

Transplantation is not the ultimate answer to the treatment of end stage liver disease. Many questions remain unresolved. Substantial questions remain also regarding selection of patients who may benefit from liver transplantation; the stage of their liver disease at which transplantation should be performed; survival and clinical condition of patients beyond the initial year after transplantation; and overall long-range benefits and risks of transplantation in the management of specific liver diseases.

The NIH is also expanding its research on transplantation. Based on the recommendations from the Consensus Development Conference, the actions we will take are shown in the testimony.

Organ transplantation has been performed for over 20 years. In recent years, however, there has been a marked increase in the number of transplants performed. In 1982, 5,358 kidneys were transplanted, 15,000 corneas, 80 livers, 100 hearts, and 11 heart-lung combinations. The sharpest percent increase has occurred in liver transplantations. For example, since 1980, 370 liver transplants have been performed worldwide. This is compared to 170 to 200 in the preceding 17 years.

With this increase in liver transplantation has come an acute awareness of the critical shortage of suitable donors. There has always been a shortage of donors. However, the absence of an available kidney can be managed by renal dialysis while a transplant is awaited, whereas the lack of a liver or heart for transplantation may mean death.

Advances in transplantation technology over the last several years have pointed to the need for a more coordinated approach to organ procurement and donation. Voluntary organizations have traditionally taken responsibility for procuring organs for transplantation, as they do with blood supply, which is handled entirely by voluntary organizations. We believe that it would be wise to maintain the present voluntary system of organ donation and that we should not try to dictate roles to the private sector in such an effort.

This is not to say that the current framework cannot be improved upon. The President asked the Surgeon General of the United States to assist with the problem of the critical shortage of suitable organs. Workshops that he convened in June and September of this year culminated in an agreement to establish the American Council of Transplantation [ACT]. This umbrella organization will be established to develop better approaches for coordinating the efforts of the private sector in procuring organs for transplantation. The Council has identified four major goals and ways to get there as is outlined in the testimony.

The PHS is providing $100,000 in core support for ACT through a cooperative agreement that will be awarded soon. The subcommittee can be assured that the PHS will continue to provide advice and assistance to the ACT. Also, the PHS fully intends to become an active member of this worthwhile organization. We have learned a great deal from our association with the transplant surgeons and organ procurement coordinators. We recognize that there are gaps and that the current system is rather fragmented. However, the basic philosophies and the framework that guide their activities are sound. We are confident that, through ACT, the necessary improvements can be made in the system so that it will result in a highly visible, well-defined and effective program for organ procurement.

The Centers for Disease Control in the late 1970's developed an approach to organ procurement that may prove to be of some use to ACT. Through this project, it was also demonstrated that by applying a more systematic and timely approach to identifying potential donors, the number of organs actually procured could be increased.

The results of CDC's demonstration efforts have been disseminated in the professional literature and the CDC staff has provided technical assistance to procurement centers interested in increasing organ availability. In my view, the CDC study indicated that the present voluntary system of organ procurement can be managed well by the private sector.

We should keep in mind, however, even with the best system in place for procuring organs, not every person that needs a transplant will obtain one. For example, despite the existence of 20,000 brain dead persons annually, only an estimated 1,800 livers per year are obtainable for transplantation. This falloff results from several factors, including the presence of disease affecting the organs, trauma to the organ as a result of an accident, and so forth.

The Office of Health Technology Assessment [OHTA] within the National Center of Health Services Research has been asked by HCFA to evaluate the safety and effectiveness of heart, pancreas, and liver transplantation. The PHS assessment of the heart transplant will be completed after analysis of the Battelle Center national heart transplantation study is submitted in September 1984. The results of the pancreas assessment should be also available then.

In April 1982, HCFA asked the PHS to reassess liver transplantation, after the PHS had previously determined the procedure to be experimental in 1980. OHTA, as is its usual practice, published a notice in the Federal Register about its intent to evaluate these

technologies and, at the same time, contacted appropriate Federal agencies, medical speciality societies, and health insurance and manufacturing associations. With materials from these sources, information from the NIH Consensus Development Conference on Liver transplantation, and a staff review of the literature, OHTA developed its report and has sent me a draft of the recommendation regarding the safety and effectiveness of liver transplantation.

Mr. Chairman, I am reviewing that report now. Debatable issues remain, both technical and ethical, regarding selection of recipients for liver transplants. It is generally conceded that individuals who continue a pattern of substance abuse, and those with viral-induced liver disease and viremia and those with malignancy extending beyond the margins of the liver should be excluded.

My concluding remarks, Mr. Chairman, focus on title I of H.R. 4080, the National Organ Transplantation Act. My overall concern is that the bill places too much emphasis on the mechanics of distributing solid organs.

The PHS has concern about three specific elements of the bill. The first is the provision for the establishment of a new grants program to provide funds to establish or expand organ procurement organizations.

The second is the establishment of a transplantation network that would maintain a registry of people who need organs to facilitate matching of donated organs with potential recipients.

Organ procurement organizations, whether they are independently run or part of a hospital, have established procedures for matching donated organs with potential recipients. Many of these organizations will be represented on the ACT. I have already described this effort earlier in my testimony. The existing system provides a solid base on which we can build and improve upon. I feel that we should wait until the ACT is formally established and operational to see how effectively it deals with coordinating the activities of the various organizations involved. I just do not believe that Government involvement in the procurement of organs will necessarily improve the system any further.

The third provision would set up a National Center for Organ Transplantation within the department. It would be advised by an advisory council that would examine the medical, legal, ethical, and social issues related to organ transplantation. I have concerns that setting up such an organization would further fragment or otherwise duplicate the corresponding efforts of the ACT. Our role should be to help the organ procurement agencies, not compete with them.

I am also concerned that the Federal involvement in this activity would raise unrealistic expectations about the number of human organs that can technically be retrieved. There is a finite number of suitable organs and there are certain factors that limit the number that can reasonably be retrieved. This limitation will remain regardless of how we as a Nation, elect to manage our organ procurement program.

I would now like to address on element of title II of the bill. It states that medicare will cover liver transplants only if the physician meets certain criteria specified by the Secretary. I strongly oppose this provision. It would be inappropriate to alter a system

that has proven to be so successful in assuring high quality health care in this country. The scope of physician practice has traditionally and logically been controlled by a combination of State licensure, hospital staff privileges and certification by medical speciality societies.

In conclusion, I would like to comment this morning on the buying and selling of solid organs as addressed in title III of the bill. Secretary Heckler and I are opposed to the sale of human organs because we believe that such activity is immoral and goes against the principles of medical ethics. We are particularly concerned about those persons willing to sell their organs who may not fully understand the serious consequences of their action. However, we recognize we will have to consider further whether Federal sanctions are needed or whether such activities should be dealt with at the State or local levels.

Mr. Chairman, this summary of the PHS activities should bring you up to date on our most recent activities. We stand ready to provide further information on ways we can reach our desired mutual goals. I believe that these goals can be attained administratively, without additional legislation. I will be pleased to answer any questions you may have.

Thank you very much.

[Testimony resumes on p. 152.]

[Dr. Brandt's prepared statement follows:]

STATEMENT OF

EDWARD N. BRANDT, JR., M.D.

ASSISTANT SECRETARY FOR HEALTH

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to appear before you to discuss the activities of the Public Health Service (PHS) in organ procurement and transplantation as they relate to provisions in H.R. 4080. I am Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, Department of Health and Human Services. With me is Dr. Carolyne Davis, Administrator of the Health Care Financing Administration (HCFA), who will be discussing the activities of her agency as they relate to H.R. 4080.

With few exceptions, no other issue confronting the Public Health Service (PHS) at this time is as emotionally charged as this one. There is a natural tendency to associate organ transplantation with children with end-stage liver disease who await suitable donors to possibly save their lives. The tragedy occurs when the patient dies before a suitable donor organ is found. The Congress, the Administration including the President, the media, affected organizations in the private sector, and third party payers have all become involved in the issue.

Factors that affect the number of transplants performed include a shortage of suitable donors, a lack of public awareness about organ donation, lack of trained specialists and facilities, and lack of knowledge on how to preserve organs. It is on these areas that I will focus my remarks this morning.

Research Efforts in the PHS on Organ Transplantation

Much of the work of the PHS deals with the development of new knowledge in the biomedical sciences to improve our understanding of disease: its progression, its treatment, and its prevention. The National Institutes of Health (NIH) has supported research on organ transplantation for 20 years. In 1982, NIH supported 293 projects, totalling $36.5 million. The primary aims of this basic and clinical research is to develop procedures for the most effective selection of recipients of grafts, to develop optimal procedures to condition the recipient prior to transplantation in order to minimize the risk of rejection, to identify the factors that trigger the rejection of transplants, and, to develop ways in which to treat rejection.

Many of the medical and surgical techniques that have improved organ transplantation were products of research supported by NIH. Some transplant procedures are fairly well established in current clinical practice, such as cornea and kidney transplantation. Other procedures, such as heart, skin, bone, and, for some conditions, bone marrow transplantations are gaining greater acceptance and clinical success. The patient indications for transplantation are still being refined, but some patients have enjoyed long-term survival for over 10 years with cornea, kidney,

and heart transplants, while the other procedures mentioned have only shorter term follow-up. The NIH continues research on all transplantation approaches, particularly on procedures considered experimental, e.g., heart-lung, pancreas, and liver.

Despite NIH investment in research on methods for preserving organs, no new approaches have yet been developed. Although significant advances have been made in this area, more research needs to be conducted on ways to preserve organs ex vivo. At the present time, a donor liver can only be preserved up to 10 hours, a heart for up to 4 hours, and a kidney for 72 hours. A lung cannot be preserved at all. If techniques of organ preservation could be improved, the problems of organ availability could be greatly diminished.

Since 1979, the Food and Drug Administration (FDA) has made available for U.S. clinical trials cyclosporin A, a drug used along with adrenal glucocorticoids to prevent graft rejection. The drug was discovered in 1970 by the Swiss Pharmaceutical Company Sandoz and has been an important factor to increasing the availability of kidney, heart and liver transplants to more patients who need them. In September 1983, the FDA declared the new drug application approvable. Cyclosporin is not without problems--it is expensive and transplant recipients apparently have to take it for the rest of

their lives. And, we still do not know what the long-term side effects may be. Whether children with liver transplants will grow normally, what the long-term survival rates will be, what the long term risks are with respect to cancer and repeated infections are all questions for the future.

The NIH convened a Consensus Development Conference in June 1983 on liver transplantation in which the skills, resources and institutional support needed for liver transplantation were discussed. The consensus of the participants was that liver transplantation offers an alternative therapeutic approach which may prolong life in some patients suffering from severe liver disease that has progressed beyond the reach of currently available treatment and consequently carries a predictably poor prognosis.

Transplantation is not the ultimate answer to the treatment of end stage liver disease. Many questions remain unresolved. Substantial questions remain also regarding selection of patients who may benefit from liver transplantation; the stage of their liver disease at which transplantation should be performed; survival and clinical condition of patients beyond the initial year after transplantation; and overall long-range benefits and risks of transplantation in the management of specific liver diseases.

As you are aware, the requirements for conducting a liver transplantation program are formidable. Very few hospitals and

medical centers presently have the capability to make a major commitment to support such a program. Experts at the consensus conference agreed that the transplantation surgeon must assemble and train a an extensive surgical and medical team and that commitment to the program requires operating rooms, recovery rooms, intensive care units, laboratory and enormous blood bank support at all times. These requirements offer the only assurance for high quality care in performing this very difficult operation.

The NIH is also expanding its research on transplantation. Based on the recommendations from the Consensus Development Conference, the NIH will take the following actions:

- Develop a Program Announcement to stimulate research on organ preservation. This responds to the advice of experts that both new ideas and new technologies are desperately needed in this area.

- The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) will be the lead institute for an NIH-wide program announcement that will express its interest and that of other institutes in a broad range of research, for example:

  -- Studies on the pathogenesis of liver diseases by following patients who have received liver translants.

transplation, e.g., whether it is possible to use a single lobe of an adult donor liver for transplantation into a child, and techniques to improve auxiliary liver transplantation.

-- Studies on how liver transplant patients metabolize drugs, including the immunosuppressive drugs taken to prevent graft rejection.

-- Studies utilizing gene cloning and monoclonal antibodies to develop more specific methods for preventing graft rejection.

Finally, the National Institute of Allergy and Infectious Diseases will sponsor a conference, with financial assistance from the Upjohn Company, in January 1984 on the problems associated with multiple organ donation and procurement. Issues to be explored are: the means for obtaining more than one organ from a donor; guidelines that can be developed for intensive care units on how to maintain a brain dead donor, and the factors that interfere with identifying a donor early enough to ensure that the organs remain viable. Prior to the conference, a workshop will be held with the Subcommittee on Organ Sharing of the American Society of Transplant Surgeons to identify where common procedures for multiple organ procurement exist and where they differ.

PHS Activities Relating to Organ Procurement

Organ transplantation has been performed for over 20 years. In recent years, however, there has been a marked increase in the number of transplants performed. In 1982, 5,358 kidneys were transplanted, 15,000 corneas, 80 livers, 100 hearts, and 11 heart-lung combinations. The sharpest percent increase has occurred with liver transplantations. For example, since 1980, 370 liver transplants have been performed worldwide. This is compared to 170-200 in the preceding 17 years. With this increase in liver transplantation has come an acute awareness of the critical shortage of suitable donors. There has always been a shortage of donors. However, the absence of an available kidney can be managed by renal dialysis while a transplant is awaited, whereas the lack of a liver or heart for transplantation may mean death.

Advances in transplantation technology over the last several years have pointed to the need for a more coordinated approach to organ procurement and donation. Voluntary organizations have traditionally taken responsibility for procuring organs for transplantation. We believe that it would be wise to maintain the present voluntary system of organ donation and that we should not try to dictate roles to the private sector in such an effort.

This is not to say that the current framework cannot be improved upon. Toward this end, the President asked the Surgeon General of the United States to assist with the problem of the critical shortage of suitable organs. Workshops that he convened in June and September of this year culminated in an agreement to establish the American Council on Transplantation (ACT). This umbrella organization will be established to develop better approaches for coordinating the efforts of the privatesector in procuring organs for transplantation. The Council has identified four major goals to increase the availability of organs:

- to motivate the public to donate organs and tissues for transplantation,
- to improve organ identification and referral to organ procurement programs by health professionals,
- to promote the effective distribution and use of multiple organs and tissues, and
- to ensure equitable access to organs and transplantation processes.

Plans call for these goals to be achieved through initiation of a comprehensive program of public and professional education; improved communication and cooperation among organ procurement

programs, health professionals and acute care hospitals; the establishment of standards for donor management, surgical recovery and preservation of donor organs; improved mechanisms for organ procurement and distribution; and studies to determine the current and future needs for organ and tissue transplantion.

The PHS is providing $100,000 in core support for ACT through a cooperative agreement that will be awarded soon. The Subcommittee can be assured that the PHS will continue to provide advice and assistance to the ACT. Also, the PHS fully intends to become an active member of this worthwhile organization. We have learned a great deal from our association with the transplant surgeons and organ procurement coordinators. We recognize that there are gaps and that the current system is rather fragmented. However, the basic philosophies and the framework that guide their activities are sound. We are confident that through ACT the necessary improvements can be made in the system so that it will result in a highly visible, well-defined and effective program for organ procurement.

In addition to serving as the catalyst in making ACT a reality, the Surgeon General has taken further steps to implement certain pledges the made to further assist ACT in their efforts. He was instrumental in bringing together the group to discuss multiple organ donation and procurement that I mentioned earlier in my statement. He has begun a dialogue with appropriate national

pediatric organizations expressing the specific concerns about the unique aspects of pediatric transplantation. In the last couple of months, the Surgeon General has encouraged editorials in specialty journals, and has made himself and the interim officers of ACT available to promote the concept of ACT.

The Centers for Disease Control (CDC) in the late 1970's developed an approach to organ procurement that may prove to be of some use to ACT. The CDC used public health principles in order to demonstrate how to increase the numbers of organs procured. This was done in response to the perceived cost-effectiveness of transplantation and the improved quality of life for transplant recipients, together with the shortage of cadaveric organs available for transplantation.

This study was initiated to assess the number of kidneys potentially available for transplant purposes. Medical records of deceased patients were reviewed using criteria developed by transplant surgeons for determining suitability of organ donors. These record reviews demonstrated that only a small proportion of suitable donors were actually being identified within the short time available to accomplish organ procurement.

Through this project, it was also demonstrated that by applying a more systematic and timely approach to identifying potential donors, the number of organs actually procured could be increased. In fact, Atlanta and Augusta, Georgia, tripled the number of kidneys procured in a three-year period by implementing the following procedures:

- Instituting a procurement program in those hospitals which had been identified by record review as having potential donors.

- Making use of an existing operational procurement apparatus, consisting of surgeons, tissue typers, transplant coordinator, and the like.

- Establishing professional education to promote and maintain program visibility.

- Making daily visits to the hospital and the specific units to identify potential donors.

- Assessing the program's effectiveness by monitoring medical records to determine the number of potential donors and the number of donors actually being referred, to quickly identify where potential donors were being missed, and to understand the dynamics of the individual hospital.

The results of CDC's demonstration efforts have been disseminated in the professional literature and the CDC staff has provided technical assistance to procurement centers interested in increasing organ availability. The CDC results also have applicability in identifying potential donors of many types of organs.

In my view, the CDC study indicates that the present voluntary system of organ procurement can be managed well by the private sector. Beyond providing advice and assistance, interference by the federal government is unnecessary.

We should keep in mind, however, even with the best system in place for procuring organs, not every person that needs a transplant will obtain one. For example, despite the existence of 20,000 brain-dead persons annually, only an estimated 1,800 livers per year are obtainable for transplantion. This fall-off results from several factors, including the presence of disease affecting the organs, trauma to the organ as a result of an accident, physician reluctance to raise the issue of donorship with the family, unwillingness of next-of-kin to authorize the procedure, varying State laws regarding organ donation and the legal definitions of death, and failure to secure a match during the extremely short period of organ viability.

Assessment of Safety and Effectiveness

The Office of Health Technology Assessment (OHTA) within the National Center for Health Services Research has been asked by HCFA to evaluate the safety and effectiveness of heart, pancreas, and liver transplantation. The PHS assessment of the heart transplant will be completed after analysis of the Battelle Center National Heart Transplantation Study is submitted in September 1984. The results of the pancreas assessment should also be available then.

In April 1982, HCFA asked the PHS to reassess liver transplantation, after the PHS had previously determined the procedure to be experimental in 1980. OHTA, as is its usual practice, published a notice in the Federal Register about its intent to evaluate these technologies and, at the same time, contacted appropriate Federal agencies, medical specialty societies, and health insurance and manufacturing associations. With materials from these sources, information from the NIH Consensus Development Conference on Liver Transplantation, and a staff review of the literature, OHTA developed its report and has sent me a draft of the recommendation regarding the safety and effectiveness of liver transplantation.

Mr. Chairman, I am reviewing that report now. Debatable issues remain, both technical and ethical, regarding selection of recipients for liver transplants. It is generally conceded that individuals who continue a pattern of substance abuse, and those

with viral-induced liver disease and viremia and those with malignancy extending beyond the margins of the liver should be excluded from candidacy.

The PHS is urging that institutions performing liver transplants develop and maintain data available on a wide range of scientific, clinical and related issues. Data collection on long-term survival, morbidity and mortality, and quality of life would also be strengthened through this process. The PHS is currently exploring mechanisms for central coordination of data so collected.

My concluding remarks, Mr. Chairman, focus on Title I of H.R. 4080, the National Organ Transplantation Act. My overall concern is that the bill places too much emphasis on the mechanics of distributing solid organs. It falls short, however, of addressing ways in which this country can meet the increasing demands for transplantable organs.

The PHS has concern about three specific elements of the bill. The first is the provision for the establishment of a new grants program to provide funds to establish or expand organ procurement organizations. The second is the establishment of a Transplantation Network that would maintain a registry of people who need organs to facilitate matching of donated organs with potential recipients. I do not disagree that appropriate

funding, as called for in the first provision, and the network, called for in the second provision, are important aspects of a national organ procurement program. Organ procurement organizations, whether they are independently run or part of a hospital, have established procedures for matching donated organ with potential recipients. Many of these organizations will be represented on the ACT. I have already described this effort earlier in my testimony. The existing system provides a solid base on which we can build and improve upon. I feel that we should wait until the ACT is formally established and operational to see how effectively it deals with coordinating the activities of the various organizations involved. I just do not believe that government involvement in the procurement of organs will necessarily improve the system any further.

The third provision would set up a National Center for Organ Transplantation within the Department. It would be advised by an advisory council that would examine the medical, legal, ethical and social issues related to organ transplantation. I have concerns that setting up such an organization would further fragment or otherwise duplicate the corresponding efforts of the ACT. Our role is to help the organ procurement agencies, not compete with them. I am also concerned that federal involvement in this activity would raise unrealistic expectations about the number of human organs

suitable organs, and, as I have already mentioned this morning, there are certain factors that limit the number that can reasonably be retrieved. This limitation will remain regardless of how we as a Nation elect to manage our organ procurement program.

The advisory council to the National Center for Organ Transplantation would only serve to duplicate the activities of the Office of Health Technology Assessment in the National Center for Health Services Research. As I mentioned earlier, this office just completed a comprehensive evaluation of liver transplants; evaluations of pancreas and heart transplants are underway. These evaluations are available to the public as they are completed. I should add that the assessment process provides an opportunity for receiving advice from scientific and professional groups as well as public organizations.

I would now like to address one element of Title II of the bill. It states that Medicare will cover liver transplants only if the physician meets certain criteria specified by the Secretary. I strongly oppose this provision. It would be inappropriate to alter a system that has proven to be so successful in assuring high quality health care in this country. The scope of physician practice has traditionally and logically been controlled by a combination of State licensure, hospital staff privileges and certification by medical specialty societies.

In conclusion, I would like to comment this morning on the buying and selling of solid organs as addressed in Title III of the bill. Secretary Heckler and I are opposed to the sale of human organs because we believe that such activity is immoral and goes against the principles of medical ethics. We are particularly concerned about those persons willing to sell their organs who may not fully understand the serious consequences of their action. However, I we recognize we will have to consider further whether Federal sanctions are needed or whether such activities should be dealt with at the State and local levels.

Mr. Chairman, this summary of the PHS activities should bring you up to date on our most recent activities. We stand ready to provide further information on ways we can reach our desired mutual goals. I believe that these goals can be attained administratively, without additional legislation. I will be pleased to answer any questions you may have.

Mr. WAXMAN. Thank you, Dr. Brandt.
Dr. Davis.

STATEMENT OF CAROLYNE K. DAVIS, Ph. D.

Dr. DAVIS. I am pleased to be here to discuss the medicare end-stage renal disease [ESRD] program, which is administered by HCFA, and H.R. 4080, the National Organ Transplant Act.

In 1972, Congress gave the Federal Government a unique role by providing medicare protection to virtually all persons with ESRD. Currently, medicare protects approximately 93 percent of people receiving any ESRD services.

Medicare costs for ESRD patients were about $2 billion in 1982. This was about 4 percent of total program expenditures and represents about 9 percent of part B expenditures. These expenditures were for one-quarter of 1 percent of medicare beneficiaries, and the expenditures have grown much faster than were originally projected when the law was passed.

Kidney procurement is performed by Organ Procurement Agencies [OPA's]. These agencies perform or coordinate harvesting of donated organs, preservation of donated kidneys, transportation of donated kidneys, and maintenance of a system to locate prospective recipients for harvested organs.

There are 36 independent OPA's located in 22 States and the District of Columbia which are approved to participate in medicare. In addition, approximately 140 hospitals operate some aspect of an organ procurement program.

The independent OPA's usually coordinate a network of participating hospitals that have agreed to identify potential kidney donors. OPA personnel go to a hospital after removal of kidney tissue to preserve the tissue in the appropriate apparatus. An OPA transplant coordinator is responsible for transporting donated kidneys from the donor site to the transplant hospital for transplantation. There are 157 transplant centers which meet medicare certification requirements.

Computer matching systems have been developed to permit effective organ sharing between geographically distinct transplant centers. OPA's are responsible for locating the best recipient match for the donated kidney.

One intermediary, Aetna Life and Casualty of Hartford, Conn., services all independent OPA's and all independent histocomptability (tissue typing) laboratories. Hospitals having their own OPA's are reimbursed by their intermediaries through their kidney acquisition cost centers. Medicare reimbursement for procurement services provided by these entities is based on reasonable cost.

In the September 1, 1983 Federal Register, we proposed an interim final rule on prospective payment for medicare inpatient hospital services. In view of the unique characteristics of organ procurement activities and the desirability of maintaining an adequate supply of kidneys, we proposed that these kidney acquisition costs should be handled outside the prospective payment system. As a result, kidney acquisition costs have been removed from the standardized amounts and from the cost weight for DRG 302, kidney transplant.

My complete testimony highlights the research and demonstration activities that we believe are important in both ESRD and transplantation. We currently have a 5-year plan for research and demonstration projects in the ESRD area. In the text of my testimony is a summary of the various research activities.

In terms of our coverage decisions and the activities related to that, the medicare statute clearly states that medicare should pay only for services which are reasonable and necessary. To be reasonable and necessary, it must be safe and efficacious. Thus, medicare does not pay for devices, procedures, or techniques that are considered to be investigational as this does not meet those criteria.

When a coverage issue such as organ transplant is brought to HCFA's attention, the Office of Coverage Policy conducts a search of the medical literature. If it appears from the reviews that the procedure may need further investigation, the issue is referred to the HCFA physician panel.

The panel will either resolve the question or refer it to the Public Health Service on either an informal basis or with a request for a full assessment.

A full assessment as to safety and efficacy involves consultation with medical specialty groups and other professional organizations. When the Public Health Service completes the information gathering and evaluation process, it makes a formal recommendation to HCFA. HCFA then decides whether the device or procedure should be covered. At present the medicare program's coverage of organ transplants is limited to kidney and cornea transplants.

Under medicaid, we will match the State's funds for any organ transplants they choose to cover. Questions for medicare coverage have arisen with respect to heart, liver, and pancreatic transplants.

In the area of heart transplants, a study financed by the Health Care Financing Administration is now under way on all aspects of coverage of heart transplants. Medicare is paying for heart transplants at 6 medical centers for 15 transplants. We have already paid for 14 of them. The study is scheduled to be completed in June 1984, with the evaluation to be finished 3 months later. When this study is completed and we have the evaluation in hand, we will then make a decision regarding coverage of heart transplants under medicare.

In the area of liver transplants, in April 1982, we referred questions of safety and efficacy of liver transplants to the Public Health Service for further assessment.

It is my understanding that the Public Health Service is in the final stages of considering this question and we expect their advice soon.

In the area of pancreatic transplants, we asked PHS for its recommendation as to these transplants, especially with respect to the ESRD beneficiaries who are diabetic and have undergone kidney transplants.

My comments on H.R. 4080, the National Organ Transplant Act, are directed to provisions that directly impact the medicare and medicaid programs. The bill's proposed transplantation network is to be funded in an amount not to exceed $2 million in any fiscal year and is to be financed from the Federal hospital insurance trust fund.

There is presently a number of organ procurement agencies and there is considerable new activity developing in the private sector.

While the revenue to be provided through the trust fund is relatively small, I believe it is inappropriate to add yet another obligation on our already overburdened financial base.

We also wish to maintain the current method for coverage determinations. I do not believe the proposed new advisory council is necessary since its purposes are met with our current cooperative arrangements with the Public Health Service.

Title II of H.R. 4080 would amend titles XVIII and XIX of the Social Security Act to permit reimbursement for organ transplant procedures at designated facilities. It provides authority for the Secretary—after consulting with the Assistant Secretary of Health—to set the medical criteria for assuring that items and services furnished are reasonable and necessary and that the conditions under which services are to be provided also meet minimum criteria.

It is our understanding that the intent of this section is to allow the Secretary to designate the number and type of hospitals which provide organ transplants and to extend coverage to selected groups of people. However, the actual language would appear to apply to all medicare benefits, not solely to transplants.

The same section specifies payments may be made to centers designated by the Secretary only if the center does not discriminate on a number of bases, including the ability to pay. We are concerned about the impact of that provision on the financial stability and viability of these centers given the enormous cost of transplant procedures.

Title II also would require the States to develop written policies for coverage under medicaid State plans for organ transplant procedures. In the absence of such policies, the State plan would be deemed to provide for coverage in the same manner as covered under medicare.

It would mandate that States pay for services at the medicare rate using the DRG payments schedule and restricts State coverage to procedures covered under the medicare plan. I have some concerns with that. The States have always had the responsibility for making coverage and reimbursement decisions for their medicaid programs. It appears that this provision would take us in the opposite direction, with no compelling reason for doing so.

Finally, I would like to note that HCFA will not pay a bounty for kidneys. Our instructions to the intermediaries from the very beginning of the program in July 1973 have stated this position, and I quote:

> No program reimbursement may be made for the kidney itself. If the donor sells his kidney, the purchase price may not be reflected in any program payment.

In conclusion, HCFA opposes the enactment of H.R. 4080 for the reasons that I have outlined and for those suggested by Dr. Brandt. The goals are indeed laudable, but the means suggested will not allow us to meet the ends any faster or more efficiently than we can today. In fact, I have some serious concerns that there might be some risks in more bureaucracy and less efficiency in that system.

I thank you for the opportunity to comment on this bill. I do look forward to continuing to work with you on these important issues.

[Testimony resumes on p. 174.]

[The statement of Dr. Davis follows:]

STATEMENT OF

CAROLYNE K. DAVIS, PH.D.

INTRODUCTION

MR. CHAIRMAN, I AM CAROLYNE K. DAVIS, THE ADMINISTRATOR OF THE HEALTH CARE FINANCING ADMINISTRATION (HCFA).

I AM PLEASED TO BE HERE TO DISCUSS THE MEDICARE END-STAGE RENAL DISEASE (ESRD) PROGRAM, WHICH IS ADMINISTERED BY HCFA, AND H.R. 4080, THE NATIONAL ORGAN TRANSPLANT ACT.

ESRD RESPONSIBILITIES

IN 1972, CONGRESS GAVE THE FEDERAL GOVERNMENT A UNIQUE ROLE BY PROVIDING MEDICARE PROTECTION TO VIRTUALLY ALL PERSONS WITH ESRD. CURRENTLY, MEDICARE PROTECTS APPROXIMATELY 93 PERCENT OF PEOPLE RECEIVING ANY ESRD SERVICES.

MEDICARE COSTS FOR ESRD PATIENTS WERE ABOUT $2 BILLION IN 1982. THIS WAS ABOUT FOUR PERCENT OF TOTAL PROGRAM EXPENDITURES AND REPRESENTS ABOUT NINE PERCENT OF PART B EXPENDITURES. THESE EXPENDITURES WERE FOR ONE QUARTER OF ONE PERCENT OF MEDICARE BENEFICIARIES, AND THEY HAVE GROWN MUCH FASTER THAN WERE ORIGINALLY PROJECTED WHEN THE LAW WAS PASSED.

IN JULY 1973, AT THE BEGINNING OF THE MEDICARE ESRD PROGRAM, THERE WERE APPROXIMATELY 15,000 ESRD PATIENTS, OF WHOM 1,500

RECEIVED TRANSPLANTS. IN 1978, PUBLIC LAW 95-292 WAS ENACTED TO ENCOURAGE EFFICIENCY AND ECONOMY IN THE ESRD PROGRAM. IN PARTICULAR, THE LEGISLATION ENCOURAGED HOME DIALYSIS AND TRANSPLANTATION TO REDUCE LONG-TERM PROGRAM COSTS.

MEDICARE/MEDICAID ELIGIBILITY FOR TRANSPLANT RECIPIENTS

THE SOCIAL SECURITY ACT PROVIDES MEDICARE ENTITLEMENT FOR CURRENTLY OR FULLY INSURED INDIVIDUALS WITH END-STAGE RENAL DISEASE WHO REQUIRE REGULAR KIDNEY DIALYSIS OR RECEIVE A KIDNEY TRANSPLANT. THIS COVERAGE ALSO APPLIES TO A FULLY OR CURRENTLY INSURED INDIVIDUAL'S SPOUSE OR DEPENDENT CHILD IF ONE OF THEM EXPERIENCES ESRD AND INITIATES A REGULAR COURSE OF DIALYSIS OR RECEIVES A TRANSPLANT.

THE FIRST DAY OF ENTITLEMENT TO MEDICARE VARIES DEPENDING ON THE MODE OF TREATMENT. IN GENERAL, AN INDIVIDUAL ON DIALYSIS RECEIVES BENEFITS THREE MONTHS AFTER THE START OF DIALYSIS, OR IF AN INDIVIDUAL PARTICIPATES IN SELF-CARE TRAINING DURING THE FIRST THREE MONTHS OF DIALYSIS, ENTITLEMENT BEGINS WITH THE MONTH THE REGULAR COURSE OF DIALYSIS BEGINS. AN INDIVIDUAL WHO RECEIVES A KIDNEY TRANSPLANT BEGINS ENTITLEMENT WITH THE MONTH OF THE TRANSPLANT OR 2 MONTHS EARLIER IF HE OR SHE IS HOSPITALIZED IN PREPARATION FOR THE TRANSPLANT.

COVERAGE ENDS 36 MONTHS AFTER THE MONTH OF TRANSPLANT UNLESS THE TRANSPLANT FAILS AND THE INDIVIDUAL BEGINS A COURSE OF DIALYSIS OR RECEIVES ANOTHER TRANSPLANT.

THERE ARE NO ELIGIBILITY REQUIREMENTS IN THE MEDICAID PROGRAM THAT ARE SPECIFIC TO PERSONS WHO REQUIRE ORGAN TRANSPLANTS. PERSONS WHO REQUIRE ORGAN TRANSPLANTS MUST MEET THE SAME CATEGORICAL AND INCOME AND RESOURCE STANDARDS THAT ALL OTHER PERSONS MUST MEET IN ORDER TO BECOME ELIGIBLE FOR MEDICAID. IF THESE REQUIREMENTS ARE MET, THE INDIVIDUAL IS ELIGIBLE FOR ANY OF THE MEDICAID PROGRAM SERVICES OFFERED BY HIS/HER PARTICULAR STATE. THE AVAILABILITY OF ORGAN TRANSPLANTS TO A MEDICAID-ELIGIBLE THEN DEPENDS ON WHETHER A STATE HAS CHOSEN TO COVER SUCH SERVICES UNDER ITS MEDICAID PLAN.

MEDICARE COVERAGE AND REIMBURSEMENT FOR KIDNEY TRANSPLANTATION

BOTH PARTS A AND B (HOSPITAL INSURANCE AND SUPPLEMENTARY MEDICAL INSURANCE) OF MEDICARE HELP PAY FOR KIDNEY TRANSPLANT SURGERY. PART A HOSPITAL INSURANCE WILL COVER INPATIENT HOSPITAL SERVICES FOR BOTH THE KIDNEY RECIPIENT AND THE DONOR. THESE SERVICES MAY INCLUDE A PRE-EVALUATION, THE KIDNEY PROCUREMENT, AND THE ACTUAL TRANSPLANT OPERATION. PART B MEDICAL INSURANCE WILL PAY FOR A SURGEON'S RENAL

TRANSPLANTATION SERVICES ON A COMPREHENSIVE PAYMENT BASIS THAT INCLUDES SUPERVISION OF IMMUNOSUPPRESSANT THERAPY OVER A PERIOD OF 60 DAYS FOLLOWING SURGERY, OR PAYMENT CAN BE MADE SEPARATELY. THE PAYMENT CAN VARY DEPENDING ON WHETHER THE RENAL SURGEON PERFORMED OTHER SURGICAL PROCEDURES AT THE TIME OF THE TRANSPLANTATION OR WHETHER HE/SHE PROVIDED SUPERVISION OF THE IMMUNOSUPPRESSANT THERAPY OVER A PERIOD OF 60 DAYS FOLLOWING SURGERY. THIS PAYMENT IS A VARIATION OF THE REASONABLE CHARGE METHOD USED BY THE MEDICARE PROGRAM TO PAY FOR ALL PHYSICIANS' SERVICES. THE MAXIMUM PROGRAM AMOUNTS CURRENTLY ALLOWED BY MEDICARE CARRIERS FOR RENAL TRANSPLANTATION BY A SURGEON, INCLUDING IMMUNOSUPPRESSANT THERAPY FOR 60 DAYS, RANGES FROM $1,734 TO $2,875. ANY NECESSARY AND REASONABLE MEDICAL SERVICES PROVIDED TO THE PATIENT OUTSIDE THIS TIME PERIOD ARE PAID UNDER THE USUAL REASONABLE CHARGE SYSTEM.

PAYMENT FOR SURGEONS WHO PERFORM CADAVERIC DONOR EXCISIONS IS MADE AT 100 PERCENT OF THE REASONABLE COST UNDER PART A. A RECENT INTERMEDIARY SURVEY INDICATED THAT A MEDIAN COST OF APPROXIMATELY $900 IS PAID BY INDEPENDENT ORGAN PROCUREMENT AGENCIES FOR A SURGEON'S REMOVAL OF CADAVERIC KIDNEYS. ALL PHYSICIANS' SERVICES RENDERED IN CONNECTION WITH REMOVAL OF THE LIVING DONOR'S KIDNEY ARE REIMBURSED USING MEDICARE REASONABLE CHARGES. AVERAGE PAYMENTS ARE APPROXIMATELY $1,100 FOR THIS SERVICE.

KIDNEY PROCUREMENT

KIDNEY PROCUREMENT IS PERFORMED BY ORGAN PROCUREMENT AGENCIES (OPAS). THESE AGENCIES PERFORM OR COORDINATE HARVESTING OF DONATED ORGANS, PRESERVATION OF DONATED KIDNEYS, TRANSPORTATION OF DONATED KIDNEYS, AND MAINTENANCE OF A SYSTEM TO LOCATE PROSPECTIVE RECIPIENTS FOR HARVESTED ORGANS.

THERE ARE 36 INDEPENDENT OPAS LOCATED IN 22 STATES AND THE DISTRICT OF COLUMBIA WHICH ARE APPROVED TO PARTICIPATE IN MEDICARE. IN ADDITION, APPROXIMATELY 140 HOSPITALS HAVE THEIR OWN ORGAN PROCUREMENT PROGRAMS.

THE INDEPENDENT OPAS USUALLY COORDINATE A NETWORK OF PARTICIPATING HOSPITALS THAT HAVE AGREED TO IDENTIFY POTENTIAL KIDNEY DONORS. OPA PERSONNEL GO TO A HOSPITAL AFTER REMOVAL OF KIDNEY TISSUE TO PRESERVE THE TISSUE IN THE APPROPRIATE APPARATUS. AN OPA TRANSPLANT COORDINATOR IS RESPONSIBLE FOR TRANSPORTING DONATED KIDNEYS FROM THE DONOR SITE TO THE TRANSPLANT HOSPITAL FOR TRANSPLANTATION. THERE ARE 157 TRANSPLANT CENTERS WHICH MEET MEDICARE CERTIFICATION REQUIREMENTS.

COMPUTER MATCHING SYSTEMS HAVE BEEN DEVELOPED TO PERMIT EFFECTIVE ORGAN SHARING BETWEEN GEOGRAPHICALLY DISTINCT

TRANSPLANT CENTERS. OPAS ARE RESPONSIBLE FOR LOCATING THE BEST RECIPIENT MATCH FOR THE DONATED KIDNEY.

ONE INTERMEDIARY, AETNA LIFE AND CASUALTY OF HARTFORD, CONNECTICUT, SERVICES ALL INDEPENDENT OPAS AND ALL INDEPENDENT HISTOCOMPATIBILITY (TISSUE TYPING) LABORATORIES. HOSPITALS HAVING THEIR OWN OPAS ARE REIMBURSED BY THEIR INTERMEDIARIES THROUGH THEIR KIDNEY ACQUISITION COST CENTERS. MEDICARE REIMBURSEMENT FOR PROCUREMENT SERVICES PROVIDED BY THESE ENTITIES IS BASED ON REASONABLE COST.

IN THE SEPTEMBER 1, 1983 FEDERAL REGISTER, WE PROPOSED AN INTERIM FINAL RULE ON PROSPECTIVE PAYMENT FOR MEDICARE INPATIENT HOSPITAL SERVICES. IN VIEW OF THE UNIQUE CHARACTERISTICS OF ORGAN PROCUREMENT ACTIVITIES AND THE DESIRABILITY OF MAINTAINING AN ADEQUATE SUPPLY OF KIDNEYS, WE PROPOSE THAT THESE KIDNEY ACQUISITION COSTS SHOULD BE HANDLED OUTSIDE THE PROSPECTIVE PAYMENT SYSTEM. AS A RESULT, KIDNEY ACQUISITION COSTS HAVE BEEN REMOVED FROM THE STANDARDIZED AMOUNTS AND FROM THE COST WEIGHT FOR DRG 302, KIDNEY TRANSPLANT.

TRANSPLANTATION PATIENT BACKGROUND

TRANSPLANTATION IS NOT A TREATMENT THAT IS SUITABLE FOR ALL ESRD PATIENTS. PATIENTS WHO ARE GOOD TRANSPLANT CANDIDATES MUST MEET A VARIETY OF CRITERIA DETERMINED BY THE MEDICAL

COMMUNITY. USUALLY, TRANSPLANT CANDIDATES MUST BE SUFFICIENTLY STABLE MEDICALLY TO TOLERATE THE PROCEDURE, AND HAVE NO SECONDARY DIAGNOSIS, AND BE BETWEEN 10 AND 55 YEARS OF AGE. IT IS IMPORTANT TO NOTE THAT THE POOL OF PATIENTS FOR TRANSPLANT ARE USUALLY THE SAME PEOPLE WHO ARE CANDIDATES FOR HOME DIALYSIS.

AS I NOTED EARLIER, THERE WERE APPROXIMATELY 15,000 PATIENTS AT THE BEGINNING OF THE MEDICARE ESRD PROGRAM OF WHOM 1,500 HAVE HAD KIDNEY TRANSPLANTS. IN 1982, THERE WERE MORE THAN 70,000 ESRD PATIENTS AND 5,358 TRANSPLANTS PERFORMED. OF THE 5,358 TRANSPLANTS PERFORMED LAST YEAR, 1,677 WERE FROM LIVING RELATED DONORS AND 3,681 USED CADAVERIC KIDNEYS.

POST TRANSPLANT SERVICES FOR SUCCESSFUL PATIENTS INCLUDE PERIODIC OUTPATIENT EXAMINATIONS TO MONITOR FOR REJECTION, TO PRESCRIBE MEDICATIONS, AND TO MONITOR FOR RECURRENCE OF KIDNEY DISEASE.

GENERALLY, TRANSPLANT PATIENTS WILL COST THE MEDICARE PROGRAM LESS THAN DIALYSIS PATIENTS.

SURVIVAL OF TRANSPLANT PATIENTS

SURVIVAL RATES OF TRANSPLANT PATIENTS HAVE IMPROVED DRAMATICALLY IN THE LAST TWO TO THREE YEARS. RECENT

EXPERIENCES AT THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, AND AT THE UNIVERSITY OF MINNESOTA SHOW A LIVING RELATED DONOR GRAFT SURVIVAL RATE OF 95 PERCENT IN ONE YEAR. THIS IS DUE TO BOTH NEW TECHNIQUES OF TRANSPLANTATION AND NEW DRUGS.

REHABILITATION, IMPROVED QUALITY OF LIFE, AND WORK POTENTIAL APPEAR TO BE THE HIGHEST FOR TRANSPLANTED PATIENTS. INDIVIDUAL STATISTICS OF MANY FACILITIES WHICH PERFORM TRANSPLANTATION INDICATE THAT 40 PERCENT OR MORE OF THEIR SUCCESSFUL TRANSPLANT PATIENTS RETURN TO AN EQUAL OR HIGHER LEVEL OF WORK AND QUALITY OF LIFE THAN WHAT THEY HAD ENJOYED PRIOR TO THE ONSET OF ESRD. FOR THESE REASONS, AS WELL AS ANTICIPATED PROGRAM SAVINGS, I HAVE BEEN ANXIOUS TO WORK TO INCREASE TRANSPLANTATION DURING MY TENURE AS ADMINISTRATOR, AND I AM PARTICULARLY PLEASED THAT NEW TECHNOLOGY WILL AID US IN WORKING TOWARD THE GOAL OF INCREASING TRANSPLANTS.

RESEARCH AND DEMONSTRATION PROJECTS IN TRANSPLANTATION

RESEARCH AND DEMONSTRATION IS AN IMPORTANT AGENCY ACTIVITY ESPECIALLY IN ESRD AND TRANSPLANTATION BECAUSE OF THE ESCALATING COSTS ASSOCIATED WITH THE TYPE OF CARE NEEDED BY THE ESRD PATIENT. HCFA CURRENTLY HAS A FIVE-YEAR PLAN FOR RESEARCH AND DEMONSTRATION PROJECTS IN THE ESRD AREA,

INCLUDING TRANSPLANTATION. SPECIFICALLY, WE HAVE SEVERAL MAJOR STUDIES GOING ON WHICH I WOULD LIKE TO DESCRIBE FOR THE SUBCOMMITTEE.

A GRANT TO BATTELLE MEMORIAL INSTITUTE IN 1981, NOW NEARING COMPLETION, EXAMINES FOR HCFA "THE IMPACT OF ALTERNATIVE TYPES OF THERAPY ON PATIENTS WITH END-STAGE RENAL DISEASE." AMONG OTHER THINGS, THE STUDY FOCUSES ON SEVERAL VARIABLES, INCLUDING AN EXAMINATION OF THE QUALITY OF LIFE, THE QUALITY OF CARE, AND THE COST OF CARE TO PATIENTS UNDERGOING DIFFERENT TYPES OF THERAPY FOR TREATMENT OF ESRD.

IN THE FALL OF 1981, THE UNIVERSITY HEALTH POLICY CONSORTIUM BEGAN A MULTI-YEAR STUDY INTO "METHODS FOR INCREASING PUBLIC PARTICIPATION IN KIDNEY DONATION PROGRAMS." THE STUDY ADDRESSES THE METHODOLOGIES AND STRUCTURE OF ORGAN PROCUREMENT. THE FIRST PHASE OF THIS HCFA-SPONSORED GRANT WAS TO STUDY THE OPERATIONAL EFFICIENCY OF THE INDEPENDENT ORGAN PROCUREMENT AGENCIES AND TO MEASURE THEIR EFFECTIVENESS IN OBTAINING AND DISTRIBUTING KIDNEYS.

ONE OF THE GOALS OF THIS STUDY IS TO CORRELATE AND ANALYZE THE STATE OF THE ART IN ORGAN PROCUREMENT IN ORDER TO DEVELOP A MODEL OF A SUCCESSFUL KIDNEY PROCUREMENT AGENCY. A SECOND GOAL IS TO DESCRIBE AND EVALUATE DIFFERENCES AMONG INDEPENDENT ORGAN PROCUREMENT AGENCIES.

WHILE THERE ARE SOME AREAS OF AGREEMENT AMONG INDEPENDENT ORGAN PROCUREMENT AGENCIES, THERE ARE CERTAINLY MANY AREAS OF DISAGREEMENT AND CONTROVERSY. FOR EXAMPLE, UNDER THE STUDY WE LEARNED THAT PUBLIC EDUCATION IS THE MOST CONTROVERSIAL ASPECT OF ORGAN PROCUREMENT. THE STUDY HAS INDICATED THAT SOME INDEPENDENT ORGAN PROCUREMENT AGENCIES BELIEVE THAT PUBLIC EDUCATION IS INEFFECTIVE AND SHOULD NOT BE PART OF ORGAN PROCUREMENT EFFORTS. OTHER INDEPENDENT ORGAN PROCUREMENT AGENCIES CONSIDER PUBLIC EDUCATION TO BE SUCCESSFUL AND THINK THAT THE PUBLIC ATTITUDE INFLUENCES THE WILLINGNESS OF MEDICAL PROFESSIONALS TO ASSIST IN PROCUREMENT EFFORTS.

IN APRIL HCFA AWARDED A TWO-YEAR GRANT TO BRANDEIS, ENTITLED "DEVELOPING INCENTIVE SYSTEMS TO INCREASE THE SUPPLY OF CADAVERIC KIDNEYS FOR TRANSPLANT" TO CONTINUE THE STUDIES OF ORGAN PROCUREMENT. THE EMPHASIS OF THIS STUDY IS ON FINDING WAYS TO INCREASE THE NUMBER OF DONORS. IN ADDITION TO DEVELOPING A SET OF INCENTIVE SYSTEM OPTIONS, AN EXPERT PANEL WILL ASSESS THEIR FEASIBILITY AND THE GRANTEE WILL DESIGN A FIELD DEMONSTRATION TO ASSESS THEIR IMPLEMENTATION POTENTIAL.

IN SEPTEMBER 1983, HCFA AWARDED A ONE-YEAR DEMONSTRATION GRANT TO THE OREGON DONOR PROGRAM TO INCREASE PUBLIC

AWARENESS OF THE NEED FOR ORGAN DONORS BY DEVELOPING AND THEN SHOWING VIDEO TAPES ON THIS SUBJECT TO APPLICANTS FOR DRIVER'S LICENSES.

ALSO, IN SEPTEMBER 1983, HCFA AWARDED A FIVE-YEAR RESEARCH GRANT TO THE UNIVERSITY OF MICHIGAN TO DO A COMPREHENSIVE ASSESSMENT OF THE "RELATIVE EFFECTIVENESS AND COST OF TRANSPLANTATION AND DIALYSIS END STAGE RENAL DISEASE." THIS STUDY WILL BUILD UPON THE WORK DONE AT BATTELLE IN THEIR NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY BY SHIFTING THE FOCUS TO A COMPLETE CENSUS OF ALL PATIENTS AND FACILITIES IN A CONFINED GEOGRAPHICAL AREA - I.E., STATE OF MICHIGAN. THE STUDY WILL MERGE THE MICHIGAN KIDNEY REGISTRY DATA WITH THE ESRD PROGRAM'S ADMINISTRATIVE RECORDS TO PRODUCE A COMPREHENSIVE EPIDEMIOLOGICAL RESEARCH FILE.

THROUGH OUR GRANT SOLICITATION PROCESS, WE ARE CONTINUING TO LOOK FOR PROPOSED APPROACHES TO ANALYZE DIFFERENCES IN OUTCOMES AND RELATED FACTORS IN KIDNEY TRANSPLANTS AND FOR DEVELOPMENT AND TESTING OF SYSTEMS THAT INCLUDE INCENTIVES TO PROMOTE AVAILABILITY OF KIDNEYS. APPLICATIONS FOR ADDITIONAL RENAL STUDIES WILL BE REVIEWED AS PART OF OUR NEXT GRANTS APPLICATION CYCLE. WE HOPE THAT FUTURE RESEARCH ON ESRD ISSUES WILL PROVIDE THE NEEDED DATA TO REVISE AND RESHAPE OUR POLICIES AFFECTING THIS SEVERELY ILL POPULATION.

COVERAGE DECISIONS AND ACTIVITIES

THE LAW STATES THAT MEDICARE SHOULD PAY ONLY FOR THOSE SERVICES WHICH ARE REASONABLE AND NECESSARY. THEREFORE, MEDICARE DOES NOT PAY FOR DEVICES, PROCEDURES, OR TECHNIQUES THAT ARE CONSIDERED TO BE INVESTIGATIONAL. WHEN A COVERAGE ISSUE SUCH AS AN ORGAN TRANSPLANT IS BROUGHT TO HCFA'S ATTENTION--BY, FOR EXAMPLE, ONE OF OUR FISCAL CONTRACTORS OR A REGIONAL OFFICE - THE OFFICE OF COVERAGE POLICY CONDUCTS A SEARCH OF THE MEDICAL LITERATURE AND ALSO REVIEWS ANY OTHER BACKGROUND MATERIAL THAT HAS BEEN SUBMITTED REGARDING THE ISSUE. IF IT APPEARS FROM THESE REVIEWS THAT THE DEVICE OR PROCEDURE MAY BE IN AN INVESTIGATIONAL STATE OF DEVELOPMENT, THE ISSUE IS REFERRED TO THE HCFA PHYSICIANS PANEL FOR REVIEW. THAT PANEL EITHER RESOLVES THE QUESTION OR REFERS IT TO THE PUBLIC HEALTH SERVICE (PHS) ON EITHER AN INFORMAL INQUIRY BASIS OR WITH A REQUEST FOR A FULL ASSESSMENT AS TO SAFETY AND EFFICACY. INFORMAL REQUESTS USUALLY INVOLVE A MORE INTENSIVE REVIEW OF THE MEDICAL LITERATURE, DISCUSSIONS WITH OTHER GOVERNMENT COMPONENTS, AND CLARIFICATION OF, AND RESPONSE TO, SPECIFIC QUESTIONS RAISED BY THE PANEL.

A FULL ASSESSMENT AS TO SAFETY AND EFFICACY INVOLVES THE CONSULTATION WITH AFFECTED MEDICAL SPECIALTY GROUPS AND OTHER PROFESSIONAL ORGANIZATIONS AND THE GATHERING OF INFORMATION AS TO THE CONSENSUS WITHIN THE MEDICAL COMMUNITY

REGARDING THE SAFETY AND EFFICACY OF THE SERVICE OR PROCEDURE. WHEN PHS HAS COMPLETED THE INFORMATION-GATHERING AND EVALUATION PROCESS, IT MAKES A FORMAL RECOMMENDATION TO HCFA WITH RESPECT TO THE SAFETY AND EFFICACY OF THE DEVICE OR PROCEDURE, AND HCFA THEN DECIDES WHETHER THE DEVICE OR PROCEDURE SHOULD BE COVERED BY MEDICARE.

AT PRESENT, THE MEDICARE PROGRAM'S COVERAGE OF ORGAN TRANSPLANTS IS LIMITED TO KIDNEY AND CORNEA TRANSPLANTS. UNDER THE MEDICAID PROGRAM, WE PRESENTLY MATCH THE STATES' FUNDS FOR ANY ORGAN TRANSPLANT THEY CHOOSE TO COVER.

THE QUESTION OF MEDICARE COVERAGE HAS ARISEN WITH RESPECT TO COVERAGE OF HEART TRANSPLANTS, LIVER TRANSPLANTS, AND PANCREAS TRANSPLANTS. I WOULD LIKE NOW TO DESCRIBE BRIEFLY OUR CONSIDERATION OF EACH OF THESE TYPES OF TRANSPLANTS.

HEART TRANSPLANTS

A NATIONAL STUDY, FINANCED BY HCFA, IS NOW UNDERWAY OF ALL ASPECTS OF COVERAGE OF HEART TRANSPLANTATION UNDER MEDICARE. THIS INCLUDES: 1)THE ESTIMATIONS OF THE POTENTIAL NEED FOR HEART TRANSPLANTS; 2)THE SURVIVAL OF HEART TRANSPLANT RECIPIENTS; 3)THE POTENTIAL AVAILABILITY OF DONOR HEARTS;

4)THE COST OF PERFORMING HEART TRANSPLANTS; 5)THE REHABILITATION AND QUALITY OF LIFE OF HEART TRANSPLANT RECIPIENTS; AND 6)THE LEGAL AND ETHICAL ASPECTS OF HEART TRANSPLANTATIONS.

THE PROJECT STAFF INCLUDES AN INTER-DISCIPLINARY TEAM OF RESEARCHERS WITH EXPERTISE IN SUCH AREAS AS MEDICAL SOCIOLOGY, CARDIOVASCULAR MEDICINE, TRANSPLANT SURGERY, HEALTH ECONOMICS, CARDIOLOGY, POLITICAL SCIENCE, LAW, MEDICAL ETHICS, GEOGRAPHY, AND PSYCHOLOGY. AS PART OF THAT STUDY, MEDICARE IS PAYING FOR A LIMITED NUMBER OF HEART TRANSPLANTS AT SIX MEDICAL CENTERS PARTICIPATING IN THE STUDY. AT PRESENT, PLANS CALL FOR LIMITING PAYMENT TO 15 TRANSPLANTS. AT THIS TIME, HCFA HAS PAID FOR 14 HEART TRANSPLANTS PERFORMED UNDER THIS STUDY.

THE STUDY IS SCHEDULED TO BE COMPLETED IN JUNE 1984, AND THE EVALUATION IS TO BE FINISHED THREE MONTHS LATER. WHEN THE ENTIRE STUDY PROCESS IS COMPLETED, HCFA WILL MAKE A DECISION REGARDING COVERAGE OF HEART TRANSPLANTATION UNDER MEDICARE.

LIVER TRANSPLANTS

AT THE END OF 1980, PHS RESPONDED TO A HCFA REQUEST FOR GUIDANCE ON LIVER TRANSPLANTS. THE PHS DETERMINATION WAS THAT LIVER TRANSPLANTS WERE STILL INVESTIGATIONAL. SINCE

THEN, CYCLOSPORIN A, AN IMMUNOSUPPRESSANT DRUG, HAS BEEN MORE WIDELY USED, AND THERE IS SOME EVIDENCE THAT IT HAS HAD A FAVORABLE EFFECT ON LIVER TRANSPLANTATION. THEREFORE, IN APRIL 1982, HCFA REFERRED THE QUESTIONS OF SAFETY AND EFFICACY OF LIVER TRANSPLANTS TO PHS FOR REASSESSMENT.

HCFA ASKED PHS TO CONSIDER THE QUESTIONS OF MEDICARE COVERAGE IN TERMS OF SPECIFIC SUBGROUPS OF POPULATION. THIS WAS DONE BECAUSE THERE ARE SOME INDICATIONS THAT THERE ARE DIFFERING SUCCESS RATES IN LIVER TRANSPLANTS PERFORMED ON CHILDREN AND ADULTS, AND THAT RECENT "BREAKTHROUGHS" HAVE FAVORABLY AFFECTED ONLY THE SURVIVAL RATES OF CHILDREN. THE DEPARTMENT IS IN THE FINAL STAGES OF CONSIDERING THIS QUESTION.

PANCREAS TRANSPLANTS

HCFA HAS ALSO ASKED PHS FOR ITS RECOMMENDATIONS AS TO THE SAFETY AND EFFICACY OF PANCREAS TRANSPLANTS, ESPECIALLY WITH RESPECT TO ESRD BENEFICIARIES WHO ARE DIABETIC AND WHO HAVE UNDERGONE KIDNEY TRANSPLANTS.

H.R. 4080

I WOULD NOW LIKE TO DISCUSS H.R. 4080, THE NATIONAL ORGAN TRANSPLANTATION ACT. MY COMMENTS ARE DIRECTED AT THOSE

PROVISIONS DIRECTLY IMPACTING THE MEDICARE AND MEDICAID PROGRAMS.

THE BILL PROPOSES THAT THE TRANSPLANTATION NETWORK IS TO BE FUNDED AT AN AMOUNT NOT TO EXCEED $2 MILLION IN ANY FISCAL YEAR, AND IS TO BE FINANCED FROM THE FEDERAL HOSPITAL INSURANCE TRUST FUND. AS YOU KNOW, WE PRESENTLY HAVE A NUMBER OF ORGAN PROCUREMENT AGENCIES, AND THERE IS CONSIDERABLE NEW ACTIVITY DEVELOPING IN THE PRIVATE SECTOR. WHILE THE REVENUE TO BE PROVIDED THROUGH THE TRUST FUND IS RELATIVELY SMALL, WE THINK IT IS INAPPROPRIATE TO ADD STILL ANOTHER OBLIGATION ON AN ALREADY OVERBURDENED FINANCIAL BASE.

WE ALSO WISH TO MAINTAIN THE CURRENT METHOD FOR COVERAGE DETERMINATIONS WHICH I DISCUSSED EARLIER, AND DO NOT BELIEVE THAT A NEW ADVISORY COUNCIL IS NECESSARY, SINCE THE PURPOSES OF IT ARE MET WITHIN OUR COOPERATIVE ARRANGEMENTS WITH THE PHS.

TITLE II OF H.R. 4080 WOULD AMEND TITLES XVIII AND XIX OF THE SOCIAL SECURITY ACT TO PERMIT REIMBURSEMENT FOR ORGAN TRANSPLANT PROCEDURES AT DESIGNATED FACILITIES. IT PROVIDES AUTHORITY FOR THE SECRETARY, AFTER FIRST CONSULTING WITH THE

ASSISTANT SECRETARY OF HEALTH, TO SET THE MEDICAL CRITERIA FOR ASSURING THAT THE ITEMS OR SERVICES FURNISHED UNDER MEDICARE ARE REASONABLE AND NECESSARY, AND THAT THE CONDITIONS UNDER WHICH THE SERVICES ARE TO BE PROVIDED ALSO MEET MINIMUM CRITERIA.

IT IS OUR UNDERSTANDING THAT THE INTENT OF THIS SECTION IS TO ALLOW THE SECRETARY TO DESIGNATE THE NUMBER AND TYPE OF HOSPITALS WHICH PROVIDE ORGAN TRANSPLANTS AND TO ALLOW US TO EXTEND COVERAGE TO CERTAIN GROUPS OF PEOPLE. IT APPEARS, HOWEVER, THAT THE ACTUAL LANGUAGE WOULD APPLY TO ALL MEDICARE BENEFITS AND NOT SOLELY TO TRANSPLANTS.

THIS SECTION GOES ON TO SPECIFY THAT PAYMENTS MAY BE MADE TO CENTERS DESIGNATED BY THE SECRETARY ONLY IF THE CENTER DOES NOT DISCRIMINATE ON A NUMBER OF BASES, INCLUDING ABILITY TO PAY. WE ARE CONCERNED ABOUT THE IMPACT OF THIS PROVISION ON THE FINANCIAL STABILITY AND VIABILITY OF THESE CENTERS, GIVEN THE ENORMOUS COST OF TRANSPLANT PROCEDURES.

TITLE II ALSO WOULD REQUIRE STATES TO DEVELOP WRITTEN POLICIES REGARDING COVERAGE UNDER THE MEDICAID STATE PLAN FOR ORGAN TRANSPLANT PROCEDURES. IN THE ABSENCE OF SUCH POLICIES, THE PLAN SHALL BE DEEMED TO PROVIDE FOR COVERAGE IN THE SAME MANNER AS COVERED UNDER MEDICARE. IT WOULD ALSO MANDATE THAT STATES PAY FOR THESE SERVICES AT THE MEDICARE RATE, USING DRG PAYMENTS, AND RESTRICTS STATE COVERAGE TO THOSE PROCEDURES COVERED UNDER MEDICARE.

AS YOU KNOW, THE STATES HAVE ALWAYS HAD THE RESPONSIBILITY FOR MAKING COVERAGE AND REIMBURSEMENT DECISIONS FOR THEIR MEDICAID PROGRAMS. THIS PROVISION WOULD TAKE US IN THE OPPOSITE DIRECTION, WITH NO COMPELLING REASON FOR DOING SO.

FINALLY, I WOULD LIKE TO NOTE THAT HCFA WILL NOT PAY A BOUNTY FOR KIDNEYS. INSTRUCTIONS TO INTERMEDIARIES FROM THE BEGINNING OF THE PROGRAM IN JULY 1973, HAVE STATED THIS POSITION: "NO PROGRAM REIMBURSEMENT MAY BE MADE FOR THE KIDNEY ITSELF, I.E., IF A DONOR SELLS HIS KIDNEY, THE PURCHASE PRICE MAY NOT BE REFLECTED IN ANY PROGRAM PAYMENT."

CONCLUSION

IN GENERAL, HCFA OPPOSES ENACTMENT OF H.R. 4080 FOR THE REASONS I HAVE OUTLINED AND THOSE SUGGESTED BY DR. BRANDT. WHILE THE GOALS ARE LAUDABLE, THE MEANS SUGGESTED WILL NOT ALLOW US TO MEET THESE ENDS FASTER OR MORE EFFICIENTLY THAN WE CAN TODAY. IN FACT, THERE ARE SOME SERIOUS RISKS OF MORE BUREAUCRACY AND LESS EFFICIENCY. THANK YOU FOR THE OPPORTUNITY TO COMMENT ON THIS BILL AND I LOOK FORWARD TO CONTINUING TO WORK WITH YOU ON THIS VERY IMPORTANT TOPIC.

Mr. WAXMAN. Thank you very much, Dr. Brandt and Dr. Davis. Dr. Brandt, your testimony seems to say to us that there is an American Council on Transplantation which has been set up by the Department and given $100,000. It has in its membership all the various groups involved in the field.

You seem to be saying to us that we should just wait until this organization comes up with some better way to coordinate the procurement of organs and matching of donors and donees.

How long do you think that will take? What time do you have in mind before we can see an improvement in the situation?

Dr. BRANDT. Let me first say, Mr. Chairman, we did not set up this council. In fact, our only role in this was to explore through two workshops with the private sector organizations what they felt would be the better way to go to accomplish the goal of enhancing organ procurement.

It was those organizations that determined to set up the American Council for Transplantation.

Dr. Friedlaender, who will be testifying somewhat later, can probably give you some concept of the timetable, but I think our objective and our fundamental belief in this system is that it can build on the existing system.

If, in fact, we set up a Federal system, then there is no reason for the private sector to be involved any longer, and I think in terms of timing, by the time we would accomplish, and it would be we in this case, if the bill is passed, and set up this system, I think it is probably going to take just about as much time as it takes the council to get its operations going and under way.

So that I don't think—I think the issue the Congress is faced with in making a decision is whether we are going to permit a voluntary private organization to go or are we going to supplant it with a Federal system.

We have an analogy in the blood; 10 years ago we were in the same situation with blood in this country—just a little over 10 years ago. The decision was made at that time to go with the voluntary effort.

The American Blood Commission was formed. The Public Health Service put money into that, gave technical assistance. Organizations now provide blood, I think, in a very effective and efficient manner in this country.

This was pointed out by Congressman Gore; 97 percent—I thought it was a little higher than that—of whole blood now comes from volunteers through that kind of a system.

I think that is something that must be tried also with solid organs.

Mr. WAXMAN. You state in your testimony you acknowledge the fact that there are gaps, that the current system is rather fragmented, and that people are not able to obtain organs that otherwise could be available to them.

Yet I get no sense of urgency, if we are going to wait for a council on transplantation with three or four staff people and a funding of $100,000 to act. I get no sense of urgency that we are going to make this situation better, faster.

Dr. BRANDT. Well, my guess, Mr. Chairman, is we are talking about the same time. I don't think the Federal Government can

put something into operation any—it is not that we disagree with the outcome or the goals. I fully agree that some kind of system—obviously a national system clearly is—I think we have to not get our expectations too high.

The facts are that you cannot transport livers all over the world or all over parts of this country, from one part to another, because the organ just doesn't survive that long. So it has got to be built along a subnational system, a regional based system, in large part, just to handle the logistics of organ viability.

But we don't—we certainly agree that some efficiency must be brought to the system, that it can be markedly improved. The issue is should it be done by Government or by the people out there already doing it.

Mr. WAXMAN. The people already doing it acknowledge that there are 20,000 brain-dead people annually, and of those, at most 1,800 livers per year are obtainable for transplantation. In fact, there is a tremendous potential for more organs to become available for transplantation purposes, and as hard as they are working and as heroically as they are doing their jobs, it is not sufficient.

Dr. BRANDT. I think the real issue, in the case of livers in particular, is, of course, to encourage more donations, because, in fact, we are getting nowhere near the potential for liver donations in this country, and that that is going to become a sizable problem.

But again, in the specific instance of livers, that in particular presents itself own logistics problem, because you are talking about 8 to 10 hours following the decision to remove the liver from the donor before that liver has to be implanted.

So that, again, ideally perhaps one would never waste a liver. But I think the facts are just from the sheer logistics that we cannot anticipate that every liver—we will have any kind of a system that is 100 percent effective.

I think we have the same concerns. We look at the same general approach. I just happen to believe that the folks out there who are willing and able and committed to participating in the American Council ought to be given a chance before the Federal Government moves in and takes it over and removes their opportunity to do the job.

Mr. GORE. Will the Chair yield?

Mr. WAXMAN. Yes.

Mr. GORE. Just briefly. We have heard three times now the statement that what is proposed is a Federal Government takeover of the system when, in fact, nothing of the sort is proposed. The private systems would continue in place.

All we are talking about in that provision of the bill is to give incentives to those private networks to follow certain guidelines that will have the effect of bringing them into closer coordination with each other, closer coordination with the medical community in their regions, and closer coordination with the other networks around the country.

The program would still be run by the same people. The Federal Government would not be taking it over. The Federal Government would be encouraging closer coordination.

Now, my question——

Mr. WAXMAN. I would like to hear the answer from Dr. Brandt to this statement.

Dr. BRANDT. I think the provision of the bill, Mr. Gore, that sets up the national computerized system, for example, is something that ultimately will come about through the private sector, and I think—I liken it a little bit to——

Mr. GORE. Well, that is a contract with a private, nonprofit entity. It is an authority to contract with a private, nonprofit entity, again, to coordinate a national computer registry.

Dr. BRANDT. I would suggest why shouldn't we let the private organizations do that themselves, if they are willing and able to do it.

Mr. GORE. Because they have not done it yet. They have been involved in this for years, and it is not done.

Dr. BRANDT. Well, I agree that it has not been done, but we also haven't had legislation for years, either.

So I think the issue is who is going to come first. I would liken it somewhat to your analogy in your statement about the fact that when people started paying for blood, voluntary donations came down.

I think when the Federal Government starts running something like this kind of computer-based system—irrespective, as you know if the Federal Government funds it, it is going to essentially run it, that we are going to discourage——

Mr. GORE. Again, Dr. Brandt, you are still using the same premise, that the Federal Government is going to run it, take it over. You keep using that phrase.

It is just not going to happen. Again, you rely on this principle of no Government involvement, the private sector ought to run it entirely. Would you propose withdrawing the $30 million a year that the Federal Government is now paying to these private networks?

Are you in favor of Government involvement to the tune of $30 million a year in an uncoordinated, haphazard fashion, or is it simply the coordination that you are opposed to?

Dr. BRANDT. Well, there are two aspects to your question. In the first place, clearly that money would continue to flow because it has as its purpose to help our beneficiaries.

That is its goal, and it is its objective. Clearly, that sort of thing would continue.

Mr. GORE. That is Federal involvement; isn't it?

Dr. BRANDT. It is Federal payment under an entitlement program to beneficiaries. I think that is an important responsibility, and I certainly have no problems with that. Clearly I am not in favor of it being uncoordinated.

I just think the issue is who is going to coordinate it.

Mr. WAXMAN. Mr. Gore, I am going to recognize you in a minute. I am very disappointed to see the administration's response to this legislation.

Colleagues come up to me constantly telling me there is not a week that goes by without hearing from a family that is looking for the opportunity for transplantation for a loved one. I don't understand the administration's hesitation to get involved. It seems to me that to have the Federal Government involved in setting up a computer that can match the donors to the donees, and giving grant money to the private sector so that voluntary groups can en-

courage greater contribution of these organs, is a very appropriate role for us.

We have the President of the United States expressing his personal view to the country on behalf of children that he hopes somebody will come forward, and that his administration certainly ought to support legislation that can do something in a very constructive way, and not just stand back with an ideological knee-jerk appropach, "don't get the Federal Government get involved."

In fact, the Federal Government is paying for most of this now through medicare. What computer system is available is paid for by the medicare system. I just would like to express my disappointment and hope that as we work on this legislation we push aside ideology, and try to get down to practical solutions where, in fact, the Government can play a very important role.

Mr. Nielson.

Mr. NIELSON. Dr. Brandt, Congressman Gore testified that the Federal Government is spending $30 million on kidney transplantation, yet there is no national strategy. Is that an accurate statement?

Are you spending $30 million without a national strategy?

Dr. BRANDT. That falls into Dr. Davis' category.

Dr. DAVIS. We are spending roughly $2 billion a year on the entire costs of the renal disease program.

Mr. GORE. Excuse me. They are paying $2 billion for the renal program, $30 million to the separate organ procurement networks.

Mr. NIELSON. What is the strategy you have?

Whatever amount you are spending, Representative Gore says you are spending without any kind of a strategy. Is that an accurate statement?

Dr. DAVIS. Well, I think that our strategy has been to pay the costs for the organ procurement agencies. Clearly startup costs can be amortized over a 5-year period of time, and those costs are recognized as part of the overall costs in the organ procurement agencies.

We also pay all of the reasonable and allowable costs of the activities that are associated with the acquisition of the kidney for transplant. That does include the costs for the computer.

I did mention in my testimony that we have awarded a grant to study independent organ procurement agencies and hospitals organ procurement agencies. In our effort to try to understand what the distinguishing features are between the independent and the hospital-based organ procurement agencies, Brandeis University is doing a 1-year study to look at the effectiveness both procurement and costs in these two areas.

Mr. NIELSON. Are you going to keep the studies going?

Dr. DAVIS. No, sir, I expect at the end of this year we will learn more about the activities that relate to organ procurement.

It is very clear that we still have a waiting list of roughly 7,000 individuals who are awaiting transplants. But one of our concerns has been the whole area of getting public acceptance of organ donations.

One of our concerns has to be to try to look at why we may have a lack of available organs. In some areas of the country the organ

procurement agencies tell us that it is due to an absence of State standards for when death actually has occurred.

In other cases, there are racial and religious attitudes relative to the donation of organs and a lack of knowledge on the need to donate organs. It is a number of these factors that we are looking at now. Different organ procurement agencies believe that the public awareness and acceptance of organ donations comes through public relations activities.

Some of them are much more successful—and much more in tune in terms of the belief that this is a needed activity—than others are. We are trying to ascertain what are the most important reasons for why somebody gives an organ, and then to build from there.

Mr. NIELSON. Thank you.

Dr. Brandt, I would like you to react to another comment of Mr. Gore's. He said there are too many organ procurement agencies. Do you agree with that statement?

Dr. BRANDT. With his explanation of what he said, I think that one might come up with that conclusion. On the other hand, it would not bother me to have several organ procurement agencies representing hospital transplant centers in the same general locality, because I think in fact hospitals who are involved in transplantation must have some sort of organ procurement activity going.

Mr. NIELSON. So you don't think there are too many agencies?

Dr. BRANDT. I don't think there are too many, if that is the basis for the statement.

Mr. NIELSON. Is there a problem of coordinating among the agencies?

Dr. BRANDT. Obviously there is a problem to coordinate it. Our proposal for coordinating is in large part—I don't want to put everything in the lap of the American Council, but I think the best way to do it is to pull the professionals together as that organization proposes to do, and let them come up with a solution to the way to best accomplish the coordination.

Mr. NIELSON. It has been stated the National Center for Organ Transplantation function is to carry out the organ procurement activities of medicare and medicaid. Either you or Dr. Davis, what are those activities, organ procurement activities, and how are they currently administered?

Dr. DAVIS. Would you tell me the name of the organization?

Mr. NIELSON. National Center for Organ Transplantation.

Dr. DAVIS. OK. Yes. Right now medicare program funds the independent organ procurement agencies. Those organ procurement agencies are linked through United National Organ Sharing by a 24-hour telephone and computer operation.

I think it is instructive to recognize that of the 6,955 kidneys that were harvested last year from cadavers, 3,684 were used at the site.

They opted then to use a majority of the transplanted kidneys there rather than transport them elsewhere. Roughly less than 2,500 were transported elsewhere. I believe that the current system is working in the area of kidney transplants.

That is the only organ transplant we are paying for at this point in time other than the cornea.

Mr. NIELSON. OK. Dr. Brandt, H.R. 4080 appears to want to change the current organ procurement agencies to an independent set rather than a hospital set. Do you think that has some disadvantage?

Dr. BRANDT. Well, I think it has some disadvantage, yes. It potentially has some other kinds of advantage. But I think under the way the system works now, and the fact that we are able to do more and more transplants all the time is based in large part upon the hospitals that have active transplantation programs having offices and activities associated with the procurement of organs.

Some of those are quite successful. I personally would hate to see them in any way downgraded or otherwise compromised by any other kind of activity, irrespective of what it might be.

I think they are critical, whether you have independent, areawide activities or not. The hospital-based ones are still going to be important.

Mr. NIELSON. Three brief questions here. Perhaps you can answer yes or no.

The Health Care Financing Agency asked you several years ago to reassess the safety and efficacy of liver transplants. Have you given those recommendations?

Dr. BRANDT. We have not given them to it. Rather than say years ago, it is 1 year ago. The reason is that there are still questions in our mind, and I think in other people's minds, about the specific conditions that—for which liver transplantation is effective, and second, the timing at which the transplant should be done.

We are currently working through that. That is where we are.

Mr. NIELSON. When do you anticipate getting that report to them?

Dr. BRANDT. Soon.

Mr. NIELSON. Let's be more specific.

Dr. BRANDT. I can't be really more specific. I would like to have had it yesterday. We are working as rapidly as we can.

I hope it will be in a matter of a short while.

Mr. WAXMAN. Would the gentleman yield to me on that point? I might just point out, while you are reluctant now to commit to a time, we were told in hearings before the summer that by Labor Day we would have a report.

This is a recommendation that has been worked on by the National Center for Health Care Technology, which has suffered enormous budget cuts. Do you feel perhaps that budget cuts have weakened them to the point where they cannot meet the deadlines you expect of them?

Dr. BRANDT. No, sir. As a matter of fact, I am the one that told you that, I think, Labor Day, because that was my original goal. I certainly testified to that before Chairman Gore's subcommittee.

It is not in the National Center for Health Services Research. It is actually in my lap right at the moment. They have done their work and met the deadline I gave them.

So the delay is now in my office, not in them.

Mr. NIELSON. Dr. Davis, you don't cover kidney acquisitions in your prospective payment system. Why not?

Dr. DAVIS. The reason why not is because of the variability on the transportation costs. We recognize that the kidney acquisition cost has a great deal of variability, depending on the nearness to the transplant organ. We wanted to collect some more data and study that. We decided that until we knew more about the reasons for that cost differential, we would leave it outside of the prospective payments system. We have it as a passthrough at this moment.

Mr. NIELSON. How are you handling cornea transplants?

Dr. DAVIS. They are handled within the system. A cornea transplant is a relatively easy procedure in terms of acquiring the donated organ. Almost every institution can do them, and there is not the need for excessive transportation costs.

Mr. NIELSON. Do you know how many States cover kidney and other transplants through their medicaid?

Dr. DAVIS. All the States cover kidney transplants through their medicaid programs.

Mr. NIELSON. The last question I have is a statement you made, Dr. Brandt, on page 12 of your statement. You said, and I find it rather discouraging, that there are 20,000 brain-dead people available and only 1,800 donate livers from that group.

You mentioned, among other things, physician reluctance to raise the issue of donorship with the family, unwillingness of next of kin to authorize the procedure, and varying State laws regarding organ donations and the legal definition of death.

As to the latter part, do you think a national law is necessary on organ donations, a legal definition of death which is the same in all the States?

Dr. BRANDT. There is a model law for definition of death, which has been recently promulgated and is being adopted by the States pretty much.

Mr. NIELSON. You don't think there needs to be national legislation?

Dr. BRANDT. I don't think so.

Mr. NIELSON. On the other two—how can we get over the reluctance of the physician to ask the potential donor or the next of kin to authorize it? How can we get over that?

What kind of education must we have, regardless of whether this bill passes or not? What can we do to improve the number of donors?

Dr. BRANDT. I think one has to recognize, Mr. Nielson, right off the bat that there are some people who have religious objections to the donation of organs.

Mr. NIELSON. But not nine-tenths of the population.

Dr. BRANDT. I agree with that. But I think we have to fully recognize that there are some people who will never donate because of either religious or other kinds of objections to the donation.

I think that what is clearly needed is continuing work with physicians to try to increase their awareness and their ability to deal with patients—I mean, with next of kin. In some instances, this is done largely by a third party, not by the physician.

Mr. NIELSON. But I get the impression, the way it reads here, that it is the physician's reluctance to raise the issue at the time of

the accident, and also the unwillingness of the next of kin to authorize it on the spot. These are decisions being made under stress.

Should there be some preparation? You are talking about the religious aspects. I understand that. But a lot of them seem to be the fact that we just don't ask at the right time, and we don't prepare them for the possibility.

Dr. BRANDT. I think that is absolutely correct. I think our society is slowly getting the message, that, in fact, organ donations are of value and will save lives. Certainly anyone who owns a television set cannot help but be aware of all of the emphasis on liver transplantations in the past year or so.

The Kidney Foundation, Mr. Gary Coleman, particularly, carrying the lead, have had a number of good advertisements, and I think we have to continue all these efforts to try to get people prepared for the possibility of donating organs and authorizing donations from their loved ones.

Mr. NIELSON. I thank the witnesses for their testimony.

Mr. WAXMAN. Dr. Davis, you indicated that studies have been let out to various experts to study the organ transplant system. I wonder if you are aware that Dr. Evans of Battelle and Dr. Prottas from Boston testified before our committee in July. Their studies indicated a program like that proposed in this legislation would strengthen the Nation's transplant efforts.

Dr. DAVIS. I am aware of their testimony before the committee. What they clearly indicated was the need for more national coordination. I believe that the private sector effort that we now have through the American Council on Transplantation can certainly be an effective coordinating mechanism.

Mr. WAXMAN. I just want to point out to both of you that the researchers you hired to do a study indicate this is the approach we ought to take. The surgeons who do transplant surgery tell us they think we need Federal involvement along the lines of this bill. The people who are working on organ procurements tell us that they want this kind of legislation. And the people who are waiting for organs tell us they want this legislation.

I am amazed to hear the administration come in and dismiss all of that and say that we ought to rely on this council. It may take years, as far as I can see, with three staff people, to ever get a system in place that all these people who are working in the field say we need and can put in place with this legislation.

Dr. DAVIS. Mr. Chairman, I would like to point out that the study you are referring to simply mentions the necessity and the importance of an organ retrieval network at a national level. They do not say that it must be federally funded or federally initiated.

I again would respectfully state that I think that the new activities that we have seen and the coordination that can come about through the American Council on Transplantation can be an effective mechanism for doing this.

Dr. BRANDT. I can't believe, Mr. Chairman, from the ones that I have talked to in the transplant business, that they care one way or the other whether this is a Federal system or a private system; that is, a voluntary system. What they want is a system. And we fully agree with that. That is not the issue.

I think were you to suggest to the hematologists and to those same surgeons we set up the same kind of system for blood that this legislation proposes, I think they would become very concerned about that, because they have something that works and gets them blood and that gets their patients blood. And that is the real issue.

We are not dismissing out of hand those things, and we are not trying to react in knee-jerk fashion. I think what we are saying is that in the only other organ for which—which is blood, which is an organ, that that is a voluntary, private activity; it works. And it seems to me that to dismiss the possibility that the private—a comparable private voluntary activity might develop—I agree with you on the urgency. But I don't think that the activities here can be accomplished any faster really than what that council is likely to do.

So that, again, we don't disagree with the goals or the objectives. We don't disagree with what that report said. It is only the mechanism.

Mr. WAXMAN. Mr. Gore.

Mr. GORE. Thank you, Mr. Chairman. I appreciate the courtesy of the subcommittee in allowing me to ask a few questions.

I hope our witnesses will understand that I have very strong feelings about this legislation, and I am very frustrated at your testimony, frankly. You keep talking about a private sector effort, and you keep ignoring the fact that the Federal Government is paying for it now.

It is paying for it now, isn't it?

Dr. BRANDT. The Federal Government will obviously continue to pay its share of organ transplant costs and organ procurement costs.

Mr. GORE. The computer is paid for by the Federal Government also, isn't it?

Dr. DAVIS. For the kidney acquisition program, yes, it is.

Mr. GORE. You keep talking about a private sector effort. But the taxpayers are paying for it. What you are really opposed to is coordinating it and making it work. What you really are in favor of is just a slow approach and hope that it will take care of itself.

I need to apologize to you, doctor, because in my statement I said I was pleased that you at least supported the provision of the bill to ban the buying and selling of human organs. But you cannot even bring yourself to support that provision of the bill, can you?

Dr. BRANDT. I think by our declaration it is immoral and unethical, I certainly don't support that.

Mr. GORE. You say it is immoral and unethical. But when it comes to passing a law to do it, you say let's take a slow approach and maybe the States and localities will do it. We are not sure whether or not the Federal Government ought to do anything. You are not sure whether you can even support that provision, because you need further study, further study.

You have had studies on this whole thing. Dr. Davis, you and I talked back in April about the studies. You have had studies; you have had recommendations on how to deal with transplants. You had, oh, kidney transplants. Your Office of Special Programs back in July of 1981 gave you not only a study, but a specific recommen-

dation; right? And you reviewed it; right? You completed your work on the overall strategy.

I asked you. You said you held the recommendation in abeyance "until we completed work on the overall strategy."

Has the overall strategy been completed? Yes, it has. OK. Now, why has the recommendation remained in abeyance?

Incidentally, is that recommendation still in abeyance, the one that came in July of 1981?

Dr. DAVIS. Well, sir, there were several recommendations that came in July 1981.

Mr. GORE. The CDC recommendation.

Dr. DAVIS. Yes, it is still in abeyance because in the interim a great deal has happened. We have funded a study from Brandeis that looks at independent and hospital-based organ procurement agencies.

Mr. GORE. Are you studying the first study?

Dr. DAVIS. No, sir. I have elected instead to find out more about what it is that makes some organ procurement agencies more successful than others. The CDC study would have mandated one person in each State to encourag organ donations.

My attempt to ascertain more specifically why the successful organ procurement agencies were as successful as they were versus ones that did not have that success rate seems to me more appropriate. It is a 1-year study. We expect completion in December 1983. Shortly thereafter, then, I expect to be able to take some action based upon the knowledge of what is the most successful way of attaining organs.

Mr. GORE. You are talking about Dr. Protus' study there.

What about the CDC recommendation on the demonstration programs?

Dr. DAVIS. I would prefer to utilize the most recent information. I think the CDC study was done and reported back in 1980. A great deal has happened in the interim.

It seems to me that the most relevant study would be the most recent study.

Mr. GORE. Well, when that one is completed, you would be reluctant to act on it, because the most relevant one would then be the one you started next.

Dr. DAVIS. No, Mr. Gore. I have every intention to react to the findings that would come in from this new study.

Mr. GORE. Well, I don't have any confidence in your willingness to act at the Federal level unless we make you act, because your whole approach has been to wait and wait and drag your feet and hope that the problem will solve itself. The same is true with this reimbursement for livers.

Isn't it extremely unusual for you to take the recommendations of that office, Dr. Brandt, and take it up into your personal office and sit on it? How long is this going to take? And with what other reimbursement decisions have you done this?

Dr. BRANDT. I have not, as you put it, sat on any. This is the most complex one we have had to deal with since I have been around here, because it has to do with attempting to define indications.

I think, sir, that as you look at the NIH Consensus Development Conference results, which I happen to have here in front of me, it in fact leaves lots of questions, just about as many questions as it answers. And I think that is what we are trying to deal with.

Perhaps the issue of alcohol-related liver cirrhosis and alcohol hepatitis, when do you transplant those people, et cetera, those are the kinds of questions that I think we have to try to make some kind of a recommendation on. That is what I am trying to do.

Mr. GORE. What other decisions on reimbursement of technology have you personally—after you get the recommendation from the office that has this responsibility, what other ones have you taken personally?

Dr. BRANDT. This is the only one that I have—in which I have had some questions in my mind, and have taken it. I have looked at almost all the others, and have been willing to send them on directly.

Mr. GORE. Didn't you get a decision on heart transplants, Dr. Davis, back in February of 1980? Didn't you get a recommendation?

Dr. DAVIS. It is my understanding that during the previous administration there was some discussion relative to heart transplantion, and that there was a staff recommendation.

Mr. GORE. That it be covered; right?

Dr. DAVIS. Yes at that point in time in the previous administration. However, then Secretary Harris determined that there should be a study to look further at the implications relative to quality of life and to a number of other factors before such a determination would be made. That is the Battelle study. I am certain you are quite familiar with that. You mentioned Dr. Evans' work before.

Mr. GORE. Well, the science hasn't changed from administration to administration. The efficacy of the procedure has increased.

Dr. DAVIS. I think the kinds of concerns that were within the document at that point in time stated that only selected facilities should do the procedure and that candidates should meet certain age specifications and other kinds of criteria. It was Secretary Harris' decision that those particular issues needed further clarification because when medicare makes a determination of coverage, in general it is not isolated to specific groups at specific institutions. There was a need for looking further at a number of these particular variables.

Mr. GORE. What caused the concern, then, was their recommendation that it be confined to limited centers.

Dr. DAVIS. I cannot tell you what their concerns were. I wasn't in the previous administration.

Mr. GORE. Now, the recent NIH Consensus Conference on liver transplants also indicated that the procedures should be limited to centers, to particular centers that had the commitment of resources and expertise necessary. So this is a common thread when you have these new cutting edge technologies, and you are trying to decide when to designate them to the public and make them available. It is a common recommendation of people who have studied this problem that it be done first in limited centers that have the resources and the commitment.

Do you agree with that as a general principle, Dr. Davis?

Dr. DAVIS. I think it is a common thread throughout these particular areas of transplantation. But the legal issues that arise from that are something that one does need to step back and study. The medicare program traditionally has not dealt with these particular issues before in terms of saying we would only cover selected patients or selected institutions.

Mr. GORE. It is a pretty good idea, though, isn't it, when you have these cutting edge technologies and the procedures are difficult; yet they save lives in a very high percentage of the cases where they are tried? And the percentage, you can expect it to be much lower in the centers that have not done it and have not committed the resources. It is a pretty good idea to limit it to those centers that have the expertise, wouldn't you say?

Dr. DAVIS. Well, again I think it brings up the kind of legal and ethical implications relative to access. These are the issues I assume Dr. Brandt has been trying to discuss.

Mr. GORE. Well, I think it raises very serious ethical problems if you take the other approach. If you say it has to be everything or nothing—if you say that the smallest hospital that has never done the procedure, doesn't know how to do it and doesn't have the resources is to be treated exactly the same as Dr. Tom Starzl's facility in Pittsburgh, that has pioneered a procedure, then by taking an all or nothing, either/or approach, you are condemning a lot of people to death whose lives could be saved if they could have access to the procedure in selected centers.

Dr. DAVIS. I am not saying that we wanted to defend that. I am simply saying it raises a number of these issues we have to look at.

Mr. GORE. You want to study it more.

Dr. DAVIS. I think that is appropriate. It is a very significant and important decision.

Mr. GORE. Well, tell me again, you are also in favor of banning—let me, so I am clear on this—you are also opposed to the provision of the bill banning organ sales because you want to study that some more also, Dr. Brandt?

Dr. BRANDT. As far as I am concerned, sir, that is a legal problem as to whether it is most appropriate to do it at the Federal level or the State level. I am not a lawyer, obviously, and have demonstrated that clearly.

Mr. GORE. But you are taking the same approach on the rest of the bill. You say you don't have any argument with the goals; it is just whether or not the Federal Government ought to do anything, or whether we ought to wait and let the problems take care of themselves. And you are taking the same approach with the proposal to ban organ sales, aren't you?

Dr. BRANDT. I am taking the approach that until I get the advice of all of the lawyers who tell me which one is the more appropriate way to go, yes, I am personally.

Mr. GORE. Let me just conclude—so I don't abuse the courtesy of the subcommittee, which I deeply appreciate—let me just conclude by saying that I am extremely disappointed with what I view as a true knee-jerk reaction on the part of the administration, automatically opposing any Federal role that in this case is necessary to solve the problems which are clearly evident. And this idea of setting up a private council, giving them $100,000 and asking them to

meet again next year some time, and hope that eventually they will come up with some solutions, you know, it is just patently ridiculous and completely and totally inadequate.

One final question: Have you asked the members of this council what they feel about this legislation? I have talked with them privately. Have you asked them?

Dr. BRANDT. They will be testifying.

Mr. GORE. Some will. Not necessarily in that capacity.

But have you asked them what they feel about the legislation?

Dr. BRANDT. We have asked some of them, yes, how they feel about it. And, again, their issue is to try to get a system. That is the important thing.

Mr. GORE. They are in favor of it, aren't they?

Dr. BRANDT. Of having a system?

Mr. GORE. Of the legislation.

Dr. BRANDT. Well, I don't think all the people that are involved are in favor of the legislation, no, sir. Again, I would go back and say that we have some examples of systems that work, that do not involve and were not established by the Federal Government. And I think—it would be easy again to pull in the blood people, too, I guess—but I see no reason to do it. It is working; we ought to leave it alone.

Mr. GORE. Mr. Chairman, I want to thank you.

And to both witnesses, I hope you understand that I feel very strongly about this, in part because I have had so many dealings with families who are encountering this problem, and they want some action. And the people of this country want some action. And they want better than folks—well, anyway, we need some action.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Gore.

Dr. Brandt and Dr. Davis, we are going to hear from a number of witnesses today, some of whom are involved in your council efforts. As we talk to them and hear their ideas, we want to look at suggested changes in this legislation and we want to revisit this question with you, because I do agree with Mr. Gore that we ought to pass legislation; there should be an appropriate Federal rule.

I would hope that each of you would assign a principal staff person to work with our staff, so that we can produce a piece of legislation that will accomplish the objectives that I know we share.

Thank you very much.

Dr. DAVIS. Thank you.

Dr. BRANDT. Thank you.

Mr. WAXMAN. Our next panel consists of senior officials of the Nation's most important organ transplant organizations: Dr. Oscar Salvatierra, the president of the American Society of Transplant Surgeons; he is accompanied by one of the Nation's pioneers in the transplantation of livers, Dr. Thomas Starzl; Mr. Gene Pierce is the executive director of the Southeastern Organ Procurement Foundation in Richmond; Dr. Keith Johnson is the president of the Association of Independent Organ Procurement Agencies; and Ms. Amy Peele is president of the North American Transplant Coordinators Organization.

I would like to welcome each of you to our hearing today. Each of your prepared statements will be made part of the record in full. We would like to ask each of you to summarize your prepared statement in around 5 minutes so members of the committee can have an opportunity to inquire further about some of the points of dispute.

Dr. Salvatierra, why don't we start with you.

STATEMENT OF OSCAR SALVATIERRA, M.D., PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS; AMY S. PEELE, PRESIDENT, NORTH AMERICAN TRANSPLANT COORDINATORS ORGANIZATION; CHARLES CARTER, M.D., VICE PRESIDENT, SOUTHEASTERN ORGAN PROCUREMENT FOUNDATION; KEITH JOHNSON, M.D., PRESIDENT, ASSOCIATION OF INDEPENDENT ORGAN PROCUREMENT AGENCIES; AND THOMAS E. STARZL, M.D., PH. D., PROFESSOR OF SURGERY, UNIVERISTY OF PITTSBURGH

Dr. SALVATIERRA. Mr. Chairman, I am here today representing the American Society of Transplant Surgeons. This society includes over 300 surgeons specializing in organ transplantation throughout the Nation. Our purpose today is to provide the subcommittee with our view and recommendations concerning H.R. 4080, recently introduced by Representative Gore and you, Mr. Chairman.

We want to say at the outset how pleased we are to participate in these hearings. We have been especially gratified by the earnest attention to this subject by you and Mr. Gore and by many others in Congress and the administration.

It is our view that organ transplantation is entering a new era of success and that all of us should seek creative approaches to the variety of problems and challenges arising from our progress in this field. The bill before you today represents a significant contribution to the resolution of a number of critical public health problems in the field. We have carefully reviewed the provisions of H.R. 4080 and we are in strong support of the intent of the bill.

I would now like to make some selected comments from my written testimony. As you know, effective regional programs for the procurement of donor organs are absolutely essential for the efficient and equitable operation of transplant programs.

Our society convened a workshop on organ procurement in May of this year with representatives of the National Neurosurgical and Trauma Societies. This 2-day meeting reviewed a spectrum of problems relating to organ procurement. It strongly underscored the need to strengthen our regional procurement efforts, a position our society strongly supports, and whereby we also therefore support the provisions in section 101.

In those cases where there are presently multiple local agencies, we believe the Secretary should offer assistance to the organization of a regional agency which would have the greatest potential to integrate all procurement activities and to work efficiently with the area transplant centers. Overall, we believe that organ procurement agencies should be evaluated in terms of their ability to assure, one, quality control in surgical organ procurement; two,

quality control in organ preservation; and three, equitable distribution of organs among patients and participating transplant centers.

Section 101 of the bill also includes provisions for the support of a private national entity to facilitate the distribution of organs amongst regions of the Nation and to maintain a registry of individuals needing organs. We are concerned that some donated organs are not used because a suitable recipient was not identified within the region.

In addition, patients with high antibody levels can often best find a suitable donor organ through a well-coordinated national effort. Unfortunately, the number of sensitized patients is increasing and their difficulty with being matched with a compatible organ is a major national problem. If there were a national computerized information base, it would greatly facilitate organ distribution on an interregional basis.

Our society took a formal position at its 1983 meeting to help establish a single nationwide computerized network that would incorporate placement of organs that could not be placed regionally and to facilitate the identification of organs for potential recipients with high antibody levels.

There is one aspect of this proposed national network which we wish to comment on further. We believe that it is important that an organ distribution system be based on the premise that regional organ needs are the first priority with national availability of donated organs occurring when organs cannot be placed regionally.

While we believe much of the responsibility for strengthening and improving on organ transplant programs lies in the private sector, we do believe there is a definite and proper role for the Federal Government. The provisions included in this bill describe a role which is supportive and complementary to efforts now underway outside the Government. The Government can be a catalyst for some new initiatives as well as a preserver of the strengths inherent in our present system. We believe this bill strikes an appropriate balance.

An example of where the private sector and Government can work together is, for example, in maintaining a registry. We want to express our support for the provision of section 374(c) which directs the Secretary to establish a national registry for data concerning organ transplant outcomes. Federal assistance in this area would be valuable.

The American Society of Transplant Surgeons would be willing to join with the NIH and other interested parties in the reestablishment of a reliable data collection system as was previously maintained through the joint efforts of the American College of Surgeons and the NIH. Most importantly, this registry could provide valuable information to a transplant technology assessment program which would evaluate emerging transplantation therapies.

We are very optimistic at this time that our success with organ transplantation in the heart and liver areas at relatively few centers can be expanded to more centers. However, we are mindful of the need for planned and managed expansion that makes the most of economies of scale and enhances quality. Thus, your proposed new authority to permit the Secretary to gradually and on a targeted basis expand medicare and medicaid coverage of new proce-

dures and therapies without new eligibility entitlement is well-founded, and we support the provisions in title II of this bill.

We perceive this to be completely different from the end stage renal disease entitlement legislation and without the risk of excessive cost that would be inherent by such an entitlement program. In addition, and most importantly, private insurance carriers look to medicare for standards of reimbursement and coverage, and these amendments would provide a means whereby the responsibility for reimbursement of these transplant procedures is shared with privately based purchasers of health care services.

It should also be noted in this connection that successful organ transplantation requires the use of immunosuppressive drugs indefinitely. The most promising of these drugs at present, and the one responsible for impressive results in transplantation of all organs, is cyclosporine.

Estimates of the cost of drug regimen vary, but the average is about $5,000 for the first year and lesser amounts as the drug dosage is later decreased.

Unfortunately, many patients will be unable to afford this drug, and, therefore, be denied its benefits because of their compromised economic status following catastrophic illness and because of the lack of provisions of many third-party carriers, including medicare, to cover outpatient costs of this drug.

We would like to suggest that strong consideration be given to provide suitable coverage for outpatient costs of this drug for medicare-eligible patients during the period of continued medicare eligibility.

When considered in relationship to the overall cost of alternative therapies, either for the maintenance of terminal care, or for transplantation without cyclosporin, we believe that coverage for this drug will be shown to be cost-effective.

In addition, we strongly recommend that coverage of outpatient cyclosporin by private insurance carriers be placed on the agenda of the Advisory Council to the National Center for Organ Transplantation.

Mr. Chairman, we have all been appalled, as have you, Mr. Gore and others, with the recent proposals dealing with the sale of human organs. We want to state categorically our opposition to such schemes and our intention to discourage such activities.

We strongly support the provisions in this bill which make it unlawful to engage in plans for the sale of human organs. The existence of such scheme, however abhorrent, very clearly underscores our present problem with shortage of organs for transplantation.

In summary, our society is committed to supporting a variety of efforts to promote organ donation, to improve the efficiency and effectiveness of organ distribution systems, and most important of all, to provide timely organ transplants for many of our citizens desiring this therapy.

I want to express my sincerest appreciation to all members of this subcommittee for their interest and deep consciousness in these major public health issues that impact on the lives and welfare of many of our citizens and their families.

I also want to thank you, Mr. Chairman, for this opportunity to testify on this important legislation. We want to continue our work

with you and your staff to build understanding and support for this measure.

Thank you.

[The statement of Dr. Salvatierra follows:]

Statement of the American Society of Transplant Surgeons
Before the Subcommittee on Health and the Environment
on H.R. 4080, The National Organ Transplant Act

Mr. Chairman, I am Oscar Salvatierra, M.D., Professor of Surgery and Urology and Chief of the Transplant Service at the University of California at San Francisco. I am here today representing the American Society of Transplant Surgeons in my current capacity as President of the Society. The Society includes over 300 surgeons specializing in organ transplantation throughout the nation.

Our purpose today is to provide the Subcommittee with our views and recommendations concerning H.R. 4080, recently introduced by Representative Albert Gore and you, Mr. Chairman. We want to say at the outset how pleased we are to participate in these hearings. We have been especially gratified by the earnest attention to this subject by you and Mr. Gore and many others in Congress and the Administration. It is our view that organ transplantation is entering a new era and that all of us should seek creative approaches to the variety of problems and challenges arising from our progress in this field. The bill before you today represents a significant contribution to the resolution of a number of critical public health problems in this field.

We also want to express our appreciation for the opportunity afforded to the Society to comment on this legislation during its development. Prior to is introduction, we were consulted by your staff on a number of issues; and we want to thank those members of Mr. Gore's staff and the staff of the Subcommittee for their interest and receptivity to our suggestions.

We have carefully reviewed the provisions of H.R. 4080, and we are in support of the intent of the bill. We do, however, have several recommendations to offer which we believe will strengthen the

measure and increase its acceptability.

Assistance for Organ Procurement Agencies

As you know, effective regional programs for the procurement of donor organs are absolutely essential for the efficient and equitable operation of transplant programs. While some locations in the nation have effective organizations, many areas need help in establishing regional organ procurement agencies or in expanding the scope of operations in existing agencies. We all realize that the need for donor organs exceeds the present supply, and this is expected to become more of a problem in the future with the anticipated increase in frequency of organ transplantation in the future - whether kidney, heart, heart-lung, liver or pancreas. Strong regional organ procurement agencies can significantly increase the number of available organs.

Our Society convened a workshop on Organ Procurement in May of this year with representatives of the national neurosurgical and trauma societies. This two day meeting reviewed a spectrum of problems relating to organ procurement. It strongly underscored the need to strengthen our regional procurement efforts, a position our Society strongly supports.

Our experience suggests that, in most areas, an area-wide regional agency is the best model to assure a coordinated approach to the identification of donors and the appropriate distribution of organs. While there are a range of factors which influence the decision to be an organ donor, we know that a very large number of potential donors are never identified because of a lack of coordination and education of the health professionals who manage the

care of potential donors. A successful organ procurement agency establishes linkages with physicians and other health professionals throughout the area which increase their awareness of the need for donor organs and assist in the necessary patient or family counseling.

Equally important is the role of the organ procurement agency in supporting the procurement teams. Because of the scarcity of organs, we must seek to reduce the wastage of organs arising from improper removal, storage, or shipment of donor organs. These activities require close and regular contact between the agency, hospital personnel, procurement teams, local community groups, and a myriad of others best managed from the area-wide agency level. We believe these area agencies must always be the foundation of the organ procurement and distribution system.

As the grant provisions in Section 101 of the bill are implemented, we believe it will be important for the Secretary to build carefully on the existing regional procurement systems, the foundation of an effective organ procurement effort. As we noted above, in some areas, the existing agency may be performing well; but a lack of resources has often limited the scope of its area activities. In such instances, we believe support should be directed toward the existing agency rather than toward the establishment of a new entity without any previous experience. In those cases where there are presently multiple local agencies, we believe the Secretary should offer assistance to the organization of a regional agency which would have the greatest potential to integrate all procurement activities and to work efficiently with the area transplant centers.

Overall, we believe that organ procurement agencies should be

evaluated in terms of their ability to assure:

1) quality control in surgical organ procurement;
2) quality control in organ preservation; and,
3) equitable distribution of organs among participating transplant centers.

We also want to express our strong support for the provisions which permit existing agencies based in transplant centers to compete fairly with independent agencies for the grant support.

U.S. Transplantation Networks

Section 101 of the bill also includes provisions for the support of a private, national entity to facilitate the distribution of organs among regions of the nation and to maintain a registry of individuals needing organs. It is evident to us that, at present, there are gaps in the inter-regional coordination of organ distribution. In several regions of the country, there is efficient sharing of information concerning the need and the availability of organs for transplantation. However, we are concerned that some donated organs are not used because a suitable recipient was not identified within the region. In addition, patients with high antibody levels may best find a suitable donor organ through a well-coordinated national effort. Unfortunately, the number of these sensitized patients is increasing, and their difficulty in being matched with a compatible organ is a major national problem. If there were a national information base, it would greatly facilitate organ distribution on an inter-regional basis. Our Society took a formal position at its 1983 meeting to help establish a single nation-wide computerized network that would coordinate placement of organs that

long-term costs to Medicare may actually be reduced. Obviously, if we are able to successfully treat and rehabilitate patients with renal failure through transplantation, then the continuing, catastrophic fixed costs of dialysis and the disability it fosters can be reduced.

We are very optimistic, at this time, that our success with organ transplantation at relatively few centers can be expanded to more centers. However, we are mindful of the need for planned and managed expansion that makes the most of economies of scale and enhances quality. Thus, your proposed new authority to permit the Secretary to gradually, and on a targeted basis, expand Medicare and Medicaid coverage of new procedures and therapies, without new eligibility entitlement, is well founded. We perceive this to be completely different from the ESRD entitlement legislation and without the risk of excessive cost that would be incurred by such a program. In addition, and most importantly, private insurance carriers look to Medicare for standards of reimbursement and coverage; and these amendments would provide a means whereby the responsibility for reimbursement of these transplant procedures is shared with privately-based purchasers of health care services.

It should be noted, in this connection, that successful organ transplantation requires the use of immunosuppressive drugs indefinitely. This means that patients with organ transplants will be faced with significant drug costs for the rest of their lives. The most promising of these drugs at present, and the one resonsible for impressive results in transplants of all organs, is Cyclosporine. Estimates of the cost of this drug regimen vary, but the average is about $5,000 for the first year and lesser amounts as the drug dosage

is later decreased. Unfortunately, many patients will be unable to afford this drug because of their compromised economic status following catastrophic illness and because of the lack of provisions of many third party carriers, including Medicare, to cover outpatient costs of this drug. We would like to suggest that strong consideration be given to provide suitable coverage for outpatient costs of this drug for Medicare-eligible patients desiring the period of continued Medicare eligibility. When considered in relation to the overall costs of alternative therapies, we believe that coverage for this drug will be shown to be cost-effective. In addition, we recommend that coverage of outpatient Cyclosporine by private insurance carriers be placed on the agenda of the advisory council to the National Center for Organ Transplantation.

Sale of Organs

Mr. Chairman, we have been appalled as have you, with the recent proposals dealing with the sale of human organs. We want to state categorically our opposition to such schemes and our intention to discourage such activities. We strongly support the provisions in this bill which make it unlawful to engage in schemes for the sale of human organs.

The existence of such schemes, however abhorent, underscores the critical shortage of organs for transplantation. We are committed to supporting a variety of efforts to promote organ donation, to improve the efficiency and effectiveness of the organ distribution system, and most important of all, to provide timely organ transplants for many of our citizens desiring this therapy.

Thank you for this opportunity to testify on this important

would not be placed regionally and to facilitate the identification of organs for potential recipients with high antibody levels.

There is one aspect of this proposed national network which we wish to comment on further. We believe that it is important that an organ distribution system be based on the premise that regional organ needs are the first priority, with national availability of donated organs occurring when organs cannot be placed regionally. We do not believe that it would be feasible or more equitable to centralize organ distribution within a national organization.

National Center for Organ Transplantation

In view of the growth of organ transplantation and the initiation of several new federal support programs, we strongly support the identification of an administrative focus for management of these programs and for a national advisory council to assist the agency in these tasks. In particular, there is a continuing need for public and professional educational programs which could be supported by the new national center. As the bill notes, there remain a number of serious and difficult public policy issues related to organ transplantation which could be illuminated by an advisory council composed of individuals broadly representative of the private sector. We have some suggestions on the physician composition of the advisory council. Important is the inclusion of a neurosurgeon and/or trauma surgeon and a representative of the American Society of Transplant Physicians. There should also be a representative of histocompatibility testing, whether a physician or Ph.D. In addition, if this advisory council is to be effective, it needs more representation from the group that will have the primary responsibility for the organ

procurement effort, namely the transplant surgeon. In view of their critical role and involvement, there should be strong consideration for six transplant surgeons for the advisory council, even though this may mean increasing the number of advisory council members. That would also permit maximum on site expertise during council deliberations from all fields of organ transplantation - whether kidney, heart, heart-lung, liver, or pancreas. Also, with the rapid evolution of the field, this cross-sectional representation of organ transplantation is essential.

While we believe much of the responsibility for strengthening and improving on organ transplant programs lies in the private sector, we do believe there is a proper role for the federal government. The provisions included in this bill describe a role which is supportive and complementary to efforts now underway outside of government. The government can be a catalyst for some new initiatives as well as the preserver of the strengths inherent in our present system. We believe this bill strikes an appropriate balance.

An example of where the private sector and government can work together is in maintaining a Registry. We want to express our strong support for the provision in Section 374(c) which directs the Secretary to establish a national registry for data concerning organ transplant recipients. It is exceedingly important to continue and expand our longitudinal studies of transplant recipients. This activity provides the vital outcome data essential for the evaluation of this therapy. Presently, it is beyond the capacity of any single transplant center to maintain such a collective data base. Thus, such federal assistance would be extremely valuable. The American Society

of Transplant Surgeons would be willing to join with the NIH and other interested parties in the re-establishment of a reliable data-collection system as was previously maintained through the joint efforts of the American College of Surgeons and the NIH. This would not only be important as a quality control and assurance system, but it would allow transplant surgeons and patients to be fully informed of transplantation outcomes and would foster the application of the more successful transplantation strategies. Most importantly, it would also provide valuable information to a transplant technology assessment program which would evaluate emerging transplantation therapies.

Medicare/Medicaid Amendments

As a physician, of course, I see the day-to-day human need of patients; and, I believe we must find ways to offer transplants to those for whom this is the only reasonable therapy, and that the ultimate costs, in fact, are small. I realize, and this Subcommittee knows only too well, the costs of health care are a major public policy problem; and difficult choices face us. However, we believe organ transplantation can, in fact, offer some help in the ongoing struggle to keep Medicare and Medicaid health costs in line with our resources for this purpose. That is why we strongly support the provisions in Title II of this bill which establish an orderly and equitable coverage policy for Medicare and Medicaid.

We have all witnessed the growth of the Medicare and Medicaid programs since 1965. In particular, the renal disease program has had an explosive growth. On the other hand, our recent experience in organ transplantation, particularly kidney transplants, suggests that legislation. We want to continue our work with you and your staff to build understanding and support for this measure.

Mr. WAXMAN. Thank you very much, Dr. Salvatierra.

Ms. Peele, we would like to recognize you next, and I would like to emphasize we would like a summary in around 5 minutes, because we are going to be pressed for time otherwise.

STATEMENT OF AMY S. PEELE

Ms. PEELE. Representative Waxman, members of the committee, my name is Amy S. Peele, president of the North American Transplant Coordinator's Organization and senior transplant coordinator at Rush-Presbyterian-St. Luke's Medical Center, Chicago, Ill. I welcome the invitation to testify before this committee on behalf of the members of NATCO.

The North American Transplant Coordinators Organization is a national, nonprofit organization representing over 400 professionals in the United States, Canada, and several foreign countries.

Our dedication is "that there be a better quality of life for the thousands of patients with end-stage organ failure, and a respect for those who shared."

I want to elaborate on the members and what are the responsibilities of each coordinator. I will simply state there are various duties assigned to the coordinator, depending on the institution's need for that coordinator.

That may entail procurement or it may entail the responsibility and care of the recipient after they have received that said organ.

With the medicare involvement for end-stage renal disease in 1972, a network of procurement agencies was established throughout the entire United States.

So, ladies and gentlemen, since that time, there has been a mechanism established across the country to obtain and distribute cadaver organs and tissues for transplantation.

The Government reimburses that system through medicare but fails to recognize its existence and continues to mislead the public by claiming there is no system to facilitate the sharing of human organs. And that myth is perpetuated by reports from the news media.

It is not by chance that 30,000 patients in the United States received cadaver kidney transplants since 1972, nor is it by chance that last year over 90 patients underwent liver transplants and less than half that amount received heart and heart/lung transplants.

It is only through the efforts and dedication of the transplant community that these patients received new leases on life. The organ sharing system does work, but there is room for improvement and expansion.

The National Organ Transplant Act can improve and expand that organ sharing system, thereby allowing thousands more end-stage organ disease patients another chance at life that only a healthy donor organ can bring.

Title I of the National Organ Transplant Act authorizes a program of grants for the development and expansion of local organ procurement organizations throughout the Nation.

In theory, this is an excellent idea, however, the application of those funds to these organizations should not take place without a thorough review of the procurement systems already in place.

That review would include:

One, an understanding of the Health Care Finance Administration's current level of involvement towards procurement efforts.

Two, the already established 32 regional end-stage renal disease networks currently funded by the Federal Government.

Three, the successful involvement at the Aetna Insurance Co.'s relationship with all independent organ procurement agencies.

Four, the United Network of Organ Sharing and its success in distributing cadaver kidneys via a computer system.

Five, NATCO's two 24-hour telephone hotlines to facilitate the retrieval and distribution of donor organs.

The NATCO 24-ALERT system began on September 23, 1982. This system, accessed by telephone, gives the caller a listing of urgently needed livers, hearts, and heart/lung combinations from the 15 transplant centers that perform these operations across the United States and Canada.

Since its inception 1 year ago, the 24-ALERT system has facilitated the transplantation of 122 livers at 9 centers, 73 hearts at 9 centers and 2 heart/lung combinations at 2 centers.

The system's success is due to the fact it was designed by transplant coordinators to meet their specific needs. It is also successful because it is easily accessed by telephone. This telephone system can complement the computerized system mentioned as part of the National Organ Transplant Act.

Title II of the bill revises title XVIII of the Social Security Act to permit the Secretary to pay for organ transplants and other investigative procedures at a limited number of specialized centers.

NATCO strongly supports this provision of the bill because it will increase the number of medical centers performing extra-renal organ transplants across the country.

There has been much discussion over the past several months about the lack of donor livers for transplantation. The reality is that the University of Pittsburgh received 523 calls alerting them to the availability of donor livers in 1982.

Only 80 of those livers were recovered and transplanted by the Pittsburgh program. 102 of the donor livers offered were declined by the Pittsburgh group because the transplant team was exhausted or the hospital could not accommodate another liver transplant patient.

However, I must note that all those potential referrals were then passed on, if not immediately, to all the other liver transplant programs in the country.

So, the shortage of donor livers is not as dramatic as portrayed by the news media. It is the lack of adequate liver transplant programs that precludes a larger number of patients from receiving therapeutic liver transplants.

Exempting organ procurement activities from the medicare prospective payment plan shows a great deal of foresight on the part of Representative Gore. This action will continue to support the present system and allow for its growth.

NATCO supports the revision of title XIX of the Social Security Act to require States to develop written policies for the payment of transplant procedure under medicaid, to require that State medicaid programs participate in any transplant program established

under medicare, and that designated transplant centers serve medicaid patients.

NATCO strongly agrees with title III of the bill prohibiting the sale of human organs and the penalties for violating this act.

Our final recommendation to this committee is to suggest that the Federal Government, through the Joint Commission on the Accreditation of Hospitals, mandate the establishment of policy and procedures in every hospital for the declaration of brain death and for the referral or organ and tissue donors for transplantation.

JCAH should require that upon every death in an accredited hospital, the deceased's next of kin be asked their position regarding organ and tissue donation.

In closing, I thank you for the opportunity to discuss NATCO's position regarding the National Organ Transplant Act.

We, as coordinators, are aware that although a successful organ procurement system exists, there is need for improvement and expansion. The National Organ Transplant Act with our recommendations can bring about this improvement and expansion, especially in the areas of public education and professional participation in the transplanting of human organs and tissues.

[The statement of Ms. Peele follows:]

TESTIMONY OF

AMY S. PEELE, PRESIDENT

NORTH AMERICAN TRANSPLANT COORDINATOR'S ORGANIZATION

Representative Waxman; Members of the Committee:

My name is Amy S. Peele, President of the North American Transplant Coordinator's Organization (NATCO) and Senior Transplant Coordinator at Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois. I welcome the invitation to testify before this committee on behalf of the members of NATCO.

The North American Transplant Coordinators Organization (NATCO) is a national, non-profit organization representing over 400 professionals in the United States, Canada and several foreign countries. Our dedication is "THAT THERE BE A BETTER QUALITY OF LIFE FOR THE THOUSANDS OF PATIENTS WITH END-STAGE ORGAN FAILURE....AND A RESPECT FOR THOSE WHO SHARED."

The members of NATCO represent various aspects of the transplant community, including physicians, nurses and allied health professionals working with the organ recipients and those whose main objective is to obtain and distribute the valuable human organs and tissues so desperately needed by the waiting victims of end stage organ failure. NATCO members provide information to medical personnel and to the general public regarding all aspects of organ transplantation. In addition, NATCO disseminates information to its members concerning new techniques in organ procurement, preservation and transplant surgery.

The role of transplant coordinators varies greatly across the country according to the needs of the institutions for which they work. Some coordinators only deal with the recipient, assisting physicians with determining a patient's medical suitability for transplant, arranging for necessary laboratory and diagnostic testing, communicating with other health care providers (physicians, dialysis units, etc.) to keep current on the status of the patient, providing for the collection of frequent blood samples for tissue matching with specific donor organs, and educating and preparing the patient emotionally and otherwise for the future transplant procedure.

Procurement coordinators are specifically responsible for organ recovery. This includes developing a network of hospitals within a geographical area whose staffs will refer donors for organ and tissue recovery. The coordinators travel to these hospitals to meet with administrators, medical boards, nursing and other ancillary personnel to

assist in formulating policies and procedures for the determination of brain death and organ donation. Frequent surveillance visits and continuing-education programs are offered as a means of keeping organ donation "alive" in the minds of the professionals in these hospitals. Procurement coordinators develop protocol manuals, posters, slide shows, telephone stickers, etc., for distribution in hospital emergency rooms and critical care units, the places where donor identification is likely to occur. A procurement center has a 24-hour "hot line" and a coordinator is available day and night to assist the donor hospital with the legal issues, medical management of the donor, obtaining consent from the appropriate next-of-kin, and organizing the surgical team for the recovery of organs and tissues.

When the organs or tissues are obtained, coordinators may be present in the operating room to help in the preparation and preservation for transplantation. Within the transplant center they may arrange for the final cross-matching and then admission of the suitable recipient. If the organ cannot be used by the local transplant program, the coordinator, using a national computer system, may arrange for the sharing and transporting of the recovered organ to another center - all in a time period short enough to ensure its viability.

Needless to say, one person cannot handle all the responsibilities described and many programs have a few persons hired under the general title of Transplant Coordinator. It must be recognized, however, that these centers work under conditions of extreme austerity and coordinators have learned to tap all available resources to ensure the efficacy of their programs.

With the Medicare involvement for end-stage renal disease in 1972, a network of procurement agencies was established throughout the entire United States.

So Ladies and Gentlemen, since that time, there has been a mechanism established across the country to obtain and distribute cadaver organs and tissues for transplantation.

The government reimburses that system thru Medicare but fails to recognize its existence and continues to mislead the public by claiming there is no system to

facilitate the sharing of human organs. And that myth is perpetuated by reports from the news media.

It is not by chance that 30,000 patients in the United States have received cadaver kidney transplants since 1972, nor is it by chance that last year over 90 patients underwent liver transplants and less than half that amount received heart and heart/lung transplants.

It is only through the efforts and dedication of the transplant community that these patients received new leases on life. The organ sharing system does work but there is room for improvement and expansion.

The National Organ Transplant Act can improve and expand that organ sharing system thereby allowing thousands more end-stage organ disease patients another chance at life that only a healthy donor organ can bring.

Title one of the National Organ Transplant Act authorizes a program of grants for the development and expansion of local organ procurement organizations throughout the nation.

In theory this is an excellent idea, however, the application of those funds to these organizations should not take place without a thorough review of the procurement systems already in place.

That review would include:

1. an understanding of the Health Care Finance Administration's current level of involvement towards procurement efforts.
2. the already established 32 regional end-stage renal disease networks currently funded by the federal government
3. the successful involvement of the Aetna Insurance company's relationship with all independent organ procurement agencies
4. the United Network of Organ Sharing and its success in distributing cadaver kidneys via a computer system
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The NATCO 24-ALERT system began on September 23, 1982. This system, accessed by telephone, gives the caller a listing of urgently needed livers, hearts and heart/lung combinations from the 15 transplant centers that perform these operations across the United States and Canada. This system is not in competition with the computerized United Network for Organ Sharing.

Since its inception one year ago, the 24-ALERT system has facilitated the transplantation of 122 livers at 9 centers, 73 hearts at 9 centers and 2 heart/lung combinations at 2 centers. The system's success is due to the fact it was designed by transplant coordinators to meet their specific needs. It is also successful because it's easily accessed by telephone. This telephone system can complement the computerized system mentioned as part of the National Organ Transplant Act.

Title two of the bill revises title XVIII of the Social Security Act to permit the Secretary to pay for organ transplants and other investigative procedures at a limited number of specialized centers.

NATCO strongly supports this provision of the bill because it will increase the number of medical centers performing extra-renal organ transplants across the country.

There has been much discussion over the past several months about the lack of donor livers for transplantation. The reality is that the University of Pittsburgh received 523 calls alerting them to the availability of donor livers in 1982. Only 80 of those livers were recovered and transplanted by the Pittsburgh program. 102 of the donor livers offered were declined by the Pittsburgh group because the transplant team was exhausted or the hospital could not accomodate another liver transplant patient.

So the shortage of donor livers is not as dramatic as portrayed by the news media. It the lack of adequate liver transplant programs that precludes a larger number of patients from receiving therapeutic liver transplants.

Exempting organ procurement activities from the Medicare prospective payment plan shows a great deal of foresight on the part of Representative Gore. This action will continue to support the present system and allow for its growth.

NATCO supports the revision of Title XIX of the Social Security Act to require

states to develop written policies for the payment of transplant procedures under Medicaid, to require that state Medicaid programs participant in any transplant program established under Medicare, and that designated transplant centers serve Medicaid patients.

NATCO strongly agrees with Title III of the bill prohibiting the sale of human organs and the penalties for violating this act.

Our final recommendation to this committee is to suggest that the federal government, through the Joint Commission on The Accreditation of Hospitals (JCAH), mandate the establishment of policy and procedures in every hospital for the declaration of brain-death and for the referral of organ and tissue donors for transplantation.

JCAH should require that upon every death in an accredited hospital, the deceased's next-of-kin be asked their position regarding organ and tissue donation.

In closing, I thank you for the opportunity to discuss NATCO's position regarding the National Organ Transplant Act.

We, as coordinators, are aware that although a successful organ procurement system exists, there is need for improvement and expansion. The National Organ Transplant Act with our recommendations can bring about this improvement and expansion especially in the areas of public education and professional participation in the transplanting of human organs and tissues.

Mr. WAXMAN. Thank you very much.
Dr. Carter.

STATEMENT OF CHARLES CARTER, M.D.

Dr. CARTER. Mr. Pierce being ill yesterday and was unable to be here, so I am representing him. My name is Dr. Charles Carter. I am vice president of the South-Eastern Organ Procurement Foundation, located in Richmond, Va.

I appreciate the opportunity of being able to give this testimony.

As a way of understanding the organization I represent, I wish to briefly describe its history and activities relative to organ procurement and transplantation. This is relevant because several portions of the bill have reference to activities developed by SEOPF over the years.

SEOPF was originally organized in 1969 with nine transplant centers in four States and the District of Columbia. The purpose of the group was to pool recipients in order to provide the best match for the kidneys retrieved by the centers.

Tissue typing was considered very important for improving graft survival, however, large recipient pools were required to obtain good matches.

Funding to develop the system was obtained from the kidney disease and control program of the Public Health Service. This system worked by matching kidneys from donors with recipients with the best histo compatibility techniques available at the time.

Today, about 6,500 potential recipients are in this computer. Of this group, about 50 percent are highly sensitized, and, therefore, very difficult to match.

In January 1977, the SEOPF computer system became available to any transplant center in the United States who wished to share organs. This was the birth of the United Network for Organ Sharing.

The United States was divided into nine regions with SEOPF being one of these regions. The regions were established along already existing geographical boundaries or between previously arranged sharing programs.

Several meetings were held with the UNOS centers for information sharing and for input from the centers using the system. In addition, some very loose guidelines for sharing were developed.

Many of the problems that we faced 15 years ago in kidney retrieval and transplantation is similar to that of the other major organs that receive so much attention today such as the liver, heart, lungs, pancreas, et cetera.

In 1979, an 800 telephone number was installed to respond to requests for information concerning organ donation. This number was placed on much of the education material prepared and distributed by SEOPF.

In July 1982, a pilot program, supported by the American Kidney Foudnation was begun to distribute organs, arrange transportation, and serve as a center for information.

In the first year of operation, transportation costs in SEOPF have decreased and kidney utilization has increased. It has been a

referral center for information and assistance throughout the United States.

The Kidney Center, which is really a misnomer because it has assisted with all organs, will be renamed. To date, medicare has not agreed to the reimbursement for the central system even though the center is currently handling over 100 organs a month.

A move was implemented several months ago between SEOPF and the American Society of Transplant Surgeons to incorporate the United Network for Organ Sharing. One committee meeting representing all phases of transplantation—surgery, nephrology, immunology, organ retrieval and administration—from throughout the United States resulted in the preparation of articles of incorporation.

In regards to the bill, H.R. 4080, there are several points which should be addressed.

One, a minimum number of organs should be retrieved per population area in order to qualify as an organ procurement center.

Two, the director should be a physician who receives some salary but not necessarily a full-time salary.

Three, the transplant physician in the geographical area served by the organ procurement agency should be responsible for the operations and governance of the agency. If more than one transplant center is in the area, each should have responsibility for the agency.

Four, the amount of funds appropriated seems excessive in light of the revenue that will be generated from the procurement of organs within the first year. Funds would be required for initial operating costs and for capitalized equipment.

Five, planning funds should be held to a minimum. Using the CDC study to evaluate the potential obtainable and useable organs in an area should not take long. Arranging working agreements and detailing operating matters should not take long. Total planning should be done within a 3- to 4-month period.

Section 373 provides funding for planning and startup of an organ procurement agency. As stated above, planning funds should be made available for a short period of time, for example, 3 to 4 months, and should not exceed $20,000.

Initial funding for starting an independent organ procurement organization should not exceed $150,000 for the first year and $75,000 for the second. These amounts should be used only for capitalization items and operating expenses over the short term. Organ retrieval will result in an offset of the overall operating costs of the agency.

A transplant center should be designated as one that meets the criteria previously established by Health and Human Services.

Section 374 authorizes the establishment of the National Center for Organ Transplantation. As in all governmental programs where funds are provided, there must be a responsible agency.

As it has been with the end-stage renal program, so should it be with this program. It would provide for an identifiable group with proper responsibility to respond to problems in organ retrieval.

The advisory council is a must in order to give overall direction to the effort of organ retrieval and transplantation. It is important

that a proper mix of individuals representing the many disciplines have the proper input.

It is unclear as to why the National Institute of Health should maintain a registry of recipients of organ transplants. This data on all tissues and organs may be submitted to them in total from the national data collection section of the U.S. Transplant Network.

Title III, section 301 making the sale of human body parts illegal is most important and should be passed as quickly as possible, either as a part of this bill or a separate one.

In summary, H.R. 4080 addresses itself to a number of problems that have been presented by the media over the past year. The transplant community has made great strides over the past 15 years, primarily from the procurement and transplantation of kidneys. The results of these early efforts can be utilized with other organs such as the heart, lung, liver, et cetera.

The passage of this bill will increase the number of organs available for transplantation and provide a new life for the thousands who are waiting currently for a transplant and the many thousands who have, as yet, not been diagnosed with the failure of a transplantable organ.

The bill H.R. 4080 has merit and with limitations relative to funding and the careful construction of organ procurement agencies, it is recommended that the bill be passed.

[The statement of Mr. Pierce follows:]

The Executive Committee

of the

South-Eastern Organ Procurement Foundation

Mr. Chairman, I am Gene Pierce, the Executive Director of the South-Eastern Organ Procurement Foundation (SEOPF) which is located in Richmond, Virginia. I am pleased to report to this committee, the recommendations of the Board of Directors and its Executive Committee concerning the bill HR 4080 which is under review today.

As a way of understanding the organization I represent, I wish to briefly describe its history and activities relative to organ procurement and transplantation. This is relevant because several portions of the bill have reference to activities developed by SEOPF over the years.

SEOPF was originally organized in 1969 with nine (9) transplant centers in four states and the District of Columbia. The purpose of the group was to pool recipients in order to provide the best match for the kidneys retrieved by the centers. Tissue typing was considered very important for improving graft survival, however, large recipient pools were required to obtain good matches.

Funding to develop the system was obtained from the Kidney Disease and Control program of the Public Health Service. Once the funds were obtained an on-line computer system became operational in December 1969 with fewer than 100 potential kidney recipients entered in the catalog. Genetic typing information on each recipient was fed into the computer. Similar data on retrieved kidneys was fed into the central computer from the donor center and the best matches in descending order were

printed out by the computer. Incidently, the General Electric time-sharing system was used, however, programming was done by SEOPF personnel.

It was found that computer selection of the best matches would result in a positive crossmatch after shipping the kidney to the recipient center thus rendering the kidney unuseable unless it could be placed in another recipient with a lower match. Cross-match trays were developed which contained the serum of the highly sensitized patients on the computer waiting list. These trays were prepared centrally and distributed to the various transplant center laboratories. The purpose of the trays was to crossmatch the cells from a donor with the serum from the recipients prior to shipping a kidney. This resulted in an increase in kidney useage and increased the transplantation of the highly sensitized patients.

Today about fifty percent (50%) of all 6,500 potential recipients in the computer are highly sensitized and this figure is increasing each year.

In January, 1977, the SEOPF computer system became available to any transplant center in the U.S. who wished to share organs. This was the birth of the United Network for Organ Sharing (UNOS). The United States was divided into nine regions with SEOPF being one of these regions. The regions were established along already existing geographical boundaries or between previously arranged sharing programs. Several meetings were held with the UNOS centers for information sharing and for input from the centers

using the system. In addition, some very loose guidelines for sharing were developed.

Because of the increasing costs of utilizing the G.E. computer system, SEOPF bought and installed two IBM Series I computers in 1979. This resulted in a considerable savings and costs were shared by the users of the system. This system has been most effective, however, they cannot do many of the programs that are needed, therefore, two new computers - a VAC 750 and 730 are in the process of being installed. UNOS has grown so that today one hundred and forty-four transplant centers in the U.S. are on the system, either directly of indirectly (such as a procurement agency which works with several transplant centers.)

In 1977, SEOPF established a Quality Control program consisting of extensive data collection for procured and transplanted organs. The papers written and published in all the major journals as well as those prepared for presentation world-wide has had an effect in improving organ retrieval efforts and increasing graft survival.

In May, 1977, SEOPF pioneered in the first long-distance heart recovery from the University of Indiana in Indianapolis to Richmond, Virginia. Techniques of this first transplant have been duplicated with some refinement to organs thus removed today.

Many of the problems that we faced fifteen years ago in kidney retrieval and transplantation is similar to that of the other major organs that receive so much attention today such as the liver, heart, lungs, pancreas, etc.

We have learned over the years to extend kidney preservation from a few hours to as much as several days. Surgeons have learned to trust each other in procurement and are willing to accept organs removed from a colleague thousands of miles away. Methods of distribution have been developed that makes organ sharing an efficient operation. We have developed independent organ procurement efforts that have resulted in the increase in organ retrieval. Education programs aimed at the public and profession have increased the awareness of the need for organ donation since the early days. Computer programs have been improved until today there is a very sophisticated computer registry and matching system in place and used nationally.

In 1979, an 800 telephone number was installed to respond to request for information concerning organ donation. This number was placed on much of the education material prepared and distributed by SEOPF. Materials consisted of TV spots, radio spots, print ads, brochures, etc. which were distributed throughout the United States.

In July, 1982, a pilot program, supported by the American Kidney Fund was begun to distribute organs, arrange transportation and serve as a center for information. In the first year of operation, transportation costs in SEOPF have decreased and kidney utilization has increased. It has been a referral center for information and assistance from throughout the United States. The Kidney Center which is really a misnomer because it has assisted with all organs, will be renamed. To date Medicare has

not agreed to the reimbursement for the central system even though the center is currently handling over 100 organs a month.

A move was implemented several months ago between SEOPF and the American Society of Transplant Surgeons to incorporate the United Network for Organ Sharing (UNOS). One committee meeting representing all phases of transplantation (surgery, nephrology, immunology, organ retrieval and administration) from throughout the United States resulted in the preparation of Articles of Incorporation and a By-Laws committee is preparing a tentative set of By-Laws for review by the two committees. There are currently no funds to officially establish the UNOS of as organized body.

The bill HR 4080 has some interesting features which are needed today. There are a number of geographical areas in the United States today that are not covered by organ retrieval efforts. The reasons may be many, however, one heard frequently is that universities will not permit the placement of university-employed personnel in locations off-campus, such as another city.

There are other areas that are not very effective in their retrieval efforts, this may include an entire state. These programs could be improved and expanded to increase the organs retrieved. One problem that is encountered at some universities is the procurement personnel are engaged in other activities which prevent them from devoting their total effort to organ retrieval. There are transplant centers that have expressed

interest in establishing an independent procurement agency, however, obtaining funds have been difficult. On many occasions doctors have jointly borrowed funds to establish a free-standing agency.

An independent organ procurement agency should be non-profit and should include all of the components as stated under Section 371 of bill HR4080. However, there are several points which should be addressed:

1) A minimum number of organs should be retrieved per population area in order to qualify as an organ procurement center.

2) The director should be a physician who receives some salary but not necessarily a full-time salary.

3) The transplant physician in the geographical area served by the organ procurement agency should be responsible for the operations and governance of the agency. If more than one transplant center is in the area, each should have responsibility for the agency.

4) The amount of funds appropriated seems excessive in light of the revenue that will be generated from the procurement of organs within the first year. Funds would be required for initial operating costs and for capitalized equipment.

5) Planning funds should be held to a minimum. Using the CDC study to evaluate the potential obtainable and useable organs in an area should not take long. Arranging working agreements and detailing operating matters should not take long. Total planning should be done within a three to four month period.

It should be pointed out that organ procurement, whereas vital, is only one phase of transplantation. The good programs are those that have a fully integrated program representing all disciplines.

Section 372 of HR 4080 provides for the establishment of the national system which in essence is an extention of the current UNOS system. It encompasses some of the programs of SEOPF and extends them for all areas of the United States from computer registration of all tissues and organs to serum sharing for all organs from data collection and analysis to the national organ distribution and exchange center.

A serious problem has been in the area of educating the general public and the medical profession concerning organ donation and retrieval. In addition, no mechanisms have been established for determining the effectiveness of organ donor programs. Funding through this bill would provide for this.

Section 372 could provide financial support for the national system which is currently being incorporated as the United Network for Organ Sharing.

Section 373 provides funding for planning and start up of an organ procurement agency. As stated above, planning funds should be made available for a short period of time, e.g., three-four months and should not exceed $20,000.

Initial funding for starting an independent organ procurement organization should not exceed $150,000 for the first year and $75,000 for the second. These amounts should be used

only for capitalization items and operating expenses over the short term. Organ retrieval will result in an offset of the overall operating costs of the agency.

A transplant center should be designated as one that meets the criteria previously established by Health and Human Services.

Section 374 authorizes the establishment of the National Center for Organ Transplantation. As in all governmental programs where funds are provided there must be a responsible agency. As it has been with the end-stage renal program, so should it be with this program. It would provide for an identifiable group with proper responsibility to respond to problems in organ retrieval.

The advisory council is a must in order to give overall direction to the effort of organ retrieval and transplantation. It is important that a proper mix of individuals representing the many disciplines have the proper input.

It is unclear as to why the National Institute of Health should maintain a registry of recipients of organ transplants. This data on all tissues and organs may be submitted to them in total from the national data collection section of the United States Transplant Network.

Title III, Section 301 making the sale of human body parts illegal is most important and should be passed as quickly as possible either as a part of this bill or a separate one.

SUMMARY - HR 4080 addresses itself to a number of problems that have been presented by the media over the past year. The transplant community has made great strides over the past fifteen years primarily from the procurement and transplantation of kidneys. The results of these early efforts can be utilized with other organs such as the heart, lung, liver, etc.

The passage of this bill will increase the number of organs available for transplantation and provide a new life for the thousands who are waiting currently for a transplant and the many thousands who have, as yet, not been diagnosed with the failure of a transplantable organ.

The bill HR 4080 has merit and with limitations relative to funding and the careful construction of organ procurement agencies, it is recommended that the bill be passed.

Mr. WAXMAN. Thank you very much.
Dr. Johnson.

STATEMENT OF KEITH JOHNSON, M.D.

Dr. JOHNSON. Thank you, Mr. Chairman, members of the subcommittee, my name is Keith Johnson, I am transplant nephrologist and codirector of the Nashville transplant program. I am here, however, representing the Association of Independent Organ Procurement Agencies.

At the present time, there are 36 of these independent organ procurement agencies, and in 1982, these 36 agencies accounted for the retrieval of 40 percent of the cadavaric renal grafts that were performed in that year in the United States.

In addition, their record in the retrieval of hearts, livers, and other organs and tissues for transplantation has also been exceedingly effective. We appreciate the opportunity to come before the subcommittee and to express our views related to the National Organs Transplant Act and how this may affect organ retrieval in the United States.

Mr. Chairman, I think it must be appreciated and acknowledged that there currently exists exceedingly effective systems for organ retrieval and sharing in this country. This current system includes a national computerized registry for the matching of kidneys with potential kidney transplant recipients.

It includes organ procurement agencies at the local level, both independent and hospital-based. It also includes regional organizations, such as the South-Eastern Organ Procurement Foundation, that assists in the sharing of serum so that highly sensitized patients, those unfortunate patients who have developed high levels of cytotoxic antibody and, therefore, are incompatible with the majority of available kidneys, have the maximum chance to receive transplantation.

Thus, I think it is imperative that any legislation seeking to improve upon this record of organ retrieval must not disrupt the system that already exists.

Such legislation should build upon this firm foundation to achieve the desired results of providing organs for more patients.

I believe that the National Organ Transplant Act is successful in accomplishing this end.

The proposed legislation, through its granting mechanisms for local organ procurement and retrieval organizations, and support of a national U.S. transplant network, allows for the accelerated development and expansion of the system currently in place.

And, yes, we do feel that there is urgency about this whole question. A series of regional organizations, modeled after the South-Eastern Organ Procurement Foundation, to which each region's organ procurement agencies and transplant centers would belong, could provide the vital link between the transplant network and the various local organizations that actually retrieve the kidneys.

These regional organizations would be responsible for developing their own region's serum sharing plan.

Under this format, one could also envision that sharing across regions would be possible, thus accomplishing for the first time the national serum exchange, which is so important for these highly sensitized patients.

The independent organ procurement agencies currently in existance have expressed a single concern about the National Organ Transplant Act. That being the requirement for modification of the composition of their board of directors, if they be free-standing IOPA's, and the exclusivity of the authority by the advisory board in instances where the IOPA is part of a parent organization.

It is suggested that this legislation could be significantly strengthened by providing for an advisory board for all currently existing IOPA's, whether free-standing or part of a parent structure.

This advisory board could have or would have authority, but not exclusive authority, over the policy for organ procurement. Such a modification would allow for the assurance of involvement by hospital administrators, neurosurgeons, neurologists, ICU nurses, and the general public, which we all think is essential to a successful program, but would not disrupt the existing structure of the independent organ procurement agencies.

With this modification, the National Organ Transplant Act should achieve the desired goal of fostering organ retrieval through further development and expansion of the currently highly successful systems for organ retrieval, and we certainly support this legislation.

Mr. Chairman, members of the subcommittee, thank you very much for the opportunity to offer our comments.

[The statement of Dr. Johnson follows:]

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Testimony of

Keith Johnson, M.D.
President, Association of Independent
Organ Procurement Agencies

Currently in the United States there exist 36 independent organ procurement agencies. These agencies in 1982 were responsible for the retrieval of 40% of all cadaveric kidneys used for transplantation. As president of the Association of Independent Organ Procurement Agencies, I am privileged to represent the agencies before the Committee today. I would like to thank the Committee for the opportunity to discuss the status of organ retrieval in this country and the effect that the National Organ Transplant Act will have on this effort.

In recent years the field of transplantation has enjoyed improving patient and graft survival not only following kidney transplantation but also following the transplantation of other organs as well. This improved success may be ascribed to better management of the rejection process through both the improved use of currently available immunosuppressant methods as well as to the advent of a totally new immunosuppressant agent - Cyclosporine.

As the news of these improved results has come to the attention of the consumer, more and more patients are becoming motivated to seek transplantation. With the dissemination of this data through professional journals more and more physicians are referring patients for transplantation. The inevitable increase in the demand for transplant services is resulting in a considerable increase in the demand for transplantable organs. The current organ retrieval effort in the United States has produced a record of success that is second to none in the world today. Nevertheless, it is still more appropriate at this time of increasing need to evaluate the already successful systems that have become established to provide tissues and organs for transplant and to see how these might be improved upon.

In order to improve upon this already exemplary record in organ retrieval there are, I believe, certain needs that must be met.

First. It is important that the establishment of effective organ retrieval efforts be encouraged in areas where currently no such efforts exist. Patients are referred for transplantation from all regions of the country and all areas of each region. All these areas must also have access to organ retrieval expertise so that they may participate in the effort to find organs for those patients they themselves refer for transplantation. The only way that we are going to

be able to meet the growing need for organs and tissues is to encourage and assist all acute care hospitals to become involved in the effort to locate suitable donors. This may require the establishment of new organ retrieval organizations where none currently exist or the consolidation of ineffective organizations into a single effective one. The cooperation of effective organ retrieval organizations with the acute care hospital in the identification of suitable organ donors continues to be the key to success in organ retrieval.

Second. Public and professional education is important to attain greater acceptance of the process of organ donation. Continuing professional education is of great importance in achieving participation by the acute care hospital. Administrators, nurses, technicians and physicians must understand the process of organ retrieval in order to cooperate with it. Public education is an essential ingredient to improving permission rates for donation once the donor has been identified.

Third. Logistics must be in place to insure that retrieved organs are transplanted into the appropriate recipient. In order that all potential transplant recipients might be accessible to all organ retrieval organizations, a truly national system is required to provide a computerized listing of all patients waiting for transplantation. Such an effective system could decrease the wastage of organs caused by the inability to locate a suitable recipient or the excessive lapse of time between the removal of the organ and it's transplantation. There is also a pressing need for a system of serum distribution to help identify compatible kidneys for those patients who have become highly sensitized through prior transplants or multiple blood transfusions. These patients have developed antibodies in their system that make them incompatible with the vast majority of organs made available for them. The test for compatibility requires white blood

cells from the donor of the organ and a blood sample from the proposed recipient. Wide distribution of serum from these potential recipients to multiple organ retrieval organizations improves the recipient's access to organs and the likelihood that a compatible organ will be found for them. A large and increasing number of these sensitized patients currently exists. To give them the maximum chance for transplant a more widely spread system for sharing serum than currently exists is needed.

Fourth. Finally, a mechanism is needed to discourage those individuals and organizations whose primary motivation is entrepreneurial from becoming involved with organ retrieval. The realization of profit from the retrieval and sharing of donated organs and tissues is morally indefensible and practically could very rapidly turn off public acceptance of the concept of organ donation. The key word in organ retrieval is truly "donation".

It must be appreciated and acknowledged that there currently exists exceedingly effective systems for organ retrieval and sharing in this country. This current system includes a national computerized registry for the matching of kidneys with potential kidney transplant recipients. It is imperative that any legislation that attempts to improve organ procurement not disrupt the system that already exists and functions so well. Such legislation should seek to build upon this firm foundation to achieve the desired results. I believe the National Organ Transplant Act is successful in accomplishing this end. The proposed legislation through it's granting mechanisms for local organ retrieval organizations and support of a national United States transplant network allows for the accelerated development and expansion of the system currently in place. A series of regional organizations modeled after the South Eastern Organ Procurement Foundation, to which each region's organ procurement organizations and transplant centers would belong, could provide the vital link between the "United States Transplant Network" and the various organ procurement organzations. These regional organizations would be responsible for developing their own region's serum sharing plan for the highly sensitized transplant

recipients in that region. Under this format serum sharing between regions would also be possible thus accomplishing for the first time a national serum exchange. Finally, through the assurance that organ procurement organizations must be not-for-profit and the prohibition of organ purchases the proposed legislation effectively addresses the entrepreneurial issue.

Independent organ procurement agencies currently in existance have expressed a single major concern about the National Organ Transplant Act, that being the requirement for modification of the composition of their board of directors if they be free standing IOPA's and the "exclusivity" of authority by the advisory board in the instances where the IOPA is a part of a parent organization. It is suggested that this legislation could be significantly strengthened by providing for an advisory board for all currently existing IOPA's whether free standing or part of a parent structure and that this advisory board have authority but not "exclusive" authority over policy for organ procurement. Such modification should allow for the assurance of the involvement by hospital administrators, neurosurgeons and neurologists, ICU nurses and the general public but would not disrupt the exisitng structure of the IOPA. With this modification, the National Organ Transplant Act should achieve the desired goal of fostering organ retrieval through further development and expansion of the current highly successful systems for organ retrieval.

Mr. WAXMAN. Thank you very much.

Dr. Starzl, I understand you were originally going to accompany Dr. Salvatierra to answer questions. You have a prepared statement. Would you like to give us a summary of that statement?

STATEMENT OF THOMAS E. STARZL, M.D., PH. D.

Dr. STARZL. Yes, sir, Mr. Chairman, I had a statement and it will be passed around, but I don't want to waste time getting into that. I make some comments?

Mr. WAXMAN. Yes.

Dr. STARZL. It is obvious to me that this committee is extremely well informed. Mr. Waxman, you may or may not remember it, but you and I talked for almost an hour about 3 years ago about where I thought cyclosporin might be going at that time, and what effect and impact it would have on the end-stage renal disease program, and the cost efficiency of that program. Of course, I have been extremely impressed with Mr. Gore's knowledge and never more so than this morning, with the penetrating questions he has asked, which if he will ask me, I think I can provide some answers for.

I didn't know when I came whether I thought this bill would be truly useful or not, but I am absolutely convinced, after hearing what has gone on this morning, that it will be not only useful, but obligatory.

Many of the discussions that I have heard this morning were very nearly incredible to me, including the lack of understanding about where the heart transplant programs have come from. The

reason I know that story with some intimacy is I was one of the 12 members who wrote the white paper that translated into the document that eventually set up those half a dozen centers.

We submitted that report in the spring of 1980, and at a news conference, the Secretary of Health, Pat Harris, indicated her disinclination to go forward with the recommendations of our white paper. Thus, it was amazing to us when in the Federal Register of January 1981, almost verbatim, our white paper appeared as a solicitation for heart centers which then evolved into the six centers set up around the country which received no funding.

The HCFA's position that cardiac transplantation was an experimental procedure, expressed at that time and continued up to the very present moment has served to wave off insurance carriers and to create a double class of medical care for our citizens, one for those who could pay and the other for those who couldn't.

The history of these events, in many ways, has been bewildering to me as I have heard the kind of testimony given by HCFA officials this morning.

Now, as far as liver transplantation is concerned, I really disagree with Dr. Brandt on a number of scores, and I don't want to go into them in great detail because the list is too long. To begin, preservation techniques are sufficiently advanced to permit interexchange of organs under the appropriate circumstances from coast to coast, and including Canada. I am not inventing that.

We retrieve livers in Denver, Colo., as many as five in one week and brought them to Pittsburgh where they all worked. Other livers have come to Pittsburgh from Los Angeles, Phoenix, Ariz.,

Furthermore, I don't think that the consensus conference was equivocating in any way in its pronouncement of liver transplantation as a service, and as the only reasonable service for many people with end stage liver disease.

I can't imagine the necessity for contemplating those opinions and those reports for very long, as was just decribed.

The problems that we are facing are deeply human, and in order to make that point, I am going to—and with the patient's permission—tell you what I did last night, and you can judge for yourselves whether our system has flaws and needs repair.

Yesterday afternoon, I was at the American College of Surgeons in Atlanta, and because there was a potential donor in Detroit, I flew back to Pittsburgh and then flew to Detroit. We removed a liver, brought it back, and worked all night until I came here. Where I would have liked to place the organ was in a very deserving woman named Judy Tazalar, who also is from Michigan, but the Michigan Medicare-Medicaid Agency has made a determination that Judy Tazalar cannot be funded for care by liver transplantation. At the same time, they have made the nearly schizophrenic determination that she can be admitted to the hospital and have her care paid for for any other kind of therapy.

So, she has been admitted to the hospital five times in the last 6 months or so, three of them I believe at our place. I don't know the cost of her care, but I would be very surprised, since we have averaged figures on this kind of hospitalization, if the cost were in the range of $150,000, and this to go down a hopeless cul-de-sac of ineffective treatment.

Now, there has to be something wrong with the system in which a State agency has rendered such a decision, and the reason that they rendered the decision is because of the nomenclature used within the Federal bureaucracy that liver transplantation—and this goes back to a determination by the Health Care Technology Group—that this was an experimental operation. This has been a position which HCFA apparently has not been willing to change, even in spite of a positive consensus conference.

As we all know, the consensus development document was here before us this morning. It has no equivocating statements.

I don't really believe this is a political problem. In the case of Mrs. Tazalar, as was the case with the Brandon Hall child and with other children and patients of whom you are aware, we had the powerful support of the White House, just as with the Tazalar woman.

Mr. Reagan wants to have her treated, in which connection he has called the Governor of Michigan. Mr. Reagan, of course, is a Republican, the Governor of Michigan is a Democrat, but both would like to have this patient treated.

Thus, the concern that is being expressed is not limited to a given party or to any branch of the government, and the barriers, as I see it, are within the bureaucracy and go back for years.

This is an example of how we are failing. The solutions have to do with many aspects of organ transplantation as we practice it, but two main categories are procurement where I think things do have to be improved, and can be improved; and the other is how to pay for those patients, those anguished people who appeared before you before, so they can be admitted to the hospital and taken care of properly.

This could be done, as I think we realize, by changing the bureaucratic guidelines, but if the bureaucracy is so resistant to changing guidelines, then it will require a law, but either the problems of organ procurement or those of hospitalization could be changed overnight by somebody, in the bureaucracy, in HCFA particularly, who would be willing to take administrative action. I know and you know, too, Mr. Gore, that in the problems with another Federal agency, CHAMPUS, in which the President and the people at the White House were trying desperately to get CHAMPUS to change its position, that part of their own administration would not respond to their entreaties.

One could, with a stroke of a administrative pen, change the whole procurement network nationwide simply by saying that medicare—or HCFA—will not fund organ procurement agencies that are disinterested in extra renal organs. It could be stipulated tht acute care hospitals could not receive medicare payment unless they had provisions and policies about brain death and solicitation of organ donation from the families of victims who are brain dead.

These things can be done within the existing laws or failing that, laws could be written.

Now, as we look down the road, I see very real problems which are not absolutely and specifically addressed in the law under discussion today.

The dreams and hopes that I have and that we all have about the extension of transplantation technologies to extrarenal organs

depend to an extraordinary degree on the improvements that have been made in immunosuppression, in particular with cyclosporine.

Oscar has raised the question of who is going to pay for this drug. We don't see a means of funding. I don't care whether that means focusing on cyclosporine or the next fine drug that comes through. But there should be some kind of generic provision so that new technologies can be applied and paid back.

Of course, Keith Johnson, at the other end of this witness table, realizes the struggle we had only 2 or 3 years to go to get the technique of thoracic drug drainage to get funded in a way that would allow our outpatients to be treated.

By the way, there is one thing that has always deeply troubled me. If you want me to stop, I will. Or if you want me to finish, I will.

Mr. WAXMAN. I want you to finish, if you can do it in another minute or two.

Dr. STARZL. What I have to say might take about a week. I will get down to the bottom line.

Mr. WAXMAN. I have a feeling you know so much about this field, each of you do, you could give us the benefit of many hours of lectures.

Dr. STARZL. I think as we look at this legislation, and this is a point two of the witnesses have already peripherally spoken to, there has to be created parity of other organs and the kidney, in the procurement network which as Mr. Gore correctly said is already federally funded. The procurement agencies cannot be little cottage industries devoted to only the kidney transplant programs. There is only one set of donors for all the needed organs and the organs are a resource of the entire United States. This concept has to be built into the system.

We have a problem here which I said at the outset is not political in nature. People of both parties in the House and in the Senate, people in the White House, our Surgeon General, who spends almost full time working on this problem, all want something done. People within the NIH are passionately interested in getting these technologies applied. I can't understand with so much support for what is obviously a great development in society and in medicine why something isn't done and why there seems to be a kind of infighting of a political nature going on all the time.

Thank you.

Mr. WAXMAN. Thank you very much.

You ended with a question of frustration of why something is not being done. Well, I hope something will be done, and the participation of each of you on this panel and other witnesses today I hope will lead to legislation that will be very helpful and constructive.

The Reagan administration witnesses, however, after they looked at this bill, said to us, "Don't pass anything at all, allow this American Council on Transplantation to work with the private sector to make the system effective."

Now, all of you are in the private sector. Do any of you think that we ought not to pass any legislation along the lines of H.R. 4080?

Let me just ask each of you down the line to go on record whether you think we need legislation or not.

Dr. STARZL. Yes, I do.

Ms. PEELE. Yes.

Dr. SALVATIERRA. Definitely.

Dr. CARTER. I think legislation is needed. I would like to make just one comment, if I could.

What this legislation really does is help this automobile of organ-sharing which is barely chugging down the road to get some gas and get some air in the tires. We need to get moving. Transplant coordinaters are overworked, we need more of them. We need to have these people out in areas where they can affect the population.

This is a grassroots problem. All the national TV exposure in the world won't take care of the problem. It is a temporary help. We need people in the grassroots talking to the constituents, if you will, of your areas that can encourage people to donate. It is a people-to-people problem. It is not something that can be handled at upper levels.

Dr. JOHNSON. Absolutely.

Mr. WAXMAN. Thank you very much.

Dr. Salvatierra.

Dr. SALVATIERRA. If I may, Mr. Chairman, there is another support source. I have been asked to transmit a letter to you from the cardiac transplant surgery group at Stanford. I would just read the last paragraph:

> For the reasons enumerated, I and other members of the transplantation program here at Stanford University strongly endorse the proposed legislation and hope for its speedy passage. We request that you transmit our strong support to members of the subcommittee and the House of Representatives before whom you will be testifying in the near future.

Mr. WAXMAN. Who signed that letter?

Dr. SALVATIERRA. That was signed by every member of the cardiac transplant program at Stanford, Dr. Norman Shumway, Dr. Edward Stinson, Dr. Stuart Jamison and Dr. Phil Oyer. [See p. 236.]

Dr. STARZL. Mr. Waxman, none of us like the idea of appearing before the committee with hands out and enumerating where moneys can be spent. My central appeal is that because there is such wide support from all agencies and from both parties in the Government that what is really needed is to remove the impediments to cardiac transplantation, the impediments to multiple organ donation and to liver transplantation which have been put in place over a period of years within the bureaucracy.

These are impediments which have the effect, Dr. Brandt and Ms. Davis, of subverting the very objective which you have enunciated, which is full involvement of third-party insurance carriers. If you create a situation in which the bureaucracies pronounce transplant procedures to be experimental, that is an open invitation for the third-party insurance carriers not to participate in these new developments. And that is precisely what has happened, as I believe you know, Mr. Gore, from your earlier committee hearings.

Mr. WAXMAN. Thank you. I am going to recognize Mr. Gore now.

Mr. GORE. I will be very brief. I appreciate my colleague's courtesy.

Did I understand you correctly, Dr. Starzl, have you been up all night long?

Dr. STARZL. Yes, I have.

Mr. GORE. Performing a——

Dr. STARZL. We brought a liver back for a transplantation actually that was finished after I came here. But the real issue was that we obtained the liver from Michigan, we had a Michigan woman in our own hospital, and we could not put the liver in from a Michigan donor to a Michigan recipient. We had to find somebody else, because of the stricture imposed by Michigan medicare which we appealed and which Mr. Reagan has tried to appeal by calling the Governor.

Downstream from the Governor somewhere is a policy instrument of such power, analogous to that which we have just seen in CHAMPUS, that it is almost impossible to overturn it.

Mr. WAXMAN. Would the gentleman yield for a minute? I would like to point out that the representatives of the Reagan administration were here a short time ago, and they told us they did not want a national policy because they wanted each State to make its own decision.

Dr. STARZL. I don't believe they know often there in the White House what these people are saying here.

Mr. WAXMAN. I can't believe they know either. Because if the President is saying he wants this kind of surgery to go on in Michigan and his representatives tell us "Don't change the law because we want the State of Michigan"——

Dr. STARZL. Mr. Reagan has intervened personally in many cases, as you well know, and so has Dr. Koop, the Surgeon General.

There is a discordance of both sentiment and action here that we see within the administration. I think the administration is a heterogeneous group. What it boils down to is that certain bureaucratic policies go on from administration to administration.

Mr. GORE. Let me read you from Dr. Davis' statement. She is the Administrator of this program for the President.

> As you know, the States have always had the responsibility for making coverage and reimbursement decisions for many medicaid programs. This provision would take us in the opposite direction, with no compelling reason for doing so.

Here you are, the most distinguished transplant specialist in the entire country, having pioneered the procedure, here you are flying around the country, taking a liver from one State to another because the current system for making these decisions is an irrational one.

It is ironic that you would stay up all night long, flying from one State to another with a liver, completing the operation, coming here to testify without any sleep, and sitting through testimony by the administration saying there is nothing wrong with the current way of solving the problems.

Dr. STARZL. If you took a vote of those administrative officials sitting in the White House, and if by administration you are one referring to the entire administration, I will bet 90 percent of them would want to put forward some kind of legislation, such as contained in your bill.

Mr. GORE. I have talked with a lot of people privately who support the legislation. But the administration's position is unfortu-

nately that the Government ought not do anything really in this area.

Dr. STARZL. I really don't believe that that is true. But anyway, that is another matter.

Mr. GORE. Well, you mentioned CHAMPUS. I may be overstating it slightly. I really don't think so. You mentioned CHAMPUS, where we had the same thing. The arguments were very clear and lucid. We had to pass—I had to pass an amendment on the floor of the Congress to make them change their policy on reimbursement of liver transplants where CHAMPUS was concerned.

I just wanted to say, in response to your statement, Dr. Starzl, that the dispute is not political in nature. I think there are political elements to it. It is not political in the sense that there is no disagreement on a personal level between the chairman of this subcommittee and the President of the United States or between you and Dr. Brandt or whatever about the need to move forward on organ transplantation.

But while the President and Dr. Koop and Dr. Brandt are extremely compassionate individuals, and more than willing to help on a personal basis, they are not willing to take the actions necessary to solve it on a national basis. I really think it is because of a fundamental political disagreement, and that is whether or not we, the American people, have the right to work together through Government to solve a problem that is national in scope.

Dr. STARZL. But I am asking you—because I in my turn indicated such flexibility of intellect as to carefully listen to what you said this morning and to understand it and really to substantively change my position—I am asking you to do the same.

I am asking you to realize, because I know the roots of difficulty and where they came from, that the central problems that we are facing really didn't start with this present administration. The whole heart transplant problem grew up in the Carter administration and the administration responsible for putting these guidelines and nomenclatures into the books were products of an earlier time.

I believe that if somebody here really would go over there and talk to people at the White House, they would find that these actions and attitudes which we heard about this morning do not really reflect what is going on in the White House. These roots of the problem were here before. I think there isn't anyone at this table that wouldn't agree with me on that score.

Mr. GORE. Well, let me just summarize by saying I agree that it ought not be political in nature. Certainly the strong bipartisan support in the Congress for this legislation indicates that it is not a Democratic or Republican initiative in any way. It is a response to the problems that we are encountering in trying to encourage more transplants. The bill has emerged out of discussions with people at this table and others who have been involved in transplantation around the country for a long time.

I appreciate some of the suggestions for fine tuning that have been made in some of the statements. Most of all, I appreciate the expressions of strong support from the witnesses here. They are very, very encouraging. When I said earlier that a lot of heroism had been demonstrated by the individuals in this country who have made this system work as well as it does at the present time, I

really meant that; and it applies to each person sitting at this table and to the many hundreds and thousands of others that you work with on a regular basis.

This, I hope, will continue to be a cooperative effort, to help you and the remarkable things you have done.

Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Walgren.

Mr. WALGREN. Thank you, Mr. Chairman.

Just pursuing along this same line, Dr. Starzl and I had correspondence earlier in the month of September in which he clearly indicated his reservations about moving on a national level and trampling on some of the local and regional values and trust and working relationships that must be in place if this area is supposed to function well. I just thought I would say that to underscore the flexibility of mind which he brought with him today, and I am sure others have, too.

I think that is really helpful in the legislative process because too often none of us will change our minds once we express any opinion, reservation or otherwise, about some legislation; and then it is more difficult to get the sides together. Flexibility can enable a great deal to happen. With the expression of support of this legislation by everyone on the panel, I think that should resolve the issue almost about whether or not something is needed here.

Is the Health Care Finance Agency designating this procedure as experimental?

Dr. STARZL. It seems to be; yes.

Mr. WALGREN. We do have a consensus conference report. Is that a very recent event?

Dr. STARZL. That was in June.

Mr. WALGREN. I just wanted to ask if we could go back again and ask ourselves what is the problem with them moving beyond the experimental designation? And we have said we cannot understand why they don't.

Does anybody have any suggestions as to why even in the face of the President's personal support for this kind of thing happening, they have not?

Dr. STARZL. Maybe if Dr. Brandt is still here, it would be fair to ask him that question.

Mr. WALGREN. Is Dr. Brandt still here?

Mr. WAXMAN. Dr. Brandt testified that that issue is still in his office. He is still considering the matter.

Mr. WALGREN. I see.

Dr. STARZL. One of the problems, Mr. Walgren, if I may—because you are from Pennsylvania and you might even be sympathetic about this—is exemplified by a process called fair appeal that we have pursued at the University of Pittsburgh, both with liver transplantation before the consensus development and on behalf of our cardiac recipients. In essence, patients were treated through HCFA agencies such as medicairs which declined hospital payment. We really didn't care about the professional fees. The agencies declined hospital payment for liver or heart recipients on the grounds that it was an experimental procedure. Recourse was through the process of fair appeal.

So I went down for the liver patients and—Dr. Henry Bahnsen, one of the most distinguished cardiac surgeons in the world, went down on behalf of the heart patients. We had our fair hearing by an official sent over from Harrisburg. At the end of the hearing, they denied the fair appeal. So I asked the man who gave me the fair appeal the basis for it, and he said, "It is experimental, and that is a HCFA ruling."

I said, "OK. Who pays your salary?" He said, "HCFA pays my salary." I said, "What if you ruled against the agency that pays your salary?" He said, "They would fire me." So that was the fair hearing.

I think we really have to look within the bureaucracy, not look within the high-minded people who sit in the Senate and the House and in the White House, for that matter. We have to look at the substructure. Within the substructure, the NIH which has been frequently cited this morning could not have been more sympathetic to our efforts. In other words, I don't think that HCFA or another part of the substructure, should hide behind the NIH as appeared to be the situation this morning.

I hope my comments do not sound as abrasive as they might seem to be.

Mr. WALGREN. Well, they certainly don't to me. I think it is a classic problem that is not just in the medical area, where you cannot get the bureaucracies to respond sufficiently—and I am afraid in cases where it is compelling, and this is—that legislatively is the only way we can really make it happen. And I hope that the administration will be as sympathetic in approving legislative redirection as they are apparently in the individual case.

Dr. STARZL. Some of the things that we hear are just pure jive. What good does it do to wait another year to take some kind of reform measures based on a study about which centers are effective procurement centers and which are not? I know what makes an effective procurement center. A 10-cent phone call would give the answer to that. And I bet you everyone at this table could do the same thing.

You work at it; you have a lot of organs. If you don't, you won't get a lot of organs.

Mr. WALGREN. Thank you, Mr. Chairman.

Mr. WAXMAN. We are going to have testimony in a few minutes about the question of buying and selling kidneys on a commercial basis.

For the record, Dr. Salvatierra, let me ask you this question: Does the donation operation pose any risk to the donor; and is the risk significant? And can an individual function as well with one kidney as with two?

Dr. SALVATIERRA. The process of donation does pose some risk. But with the care of the primary practitioner and the specialist involved in this field, these can be minimized.

The risks, more specifically are these: there is a risk of anesthesia, there is a risk of surgery and complications of surgery, and there also is the risk of subsequent life with one kidney.

I am very much concerned when we are dealing with profiteers that might exploit people because they are in a desperate economic situation, and which profiteers would not have the capability or the

commitment to carefully screen and provide for long-term followup of the donor as is absolutely necessary.

Mr. WAXMAN. Long-term followup after the operation?

Dr. SALVATIERRA. Yes.

Mr. WAXMAN. Why would that be necessary?

Dr. SALVATIERRA. Because risks, though minimal—but they are there—of having one kidney. For example, remote possibility of cancer. Also, that individual has the remote possibility of perhaps injuring the organ through some traumatic event. And we are in a mechanized society, and that possibility is real.

Mr. WAXMAN. So you don't think that the donor will be protected if that person goes in to sell one kidney and then walks out hoping to function using the one that is left without further supervision?

Dr. SALVATIERRA. That is one of the major problems. The interests of the donor certainly will not be protected.

Mr. WAXMAN. What about the recipient?

Dr. SALVATIERRA. The recipient most often will obtain a suitable organ if a related compatible kidney is not available—would obtain a suitable organ from a carefully screened cadaver source, an unrelated source. And this is a major concern of a commercial enterprise—that the recipient may be at risk from an improperly screened donor.

There are other problems, and we have addressed those problems. We want to make it better. But this type of commercial effort, I think, will destroy a system that is based primarily on altruism and may very well erode the voluntary system we have.

Mr. WAXMAN. Let me ask further about the recipient. Are you concerned as a surgeon that there may be kidneys from people who are indigent or maybe even from Third World countries who will sell their kidneys because of economic circumstances, and that these kidneys may be of poor quality or carry some kind of infection?

Dr. SALVATIERRA. I am more concerned by the fact that one would tend to exploit people who are in a desperate economic state.

In reference to the second part of your question, as far as the evaluation of that donor prior to proceeding with that operation for removal of the kidney, it is a very extensive and meticulous process. Certainly, if one is considering using donors from other countries where perhaps there may be some diseases or problems inherent to that area, this evaluation would certainly have to be much more extensive.

When one's primary motivation in this process is to carry this out for profit, I question whether the appropriate and proper commitment to that donor is protected at all costs.

Dr. STARZL. Mr. Waxman, could I comment?

I am deeply against the practice, myself. But I wonder if in the overall perspective of this bill, that fourth provision really belongs.

Mr. WAXMAN. Do you think we ought to permit the buying and selling of organs?

Dr. STARZL. Well, let me put it a different way. That may be the kind of legislation that would be in the long run go beyond what we would want to achieve. I mean, there might be a law against the buying and selling of blood or something like that. And we

have heard testimony this morning that volunteer blood is better, anyway. But there is no such law.

Mr. WAXMAN. I beg your pardon. In some States, there are laws.

Let me ask Ms. Peele, because she works with a voluntary donation organization: What do you think the impact would be on people donating their organs if they knew that others were selling their organs? Would that inhibit, do you think, the next-of-kin or others from donating—would this undermine the Nation's voluntary system of organ donation?

Ms. PEELE. I think in my professional experience in the last 5½, 6 years, I have had occasionally a family with allowing, say, "Who is going to pay the hospital bill," or, "How are we going to get some money," or, "What are we going to get if we do this?" And my colleagues and myself always come back with, "That is the gift they are giving, and they will get to know somebody else's life has been improved." I know that has always been enough for them.

And I feel strongly if that did occur, if that was allowed to happen, I can imagine a number of families that would be calling my office and offices across the country asking, "Well, now, this has occurred; what kind of rebate are we going to get? What kind of financial kickback is in it for us now?" I am very fearful of that. Professionally I would not agree with the buying and selling.

Mr. WAXMAN. We are going to have to move on, because we have other witnesses today. But let me thank each of you for participating in this hearing and working on this legislation. We want you to review the bill and further give us your thoughts as to how we can improve it. We appreciate your being with us.

[The following letter was received for the record:]

STANFORD UNIVERSITY SCHOOL OF MEDICINE • STANFORD, CALIFORNIA 94305 • (415) 497-5771
DEPARTMENT OF CARDIOVASCULAR SURGERY

October 13, 1983

Oscar Salvatierra, Jr., M.D.
President, American Society of Transplant Surgeons
University of California at San Francisco
Third and Parnassus
Room 884 M
San Francisco, California 94143

Dear Oscar:

I am writing in regard to the Bill, introduced by Mr. Gore, undergoing review by a subcommittee in the House of Representatives at present. It is my understanding that this Bill addresses four important issues in the field of organ transplantation. First, it would provide financial support for the establishment of demonstration projects in multiple organ donation and procurement. Second, it would provide financial support for the establishment of a national computerized registry system intended to facilitate matching of procured organs with appropriate recipients. Third, it would amend existing Medicare and Medicaid guidelines in order to provide for reimbursement for transplantation procedures involving all organs (not simply kidney) at specialized transplantation centers that satisfy specific qualifying criteria. Lastly, this Bill would legislatively establish the illegality of the transfer of human organs for remunerative purposes ("buying or selling").

As you know, Dr. Norman Shumway has previously testified in preliminary hearings in regard to this proposed Bill. He advanced strong support toward its passage. I and other members of the heart and heart-lung transplantation program here at Stanford feel similarly. I believe that passage of this legislation would establish an evenhanded approach to organ transplantation in general, a concept amply justified by the comparable therapeutic results obtained at present in the transplantation of kidneys, hearts, combined heart and lungs, livers, etc. The time is long past due for recognition of the fact that organ transplantation in this country at the present time involves multiple organ donation and procurement systems and that reimbursement for multiple organ transplantation procedures on an equal basis is thoroughly justified.

For these reasons I and other members of the transplantation program here at Stanford University strongly endorse the proposed legislation and hope for its speedy passage. We request that you transmit our strong support to members of the subcommittee in the House of Representatives, before whom you will be testifying in the near future. Thank you for the opportunity to review the proposed legislation and to state our strong support of it. Best personal regards as always.

Sincerely yours,

Edward B. Stinson, M.D.
Professor, Department of
Cardiovascular Surgery

Norman E. Shumway, M.D., Ph.D.
Professor and Chairman,
Department of Cardiovascular Surgery

Stuart W. Jamieson, M.D.
Assistant Professor,
Department of Cardiovascular Surgery

Philip E. Oyer, M.D., Ph.D.
Associate Professor,
Department of Cardiovascular Surgery

EBS/mlk

Mr. WAXMAN. Our next witness is Dr. Barry Jacobs, the medical director of the International Kidney Exchange. He is here today to discuss his proposals to increase the number of kidneys available for transplantation.

STATEMENT OF BARRY JACOBS, M.D., MEDICAL DIRECTOR, INTERNATIONAL KIDNEY EXCHANGE, LTD.

Dr. JACOBS. You have my position paper. Let me just get right to the point of what we are here about.

Everything I heard today from Dr. Brandt, sitting on his butt, from everyone else here, talking about need—there is no question about the need. There is no question about the problem.

A fancier computer is not going to solve the problem. With 22,000 brain dead people where organs could have been removed last year, only 1 out of 10 had them. A fancier computer may save a few percentage on wasting of organs. Maybe it will improve the kidney transplant rate. Right now with cyclosporine, a kidney will last 80 percent or more over 5 years.

The technology is here. Congressman Gore and myself have been on television, various programs. We must have generated abou $50 million worth of free publicity. I think the test will be, look over the next 6 months and see what increase in altruism—as Dr. Salvatierra said, we are in the altruistic business here—let's see what that $50 million in free publicity has done in altruism of brain dead people's families willing to dedicate more organs. I don't think it will make a dent in the budget.

There are 70,000 Americans out there who could have transplants and only 5,000 something or other last year had it.

They talk about the risk to the donor and they talk about altruism. You know about 500 or 600 or more transplants last year came from healthy people—relatives, fathers, mothers, and brothers. The chance of having a stranger's kidney match your son's or your daughter's kidney is greater than you matching your own family's kidneys because if the pool is large enough, your genes and your wife's genes mix into your child. So the chance of getting a stranger's kidney, a cadaver's or living stranger's is irrelevant.

It is better that the pool is large enough so that is relevant. I agree with Dr. Salvatierra, the donors have to be screened, whether it be cadaver donors, where you only have a short period of time to do the blood testing, a live person, they have to be protected in the future or followed up and is advised and fully informed. They seem to imply that if someone is going to sell a kidney they are going to walk into a room, give up the kidney and be lost forever.

You have to talk to the family doctor or the person, the surgeon who is going to operate, the hospital is getting the informed consent as well; the psychiatrist who has to evaluate the person before they give you a kidney for money or love. There is a whole bunch of safeguards in the system now. The problem is nothing has been done, effectively done to increase the number of organs.

What I am proposing is simply a monetary program. It is a two-phased monetary program. Where people fully informed, consenting adults, could give up a kidney if they wanted to, and more im-

portantly, and the major thing is for the Government to offer the incentive to people to sign up while they are healthy.

Most States have the place where you can sign up on the drivers license, or they can register with the post office like a draft. Give some people money incentives to sign up while they are alive, should their organ be used if they are brain dead and if their organs could be harvested or used for someone to live, whether heart, lung, or kidney, give them the monetary incentive to sign up so that there will be made known in advance while they are alive, so when and if they die, that their organs, their name will be in the computer, the hospitals all over the country will have the printout sheets they can check, is this person registered, is there a desire, the desire while alive was to give up the organ to benefit someone who could use them.

What is the incentive? Like an insurance company, the Government can give $10 or $20,000, whatever it takes to get a massive number of people to sign up and then solve the entire transplant program. The computer—you heard them, they match all over the country now. They are not one organization in Richmond, another one in California, the computers talk to each other every day. Maybe if the Government steps in it will improve the matching, speed it up a little bit.

That is not going to solve the problem. The problem is the availability of organs that don't exist and having more dedicated people like this woman sitting next to me, more dedicated people like her going out into the community and knocking on doors and working in emergency rooms and that may improve a little bit.

We have done 50 million dollars' worth of free publicity last week. I doubt if it has made a dent in the problem. The more publicity, more TV commercials, more people knocking on doors is not going to give the personal incentive to give up the organ. It is the monetary incentive that the Government can say we are going to give you a $20,000 insurance policy that if you die and if we can harvest your organs—which means they are brain dead on the respirator—if they can harvest the organs, then your family will get a burial payment, payments for your family to go on.

That is the major problem. It is not fancier computers, not the technology. The technology is here, the fancy computers already talk to each other. It is getting availability of organs that don't exist. And whether it be from healthy living people, who want to give it up now—we gave a whole bunch of letters—we have one from a lawyer in Washington, D.C. He wants to donate free, and complete our form. He wants to do it anyway. People want to donate for free. People want to donate for money. They don't know where to even go. There is no incentive for them to give up an organ.

When a person is lying brain dead, I can't conceive of them arguing about their little daughter's kidney or liver or how much they are going to get for it. It is not going to interfere with the existing people waiting for organs. They are waiting for organs that don't exist in the cadaver pool. If you can get more organs available, then you can take them off the list, let them have an organ, and more people then will move up the list and just improve the whole problem and take care of it.

Mr. WAXMAN. So it is your position that the altruism is not enough. People are not going to want to contribute their organs to save the life of another should they find themselves brain dead, people are not going to want to contribute?

Dr. JACOBS. If they find themselves brain dead they can't make a decision.

Mr. WAXMAN. They make it in advance. One of the purposes of the whole legislation and the organization that hopes to carry out this purpose of this legislation is to encourage physicians to tell their patients that they ought to be aware of organ donation, or the next of kin ought to know if a relative is brain dead that an organ can be contributed.

Dr. JACOBS. These organizations have been out there.

Mr. WAXMAN. I want to finish my statement, then I will let you finish yours. The whole purpose of this bill is to notify people and inform them of all the people waiting, and that they, while they don't think about it now, may find themselves in that circumstance, and to encourage them to discuss with their relatives or physicians the fact that they may well want to contribute an organ. You think that is not going to be sufficient and we have to have a system of buying and selling organs and go to people who want the money in order to get them?

Dr. JACOBS. Not buy it and sell it. Make equitable distribution. Offer the incentive, let the Government run it, offer the monetary incentive for people to sign up.

Mr. WAXMAN. Do you think money is the only incentive that will motivate people?

Dr. JACOBS. It is not the only incentive but it is the only one that is going to make a difference. When you have 22,000 brain-dead people, and 2,200 of them, 10 percent of them are, through the families and coordinators, begging them to give up the organs, and only 10 percent give up the organs. Sometimes they could have given them up, the family has to think about it, and they end up with pneumonia, infection sets in, you can't put an infected organ into somebody, you will kill the recipient.

So give them the incentive now. Why would anybody in their right mind go around the country now, give up and organ? You could have signed up on the drivers license for years in many States. It is pathetic but almost nobody signs up. We got all the publicity now, cameras and everything. It hasn't made a dent in the situation. For every $1,000 the Government spends in insurance policy for organs, as an incentive to sign up, they will save $14,000 or more on transplantation.

We are spending $2 billion a year for kidney dialysis, keeping 70,000 people alive. Congressman Gore talked about the dehumanization on our machines. To get them off of it, the Government can save money by offering a little insurance policy as the incentive to sign up, as the incentive to sign up so that the pool of potential organs being available will markedly rise and all this begging and pleading will just disappear.

Mr. WAXMAN. For the record, are you involved in a business now involving organs? Are you commercially involved in the commercial sale of organs?

Dr. JACOBS. Let me explain where it is at. We just set up a proposal, and it is just at the initial phase of the proposal. What really happened, I think it is misunderstood what we did. I wrote letters to 7,500 hospitals asking them would they be interested in participating in transplantation doing the transplant operations, or doing the removal of the kidney. That is what we mailed out to 7,500 hospitals to see what response their was.

And about 5 days later, or a week later, I was interviewed by the Washington Post and on television. All we have done is mail out a letter to 7,500 hospitals. Because of the publicity from television, hundreds of donors called in. We xeroxed as many as we could of the applications and letters and gave it to your committee just on Friday, I think it was.

Mr. WAXMAN. Is it your intention to become a middleman, a broker, to charge a fee for contacting a donor and obtaining an organ in order to give it to a donee?

Dr. JACOBS. If we can locate, if a couple of things happen, if we locate the number of hospitals that we would need to participate. If we can do that and the physicians are willing to cooperate in the program, which means all of the doctors involved, if we can do that, and if nothing is done about raising the number of organs available—fancy computers don't do it—then it is our intention to go ahead, not buying and selling organs; setting up a private program independent of the existing program, having healthy people if they want to sell a kidney that is their decision to make. They can set a price if they want. That is their own business, we have nothing to do with that. And help match make the blood typing information available to the recipients through their doctors, they can decide if they can afford it, is it a good match.

Mr. WAXMAN. How would you be compensated?

Dr. JACOBS. Well, there would be—if the person, the recipient, not the donor, if the recipient could afford, without indigence—there will be a sliding scale brokerage fee that would cover the cost we would incur. Then what would be left from the brokerage fee would be used to advance the cost to those who couldn't afford it so they could purchase a kidney, go back to work, reimburse the fund, which would then have the money available for the next person downstream. I hope the Government can take it over and do it on their own. I don't want to do it. Something has to be done about it.

Mr. WAXMAN. How would you assure that potential donors who are motivated solely by making some money would fully disclose all their medical conditions that might affect the outcome of the surgery?

Dr. JACOBS. First, we have to have their family physician give them—in other words, their doctor, they have had some doctors in the past. Their doctors, or clinics or wherever they get their medical care, has to make the medical records available so they have to sign a consent to release their medical records, which is their right to do as a patient. Release the medical record. They will have to be counseled by their own doctors.

No. 3, they would be evaluated by a psychiatrist to be sure they are making an informed decision and they undersand what the risks are, then they have to be counseled by their own doctor with regard to risks. Then when the matches are made up they will be

going into a hospital and the surgeons operating in the hospital will be counseling them. It is all elective.

Mr. WAXMAN. Usually people who are indigent, who are doing something to make money, don't have a family physician.

Dr. JACOBS. They all have clinics.

Mr. WAXMAN. You get somebody with a stamp on there that says it is OK, they are fine?

Dr. JACOBS. They have to have gone to some institution in the past for some medical care. Those records will have to be made available. A stranger doesn't come out of the woodwork in this country. Whatever the system is, whether a private physician or a clinic or in the Army, they have been treated in the past. That is No. 1. That is just background. Of course, if you are talking about a cadaver lying on a slab or on a respirator, what information do they know about that person? There is not time to get their medical records.

Mr. WAXMAN. Cadaver donors are the same under either circumstance. I would assume the indigent who came in to get some money would be someone donating a kidney because they can survive with one kidney.

Dr. JACOBS. That is correct.

Mr. WAXMAN. Talking about someone brain damaged because of an accident, I assume there is no way to make much money. It would be a question whether they are willing to pay or their family have already discussed it and made a decision whether they are willing to——

Dr. JACOBS. I think you are missing something. There are two reasons why you want to know about the past medical history of the donor. One is to protect the donor and the other reason is to protect the recipient. For the protection of the recipient there is more information available with testing in an elective time in the healthy walking person as opposed to the cadaver. For protection of the recipient, a noninfected, not on a respirator, no needles in their body, a noninfected donor has a better kidney, a safer kidney, to a small degree a safer kidney than one lying on a respirator.

With regard to the protection of the donor, they have medical records in the past. They will have seen some physicians in the past. They will have to see other independent physicians in the program that I am proposing. In the program we are proposing, they would have to see a physician, they would have to see a psychiatrist. All the blood tests, kidney X-ray studies to be sure that they are healthy, that they do have two normal functioning kidneys and are psychologically sound and there is no coercion as an inducement.

Mr. WAXMAN. This idea of a commercialization of organs is based on a premise that people, if asked, would not voluntarily donate an organ and make this program succeed where we match donees and donors in order to save lives. Is that a correct statement?

Dr. JACOBS. It is correct because it hasn't worked for years. They talk about need. No one denies the need. No one denies that the Government ought to fund. It is not experimental anymore. I heard Dr. Brandt this morning talk about how do you know the criteria for the patients and alcoholic hepititus? That is a medical decision.

Mr. WAXMAN. You think that no matter what other programs we undertake—to inform people, to set up a computer system, to try to encourage the physicians to talk to patients, and members of the family about donating organs—to encourage people to donate on a voluntary basis, there is not going to be enough of an incentive, and that what we need is to pay people?

Dr. JACOBS. I hope that talking to them, I hope that putting in these coordinators in multiple areas in every State, I hope that would work, but it hasn't worked for years. It has been so dismal a failure, pathetic.

Mr. WAXMAN. You don't think——

Dr. JACOBS. I don't think it will work. I don't think it will work and I think the Government can simply make a reasonable incentive for people to sign up so if their organs could be used when they are dead, the person will have made their will known.

Mr. WAXMAN. I understand.

Dr. JACOBS. Once more, I don't think it will work.

Mr. NIELSON. Excuse me, I wanted to ask a question.

Dr. JACOBS. I don't think it will work. It hasn't worked yet.

Mr. NIELSON. Dr. Jacobs, would you clarify for me—I didn't hear all the testimony, although I have read it. Are you proposing the Government do the buying and selling of these organs, or do you propose it be private enterprise?

Dr. JACOBS. With regard to the monetary incentive to have the person sign up while they are alive, so if they die, if their organs could be used, that they be equitably distributed. I proposed the Government do it. And with regard to the healthy, living people, the National Kidney Foundation—Fortune Magazine quotes their brochure—it is safe for the donor to give it. I think healthy living people, the ones that are healthy, can make a decision to give up an organ.

I think the Government ought to get involved in doing it. If the Government doesn't get involved in doing it, I think the private sector ought to get involved in doing it with the appropriate safeguards we now have in the medical profession.

Mr. NIELSON. Irrespective of whether you like this bill or not, do you think it will help encourage people to donate organs? Do you think it will work in that direction? Will this bill help or hinder that process, yes or no?

Dr. JACOBS. It won't hinder, it will minimally help. The main thrust of the bill, the most important aspect of the bill is recognizing, not the kidney, with regard to the heart and liver that is no longer experimental and making them available for the people. It is not only they need more organs, but it is the one they get can't get the hospital bills paid. You can't go to the hospital until you put down $80,000. It is a fact of life. He can waive his fees but not the university hospital fees.

Mr. NIELSON. How about section 3 of the bill? Witnesses say they are opposed to it, basically that is buying and selling organs. That is what the section deals with.

Dr. JACOBS. It is very simple.

Mr. NIELSON. Are you for that section or are you against it?

Dr. JACOBS. I am against it. Like the Soviet Union, in the Soviet Union they have no transplant problems because the organs belong

to the State pocket. It is creating a communistic system on organs. It is saying a healthy consenting adult in the present medical system with all their safeguards we have with the hospital and physicians, can't make their own determination for his own body.

I respect Congressman Gore's ethics and his ethics and morals are fine. To impose his ethics on everybody else, when we came off the Today show, 30 people called up. Every one of the 30 were in favor of what I was proposing, the right of the individual to make that decision for themselves. The safeguards are out there. The medical profession is the most regulated in the world.

Mr. NIELSON. Do you have an alternative version to section 3. It is a problem. Do you have some way we can amend section 3 to make it acceptable?

Dr. JACOBS. Yes, sir.

Mr. NIELSON. Would you present it to us?

Dr. JACOBS. Very simply.

Mr. NIELSON. I mean in writing.

Dr. JACOBS. Yes, some safeguards.

The safeguards exist. I will be glad to. If someone is going to give up an organ, make certain requirements they have to be seen by an independent psychiatrist or psychologist to evaluate their competency to make the decision; that their medical records——

Mr. NIELSON. I presume anyone who makes the decision is somehow not in full command of his faculties, is that what you are saying?

Dr. JACOBS. Not at all. I am suggesting if you want legislation——

Mr. NIELSON. What you are saying is if I make that decision, I have to see a psychiatrist to make sure I am in my right mind to make this decision.

Dr. JACOBS. What I am saying is that a psychiatrist would be the one to determine the adequacies of an informed consent decision if you want to pass legislation.

Mr. NIELSON. Won't that dry up the number who will offer their organs? If they have to go then to see a psychiatrist, won't that dry up——

Dr. JACOBS. No, they won't have to pay for it.

Mr. NIELSON. I don't care who pays it.

Dr. JACOBS. Everyone else is concerned with who is paying it. It won't dry it up at all. There is no stigma. It is simply a safeguard for the patient.

Mr. NIELSON. Do I have to make what I consider a humanitarian decision, then defend that before a psychiatrist or psychologist?

Dr. JACOBS. You are missing the point. It is not just for sale. It is any healthy person, whether it be a loved one giving up it for their child or a stranger giving it up free, donating free to a stranger or someone, a stranger selling it for a stranger.

I think any of those people, because you talk about guilt, the guilt that makes a mother give up a kidney for a son is hideous guilt. We are talking about the "Jewish mother" thing. That is guilt you are putting on somebody. That is a guilt trip. Those people will suffer psychological damage afterwards.

Mr. NIELSON. Maybe I misunderstood what you have said. I thought you said you had to have safeguards. Anyone who says that they are going to give their organs——

Dr. JACOBS. Give or sell.

Mr. NIELSON [continuing]. Has to have a psychological examination to make sure he is in his right mind to do so. Is that what you said?

Dr. JACOBS. No.

Mr. NIELSON. What did you say?

Dr. JACOBS. If a healthy person, anyone who is going to give or sell a kidney, give it away free or sell a kidney to a relative or stranger, ought to have appropriate independent psychological evaluation to be sure they know what they are getting into, that they are not emotionally disturbed or financially disturbed so they can give informed consent, rational, informed consent.

Mr. NIELSON. That is exactly what I thought you said. I object to that.

Dr. JACOBS. What do you object to?

Mr. NIELSON. I think you will dry up the supply.

Dr. JACOBS. There is no supply right now. We are talking about healthy living people; there is no supply in healthy living people.

Mr. NIELSON. Dry up the potential supply, would go counter to the number of people who wish to give organs.

Dr. JACOBS. You are going to make it illegal to buy or sell, how are you going to dry it up? It doesn't make sense.

Mr. NIELSON. Whether you buy or sell or not, the fact is that——

Dr. JACOBS. Or give it free.

Mr. NIELSON. Or I think if you would have to submit to some kind of psychological examination afterwards, I think you will cut down the supply.

Dr. JACOBS. I disagree with you.

Mr. NIELSON. That is my opinion.

Dr. JACOBS. I respect it.

Mr. GORE. I will be brief because Dr. Jacobs and I have had an opportunity to discuss this together before, and we will have another opportunity next month with a series or group of bioethicists who are going to come to discuss this in some more detail.

But, just for the record, Dr. Jacobs, what I have heard you propose in the past is not inconsistent with this. But just so we will have more of the details on the table, I have heard you talk about going to South America and Africa, to Third World countries, and paying poor people overseas to take trips to the United States to undergo surgery and have a kidney removed for use in this country. That is part of your plan, isn't it?

Dr. JACOBS. Well, it is one of the proposals.

Mr. GORE. And——

Dr. JACOBS. You have to understand something——

Mr. GORE. You had said also in the past that the payment would vary depending upon the individual involved.

Dr. JACOBS. As it does in this country, it is up to them to decide.

Mr. GORE. And that some of these potential donors probably wouldn't ask very much because they would get a chance to see America.

Dr. JACOBS. What their motivation is is up to them.

Mr. GORE. They might be willing to give you a cut-rate price just for the chance to see the Statue of Liberty or the Capitol or something.

Dr. JACOBS. What their motivation is is not important. Some of them may want to do it free. Whatever their decision, it is their decision, just as a mother will give it to a son or not, or an American would sell it or not. What their motivation is is not the——

Mr. GORE. Could they put it up as collateral on a car loan?

Dr. JACOBS. I don't understand what you are saying.

Mr. GORE. If they sell it pending the operation, could they put up their kidney as a collateral on a loan of some kind?

Dr. JACOBS. I have no idea. You are the lawyer, I am a doctor.

Mr. GORE. Well, if it has a property right——

Dr. JACOBS. You are the lawyer, so you can answer your own questions.

Mr. GORE. Actually, I am not, so I am asking because——

Dr. JACOBS. I am not a lawyer either, so you will have to ask one of the others.

Mr. GORE. It is your proposal.

Dr. JACOBS. My proposal is that they decide what they want to do with their body. Every American has the independent right, assuming they can make an intelligent, informed decision, to make it, fully protected, in our system. That is up to the individual.

If you want to say what the Soviet Union style of medicine is, you can or you can't give up your organs, well then that is what you are going to impose on this country by your legislation.

Mr. GORE. Let's suppose someone in the Third World wanted an operation for another health problem and came here but couldn't pay for it. Could they have an operation for something wrong with their appendix or something else and then——

Dr. JACOBS. Come to America?

Mr. GORE. In order to pay for it, tell the doctor to just take the kidney out while you are in there and use that to pay for the operation.

Dr. JACOBS. I have no idea what American hospitals are going to do in charging. That is simply up to them and in the American hospital, I doubt that could ever happen.

Mr. GORE. Now you have also said on several occasions in the past, including in an article you wrote for USA Today, that the Federal Government is currently paying 300 people in a pilot program to——

Dr. JACOBS. Not paying, had made an offer, I was told. Do you want me to go into that?

Mr. GORE. You wrote that the Federal Government has a pilot program to pay 300 people to have their kidneys removed, healthy people, and donate them to others.

Dr. JACOBS. That is what I was advised.

Mr. GORE. My question, for the record, is: Where is this pilot program?

Dr. JACOBS. I was told that it is a group in Hawaii, that is an independent organ procurement organization that had made arrangements with the Health Care Financing Administration, through a proposal that they made about 4 months ago, to get funding, I was advised.

Mr. GORE. What is the name of the group?

Dr. JACOBS. I was going to bring it to your committee.

Mr. GORE. No, you said you were going to tell me that information. Do you happen to know the name of the group?

Dr. JACOBS. I have it at home.

Mr. GORE. Can you remember off the top of your head?

Dr. JACOBS. About five words and a name and they are in Hawaii.

Mr. GORE. How much money are they getting from the Federal Government?

Dr. JACOBS. What they told me, because I haven't seen the papers——

Mr. GORE. What individual told you?

Dr. JACOBS. The man who ran it.

Mr. GORE. Do you remember his name?

Dr. JACOBS. This is about a month ago. I have it at home. I will give the information to your committee.

Mr. GORE. Do you remember his name?

Dr. JACOBS. No.

Mr. GORE. Was it a long-distance call from Hawaii?

Dr. JACOBS. He was in Washington and wanted to meet with me down in Washington. I couldn't get away that day.

Mr. GORE. Did he call you up?

Dr. JACOBS. At home, yes.

Mr. GORE. To tell you about the program that he was getting funded by the Federal Government?

Dr. JACOBS. He wanted to talk to me about a number of things, one of which was that. Let me tell you what he advised me that he got. He told me he approached the Federal Government about 4 months ago with a proposal wherein he wanted funding, a grant, to set up a program with 300 individual donors, would be paid $20,000 per person to donate, healthy people, to donate a kidney, and that there will be a $10,000 brokerage fee paid to their organization for making those arrangements. That is what he told me.

The reason why he called me, he said, I was unable to make any arrangements in getting the things together; he tried to run an ad in the Enquirer newspaper, and that was turned down.

Mr. GORE. The National Enquirer turned him down?

Dr. JACOBS. I can't believe it. That is what he told me.

Mr. GORE. I see.

Dr. JACOBS. That is rather amazing. That is what he told me. That is why he wanted me to see if I could work with them and do something, and I said I am not going to turn that down. Of course, first we have to get our program going.

Mr. GORE. Well——

Dr. JACOBS. Have you checked it out?

Mr. GORE. We have checked it out thoroughly. There is no such pilot program.

Dr. JACOBS. The guy lied to me. All I can tell you is what he told me. That is what I told you last week.

Mr. GORE. You have written it in a national newspaper.

Dr. JACOBS. That is what I have been advised.

Mr. GORE. And left the impression that the Federal Government is engaged in this kind of thing, and it is not. There is no such program.

Dr. JACOBS. Well, all I can tell you is what they have told me. I will get their names, and you can speak to them.

Mr. WAXMAN. We will hold the record open. We would like to get the information.

Dr. JACOBS. I would like to get it.

Mr. WAXMAN. The information you have, who called you?

Dr. JACOBS. I want to give that to you.

Mr. GORE. One final line of questions, very briefly, Mr. Chairman.

We could take a lot of time on this.

Is it your understanding of the hippocratic oath—you are a medical doctor, right?

Dr. JACOBS. Yes. Licensed in Maryland.

Mr. GORE. Is it your understanding of the hippocratic oath that it says first do no harm?

Dr. JACOBS. That is my understanding.

Mr. GORE. Now, let's say a healthy individual comes into your office and asks you to take out his kidney so he can get some money for the kidney. Isn't that unethical for you to permit that operation?

Let me ask you a specific question. Doesn't that violate part of the hippocratic oath which says first do no harm?

Dr. JACOBS. No, it doesn't, because the hippocratic oath was thousands of years old before we even had the ability to do transplantation. You have to balance the risks.

Let me explain something to you. Last year hundreds of family members, living family members, put themselves on the same block and had their organs removed.

Mr. GORE. That is very different.

Dr. JACOBS. No, it is not different. The risk to that mother is the same risk to that stranger. The motivation is different, but the same risk, the same harm potential is there.

It is minimal. But the same risk is there for the mother or the brother to a sister giving up a kidney as it is to a stranger. If you are talking about do no harm, Dr. Salvatierra was one of the ones who pioneered doing related donors in San Francisco.

Ask him why he does harm yet his organization comes out against doing harm.

Mr. GORE. But there the donor, without any other consideration involved, is making a conscious choice to balance the health benefits for a family member against the health risks for the individual donor.

Dr. JACOBS. So is the stranger.

Mr. GORE. No, because the stranger is doing it for monetary gain, and a doctor participating in a procedure that inflicts harm on the patient in return for monetary gain is performing an unethical act in violation of the hippocratic oath.

Dr. JACOBS. Forget about the hippocratic oath because it doesn't talk about kidney transplantation.

It didn't exist in the days of kidney transplantation, which is now. You have to talk about the modern aspects of it and the

donor, whether it be a mother or a stranger, is under the same risk and plenty of mothers and plenty of sisters and brothers were under the knife last year to give up kidneys, and they are doing it for a relative, and even others, cousins and uncles are giving it up for relatives in the family.

Now, you have to understand what the motivation is there. There is a lawyer from Washington who wrote to us who wants to give up his kidney free to a stranger. That lawyer giving it up free to a stranger is under the same risk as a mother and sister and the same doctor will operate.

Mr. GORE. Let me just conclude.

Dr. JACOBS. If you want to legislate the hippocratic oath, that is what you are going to have to legislate.

Mr. GORE. Let me conclude by thanking the witness. I think this proposal that he has made—and incidentally, others have made similar proposals. Another business was started based in Maine with nationwide solicitation, some other countries have had a similar experience, and other medical advances will force us to deal with similar questions in the future.

But I think that this proposal has stirred as much interest and conversation as it has because it forces us to confront basic values and weigh them against one another. I enjoyed discussing this.

But the proposal is so unsound in my view, and you understand I disagree with you fundamentally, that I think the legislation should be passed.

Dr. Jacobs has accused me in the past of having a Bible-belt mentality, Mr. Chairman.

Dr. JACOBS. Which I respect.

Mr. GORE. To that I will plead guilty and rest my case.

Dr. JACOBS. That is the final answer. I rest my case on that, too—whether his religion or morals should be made into law in this country or those people should have the right to decide on their own bodies, with proper safeguard, to do with their own bodies as they choose.

Mr. WAXMAN. How far would you go? As I understand your theory of a person having absolute say over any part of his body.

Dr. JACOBS. Not any say, because you cannot——

Mr. WAXMAN. You are talking about kidneys.

Dr. JACOBS. Only kidneys.

Mr. WAXMAN. Why not go beyond kidneys?

Dr. JACOBS. Because beyond that is suicide.

Mr. GORE. What about eyes?

Dr. JACOBS. That is a vital organ. A kidney is not a vital organ if you have two of them.

Mr. GORE. You have two eyes.

Dr. JACOBS. You lose your stereo vision. The National Kidney Foundation talks about the minimal risk in encouraging strangers to donate.

Mr. WAXMAN. So in your view of morality there is a limit to it because you are going to make a decision as to how far someone else can decide what to do with his body?

Dr. JACOBS. If is is a nonvital organ, it doesn't mutilate the person.

Mr. WAXMAN. How about an arm?

Dr. JACOBS. That is mutilation. There are laws against that.

Mr. GORE. There is harm from donating a kidney.

Dr. JACOBS. The National Kidney Foundation says otherwise—there is no harm. The risk is most minimal. Mothers and brothers and uncles and cousins giving up a kidney know that is a minimal risk.

Mr. GORE. The same people who printed that have come out strongly condemning your proposal.

Dr. JACOBS. Let me give you the final answer on that. They control $2 billion of money. The kidney specialists in this country, the nephrologists, control the flow of $2 billion of their private dialysis centers. Most of the centers are privately funded.

If you want to do something effective in this world, cut the price of dialysis in half. You will find out the same 70,000 people are still getting quality dialysis.

The doctors would be driving Ford Escorts instead of Mercedes.

Mr. GORE. You are charging them with being corrupted by the profit motive?

Dr. JACOBS. They have a reason to maintain the status quo. The kidney specialists controlling $2 billion worth of dialysis money have a personal reason. They have their own personal motives, and $2 billion is certainly a lot of motive to control it and come out with a position now that was previously contrary to their other position.

Mr. WAXMAN. I thank you very much for your testimony. I gather this will be the beginning of a discussion that is now brought to people's consciousness, because we are now confronting certain moral questions which I think we have to look at.

Dr. JACOBS. One more question nobody has confronted is the brain-dead person. Before they die, if they can make their decision known, and if they are willing to make a decision and the monetary incentive will be what will make them make their decision——

Mr. WAXMAN. Or humanitarian concern. Like you, I am not so cynical to dismiss the idea that people have some humaniterianism, some magnanimity in their last moments.

Dr. JACOBS. The way to tell is simply do what you are proposing. You will find out a year or two from now, instead of going for 5,000 transplants you may have reached 6,000. By that time there will be 90,000 Americans waiting for transplants on dialysis.

Mr. WAXMAN. We will have to look at it again.

Dr. JACOBS. Obviously, the final answer is what works. You will know it. It is your way or my way. But one way is going to finally work.

That is the final answer.

[Dr. Jacobs' prepared statement and letter in answer to questions during the hearing follow:]

H. BARRY JACOBS, M.D.
Diplomate of the American Board of Surgery
Diplomate of the National Board of Medical Examiners
Medical Director

TOLL FREE 800-336-0332
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International Kidney Exchange, Ltd.

11345 Sunset Hills Road
Reston, Virginia 22090 U.S.A.

The voluntary organ donor program in this country is a dismal failure. Too many citizens -- children, women and men -- anxiously await the health-sustaining and life-saving kidney which they will never receive. Not under the current donor program which offers neither incentive nor motivation for people to give up one of their kidneys to a stranger. There is no stronger motivation than a monetary one. There are two ways in which our government can go about relieving the endless wait of 70,000 Americans -- an often unfulfilled wait for a life-saving kidney, and save $2 billion per year (the cost of dialysis).

One of these options involves the establishment of a donor bank whereby any healthy citizen can "will" their kidneys, for removal after their death, to a national kidney bank. If the organs can be used, the government can then financially compensate the deceased donor's family, as per the donor's wishes. A match would then be made between the donor's kidney and someone awaiting a kidney. Priority would be given to length of waiting time, quality of the match and medical necessity, regardless of social or financial status on the part of the recipient.

The government would fund the medical costs involved -- at a considerable savings over even one year of dialysis for a kidney patient today. Since 80% of transplanted kidneys will function for more than five years, each additional kidney transplant will save $142,000 over five years. For every thousand dollars used to purchase a kidney, the government will save $15,000 or more in the cost of dialysis. This concept is really no different from the Lion's Eye Bank or the annual Red Cross Blood Drive. The donor makes the rational decision to donate his kidneys, or eyes, before death, and, in so doing, helps not only his own family, which received a monetary "insurance" benefit, but two kidney patients who otherwise are doomed to an existence of living on a dialysis machine.

The second option is for the government to fund a program whereby an informed and consenting adult kidney donor can be compensated for donating one kidney while still alive, and enjoy both the financial and spiritual rewards of helping an otherwise helpless and hopeless individual -- one handcuffed to a dehumanizing kidney dialysis machine. Because of shortages, kidney transplant operations help less than one out of ten patients. The majority of the 5,000 kidneys transplanted each year come from only 2,200 brain-dead citizens whose families gave permission for organ removal from their loved one.

This program would not interfere with the limited source of brain-dead donor kidneys. In fact, this source would be augmented considerably.

There is a slight to moderate risk in transplanting cadaver kidneys due to a higher chance of infection caused by various methods used to keep the patient alive and ready for transplantation. All brain-dead respirator patients develop pneumonia (it is only a matter of days) and the infection risk to all their organs increases as each hour passes. Healthy donor kidneys are safer, more medical information about the donor is available and obtainable, more time is available to perform extensive testing, and the operations are electively scheduled.

God gave us two kidneys. We need only one-half of one kidney to live a normal healthy life. God also gave us the intelligence and ability to perform kidney transplantation operations. Some doctors raise the moral issue of risk when money is involved, but imply the risk is less for healthy close relatives donating a kidney. The risk to the donor is the same even though their motivation may be different. With a large enough "donor pool" a non-related donor's kidney has a very good chance of being a better match than, for example, a mother for her son.

The risk for serious injury or death is much less than one per thousand donors. It is the responsibility of the private physicians and operating surgeons to fully inform both donors and recipients of their respective risks, and to do everything necessary to minimize all risks.

The government should not have to fund the cost of organ transplantation. It is a well established principle of civil law that the one who causes the damage should be responsible for the cost of correcting the damage. Alcohol is the greatest cause of liver failure and a contributing cause of kidney failure. A slight increase in the tax on alcohol, borne by the users of alcohol who are subjected to the risk of alcohol, would pay for the cost of organs and for liver and kidney transplantation. Likewise, tobacco is a major cause of heart and lung disease, and a slight increase in the user tax for tobacco would pay for heart and lung transplantation operations and for the purchase price of those organs. This type of user tax is not unlike the tax for gasoline which is used to pay for construction and repair of roads.

In the final analysis, the kidney debate should be resolved by individual doctors and their patients; not by politicians.

H. Barry Jacobs, M.D.

H. Barry Jacobs, M.D.
Medical Director

10/13/83

H. BARRY JACOBS, M.D.
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October 19, 1983

The Hon. Henry A. Waxman
Chairman
Subcommittee on Health and
the Environment
2415 Rayburn House Office Building
Washington, D.C. 20515

The Hon. Albert Gore, Jr.
Chairman
Subcommittee on Investigations
and Oversight Committee on
Science and Technology
822 House Office Building
Annex 1
Washington, D.C. 20515

Dear Congressmen:

It was a pleasure appearing and testifying before your committee hearing on Monday, October 17, 1983.

One of the members of your panel asked me to advise him what I believe would be appropriate psychiatric or psychological evaluations of all healthy, living donors. This includes both those who donate free for family members, as well as those who sell their kidney to a stranger.

You must understand that there is substantial emotional coercion involved when a family member donates a kidney for a loved one, and subsequent emotional problems in the future can develop from that. Emotional guilt is a strong persuader as well as the cause of psychological injury.

My recommendation is that any individual who will be subjected to an operation to give up a healthy kidney, be evaluated by a licensed psychiatrist or psychologist, independent of the transplant organization or doctors, in order to make the determination that the individual fully understands all the consequences, both emotional and physical, of their proposed surgery and that they can truly give informed consent.

As you heard on Monday, hundreds of patients every year, living related patients, are being subjected to the same risk physically that a stranger is subjected to, but the emotional risks for relatives donating kidneys are much greater, both immediate and long term.

You wanted to know the name of the organization which advised me that the government, Health Care Financing Administration, (H.C.F.A.), has approved a pilot experimental program to pay for 300 kidneys from healthy,non-related donors, offering the donors $20,000 per kidney and offering the broker $10,000 per transaction. I was recently advised that this was when Mr. Schweiker was in charge of Health and Human Services, and, as a pilot program, it did not need official approval from Congress. This apparently is why Congressman Gore was unable to locate this information through his careful research.

The organization is called Internationale Societe for Vital Organ Replacement, Ltd., Eighth Floor, 1136 Union Mall, Honolulu, Hawaii 96813, 808/523-1770. This is a Delaware corporation. The man who apparently is in charge of this group, and the one who advised me of this pilot program, is Clifford Laughton.

At the request of Congressman Gore, I have set aside November 1st and 3rd on my schedule. Please advise me as soon as possible which of these two days, if any, my testimony would be needed, so that I may make appropriate arrangements.

Sincerely yours,

H. Barry Jacobs, M.D.

H. Barry Jacobs, M.D.
Medical Director

HBJ/fca

Mr. WAXMAN. Thank you very much, Dr. Jacobs.

Our final witness today is Dr. Gary Friedlaender, a professor of orthopedic surgery at Yale University, and the interim president of the recently established American Council on Transplantation.

We are pleased to have you with us. We have your prepared statement. It will appear in the record in full. We would like you to summarize it, if you would.

STATEMENT OF GARY E. FRIEDLAENDER, M.D., INTERIM PRESIDENT AMERICAN COUNCIL ON TRANSPLANTATION

Dr. FRIEDLAENDER. Thank you very much.

Scientific, surgical, and medical expertise has enhanced the feasibility and efficacy of organ and tissue transplantation, but efforts at acquiring, financing, and equitably distributing these precious transplantable resources are not, at the present time, providing everyone in need with the opportunity to benefit by this approach.

Indeed, the problem could get worse in the future, and it is our collective conscience, wit, and wisdom that must minimize, if not eliminate, the tragic circumstances of unmet needs.

These requirements encompass an appropriate supply of kidneys, livers, and other solid organs, but also tissues including bone, corneas, and skin. Futhermore, without a mechanism to pay for transplant procedures and hospitalization, people will continue to be denied the full benefits of modern medicine.

Currently, we are considering approaches to increase the availability to tissues and organs for transplantation. Several honorable alternatives exist.

Our duties are now to identify and support in unison a comprehensive and feasible approach that has as its goals increased numbers of tissues and organs suitable for transplantation, appropriate facilities and personnel for implementing recovery, equitable distribution and transplantation of these precious resources, continuing support of basic research to insure an even brighter future, and a system of financial support that the public as a whole and as individuals can afford, and not afford to be without.

Let's look at the problem and proposed solutions more specifically. First, the public owes a great debt of gratitude to Congressman Gore for his recognizing the dilemma, raising our collective awareness and understanding to unprecedented heights, and proposing legislation that addresses and provides potential solutions to many of our concerns.

The approach is intelligent, logical, and, within the defined limits of organ recovery and distribution, comprehensive.

Praise for the National Organ Transplantation Act will not be hard to find, but I think it would be constructive to point out aspects of this proposal that might benefit from further thought, discussion, and perhaps even change.

Please keep in mind that I am firmly committed to identical goals and similar solutions, and concern or even opposition to portions of the National Organ Transplantation Act must not be construed as a vote against our mutual desires.

The public would benefit by passage of this legislation even in its present form, but the public might benefit to an even greater degree by considering alternative suggestions, as well.

First, I am somewhat concerned by the overwhelming focus of the Transplantation Act on viable organs, taking little substantive interest in tissues such as bone, corneas, and skin for which there is a great public need, and recognizing there are also differences in the potential donor pool, recovery mechanisms, storage and distribution techniques, and transplantation approaches that must be recognized and accommodated and certainly not obstructued, even inadvertently, by legislation too narrowly focused.

These concerns should be easy to resolve if recognized and addressed.

I am also left wondering how the proposed national strategy will specifically provide a satisfactory approach to not only see that tissues and organ acquisition costs are met, but also how the public will pay for transplantation procedures even if the tissues and organs are available.

Most of all, I am impressed there are presently mechanisms in place to identify potential donors, recover tissues and organs, and distribute them. It would be premature to call this a well-organized and comprehensive system, but even in its current state this fragmented approach has supported the transplantation of 25,000 kidneys over the past 5 years, 500 livers, and smaller numbers of hearts and lungs. It has provided at least 15,000 corneas last year alone, an increasing percentage of the 100,000 to 200,000 bone grafts required annually in the United States, and numerous skin grafts for burn victims.

A more advanced version of this system, if you will, has provided us with millions of units of the highest quality blood the Nation has ever had available and done so through a totally nonprofit and almost completely voluntary system of donation without financial compensation to the donor.

I think this collective effort has been impressive, but inadequate as it currently exists, and must be made better. It does, however, provide the building blocks for a more capable system.

In fact, the United Network for Organ Sharing (UNOS) at this time represents a comprehensive national network that is already in place.

The American Council on Transplantation represents a federation of individuals and groups that have provided interest, expertise, public and medical education and financial aid to transplantation in the past, as well as presently. It is the sum total of our best efforts today, and ACT intends to provide a cohesive national direction, flexibility and innovation.

ACT can develop and implement a national strategy based on peer group expertise and guidance through a voluntary nonprofit approach. In concept, it will take a good system and make it better. Its advantages include the fact that much of the system is already in place. It currently exists.

A careful analysis of the present effort will permit an organization such as ACT to encourage, promote and expand the effective elements of the current system, identify and hopefully rectify inadequacies.

As a federation, it can combine currently fragmented resources and provide a more effective impact in areas of education, training, organ and tissue recovery, banking and equitable distribution, as well as suggest mechansism compatible with appropriate funding for transplantation.

I personally believe that appropriate education of the public and medical profession and the consolidation of our present organ and tissue recovery system based on peer-group-derived standards will result in the optimal response obtainable from the public in a country where individual needs and rights have traditionally been paramount.

I intend to propose a uniform donor permit stressing the importance of multiple tissues and organs rather than single interests. I would also suggest there be a well-developed and visible focus within the Federal Government, presumably within DHHS, to interface with a group such as ACT to share concerns and, more importantly, solutions.

ACT reflects many of the highly successful approaches embodied in the American Blood Commission formed approximately 10 years ago, and I would submit this approach again is likely to work, and in its flexiblity can do so more quickly and effectively than a system too deeply rooted within the Federal Government.

In short, the American Council on Transplantation has faith in the public and in professional organizations, and with an appropriate response from the Federal Government can address and resolve our transplantation needs effectively, comprehensively, efficiently, quickly, and with fiscal responsibility; and leading us to believe this type of approach should be pursued vigorously before alternative but obviously well-intended suggests be adopted.

Again, our goals are identical, and I envision a need for continued cooperation in identifying and resolving this challenge.

Thank you.

[The statement of Dr. Friedlaender follows:]

TESTIMONY OF

GARY E. FRIEDLAENDER, M.D.

PRESIDENT (INTERIM) AMERICAN COUNCIL ON TRANSPLANTATION

A dilemma has arisen, for which qualitatively and quantitatively there is little controversy. The good news is that scientific, surgical, and medical expertise has enhanced the feasibility and efficacy of organ and tissue transplantation, but the bad news is that efforts at acquiring, financing, and equitably distributing these precious transplantable resources are not, at the present time, providing everyone in need with the opportunity to benefit by this approach. Indeed, the good news will undoubtedly get even better in the future, and it is our collective conscience, wit, and wisdom that must minimize, if not eliminate, the tragic circumstances of unmet needs. These requirements encompass an appropriate supply of kidneys, livers, and other solid organs, but also tissues including bone, corneas, and skin. Furthermore, without a mechanism to pay for transplant procedures and hospitalization, people will continue to be denied the full benefits of modern medicine.

I was given the opportunity to present my thoughts on these matters by virtue of my position as Interim President of the American Council on Transplantation (ACT), but I am also President of the American Association of Tissue Banks, have served as Director of the U.S. Navy Tissue Bank, currently serve on committees concerned with tissue recovery, banking, and transplantation within the American Academy of Orthopaedic Surgeons, the Transplantation Society, and the American Red Cross. I am actively involved in teaching, basic and clinical research, and patient care as a member of the full-time faculty of the Yale University School of Medicine, but I have developed most pride and most concern as a member of the public. I and my loved ones are potentially donors to and potential recipients of the

benefits of medical expertise, and I have also had the experience (12 years ago) of a young family member dying from bilary atresia—at a time when her options were limited not so much by the lack of a donated liver but by the unavailable technology. But this was the past, and we must live in the present with an eye towards the future.

Currently, we are considering approaches to increase the availability of tissues and organs for transplantation. Honest and honorable people have come forth with suggestions as evidenced by legislation proposed by Congressman Gore and Senator Kennedy, responses from the Public Health Service and the Department of Health and Human Services, as well as a number of voluntary, nonprofit organizations exemplified by UNOS, NATCO, the American Association of Tissue Banks, and many other professional societies, as well as charitable and educational institutions. Indeed, no matter which of the approaches mentioned above is most favored and implemented, the public is likely to benefit. Our duties are now to identify and support, in unison, a comprehensive and feasible approach that has as its goals increased numbers of tissues and organs suitable for transplantation, appropriate facilities and personnel for implementing recovery, transplantation and equitable distribution of these precious resources, continuing support of basic research to ensure an even brighter future, and a system of financial support that the public as a whole and as individuals can afford—and not afford to be without.

Lets look at the problem and proposed solutions more specifically. First, the public owes a great debt of gratitude to Congressman Gore for his recognizing the dilemma caused by insufficient tissues and organs for transplantation, raising our collective awareness and understanding to unprecedented heights, and proposing legislation that addresses and provides potential solutions to many of our concerns. The approach is intelligent, logical, and, within the defined limits of organ recovery and distribution, comprehensive. In addition, it provides a strong Federal focus for these activities. I sat as an interested observer at hearings in April convened by Congressman Gore, listened to and read the appropriate media coverage that ensued, and had an opportunity to discuss the evolution of his concerns and solutions with knowledgeable resource personnel.

Praise for the National Organ Transplantation Act will not be hard to find, but I think it would be constructive to point out aspects of this proposal that might benefit from further thought, discussion, and, perhaps, even change. Please keep in mind that I am firmly committed to identical goals and similar solutions, and concern or even opposition to portions of the Natinal Organ Transplantation Act must not be construed as a vote against our mutal desires. The public would benefit by passage of this legislation even in its present form, but (and I was invited to express these caveats, which I will try to do in a constructive fashion) the public might benefit to an even greater degree by considering alternative suggestions as well.

I am somewhat concerned by the overwhelming focus of the Transplantation Act on viable organs. For specific portions of the bill, "organs" are defined to also include tissues such as bone, corneas and skin, or potentially include these if so stated by the Secretary. While there are many similarities between viable organs and other tissues, including a great public need for the availability, there are also differences in the potential donor pool, recovery mechanisms, storage and distribution techniques, and transplantation approaches that must be recognized and accommodated and certainly not obstructed, even inadvertently, by legislation too narrowly focused. There are places in the bill where the term "organs" can and must appropriately mean "tissues and organs" and other references where this might be contraproductive. To my knowledge, nationally recognized expertise in the banking and transplantation of various tissues and the impact of the currently proposed legislation on these matters was not previously sought in a fashion commensurate with the need as I perceive it. The concerns I have raised are probably easy to resolve, if recognized and addressed.

I am also left wondering how the proposed national strategy will specifically provide a satisfactory approach to not only see that tissues and organ acquisition costs are met, but also how the public will pay for transplantation procedures even if the tissues and organs are available. If you think it is frustrating not to have the required organ, think of the scenerio in which an organ is available but cannot be transplanted for lack

of suitable funds. It would be unconscionable to create a system by which only the most wealthy could benefit. I know that is not the desire of the honorable men and women that drafted the National Organ Transplantation Act, but the problem will not disappear by lack of direct affirmative attention.

There are presently mechanisms in place to identify potential donors, recover tissues and organs, and distribute them. It would be premature to call this a well-organized and comprehensive system, but even in its current state, this fragmented approach has supported the transplantation of 25,000 kidneys over the past five years, 500 livers, and a smaller number of hearts and lungs. It has provided at least 15,000 corneas last year alone, an increasing percentage of the 100,000 to 200,000 bone grafts required annually in the United States, and numerous skin grafts for burn victims. A more advanced version of this "system" has provided us with millions of units of the highest quality blood the Nation has ever had available, and done so through a totally nonprofit and almost completely voluntary system of donation without financial compensation to the donor.

I think this collective effort has been impressive, but most certainly it must be judged inadequate as it currently exists and must be made better. It does, however, provide the building blocks for a more capable system, and my interpretation of the National Organ Transplantation Act suggests this legislation also recognizes this resource and builds upon the same currently fragmented and somewhat disorganized but well-intended efforts I have mentioned. In fact, the United Network for Organ Sharing

(UNOS) does indeed represent a comprehensive national network that is already in place.

What does the American Council on Transplantation suggest? ACT represents a federation of individuals and groups that have provided interest, expertise, public and medical education, and financial aid to transplantation in the past as well as presently. It is the sum total of our best efforts, and ACT intends to provide a cohesive national organization with direction, flexibility, and innovation. ACT can develop and implement a national strategy based upon peer-group expertise and guidance through a voluntary, nonprofit approach. In concept, it will take a good system and make it better. Its advantages include the fact much of the system already exists and is in place. A careful analysis of the present effort will permit an organization such as ACT to encourage, promote, and expand the effective elements of the current system; identify and rectify inadequacies. As a federation, it can combine the currently fragmented resources and provide a more effective impact in areas of education, training, organ and tissue recovery, banking, and most equitable distribution, as well as suggest mechanisms compatible with appropirate funding for transplantation. I personally believe that with appropriate education of the public and medical profession and the consolidation of our present organ and tissue recovery system based on peer-group derived standards, the effort will result in the optimal response obtainable from the public in a country where individual needs and rights have traditionally

been paramount. I must also predict that ultimately science will provide for benefits we cannot afford or adequately provide, but we must be prepared to do our best and do it equitably and rapidly.

To foster the necessary cooperation between groups presently preoccupied with single organ or tissue needs, I intend to propose the Uniform Donor Permit which provides for documentation of informed consent and at the same time identifies a broad range of transplantation needs, asking potential donors or the next-of-kin to eliminate from consideration those tissues or organs that are inappropriate or not desired rather than start with a single interest. I also would suggest that there be a well-defined and visible focus within the Federal Government, presumably within DHHS, to interface with groups such as ACT, to share concerns and solutions. I am led to believe mechanisms for this type of interaction currently exist, but perhaps a more visable Advisory Council appointed by the Assistant Secretary for Health would serve a useful purpose.

ACT reflects many of the highly successful approaches embodied in the American Blood Commission formed approximately 10 years ago, and I would submit this approach is again likely to work and, in its flexibility, can do so more quickly and effectively than a systems deeply rooted within the Federal Government. ACT is capable of increasing voluntary doination of transplantable tissues and organs through improved coordination of existing facilities and promoting solutions to address inadequacies. It can do so in the context of equitable distribution, and it can inform the Legislature of its concerns regarding potential abuses of donors, recipients, and society that may arise from buying or selling of human tissues and organs so as to encourage the Congress to draft and pass appropriate measures.

In short, the American Council on Transplantation has faith in the public and in professional organizations to address and resolve our transplantation needs effectively, efficiently, quickly, and with fiscal responsibility, and leads us to believe this type of approach should be pursued vigorously before alternate and obviously well-intended suggestions be adopted.

Again, our goals are identical, and I envision the need for continued cooperation in identifying and resolving our transplantation needs.

Mr. WAXMAN. Thank you very much for your testimony and for your thoughts on the legislation.

Mr. Gore.

Mr. GORE. Thank you very much, Mr. Chairman.

Dr. Friedlaender, I appreciate the chance to talk with you here today about this. You are appearing in essence as an administration witness. You have just been appointed President of the American Council on Transplantation.

That is correct, is it not?

Dr. FRIEDLAENDER. I would take issue with that. I do not feel as if I am an administration witness. I responded to a request by the Surgeon General to participate in a steering committee approximately 4 weeks ago that wished to look at possible mechanisms, obviously within the private sector, as you are well aware, that might confront this growing dilemma concerning availability of organs for transplantation. It was that group, catalyzed certainly by the administration—but it was that group that independently went about providing a mission and goal statement, and independent of the administration-elected officers.

I don't feel any particular allegiance to any other group, except only to resolving the dilemma itself.

Mr. GORE. OK, fine. But you are appearing as President of the American Council on Transplantation that has just been appointed by the administration; correct?

Dr. FRIEDLAENDER. That is not correct.

Mr. GORE. Just looking at your statement here—if I am going wrong, tell me.

Dr. FRIEDLAENDER. No; that's not correct. It says "President of the American Council on Transplantation." It is not an appointed position by the administration.

Mr. GORE. Were you appointed to the council?

Dr. FRIEDLAENDER. I was appointed to the council as a representative of the American Association of Tissue Banks, of which I am president.

Mr. GORE. OK, fine. I appreciate the correction.

The administration-appointed members of the council, and asked different groups to provide membership on the council; is that it?

Dr. FRIEDLAENDER. Correct.

Mr. GORE. And you were not chosen by the administration?

Dr. FRIEDLAENDER. That is correct.

Mr. GORE. You were chosen by the American Council——

Dr. FRIEDLAENDER. American Association of Tissue Banks.

Mr. GORE. OK. Very good. I appreciate that.

Then after the council met, the members of the council elected you as the interim president; is that correct?

Dr. FRIEDLAENDER. That is correct.

Mr. GORE. All right, fine. I am glad we cleared that up.

Now, this American Council on Transplantation is said by Dr. Brandt to be the group that is going to provide coordination and come up with a solution to these problems that confront the national transplant network. They are putting a lot of confidence in your group.

Are you working on that group full time?

Dr. FRIEDLAENDER. I would have to admit, in deference to where my salary comes from—and that is Yale University—that this has been virtually a full-time job since the meeting at Project Hope, September 21–22. It is not my desire that I remain at this task full time beyond the next meeting.

Mr. GORE. When is the next meeting?

Dr. FRIEDLAENDER. The next meeting is scheduled—now you are talking about the entire organization?

Mr. GORE. The American Council on Transplantation.

Dr. FRIEDLAENDER. The various committees of the organization have been meeting almost continuously. The executive committee was virtually represented in toto here on the panel that preceded Dr. Jacobs. So I would say that indeed there has been considerable current and ongoing activity amongest various members of this steering committee.

As an entire group, just as the entire Congress, we will be meeting again at a later date, which is scheduled for January.

Mr. GORE. I see.

Now, the executive committee, if that was the executive committee before Dr. Jacobs, was unanimous in supporting this legislation.

Do you also support the legislation?

Dr. FRIEDLAENDER. I support a strong statement from the Federal Government in support of transplantation. Regarding the other panelist's remarks I think it may amount to the same thing that happens when many people feel the same elephant but don't get to see the whole animal at one time.

I personally interpreted their response to mean that they also wanted an effective system in place. I think the system that you have proposed is really a bird in the hand. What I am suggesting is that there may be two in the bush and that we may be good hunters in that regard.

I am also aware of the fact that if you go to Congress to solve a problem, they respond with legislation, appropriately. If you go to Midas, you get a muffler. I think when you go to the private sector, you get those very dedicated people who are very concerned trying to come up with a plan rooted in their own expertise. So what we see is, I believe, simultaneous honorable efforts from several different sources, all of which can have potential, favorable impact on the problems that we are both identifying.

Mr. GORE. So you do support the legislation?

Dr. FRIEDLAENDER. I didn't say that. I said I support a strong Federal statement. Now, I don't know enough about the workings of the Congress as to how best they should supply that statement. I may be using words inappropriately, but I would like to see the Federal Government make a statement that attests to the interest and urgency of the problem and perhaps identify the Assistant Secretary of Health as the individual to organize an appropriate response in view of this dramatic need.

Mr. GORE. Well, first of all, going back to an earlier statement, I don't think I misheard the statement of your executive committee members. They expressed support for the legislation. The chairman asked each one of them individually if they felt the legislation ought to be passed. They said yes. You seem to disagree with that; or maybe you don't.

It is not too complicated a question, in view of the fact that this hearing is a legislative hearing specifically targeted on H.R. 4080. Let me just ask you for a simple answer.

Do you support H.R. 4080?

Dr. FRIEDLAENDER. I wear many hats. That is probably why I am going bald. I am wearing the hat of the American Council on Transplantation at the present time, but I don't find that particularly in conflict with some of my other hats.

In its absolute unaltered present form, I have concern with H.R. 4080. If it were the only potential, reasonable, honorable solution to the problem, I would jump at it.

Mr. GORE. Let me ask you to take off your hat, the hat of the American Council on Transplantation, and put on your hat as a transplant surgeon.

Are you a transplant surgeon?

Dr. FRIEDLAENDER. In my opinion, I am. I transplant bone.

Mr. GORE. Have you had——

Dr. FRIEDLAENDER. I also belong to the American Society of Transplant Surgeons.

Mr. GORE. Have you had experience with kidney, liver or heart transplantation, or any organ transplantation?

Dr. FRIEDLAENDER. Well, I did certainly have some contact with this through my medical education. Furthermore, I spent 2 years as director of the Navy's tissue bank program which does encompass viable organ transplantation. I am an orthopedic surgeon by training.

If you ask me to wear the hat of which I am most proud, it is as a member of the public.

Mr. GORE. OK. As a member of the public, do you support this legislation?

Dr. FRIEDLAENDER. Understanding the two alternatives that I perceive, going forward—we are really just singing very slightly different refrains of the same tune—I don't think we are in an adversary position.

Mr. GORE. I hope not. I am trying to make sure we are not. I am trying to hear your refrain, though.

Dr. FRIEDLAENDER. I am trying to draw closer—and I respect what Dr. Starzl stated, who, I might add, when I was a medical student, I enticed to come and talk to our medical school class, and have been delighted in following his progress ever since. His concern was that there have been obstacles, regulatory and legislative obstacles, that have appeared. They were not originally put down as obstacles. They were put down in good faith. But they have become—they have grown into obstacles that have actually prevented some of the things that we are all here trying to accomplish.

My concern, as a naive member of the public perhaps, is that I don't want to see obstacles that are the result of a zealousness, which I appreciate, that may in some way actually impede our progress towards optimum transplantation efforts and its availability to everyone in this country, from kidneys to bone to cornea to skin.

Mr. GORE. Is it fair to say that with bone transplantation there is less of a time element?

Dr. FRIEDLAENDER. Absolutely.

Mr. GORE. Less of a sense of urgency than with heart, liver, and kidneys?

Dr. FRIEDLAENDER. If you can translate a difference in the sense you have urgency from collection at the time of the last heartbeat with kidneys to within approximately 12-24 hours for bone, if 24 hours makes a difference between urgency or not, I would accept that point.

Mr. GORE. I guess I am still not quite clear on what your view of the legislation is. I hate to be obtuse about it, if I appear to be.

Are you supporting or opposing it?

Dr. FRIEDLAENDER. I am firmly in support of moving ahead with a program that comprehensively addresses the issues we have been talking about today. Now, in some regards—and I have to put my ACT hat back on, and I would also like to take minimal credit for the acronym "ACT"—it does reflect the way I feel about it—I do think we are in a position to move ahead rapidly.

What I am having trouble with also is grasping why a Congressmen such as yourself, with an intense interest, is opposed to bringing together the best parts of the system we have today and trying to enhance it and move it forward. The same problem you are having, understanding where I am having trouble embracing your particular position.

Mr. GORE. I am not opposed to your council. I support your council. We brought together the leading experts in the country in our hearings last spring. We have reviewed the available studies and we have acted upon those studies. Instead of continuing to study them, we are proposing to move. So I support you. I support your actions. I think the council is fine.

I think it is woefully inadequate because I don't think it is going to accomplish the goals that need to be reached.

Dr. FRIEDLAENDER. I am disturbed that you find it inadequate in the sense that we are both talking about using the identical, same building blocks in our respective approaches. The expertise that you are talking about and I am talking about is identical. The same people are going to accomplish the goals we have set out for ourselves whether they do so within one framework or the other. What we are trying to decide is which framework we should use.

Mr. GORE. Very quickly, to give you a specific example, the system cannot be expanded to encompass other organs without legislation. We have——

Dr. FRIEDLAENDER. Your legislation cannot. Working within the private sector, all we have to do as a group is identify the need and include it.

Mr. GORE. But medicare is not going to do it.

Dr. FRIEDLAENDER. I think that is a shortcoming of the legislation. It is not comprehensive in providing a funding solution——

Mr. GORE. For the nonrenal organs?

Dr. FRIEDLAENDER. For all transplantation.

Mr. GORE. Yes.

Dr. FRIEDLAENDER. Through the medicare system?

I am not aware—perhaps I am bound down in an inability to understand the legalese, but I did not get the impression that H.R. 4080 would pay for everything from donor education, identification

and acquisition to transplantation. I have been waiting by my telephone since I came here in April for a call to initiate a meaningful dialog. I suspect, have hoped, and think that the resolution of this process is really rather simple and straightforward and only requires an open dialog and flexible attention.

Mr. GORE. I hope so.

Just to pin down the one final question as to whether you would support or oppose——

Mr. WAXMAN. Mr. Gore, I am going to interrupt you. I think you have asked that question. We have the kind of answer we are going to get. I think the next thing is for you to talk and see if you can get together on a piece of legislation, if that is possible.

Also, for the record, I asked the panel members whether they thought we ought to adopt legislation. I did not ask them specifically this bill, although I think most of them were in favor of this bill. And every single one said that he or she was in favor of passing legislation. That is inconsistent with the administration's testimony, where they thought we ought to pass no legislation and leave the American Council on Transplantation to continue to function and maybe come up with some recommendations down the road.

Do you think we ought to pass any legislation?

Dr. FRIEDLAENDER. I think that the Federal Government ought to initiate a very firm, clear statement. Now, whether that statement is a resolution or legislation, I cannot tell you at this moment which is most appropriate.

Mr. WAXMAN. Dr. Friedlaender, we appreciate your input. We want more of it. We are looking at legislation. We hope to pass this bill because we think there is a sense of urgency, and we ought to do something about the problem and not just wait for another study to be conducted.

Maybe there are other ways—obviously, there are other ways of making statements.

As we look at this legislation, to move it forward, we would like your input. We would like to hear what thoughts you have about specific sections and what changes ought to be made and how you think the policy objectives can best be carried out.

Mr. FRIEDLAENDER. I would be delighted. I really think we are all singing the same song.

Mr. WAXMAN. Very good. Thank you very much.

That concludes our business for today. The subcommittee stands adjourned.

[Whereupon, at 1:45 p.m., the subcommittee adjourned subject to the call of the Chair.]

[The following statements were received for the record:]

Statement of the Honorable Joe Skeen

Submitted to the

Subcommittee on Health and the Environment

Committee on Energy and Commerce

October 17, 1983

Mr. Chairman, there is a critical need in the United States for a national policy regulating organ transplants. To that end, I am pleased to join with you and Congressman Gore in sponsoring the National Organ Transplant Act of 1983, to address the problems associated with the growing demand for transplantable organs.

No where is the human drama surrounding science greater than it is for organ transplants. The fate of waiting organ recipients, hoping that somewhere in the United States someone with matched organ characteristics has had the vision and charity to provide for the donation of organs after death, is always a poignant story.

Improvements in surgical techniques and new anti-rejection drugs have helped over 5,000 people benefit from organ transplants in 1981. However, thousands of would-be recipients still died that year because they could not be matched with the organs necessary to save their lives. At the same time, thousands of donated organs go to waste each year because there is no nationwide system of matching organs to donors who need them. I believe it's time these needless tragedies end. It seems such a short time ago that I lost my sister Joyce to

glomerulo nephritis, an incurable kidney disease. It was actually 1962; she was 28 years old. There were no options then, despite the best intentions of the medical profession, there simply wasn't anything they could do. And I am learning now, only six months after my niece underwent successful kidney transplant surgery, how the recent breakthroughs in transplant technology can make a bright and hopeful new life from one burdened with debilitating medical treatments or death.

Mr. Chairman, I feel strongly that this is an issue whose time has come. This is a totally bipartisan issue that transcends politics, and I will urge my colleagues on the Committee on Science and Technology to cosponsor the bill. Because of this nation's technology, there is hope for thousands of Americans who once knew no hope. This legislation will see to it that no one who needs a transplant operation to continue to live will have to go without one.

TESTIMONY: HOUSE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

Samuel Gorovitz

Congessman Waxman and Members of the Subcommittee, I welcome the opportunity to discuss some of the problems associated with recent developments in transplant surgery. I take it that these facts, at least, are uncontroversial: that there has been a sharp, recent increase in our capacity to transfer living tissues of various kinds successfully from donors to recipients, that there is in consequence a large and growing shortage of transplantable materials, and that controversial economic, political, and moral issues swirl around our efforts to respond to this new situation.

How can we best meet the vital needs of patients who require transplant surgery, while respecting the various related interests and concerns which come into play? We are faced here with choices which, in the words of Richard Titmus, "lead us, if we are to understand these transactions in the context of any society, to the fundamentals of social and economic life." The question of how to close the gap between the demand for and the supply of transplantable organs is no less than the question of what sort of society we wish to advocate, endorse, and nurture.

The range of possible responses is great. We have heard proposals to presume consent on the part of prospective donors in the absence of clear evidence to the contrary, proposals to establish commercial markets in organs, and proposals to increase the efficiency of the present approaches to collection and distribution through devices ranging from tax incentives to public

education. I am not aware that anyone has yet proposed seriously that transplantable organs should be available without regard to the wishes of the person whose organs are at issue -- but at this point such a proposal would not surprise me.

The focus of this testimony is the question: what should the government do, promote, permit, or prohibit in respect to organ transplantation? Any response to that question must rely on a broader conception of the proper role of government generally. So I want to be clear at the outset about some of my convictions in that respect.

It is not the responsibility of the government to be the solution of first resort to the problems of contemporary society; rather, the private sector is our best hope for meeting a broad range of needs. The government has a responsibility to step in only where it must, to safeguard the public interest. Further, the government should exercise great caution in enacting prohibitions on behavior. Only where it can bear the burden of sustaining a persuasive argument may it properly constrain the behavior of citizens; it has no business prohibiting actions merely because they are offensive to the sensibilities of a portion of the citizenry, or because they could conceivably lead to abuses of other more serious sorts in the future. Nor may it require actions simply because they would be in the public interest. Requiring actions (such as the payment of taxes or participation in national defense in wartime) or prohibiting actions (such as violation of the civil liberties of citizens) requires strong justification indeed.

It is for this reason that I argued, in testimony last year before the Subcommittee on Investigations and Oversight, that the appropriate role for the government in respect to the shortage of organs is a catalytic role rather than a coercive one. To require the donation of cadaver organs would be to ride roughshod over the rights of individuals to exercize discretion over the disposition of their bodily parts. Even to presume consent in the absence of dissent would be to place the burden where it does not belong. Those who prefer not to donate organs, for reasons of religion, superstition, or squeamishness, or for no reason at all, would be cast into a defensive position in which they might feel hard pressed to protect themselves and their families against intrusions of a most intimate sort.

Yet the problem remains and grows, so something must be done. An ideal solution would lie in a massive shift in national sentiment about transplantation -- a shift that would greatly increase the number of participants in donation plans, and would also greatly diminish the barriers, psychological and economic, to participation by the medical profession in efficient patterns of collection and distribution of organs.

Ideal solutions are always elusive, and it is necessary to ask whether it is possible even to approximate to them to a significant extent. With respect to organ transplantation, we do not yet know the answer to that question. The large shortage of organs is too recent, and our current modes of response to that shortage are too unsystematic, for us to have a good basis for knowing what we can yet achieve in the way of an enlightened collective response.

It is time now to put that question to the test. The newly created American Council on Transplantation may become an effective instrument for rationalizing our methods of collecting and distributing organs and of increasing public participation in donation plans -- but that will require it to have significant financial and institutional backing, a firm and energetic resolve to meet its objectives, and a fair bit of good luck. Its prospects of success will be greatly enhanced by the passage of HR4080, which, without being coercive or intrusive, fosters a major increase in our structural capacity to strive effectively for an adequate solution based on a voluntary and altrustic response to the plight of potential transplant recipients. This bill aims to ameliorate what Renee Fox and David Willis have called "our overriding individualism" by facilitating our "connectedness" with one another in response to vital needs.

It is crucial that such an approach be given every reasonable chance of success, for the alternatives are grim indeed. The demand for transplantation will continue to increase, as will the variety of transplantable tissues. Today, we focus mainly on kidneys, corneas, and livers, knowing that other organs, such as lungs and hearts, are also transplantable. But skin, bone, and muscle are transplantable, too, and recent successes in the reattachment of digits and limbs suggest that it is entirely reasonable to anticipate transplantation of such parts in response to major trauma. It would be naive not to realize that we are just now at the beginning of the problems associated with our newly developed capacities of medical and surgical intervention.

And what are those grim alternatives? One of the worst would be a governmental take-over of the whole domain, responding to national shortages with national systems of allocation in accordance with national criteria, supported by mandatory and intrusive processes of collection. The disadvantages of such a scheme, I trust, need no elaboration here. Another alternative to the present shortage is to allow a commercial market to flourish, linking supply and demand through the mechanisms of free-enterprise. The disadvantages of <u>that</u> scheme do require some elaboration.

Already, H. Barry Jacobs of Virginia has established a business for the commercial brokering of kidneys. As you doubtless know, he proposes to buy kidneys from persons, largely in the third world, for whatever price he needs to pay to induce them to make the sale, and then to sell the kidneys to affluent Americans who need transplantable organs and are in a position to meet the costs. The brokerage fees will make the enterprise, in Jacobs' own words, "a very lucrative business."

A frequent initial reaction to this scheme is that it is morally repugnant. But so might an appendectomy be to someone who is naive about the reasons for and benefits of abdominal surgery. Is the distaste engendered by the scheme not also a result of a shallow reaction prompted by an unfamiliar solution to a new but vital problem? That, at least, is what Jacobs would have us believe. We had best consider the merits of his case. For it is not simply a question of the economic ambitions of one ex-practitioner from Virginia; it is a question of

determining important features of the distribution of vital resources for the challenging years to come.

People beset by extreme poverty, malnutrition, and ignorance live in desperate circumstances. So, too, do those with end-stage renal failure. As Jacobs points out, his plan will deliver kidneys to people who need them, and cash to people who need it, quite possibly to the mutual benefit of both. And with the traditionally admirable flexibility of the free-market system, the scheme can be fully functioning in short order, long before the catalytic efforts of the government or the American Council on Transplantation can take effect.

But many assumptions in the Jacobs scheme are open to challenge. The risks to donors are greater than he has admitted, for example. And the scheme makes a mockery of informed consent, as is evident to anyone familiar with Federal regulations protecting human research subjects, which reflect a sensitive awareness that desperate circumstances can be implicitly coercive, and that the provision of excessive inducements to the oppressed can constitute a violation of their autonomy. And there are problems of quality control that might be insuperable.

We miss the most fundamentally important issues, however, if we focus our attention on such weaknesses in the proposal that there be a commercial market in kidneys. There are very much larger matters at stake.

There are various standards for judging the greatness of a society. One measure is by the peaks of its achievements in the arts and culture, or in technology. Another measure is the average material standard of living of its people. A third

criterion is that of the scope of its territorial authority. And so on.

I have always thought that one appropriate standard for judging the greatness of a society is that of how it treats those whom it treats least well. The analogue at the level of the family is compelling, at least. No matter how we admired the talented, affluent, accomplished family next door, our judgment of them would plummet if we discovered that they had one family member whom they abused, whose interests they ignored, whose needs left them unmoved, and whom they exploited to their own maximum advantage. Such a discovery would provide us with important information about their character and integrity -- about their sense of connectedness to one another and their sense of justice within a social structure. Judged by the analogous criterion, American society does not yet live up to its loftiest ideals.

Another criterion for judging the greatness of a society is the way it treats its most seriously disadvantaged. (This criterion is related to, but is not the same as, the previous one.) People in grinding poverty, and those beset by life-threatening illness, are surely in highly disadvantaged circumstances. What societal response do we wish to endorse for responding to their plight?

A free-market model is based on the values of competition, individual initiative, and the elasticity of supply and demand in response to market forces. But medical need is no respector of success in the world of commerce. The poor are more likely, not

less likely, to be seriously ill, and their ability to obtain medical care is seriously compromised by their poverty. To distribute vital resources according to abilty to pay is to set aside all concern for medical need as the primary determinant of access. It is to set aside considerations of compassion and cooperation, and abandon the effort to fashion a society in which mutual supportiveness is our response to desperation. It is to sanction the expansion of unfettered commercialism into dimensions of life which could just possibly provide us the opportunity to achieve a greater sense of community and of national purpose than we have previously known, except in the face of external threat. It is to ask far too little of ourselves.

The argument for a commercial market in kidneys might have greater force had we put ourselves to the test, and failed. But we are just now acknowledging a new national need, and HR4080 seeks to fashion a constructive response to that need. It is far too soon to judge that response a failure; it is too soon even to decide, as we may be able to decide a year from now, whether that response has been able to match the sizzling pace of new medical developments.

The only barrier to the commercialization of life in the manner proposed by Jacobs is a new legislative prohibition. No present law prohibits the scheme. I urge you to support that prohibition for many reasons, and I do so as one reluctant to endorse any unnecessary restriction on individual liberty. Such a prohibition, however, is necessary to put to the test our capacity as a nation to meet the present shortage, and to fashion ways to deal with future shortages, with a due regard for the

dictates of equality and social justice. The credo of the French revolution -- liberty, equality, and fraternity -- can remind us at times like this that we are well advised to temper our passionate and worthy defense of liberty with a due consideration of the social context without which our liberty would be a tragically empty achievement.

An additional reason for supporting the prohibition derives from the symbolic significance of the proposed market in organs. At a time when we urgently need to nurture good relations with the nations of the third world, our international credibility would be dealt a severe blow by our tolerance of a plan according to which the poor in underdeveloped countries were exploited as a source of spare parts for rich Americans. Our antagonists behind the iron curtain would love such a public relations windfall -- and they would be right.

Nor should we be swayed by the claim that commercial markets in live organs will develop elsewhere no matter what we do, and that wealthy Americans will be the recipients in any case. Whether or not that is so remains to be seen, but has no bearing on the fact that we must act rightly as we can best judge the right. If we want the world to be inspired and informed by our example as a humane and just society, we must be prepared to provide that example.

I am concerned, of course, with what such markets would do to those whose destitution and desperation might move them to sell bodily parts in the hope of gaining a foothold for the climb out of poverty. But I am concerned even more about what such

behavior would do to the rest of us, and what it would reveal about our compassion, our commitment to equality, our willingness to face common problems with collective resolve, our capacity to make voluntary efforts in the public interest, and more.

That the poor are exploited is unarguable. That their poverty seems intractible is a continuing tragedy of our unprecedentedly affluent society. I hope that history will be able to judge us as a society that never abandoned its struggle to eliminate that poverty, that strove ever to enhance and enrich its respect for individuals and for their capacity for mutual aid, and that faced the problems of an awesome new technology with humanity and efficiency both, rather than as merely another commercial opportunity. I believe there is a legitimate public interest in bringing this about, and it is in that interest that I urge your support of HR4080 in its entirety.

NATIONAL ORGAN TRANSPLANT ACT

MONDAY, OCTOBER 31, 1983

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Los Angeles, Calif.

The subcommittee met, pursuant to notice, at 12 noon, in Seton Hall Auditorium, St. Vincent Medical Center, 2131 West Third Street, Los Angeles, Calif., Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the Subcommittee on Health and the Environment will now come to order.

I would like to welcome our guests to this hearing on behalf of the Health and the Environment Subcommittee of the Energy and Commerce Committee of the House of Representatives.

Today the subcommittee has convened to receive testimony on H.R. 4080, the National Organ Transplant Act. The legislation proposes to establish a nationwide system for matching donated organs with waiting recipients. It also provides the framework and necessary incentives for increasing the supply of organs available for transplant.

It will do so without relying on the sale of human organs as some have suggested. In fact, the bill explicitly prohibits organ sales and imposes strict criminal penalties on those who would promote such practices.

The donation and transplantation of human organs is an emotional issue. When living donors are involved, as is common with kidney transplants, the gift of life is motivated by love, not profit.

In recent months, proposals have been made to encourage otherwise healthy individuals to sell one of their kidneys in exchange for payments ranging from $6,000 to $50,000. It would be tragic if these commercial ventures are allowed to proceed. Our efforts to promote voluntary organ donations would collapse. Health risks of transplant patients would greatly increase. Human organs should not be treated like fenders in an auto junkyard.

Since the subcommittee began its investigation of this subject, I have read letters from many individuals interested in selling their kidneys. While the reasons vary, the following excerpts are typical.

From Gatlinburg, Tenn., a man wrote:

> I am seriously interested in selling one of my kidneys. I have a large family and inflation hit us hard. I don't make enough money at my present job to support us, so I need the money to go back to school to learn a new trade.
>
> I am a poor family man with a wife and three children to support. By the time I'm through trying to catch up on past-due bills, I haven't any money left for grocer-

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ies. I can't afford any kind of medical insurance to use to take my kids to the doctor when they are ill. My wife has been ill and her health is getting worse. What hospital would treat her and take her in without insurance?

And the writer goes on to oppose this legislation because it would, in his words, "take away the only thing we have left."

A woman wrote, "I have a daughter age 13 and she has a spinal condition. I feel the only way I can get funds for further medical treatment is by offering my organs for sale."

We also have on file serious offers from individuals anxious to buy an organ. One woman wrote, "My mother is in need of a kidney. We will pay whatever is necessary."

Surely this Nation can develop an effective and equitable system of organ donation which does not rely on greed, desperation, or poverty as its motivation.

Kidney donations by the living are not risk-free. The risks are significant. The risks increase when the motivation for donation is other than love. Economically and medically, the sale of human organs is a bad investment. Ethically the specter of individuals coerced to sell their kidneys, to place their lives and their families in jeopardy represents one of the cruelest forms of human exploitation.

The notion that when one kidney is removed the other takes over is medically dangerous. A person with one kidney does not have full kidney functions. No one knows for sure what risks of disease or shortened life are incurred by people who take the gamble of giving up so vital an organ as a kidney.

Two or 3 years ago, we did not hear much about transplants. Yet dramatic advances have been made. The use of the drug Cyclosporin A has improved the efficacy of kidney transplants, lengthened the life expectation of heart transplant patients, and elevated liver transplant operations beyond clinical experimentation.

Today, the transplantation of human organs represents nothing short of a scientific miracle. It promises to revolutionize medical practice and human existence.

Transplantation is a matter of intense public interest and concern. If we site a single responsible factor it is probably our introduction to young Jamie Fiske. Her efforts to survive in a medical system which was insensitive or incapable of responding to her needs became a concern for even the President of the United States, and likely for every person here today.

Last July, the President took to the airwaves and issued a plea to find a liver donor for another child. He pledged the full resources of the Federal Government on her behalf. Medicaid would pay the medical costs. An Air Force jet would stand ready to help with transportation.

It was a dramatic response to an urgent situation. It was also a public recognition that the miracle of transplantation has expanded faster than our health care delivery system's ability to deal with it.

Without improvements in the planning and financing of transplant operations, they may become a medical option available only to the rich or those clever enough to achieve media celebrity.

Each year hundreds of donated organs, kidneys, livers, and hearts, are discarded or exported overseas. It occurs despite the

tireless efforts of those involved in organ procurement nationwide. Despite an estimated 20,000 potential donors, fewer than 15 percent are able to give the gift of life. We must develop a national system which will translate the compassion of the American people into life saving transplant operations.

We know that three out of four Americans would donate if given the chance. Thousands of patients are waiting for the call that a donor organ has become available for them. For as many as 50 percent of these patients, this call will never come. Many on waiting lists will die before an organ becomes available.

Our task today is motivated by a sense of urgency. All across the United States, dedicated people are working in the field of organ procurement and transplantation. Right here in southern California, the Regional Organ Procurement Agency does an outstanding job of bringing together organ donors, recipients and top-notch medical talent.

Yet it is under-staffed and could, with additional resources, significantly increase the number of organs available for transplantation. This agency depends upon a system based on voluntary donations. It will be destroyed if the miracle of organ transplantation becomes just another vehicle for making money.

Our testimony this afternoon will be helpful in guiding the subcommittee's actions on this legislation, and we are looking forward to hearing from the witnesses that are here with us today.

Our first witnesses have been asked to discuss the medical and ethical issues involved in organ transplantation. Today the number of patients in need of transplants exceeds the number of organs available for transplantation. As we gain greater experience with the transplantation of livers, hearts, and other vital organs, the gap between donors and recipients may widen.

Some have suggested that the problem rests with our reliance upon a voluntary organ donation system. They argue that by providing financial incentives to prospective donors or their families, the number of organs available for transplantation will increase.

We were scheduled to have with us Clifford Laughton from Honolulu, Hawaii, who is a founder of the International Society for Vital Organ Replacement, and unfortunately, at the last minute, he contacted us and said he was unable to be here.

But we do have the other members of the panel: Robert Ettenger, a physician at UCLA and President of the American Society of Transplant Physicians; and Bernard Towers, president of Anatomy, Pediatrics and Psychiatry at UCLA, and codirector of their program in medicine, law and human values.

I would like to ask each of them to come forward and take seats at this table.

We are pleased you could be with us. This is an unusual setting for a congressional hearing, but the testimony you will be giving today will become part of the record. It will be made part of the total record on this legislation and will be shared with the members of the subcommittee as we work on this legislation.

Dr. Towers, why don't we start with you?

STATEMENTS OF BERNARD TOWERS, M.D., Ch.B., PROFESSOR OF ANATOMY, PEDIATRICS AND PSYCHIATRY, AND CODIRECTOR, UCLA PROGRAM IN MEDICINE, LAW AND HUMAN VALUES; AND ROBERT B. ETTENGER, M.D., PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT PHYSICIANS

Dr. TOWERS. Thank you, Mr. Waxman, and I am very glad to have the opportunity of expressing appreciation of this very important bill, the aim of which is to promote availability of organs and tissues for transplantation to the bodies of sick people who need them.

I welcome these proposals to utilize to the maximum the technical facilities which our inventiveness has created for saving life and alleviating suffering.

The question of buying and selling organs, and I was asked to address my remarks to title III primarily, this question dates back 150 years to the time in Great Britain when there was a heavy trade in dead bodies by body snatchers, grave diggers who would exhume bodies and sell them to medical schools for scientific purposes.

It led, in time, to a couple in Edinburgh in the 1820's, who took to murdering people in order to get an increased supply of such dead bodies which they supplied to the anatomy schools in Edinburgh. Burke was hanged in Edinburgh in 1829, and it was that that led to the British Anatomy Act in 1832, which forbade the sale of bodies, but which did allow for reasonable costs associated with the removal, storage, and transplantation of human corpses.

We at UCLA, in our Department of Anatomy, have had a very successful willed body program for over a quarter of a century.

Now, the relevance of this history about the sale of cadavers to our modern dilemma of inadequate supplies of both cadaveric and living bodily organs is shown by that very successful recent novel written by a Harvard M.D., Dr. Robin Cook, called Coma. It was made into a film subsequently. In that novel, in that film, entrepreneurs a good more sophisticated than Burke and Hare, used an identical ethic in order to move from situations of accidental death to those of contrived murder in order to meet the market's demand.

I am not suggesting that the aim of title III is to prevent murder, although it may well do so in due course.

The most famous contribution to the question of the ethics of buying and selling human tissue is by Richard Titmuss, the sociologist, in a book called The Gift Relationship: From Human Blood to Social Policy. Of all human tissues, blood is the one that a donor replaces most easily and quickly, and yet Titmuss mounted powerful arguments against the collection of blood for sale.

In 1977, the controversy between the American Red Cross and the American Association of Blood Banks was building, the Red Cross going for volunteer donors for blood, the Association of Blood Banks going for purchase of blood. I organized and moderated a panel discussion in the series which we call The Medicine and Society Forum at UCLA, and the title of the discussion was "Blood for Transfusion: To Give or to Trade?" This is the question that you

are dealing with today with other human tissues and organs: Should they be given or should they be traded?

The societal benefits of restricting or prohibiting—and California now prohibits the sale of human blood—the benefits and disbenefits of buying and selling blood were clearly shown. We remember very clearly in downtown Los Angeles those terrible days when the indigent and poor would go and sell their life blood for the sake of yet another bottle of liquor or whatever else it was that they needed or thought they needed to continue with their life.

Now, there are utilitarian arguments against the purchase of blood, against the purchase of bodily organs. If there are such sales, then the chances of transmission of disease is much increased. But I do not think that utilitarian arguments ought to be the basis of the legislation. I think there are much more powerful deontological arguments, rule-based arguments, about what it is to be a human being and what it is to have been a member of society and to have died.

I think that if it should become the case that organs of dead people or organs of living people should be offered for buying and selling, then I think this would represent a major degradation for humankind.

It will be objected that if financial recompense is not offered, the supply of donor organs will continue to be inadequate. I do not believe this. As you have already said, Mr. Chairman, it is the case that there are many, many people prepared to offer as a gift relationship, as Titmuss put it, as part of that bonding relationship between members of the human species, to offer their tissues or their organs to other members who need them more than they do, and I am thinking here particularly of the kidney.

We need to educate the public about the remarkable social benefits that flow from the gift relationship, and I see that your bill does contain in section 374(a)(2) the seeds of a really major educational project to educate the society. This American society is as generous as any society has ever been when the need is pointed out to them, and I think that a major part of the funding that will be appropriated for this bill should go into those educational purposes.

Finally, I hope that the wording in the title III of the section 301(c)(3) does not imply that human organs or tissues may be bought and sold with impunity within any one State. It refers to cross-State boundaries. I hope that any such buying and selling of organs and tissues will constitute a Federal offense.

Thank you, Mr. Chairman.

[Dr. Towers' prepared statement follows:]

To: The Chairman and Members of the Subcommittee on Health and the Environment, re. Title III of HR 4080, Prohibition of Organ Purchases. Testimony of Bernard Towers, M.B., Ch.B., Professor of Anatomy, Pediatrics and Psychiatry, and Co-Director, The Program in Medicine, Law and Human Values, University of California at Los Angeles.

I am glad to have this opportunity to express my appreciation of this very important (even "essential") section of a wise, far-reaching and very necessary Bill, the aim of which is to promote the availability of human organs and tissues for transplantation into the bodies of those sick people who need them. I welcome these proposals to utilize to the maximum the technical facilities which human inventiveness has created for the saving of life and the alleviation of suffering.

Modern legislation concerning the use of human cadavers for medical purposes goes back to the British Anatomy Act of 1832. This Act of Parliament was a direct outcome of the successful prosecution and conviction on charges of murder of the infamous couple Burke and Hare who, having discovered that it was profitable to supply fresh corpses to the Anatomy Schools in Edinburgh, went the further step of ensuring an adequate supply by murdering a series of victims. The Act prohibited the sale of bodies, but made it possible for licensed Schools to acquire them by assuming "the reasonable costs associated with the removal, storage and transportation" of human corpses (to use the language of Title III, SEC. 301 (c) (2)). Similar legislation exists in California, and we at the UCLA School of Medicine have had a very successful "Willed Body Program" for a quarter of a century.

The relevance of this history about cadavers to the modern dilemma of inadequate supplies of both cadaveric and living bodily organs is shown by the recent novel (and film) Coma, by Robin Cook, M.D., wherein entrepreneurs much more sophisticated than Burke and Hare have used an identical ethic to move from situations of accidental death to contrived murder in order to meet the market's demand for human organs and tissues in a free economy where every organ had its price.

I am not suggesting that the major aim of Title III is to prevent murder, though it might indeed accomplish that. The moral argument in its favor should, in my opinion, be couched much more positively than that.

The most famous contribution to the question of buying and selling human tissue is that by the sociologist, Richard M. Titmus, The Gift Relationship: From Human Blood to Social Policy (New York: Pantheon Books, 1971). Of all human tissues, blood is the one that a donor replaces most easily and quickly. And yet Titmus mounts powerful arguments against its collection for sale. In 1977, when the controversy between the American Red Cross and the American Association of Blood Banks was building, I organized and moderated a panel discussion, in the series entitled "UCLA Medicine and Society Forum," under the heading Blood for Transfusion: To Give or to Trade? The societal benefits of restricting or prohibiting (as California, in fact, now does) the buying and selling of blood for transfusion were clearly shown on both utilitarian and deontological principles of what constitutes "the common good." I hope that the phrase "any other human organ or tissue" in Title III, SEC. 301 (c) (1) implies blood as well as the other tissues specifically mentioned.

Utilitarian arguments against the purchase and sale for profit of human organs and tissues include the increase of risks of transmission of disease and, at a deeper level, the eminent social dangers of exploitation of poor, sick people who might be persuaded (by themselves or others) to further impoverish their lives for the sake of some immediate and transitory benefit. One remembers only too well those commercial blood-banks in downtown Los Angeles whose clients would gladly sell their life-blood in exchange for the price of yet another bottle of liquor.

Deontological arguments against "organs for sale" include moral precepts such as respect for persons. It is offensive to make a person's body into a "thing" for purposes of gain, even if the gain appears to be mutual. Though a person may always give freely of himself/herself, that very powerful bond that is developed in a true "gift relationship" is destroyed or aborted when the transaction (in something so intimate as parts of one's own body) becomes contaminated by the exigencies of trade.

It will be objected that if adequate financial recompense is not offered for living organs and tissues the supply of donor organs will continue to be inadequate. I do not believe this, and I notice that HR 4080 does contain (Title I, SEC. 374 (a) (2))

the seeds of an appropriate resolution of the problem, where it is stated that "The National Center shall conduct a program of public information to inform the public of the need for organ donations." The American public, if properly approached, is the most responsive and most generous public that one has ever known. What I advise is that the bland phraseology of SEC. 374 (a) (2) be reworded to convey the sense of dramatic need in these areas of concern. We need to educate the public about the remarkable social benefits that flow from The Gift Relationship, as spelled out by Titmus. The human species is currently involved in a major paradigmatic shift in social conscious-awareness, away from the rapacious ethic of nineteenth-century "Social Darwinism" into an ethic of caring for our small "Space-Ship Earth" and everyone who is on it or in it.

The Congress of the United States could effect a great advance in this increasing sense of social awareness and social consciousness if HR 4080 insisted more forcefully than does the present draft, on the urgent need for truly effective education of the public about the life-saving techniques that we now have available, provided only that there are enough donors of human organs and tissues to make full use of the skills now available. Top priority should be given to adequate funding of such an educational program.

One final comment on Title III: I hope that the language of SEC. 301 (c) (3) does not imply that human organs or tissues may be bought and sold with impunity within State boundaries. I would hope that any such activities would constitute a Federal offense.

Mr. WAXMAN. Thank you very much, Dr. Towers.
Dr. Ettenger.

STATEMENT OF ROBERT B. ETTENGER, M.D.

Dr. ETTENGER. Thank you.

On behalf of the officers and executive council of the American Society of Transplant Physicians, I wish to thank you for this opportunity to give our feelings about this.

Mr. Chairman, the art and science of transplantation have progressed dramatically in the last 10 years. Advances in tissue typing, surgical techniques, immuno-suppressive drugs and pre- and post-transplant patient care have allowed success rates in organ transplantation which continue to improve.

This improvement has had the impact of focusing professional and public attention on the field of organ transplantation, in general, and specifically on the supply of donor organs.

Today the supply of cadaveric organs is clearly inadequate to meet the demands of a rapidly improving transplantation technology. For some patients, death may well intervene before a suitable cadaveric donor can be found. It is estimated that only 10 percent or less of all suitable cadaver organs are made available for transplantation.

In an effort to meet this need, a number of new plans and ideas have been put forward. One plan which has received a great deal of publicity and attention proposes allowing unrelated individuals to donate their organs, in this case, one of their kidneys, for a free-marked determined price. The argument is made that with the new advances in immunosuppressive drugs, and in particular with the upcoming availability of Cyclosporine, the success of unrelated transplants warrants the retrieval of kidneys from living donors to relieve the scarcity of cadaver organs.

However, in view of many physicians engaged in transplantation, this free-market sale of an individual's organs is morally offensive and ethically indefensible. It is immoral to offer incentives to undergo permanent physical damage.

The opportunities for coercion of the poor to yield a perfectly matched organ is at once heart-rending and frightening. Many centers have grappled with the ethical considerations implicit in living-related donation, and have come to accept it only because of the high motivation of the donor and the improved success of the recipient.

Neither of these is the case with a purchased kidney from a living, unrelated donor. There is no data to suggest that kidneys taken from living, unrelated donors will function any better, any more quickly or any longer than those from cadaveric grafts.

Even with Cyclosporine and other new immunosuppressives, the success of a kidney transplant is by no means assured, with post-operative complications and side effects being the usual course of events rather than the exception.

It is impossible for physicians to ethically justify removal of kidneys from living, unrelated human beings when we are utilizing only a small fraction of the available cadaveric organs. Efforts must be directed toward procedures which will bring home to every

individual the need and mechanism for allowing themselves or their loved ones to become organ donors.

Much of the responsibility for this lies with the medical community. Reluctance to broach the subject of organ donation with next-of-kin at the time of death has been one major impediment to adequate donor retrieval. A number of legislative steps could be envisioned which would improve the situation immensely.

One alternative would be that we in the United States could adopt an anatomical gift act, similar to that one operative in France. There every individual is regarded positively as an organ donor at the time of death unless they or their next-of-kin have indicated otherwise. Such an approach, rather than being a coercion, allows medical personnel to freely and easily approach the next-of-kin about organ donation at the appropriate time without any fear of litigation, either real or, more likely, imagined.

But whatever mechanism is chosen to improve retrieval of cadaveric organs, a success in this endeavor is clearly preferable to a free-market sale of kidneys from the living. The free-market sale concept has been put forward only because medical, governmental and lay communities alike have failed to provide adequate mechanisms to procure cadaver donors and keep pace with improving transplantation technology.

The best answer to the ethically distasteful free-market sale concept is the institution of appropriate policies to assure an adequate supply of cadaver donor organs. The officers and the Executive Council of the ASTP, representing over 500 doctors directly concerned with organ transplantation on a daily basis, very much support the general concept and outline of the National Organ Transplant Act. It clearly addresses many of the problems confronting this area of medicine today.

We wholly and enthusiastically support titles II and III.

In connection with the problem I discussed of organ retrieval, we are pleased that title II exempts organ procurement activities from the medicare DRG prospective cost limits, since these could discourage hospitals from actively pursuing donation of organs.

We support, as well, the medicare and medicaid coverage of organ transplants at specified centers, and absolutely concur with title III, the prohibition of sale of human organs.

We support the general concept and outline of Title I with its national center for organ transplantation and its advisory counsel.

The ASTP will be more than ready to participate in any and all appropriate ways.

With regard to the U.S. transplantation network we are very supportive of the concept. Nationwide sharing of organs may be the only way for an increasing proportion of our patients to ever receive a kidney transplant. However, we would like to suggest that before such a network is formally initiated a study panel of transplantation professionals be convened. This panel should include representatives from the various disciplines and organizations involved in transplantation.

Such a study committee needs to be convened to address the myriad of potential scientific problems which has hampered the formation of such networks in the past.

Mr. Chairman, I wish to thank you for this opportunity for letting us express our views.

[Dr. Ettenger's prepared statement follows:]

American Society of Transplant Physicians

AMERICAN SOCIETY OF TRANSPLANT PHYSICIANS

Secretary-Treasurer:
Lawrence G. Hunsicker, M.D.
Nephrology Division
University of Iowa
Medical College
Bldg. 3, Veterans Administration
Medical Center
Iowa City, IA 52240

October 7, 1983

To The Editor:

The art and science of transplantation have progressed dramatically in the last ten years. Advances in tissue typing, surgical techniques, immunosuppressive drugs and pre- and post- transplant patient care have allowed success rates in organ replacement which continue to improve. This improvement has had the impact of focusing professional and public attention on the field of organ transplantation in general and specifically on the supply of donor organs.

It appears clear that the supply of donor organs is presently insufficient to permit prompt transplantation for all those who need it. This shortage of organ donors sometimes translates to waiting times measured in years rather than months. Such waiting times are manifestly too long, particularly for patients awaiting liver, heart or heart-lung transplants. For these patients, death may well intervene before a suitable cadaveric donor can be found. Patients awaiting kidney transplantation are not under such severe time constraints, because of the availability of dialysis. Nevertheless, the relatively frequent requirement for a well-matched kidney and the paucity of donor organs often impose inordinate and heartbreaking delays until transplantation can be attempted.

At present there are two sources of donor organs available for transplantation: cadaver donors and family members, i.e. living related donors. The latter obviously can only be donors in a situation where the desired organ is paired , and the removal of one of the organs does not imply permanent disability or death for the donor. Even with kidney donation, however, there are small but real immediate risks of surgery and possible but unknown long-term consequences. As a result, living donation has in the past been restricted to those close relatives whose deep motivation prompts donation to a loved one despite these palpable risks. It has been considered medically ethical to do this because kidneys from living related donors have, by and large, a significantly decreased incidence of immunologic rejection.

Kidneys from dying individuals (termed "cadavers" in medical parlance) represent the major source of organs in most renal transplant programs. The graft and patient outcome in cadaver renal transplantation is not as good as that obtained with living-related transplants. Nevertheless, results with cadaveric kidneys are getting better because of the advances noted above.

Today the supply of cadaveric organs is clearly inadequate to meet the demands of a rapidly improving transplantation technology. It is estimated that only 10% or less of all suitable cadaver organs are made available for transplantation. In an effort to meet this need, a number of new plans and ideas have been

put forward. One plan which has received a great deal of publicity and attention proposes allowing unrelated individuals to donate their organs, in this case one of their kidneys, for a "free-market" determined price. The argument is made that with the new advances in immunosuppressive drugs, and in particular the upcoming availability of Cyclosporine, the success of unrelated transplants warrants the retrieval of kidneys from living donors to relieve the scarcity of cadaver organs. However, in the view of many physicians engaged in transplantation, this "free-market" sale of an individuals organs is morally offensive and ethically indefensible. It is immoral to offer incentive to undergo permanent physical damage. The opportunities for coercion of the poor to yield a "perfectly-matched" organ is at once heart-rending and frightening. Many centers have grappled with the ethical consideration implicit in living-related donation and have come to accept it only because of the high motivation of the donor and the improved success of the recipient. Neither of these is the case with a purchased kidney from a living-unrelated donor. There is no data to suggest that kidneys taken from living-unrelated donors will function any better, more quickly or longer than cadaveric grafts. Even with cyclosporine and other new immunosuppressives, the success of a kidney transplant is by no means assured, with post-operative complication and side effects being the usual course of events rather than as the exception.

It is impossible for physicians to ethically justify removal of kidneys from living unrelated human beings when we are utilizing only a small fraction of the available cadaveric organs. Efforts must be directed towards procedures which will bring home to every individual the need and mechanism for allowing themselves or loved ones to become organ donors. Much of the responsibility for this lies with the medical community. Reluctance to broach the subject of organ donation with next-of-kin at the time of death has been a major impediment to adequate organ retrieval. A number of legislative steps can be envisioned which would improve this situation. For example, specific wording could be adopted which would guarantee immunity from legal liability for the purpose of approaching family members to discuss organ donations. Alternatively, we in the United States could adopt an anatomical gift act similar to the one operative in France. There, every individual is regarded positively as an organ donor at the time of death unless they or their next-of-kin have indicated otherwise. Such an approach rather than being a coercion, allows medical personnel to freely and easily approach the next-of-kin about organ donation at the appropriate time without fear of litigation, either real or more likely, imagined.

Whatever mechanism is chosen to improve retrieval of cadaveric organs, a success in this endeavor is clearly preferable to a "free-market" sale of kidneys from the living. It may be argued that even today in the United States certain unrelated individuals, such as spouses, have become kidney donors. However, this has been carried out only in rigorously controlled scientific settings and only after an Institutional Review Board (IRB) of the hospital has approved it from a medical ethics standpoint. This is in no way comparable to the proposed "free-market" sale. The "free-market" sale concept has been put forward only because the medical, governmental and lay communities alike have failed to provide adequate mechanisms to procure cadaver donors and keep pace with improving transplantation technology. The best answer to the ethically-distastful "free-market" sale concept is the institution of appropriate policies to assure an adequate supply of cadaver donor organs.

Charles B. Carpenter, M.D.
Robert B. Ettenger, M.D.
Terry B. Strom, M.D.
American Society of Transplant Physicians

Mr. WAXMAN. Let me thank both of you for the testimony you have given.

Let me review some of the issues that have been raised in this whole question of organ procurement. Cyclosporine A is a new drug that is allowing organ transplants that were once very risky to be successful surgical procedures. We are talking about a whole new breakthrough now in the ability to transplant organs.

Are we finding that with this new technological breakthrough there is a growing gap between those who may want and need an organ transplant and the number of organs that will be available to them? Dr. Ettenger.

Dr. ETTENGER. I think that is probably very true. I think we should not yet overestimate the impact that Cyclosporine will have because, as I indicated in my testimony, it is frought with problems to learn how to use it correctly.

However, with that caveat, I think that as transplantation does open up, there is an enlarging group of patients that I alluded to, the so-called high antibody patients, those patients who are on dialysis with high levels of antibodies such that finding a compatible transplant becomes a more and more difficult situation, and as we get farther into transplantation and as we notice that these high antibody patients are more than likely those patients who have rejected a first kidney, we find that an increasing number of our patients on dialysis represent these high antibody patients that require a very, very good match. In that situation, even the regional, however active the region is, will often not find a compatible kidney for a number of years, and I think in that situation this speaks to the need of some very much more wide areas of sharing.

Mr. WAXMAN. So we need a broader area of procurement for organs because of the fineness of the match required for the increasing number of high antibody patients.

Doesn't that argue for us to do whatever is going to be necessary to obtain more organs so that people can have the possibility of an organ transplant?

Dr. ETTENGER. Absolutely. It goes without question. Unless we broaden the pool dramatically, then the waiting time for our patients on dialysis is just going to increase. I know that at our own center, the majority, the overwhelming majority, of children awaiting transplants represents these high antibody patients for whom we really need a very, very good match.

Mr. WAXMAN. Well, let me play devil's advocate. We had a Dr. Barry Jacobs testify in Washington. He is an individual who has suggested that he would like to be in the business of brokering kidneys. He thinks that he could pay $10,000 for a kidney and then turn around and sell it for maybe $20,000, and someone would receive $10,000 as an incentive to donate the kidney. He would make a little money on it as well, and there would be a larger pool of organs for transplantation.

Why don't we turn to that kind of buying and selling of organs in order to enlarge the pool so that there will be more organs available to those who need them?

Dr. ETTENGER. I think there are a number of reasons why we do not. No. 1 are the reasons that I alluded to, the ethical reasons, the

fact that we are only using less than 10 percent of cadaver organs right now.

No. 2, you think that patients will say, "I will take a kidney from anywhere." In talking with my patients and the parents of my patients, in fact, just talking last week with one boy who has been waiting 5 years for a kidney, they do not want it. They much more actively respond to the gift, the cadaver donation, et cetera, and not people coming to sell.

Mr. WAXMAN. Dr. Towers—oh, excuse me.

Dr. ETTENGER. And I think, No. 3, the situation is that if we abandon the voluntary organizations that we have and the volunteer gifts, the possibility that that will dry up because of the buying and selling may ultimately result in a reduction, an ultimate reduction, in the pool rather than in a further expansion in the pool.

Mr. WAXMAN. You think there could be a reduction in the pool because people will not be willing to voluntarily donate their organs because there is a business out there where organs can be bought and sold?

Dr. ETTENGER. I think there certainly is that worry.

Dr. TOWERS. As I recall in this morning's Los Angeles Times, there was a letter from somebody who said almost precisely that.

Mr. WAXMAN. That was an interesting letter to read. This person indicated he was willing to donate his organs, but then when he heard there may be money involved he wanted to do it only for money.

Dr. TOWERS. Or to opt out.

Mr. WAXMAN. Dr. Towers, you seem to reject the utilitarian arguments as the ethical basis for prohibiting organ sales.

Dr. TOWERS. No, I think that there can be powerful arguments raised on a utilitarian basis against the sale of kidneys because I think the dangers inherent for society generally are very considerable in the buying and selling of organs in terms of the possibility of increased spread of disease, just as with infected blood. For instance, there has been a good deal of evidence that disease has been spread as a result of people selling their blood who, in fact, did not declare some of the diseases that they suffered from. That might be a possibility.

But I do not think that the utilitarian argument should be the binding argument. I think much stronger are the deontological arguments, that is, the rule-based arguments, which suggest that human beings are not, as you said in your opening statement, like cars, like automobiles, of which parts can be bought and sold. There is something inherently offensive to the human conscience, I think, about treating a fellow human being as a thing. We must treat fellow human beings as persons and not as things, and the buying and selling of parts of human beings makes them into things, and I think that is morally repulsive.

Now, I do think that there is a new ethic which is growing, an ethic of increased conscious-awareness of our unity as members of a single species, homo sapiens, on the face of the Earth. I think the advent of the space age, the time at which the first astronauts looked back on the Earth and said, "Now, we're coming home," meant not to Houston, Tex., or their apartment. They meant they

were coming to Earth, to our home, which has given us a whole new way of looking at the Earth and the need to conserve all of the environment of the Earth.

Now, part of the environment are our fellow human beings. The idea of the gift relationship, of giving something to a fellow human being, is something that cements that bonding, and I think is something to be promoted, by all means at our disposal.

The 19th century idea that success goes to the strongest and the most aggressive and the most warlike is clearly out of date now. It is old fashioned. We really must look to a new ethic of worldwide cooperation, and the possibility of donating an organ or donating tissues, donating blood to a fellow human being is something that I think, as Titmuss pointed out in his book, The Gift Relationship, is something that can bond us as a society very well together if only we are educated enough to do it.

Mr. WAXMAN. So both of you agree that we need to increase the pool of organs for transplant purposes, and we do not need utilitarian bases to appeal to people's greed; that there will be sufficient organs available if we appeal to people's humanity and willingness to try to save the life of another.

Dr. TOWERS. I would hope so, provided that we have a big enough educational campaign for it.

Mr. WAXMAN. What do we need to do by way of an education campaign? Obviously a hearing such as this will make more people aware of the fact that they may well, if they have an accident, be able to contribute an organ, and that they may want to think in advance about giving an organ for transplant purposes should circumstances like that occur.

But what else can we do?

Dr. ETTENGER. I think you will have people today who will be testifying who may be better able to speak to that, and I refer specifically to Dr. Terasaki, the head of the Regional Organ Procurement Agency here.

However, there are a couple of things that have been mentioned by some of the members of the ASTP around the country. One is to continue to realize that perhaps the best educational campaigns are those that are done locally. The New England Organ Bank, in the wake of the Jamie Fiske donation increased their donor pool 70 percent within weeks of the Jamie Fiske incident, and I think that this has been reflected around the country and has been repeated around the country.

One of the things that has come up repeatedly in talking with other members of our organization is the primacy of the local organ procurement agencies with regard to public education.

Second, as I alluded to, public education and medical education must go hand in hand. We must have a professional education system. We have a very active one here in southern California, but the physicians or the nurses or the social workers who first approach the potential organ donor need to be made to feel free that they can go and approach them without any fear of litigation or anything of that sort.

There are a number of ways that we might approach that, and I would hope that in future legislations that there be some mechanisms that are refined to allow that to happen.

Mr. WAXMAN. Well, let me thank both of you very much. I think the testimony you have given us is completely thought out, thoroughly knowledgeable, and very helpful to us as we look at the legislation and try to deal with this issue which has its emotional components, but also a very clear ethical component as well.

I think that people sometimes do not realize that charity benefits not only the recipient of the charity, but the one who gives, as well. In an ethical view, as we try to make humanity more human, we ought to realize that people can be appealed to and will respond on a humanitarian basis, and we need to move toward that as a basis for dealing with this new technology and the new opportunities it holds for us.

Thank you both very much.

Dr. ETTENGER. Thank you.

Dr. TOWERS. Thank you.

Mr. WAXMAN. Our next panel represents a virtual Who's Who in the field of organ transplantation. We have four of California's, if not the Nation's, most prominent and experienced authorities in this emerging area of medicine. Dr. Oscar Salvatierra is from the University of California at San Francisco and is an expert in kidney transplants involving living, related donors. He also serves as president of the American Society of Transplant Surgeons.

Dr. Paul Terasaki is believed by many to be the father of organ procurement in California. He is a noted researcher and serves as administrator of the Los Angeles Regional Organ Procurement Agency.

Dr. Robert Mendez is a kidney transplant surgeon here at St. Vincent's and has many years experience in this field, and I want to also ask Dr. Thomas Berne to join this panel.

Dr. Thomas Berne is a transplant surgeon and chief of the transplant unit at County USC Medical Center.

We are pleased to have each of you with us today, and we welcome you to the hearing. We will call on Dr. Salvatierra to lead off.

STATEMENTS OF OSCAR K. SALVATIERRA, M.D., PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS; PAUL I. TERASAKI, PH. D., PRESIDENT, THE TRANSPLANTATION SOCIETY; ROBERT MENDEZ, M.D., UROLOGICAL CONSULTANTS MEDICAL GROUP, INC.; AND THOMAS V. BERNE, M.D., CHIEF, RENAL TRANSPLANT UNIT, DEPARTMENT OF SURGERY, LOS ANGELES COUNTY USC MEDICAL CENTER

Dr. SALVATIERRA. Mr. Chairman, I am here today as president of the American Society of Transplant Surgeons, representing that society.

This society includes over 300 surgeons specializing in organ transplantation throughout the Nation, and the organs involved, all familiar to you, kidney, heart, heart/lung, liver and pancreas.

Our purpose today is to provide the subcommittee with our view and recommendations concerning H.R. 4080, recently introduced by you and Representative Gore. We have been especially gratified by the earnest attention to this subject by you, Mr. Waxman. In fact, Mr. Chairman, you have continued to assume a vital role in the ad-

vancement of accessibility to organ transplantation since your interventions while a member of the California State Senate.

H.R. 4080 represents a significant contribution to the resolution of a number of critical public health problems arising in the field of organ transplantation as it enters a new era of success. We have carefully reviewed the provisions of H.R. 4080, and we are in strong support of the bill.

There are some minor modifications which we have discussed with your staff and have presented in written prior testimony at the recent hearings in Washington on October 17.

I would now like to make some selected comments in reference to the bill.

Our society convened a workshop on organ procurement in May of this year with representatives of the National Neurosurgical and Trauma Society. This 2-day meeting reviewed a spectrum of problems relating to organ procurement. It strongly underscored the need to strengthen our regional procurement efforts, a position our society strongly supports, and whereby we also, therefore, support the provisions in section 101 of the bill.

We believe that regional organ procurement agencies should be evaluated in terms of their ability to assure, first, quality control in surgical organ procurement; second, quality control in organ preservation; and, third, equitable distribution of organs among patients and participating transplant centers.

In addition, the director of such an agency need not be full time, as this could effectively exclude the most administratively and clinically experienced individuals from this most important position.

Section 101 of the bill also includes provisions for the support of a private national entity to facilitate the distribution of organs among regions of the Nation and to maintain a registry of individuals needing organs. We are concerned that some donated organs are not used because a suitable recipient was not identified within the region, and this has been the case in California, as well as other States.

In addition, patients with high antibody levels will best find a suitable donor through a well-established, coordinated national effort.

Our society took a formal position at its 1983 meeting to help establish a single nationwide, computerized network that would incorporate placement of organs that could not be placed regionally, and to facilitate the identification of organs for potential recipients with high antibody levels, which is a major national problem.

While we believe much of the responsibility for strengthening and improving organ transplant programs lies in the private sector, we do believe there is a definite and proper role for the Federal Government. The Government can be a strong catalyst for some new initiatives, as well as a preserver of the strengths inherent in our present system.

We believe this bill strikes an appropriate balance.

An example of where the private sector and Government can work together is, for example, in maintaining a registry. We want to express our support for the provision of section 374, which directs the Secretary to establish a national registry for data con-

cerning organ transplant outcomes, and this would be for organ transplant outcomes of all organs, whether they be kidney, heart, heart/lung, liver or pancreas.

The American Society of Transplant Surgeons would be willing to join with the NIH and other interested parties in the re-establishment of a reliable data collection system as was previously maintained through the joint efforts of the American College of Surgeons and the NIH. Most importantly, this registry could provide valuable information to a transplant technology assessment program, which would evaluate emerging transplantation therapies, and that has been a major problem in recent years and, in fact, has led us to some of the difficulties that we are addressing today.

We are very optimistic at this time that our successes with organ transplantation in the heart and liver areas, at relatively few centers, can be expanded to more centers.

Your proposed new authority to gradually, on a targeted basis, expand medicare and medicaid coverage of transplantation procedures without new eligibility entitlement is well founded, and we support the provisions in title II of this bill. I have been implored to speak in strong support of this provision by the chairman of our own Cardiac Transplantation Committee of the American Society of Transplant Surgeons, by all members of the Stanford Cardiac Transplantation Group, and by members of the two principal institutions performing liver tranplantation, the University of Minnesota and the University of Pittsburgh.

We perceive this provision to be completely different from the end stage renal disease entitlement legislation and without the risk of excessive costs that would be inherent by such an entitlement program.

In addition, and most importantly, private insurance carriers look to medicare for standards of reimbursement and coverage, and these amendments would provide a means whereby the responsibility for reimbursement of these transplant procedures can be shared with privately based purchasers of health care services.

The major caution I have about title II is that the Secretary and Assistant Secretary for Health must not act in a manner to disregard accepted scientific input, but rely strongly, for example, on the available clinical and scientific expertise in the cardiac and liver transplantation area.

It should also be noted that successful organ transplantation requires the use of immunosuppressive drugs indefinitely. The most promising of these drugs at present, and the one responsible for impressive results in transplantation of all organs, is Cyclosporine. Estimates of the cost of the drug regimen vary, but the average is about $5,000 for the first year, and lesser amounts as the drug dosage is later decreased in succeeding years of successful graft function.

Unfortunately many patients will be unable to afford this drug and, therefore, be denied its benefits because of their compromised economic status following catastrophic illness and because of the lack of provisions of many third party carriers, including medicare, to cover out-patient costs of this drug. We would like to suggest that strong consideration be given to provide suitable coverage in

some way for the out-patient costs of the drug for medicare eligible patients during the period of continued medicare eligibility.

When considered in relationship to the overall cost of alternative therapies, either for the maintenance of terminal care or for transplantation without Cyclosporine, we believe that coverage for the drug will be shown to be cost-effective.

In addition, we strongly recommend that coverage of out-patient Cyclosporine by private insurance carriers be placed on the agenda of the Advisory Council to the National Center for Organ Transplantation.

Last, Mr. Chairman, we have all been appalled, as have you, with the recent proposals dealing with the sale of human organs. We want to state categorically our opposition to such schemes and our intention to discourage such activity. The American Society of Transplant Surgeons is in the process of surveying all of the transplant centers throughout the United States. In the short period since the survey questionnaire was sent, we have had more than a 90 percent response, and the responses have indicated a unanimous expressed desire for the strongest possible position against the selling of human organs.

Accordingly, the American Society of Transplant Surgeons has adopted a resolution, along with the International Transplantation Society and the American Society of Transplant Physicians. I would like to read an excerpt of this resolution, which states that the removal of organs or the transplantation of organs obtained commercially will not be handled by any member of these transplantation societies, and anyone doing so will be expelled.

Mr. Chairman, you can see we, therefore, strongly support the provisions in the bill which make it unlawful to engage in plans for the sale of human organs. The existence of such schemes, however abhorent, very clearly underscores our present problems with the shortage of organs for transplantation.

In summary, our society is committed to strongly supporting a variety of efforts to promote organ donation, to improve the efficiency and effectiveness of organ distribution systems, and most important of all, to provide timely and successful organ transplants for many of our citizens desiring this therapy. In order to achieve the latter objective, we sincerely hope that you and Congress will give high priority to the appropriate medicare/medicaid amendments that can make it possible to achieve these ends.

Mr. Chairman, I want to express my sincerest appreciation to you and all members of your subcommittee with whom we have had previous contact for their interest and deep consciousness in these major public health issues that impact on the lives and welfare of many of our citizens and their families.

I also want to thank you again, Mr. Chairman, for this opportunity to testify on what I consider to be extremely important legislation. We want to continue our work with you and your subcommittee to build an understanding in support for this measure and its eventual passage.

Thank you.

Mr. WAXMAN. Thank you very much, Dr. Salvatierra.

Dr. Terasaki.

STATEMENT OF PAUL I. TERASAKI, PH. D.

Dr. TERASAKI. Thank you very much, Congressman Waxman.

Mr. WAXMAN. Could you speak right into the mike?

Dr. TERASAKI. Yes. As you have just heard from Dr. Salvatierra, it is now quite unlikely that anybody would be able to sell an organ in the United States for transplantation because in the United States there are three main societies to which the transplant physicians belong. One is the American Transplant Surgeons, of which Dr. Salvatierra is the president. The other is the American Society of Transplant Physicians, and you just heard from the president-elect, Dr. Ettenger. It turns out that the International Society is also represented in the United States, and I happen to be the president at the present time. All three societies have issued this joint statement, saying that they would expel anybody who would be involved in such a scheme.

So we think that the transplant group, those involved in transplantation, have clearly rejected this proposal. We believe that it will not be done in the United States.

Second, I would like to commend you for putting together such an excellent proposal in this bill 4080. Personally I would like to support it since it would help transplantation. It gets at the most important point about transplantation, that is, the lack of donors. It is important to get kidneys from people who do not need them any more, that is, the cadaver donors.

I just have only two small comments as to details within the bill. One is the statement that the director of the Organ Procurement Agency has to be full time. We believe that there are many directors who are involved both in transplantation and research, who are also directors of the organ procurement agencies. So the wording "full time director" should be struck.

The second is that it is quite important to have a registry because, as you mentioned, we do need to monitor the progress, to see how transplantation is going, to see how effective it is in comparison to dialysis, to make sure what transplant physicians tell us is really true, that the patients are surviving better, and that different drugs, for example, Cyclosporine, is really doing a good job.

So we do need the facts, and that you can provide for by having an effective scientific registry.

The other important thing is that we need to find out how to allocate kidneys because there is actually a debate today in scientific circles as to what is the best way to allocate kidneys. Tissue typing was developed for that purpose because we thought that if we matched the donors and recipients we would have good results. That sort of makes sense.

But unfortunately, when you come down to the facts and look at the data, it is sometimes difficult to prove that that is the case, at least in our current state of knowledge. Because of that, some people have gone to the other extreme and said that tissue typing is not necessary, that we can just put in kidneys without bothering about tissue typing.

The facts are that we are currently in the state where we are not too sure exactly how it could be used. We are developing the methods for using it. So this makes it very important for the registry to

watch what is being done, to develop the new methods for the future. It is a scientific kind of activity which possibly you may not have been thinking of doing, but we think should be done.

The NIH is concerned with many more basic problems and may not fund this sort of activity. In fact, they have stopped funding the activity in the mid-1970's when the ESRD program came into effect.

Finally, we would like to state at least from the Southern California Regional Organ Procurement Agency point of view that we think the bill would help transplantation, and we would like to congratulate you for putting together this bill.

Thank you very much.

[Dr. Terasaki's prepared statement and attachments follow:]

Testimony - Subcommittee on Health and the Environment for Congressman Henry A. Waxman, October 31, 1983

By: Paul I. Terasaki, Professor of Surgery, Director of UCLA Tissue Typing Laboratory, UCLA School of Medicine

Re: HR4080

In general, I find the bill HR 4080 to be one that is likely to advance the field of transplantation. Timely help such as this will prevent escalation of the 2 billion dollars currently being expended on the End Stage Renal Disease programs. Improved kidney transplants is the best solution in achieving a high quality of life for the patient as well as controlling the expense to society.

There are two specific points on the bill which I wish to comment on. First, although transplantation has graduated from being merely a research procedure, the field is still in its developmental stages and transplantation is not yet an established routine. I do not believe that the organ procurement agencies should exclude physicians as directors of the organ procurement organizations. The requirement that the directors be full time (page 4, line 14) would, in effect, exclude all MDs and Ph.D.s since almost none of the current directors are full time. Although the implication might be that full-time commitment is necessary, active participation with transplant programs and research units is as urgent. Such a relationship is achieved by joint appointments. Complete separation of OPOs from universities and research institutes will tend to prematurely fix the OPOs, divorced from the advancing frontiers of

transplantation. Those OPOs now with universities should be allowed to continue.

Thus, the word "full-time" should be deleted from sec 371 (b)(I)(H) (page 4, line 14).

The second point I wish to make is that the scientific registry provided by sec 374 (c) (page 12, line 14) is an extremely important provision which should be separately established from the National Network and should be directly responsible to the National Center for Organ Transplantation. A scientific registry to analyze, compare and make recommendations for future allocation methods should be decoupled from the day-to-day activities of the National Network. The National Network has a formidable list of 7 tasks (page 6, 7) having to do with expediting the transport of kidney and blood sera from donor centers to the appropriate recipient centers.

A nationwide registry as part of a National Center for Organ Transplantation should provide data on the outcome of transplantation by continuous evaluation of the effectiveness of this therapy. We already know that there are still many instances in which the kidney must be removed or the patient dies. It is important to identify the factors responsible for these failures so that future patients being transplanted would not be subject to these same mistakes. Failures may occur at higher rates in certain situations or certain centers. Factors operational in different subsets of patients must be studied and identified.

Another important function of the registry is to determine how kidneys should be allocated. In some quarters it is thought that the

best allocation is by tissue typing, or HLA typing. That is, if a kidney is found to be HLA compatible with any recipient anywhere in the country, the kidneys should be sent to that recipient. On the other hand, there are others who believe that histocompatibility considerations are unimportant. According to these physicians, kidneys will be used at whatever hospital they are found. By this latter scheme, it is rarely necessary to ship kidneys outside a given region. There are several regions in the United States which practice this approach. In order to determine how to allocate kidneys, a registry is required to obtain data on the effectiveness of different procedures. Aside from histocompatibility, there are many other factors to be considered, such as length of time the kidney is preserved, whether the patients have been pretreated with transfusions, what type of drugs are used for immunosuppression, etc. From the data gathered to date, it appears that all these factors are actually of importance and that complex interactions occur between the different variables. This means that it is necessary to develop computer programs that will evaluate the different factors and assign relative weights to them. We have developed prediction formulas and are currently refining them further for use in future selection of donor and recipient pairs. Though this method of selection and allocation of kidneys is complex and must constantly be refined as new factors such as cyclosporin are introduced, we believe that eventually computer technologies should be used. In addition, since we already have data on 40,000 transplant patients, it is important to utilize this background information for the selection of new cases. We should not be

approaching every new case as though nothing had been learned from prior experience. The computer programs that have been developed based on the registry data allows the use of prior retrospective data for the selection prospectively of new donor-recipient pairs.

As noted earlier, one of the important functions of the registry is to monitor continuously the outcome of transplantation. We recently published yearly trends in patient and graft survival rates from the UCLA registry. It can be noted that patient survival rates have steadily improved from years 1968 to 1981. One interesting finding has been that the kidney graft survival rate (loss of kidney or death) had actually decreased from 1968 to 1975 despite supposed advances and improvment of transplantation. Graft survival rates started to change in 1975 and has continuously improved at a rate of 2.7% per year since that time. Evidence was provided through the registry that a marked change in the transfusion policy had occurred and that half the patients transplanted in 1977 were grafted without prior transfusions whereas only 10% of the patients were transplanted without transfusions in 1981. This marked change in the transfusion policy is thought to have been responsible for the increasing graft survival rate. During each of the quarters, it was further shown that patients who had prior transfusions had a higher graft survival rate than those who were transplanted without prior transfusions.

The transfusion effect was first discovered using the UCLA Transplant Registry in 1972. At that time, only a few patients who were not transfused were available for analysis from multiple centers. Although it is often

argued that data collected from many centers is not as accurate as those from a few large centers, this example demonstrates that there is an advantage to accumulating data from many centers especially when the number of cases in a given category is small. Moreover any factor which is of importance should be verifiable in the total data considering all centers. If the factor is "washed out" when applied to all centers, we can conclude that the factor is a minor one. Anything of importance should stand up on extensive application throughout the country. Thus data from a national registry is important for identifying factors as well as for verifying the ultimate value of given factors.

The first kidney transplant registry founded in 1963 in Boston had data on 3,000 patients. This registry was replaced in 1969 by the Chicago registry funded by the American College of Surgeons and NIH. Though this was a valuable registry, funding was discontinued in 1976 with the initiation of the ESRD program. After competition and selection of bids, the Value Engineering Company in Arlington, Virginia was awarded the registry. In a few years it became apparent that even though this registry was a compulsory registry as opposed to the prior ones which were voluntary, and it was funded at levels many times that of prior registries, it could not produce any results. After floundering for a few more years, it was transfered to HCFA, where some recent progress appears to have been made. The NIH also established a registry in 1970 which was eventually discontinued in 1980.

The UCLA Registry initiated in 1969 has continuously grown for 15 years to the present time. It currently contains data on 40,000 transplant patients, the largest number in any registry. More than 100 publications in scientific journals have been published from this registry. Funds for the registry came for a brief period from the Regional Medical Program, and more recently in part from a small research grant ($80,000) from the NIH. Some aid is also provided by the ESRD program through the Southern California ROPA.

The third registry which is active in the United States is the SEOPF registry established about 1978. The registry has produced approximately 15 scientific publications.

It is important for the National Center for Organ Transplantation to support a strong scientific registry not only for kidney transplants but for other vital organs. It is urgent that such a Registry be directly responsible to the National Center for Organ Transplantation rather than simply being a part of a National Network.

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Brief Reports

Improving Success Rates of Kidney Transplantation

Paul I. Terasaki, PhD; Sondra T. Perdue, MS; Nori Sasaki, MA;
M. R. Mickey, PhD; Lesley Whitby

• **One-year patient survival rates have improved remarkably, from 84% in 1968 to 97% in 1980 for parental donor grafts, and from 65% to 90% for cadaver donor grafts. In contrast, graft survival rates showed a steady decline from 1968 to 1975 but subsequently improved at a rate of 2.4% per year for parent donor transplants and 2.7% per year for cadaver donor transplants. During this period of improving survival rates, the pretransplant transfusion exposure rate increased from 52% in 1977 to 91% by 1981. We conclude that transplantation has now reached a new level of acceptability as a clinical treatment modality and that blood transfusion has produced its effect on graft survival when results are disseminated over a large number of transplant centers.**

(*JAMA* 1983;250:1065-1068)

SIX years ago we called attention to the fact that the yearly success rates of kidney transplantation in North America had declined each year from 1968 to 1975.[1] This alarming deterioration occurred despite improvements in immunosuppression, histocompatibility testing, and overall transplantation experience. A dramatic reversal has occurred in the past six years. Most striking has been the recent steady improvement in the average

See also pp 1053 and 1072.

transplantation results of more than 100 North American transplant centers. Evidence shows that recovery from the previous downward trend seems largely attributable to the adoption of a pretransplant transfusion policy by most centers.

From the Department of Surgery, UCLA School of Medicine, University of California, Los Angeles.
Reprint requests to UCLA Tissue Typing Laboratory, 1000 Veteran Ave, Los Angeles, CA 90024 (Dr Terasaki).

Methods

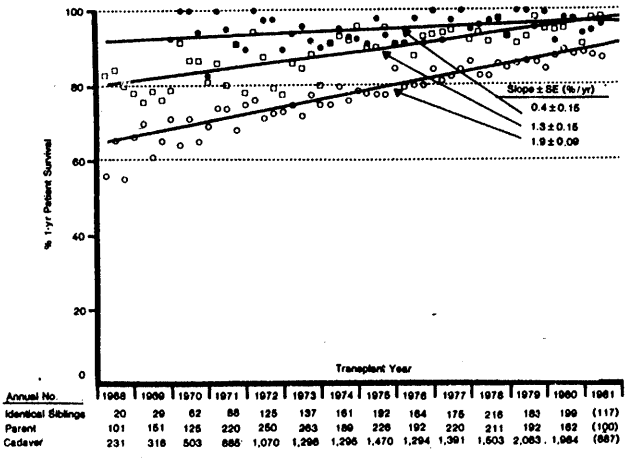
Through the voluntary collaboration of more than 100 centers, mostly in the United States and Canada, data on various aspects of kidney transplants were gathered during the past 14 years.

The participating centers currently report approximately 3,500 transplants annually, accounting for more than two thirds of the transplants performed in North America. The centers represent all geographic regions, and all transplants within a given transplant center are reported to the registry. The base of reporting centers is relatively consistent for the years analyzed; the primary changes are additions of centers over the years, and newer centers do not have differentially higher survival rates than older centers.

The survival rates were computed as actuarial estimates from cohort life tables.[2] Estimates in the text are given as estimate ± SE of estimate. Lines fitted to data points are from weighted least square regression.[3] P values cited are for the statistical two-sided test of the slope coefficient differing from zero (no effect). Only first transplants were considered.

Results

Patient Survival Rates.—During the past 14 years, patient survival rates



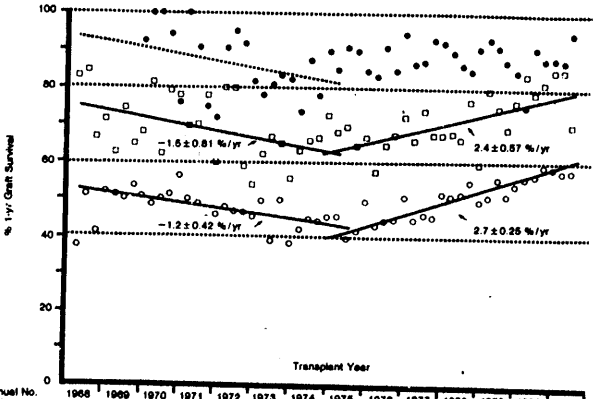
Annual No.	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981
Identical Siblings	20	29	62	88	125	137	161	192	164	175	216	183	199	(117)
Parent	101	151	125	220	250	263	189	226	192	220	211	192	162	(100)
Cadaver	231	316	503	885	1,070	1,298	1,295	1,470	1,294	1,391	1,503	2,083	1,984	(887)

Fig 1.—First-post-transplant-year patient survival rates in three donor categories plotted by transplant date. Statistically significant linear regression lines are fitted to each category. Slope estimates (±SE) from regressions are given as percent per year. Numbers at bottom of figure are total cases plotted for each year (half of year for 1981). Actual points are shown for each calendar quarter within year (January through March, April through June, July through September, October through December). Although identical-sibling donor cases are not plotted for 1968 through 1969 because of small numbers per quarter, they were included in additional analyses such as regressions. Solid circles indicate identical sibling donor; squares, parent donor; and open circles, cadaver donor.

have been continually increasing (Fig 1). The one-year patient survival rate for HLA-identical sibling transplants rose from 86% ±7% for 1968 to 97% ±1% for 1980 transplants. For parental donor transplants, there was a similar increase from 84% ±3% for 1968 to 97% ±1% for 1980. Therefore, the survival rate of patients with parental donor transplants done in 1980 reached the same level as that of patients with HLA-identical sibling transplants. Cadaver donor patient survival improved to an even greater extent: from 65% ±1% in 1968 to 90% ±1% in 1980. The regression estimates for these increases are 0.4% ±0.15%/yr for identical siblings ($P<.01$), 1.3% ±0.15%/yr for parent donors ($P<.001$), and 1.9% ±0.09%/yr for cadaver donors ($P<.001$).

Graft Survival Rates.—These curves are decomposed into two parts with good linear fit. The first-year graft survival rates, particularly for parent and cadaver donor transplants, steadily declined during the eight years from 1968 through 1975 (Fig 2), similar to survival rate statistics published in 1976.[1] The declines are about the same for both categories, 1.5% ±0.81%/yr ($P<0.07$) and 1.2% ±0.42%/yr ($P<0.01$), respectively. Although a similar decline is seen in the HLA-identical sibling category, it is not statistically significant. Since 1975, there has been a steady increase in survival rates for parent and cadaver donor transplant categories. Again the increases are similar: 2.4% ±0.57%/yr ($P<.0005$) and 2.7% ±0.25%/yr ($P<.001$), respectively. The annual first-year graft survival rate increased from a low of 80% ±3% for 1973 to 86% ±3% for 1980 for HLA-identical sibling transplants, from 63% ±3% for 1973 to 82% ±3% for 1980 for parental donor transplants, and from 44% ±1% for 1975 to 56% ±1% for 1980 for cadaver donor transplants.

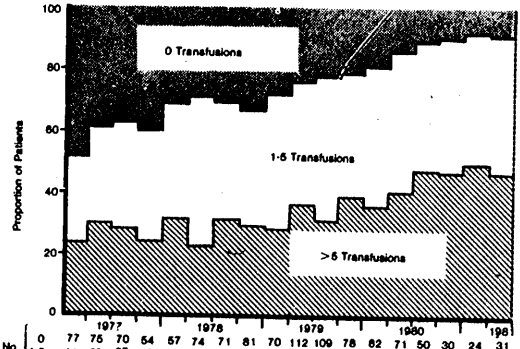
Increasing Rate of Transfusions.—Reexamining the relationship between transplant success and pretransplant transfusions, a clear trend toward increasing numbers of transfusions during the years 1977 through mid-1981 is demonstrable among patients receiving cadaver donor transplants (Fig 3). The overall proportion of patients receiving transplants without any prior transfusions fell from 48% in early 1977 to 9% by 1981. Patients with more than five transfusions rose from 24% of the patients at the beginning of 1977 to 50% by 1981. There were comparable shifts in other transplant donor categories. Thus, a definite overall change in transfusion policy occurred during this period. If survival rate for these years is regressed on the proportion of patients receiving transfusions (zero transfusions *v* greater than zero transfusions) rather than years, a good linear fit is also obtained with a highly significant slope coefficient ($P<.0001$).



Annual No.	1968	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981
Identical Siblings	20	29	62	88	125	137	161	192	164	175	216	183	199	(117)
Parent	101	151	126	220	250	263	189	226	192	220	211	192	162	(100)
Cadaver	231	316	503	886	1,070	1,298	1,256	1,470	1,294	1,391	1,503	2,063	1,984	(887)

Fig 2.—First-year graft survival rates in three donor categories plotted by transplant date. Solid lines drawn are regression lines with statistically significant nonzero slopes fitted to data within donor category for years 1968 through 1974 and 1975 through 1981. Estimates indicated for each line are slopes (± SE) from regression. Dotted line for HLA-identical sibling transplants from 1968 through 1974 is similar regression line although slope is not statistically different from zero at P less than .1. Numbers at bottom of figure are total cases plotted for each year (half of year for 1981). Actual points are shown for each calendar quarter within year (January through March, April through June, July through September, October through December). Solid circles indicate identical sibling donor; squares, parent donor; and open circles, cadaver donor.

Improved Survival Rates With Transfusions.—Although the relationship between transfusions and transplant outcome has been repeatedly analyzed,[4] we show here superior outcome after transfusions even with 18 consecutive independent patient sets (Fig 4). Graft success rates were higher in all but one subset of patients receiving greater than five pretransplant transfusions compared with patients without transfusions. Lines fitted separately to the zero transfusion and to the greater than five transfusion categories indicate that changes apparent in the overall cadaveric donor graft survival are not evident within each transfusion category.



No.																			
0	77	75	70	54	57	74	71	81	70	112	109	78	82	71	50	30	24	31
1-5	44	59	67	48	65	123	84	68	109	176	212	143	157	214	181	134	130	162
>5	39	57	52	34	58	60	72	68	70	159	150	140	118	202	208	141	151	186

Fig 3.—The proportions of first cadaver donor transplant recipients with zero, one through five, or more than five pretransplant transfusions by transplant date. Numbers at bottom of figure are cases within each transfusion category by calendar quarter.

Comment

One of the most important medical advances of the past three decades has been the emergence of treatment for end-stage renal disease. Wide-

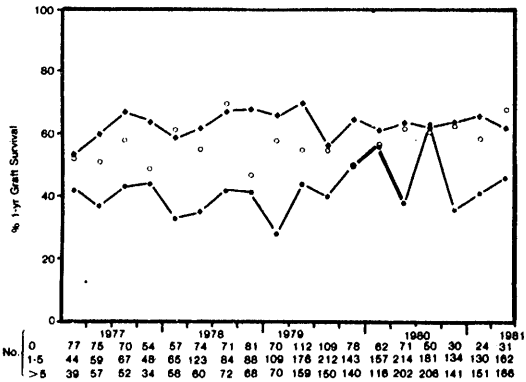


Fig 4.—First-year graft survival rates for cadaver donor transplants by transplant date, classified by number of pretransplant transfusions. Numbers at bottom of figure are cases within each transfusion category by calendar quarter. Diamonds indicate greater than five pretransplant transfusions; open circle, one through five pretransplant transfusions; and solid circles, zero pretransplant transfusions.

spread institution of dialysis technology has resulted in the current dialysis of 55,000 patients in the United States alone. A mere 30 years ago, all of these patients would have died. However, there has been an economic price to pay for this advance, namely, a current cost of $1 billion per year. Because these patients will continue to undergo dialysis along with new patients, an ever-increasing, spiraling social burden is imposed. Patients undergoing dialysis are a new type of patient who are not simply cured by medical treatment but who require the same intensive treatment for the rest of their lives.

Close on the heels of this technological accomplishment has been the development of clinical kidney transplantation. Worldwide, more than 60,000 patients have had transplants in the past 20 years and more than 30,000 are surviving today with their allografted kidneys. Although it is generally accepted that the quality of life of a patient with a successful transplant is far better than that of a patient undergoing dialysis, the risks of transplantation, particularly the risk of death, have been given as the major drawback of transplantation. As a result, only about 5,000, or 10%, of the patients undergoing dialysis in the United States are being listed on waiting transplant pools for a kidney transplant.

With the assumed higher mortality associated particularly with cadaver donor transplantation, patients and physicians alike understandably may have favored continuation of dialysis as opposed to transplantation. Contrary to general impressions, however, a consistent reduction in mortality rates has occurred during the past ten years. From an almost unacceptably high first-post-transplant-year mortality rate of 35% for cadaver donor transplants in 1968, the present nationwide first-year mortality rate even for cadaver donor transplants has been reduced to 10% overall. In some individual centers, the first-year mortality rate is now 5% or less.[1] This improvement has occurred despite concurrent increases in the proportion of transplant recipients who are high risk because of such factors as diabetes.

The policy of removing kidneys that are being rejected instead of continuing immunosuppression has been widely adopted in recent years. Because such patients are returned to dialysis, it follows that improvement in patient care, including dialysis, has contributed to increasing transplant recipient survival rates. Because the dialysis first-year mortality rate is approximately 10%,[2] transplantation currently does not add a substantial risk to a patient with end-stage renal disease.

Aside from the recent attainment of almost no additional mortality risk with transplantation, the probability of having a functioning graft has increased in the past six years in contrast to the steady deterioration of results noted between 1968 and 1975. The improvement has been consistent during the past six years, averaging more than 2% per year.

We postulated in 1976 that withholding transfusions from patients undergoing dialysis had resulted in the declining transplant success rates between 1968 and 1975.[3] A progressive nationwide change in transfusion policy since 1977 has been apparent (Fig 3). This policy change has closely paralleled the increased transplant graft survival rates.

The high patient survival rates along with the improving graft success rates suggest that kidney transplantation has matured sufficiently to enter a new stage of development. Clearly, transplantation should be made available to more patients undergoing dialysis, and current regulations, at least in the United States, are perhaps inadequate because only 10% of patients undergoing dialysis are on transplant waiting lists. Recognition by the medical community of the overall improvements in the results of kidney transplantation may lead to better utilization of this treatment option.

This study was supported in part by the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases grant AM 02375-24.

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THE TRANSPLANTATION SOCIETY

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The International Transplantation Society, the American Society of Transplant Surgeons, and the American Society of Transplant Physicians strongly condemn the recent scheme for commercial purchase of organs from living donors. This completely morally and ethically irresponsible proposal is rejected as abhorrent by all members of the Transplantation Societies. Removal of organs and transplantation of organs obtained commercially will not be handled by any member of the Transplantation Societies, and anyone doing so will be expelled.

Paul I. Terasaki, Ph.D.
President, Transplantation Society

Oscar Salvatierra, M.D.
President, American Society of Transplant Surgeons

Charles Carpenter
American Society of Transplant Physicians

Mr. WAXMAN. Thank you very much, Dr. Terasaki.
Dr. Mendez.

STATEMENT OF ROBERT MENDEZ, M.D.

Dr. MENDEZ. Congressman Waxman, it is my pleasure to testify before your Subcommittee on Health and the Environment on the hearing of H.R. 4080, the National Organ Transplant Act.

I want to commend you and your subcommittee for attention to a much needed bill to help organize and make more efficient the procurement of human organs for the treatment of end stage diseases affecting a significant portion of our medical community.

The National Organ Transplant Act has within its bill a comprehensive and excellent approach to the development and needs of organ transplantation.

In addressing the first aspect of the bill, I would like to make some recommendations for minor changes within the bill. On title I, the lines 6 and 7 of the Organ Procurement Organization, I feel that the defined service area should be a geographical area that covers a population of at least 2 million and a minimum number of five transplant centers. This would allow perhaps the ongoing development of existing OPO's that have already established excellent relationships with various organ procurement hospitals.

The cooperation between multiple organ procurement organizations in these areas would still be guaranteed by the national criteria used for organ sharing.

With regard to the second on the U.S. transplant network, this is an outstanding idea and one whose time has finally come. With the development of various regional centers, an embryonic attempt to create a U.S. transplant network has been carried out by the United Network of Organ Sharing members in the last year or two.

Also, as you have heard from Dr. Salvatierra, the ad hoc committee of the American Society of Transplant Surgeons has committed itself to the development of a national sharing network.

I would recommend, however, that under the administration and the directorship of this type of network, that more emphasis be placed on the physician membership for the decisions and primary goals for this network will be the equitable distribution of organs to recipients and the medical assessment of the needs for these organs.

Thus, it would also diminish the special interest groups that may want to have significant input into such a directorship.

Another aspect should be made about the need for organs at this time. Though in several centers, because of the aspect of sharing organs by blood typing only and not tissue typing, there are some regional areas in which there are excess amounts of kidneys and others in which there is a dirth of kidneys. Overall we feel that there is a dirth of kidneys in the United States, and this is at a time when virtually only 5 or 10 percent of patients on renal dialysis presently are on transplant lists.

In the southern California community, only 5 percent of those potential individuals who may receive a transplant are presently on transplant lists. If this percentage should only be doubled, we

would certainly be in dire straits with regards to the numbers of kidneys available for them.

With regard to your title II, medicare and medicaid amendments, I heartily endorse and support your efforts to extend the coverage of medicare and medicaid payments to nonrenal organ transplant recipients, such as liver, heart, pancreas diseased patients, who would greatly benefit by this organ transplantation.

It has been tragic to approach an organ procurement situation and only be able to remove the kidneys when the livers and the pancreases are available, but have not been able to be used because of economic means.

We heartily endorse, once again, your excellent attempt to continue organ sharing on a humanitarian basis, preventing the financial gain in the sale of commerce and trafficking of organs for transplantation purposes.

Last, I would like to mention that the goal and purpose of this new legislation should be to promote the cooperation and retrieval of organs for transplantation purposes, and thus, should be written in such a manner to not prevent the spontaneous growth and development of agencies unaffiliated with governmental institutions, much in the same way as the growth and development of the Red Cross units and charitable, religious and community organizations have spontaneously developed through the years for the benefit of health purposes.

Once again, I want to thank you very much for the opportunity to speak before you and to commend you for this excellent bill that you have proposed.

Thank you.

[Dr. Mendez' prepared statement follows:]

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October 31, 1983

Henry A. Waxman
Chairman, Subcommittee on
Health and the Environment
U. S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health and the Environment
2415 Rayburn House Office Bldg.
Washington, D.C. 20515

WRITTEN TESTIMONY

Dear Mr. Waxman:

It is my pleasure to testify before your Subcommittee on Health and Environment at a hearing on H.R. 4080, the "National Organ Transplant Act".

In general, I commend you and your Subcommittee for attention to a much needed bill to help organize and make more efficient the procurement of human organs for the treatment of End-stage diseases effecting a significant portion of the medical community of our country. The National Organ Transplant Act has within its bill a comprehensive and excellent approach to the development and needs of organ transplantation.

Addressing the first aspect of the bill and authorization of Programs for grants for the development of local procurement organizations throughout the nation, I am in full concurrence that this need be done but would recommend under line 6 and 7 that the Organ Procurement Organization have a defined service area that would cover a geographical area of population size no smaller than two million individuals or cover a geographical area that has a minimum of five Transplant Centers. This would allow the development of perhaps more than one organ procurement organizations in such densely populated areas where multiple transplant centers exist and have all ready established excellent relationships with organ procurement hospitals. It still prevents the unnecessary development of a significant number of organ procurement organizations that would be inefficient. The cooperation between these multiple organ procurement organizations in a smaller geographical area would be guaranteed by the national criteria used for organ sharing.

With regard to the section on the United States Transplant Network, this is an outstanding idea and one whose time has finally come. With the development of various regional centers, a embryonic attempt to create a United States

transplant network has been carried out by the United Network of Organ Sharing members in the last year or two. Also, the American Society of Transplant Surgeons Ad Hoc Committee on organ sharing has committed itself to the development of a National Sharing Network. The importance in establishing such a network should be that any member Network Transplant Center may voluntarily join the network or not and may not be required to do so if for some unknown reason they would desire to remain autonomous. Along these lines, those individuals who however, would volunteer to join the United States Transplant Network would agree to share all their kidneys procured in a method established by the Board of Directors of the U.S. Transplant Network. It is also strongly recommended that the Administration of the U.S. Transplant Network under line 8 of page 11, be changed to read: "Of the fifteen members appointed by the secretary, that instead of six, ten members shall be appointed from physicians who are emminent in the various specialties of medicine related to human organ transplantation." Since the primary goal and aim of this Network will be the equitable access by patients to organ transplantation and by medically assessing the needs of organ transplantation it would be to the benefit of the patients to have more physician input. This may also diminish the special interest groups from dominating or having too large a voice in the manner of distribution of kidneys on a non-medical basis.

I would also recommend a change on page 8, line 8 and 9 to read: "The Secretary may make a grant for more than one organ procurement organization which will serve in the same geographical area, if that geographical area is over two million in population or has greater than five Transplant Centers in its area." This again would be to promote efficiency and to allow continuation of many of the excellent relationships all ready established amongst the existing O.P.O.'s. Cooperation between the O.P.O.'s would of course again be guaranteed by the national requirement of organ sharing made by the National Council of the U.S. Transplant Network.

With regard to Title II - MEDICARE AND MEDICAID AMENDMENTS, I heartily endorse and support your efforts to extend the coverage of Medicare and Medicaid payments to non-renal organ transplant recipients such as, liver, heart and pancreas diseased patients who would greatly benefit by organ transplantation.

Lastly, on Title III - PROHIBITION OF ORGAN PURCHASES, I once again heartily endorse this excellent attempt to continue organ sharing on a humanitarian basis preventing the financial gain in the sale of commerce or trafficing of organs for transplantation purposes.

Lastly, it should be the goal and purpose of this new Legislation to promote the cooperation and retrieval of organs for transplantation purposes and thus should be written in such a way as to not prevent the spontaneous growth and development of agencies unaffiliated with governmental institutions much in the same way as the growth and development of Red Cross Units and charitable religious and community organizations have spontaneously developed for the benefit of health purposes.

Respectfully submitted,

Robert Mendez, M.D., F.A.C.S.
Director, Renal Transplantation
St. Vincent Medical Center, L.A., CA.

President,
Western Association of
Transplant Surgeons

RM:mjf

Mr. WAXMAN. Thank you very much, Dr. Mendez.
Dr. Berne.

STATEMENT OF THOMAS V. BERNE, M.D.

Dr. BERNE. I would also like to commend you for your efforts and the work that has been done on proposing H.R. 4080.

In the interest of time, I would simply like to support strongly the testimony of Dr. Salvatierra and Dr. Terasaki and Dr. Mendez, specifically the points that we do very much need an outcome registry on a national basis that functions. The existing one within HICFA is basically a waste of money, as I think all of us see it.

The other matter in regard to the full-time director, I think the point has been clearly made by Dr. Terasaki. I would like to say he himself has been the Director of our local procurement agency here as a part-time effort, and he has done an outstanding job in that way.

I would like to discuss just briefly one of the major portions of the bill, and that is in regard to the strengthening of the local organ procurement organizations. Since 1968, all of the transplant centers in the Greater Los Angeles metropolitan area have worked quite harmoniously within one organ procurement and sharing program. The maintenance of standards, coordination, tissue typing, financial management, and public, and to a certain degree, professional education have been done under the direction of Dr. Paul Terasaki and this organization which we call the Southern California Organ Procurement Agency.

This agency already functions much as H.R. 4080 envisions for the local organ procurement organizations. However, there are several large metropolitan areas in this country where there is little cooperation between transplant centers, and the requirements of H.R. 4080 for organ procurement organizations to receive grants would, I think, encourage these centers to work together much better.

Also, despite the high level of sophistication and cooperation of the organ procurement effort in southern California, there are many things that need to be done which have been impossible because of limited financial resources. The most important of these, I believe, and I think it was mentioned earlier by Dr. Ettenger, is professional and public education.

There was a brief period of time when some Federal money was available through regional medical programs, and with that appropriation, we were able to carry out a strong educational effort, which helped very much, but the money disappeared, and that educational efforts has dropped off to a very low level now. This program must be resumed to strengthen and carry out a much stronger educational effort than we have now.

We need to enlist the full cooperation of community hospitals and their medical staffs in the identification of potential organ donors. Also, much more must be done to let the public know of the need for organ donation, the circumstances of donation, and how to initiate donation. Both of these could be supported by the grants which H.R. 4080 would provide for the organ procurement organizations.

Thank you very much for the opportunity to testify on this important bill.

[Dr. Berne's prepared statement follows:]

Testimony of Thomas V. Berne, M.D. to the Subcommittee on Health and Environment Hearing on HR 4080, The National Organ Transplant Act, October 31, 1983

I am Thomas V. Berne, M.D., Chief of the Renal Transplant Unit, Los Angeles County-University of Southern California Medical Center. I would like to speak in support of HR 4080, the National Organ Transplant Act. I believe that passage of the bill would provide solutions for several major problems which plague organ transplantation in the United States today.

The basic need addressed by HR 4080 is the lack of a national organ exchange network and registry. Although two "national" registries exist, the United Network for Organ Sharing and the UCLA Tissue Typing Laboratory, neither has achieved real nationwide acceptance. For some time it has been clear that this has limited our ability to find kidney transplants for a small percentage of our patients that are very difficult to match. With the increasing transplantation of other organs, particularly hearts and livers, the necessity of a central "matching" organization, the United States Transplant Network in this bill, has become much greater. Also, because there will be fewer heart and liver transplant centers in each region it will be even more important to exchange more organs between regions of this country.

The other very important provision of the bill is the strengthening of the local organ procurement agencies. The Los Angeles Metropolitan Area, including all transplant centers in Los Angeles, Orange, Riverside, and San Bernardino Counties have worked very harmoniously together within one organ procurement and sharing program since 1968. The coordination, tissue typing, financial management and public education have been done under the direction of Dr. Paul Terasaki at UCLA and this organization is called the Southern California Regional Organ Procurement Agency. This agency already functions much as HR 4080 envisions for the local organ procurement organizations (OPO's). However, there are several large metropolitan areas in this country where there is little cooperation between transplant centers. The guidelines for OPO's would encourage these centers to work together. Also, despite the high level of sophistication and cooperation of the organ procurement effort in Southern California, there are many things that need to be done which have been impossible because of limited financial resources. The most important of these are professional and public education. The staff of our organ procurement agency is presently mostly part time. There was a brief period of time when some federal money was available from the Regional Medical Programs appropriation when we were able to carry out a strong education effort. This program must be resumed in order to enlist the full cooperation of community hospitals and their medical staffs in the identification of potential organ donors. Also, much more must be done to let the public know of the need for organ donation, the circumstances of donation and how to initiate donation. Both of these could be supported by the grants which HR 4080 would provide for the OPO's.

The creation of the National Center for Organ Transplantation is a logical step to provide the natibnal leadership and coordination of a logistically complex form of medical therapy which is rapidly increasing in medical applicability. One important provision is for the formation of an advisory council which can address the special ethical and social issues raised by transplantation. A most difficult problem which will be addressed frequently in the near future is the problem of allocation of expensive and limited resources.

A few specific details upon which I would like to comment are:

1) I do not believe that the Director of an Organ Procurement Organization need be "full-time". We have functioned very well in this area under the direction of Dr. Paul Terasaki and this has not been a "full-time" effort (pg. 4, line 14).

2) I think Part H "Assistance for Organ Procurement Organizations" needs to include language which would discourage the setting up of new duplicative OPO's for the purpose of obtaining grant money.

3) The OPO's should be specifically encouraged to be involved in Public Education. This charge should be included along with professional education in paragraph (2)(B) (Pg. 4, line 24)

4) I believe strongly that the "National Center for Organ Transplantation" should have included in its charge the collection, analysis and publication of data on transplant outcome. This charge should be included in section (3)(C) page 12, following line 19. This information would be critical for the effective work of the National Center in regard to decision about future allocation of medical resources, and would be an important tool for the improvement in transplantation success. Although this bill (HR 4080) is directed mainly at organ procurement, the National Center would be the ideal place for such an Outcome Registry. The existing "Medical Information System" for renal transplantation (within HICFA) has been of no value and is presently a waste of federal money.

Thank you for the opportunity to testify on this important bill.

Mr. WAXMAN. Thank you very much, Dr. Berne.

Let me ask you about the California experience with organ donations. According to studies that I have seen, an area with a population of 7.5 million people, such as Los Angeles County, could be expected to obtain more than 800 kidneys. How many kidneys were actually obtained in the L.A. area last year, if any of you know that figure?

Dr. TERASAKI. Yes. There were 260 transplants done from cadaver donors.

Mr. WAXMAN. So that is probably 25 percent of the theoretically available pool of kidneys? Does that figure seem accurate to you? From what I have heard, this rate is slightly above the national average, but obviously far below what would be an optimal system.

I guess that leads us to the question both for kidneys and other organs: Are we doing everything that we need to be doing to procure potentially available organs in California? What more do you think can be done?

Dr. MENDEZ. I think as Dr. Berne pointed out, we can certainly increase our efforts in public education and to some degree in professional education, but as mentioned by the Fiske case, public education is a highly important aspect. It is presently very poorly, if at all, funded.

Mr. WAXMAN. Do you think the problem is also one of physician information? Are you finding here in southern California that physicians are reluctant to talk to the next-of-kin when there is a brain death? Is this a big part of the reason, or do you think it is really a small part and what we really need is to have the public more aware of the potential they have under those kinds of circumstances to save a life?

Dr. Berne.

Dr. BERNE. Well, it is sort of a medium-sized part. It is significant.

There is some natural reluctance. I think if you talk to a neurosurgeon or neurologist who deals with this type of case very often, it is difficult to have spent a day or 2 days or a week fighting to save someone's life and then when it is very clear that there is no chance for survival to sort of take off one hat and put on another hat and go out and talk to the family about the donation. It is much, much easier if that family is aware of the circumstances under which donation might occur and the family brings it up to the physician. It just makes a much more positive sort of experience out of the donation process.

That is why we are so interested in getting the public to understand the need and the circumstances under which donation might occur and getting more people to talk over among their family whether they are interested in donating when the time comes so that it removes the last bit of burden from the physicians caring for brain dead patients.

Mr. WAXMAN. Dr. Mendez.

Dr. MENDEZ. Congressman, the vast majority of organ procurement that is done is initiated by either the family members or the nursing staffs of hospitals and emergency rooms, and not by physicians. The level of their education, in-service education of the nurs-

ing staffs is to a high degree important in the procurement of organs.

One statement I would like to make about the numbers of transplants done in southern California last year. We did approximately 260 transplants. That did not mean we procured 260 kidneys because many kidneys were brought in from other regions through the embryonic, new UNOS system.

Mr. WAXMAN. I noted that less than 10 percent of the patients with end stage renal disease are registered for kidney transplants, and in Los Angeles the rate is actually lower than the national average. Do you think that more end stage renal dialysis patients should consider transplant operations? Do you think dialysis is an acceptable or perfect substitute for a kidney transplant? Would we have more than 10 percent if there were more kidneys available?

Dr. Berne.

Dr. BERNE. Well, I think we feel strongly that the number of patients who are referred for kidney transplantation is under where it ought to be. One important thing to keep in mind though is that transplantation has improved very rapidly very recently, and we expect it also will make another quantum improvement with the widespread use of Cyclosporine. Some of this information, I think, is not yet clearly available to the patients and to the referring physicians, and it is one of the problems that not having a registry has caused. The data does not come to us very clearly every year the way it did when the old NIH-American College of Surgeons registry was available.

Mr. WAXMAN. Yes, Dr. Salvatierra.

Dr. SALVATIERRA. If I may, Mr. Waxman, just to follow up on two points, in reference to your last question, I think there has been an honest hesitancy by some patients to proceed with cadaver transplantation knowing the results that were achievable with conventional immunosuppression and the attendant problems or complications related to that immunosuppression. Certainly there is no drug without any side effects, but hopefully Cyclosporine does look to be very encouraging, and I think with Cyclosporine we will be seeing the possibility of a 20- to 30-percent increase in the survival rate of cadaver transplantation, and this will in turn result in an increase of referral of patients for transplantation.

Last year we had approximately 5,300 transplants performed. That was up about 600 from the previous year, and before that there had really been a plateau in the number of yearly transplants that had been performed.

Certainly not all patients on dialysis are transplant candidates, but it is realistic to think—and I think this is a consensus opinion—that perhaps we might be able to transplant 10,000 patients a year. But this transplant rate will, in good part, depend on the availability of Cyclosporine to these patients.

Mr. WAXMAN. Why wouldn't we want to have all of the dialysis patients as candidates for transplants?

Dr. SALVATIERRA. A good part of the dialysis population is an elderly population. Certainly by conventional immunosuppressive medication, that group of patients would be at high risk. With Cyclosporine, certainly if we considered patients who were 55 years of

age and under, I think we can perceive about a 10,000-a-year transplantation rate.

However, giving a more specific answer to your question, it may be that with Cyclosporine we may find more patients that now will find transplantation as an acceptable process. Certainly at my own center, we are proceeding with cadaveric transplantation up to age 65 and without any incurred greater risk to that patient.

We have projected at possible cost savings, as we have projected the 10,000 transplantation rate, if that were to come about. If, for example, 40 percent of those patients were from living donor sources—and I actually think in the future if cyclosporine proves effective, the living related transplantation rate will decrease in favor of the cadaver rate.

Mr. WAXMAN. The number will decrease or increase?

Dr. SALVATIERRA. The living related probably will decrease.

Mr. WAXMAN. Decrease.

Dr. SALVATIERRA. If we were to perform 10,000 transplants this next year, 40 percent from living related sources, and 60 percent from cadaver sources, utilizing Cyclosporine, and compare those patients, the cost of their therapy, with 10,000 patients on dialysis. Over a 4-year period we would envision over a $400-million cost savings.

And if I may just mention one other thing, and, in essence, echoing the remarks that Tom Berne made, what we would like to see with organ donation is that it be a natural process. I think very critical here will be that families, just as they discuss their wills ahead of time or make important family decisions, that somewhere within that realm they have discussed what might be done at the time of death, perhaps some direction could be made toward a more explicit consent.

I really do not know the answer, but perhaps if this bill does become law, we could make this a part of the agenda for the advisory council to the National Center for Organ Transplantation.

Mr. WAXMAN. Let me throw out a statement as a challenge to you. Dr. Barry Jacobs, who is interested in going into the business of buying and selling organs, claims that the reason only 10 percent of the dialysis patients are registered for a kidney transplant is because there are not enough kidneys available for transplant purposes. They are aware of that, and therefore, not thinking about the possibility of a transplant. If Dr. Jacobs were permitted to go out and enlarge the pool of kidneys through using the profit incentive motive, that would encourage more patients to register. How do you respond to that kind of statement?

Dr. SALVATIERRA. Well, I can respond to that statement from my own personal experience at the University of California, San Francisco. We performed, last year 165 transplants, which was the largest number in the country. This year we will be probably closer to 200 transplants, but we cannot meet the needs of the patients in our area. We have a backlog of over 480 patients who are awaiting cadaver kidneys, over 50 patients who are awaiting living related kidneys. The referral rate there for that area of northern California is over 95 percent, but there has not been a single patient who has asked in any form or way to be involved in the purchase of a kidney.

Mr. WAXMAN. Dr. Berne, you criticized HICFA's medical information system for renal transplantation. Would you elaborate on what you view as its major deficiencies? What are the critical components of a scientific registry and what would benefit your work as a surgeon?

Dr. BERNE. I hate to be very specific and I would rather not be very specific about the defects. I know that there have been changes. I will simply say that we have been submitting data to the HICFA registry for a number of years since the change in the regulations which brought the medical information service into being, and at the present time, the data is presented in such a way that it is considered by most of those who might utilize it as being inaccurate. The time from its collection to its publication is much too long, and it has not been useful in making any kinds of decisions about particularly the outcome of various types of therapy or tissue typing or the other areas on which we had hoped that it would give us information.

The elements that are necessary in a registry, I believe, are the things that I just mentioned the HICFA program did not provide. We have to collect the data in such a way that it is believable; therefore, it is accurate. It must be processed rapidly enough that it is usable on a timely basis, and the type of data collected needs to have some bearing to its ultimate use to improve outcome in transplant patients.

The way that this was done with the American College of Surgeons/NIH registry run by Dr. Bergan for a period before the MIS, I think, was quite good. There are modern areas of computerization and other things that could be applied to that, but they did an excellent job.

Mr. WAXMAN. We had testimony from the Reagan administration that a comprehensive scientific registry is likely to develop without Federal assistance, perhaps under the auspices of the American Council on Transplantation. Do you agree, or do you think Federal assistance is necessary?

Dr. BERNE. Likely is kind of a hedging word. I think that there is such a strong feeling among people doing transplantation that something has to be done that a strong effort will be made somehow to get a functioning outcome registry. The problem is that without a source of funds to do this, there will be a delay, a considerable delay in getting it in place. The quality of it may suffer some from inadequate funding, and I suspect that it will take money from other areas that we also feel strongly need assistance where that money could better go.

Mr. WAXMAN. Dr. Terasaki, you now maintain the largest registry of clinical conditions and outcomes for transplantations. What information do you need to make the maximum use of your registry?

Dr. TERASAKI. Well, we would like to collect even more data than we do today, but since everything is on a voluntary basis, it is difficult to ask transplant centers to supply us with any more than they do today. We correspond with the centers on a monthly basis and return the updated output to each center monthly. There are 40,000 patients.

And I would like to mention that there is a difference between a scientific registry and a census registry. Census is where you want to make sure that you collect every single case, and you more or less count up what has happened. In a scientific registry you are trying to find out new factors and try to think about what is going on.

Mr. WAXMAN. How much do you figure the approximate cost of a strong national clinical registry would be?

Dr. TERASAKI. I am not too sure.

Mr. WAXMAN. If you want to send us a figure later, we would be interested in your views on it.

I understand that brain death has not been adopted by all the 50 States as a basis for declaring death. The President's Commission on Bioethics recommended adoption of a uniform national definition of death. Has lack of a uniform definition hampered organ donation activities?

Dr. SALVATIERRA. It has in some States. The threat of civil and criminal liability certain has been a deterrent to organ donations in some States.

Mr. WAXMAN. Do you think we need Federal legislation in this area?

Dr. SALVATIERRA. That is a difficult question for me to answer. I mean I do not know the exact way to obtain what we really want, and what we really want is that there be some uniform declaration or recognition of brain death, as was established by the President's Commission.

We ourselves, as a result of our joint meetings with the neurosurgeons, are coming out with some editorials in the neurosurgical journals, but we do need some help and actually perhaps people like you can best advise us how we might approach this, but it has clearly, I think, been a deterrent in some States, the lack of such a brain death law.

Dr. MENDEZ. It has not only been a deterrent to the actual procurement, but certainly in the sharing of organs there are many centers that will not accept kidneys from centers in which the organs were procured after cardiac arrest, feeling that they are inferior organs and may not function as well.

Mr. WAXMAN. Well, it is something that we want to work on with you.

Dr. SALVATIERRA. That is right.

Mr. WAXMAN. The Reagan administration testified that they thought it was unethical, and certainly wanted to stop entrepreneurs from getting into the business of buying and selling organs, but they opposed the provisions in our bill to make it a Federal crime. They argued that such practices might best be deterred through enactment of State and local laws. Do you have any views on that proposition?

Dr. MENDEZ. I think as Dr. Terasaki mentioned in his opening statement, with all of the major societies, physician societies, in the U.S. opposing vigorously this aspect of this type of activity, it is just not going to happen in any volume whatsoever. No one is really going to be doing this.

Mr. WAXMAN. So you do not think we need a Federal law to prohibit it. The practice will be pretty much nonexistent because of

the organizations opposing it and most of the transplant physicians not engaging in transplants using organs procured through sale; is that right? Dr. Terasaki.

Dr. TERASAKI. Well, I think there might be a problem in that in that physicians who are not qualified may go ahead and start transplantation. So I do believe that Congress should take the leadership role here in outlawing such a thing.

Mr. WAXMAN. And you would support a Federal law?

Dr. TERASAKI. Yes. I think that Congress should take that responsibility to do that.

Mr. WAXMAN. Dr. Berne.

Dr. BERNE. I agree. I think there is a snowballing effect of support from Congress. I am not exactly sure what the effect of a Federal law would be if people were not moved across State lines for the purpose of donation but certainly even if that were all that it controlled, it would, I think, set the precedent that would make it easier to get State legislatures to follow suit.

Mr. WAXMAN. Dr. Salvatierra.

Dr. SALVATIERRA. Our executive Council, American Society of Transplant Surgeons, does support this particular position, does support Federal legislation. The penalties that we may pay if this gets started may be too great.

One can look at the moral and ethical issues. You will be discriminating against the poor because it is the poor or that individual with economic difficulties who will most likely serve as donor and risk his health.

But then the other thing that has not been mentioned is that organs are also going to go to the highest bidder, and that is also going to place the poor with the same desperate illness, requiring transplantation, at a tremendous disadvantage as far as access to the organ transplant.

Then there are the health risks to both the donor and the recipient, and third, and very important is the fact that the sale of organs could undermine our voluntary donor system, which does depend on altruism and humanitarianism.

We have primarily been talking about kidneys because that is a paired organ.

However, we are also dealing with multiple organ donation, and I think that would be discouraged. This could have a devastating effect on the donation of organs which are not paired, such as the heart, the liver, and which can only be obtained from actual cadaver sources. So I think there are several real risks, and we ourselves who are committed to transplantation and as members of the respective societies, we have, as a group, spoken out, but this certainly does not deter other individuals from undertaking some of these processes, and the risks I think are too great.

Mr. WAXMAN. Dr. Salvatierra, there has been some confusion about your position on this legislation due to your membership on the American Council on Transplantation. Would you care to set the record straight?

Dr. SALVATIERRA. Yes, Mr. Waxman. The American Council on Transplantation is an umbrella organization of organizations that is primarily committed to professional and public education regarding transplantation and related issues.

I support this organization in regards to the objective of brining these groups together for the first time to discuss some common problems. However, the issues facing transplantation today are of a more critical nature and require much more urgent action than this type of loose federation could ever conceivably give.

I believe that these latter problems would be best solved by congressional action like H.R. 4080 proposes and which we have been discussing today.

There have been many patients and also many members of groups, participating organizations in the American Council of Transplantation, who have implored me to speak strongly for the problems faced by transplantation today and to support strongly the congressional bill that we are considering today.

So after careful review of the spectrum of problems faced by transplantation, I believe that the congressional steps presently being outlined and being considered today are the most appropriate and need strong support. I have indicated my position to the Surgeon General in a letter dated October 6, 1983, and I will submit a copy of this letter to you for your records.

Mr. WAXMAN. Thank you. We will include that letter as part of the record.

[The letter referred to follows:]

Record

American Society of Transplant Surgeons

Secretary:
David E. R. Sutherland, M.D., Ph.D.
Department of Surgery
Box 280
University of Minnesota
Health Sciences Center
Minneapolis, Minnesota 55455

October 6, 1983

C. Everett Koop, M.D.
Surgeon General
Department of Health & Human Services
Washington, D.C. 20201

Dear Dr. Koop:

I am writing this letter to indicate that I am taking a supportive position in regards to some Congressional legislation recently introduced. While organ procurement works well in some areas, this is definitely not universally so. I am impressed by families pleading for organs and funds to save or improve the lives of their loved ones. I am also impressed with the increasing concern of many members of the transplant community for the urgent need for the development of some concrete operative steps to be taken soon. These Congressional efforts present some immediate solutions that require strong consideration and support when one considers the present plight of many desperate patients.

I have and continue to actively support the American Council on Transplantation (ACT) as an umbrella body of organizations that will deal with professional and public education regarding transplantation and related issues. However, if my support of legislative efforts to provide help, as soon as possible, to needy and deserving patients is in conflict with my continuing to serve on the Interim Executive Council of ACT, please advise me of such.

As I examine this situation, I sincerely hope that the many well meaning people in Congress, the Administration and the transplant professionals themselves can all agree on an early solution that is, above all, in the best interest of these desperate patients and brings them and their families early relief.

I, again, commend you on your efforts and look forward to working with you in the future.

My best personal regards.

Sincerely yours,

Oscar

Oscar Salvatierra, Jr., M.D.

OS:hd
cc: Executive Council ACT
Gary Friedlaender, M.D.
William Kerr
Amy Peele, RN
Don Donny, MSW
Glenna Crooks, Ph.D.

Mr. WAXMAN. Let me thank each of you for your testimony. I want to commend you for the work that you have done in your fields, but in also giving thought to what actions we ought to take as we develop legislation. As we move this legislation forward, we want to consult with you and see how you think we can improve the proposal in order to accomplish the goals that we very much share.

Thank you very much for being with us.

Our final panel, and some of the members of this panel will be joining us a little later, bring a unique perspective to the issue of transplantation. They are from different backgrounds, but share a common and deeply personal concern. A stronger, more efficient system of matching donors with patients is not simply a matter of more money, sophisticated computers or better therapeutic techniques. It is also dependent upon public trust in a system based on voluntary donations and public awareness that organ donations are, in every sense, a gift of life.

We have joining us soon Gary Coleman, who is known to most Americans as the star of the TV show "Different Strokes." He has also been a transplant recipient and an active volunteer on behalf of the National Kidney Foundation. Mr. Coleman will be accompanied by Dr. David Ogden, president of the National Kidney Foundation.

While we are waiting for them to join the panel, we have other members who will come forward now to present their testimony.

Robert Memel is president of the Southern California Chapter of the American Liver Foundation. He is accompanied by Ms. Maria Greco, copresident of the Orange County Chapter of the American Liver Foundation.

Edward Greenberg is a kidney transplant patient from Woodland Hills, Calif.

Mr. Memel, why don't we start with you?

STATEMENTS OF ROBERT MEMEL, PRESIDENT, SOUTHERN CALIFORNIA CHAPTER, AMERICAN LIVER FOUNDATION, ACCOMPANIED BY MARIA GRECO, COPRESIDENT, ORANGE COUNTY CHAPTER; EDWARD GREENBERG, NATIONAL BOARD DIRECTOR, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPORTATION; AND GARY COLEMAN, LOS ANGELES, CALIF.

Mr. MEMEL. Thank you, Mr. Chairman.

It is a great pleasure, and I am very honored to be asked to represent the American Liver Foundation before the Subcommittee on Health and the Environment considering H.R. 4080.

I join with a number of the other members of the previous panel in thanking you, Congressman Waxman, for your compassionate attention to a matter which is of great personal interest to those of us sitting here today, as well as to many citizens of this country.

I am currently serving as president of the American Liver Foundation of Southern California, a chapter which has been recently formed. I was brought to my involvement in this organization through some very personal matters of interest.

I cannot address the technical data, which have already been so eloquently addressed by the rather awesome panel of experts already testifying, but I can address some of these issues from a personal perspective.

I am a current liver disease patient with an incurable and a progressive liver disease. My brother has lost one kidney to cancer and constantly maintains vigilance over functioning of the second. Currently neither one of us are considered transplantation candidates, and we appear on no lists. We are not currently enrolled in any programs for transplant candidates, but as part of our unconscious thinking, I am sure, only rarely raising to consciousness, is the possibility that we, too, may become transplant candidates in the future.

We are aware of the increasing acceptance of the transplant procedures, and with such, even at our relatively advanced age, we had hoped with the improvements in the procedures that should the Good Lord dictate, these will be available to us.

What I do suggest, Mr. Waxman, however, is that the pool of potential recipients of organ transplants is truly much larger than current statistics would indicate, thus making the current pool of available donors even less adequate than the current figures would indicate.

As president of the southern California chapter of the American Liver Foundation, I do have other data, experiential, anecdotal in nature, rather than of the scientific variety, that has already been presented to you to suggest that the issues this legislation addresses are of critical importance.

Not a week goes by when we don't receive inquiries. We, the officers, members, directors of the American Liver Foundation receive calls or letters from patients, and very frequently, perhaps most often, from parents of patients in obvious great distress and seeking information, guidance regarding obtaining donor organs, and regarding obtaining financial assistance in funding the transplant procedure. The people who call us, the people who write us seem completely lost and without any information as to the direction in which they may turn for information.

In a moment Maria is going to mention some specific instances of this that have happened within just the last few weeks. Currently two of our members are considering liver transplants, and I do not believe that either one of them yet appear on any list of candidates for transplant.

The best our organization can currently do, frustrating though it may be, is to make referrals to a system which we feel is not yet adequately organized or structured. We, frankly, are not sure at the local level where to refer these callers to.

Congressman Waxman, you inquired of one of the members of an earlier panel how else public awareness of the need for organ donors may be increased. We, at the American Liver Foundation, have begun to address this issue. Of course, our resources are limited. We have created a program of printed brochures, which we make available to physicians and through physician offices, as well as in places of public exposure. We have bumper stickers which our members are beginning to display and which others are beginning to display. We have donor organ cards, which we make available

wherever possible, and donor organ pins which often elicit a question about "what is that nice piece of jewelry" and gives us an opportunity to educate the inquirer.

We hope that one of our more successful programs will be the organ donor dots, which we have encouraged members of the public to attach to their insurance identification cards. It is our experience that having it attached to your license as it is in California is not often as effective as attaching it to an insurance identification form, which is presented each time the member appears and is admitted to a hospital or to a doctor's office.

I am certain that these efforts are helpful, but certainly these efforts are not the answer. We can have only a very limited impact.

Media exposure of dramatic liver transplants has had a twofold effect in our experience, one positive, and one perhaps not so positive. The dramatic media exposure has increased public awareness of organ donation needs, and in many instances to the limited funding for the medically needy.

But it also has a special effect which I have not heard yet addressed, and that is the depressing effect such coverage has on those who either are current transplant candidates or may become so in the future. Often unspoken, the feeling is: Will I have to be newsworthy when the time comes for my organ transplant? Will I get media coverage? Is my child cute enough to make the front page? Is my child in accute enough distress to make the front page? Can I enlist the President's aid in getting a liver transplant for my child? Is this, media coverage, the only way or even the best way to make my organ needs known?

This attitude infers the lack of trust which I believe exists in the present system of organ procurement and recipient matching.

Thus, Congressman Waxman, the American Liver Foundation supports the effort to fund an organized, well publicized and equitable system of organ procurement and recipient matching.

Thank you.

Mr. WAXMAN. Thank you very much.

Ms. Greco, we would like to hear from you.

Ms. GRECO. Thank you for having us here today, Congressman Waxman.

My name is Maria Greco. I am copresident of the Orange County Chapter of the American Liver Foundation. I am the victim of primary biliary sclerosis, a slowly progressive, fatal disease. There's no known cause and no known cure. It can happen to anyone, any time.

I feel that I am living with a time bomb.

No one is immune to this disease or to liver disease.

Over the years the liver has been sadly neglected. There has been a lack of funds to research liver disease. Therefore, today the only hope for some of us is a liver transplant.

Where will I go? Where will they get an organ? And how will I pay for it? These are the questions that need answers.

Luckily I do not need these answers today. I do not know on what day I am going to need these answers. However, there are people that do need the answers today. In Orange County a woman contacted me. Her name is Blanche. She has two children and no husband. She needs a transplant now. She does not have the

money. She wonders, where will they get an organ. Does a 40-year-old woman have the appeal of a Jamie Fiske? Does she have to parade her children and say they will not have a parent if I do not have a transplant?

Two days ago, being chairman and president of the Orange County chapter of the American Liver Foundation, I got a call from a woman who is totally distraught. She finally had been told her only hope is a transplant. She said, "What am I going to do? Where do I go?" She has no husband. Her husband died of a heart attack a few years ago. She has had the expense of her liver disease for the past 10 years. She has raised three children, and now she wants to know, "What do I do? Can you give me the answers?"

And, Congressman Waxman, I do not have the answers, and that is why I think it is so important. We have got to have a central place so that people like Blanche and Jerri and myself can find the answers and hopefully have some hope for a future.

And I thank you very much for having us here today.

[Brochure used by American Liver Foundation follows:]

Transplants A gift of life

Questions and Answers About the Organ Donor Program

Donated organs save lives.

Organ donation is an important decision. And it is one that should be considered carefully.

Yet for thousands of people there is no decision to make. They are waiting for a transplant . . . waiting for enough people to donate their organs leaving them a legacy of renewed life. Many wait in vain.

The human body is a storehouse of valuable tissue and organs. However, we still lack enough organs from children as well as adults for those who are in need of transplants.

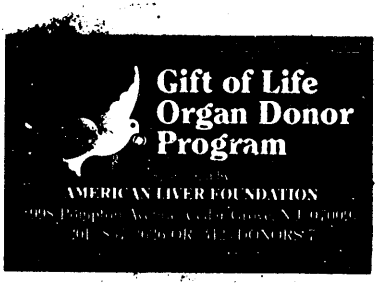
BECOME A DONOR. Give new life to someone.

How successful are organ and tissue transplants?

Transplantation of organs from one person to another was first attempted in the 19th century. However, it was not until the 1960's that significant progress was made in solving the problems of tissue preservation, surgical technique and rejection.

Today, kidney, liver and heart transplantations are well accepted therapies which are performed routinely at specialised transplant centers saving thousands of lives each year. In the United States, the number of kidneys transplanted each year is approximately 4,000. There will be approximately 100 hearts and 100 livers transplanted this year. The longest surviving recipients of both liver and heart transplantation are over 13 years post transplant.

Heart transplants now have amost 70% one year survival and approximately 50% five year survival. Corneas have approximately 90% graft survival at one year. Liver transplants have about a 60% one vear survival rate.



Questions and Answers About the Organ Donor Program

Why do we need more donors?

The success of transplantation is influenced by the quality and quantity of organs and tissues available. Liver and kidney recipients rely mostly on attending physicians and staff and concerned individuals to recognize suitable patients as donors. It is they who usually discuss with families the opportunity to donate the organs of their loved one. Carriers of Uniform Donor Cards confirm their willingness to be an organ donor.

How many people are waiting for liver transplants?

There are over 100 adults as well as children waiting for liver transplants and the number is growing annually. It would greatly facilitate the recovery of organs for transplantation if more people signed and carried Donor Cards.

If I move to a different state, do I have to fill out another card?

No, this card is legal in 50 states.

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

No. By law, determination of death is the responsibility of licensed physicians. They are required to sustain life until death has been determined with absolute certainty. The law in every state prohibits a physician who is caring for a patient from being involved in the donation and transplantation of that patient's organs after death.

What can I donate?

The Uniform Donor Card enables you to donate:

a. All organs
b. Specific organs
c. Your entire body for medical research.

Note: You can donate your entire body and/or any organs. Check with the nearest teaching hospital for details on donation of your entire body.

Can anyone sign a Donor Card?

Donor Cards are only legal documents if the donor is 18 or over. To insure that your wishes are respected, always keep the cards with you. They are legal documents.

Minors under the age of 18 may complete Donor Cards but they will not be considered as legal documents even if the signature is witnessed by a parent or legal guardian. The donation of organs of minors may be made at the time of death only by the parent(s) or legal guardian.

This should be an important consideration for parents/legal guardians or minors since there is an equal demand for pediatric as well as adult organs.

Is there a donor registry?

There is no national organ donor registry, since such a registry would be logistically and economically impractical.

What about my will?

The Donor Card is an instant will. A provision in your will may not be discovered until it is too late. Organs and tissues must be recovered immediately after death.

Can I change my mind?

Yes, simply tear up your records. New ones can be obtained at a later date if you wish.

Will my estate be paid or have to pay for organ donation?

No costs are incurred by the organ donor or his heirs. No payment may be made to the donor or the heirs.

What about funeral costs or burial arrangements?

Removal of organs or tissues authorized by a donor will not interfere with customary funeral or burial services. Furthermore, this procedure is carried out as a regular surgical procedure and will not in any way disfigure the body. Regular funeral costs, memorial services or burial arrangements remain the responsibility of relatives or persons in charge of the estate.

What about religion and transplantation?

Authorities of all major religions have indicated that signing and carrying the Donor Card is sanctioned by the life-saving traditions of each respective religion. If you have any questions about the religious acceptability of organ donation, consultation with clergy of your faith is advised.

What happens when organs are donated?

Organ and tissue retrieval is accomplished by regional organ banks. Contacting the nearest organ bank may be accomplished through your local hospital.

Special surgical teams are mobilized. The Regional Transplant Program tissue typing labs are notified to begin cross-matching and a search is made for the best possible recipient. The liver and other organs are retrieved as soon as possible, packed in ice and transported by auto, air, military transport or police helicopters to reach their destination as quickly as possible.

The Uniform Anatomical Gift Act has been passed in all fifty States. This makes it possible for anyone to legally donate his organs upon death by filling out the Uniform Donor Card. Sign it in the presence of two witnesses and carry it with you at all times. Inform your family so that your wishes will be carried out.

If you have any more questions or need more cards for your family or friends, call or write:

AMERICAN LIVER FOUNDATION
998 Pompton Avenue
Cedar Grove, N.J. 07009
(201) 857-2626

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

I give: _____ Any needed organs or parts.
or: _____ Only the following organs or parts.

For the purposes of transplantation, therapy, medical research or education.

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.

Mr. WAXMAN. Thank you very much.
Mr. Greenberg.

STATEMENT OF EDWARD GREENBERG

Mr. GREENBERG. I am here by your invitation to share with you my own personal medical history, as well as those experiences, feelings, and personal insights I have had since I became aware of the fact that I had end stage renal disease.

I am a director on a national board of the National Association of Patients on Hemodialysis and Transplantation, known as NAPHT. At our national convention, held in Sacramento, Calif., on October 21 through 23 of this year, a motion was passed opposing the sale of human organs. Further detailed information will be sent to your committee by NAPHT national office.

Because I have benefited so much as I have moved stage by stage from maximizing the useful life of my polycystic kidneys to dialyzing in a center to home dialysis to a living donor transplant protocol and finally to a successful cadaveric transplant, I am very grateful. To show my appreciation, I have become actively involved in several organizations whose goals concern kidney patients' needs and/or the betterment of the organ and tissue transplant situation.

I have mentioned my association with NAPHT. I would also like to tell you about ATAC. ATAC, the Anatomical Transplant Association of California, is a State organization whose specific purpose is to increase the availability of human tissue and organs for, first, medical transplant and, second, medical research and education. Its members consist of donor families, recipients, lay people and professionals sharing the achievement of these goals. I believe their goals parallel yours, except that your goal is national.

Now, to give you some of my medical history. In 1969 I was diagnosed as having polycystic kidneys. From 1969 until February of 1978, Dr. Alan Kanter and Dr. Dennis Sloan, nephrologists in Chicago, treated me. In February of 1978 vascular surgery to repair a fistula was done, anticipating a need in the near future. On September 16, 1978, I had a pulmonary edema episode, and on September 20, 1978, I had my first hemodialysis treatment.

As well as I had been prepared, and I do want you to know that Drs. Kanter and Sloan had fantastic personnel from the vascular surgery on, these were traumatic times for the whole family. All of these new things were happening to me. I knew they were all in my best interests, but this did not disspell the fear of the unknown.

My family, the staff and I worked it out. Early in October of 1978, my family and I were asked if we would consider home dialysis. After our many questions were answered, we as a family, decided that home dialysis was the way to go. My wife and I started training in January of 1979, and in July, we received our certification of competency and went home to dialyze.

I would recommend this mode to anyone fortunate enough to having a willing partner. Although I felt well while on dialysis, I was encouraged by the center's professional staff and my family to consider a kidney transplant as a viable alternative.

After investigating transplantation with two surgeons in Chicago and being assured by both that I was a good candidate, I chose one

surgeon because he did not require a spleenectomy nor a nephrectomy as part of his protocol. My nephrologist concurred.

After completing the protocol, I was placed on the transplant list. I waited for 2 years, never hearing from the surgeon, and continued to dialyze at home. In 1980, while visiting friends in Los Angeles, I met Barbara Schulman of Regional Organ Procurement Association (ROPA) who accompanied us to a NAPHT meeting and introduced me to Dr. R. Mendez, who was a speaker for the evening. His talk so impressed me that I made an appointment to see him.

After our consultation and an examination, he agreed to accept me as a transplant candidate. He broached the subject of live donors since I had a brother. My brother agreed to be a donor, but the necessary arrangements were extremely complicated, since I lived in Chicago, my brother in Hamden, Conn., and Dr. Mendez, as well as the lab, was in Los Angeles.

As the protocol advanced favorably, my brother's family requested that the transplant be done at Hartford Hospital, since their techniques were identical with Dr. Mendez' and it was closer to my brother's home. We concurred, and Dr. Mendez agreed to handle my postsurgical treatment.

Surgery was scheduled July 15, 1981. It was canceled on July 14 due to elevated enzymes in my brother's liver. At that point my brother told me that once he left the hospital, there was no way he could ever psych himself up again to be a donor. It had been quite an ordeal for him.

I understood and immediately contacted Dr. Mendez, who agreed to put me on his cadaveric recipient list. My family and I moved to Woodland Hills in August of 1981, took up residence while I continued to dialyze at a local center, and wait for a kidney match.

On December the 6th, 1981, I was called and told a kidney was available and to be at St. Vincent's Hospital the next morning. The final cross-match was completed, and at 3:30 p.m. on December 7, 1981, the transplant was performed.

Postsurgical recouperation was standard. As anticipated, on the eighth day, I had a rejection episode which was successfully reversed. After 3 weeks I was discharged, but 2 days later I returned to the hospital with symptoms of another rejection. I was treated for 10 additional days and then discharged.

I have suffered no further rejection episode since that time. Due to the immunosuppressant drugs I am taking, I experienced side effects: Facial puffiness, skin very susceptible to bruising, some personality changes such as having a very short fuse, and steroid diabetes.

In closing, I would like to state unequivocally that all of the side effects, pain and trauma have been worthwhile measured against the improved quality of life I am now enjoying.

Please feel free to ask anything of me that will give you the inner feelings and thoughts I had during these situations that I frankly find difficult to put on paper, but which I can usually verbalize well.

I thank you for this opportunity of appearing before you, and I close respectfully.

Mr. WAXMAN. Thank you very much, Mr. Greenberg, Mr. Memel and Ms. Greco. To come before a congressional committee and a public audience to talk about your personal situation in some ways can be difficult, but it is a real public service. So many people want to know because they are going through the same kind of situation others have gone through. They need to know what to expect and what hope there is for them.

You, of course, Mr. Greenberg, have a very happy ending to your story, and it is an inspiring one. It gives us the reason why we need legislation like this, so others can share in that same happy ending.

Mr. Memel and Ms. Greco, you raise with us the problem of those who are looking for a liver and know that it will be to them a gift of life. How many liver transplants take place in southern California or in California? Is this an unusual procedure, are there many such transplants that do take place, and are they increasing?

Mr. MEMEL. Well, currently, Mr. Waxman, it is our understanding that from our personal experience at least, most of the transplant procedures have taken place at Pittsburgh or in Minnesota. I understand that there are some facilities at Stanford, that there are facilities that have recently been opened or are in the process of being opened at UCLA, but our experience has not extended to those facilities.

Mr. WAXMAN. So by and large the surgery takes place in other centers?

Mr. MEMEL. Our experience by and large has been that they have, that our people have had to go out of State for these procedures, which has of course measurably increased the cost, and there is an ancillary feature to having to go out of State, which is the lack of information that our people have when going to Pittsburgh, going to Minnesota, about the facilities and so forth, which we do try and address.

Mr. WAXMAN. You are involved in this campaign to inform people about the gift of life organ donor program with buttons and the indications of dots on the insurance cards. We are trying to promote the voluntary donation of organs through this kind of publicity.

What is your attitude toward the idea of someone setting up some kind of payment to the heirs of those who, when they die, donate their organs? Ms. Greco.

Ms. GRECO. Quite frankly, it frightens me. The problem of paying for a transplant today is difficult enough without being faced with the prospect of having to bid on an organ. Today the situation exists that it is an economical choice as to who gets the first transplant because I know I do not have $100,000 to spend on a transplant. Neither do the other people that I know, and I know very few people that could come up with that kind of money.

However, if you are talking about selling organs, then definitely they would go to the highest bidder, and I find this even more frightening economically. It also bothers me ethically and morally.

Mr. WAXMAN. Mr. Memel, do you have any thoughts you want to add to that?

Mr. MEMEL. Yes; I believe even though there are those who are in acute distress and in a position of being extremely distraught

when they approach us about the question of organ transplant, I believe that we would face the same issues with respect to purchased organs as we currently face with those who do not believe themselves newsworthy, that they are going to have to compete in the marketplace for either media attention or for a purchased organ. I believe that it would be ineffective to have that competition in the marketplace from that standpoint.

Of course, the ethical and moral issues have been very eloquently addressed previously, and I concur with the previous speaker on that issue and with Maria on that issue, but from a practical standpoint, as well, we do not believe it would be efficient or effective.

[The following brochure was part of Mr. Greenberg's prepared statement:]

TRANSPLANT KIDNEYS DON'T BURY THEM

NAPHT

NATIONAL ASSOCIATION OF PATIENTS
ON HEMODIALYSIS AND TRANSPLANTATION

NEED

Man has been interested in transplanting tissues and organs for many centuries. Today medical science makes it possible, and a variety of vital body organs and blood components are replaced when the need arises. Techniques for transplanting kidneys and corneas are currently the most advanced.

KIDNEY TRANSPLANTS

The first successful kidney transplant took place in Boston in 1954. Since that date, much progress has been made and thousands of transplants are performed each year.

Unfortunately thousands of persons who suffer from chronic kidney failure cannot receive a much needed kidney because not enough donor organs are available. The need can be met if enough people become aware of the problem and are willing to donate their organs at the time of death. The procedure is a simple one. Simply sign a donor card and your signature will enable someone to receive the greatest gift of all—the gift of life.

LEGAL ASPECTS

A Uniform Anatomical Gift Act was approved in 1968 to help meet the legal requirements of donation. Most states have since passed legislation modeled after the Uniform Act. Individual laws are available from state authorities. The attached donor card complies with this Act. Removal of organs, authorized by a donor, will not interfere with customary funeral or burial arrangements. The estate of a donor is neither charged nor compensated for the organ.

RELIGIOUS ASPECTS

Most religious leaders feel that a donation of organs, to help improve or lengthen the life of another, is an expression of the highest humanitarian ideals. If you have any question, consult with your religious leader.

DETAILS

Anyone at least 18 years old (in most states) and of sound mind may become a donor by signing the attached card in the presence of two witnesses who must also sign. No registration of this card is necessary. It is

important to inform your family and/or physician to help insure their cooperation. The attached donor card offers you a choice of options: 1. any needed organs, tissues or parts. 2. restricts the donation to organs or parts you specify. 3. gives your entire body for anatomical study. Carry the card with you at all times. At the time of death, if circumstances permit, and the organ donation can be used, your gift will become a reality. If you change your mind anytime after signing, simply tear up this card.

YOU CAN GIVE TODAY—DONATE BLOOD

Blood transfusion was first suggested in the 1500s, and the first successful procedures took place in 1818 in England. At that time, Dr. James Blundell transfused human blood to control hemorrhage in mothers who had just given birth. Today advanced technology permits the use of components as well as whole blood. This means that one pint of blood donated by you may serve as a life-saving gift to many. Since blood cannot be stored for long periods of time, regular donations are necessary to insure an adequate supply.

Donating blood is a painless procedure which usually takes less than one-half hour. When blood is given, the body acts immediately. Fluid stored in the tissues returns to the blood stream, and red cell production speeds up. A donor's blood volume is restored in several minutes to a few hours. In 1974, the nation adopted a goal of an all-voluntary supply of blood.

Generally those over 17 and not yet 66 are eligible to donate blood. Details can be obtained by calling your local community blood center. The need for blood can only be met if you take the time to give, so that this vital human tissue will be available for you and your loved ones.

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 purposes of transplantation, therapy, medical research or education:

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

Limitations or special wishes, if any: _____

NAPHT, the largest, non-profit, voluntary kidney patient organization in the country, is dedicated to improving the quality of life for all renal patients. Promoting an Organ and Blood Donor Program is one facet of our work. NAPHT believes that those suffering from chronic renal failure should have a choice of therapy--dialysis or transplantation. If more donor kidneys are available, that choice will be possible. Activities such as this Donor Program are made possible by the voluntary contributions of a concerned and generous public.

NAPHT

NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPLANTATION
156 William Street, New York, N. Y. 10038
(212) 619-2727

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

SIGNATURE OF DONOR	DATE OF BIRTH OF DONOR
CITY AND STATE	DATE SIGNED
WITNESS	WITNESS

IN EMERGENCY CALL: (212) 861-7370

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

Mr. WAXMAN. Thank you.

We are pleased to have Gary Coleman, who is a very well known actor, with us to participate in this hearing. We are discussing legislation, as you know, that would reach out to people to inform them about donating their organs for organ transplants. The legislation has a number of parts to it, not only to reach out and encourage people, but to try to match those who are looking for organ donations and those who are going to become the donors themselves. The legislation also does one other thing. It prohibits the buying and selling of organs. You may not have had a chance to review the legislation specifically but we would like to hear from you on the whole subject because you are personally involved and have been a national spokesman for the National Kidney Foundation. We would like to hear what thoughts you may have.

STATEMENT OF GARY COLEMAN

Mr. COLEMAN. OK. I have this testimony here. I have not read it yet, so I have to see what it says. While I am reading it, I guess I could say that what I feel about selling organs is I really do not think that is necessary. If there was some way you could encourage people to sign donor cards and get donor cards that would be better because, you know, you would have all kinds of people trying to sell their organs just for the money, and you do not know where these kidneys would be coming from, especially with all of these different things that are going on right now.

I have been the chairman of the National Kidney Foundation for the last 5 years. You know that, and I have had the opportunity to do several television spots encouraging donor cards, the use of donor cards, which would be more efficient, I feel.

Basically that is all I have to say about the subject.

Mr. WAXMAN. Well, you are personally concerned about it. You had a kidney transplant; is that right?

Mr. COLEMAN. Yes, 2 years ago.

Mr. WAXMAN. And you are waiting yourself?

Mr. COLEMAN. Yes, I am waiting for another kidney, yes.

Mr. WAXMAN. And you are one of the thousands of people in this country who——

Mr. COLEMAN. Ten thousand.

Mr. WAXMAN. Ten thousand people who are waiting for the opportunity of a kidney transplant?

Mr. COLEMAN. Right.

Mr. WAXMAN. What would you say to people who are going to have the opportunity to hear you today as a spokesman for the 10,000 that are waiting for someone to donate a kidney or to those thinking about donation should they die?

Mr. COLEMAN. Well, I think the real thing for the 10,000 patients to do is really they just have to wait because I do not think selling organs is going to be profitable or logical. I am sort of tongue-tied here. I really do not know what to say, but it sounds very bad to me to try and sell organs for money. You really would not get a healthy kidney, and say that person sold his kidney and something went wrong with him. He would feel really stupid then: "Well, I sold my kidney. No wonder I am sick," you know. So you would have that kind of problem, too.

And then you would make the amount of kidney patients bigger because these people get sick, you know, the ones that sell their

kidneys. They get sick, and that will make the number of kidney patients bigger.

Mr. WAXMAN. Well, we need more kidneys. We need more organs to transplant.

Mr. COLEMAN. Yes, we need more kidneys. We need more organ donors. That is what we need.

Mr. WAXMAN. Donors, people to do it voluntarily.

Mr. COLEMAN. Right, right, right.

Mr. WAXMAN. And tell me what you are doing in this campaign to encourage people to donate.

Mr. COLEMAN. Well, in my kidney spots I encourage signing organ donor cards, and somewhere in the kidney spot explain what the procedure is, what the need is in the way of kidneys, and basically that is the kidney spot. That is the whole thing.

Mr. WAXMAN. We have a little blue card here which says "Gift of Life, Organ Donor Program." This particular card is put out by the American Liver Foundation, but if people would just take a little card like this and fill it out, they are not expecting anything to happen to them, but we know that thousands of people are in accidents and suffer brain damage. People should be more aware that they can give this gift of life, we do not need to buy kidneys or organs of any sort because there are enough people around who can donate them.

Mr. COLEMAN. Right.

Mr. WAXMAN. Well, I want to thank all of you for being with us. We are trying to move some legislation because there are so many people now heroically working as you all are to bring this whole issue to the public's attention so that they will be more aware of what they themselves can do.

We need to put a greater emphasis on that, to match the organs that are available to those who need them and to make them available through a national system. To do that seems to me will give hope and will give life to those who need it.

Mr. COLEMAN. Right.

Mr. WAXMAN. Thank you very much for being with us.

That concludes the meeting of the subcommittee. We stand adjourned, and I thank everybody for being with us today.

[Whereupon, at 2:10 p.m., the hearing was adjourned.]

[The following statements and letters were submitted for the record:]

Statement of

Mary Jane Jesse, M.D.
President

AMERICAN HEART ASSOCIATION

to the

Subcommittee on Health and the Environment

on H.R. 4080, the "National Organ Transplant Act"

October 20, 1983

The American Heart Association has carefully monitored developments in transplant surgery since the first successful heart transplantation procedure in 1967. We have supported research and training projects that have contributed substantially to the evolution of this surgical development and have given careful consideration to the social, economic, medical and ethical aspects of heart transplantation.

We believe the Food and Drug Administration acted appropriately on the basis of its findings in carefully controlled scientific studies when it approved the new immunosuppressive drug, cyclosporine A, for therapeutic use in organ transplant surgery in September, 1983.

This valuable new drug will surely be of great benefit to patients who are being treated in such established programs as renal transplantation, and in other developing transplant programs.

Now that surgeons will have an increased ability to control rejection mechanisms following organ transplant surgery, we expect this to have a profound effect on the field of organ transplantation.

We believe this development will bring new pressures to increase the number of such procedures that are performed and to establish additional transplant centers. It will also serve to give new hope to many persons now awaiting the availability of donor organs and to potential transplant recipients. It should be noted, however, that suppression of rejection mechanisms is not the only problem faced by physicians and transplant surgeons. Organ transplantation still will not be the solution for many very ill persons.

These expectations have led us to support legislative proposals now before the Congress that call for careful studies of the needs and problems in organ procurement and distribution, transplantation technology and mechanisms for reimbursement of the substantial costs of organ transplantation.

The American Heart Association maintains its position that many of the developing transplant programs -- including transplantation of the heart and of the heart and lungs -- must continue to be evaluated in order to determine the long-term effect of such procedures. This evaluation should include careful study in a limited number of centers where a clinical trial setting is possible.

This position is in no way at odds with the provisions in H.R. 4080, the "National Organ Transplant Act."

This proposal would:

- authorize a program of grants for the development and expansion of local Organ Procurement Organizations throughout the nation;

- create a United States Transplantation Network to match donated organs with potential recipients;

- establish a National Center for Organ Transplantation within the Department of Health and Human Services;

- revise Title XVIII of the Social Security Act to permit the Secretary of Health and Human Services to pay for organ transplants at a limited number of specialized centers;

- revise Title XIX of the Social Security Act to require states to develop written policies for the payment for transplant procedures under Medicaid, require Medicaid programs to participate in any transplant programs established under Medicaid and require designated transplant centers to serve Medicaid patients; and

- prohibit the sale of human organs.

This legislation was devised to establish a rational and comprehensive national strategy to cope with the increasing problems that surround organ procurement and distribution, transplantion and cost reimbursement.

The need for this proposal was identified in several Congressional hearings:

- in April, 1983 by the Subcommittee on Investigations and Oversight of the Committee on Science and Technology;

- in July, 1983 by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce; and

- in the additional hearings currently scheduled by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce on October 17 and 31, 1983.

In addition, a National Workshop on Solid Organ Procurement, held in June, 1983 by the Surgeon General of the United States, Dr. C. Everett Koop, called for greater coordination of donor organ procurement organizations, increased public and professional education on organ transplantation and the need for increased numbers of donor organs, and accelerated leadership by the Federal Government in bringing this about. The workshop recommended that this be accomplished primarily through private, rather than public efforts.

The American Heart Association believes that order must be brought out of the chaos that currently exists in organ procurement and transplantion. We believe our nation is in need of a rational, balanced public policy that will best serve the health interest of its citizens and that will resolve the many complex scientific, medical, social, economic, ethical and legal questions that have been raised.

In hearings already held, or that are currently scheduled by this committee, the committees of Congress have sought the advice and counsel of many individuals and organizations with expertise in organ procurement, transplantation and reimbursement. They have also heard from ordinary Americans who know from tragic personal experience the frustrations that can arise from, and the shortcomings that exist within the present fragmented and uncoordinated system.

We believe that after careful study of this collective evidence this committee should be able to determine if the specific national program strategy proposed in H.R. 4080 has sufficient merit -- or if additional study is required, as is proposed in other legislative initiatives before the Congress.

We support the concept that the Federal Government take the leadership in devising and implementing a national organ transplant program to facilitate progress, establish medical and scientific guidelines and criteria and coordinate the activities of national, regional and local individuals, institutions and organizations.

We are convinced that only the Federal Government has the resources effectively to implement such a program. The needs and problems are too broad and too multi-faceted to be resolved by the spontaneous efforts of organizations and institutions operating in the private sector, however sincere and well- intentioned these may be.

The American Heart Association therefore supports H.R. 4080 which we believe addresses this important problem in an appropriate and timely manner.

Thank you.

B0504

AMERICAN HEART ASSOCIATION® GREATER LOS ANGELES AFFILIATE, INC.

2405 WEST EIGHTH STREET, LOS ANGELES, CALIFORNIA 90057 • (213) 385-4231

November 8, 1983

The Honorable Henry A. Waxman
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Waxman:

The American Heart Association/Greater Los Angeles Affiliate was pleased to be represented at the hearings on H.R. 4080, "The National Organ Transplant Act," held at St. Vincent's Hospital in Los Angeles on October 31, 1983, by Mrs. Carol Waters and myself. Although not formally asked to testify, we endorse the position already taken by the National President of the American Heart Association as contained in a statement by Dr. Mary Jane Jesse on October 20, 1983.

The issue of heart transplantation and its social, economic, and prognostic elements have been particularly in the forefront in this community in recent weeks, as highlighted by the plight of Derek Gordon and his family.

The following excerpts from Dr. Jesse's comments bear repetition:

1. The American Heart Association maintains its position that many of the developing transplant programs -- including transplantation of the heart and of the heart and lungs -- must continue to be evaluated in order to determine the long-term effect of such procedures. This evaluation should include careful study in a limited number of centers where a clinical trial setting is possible.

2. The American Heart Association believes that order must be brought out of the chaos that currently exists in organ procurement and transplantation. We believe our nation is in need of a rational, balanced public policy that will best serve the health interest of its citizens and that will resolve the many complex scientific, medical, social, economic, ethical and legal questions that have been raised.

3. We support the concept that the Federal Government take the leadership in devising and implementing a national organ transplant program to facilitate progress, establish medical and scientific guidelines and criteria and coordinate the activities of national, regional and local individuals, institutions and organizations.

4. We are convinced that only the Federal Government has the resources effectively to implement such a program. The needs and problems are too broad and too multi-faceted to be resolved by the spontaneous efforts of organizations and institutions operating in the private sector, however sincere and well - intentioned these may be.

We therefore join those who formally testified in favor of H.R. 4080 in looking forward to a more consistent and structured approach to the efforts of you and your colleagues in Congress and express our commendations on what has been accomplished to date.

I would greatly appreciate your having this letter made a part of the transcript of the hearings being held on H.R. 4080.

Please let us know if we can be of further assistance in this important endeavor.

Yours truly,

L. Julian Haywood, M.D.
President, American Heart
Association/Greater Los
Angeles Affiliate

LJH:nr

111N/z

AMERICAN LIVER FOUNDATION

TESTIMONY OF

THELMA KING THIEL

representing

American Liver Foundation
998 Pompton Avenue
Cedar Grove, NJ 07009

Presented at Hearings
Before the

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
COMMITTEE ON ENERGY AND COMMERCE
"NATIONAL ORGAN TRANSPLANT ACT"

AMERICAN LIVER FOUNDATION

I am Thelma King Thiel, Executive Director and Vice Chairman of the American Liver Foundation. I am also the mother of a son who died of biliary atresia before liver transplants were a viable option.

In my position at the Foundation, I have been sharing daily the frustrations and anguish of parents and patients desperately waiting for liver donors to be found and trying to help them cope with their struggle to raise the funds required to pay for this life saving procedure.

Gentlemen, I applaud your efforts in focusing national attention on this multifaceted and fragmented problem of organ identification, procurement and distribution. There needs to be a coordinated effort to bring together dedicated, concerned and highly trained individuals, lay and professional organizations in a partnership with government to find effective solutions.

Remarkable advances in research providing life saving options for thousands of patients through transplant surgery have outdistanced our ability to change attitudes and educate millions about organ donation. It is critical that we salvage every possible organ to respond to the demand. We need every resource available to preserve life. Each of us has a key role to play and want to be partners in the process. The American Liver Foundation is anxious to work in tandem with other organizations and the government to expedite essential programs.

AMERICAN LIVER FOUNDATION

ALF has already launched a national donor awareness campaign distributing thousands of donor information sheets, donor cards, bumper stickers, t-shirts and donor dove lapel pins and tie tacks using the dove as a symbol of representing organ donation. Perhaps the most effective thing we have done is to distribute ORGAN DONOR DOTS. These pressure sensitive dots placed on medical insurance I.D. cards alert hospital personnel instantly of a patient's willingness to be an organ donor should the appropriate situation arise. Organ donor cards tucked away in wallets may not be retrieved on admission to a hospital but we all know that hospital admission clerks will insist upon seeing medical insurance identification cards to record the necessary numbers for billing purposes. Gentlemen, this is a sure fire way to increase organ donors. We have asked the American Council of Life Insurance and the Health Insurance Association of America to encourage their member companies to adopt and promote the use of these ORGAN DONOR DOTS.

Thousands of these dots have been distributed through ALF's Chapter network, women's clubs and other organizations. Your encouragement of this simple way of increasing organ donation could have a significant impact on the number of organs retrieved without the need for costly computerized record keeping.

ALF also has major concerns that quality of care for patients be assured and that geographical location be considered in the process of designation of centers. The proliferation of liver transplant units being established will escalate health care delivery costs and place a burden on medical facilities

already experiencing staffing shortages. Patients need assurance that experienced health care providers will be caring for them. Tax payers need to be assured of cost containment in the provision of these technical services.

Reimbursement for transplant surgery still remains a critical issue in spite of the consensus opinion of experts in the field designating liver transplantation as a therapeutic modality. This is causing unnecessary stress and anguish for patients and their loved ones. Now that cyclosporin has received full approval by the FDA, the high cost of this drug, often exceeding $1,000 a month, must be covered by third party payers for as long as it is needed by the patient. Without it all benefits of the transplant will be destroyed.

Currently, Prudential, CIGNA, Travelers, Metropolitan Life Insurance Company and other third party payers are providing reimbursement for liver transplants. Why is the government delaying their decision on reimbursement? Why are kidney transplants covered . . . while liver transplants are not? The Public Health Service is sitting in judgement of "who shall live and who shall die." Liver patients don't have the luxury of dialysis that kidney patients do. Without a liver transplant many victims of liver diseases will die in a short period of time.

Tragically, the 5 1/2 million dollar federal cutback in liver research funding in fiscal year 1982 drastically curtailed advances in the search for effective treatments and cures for liver diseases. Each day is precious. We need action now.

Thank you for granting me this opportunity to share our concerns.

Testimony of David A. Ogden, M.D.

President of National Kidney Foundation

National Organ Transplant Act (H.R.4080)

Los Angeles, California

October 31, 1983

Mr. Chairman, Committee Members, ladies and gentlemen: My name is David A. Ogden, M.D., President of National Kidney Foundation, Professor of Medicine and Chief of the Renal Section of the University of Arizona College of Medicine. I have actively worked in the clinical and investigative aspects of kidney transplantation for the past 20 years, and would like to speak from this perspective and for the many thousands of members of the National Kidney Foundation.

I would like to address my comments to the following issues in turn:

1. The current and highly emotional issue of kidneys for sale, or organ purchases;
2. Transplantation of foreign nationals;
3. The concept of a National Center for Organ Transplantation, a United States Transplantation Network, and qualified regional Organ Procurement Organizations.
4. Concerns regarding the current approaches to facilitating organ donation and transplantation.

Kidneys for Sale:

The National Kidney Foundation has for many years encouraged and worked for a national health policy to assure equal access to the highest quality of kidney disease care for all Americans. Our Gift-of-Life program, which has included the distribution of over 30 million donor cards, has encouraged, with considerable success, the gift of cadaver organs on a voluntary basis. These organs have been transplanted based on medical need and criteria without discrimination based on race, sex, social, or economic status.

The National Kidney Foundation is firmly opposed to the sale of donor organs for both medical and ethical reasons, as follows:

1. Experience with living unrelated donors reveals no improvement in graft or patient survival compared to cadaver donor transplants.
2. The recipient's interest in and right to the best organ available might be compromised by the donor's interest in a cash reward for donation.
3. It is immoral, and unethical, to place a living person at substantial risk of surgical complication and a small risk of death for a cash payment.
4. The long-term risk, if any, of life with a single kidney remains to be determined.
5. The temptation of a cash reward for donation would violate the basic concept and sanctity of informed patient consent to invasion of his or her body.
6. We recognize, perhaps more than most, that the need for donor organs is presently incompletely met. We fear, however, that placing a price on a donor organ will undermine the current system of a voluntary Gift of Life, and will actually decrease the number of organs now available for transplantation.

Transplantation of Foreign Nationals:

Although this topic is not part of HR 4080, it certainly relates to the concept of this bill, and I would like to address it briefly. The National Kidney Foundation believes that kidneys and other organs donated by deceased American citizens or their next of kin are inherently intended by the donor to benefit a fellow American citizen, if a suitable recipient can be identified by the matching program in effect at the time. However, we also believe the donor, above all, does not want the donation wasted for lack of a suitable recipient, and is fundamentally interested in giving a Gift of Life. Therefore, when a suitable American recipient cannot be identified, transplantation to a foreign national is entirely appropriate.

National Center for Organ Transplantation, United States Transplantation Network, and Organ Procurement Organizations:

The National Kidney Foundation strongly endorses the concept of a National Center for Organ Transplantation at the level of the Assistant Secretary for Health, and concurs in its listed functions of public education, technical assistance to organ procurement organizations, and annual evaluation and reporting of the efficiency and effectiveness of organ procurement and distribution. We also support the proposed broadly based composition of its advisory council, and its defined areas of concern including equitable patient access to organ transplantation and organ allocation, and payment for non-renal organ donation. We also feel, however, that any organ transplant advisory council should be charged with addressing a number of other issues of immediate, even pressing pertinence to organ donation and transplantation including the following:

1. Professional and para-professional education concerning organ donation including organ specific potential and suitable donor criteria;
2. Early identification of donors by emergency medical technicians, emergency room personnel, and critical care personnel;
3. Enhancing interprofessional cooperation in organ donor identification and procurement;
4. Minimizing or eliminating professional liability at all stages of potential donor identification and organ donation, perhaps including a Good Samaritan clause in appropriate legislation, through enactment of a Uniform Brain Death Law by each state, and other appropriate measures;
5. Achieving enactment of a driver's license donor law by each state, including evaluation of the optional designation method now in place in a majority of states vs. the mandatory yes-no (and possibly undecided) designation alternative;
6. Achieving third party payment and/or Medicare-Medicaid entitlement coverage of not just non-renal organ donation, but of appropriate non-renal organ transplantation at approved and designated transplant centers;
7. Achieving third party payment and/or Medicare-Medicaid entitlement payment of out-patient prescription drugs for transplant recipients, an issue brought to sharp focus by the very high cost of Cyclosporine and probably of immune suppressant drugs yet to be developed.

We strongly support the concept of a private non-profit entity, referred to in HR 4080, as a United States Transplantation Network. We feel a national registry of potential recipients, and a national acquisition, matching and distribution system is a key element in facilitating donation and efficient, effective utilization of organs. We not only endorse, but most strongly urge the collection, analysis, and regular publication of the demographics and results of organ procurement and of transplantation, including transplant outcome data, patient outcome data, and causes of loss of both untransplanted and transplanted organs and patient death. We would encourage the U. S. Transplantation Network to fund, directly or indirectly, biomedical research pertinent to whole organ acquisition, preservation and matching, and transplant immunology and treatment. We support the concept of regional Organ Procurement Organizations as non-profit entities under the general direction of the U. S. Transplantation Network.

Concerns Regarding Current Approaches:

The National Kidney Foundation is aware of three current approaches to solve the inadequacies of the present organ procurement system; the Surgeon General's recent Workshop and resultant proposals on Solid Organ Procurement; Senate Bill 1728 introduced by Senator Kennedy and others August 2, 1983; and HR 4080 introduced Oct. 5, 1983 and now under discussion. Private individuals in desperate need of a heart or liver for themselves or for loved ones have made public appeals for a donor on television. The President of the United States made a radio appeal for a liver donor. There is an obvious need for a well thought-out national plan for enhanced whole organ procurement and transplantation that addresses all needs in a cohesive manner and with a consensus for a national solution to the issues. We cannot afford a hasty, piecemeal approach to this problem. I would like to offer the resources of the National Kidney Foundation and the experience of its constituency to help develop a broad national plan that effectively addresses the issues in organ procurement and transplantation.

Thank you all for your attention.

'Cash Market' Is No Place for Trade in Vital Organs

By ARTHUR KAPLAN

9-21-83

LOS ANGELES TIMES

OP ED

It seems that hardly a week goes by without someone appealing on television or in the newspaper for an organ to save his or her life or the life of a loved one. Only last month, the media were reporting the efforts of a small Wyoming town to raise money through bake sales and car washes to pay for the costs of a liver transplant for one of the local children. In New Jersey a frantic mother had to resort to pleading in the newspapers in order to persuade state officials to pay the $100,000 fee demanded by a hospital for performing a heart transplant on her son. These and countless similar desperate efforts poignantly illustrate the inadequacy of current public policy in the field of organ transplantation.

Literally thousands of people are on waiting lists around the country, hoping day after day that suitable organs will be found for them. Nearly 4,000 await corneas to restore their sight. More than 6,000 await donor kidneys to free themselves from the tyranny of thrice weekly six-hour sessions on dialysis machines. The waiting lists are shorter for heart, liver and lung transplants, since most people needing these die long before suitable organs are located.

The plight of these people has not gone totally unnoticed. The free market abhors a vacuum; commerce eventually rushes in, especially when the potential customers are desperate. This week, the Washington Post reported on the plans of a physician in Reston, Va., to establish the International Kidney Exchange, Ltd., which would act as a brokerage house between kidney donors overseas and American recipients. Dr. H. Barry Jacobs was quoted as saying that the price set by potential donors might be as high as $10,000, and their motivation would be "whatever motivates someone to sell: greed, bills. . . ."

Such a development was inevitable. The existing system for procuring organs does not work. While most of us have heard about the need for organ donation, few of us carry donor cards. Most people can't be bothered to fill them out even when they are printed on the back of a driver's license.

Such callousness would be inexcusable if it were not for the fact that many emergency-room physicians and nurses ignore the cards, even when they chance to find them on accident victims, the preferred source of vital organs. Their fears of malpractice suits, combined with a reluctance to involve themselves in a time-consuming and financially unrewarding procedure, produce a system in which fewer than 30% of those hospitals equipped to recover organs from cadavers for transplantation do so.

Fifty years of relying upon a system of voluntary donation and public good will has produced a situation in which, according to the Center for Disease Control, only 20% of those who die each year from traumatic accidents, tumors or strokes are utilized as donors. Yet, every year national surveys show that the vast majority of Americans are willing to serve as organ donors upon their deaths. And every year thousands of people wait helplessly while the science of organ transplantation advances and the availability of organs dwindles.

A market in organs is not the answer to this tragedy. Medicine is one area where access to life-saving cure should not depend upon the ability to pay. Moreover, the prospects for abuse in such a system, particularly of the ignorant and often desperately poor residents of Third World countries, should make us move quickly to restrict any further expansion of this unattractive industry.

Rep. Albert Gore (D-Tenn.) has introduced a bill in Congress that would outlaw the sale of organs. But we could also take a positive step to bridge the gap between supply and demand in organs: We could pass a law allowing physicians to assume consent for the utilization of cadaver organs for transplant, unless a person carries a refusal card or an objection is raised by a family member.

If, as the dismal statistics would seem to prove, thinking about our own death is too difficult for any one of us individually, perhaps we can find the courage to face it collectively. The time has come to put our policies where the altruism found in the opinion polls says it is. The burden of proof in organ donation should be shifted onto those who do not want to participate, rather than being placed on the shoulders of those who are willing but reticent, or for whom it is too late to express their wishes. If we fail to act, each one of us, or someone we love, could well pay the price—if we are rich enough.

Arthur Kaplan is an associate for the humanities at the Hastings Center, Hastings-on-Hudson, N.Y.

Providing Incentives for Organ Donations

By Harry Schwartz

One needn't be very alert to the latest trends in medical journalism to notice that there is much more talk about organ transplants than there used to be. Almost every week it seems there is another mother or father on the TV news appealing for a liver to save the life of a sick baby or child. Congressmen, normally preoccupied with cost containment in medicine, have recently criticized the armed forces because their medical programs for dependents won't pay for most organ transplants. And the newswire services gave extensive national coverage to the fact that when 10-year-old Raymond Camacho died in an auto accident last July 9, his family gave permission to use all his body parts so that at least 16 people received transplants from him.

The basic reason for this upsurge is the simple fact that to an astonishing degree, the medical barrier that made organ transplants very rare until recently has been surmounted. A new drug, cyclosporine (Sandimmune is the brand name), has largely overcome the rejection problem that for many years made every transplant an event of high and perilous medical adventure.

The Food and Drug Administration is expected to approve the general use of cyclosporine soon. But already it has been used in numerous experimental programs in the U.S. and abroad with very substantial success. At Stanford University Medical Center, for example, Dr. Norman Shumway's heart transplant team a decade or so ago saw only 20% of its patients survive a year or longer. Now, Dr. Philip Oyer, an associate of Dr. Shumway, reported recently, about 80% of heart recipients at Stanford survive two years or longer.

The old Scottish recipe for rabbit stew begins with the injunction, "First catch your rabbit." So it is with organ transplants. Now that the chances of a patient receiving very substantial benefit from a kidney, liver, heart, pancreas or other organ transplant have increased enough to justify doing these operations on a large scale, surgeons and patients have run up against the hard fact that there simply aren't enough organs available for transplantation. Thousands of Americans have died or will die this year whose lives could have been prolonged if they had received the organ transplants they needed.

In an absolute sense there probably never will be enough natural organs to help all those who might benefit from transplants. About 750,000 Americans die annually from heart disease and some cardiologists estimate that at least 50,000 to 100,000 could be saved if either natural heart transplants or suitable artificial hearts were available.

But the harsh fact is that the U.S. has only about 20,000 potential donors annually. To be a potential donor a person must suffer brain death—usually because of an automobile accident or other trauma—at an age less than 40 or 45 and have been otherwise in good health. But of the 20,000 potential donors who died last year, only about 2,000 or 2,500 actually provided organs for transplantation. The resultant organ shortage is the reason mothers and fathers are on television pleading for organs to save their children's lives. So far spouses of mere adult patients who need transplants haven't been able to get much air time from TV news producers.

What this waste of about 80% of all potentially transplantable organs means can be illustrated by a simple statistic. There are about 8,000 persons on kidney dialysis, and the cost of their treatment annually is hundreds of millions of dollars. If the kidneys these patients need were available, roughly that same sum could pay for the operations to free these patients from the need for dialysis altogether. On a less mercenary note, the quality of life is simply better if an individual has a functioning kidney to cleanse his blood than if he is subject to dialysis every day or several times a week.

It is already clear that in this field, medical capability has outrun the development of societal mechanism to meet the needs created by the progress of medical technology. The result is a frantic effort to improvise the needed mechanism to get more organ donors and, very visibly, the effort of different groups to apportion blame.

Patients tend to blame doctors, asking why physicians don't intervene every time they find a suitable brain-dead patient and ask that unfortunate's relatives to permit use of the corpse's organs for transplants. Doctors, naturally enough, tend to reject the blame put upon them. They speak of the shocked and dazed conditions of fathers, mothers and other relatives suddenly told that a loved one is beyond hope because of a sudden accident or other trauma.

Such efforts to place blame do nothing to solve the basic problem: When a tragedy converts a recently healthy and vital human being into a potential organ donor, there is no fixed, known societal incentive to make everyone involved aware that their loss can be turned into a source of help and succor for others.

Why are we so afraid to use the simple capitalist technique of a reward? Why is there no societal agreement that when a potential donor is located, that donor's closest relatives will be paid a substantial sum if they agree in time to make his organs available? If all private and government health insurance agencies agreed that, say, $2,500 would be paid to the closest relatives of a donor, the possibility of organ donation would then arise naturally. Doctors would have a ploy with which to raise the question, and the deceased's relatives would have an incentive to raise the issue themselves.

Obviously the donor's relatives needn't take the money. They could designate a favorite charity to benefit instead. In that way relatives who might otherwise feel guilty at benefiting from a death could still have an incentive to cooperate.

The suggestion made here is a simple and obvious one. Why then has it been ignored to date? One reason probably is the bad press that over the years has been associated with the idea of paid donors of blood. It was long ago established that this practice tends to attract donors who have hepatitis and other transmissible diseases. A person receiving a blood transfusion is far better served if the blood has come from a voluntary donor moved only by altruism or by the requirement to donate blood if his or his family's future blood needs are to be met.

But blood donation has very little in common with the donation of such vital organs as the heart or the liver. To benefit a potential donor of such organs, one must be effectively dead.

Some people think that any intrusion of money into medical matters is morally wrong. But that is a simplistic romanticism that rarely is carried to the length of refusing to see a doctor when one is sick. The similar romanticism that refuses to provide a monetary incentive for making organ donations available is much expensive because every week, and perhaps even every day, Americans die who might be saved by a transplanted heart or liver. In the new age created by the availability of cyclosporine, a more realistic and more pragmatic attitude is required if we are to prolong the lives of the tens of thousands for whom new futures have been opened by one of the great miracle discoveries of modern medicine.

Mr. Schwartz writes frequently on scientific and medical matters for the Journal.

USA TODAY

September 27, 1983

H. BARRY JACOBS

Guest columnist

Let consenting adults sell their kidneys

RESTON, Va. — The International Kidney Exchange was formed to meet the needs of 70,000 Americans suffering and dying while handcuffed to dehumanizing kidney dialysis machines.

Because of shortages of kidneys, transplant operations help fewer than one out of 10 patients. For years, the existing "voluntary donor" system has been a dismal failure.

The majority of the 5,000 kidneys that are transplanted each year come from 2,200 brain-dead citizens. It is not our intent to interfere with this limited source of kidneys.

God gave us two kidneys. We need only one-half of one kidney to live a normal, healthy life. And God gave us the intelligence and ability to perform kidney transplantation operations.

The profit motive, which is nothing new to organized medicine, is an additional way to solve the shortage. In fact, our government has agreed to fund a pilot program to compensate 300 healthy living kidney donors, who are not related to the organ recipients, and also to pay the donors' service fees.

Each year, kidney dialysis costs taxpayers more than $2 billion. Eighty-five percent of transplanted kidneys will function for more than five years. Each additional kidney transplant will save $142,000 in dialysis costs over five years and end misery, suffering and substantial risk.

We service American recipients by bringing together only consenting adults. Their physicians choose the best match and perform the surgery. We do not participate in their fee arrangement or medical decisions. We have a standard fee, $5,000, for our services.

Assuming the government pays the service fee for indigent patients, there could be no incentive to help the rich. If made illegal, only the rich could go overseas to obtain a transplant.

Some doctors raise the moral issue of risk when money is involved, but imply the risk is less for volunteers. The risk for serious injury or death is less than 1 per 1,000 donors. It is the responsibility of the operating surgeons to fully inform both donors and recipients of their respective risks.

Stress from any cause, including financial trouble, increases the risks for disease.

Compensating the donor for blood or a kidney is the American way. Many jobs, such as that of a coal miner, have certain risks for lung disease and injury. Yet, they made informed decisions to do those jobs.

When it comes to deciding what to do with our bodies, Congress is not a better judge than the individual. In the end, the kidney debate should be resolved by individual doctors and their patients, not by politicians. Only in the Soviet Union do human organs belong to the State.

H. Barry Jacobs, M.D., is medical director of the International Kidney Exchange Ltd.

I. BARRY JACOBS, M.D.
Diplomate of the American Board of Surgery
Diplomate of the National Board of Medical Examiners
Medical Director

TOLL FREE 800-336-0332
DC and VA. (703) 435-9400

International Kidney Exchange, Ltd.

11345 Sunset Hills Road
Reston, Virginia 22090 U.S.A.

Dear Hospital Administrator:

We are involved in national and international kidney transplantation programs.

We would like to utilize the services of your hospital for these programs. The donor patients will require elective uni-lateral nephrectomies. The recipient patients will require the transplantation operation.

For either or both of these services, please give us a firm price, which should include all hospitalization services, operating room costs, and anesthesia costs. Furthermore, we need to know the fee which will be charged by the operating surgeon as well as by any treating consultants. If you cannot quote the doctors' professional fees, please have them contact us directly or supply us with their names and addresses so that we may obtain that information from them.

The nephrectomy operation can be performed at any hospital with major operating room facilities. The removed kidney is irrigated free of all blood, placed in a sterile container, packed in ice, and immediately shipped to the recipient's hospital for transplantation.

Any Medicare approved hospital can perform the nephrectomy operation and be reimbursed by Medicare for the surgery and hospitalization. Your hospital invoices those services to the transplantation hospital which, in turn, submits the unified bill to Medicare. However, advance payment will be made for privately funded operations.

Medicare has approved payment to approximately 25 hospitals to do transplantation operations. If your hospital is also interested in performing transplantation operations which will be paid for on a cash basis, please let us know. All fees will be held in escrow prior to the operation and immediately disbursed subsequent to the operation, independent of the success of the procedure.

Unlike the nephrectomy surgery, transplantation surgery will need a fully equipped hospital, including arteriography x-ray facilities, radiation therapy (to treat acute rejection), and the services of a urologist, vascular surgeon, and internist with chemotherapy experience. Since the availability of Cyclosporin, the success of transplantation surgery has significantly improved, while complications from chemotherapy have substantially diminished.

You may limit your participation to only the nephrectomy operation. The patients will arrive from various locations both from the United States and worldwide), may require additional out-patient studies, and then will be admitted for additional tests and for the nephrectomy operation. If the recipient will have the transplantation operation done at a different institution, a coordinating supervisor will work with you to arrange for the transportation of the kidney.

Please advise me as soon as possible of your interest as we shall limit participating hospitals to only one per geographic area.

Sincerely yours,

I. Barry Jacobs M.D.

I. Barry Jacobs, M.D.
Medical Director

IBJ/plg

TESTIMONY OF

MANSFIELD F. W. SMITH, M.D.

EXECUTIVE DIRECTOR

NORTHERN CALIFORNIA TRANSPLANT BANK

Congressman Waxman and Members of the Committee:

I appreciate the opportunity to provide testimony to the Committee on the subject of transplantation. In 1968, I assisted in the development of a comprehensive Transplant Bank based on the concept that a single donor could potentially provide several tissues and organs that could benefit many waiting patients. In addition to coordinating heart, heart-lung, liver, pancreas, and kidney donors for Northern California transplant centers, our staff assists in the coordination, retrieval, processing and distribution of eye tissue, middle ear grafts, dura mater, fascia lata, skin, costal cartilage, and bone grafts. Last year approximately 400 donors were referred to our Bank from family members, hospital personnel, coroners, and morticians throughout all of Northern California; from these donations over 2500 grafts were distributed for transplantation, medical research and training.

Recently, with support of a grant from the California Medical Association Education and Research Foundation, we developed the first comprehensive donor manual available in Northern California. We are also the only agency in Northern California to have implemented a toll-free 800 phone number for donor referrals. To better inform our lay community, we developed a quarterly transplant newsletter. We have also enlisted the aid of the Civil Air Patrol of California for assistance with long-distance tissue and organ retrieval. (Exhibits enclosed.)

Despite these efforts, we, too, have found that we have been unable to supply the needs of our transplant community. We have attributed this lack of success to lack of education of the general public and of medical professionals.

This past year, the Scientific Board of the California Medical Association addressed the problems of transplantation by establishing an Ad Hoc Committee on Transplantation, of which I have been appointed Chairman. This committee is comprised of transplant physicians, transplant coordinators, and medical examiners whose mission is to recommend a program that will increase the supply and facilitate the distribution of transplantable organs and tissues in California. After

18 hours of deliberations, the committee has identified some 20 issues that will be discussed at subsequent meetings. One major issue is to investigate the feasibility of adopting one statewide telephone number for donor referrals and information.

The recent exposure transplantation has received through the efforts of President Reagan, Surgeon-General Koop and this committee has been of great benefit to us, but much work still lies ahead. Therefore, we whole-heartedly endorese the intent of the National Organ Transplant Act; we believe that the following recommendations could enhance the effectiveness of this bill.

First, it must be recognized that efficient agencies do already exist for organ and tissue procurement. Duplication of these existing agencies should be avoided; rather, the growth, expansion, and coordination of these services should be encouraged.

Second, because of the inherent differences between organ and tissue donations, more expertise from the tissue banking community needs to be sought. Also, the diverse problems associated with extra-renal procurements need to be highlighted.

Third, each donor should be approached with the intent of maximizing the benefit of the donation. No single organ or tissue should assume priority.

Fourth, methods should be established to encourage better cooperation within the transplant community. We recommend the enhancement of procurement programs that have a broad viewpoint concerning donation and are not specifically involved in one area of transplantation.

Finally, we would welcome legislative efforts that would encourage donation while maintaining the sanctity of the donor. This would include public education programs; mandating cooperation of county coroners; and removing liability from medical professionals involved in the donation process.

On behalf of the Northern California Transplant Bank, thank you for raising this most important public issue to the forefront.

STATEMENT OF THE BLUE CROSS AND BLUE SHIELD ASSOCIATION
ON
H.R. 4080, THE NATIONAL ORGAN TRANSPLANT ACT
OCTOBER 28, 1983

The Blue Cross and Blue Shield Association, representing the nation's 99 Blue Cross and Blue Shield Plans, is pleased to present for the record this statement on H.R. 4080, The National Organ Transplant Act. We have carefully reviewed this bill and would like to commend Congressmen Gore, Waxman, Luken and Skeen for their forceful highlighting of the need for greater public attention to this difficult issue. This statement is divided into four major sections. The first three sections focus on issues specific to the three titles in the bill. The final section addresses the need for an autonomous broad-based entity to support assessment of complex technology.

TITLE I

Under this Title, the federal government appears to be taking on a major new role. This bill would authorize a program of grants to develop and expand local organ procurement organizations throughout the nation. In addition, the bill requires the Secretary to establish a U.S. Transplantation Network which is to maintain a national registry of individuals who need organs and operate a national computer system and a 24-hour telephone service to facilitate the matching of donor organs with potential recipients. The proposed programs would cover all forms of organ transplants (e.g., skin and cornea transplants).

We applaud the intent of this bill. We question, however, the appropriateness and practicality of the federal government taking on such a pervasive and potentially intrusive role in organ procurement activities at a time when the private sector, in

partnership with the federal government, is engaged in activity which holds much promise for addressing the very problems which this bill attempts to address.

Voluntary organizations have traditionally taken responsibility for procuring organs for transplantation. This is not to say that improvement in the coordination of these activities is not warranted. While we recognize that there are gaps and the current system is fragmented, we believe that what is required is a mechanism to coordinate the many activities of the private sector, not compete with them. In this regard, we are encouraged by the Administration's proposal to help support the American Council on Transplantation (ACT) which could provide a vehicle in the private sector for coordination of transplantation activities throughout the nation.

The overall goal of this umbrella organization is to develop better approaches for coordinating the organ procurement efforts in the private sector. The Council is to undertake a series of activities which should contribute substantially to increased availability of organs for transplantation. We are hopeful that through ACT and similar private sector activities, the necessary framework will be established to develop a more effective system of organ procurement while maintaining the flexibility and creativeness of local private sector initiatives.

Our first concern with a new federal program derives from the rather rigid and prescriptive rules it would require in order to carry out its mission. Such a prescriptive approach is clearly reflected in the provisions of the bill which specifically lay out not only the function, but the structure, of all organizations which would receive grants or contracts under the provisions of this bill.

In addition, we are concerned with the administrative feasibility of implementing a federally mandated national registry or a national network of local transplantation procurement programs which could possibly be responsible for all forms of organ transplants. We believe such a program is far broader than necessary. Several forms of transplants have become fairly common (e.g., skin, cornea) and perhaps do not warrant the national tracking required by this bill.

We further question the provision in Section 372 to support the U.S. Transplantation Network from the Medicare Hospital Trust Fund. If the Network is to serve the entire population, then it should be more broadly financed and not be funded through the trust fund which is already sorely pressed. If the Network is to serve only the Medicare population, we think it is ill-advised.

In summary, it is our opinion that private initiatives should be given a chance before we commit major public funds to activities which may be equally or better met through the private sector. If the private sector initiatives do not meet the need, and the federal government steps in, then the government grants and activities should focus on those areas of the country and those types of efficacious organ transplant procedures which have been shown to require more than the private sector efforts can supply. Except for the most unusual circumstances, the federal program should be a temporary intervention designed to stimulate or otherwise shore-up the private sector's capacities.

TITLE II

We wish to state our general support for the provisions in this title which would grant the Secretary the authority to restrict Medicare payment to services which are furnished at a limited number of designated centers.

Experience with cardiovascular surgery and other very complex procedures suggests that the medical centers with large volumes will have the best clinical results. The same experience also demonstrates that, if payment is assured, many centers with no prospect of large volumes will perform "prestigious" procedures. This experience leads us to feel that there is merit in the idea of contracting for transplant services with selected medical centers on the basis of experiential criteria. It could encourage the large caseloads for participating centers which seem to correlate with the best success rates, while achieving efficiencies likely to yield an optimum cost for each procedure. This concept fits well with our own efforts to be prudent buyers of health care for our accounts and subscribers.

While we are highly supportive of the objective of this Title, we do want to raise some concerns of a more technical nature. First, although we do not believe it is the Committee's intent, the language in Section 201 could be construed as requiring the Secretary to specify "medical criteria of general applicability" for all covered services. The Committee may want to clarify its intent by inserting "as he(she) deems appropriate" on page 13, line 14 after "the Secretary ... may determine ...". Related to that point, we would also note that the new authority granted the Secretary may be broader than intended. For example, the language on line 17, "person furnishing the services", could allow the Secretary to restrict performance of all surgical procedures to board certified surgeons. We would recommend limiting the new authority to either "procedures which require extraordinary personnel and support facilities" or to certain types of transplants.

Our second technical concern is that the language on lines 16-20 of page 13 may not allow the Secretary to establish conditions of payment based on efficiency. For example, it is not clear that the language gives the Secretary the authority to selectively contract on a basis which includes efficiency criteria although that is clearly the intent of the

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Committee as demonstrated in lines 20-23. We believe inclusion of some type of efficiency criterion represents sound public policy, and urge any necessary clarification. If such a criterion is to be included, the Committee may want to consider limiting the Secretary's selective contracting authority to procedures which are not widely available, and which also require extraordinary personnel and support facilities. Otherwise, the Committee would be granting the Secretary authority to restrict payment to specified providers for commonly prescribed services and items such as physician services or durable medical equipment.

TITLE III

We support the provisions of this Title which prohibit the sale of any human organ.

NEED FOR AN INDEPENDENT ASSESSMENT ENTITY

Our experience has led us to conclude that there is an urgent need for the establishment of an independent, broad-based entity to support the evaluation of the extraordinarily complex new technologies which are rapidly coming to the fore. In this section we will review both our usual assessment process and the difficulties with this process which have led us to this conclusion.

Usual Assessment Process

The decision to pay or not to pay for a service depends upon contract provisions that specify the scope of benefits. Most contracts exclude payment for experimental/

investigative procedures. The Blue Cross and Blue Shield Association's technology assessment process is geared to respond to the requirements of Plans administering those contracts. This requires the designation of procedures as either generally accepted medical practice or experimental/investigative. Such designations often change with time, as the application of procedures evolves.

The typical assessment process begins when a member Plan gets a claim for a procedure that is not already listed as either generally accepted medical practice or experimental/investigative. The Plan then either makes its own determination, using locally available advisory resources, or asks the Association to evaluate the new procedure. In either case, the determination often is made under the pressure of time, for there is an outstanding claim to be paid, or not paid, as the case may be.

We respond to such requests by accumulating published studies and other relevant information for presentation to a group of six physicians who constitute our Medical Advisory Committee. This Committee, and its parent Committee on Cost Containment and Professional and Provider Affairs, are charged with analyzing the data and making recommendations back to the Plan. The recommendations are then weighed by each Plan against the unique circumstances of its area.

In the typical assessment, the Committee analyzes the data to determine whether, and under what conditions, the new procedure results in predictable and desirable outcomes. That is, the analysis may show that the procedure can be used successfully when the diagnosis is x but not y. Thus, under specified circumstances, the procedure can be considered generally accepted medical practice. The skill of the practitioner in applying the procedure is <u>not</u> usually considered in these assessments.

During the process of our own technology assessments we maintain close communication with government activity. Agencies such as the Office of Technology Assessment, the National Center for Health Services Research, the Center for Disease Control and the Food and Drug Administration provide information and analysis. Staff from the Health Care Financing Administration frequently attend our meetings and participate in our discussions. In addition, the Association has built an information network with a number of medical specialty societies. Among these, the American College of Physicians and more recently the American Medical Association have established technology assessment programs that respond to inquiries from interested parties.

Difficulties With This Process

The growing number of liver and other organ transplants and the concomitant increase in demand for coverage present Blue Cross and Blue Shield Plans with new challenges. Liver transplants may currently be experimental or investigative when performed at most centers, but have arguably become accepted medical practice for certain diagnoses when performed at a select few. The varying ability and success of transplant teams and institutions reflect the early, developmental stages through which this new technology is growing. Some centers report consistently high and improving survival rates. Others appear unable to sustain equivalent success rates or to perform as well as the leading centers in their field. This variation from site to site complicates our traditional method of technology assessment. Liver transplantation, for example, seems to demand that the skills, resources and ability of the practitioners and their institutions be considered in the assessment process. The link between procedure and outcome, even for a narrowly specified set of diagnoses, is unusually dependent on the qualifications of the practitioners, and their institutional settings, and there are only a few practitioners and settings recognized as having the requisite qualifications.

Our traditional method of technology assessment has been severely strained by this new need to weigh the factor of practitioners skill and to recognize that the necessary skills are unevenly and sparsely available around the country. With the publicity attendant to these new procedures, and the paucity of institutions reporting high success rates, the nation is rapidly becoming a single medical community for purposes of organ transplantation. In our view, our ability to responsibly cope with such a situation in the future would be enhanced by two new developments: first, the effective performance of a broad-based, independent and dispassionate organization to assess these extremely complex technologies, including the issue of requisite practitioner skill and institutional support systems; and second, legally sound mechanisms for establishing payment practices such that they cover only necessary procedures for specified diagnoses for appropriate patients at qualified institutions.

The second item relates to the ability of the public and private sectors to reinforce each other in focusing resources in the most quality enhancing and cost containing fashion. We are concerned over constraints on the private sector's ability to pursue just the kind of limited contracting here proposed for the Medicare program. Thoughtfully structured and implemented, our contracting with only a limited group of centers need not be an unreasonable restraint of trade. However, the risk of antitrust allegations by disgruntled providers is very real. We do not fear the outcome so much as the costs of the process. Antitrust defense is enormously debilitating. Related matters suspend indefinitely, as resources intended for the funding of patient care are diverted to litigation. This is a matter that we would commend to the Committee's attention. It is possible that some appropriate legislative safeguards against such legal challenges could be crafted.

Need For An Independent Assessment Entity

To meet this need, we have supported the re-funding of the National Center for Health Care Technology. We have also helped to fund and have actively participated in the Institute of Medicine's effort to design a private/public sector entity to assess technology in medical care. A broadly-based mechanism, funded from multiple sources, may serve to accommodate a variety of needs for technology assessment. It could serve as an analytic clearinghouse for information on clinical trials or other clinical experiences, and could make recommendations on a procedure's efficacy, the circumstances of efficacy, or what future research may be necessary to establish these. We believe that government, as a major buyer of medical services, should be one of the participants in discussions on how best to handle transplantation, and that it is one of the appropriate funding sources for a neutral technology assessment entity.

Creation of such an entity would not only obviate the need for a National Center for Organ Transplantation, but would significantly improve the way in which we, as a society, deal with such issues. Had such an organization been in place ten years ago, it could have and should have, accumulated and evaluated the earliest information on organ transplants, identified prospectively what data should be captured to permit ongoing and consistent evaluation, and perhaps have established a research agenda to acquire additional critical information. Clearly, other technologies which are in their embryonic stages today will be confronting us in a few years with problems comparable to those now surrounding organ transplantation. The need is less for an entity focused upon a single technology than for a more versatile, continuing entity which can deal with the broad range of clinical development. Further, annual reports by such an organization, supported by both the public and the private sectors, would have a broader base of acceptance than a Secretarial report issued after consultation with the NIH Director and the FDA Commissioner.

SUMMARY

In summary, we commend the purposes of this bill, but question whether Title I of the legislation is needed at this time. The private sector has already demonstrated its ability to effectively handle many of the more common transplant procedures. However, there are many issues and concerns surrounding the less frequent transplant procedures. Clearly we need greater coordination of all our efforts. To this end, we are encouraged by the emerging efforts in the private sector to achieve greater coordination. We would prefer to see the results of these recent private sector initiatives before major government sponsored organizations are established. If these initiatives fail, government grants and other initiatives should be aimed at areas of unresolved needs as such areas are identified.

While we support the general thrust of the provisions included in Title II to provide the Secretary with authority to limit Medicare payments to designated centers, we have raised certain technical concerns with this Title.

We have mentioned our support of efforts to re-establish the National Center for Health Care Technology, and to aid and encourage the Institute of Medicine in this area. We hope that government, as a major purchaser of care, will participate with other interests in establishing improved, non-partisan means of evaluating both the status and the application of very sophisticated, very expensive technology. We would also support separate federal legislation to prohibit the sale of human organs.

We wish to again commend Congressmen Gore, Waxman, Luken and Skeen on the initiatives in this area.

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October 26, 1983

The Honorable Henry A. Waxman
Chariman, Subcommittee on Health
and the Environment
U.S. House of Representatives
2415 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Waxman:

Enclosed please find the paper authored by the officers of the American Society of Transplant Physicians, stating our position on the issue of organ retrieval and the buying and selling of organs from living unrelated donors. I apologize for the "To the editor" format, but because of the committee rules and resultant rapidly approaching deadline, I felt it was best to speed it to you immediately. This position paper will be submitted to the New England Journal of Medicine as a rapid communication Letter to the Editor, because of our strong feelings on the subject.

Thank you for allowing our society to share these views with you.

Sincerely,

Robert Ettenger M.D.

Robert Ettenger, M.D.
Assistant Professor of Pediatrics
UCLA School of Medicine

President-Elect
American Society of Transplant Physicians

RE:al
Encl.

American Society of Transplant Physicians

AMERICAN SOCIETY OF TRANSPLANT PHYSCIANS

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October 7, 1983

To The Editor:

The art and science of transplantation have progressed dramatically in the last ten years. Advances in tissue typing, surgical techniques, immunosuppressive drugs and pre- and post- transplant patient care have allowed success rates in organ replacement which continue to improve. This improvement has had the impact of focusing professional and public attention on the field of organ transplantation in general and specifically on the supply of donor organs.

It appears clear that the supply of donor organs is presently insufficient to permit prompt transplantation for all those who need it. This shortage of organ donors sometimes translates to waiting times measured in years rather than months. Such waiting times are manifestly too long, particularly for patients awaiting liver, heart or heart-lung transplants. For these patients, death may well intervene before a suitable cadaveric donor can be found. Patients awaiting kidney transplantation are not under such severe time constraints, because of the availability of dialysis. Nevertheless, the relatively frequent requirement for a well-matched kidney and the paucity of donor organs often impose inordinate and heartbreaking delays until transplantation can be attempted.

At present there are two sources of donor organs available for transplantation: cadaver donors and family members, i.e. living related donors. The latter obviously can only be donors in a situation where the desired organ is paired , and the removal of one of the organs does not imply permanent disability or death for the donor. Even with kidney donation, however, there are small but real immediate risks of surgery and possible but unknown long-term consequences. As a result, living donation has in the past been restricted to those close relatives whose deep motivation prompts donation to a loved one despite these palpable risks. It has been considered medically ethical to do this because kidneys from living related donors have, by and large, a significantly decreased incidence of immunologic rejection.

Kidneys from dying individuals (termed "cadavers" in medical parlance) represent the major source of organs in most renal transplant programs. The graft and patient outcome in cadaver renal transplantation is not as good as that obtained with living-related transplants. Nevertheless, results with cadaveric kidneys are getting better because of the advances noted above.

Today the supply of cadaveric organs is clearly inadequate to meet the demands of a rapidly improving transplantation technology. It is estimated that only 10% or less of all suitable cadaver organs are made available for transplantation. In an effort to meet this need, a number of new plans and ideas have been

put forward. One plan which has received a great deal of publicity and attention proposes allowing unrelated individuals to donate their organs, in this case one of their kidneys, for a "free-market" determined price. The argument is made that with the new advances in immunosuppressive drugs, and in particular the upcoming availability of Cyclosporine, the success of unrelated transplants warrants the retrieval of kidneys from living donors to relieve the scarcity of cadaver organs. However, in the view of many physicians engaged in transplantation, this "free-market" sale of an individuals organs is morally offensive and ethically indefensible. It is immoral to offer incentive to undergo permanent physical damage. The opportunities for coercion of the poor to yield a "perfectly-matched" organ is at once heart-rending and frightening. Many centers have grappled with the ethical consideration implicit in living-related donation and have come to accept it only because of the high motivation of the donor and the improved success of the recipient. Neither of these is the case with a purchased kidney from a living-unrelated donor. There is no data to suggest that kidneys taken from living-unrelated donors will function any better, more quickly or longer than cadaveric grafts. Even with cyclosporine and other new immunosuppressives, the success of a kidney transplant is by no means assured, with post-operative complication and side effects being the usual course of events rather than as the exception.

It is impossible for physicians to ethically justify removal of kidneys from living unrelated human beings when we are utilizing only a small fraction of the available cadavenic organs. Efforts must be directed towards procedures which will bring home to every individual the need and mechanism for allowing themselves or loved ones to become organ donors. Much of the responsibility for this lies with the medical community. Reluctance to broach the subject of organ donation with next-of-kin at the time of death has been a major impediment to adequate organ retrieval. A number of legislative steps can be envisioned which would improve this situation. For example, specific wording could be adopted which would guarantee immunity from legal liability for the purpose of approaching family members to discuss organ donations. Alternatively, we in the United States could adopt an anatomical gift act similar to the one operative in France. There, every individual is regarded positively as an organ donor at the time of death unless they or their next-of-kin have indicated otherwise. Such an approach rather than being a coercion, allows medical personnel to freely and easily approach the next-of-kin about organ donation at the appropriate time without fear of litigation, either real or more likely, imagined.

Whatever mechanism is chosen to improve retrieval of cadaveric organs, a success in this endeavor is clearly preferable to a "free-market" sale of kidneys from the living. It may be argued that even today in the United States certain unrelated individuals, such as spouses, have become kidney donors. However, this has been carried out only in rigorously controlled scientific settings and only after an Institutional Review Board (IRB) of the hospital has approved it from a medical ethics standpoint. This is in no way comparable to the proposed "free-market" sale. The "free-market" sale concept has been put forward only because the medical, governmental and lay communities alike have failed to provide adequate mechanisms to procure cadaver donors and keep pace with improving transplantation technology. The best answer to the ethically-distastful "free-market" sale concept is the institution of appropriate policies to assure an adequate supply of cadaver donor organs.

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Juvenile Diabetes Foundation International 23 East 26th Street, New York, New York 10010, 212-889-7575

EXECUTIVE OFFICE

November 11, 1983

The Honorable Henry Waxman
Chairman
Subcommittee on Health and
the Environment
2415 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Waxman:

The Juvenile Diabetes Foundation (JDF) is an international voluntary health organization dedicated to supporting and furthering research and education in diabetes. We would like to express our strong support for H.R. 4080, "The National Organ Transplant Act."

We support the various provisions included in H.R. 4080 pertaining to (1) the establishment of a grant program for the development of local organ procurement organizations; (2) the creation of a United States Transplantation Network; and (3) the establishment of the National Center for Organ Transplantation, which would serve as the Federal focal point for all organ donation and transplantation activities, public and private, throughout the United States. Furthermore, we believe that Congress should seriously consider providing reimbursement for organ transplantation procedures under the Medicare and Medicaid programs, an endeavor which would encourage private insurers to do the same. Finally, we are pleased that your bill prohibits the sale of human organs.

We would like to comment on several specific aspects of the transplantation issue that pertain to diabetes -- kidney, islet cell, and pancreatic transplantations. While kidney transplantation is important to those diabetics who have suffered kidney failure, this is but one approach to treating one of the many complications of diabetes. Recent research breakthoughs in islet cell and pancreatic transplantation are exciting because they embody the potential to cure diabetes.

Kidney Transplantation

It has been estimated by the American Society of Transplant Surgeons that as many as fifty percent of individuals with Type I juvenile onset diabetes develop uremia (kidney failure) from diabetic nephropathy (infections, hardening of the small kidney arteries, and damage to the filtering apparatus of the kidneys as a result of diabetes).

The two possible approaches to dealing with kidney failure are kidney dialysis and kidney transplantation. There are various ways a diabetic can receive kidney dialysis -- in a hospital, a free-standing clinic or in the home. However, dialysis is a very expensive and time-consuming procedure. Costs for chronic center-based dialysis, not including costs for hospitalization for associated illnesses, are estimated to exceed $25,000 every year an individual remains on dialysis. When hospital costs are factored in, the yearly costs of dialysis for a child can exceed $70,000 per year. These costs are all reimbursable through the Medicare program.

On the other hand, the average cost of a renal transplant in the first year is approximately $25,000-$35,000. This figure decreases significantly in subsequent years to a minimal maintenance cost for medication. The medical costs of transplantation procedures are expected to decline as technology improves and as new and better immunosuppressive drugs are developed. Transplantation also allows the individual to return to a more productive life.

Furthermore, the diabetic receiving kidney transplantation exceeds the survival rate of the diabetic maintained solely on dialysis. There are about 5,000 kidney transplants performed in the U.S. every year and the technology is rapidly improving. According to Dr. Eli A. Friedman, Chief of the Renal Diseases Division at Downstate Medical Center in Brooklyn, New York "at least two out of three diabetic kidney recipients will be alive and will have functioning kidneys at least three years after surgery." Dr. Friedman reports that an increasing number of kidney recipients have lived beyond ten years and a few have passed the sixteen-year mark. As technology advances and as the drug cyclosporine, with its anti-rejection qualities, becomes more widely available the number of kidney transplantations will increase significantly, embodying the potential to greatly improve the quality of life of the diabetic.

Beta Cell Transplantation

As mentioned above, we are excited about the prospects for islet cell and pancreatic transplantation. A normally functioning pancreas automatically provides necessary amounts of insulin to the system. The insulin-dependent diabetic must perform himself the function of a pancreas by monitoring blood-sugar levels and injecting proper amounts of insulin into the system at the proper times.

An exciting area of diabetes research -- and one which embodies the potential to dramatically improve the quality of life of the diabetic within the next couple of years -- is pancreatic islet cell transplantation. The islets of Langerhans contain the pancreas gland's insulin-producing beta cells. The successful transplantation of these cells into the diabetic may actually reverse diabetes in the body receiving the transplantation.

Dr. Paul E. Lacy and his team of researchers at the Washington School of Medicine two years ago successfully transplanted clusters of the insulin-producing cells from one animal species to another. Moreover, beta cells from the healthy rats transplanted into diabetic mice actually reversed the diabetes in the mice. At a recent meeting of the National Diabetes Advisory Board, Dr. Lacy stated: "Studies in rats have shown that isografts of islets will prevent, reverse, or arrest complications of diabetes involving the eyes, the kidneys, and the autonomic nervous system of diabetic recipients."

Initially, rejection of islet cells was a problem; however, seven different methods have been developed which will prevent rejection of isolated adult islets transplanted between different strains of animals and different species. A second major stumbling block, the lack of techniques for the mass isolation of islets from large animals and man, has also been overcome. Finally, new methods are being developed for the purification of islet tissue.

Pancreatic Transplantation

Ongoing studies in the area of pancreatic transplantation focus on procurement of pancreas organs, new drugs to halt rejection, and transplantation techniques. All of these areas require further investigation. Dr. David Sutherland of the University of Minnesota Medical School, a pioneer in the field

of pancreas transplants, has indicated that the potential for application of pancreas transplantation "probably exceeds that of the liver and may approach that of the kidney." As transplant technology improves in other organ transplant procedures, and with the introduction of cyclosporine, improved results with pancreatic transplants can be expected.

Recommendations

JDF is extremely excited about all of these promising areas and we are pleased to see national attention being focused on the entire issue of transplantation. As noted above, we support H.R. 4080. We would respectfully recommend that:

1. In establishing a U.S. Transplantation Network for matching donors with organs, the future need for pancreas glands for diabetics should not be overlooked.

2. The National Center for Organ Transplantation should devote some of its resources to kidney transplantation for diabetics and to the emerging opportunities embodied in islet cell and pancreatic transplantations.

3. The Advisory Council to the Center should have representation from the diabetes community.

4. Funding for research and clinical trials for islet cell transplantation should be substantially increased because of their potential to provide a cure for diabetes.

We thank you for this opportunity to comment on this important legislation. The world is thrilled with the progress made in kidney, liver, and heart transplantation. It is imperative that neither Congress, NIH, the new entities charged with coordinating transplantation efforts, nor the public lose sight of the great potential which transplantation technology offers the nation's 1.5 million insulin-dependent diabetics.

Sincerely,

Jason S. Roberts,
President

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