

THE WHITE HOUSE

WASHINGTON

April 27, 1993

MEMORANDUM FOR SECRETARY DONNA SHALALA

FROM: *CHR* Carol H. Rasco, Assistant to the President for
Domestic Policy

SUBJECT: Organ Transplants

Attached are materials sent to your office earlier this month which outlined the need for a name to attend a meeting that an Arkansas attorney and his clients, the University of Pittsburgh, hoped to have with us prior to April 22. We have contacted your office a couple of times but have no name yet...the hearings were held on April 22 as planned, and the attorney and his client still need a meeting. Please have someone forward a name or names as soon as possible as we are in the process of setting up the meeting very possibly on May 4 or 5.

In the meantime we understand that at the recent hearings a Dr. Harman from HHS was "pounded" fairly hard by Waxman to perhaps get the regulations published? The people wanting to come see us are quite concerned that the proposed regulations which include allocation formulas should NOT be published yet as they also put into place some of the problem areas being addressed by the hearings.


We will let you know as soon as we set a final meeting time next week. Thanks.

THE WHITE HOUSE

WASHINGTON

April 12, 1993

MEMORANDUM FOR SECRETARY DONNA SHALALA

FROM: Carol H. Rasco 

SUBJECT: Organ Transplants

Please see the attached which has come from John Tisdale, an attorney in Little Rock with the firm from which Bruce Lindsey comes as well as the firm where President Clinton served "Of Counsel" for two years. I would like to propose to John that we combine the meetings with Charlotte, myself and HHS personnel into one meeting. If you agree, please let Rosalyn know the name(s) and number(s) of the persons you wish to have attend from HHS and she will coordinate setting up the meeting.

Thank you.

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April 9, 1993

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Re: *University of Pittsburgh and Pending Legislation*

Ms. Carol Rasco
Director, Domestic Policy Council
THE WHITE HOUSE
1600 Pennsylvania Avenue
Washington, D.C. 20500

VIA TELECOPIER: (202) 456-2878
CONFIRMATION COPY TO FOLLOW

Dear Carol:

As I mentioned on Thursday, we have been working with the University of Pittsburgh Medical Center for some time on issues relating to allocation of organs for liver transplants in this country. The issues involve the Department of Health and Human Services ("HHS") as a result of mandates of the National Organ Transplant Act (Public Law 98-507) ("Act") enacted in 1984. There is some urgency to these issues, because the Act is up for re-authorization and hearings are scheduled on April 22nd before a subcommittee of the House Committee on Energy and Commerce. That subcommittee is chaired by Congressman Waxman from California. Also, the problems relating to allocation of available organs for liver transplant have become a part of the national debate on health care reform. I attach for you an article from the April 1, 1993 issue of *The Wall Street Journal*. Further, an entity known as the United Network for Organ Sharing, which developed the allocation procedures pursuant to a contract with HHS, justifies the current allocation system partly alleging that it has been approved by HHS. Our client has very real concerns about the quality of medical care which is being provided to transplant patients under the current allocation system, and secondarily, the increase in health care costs resulting from inequities in the current allocation system.

The principal proponent for the Act in 1984 was Senator (now Vice President) Gore. Charlotte Hays on the Vice President's staff has received a summary of the University of Pittsburgh's position on the current allocation system and because of her prior work and interest has some knowledge in the area. In visiting with Bruce Lindsey about the article in *The Wall Street Journal* and the concerns of the University of Pittsburgh, Bruce suggested that you were the appropriate person to hear these concerns on a firsthand basis. Thus, representatives of the

Ms. Carol Rasco

April 9, 1993

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University of Pittsburgh Medical Center, Sam Jones from our office and Liz Dunst from Hogan & Hartson in Washington would like an opportunity to visit with you very briefly on these matters. I know how busy your schedule is, but hope that you will have some time to visit with us. We also believe that it would be helpful to you, and ultimately to the resolution of these issues, if Charlotte Hays could attend that meeting.

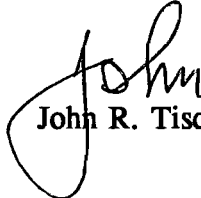
The purpose of the meeting would be to provide you with a very brief outline of the concerns and views of the medical personnel from the University of Pittsburgh Medical Center and to alert you to some of the issues and questions that will undoubtedly arise at the subcommittee hearings on April 22nd. For example, there is a Government Accounting Office report of the operations of the United Network for Organ Sharing and the organ allocation system which will be released on or before April 22nd. There are some serious issues about the lack of proper procedures and public input in the adoption of the current organ allocation system and criticism of HHS for lack of governmental oversight.

We recognize that Secretary Shalala and her Assistants are just beginning to get a handle on the various issues facing HHS. Unfortunately, because of the timing of the legislation to reauthorize the Act and the recent publicity, we think that the Administration may be forced to deal with some of these issues before it might otherwise have chosen to do so. Thus, we would hope that we could have our meeting with you and Ms. Hays before the Subcommittee hearing on April 22nd. We would also suggest that it would be appropriate for a follow-up meeting shortly thereafter between Secretary Shalala and her Assistants dealing with this problem on the one hand and representatives of the University of Pittsburgh Medical Center on the other.

I look forward to hearing from you or Roslyn about possible times for a meeting. I'm assured by representatives of the University of Pittsburgh Medical Center that they can be available anytime you can.

Cordially yours,

WRIGHT, LINDSEY & JENNINGS


John R. Tisdale

JRT/blm
Enclosure

Agonizing Choices

People Most Needing Transplantable Organs Now Often Miss Out

Policy Favors Local Patients And Lets Local Hospitals In on Lucrative Business

Should Survivability Matter?

By SCOTT McCARTNEY

Staff Reporter of THE WALL STREET JOURNAL

DALLAS — Rex Voss, 41 years old and father to four teenage boys, had been sick only a few months, but it was enough time for hepatitis C to destroy his liver.

With bleeding in his abdomen and breathing through a life-support machine, Mr. Voss lay in the intensive-care unit of Baylor University Medical Center here waiting for a liver transplant. He was listed in the nation's organ-sharing computer at the most critical level: "Status 4," nationwide emergency, likely to die soon.

At one time, a liver would probably have been available within a day for the Jackson, Miss., dairy worker. Now, one day turned into two. Then three. A week passed with no call from an organ bank.

But there were livers nearby — as close as 40 miles away in Fort Worth or 40 minutes away by air in Oklahoma. The organs went to healthier patients while Mr. Voss, pale yellow and barely conscious, waited and worsened.

Critics Blame System

Mr. Voss, some doctors say, was a casualty not only of the virus, but of the nation's system for allocating livers. Had he fallen ill just two years earlier, before a broad policy change that some contend had more to do with money than medicine, Mr. Voss might be alive today.

"The system as it is now kills people and costs considerably more money," contends Jeffrey Romoff, president of the University of Pittsburgh Medical Center, the nation's biggest transplant center.

Today's system evolved from 1984 legislation pushed through by then-Sen. Al Gore to deal with a shortage of organs available for the rapidly emerging technique of transplantation. The bill was meant to ensure that the sickest patients were treated first, and that organs weren't allocated on the basis of financial gain. The United Network for Organ Sharing, a nonprofit group in Richmond, Va., won a Health and Human Services Department contract to run the national program. It was authorized to distribute organs "equitably among transplant recipients according to established medical criteria."

Emphasizing Geography

But two years ago, a UNOS committee of 12 transplant surgeons quietly and subtly changed the way the nation distributes livers. It eliminated an emergency classification that helped funnel organs to dying patients, in effect increasing the importance of 69 geographic boundaries. An available liver is offered first to a transplant patient locally, even if the patient is healthy enough to be considered "elective" for surgery. Only if there were no takers locally is the organ offered elsewhere for critically ill patients.

The change benefited dozens of new transplant programs scurrying to get in on what had become a \$500 million market, a market that was growing so fast that hospitals were offering million-dollar signing bonuses to lure coveted transplant surgeons. Since 1988, the number of liver-transplant programs in the U.S. has nearly doubled to 105 as hospitals have sought to build their technical reputations, boost billings, fill beds, generate media attention, keep local patients in town for treatment and even lift staff morale. "There's money to be made in liver transplantation—not many people [running] hospitals around the country aren't aware of that," says transplant surgeon Todd Howard at Washington University in St. Louis.

But the policy change, coupled with the increased competition from local centers, also has made it harder for hospitals like Baylor, the nation's third-largest adult liver-transplant center, to get the livers needed to save dying patients like Mr. Voss.

"It bugs the hell out of me to see something I spent my life creating turned into a piece of merchandise," fumes transplant pi-



Rex Voss

oneer Thomas Starzl, who trained all but one of the surgeons on the 12-member committee that initiated the 1991 change. Adds Olga Jonasson, who led a transplant-policy task force in 1986: "The intent of the whole effort was that organs don't belong to surgeons, they belong to the public."

Mr. Voss's case also illustrates the nagging question underlying this debate: Which patients should be getting organs, anyway? In an emergency, should a liver be used for a 65-year-old who has been bedridden for two years and whose chances for long-term survival wouldn't be as good as those of a 41-year-old like Mr. Voss? Should Mr. Voss have been moved to a higher or lower priority after falling into a coma? What about a cancer patient with a high probability for recurrence? Or should the limited supply of organs be reserved for the "healthiest" — those with the best chance for survival?

"Transplanting the sickest first above

Please Turn to Page A6, Column 1

Agonizing Choices: Localities Get First Shot at Spare Human Organs

Continued From First Page

all else sounds honorable, but is basically dishonorable," says Ruud Krom of the Mayo Clinic, chairman of the liver committee that initiated the allocation change in 1991. "What we did with the change was give somewhat less weight to the sickest patients so other patients could be transplanted as well. The current system accepts a certain death rate."

But others suggest that transplant surgeons have too much incentive to transplant easy cases first. By maintaining a high one-year survival rate, they stand to gain more business, especially through contracts with major insurance companies. "As doctors, our job is not to try to achieve the best results; our job is to help the sickest patients," says John Najarian, a transplant pioneer at the University of Wisconsin and editor of the journal "Clinical Transplantation."

Health-care experts say they don't expect liver transplantation to be affected much by President Clinton's attempts to reform the health-care delivery system. Any package of basic benefits will probably include the service, they say. This could, however, intensify the shortage of organs.

Just Another Patient

When Mr. Voss arrived at Baylor in October, he was just another patient who had contracted hepatitis C through an unknown source. A couple of dozen patients each month flock to the program run by Goran Klintmalm of Baylor, which has some of the highest success rates in the nation.

Mr. Voss was evaluated, accepted and, after his insurance coverage was confirmed, placed on the waiting list and sent to his mother's home in Shreveport, La. In time, when he rose close enough to the top and a good match of size and blood-type came along, he was to be summoned to Baylor while a team retrieved a liver from a brain-dead donor, placed it in solutions to preserve it for as long as 18 hours and carried it back to Dallas in a Coleman cooler.

Just 10 years ago, only a handful of doctors had enough skill and ego to take a liver from one body and place it in another. With transplants, which cost \$150,000 to \$350,000, now used as treatment for a host of diseases and covered by most insurance policies, transplant centers are a growth industry.

No one has gone about establishing a new liver-transplant center with the gusto of Nazih Zuhdi, a wealthy, Lebanese-born cardiac surgeon who was determined to establish a liver capital at Baptist Medical Center in Oklahoma City. Over the past six months, Dr. Zuhdi says he has spent "multimillions," much of it from his own checkbook, to gather the talent — from a Starzl-trained surgeon and a renowned hepatologist to a 17-person research squad and a computer expert — for a liver program to couple with his already successful heart-transplant team.

Overnight, Baptist had to have an additional telephone operator. Operating rooms were remodeled, treatment rooms added on. Offices are being renovated, the prior occupants shunted to portable trailers. Plans are in the works for construction of a new transplant building, complete with garden suites and research facilities for Nobel Prize winners. "I always aim for the best," Dr. Zuhdi says.

He predicts his program — the city's second — will do 50 liver transplants this year, and 100 next year. The livers will have to come from outside Oklahoma, since only about 30 are procured in the state annually, but they will be available, he says, if mediocre programs are closed.

"Before we decide which patient takes the organ, we should decide which center takes the organ," Dr. Zuhdi says. Others may have good programs, he says, "but not like the one I have."

Benefit of Being Small

Surgeons at smaller and newer transplant centers outside of the biggest cities have benefited most from the rules change and defend it staunchly. They argue that the new policy makes transplantation more accessible and cheaper because patients don't have to be moved. The 1991 changes also put strict monitoring in place, they point out, and cut off what some considered cheating by the big centers, which sometimes diverted livers sent for emergency cases to other patients.

"My personal belief is the citizens of this country have the right to competent medical care locally," says Joseph Cofer, who did 26 liver transplants in 1992 at Medical University of South Carolina.

Mr. Romoff of the Pittsburgh Medical Center counters that big centers have the best success records, and that keeping four floors of intensive-care beds full of liver patients awaiting transplant in Pittsburgh actually generates more revenue for the medical center — \$3,000 to \$5,000 a patient a day — than if the patients received a liver and recovered, or died. (Under the new policy, the number of transplants there has fallen to 359 last year from a peak of 650 annually just a few years ago.)

And critics of the policy change point to UNOS statistics showing that nationally, more people are dying while waiting. In 1992, according to preliminary calculations, 492 people died while on the liver waiting list, 49% more than the 330 deaths in 1989. While UNOS also says the waiting list grew at an even faster pace over the same period, critics say the percentages shouldn't mirror one another unless critical patients are being ignored.

In Pittsburgh, 46 people died while on the waiting list the year before the policy change. Last year, the number almost doubled to 91. "In my mind, it can only be explained by the allocation system," Mr. Romoff says.

Those Who Have, Get

Now, 70% of transplant patients in Pittsburgh are on life-support machines before surgery because they wait so long, says Dr. Starzl, who did the world's first human-liver transplant and who now finds himself at odds with many of his disciples. "It has come to be that the indication for liver transplantation is possession of a liver, not the need for one," he snaps.

For Mr. Voss, all the added competition meant a longer wait. The wait at Baylor, lengthened by a growing caseload and a tightened supply of organs, has stretched to five months from just weeks or days. In February, Dr. Klintmalm, whose program usually averages three livers a week, went 19 days with only one.

The growing liver shortage starts at the local organ banks, private organizations that compete for organ-harvesting "franchises" among hospitals in a region. With more centers, the competition for organs has grown pretty heated. With two transplant centers in the state, Oklahoma's organ bank, which used to supply all the livers sent to Texas each year, now rarely offers a liver to Dallas. Houston's organ bank beat out Dallas's to win the right to claim available livers from Fort Worth hospitals.

'Go With the Numbers'

The question of organ availability troubled Mr. Voss, who came to Baylor on the recommendation of his Mississippi gastroenterologist. He had considered a program in Shreveport run by a Klintmalm trainee. Some patients in Shreveport had gotten livers after only a week or two, but Mr. Voss, still able to get around on his own and live at home, decided to opt for the expertise of the Baylor program. "You don't know what to do," says his mother, Mary Jo Voss. "All the doctors we talked to said to go with the numbers."

But as his wait dragged on, Mr. Voss's condition deteriorated. His liver wasn't producing coagulants, so he had to be hospitalized in Shreveport, then Dallas, for uncontrollable nosebleeds. Being in the hospital raised his priority — to no avail. For a time, he and his mother lived in a mobile home in the Baylor parking lot, hoping for a liver before it was too late.

These agonizing waits have prompted some in the transplantation community to rethink the 1991 rules change. One alternative now discussed is a "super-regional" system where available organs would be allocated across two or three waiting lists. (Small centers are opposed to the idea.) Others have proposed a European-style program, where centers would get organs based on how many transplants they did in the previous six months. Under those proposals, patients like Mr. Voss would compete for organs based more on medical criteria than on the hospital they selected.

"The issue is fairness. Why should there be such disparity in waiting time?" asks Dr. Klintmalm, who is also a member of UNOS's liver subcommittee and is now advocating change.

Another idea floated by large centers is to set a minimum one-year survival rate: A program can transplant any patient it wants, but must achieve a one-year survival rate for 75% of its patients. This would force a broader balance between relatively healthy patients, who might have a 90% chance of surviving a year, and comatose patients with perhaps only a 50% chance. If a center fell below 75%, its access to organs would be curtailed.

Cruel Reminder

During Thanksgiving week, Mr. Voss was sent to the intensive-care unit and placed on emergency status. His arms and legs were so weak they turned mushy. His kidneys began to fail. A TV set over his bed resounded during the transplant team's afternoon rounds with the theme song to "Jeopardy" — a kind of anesthesia for nurses from the constant beeping of monitors and pumps, but a cruel reminder of his plight as well. "What can you do?" his mother wondered later. "Maybe we should have stayed in Shreveport."

Faced with the current crisis, Dr. Klintmalm has decided to accept livers of marginal quality. For Mr. Voss, he would even have crossed blood-group lines and size criteria once he lapsed into coma.

While such stretches place patients at greater risk, Dr. Klintmalm has been forced to do it before and says the results to date have been adequate. "We'll take anything now," he sighs.

Meanwhile, Houston's two-year-old liver program, fed by the aggressive Houston organ bank, LifeGift, can be choosier. Last year, the organ bank discarded 12% of the livers donated because they didn't meet surgeons' standards, according to Rebecca Davis, director.

Dr. Klintmalm's team told Mrs. Voss that Rex would be listed for nationwide priority, but that they already had a patient in intensive care who was the same blood type and who would get the first available liver.

Another patient came into ICU soon after Mr. Voss. Without the UNOS emergency classification, and with the intense competition of the local allocation system, the odds were extremely long that all would get organs.

After several days of waiting, a debate began raging at Mr. Voss's bedside: Had he gone too far to transplant? His kidneys had failed and he was clearly too ill for a double transplant. Without kidney function, there was no point in giving him a liver, and no point in doing a liver/kidney combination and risking wasting two organs. The lack of livers had forced a choice: Who would live and who would die?

Rex Voss had missed his chance. "These smaller centers are scarfing up livers while this guy crashes and burns," bristles Robert Goldstein, one of Dr. Klintmalm's surgeons. "I had to tell Rex Voss's family: 'He won't be a candidate and he will probably die.'" Mrs. Voss pleaded for another chance; Dr. Goldstein promised he would come by twice a day and check for improvement. The other person in intensive care did get a liver, flown in from Detroit. She recovered and returned home to south Texas. For the two others, there was nothing Dr. Klintmalm's team could do but stand by and watch.

Mr. Voss died Dec. 8. His obituary in the local newspaper asked people to sign up as organ donors.

Matching of Tissues In Organ Transplants Hurts Blacks' Odds

By SCOTT MCCARTNEY

Staff Reporter of THE WALL STREET JOURNAL

Statistically, blacks are more likely to suffer from kidney disease than whites. Unfortunately, they are less likely than whites to receive a kidney transplant.

The reasons for this lie in the genetically based tissue-matching system used to allocate kidneys harvested from cadavers. Proponents say this system provides the best chance for successful transplants. But a growing number of scientists argue that tissue-typing has proved to be medically insignificant in most cases, as well as racially discriminatory.

In a paper to be published in the medical journal "Clinical Transplantation," Nicholas Halasz of the University of California, San Diego, calls for a reworking of the computer-driven point system. He advocates instead a system based on who has been waiting longest. He has attracted some powerful allies, including transplant pioneers Thomas Starzl of the University of Pittsburgh and John Najarian of the University of Minnesota. "We feel it's unduly prejudicial," Dr. Najarian says of the current system.

How It Works

Under the current system, a donated kidney is tested for six types of antigens, substances that can stimulate an immune response. The more antigens that match antigens in the recipient, the less likely the patient is to reject it, the medical community maintains.

Where controversy erupts is in less-than-perfect matches, known as HLA matches. In the point system, those who match five of the antigens have the best chance of getting a kidney, followed by four matches and on down. Though length of wait counts, "very minor compatibilities weigh more heavily than two or three years waiting time," Dr. Halasz says.

But studies of HLAs haven't shown that they provide a statistically greater chance of success than transplants of kidneys without antigen matches, the critics say. Doctors suggest that the necessary suppression of the body's immune system with drugs after the transplant levels the playing field. Tissue typing "doesn't mean anything, and it is costing a tremendous amount," Dr. Starzl asserts.

Black kidney patients share very few of the six antigens with the white population. Which is why they now make up one-third of the nation's kidney-transplant waiting list. Blacks also donate organs at a lower rate than whites.

Drawing Blanks

Now, some black researchers contend that other antigens beyond the six have been identified and are ignored. What's more, within the current six-antigen system, types found in blacks still haven't been characterized, resulting in blanks on the matching scorecard and making a perfect match impossible. A federally funded program to identify antigens in blacks is under way.

"It's a numbers game," says Georgia Dunston of Howard University in Washington, one of the doctors working on the black-antigens study. "It's not so much a black-white issue as a genetic issue. If you're a minority, your chances of a match are less on the numbers if you have an antigen not common to the white population."

Critics also point to the lack of blacks on the 45-member board of the United Network for Organ Sharing, the non-profit group that runs allocation programs for the federal government. Last June, UNOS elected its first black director.

"There is very little input from the patients and the public. It is driven by the tissue-typing establishment and the clinicians who have good results in patients with very poor HLA matching," says Ronald Guttman, director of the McGill Centre for Clinical Immunobiology and Transplantation in Montreal.

At a medical conference in Arlington, Va., yesterday on blacks and kidney transplantation, Dr. Starzl offered another theory on why he believes tissue typing doesn't work: His latest research shows genetic material from donors migrates into cells of recipients, overpowering "the anticipated typing effect."

Despite calculations that their tissue-typing techniques don't produce significantly better results, proponents of the current system defend their results as better than nonmatches.

"It turns out it really is one of the strongest factors," claims tissue-typing pioneer Paul Terasaki of UCLA. "Six-antigen matches have finally been accepted. But five-antigens are second best, and (transplant surgeons) aren't willing to go the next step."

Dr. Terasaki says the current system offers a compromise between trying to find the best match and offering some aid to those who wait long periods.

"The solution is to increase black donors, not take away from good matches and prevent Caucasians from getting kidneys," he says.

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DATE April 9, 1993

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April 9, 1993

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Re: University of Pittsburgh and Pending Legislation

Ms. Carol Rasco
Director, Domestic Policy Council
THE WHITE HOUSE
1600 Pennsylvania Avenue
Washington, D.C. 20500

VIA TELECOPIER: (202) 456-2878
CONFIRMATION COPY TO FOLLOW

Dear Carol:

As I mentioned on Thursday, we have been working with the University of Pittsburgh Medical Center for some time on issues relating to allocation of organs for liver transplants in this country. The issues involve the Department of Health and Human Services ("HHS") as a result of mandates of the National Organ Transplant Act (Public Law 98-507) ("Act") enacted in 1984. There is some urgency to these issues, because the Act is up for re-authorization and hearings are scheduled on April 22nd before a subcommittee of the House Committee on Energy and Commerce. That subcommittee is chaired by Congressman Waxman from California. Also, the problems relating to allocation of available organs for liver transplant have become a part of the national debate on health care reform. I attach for you an article from the April 1, 1993 issue of *The Wall Street Journal*. Further, an entity known as the United Network for Organ Sharing, which developed the allocation procedures pursuant to a contract with HHS, justifies the current allocation system partly alleging that it has been approved by HHS. Our client has very real concerns about the quality of medical care which is being provided to transplant patients under the current allocation system, and secondarily, the increase in health care costs resulting from inequities in the current allocation system.

The principal proponent for the Act in 1984 was Senator (now Vice President) Gore. Charlotte Hays on the Vice President's staff has received a summary of the University of Pittsburgh's position on the current allocation system and because of her prior work and interest has some knowledge in the area. In visiting with Bruce Lindsey about the article in *The Wall Street Journal* and the concerns of the University of Pittsburgh, Bruce suggested that you were the appropriate person to hear these concerns on a firsthand basis. Thus, representatives of the

WRIGHT, LINDSEY & JENNINGS

Ms. Carol Rasco

April 9, 1993

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University of Pittsburgh Medical Center, Sam Jones from our office and Liz Dunst from Hogan & Hartson in Washington would like an opportunity to visit with you very briefly on these matters. I know how busy your schedule is, but hope that you will have some time to visit with us. We also believe that it would be helpful to you, and ultimately to the resolution of these issues, if Charlotte Hays could attend that meeting.

The purpose of the meeting would be to provide you with a very brief outline of the concerns and views of the medical personnel from the University of Pittsburgh Medical Center and to alert you to some of the issues and questions that will undoubtedly arise at the subcommittee hearings on April 22nd. For example, there is a Government Accounting Office report of the operations of the United Network for Organ Sharing and the organ allocation system which will be released on or before April 22nd. There are some serious issues about the lack of proper procedures and public input in the adoption of the current organ allocation system and criticism of HHS for lack of governmental oversight.

We recognize that Secretary Shalala and her Assistants are just beginning to get a handle on the various issues facing HHS. Unfortunately, because of the timing of the legislation to reauthorize the Act and the recent publicity, we think that the Administration may be forced to deal with some of these issues before it might otherwise have chosen to do so. Thus, we would hope that we could have our meeting with you and Ms. Hays before the Subcommittee hearing on April 22nd. We would also suggest that it would be appropriate for a follow-up meeting shortly thereafter between Secretary Shalala and her Assistants dealing with this problem on the one hand and representatives of the University of Pittsburgh Medical Center on the other.

I look forward to hearing from you or Roslyn about possible times for a meeting. I'm assured by representatives of the University of Pittsburgh Medical Center that they can be available anytime you can.

Cordially yours,

WRIGHT, LINDSEY & JENNINGS


John R. Tisdale

JRT/blm
Enclosure

K:Wm1334.027

THE WALL STREET JOURNAL

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SOUTHWEST EDITION

THURSDAY, APRIL 1, 1993

DALLAS, TEXAS

Agonizing Choices **People Most Needing** **Transplantable Organs** **Now Often Miss Out**

Policy Favors Local Patients **And Lets Local Hospitals** **In on Lucrative Business** **Should Survivability Matter?**

By Scott McClellan

DALLAS — Rex Voss, 51 years old and father to four teenage boys, had been sick only a few months, but it was enough time for hepatitis C to destroy his liver.

With bleeding in his abdomen and breathing through a life-support machine, Mr. Voss lay in the intensive-care unit of Baylor University Medical Center, here waiting for a liver transplant. He was listed as the nation's organ-sharing coordinator at the most critical level: "Status 4," nationwide emergency, likely to die soon.

At one time, a liver would probably have been available within a day for the Jackson, Miss., dairy worker. Now, one day turned into two. Then three. A week passed with no call from an organ bank.

But there were livers nearby — as close as 40 miles away in Fort Worth or 80 minutes away by air in Oklahoma. The organs went to treatment patients with Mr. Voss, pale yellow and barely conscious, wailed and worsened.

Critic Blames System

Mr. Voss, some doctors say, was a casualty not only of the rigors but of the nation's system for allocating livers. Since he fallen ill just two years earlier, before a broad policy change that some contend had more to do with money than medicine, Mr. Voss might be alive today.

"The system as it is now kills people and costs considerably more money," contends Jeffrey Bonnell, president of the University of Pittsburgh Medical Center, the nation's biggest transplant center.

Today's system evolved from local legislation pushed through by then Sen. Al Gore to deal with a shortage of organs available for the rapidly emerging techniques of transplantation. The bill was meant to ensure that the sickest patients were treated first, and that organ wait lists be placed on the basis of medical need. The United Network for Organ Sharing, a nonprofit group in Richmond, Va., runs a Health and Human Services Department contract to run the national program. It was authorized to distribute organs "equally among transplant recipients according to established medical criteria."

Emphasizing Geography

But two years ago, a UNOS committee of 13 transplant surgeons quietly and subtly changed the way the nation distributes livers. It established an emergency classification that helped funnel organs to dying patients, in effect increasing the importance of geographic distance. An available liver is offered first to a transplant patient locally, even if the patient is healthy enough to be considered "eligible" for surgery. Only if there were no livers locally is the organ offered elsewhere for critically ill patients.

The change benefited doctors of one transplant program scribbling to get in on what had become a \$600 million market, a market that was growing so fast that hospitals were offering million-dollar signing bonuses to lure coveted transplant surgeons. Since 1988, the number of liver-transplant programs in the U.S. has nearly doubled to 146 as hospitals have sought to build their technical reputations, boost billings, fill beds, generate media attention, keep local patients in town for treatment and even lift staff morale. "There's a tendency to be made in liver transplantation—not many people (having) hospitals around the country aren't aware of that," says transplant surgeon Todd Stewart at Washington University in St. Louis.

But the policy change, coupled with the increased competition from local centers, also has made it harder for hospitals like Baylor, the nation's third-largest adult liver-transplant center, to get the livers needed to save dying patients like Mr. Voss.



Rex Voss

It began the hard part of \$60 to \$66 something I spent my life creating turned into a piece of merchandise," says Thomas Startz, who trained all but one of the surgeons on the 18-member committee that utilized the 1991 change. Adds Oren Jonasson, who led a transplant-policy task force in 1988: "The intent of the whole effort was that organs don't belong to surgeons, they belong to the public."

Mr. Voss's case also illustrates the ongoing question underlying this debate: When patients should be getting organs, anyway? In an emergency, should a liver be used for a 46-year-old who has been healthy for two years and whose chances for long-term survival wouldn't be as good as those of a 41-year-old like Mr. Voss? Should Mr. Voss have been moved to a higher or lower priority after falling into a coma? What about a cancer patient with a high probability for recurrence? Or should the limited supply of organs be reserved for the "healthier"—those with the best chance for survival?

"Transplanting the sickest first always... Please Turn to Page 16, Column 1

APR 9

THE WALL STREET JOURNAL THURSDAY, APRIL 1, 1993

Agonizing Choices: Localities Get First Shot at Spare Human Organs

Continued From First Page

All side wounds honorable, but is basically unresolvable," says Russ Eason of the Mayo Clinic, chairman of the liver committee that initiated the allocation change in 1991. "What we did with the change was give somewhat less weight to the sickest patients as other patients could be transplanted as well. The current system accepts a certain death rate."

But others suggest that transplant surgeons have too much incentive to transplant easy cases first. By maintaining a high one-year survival rate, they stand to gain more business, especially through contracts with major insurance companies. "As doctors, our job is not to try to achieve the best results; our job is to help the sickest patients," says John Najarian, a transplant pioneer at the University of Wisconsin and editor of the journal "Clinical Transplantation."

Health-care experts say they don't expect liver transplantation to be affected much by President Clinton's attempts to reform the health care delivery system. Any package of basic benefits will probably include the services, they say. This could, however, intensify the shortage of organs.

Just Another Patient

When Mr. Voss arrived at Baylor in October, he was just another patient who had contracted hepatitis C through an unknown source. A couple of dozen patients each month flock to the program run by coroner Kintzmann at Baylor, which has some of the highest success rates in the nation.

Mr. Voss was evaluated, accepted and, after his insurance coverage was confirmed, placed on the waiting list and sent to his mother's home in Shreveport, La. In three, when he rose close enough to the top and a good match of size and blood-type came along, he was to be summoned to Baylor while a team retrieved a liver from a brain-dead donor, placed it in solutions to preserve it for as long as 18 hours and carried it back to Dallas in a Coleman cooler.

Just 10 years ago, only a handful of doctors had enough skill and ego to take a liver from one body and place it in another. With transplants, which cost \$150,000 to \$250,000, now used as treatment for a host of diseases and covered by most insurance policies, transplant centers are a growth industry.

No one has gone about establishing a new liver-transplant center with the gusto of Naash Zuhdi, a wealthy, Lebanese-born cardiac surgeon who was determined to establish a liver capital at Baptist Medical Center in Oklahoma City. Over the past six months, Dr. Zuhdi says he has spent "multimillions" much of it from his own checkbook, to gather the talent — from a St. Louis-trained surgeon and a renowned hepatologist to a 17-person research squad and a computer expert — for a liver program to couple with his already successful heart-transplant team.

Overnight, Baptist had to have an additional telephone operator. Operating rooms were remodeled. Treatment rooms added on. Offices are being renovated, the prior occupants shunted to portable trailers. Plans are in the works for construction of a new transplant building, complete with garden suites and research facilities for Nobel Prize winners. "I always aim for the best," Dr. Zuhdi says.

He predicts his program — the city's second — will do 50 liver transplants this year, and 100 next year. The livers will have to come from outside Oklahoma, since only about 30 are procured in the state annually, but they will be available, he says, if medicare programs are closed.

"Before we decide which patient takes the organ, we should decide which center takes the organ," Dr. Zuhdi says. Others may have good programs, he says, "but not like the one I have."

Benefit of Being Small

Surgeons at smaller and lower transplant centers outside of the biggest cities have benefited most from the rules change and defend it staunchly. They agree that the new policy makes transplantation more accessible and cheaper because patients don't have to be moved. The 1991 changes also put strict monitoring in place, they point out, and cut off what some considered cheating by the big centers, which sometimes diverted livers sent for emergency cases to other patients.

"My personal belief is the citizens of this country have the right to competent medical care locally," says Joseph Coker, who did 25 liver transplants in 1992 at Medical University of South Carolina.

Mr. Romoff of the Pittsburgh Medical Center counters that big centers have the best success records, and that keeping four floors of intensive-care beds full of liver patients awaiting transplant in Pittsburgh actually generates more revenue for the medical center — \$3,000 to \$5,000 a patient a day — than if the patients received a liver and recovered, or died. (Under the new policy, the number of transplants there has fallen to 340 last year from a peak of 600 annually just a few years ago.)

Are critics of the policy change pointing to UNOS statistics showing that nationally, more people are dying while waiting. In 1992, according to preliminary calculations, 482 people died while on the liver waiting list, 47% more than the 329 deaths in 1990. While UNOS also says the waiting list grew at an even faster pace over the same period, critics say the percentages shouldn't mirror one another unless critical patients are being ignored.

In Pittsburgh, all people died while on the waiting list the year before the policy change. Last year, the number almost doubled to 91. "In my mind, it can only be explained by the allocation system," Mr. Romoff says.

Those Who Have, Get

Now, 70% of transplant patients in Pittsburgh are on life-support machines before surgery because they wait so long, says Dr. Starr, who did the world's first human-liver transplant and who now finds himself at odds with many of his disciples. "It has come to be that the indication for liver transplantation is possession of a liver, not the need for one," he says.

For Mr. Voss, all the added competition meant a longer wait. The wait at Baylor, lengthened by a growing caseload and a tightening supply of organs, has stretched to five months from just weeks or days. In February, Dr. Kintzmann, whose program usually averages three livers a week, went 19 days with only one.

The growing liver shortage starts at the local organ banks, private organizations that compete for organ-harvesting "franchises" among hospitals in a region. With more centers, the competition for organs has grown pretty heated. With two transplant centers in the state, Oklahoma's organ bank, which used to supply all the livers sent to Texas each year, now rarely offers a liver to Dallas. Houston's organ bank beat out Dallas's to win the right to claim available livers from Fort Worth hospitals.

'Go With the Numbers'

The question of organ availability troubled Mr. Voss, who came to Baylor on the recommendation of his Mississippi gastroenterologist. He had considered a program in Shreveport run by a Kintzmann trainee. Some patients in Shreveport had gotten livers after only a week or two, but Mr. Voss, still able to get around on his own and live at home, decided to opt for the expertise of the Baylor program. "You don't know what to do," says his mother, Mary Jo Voss. "All the doctors we talked to said to go with the numbers."

But as his wait dragged on, Mr. Voss's condition deteriorated. His liver wasn't producing coagulants, so he had to be hospitalized in Shreveport, then Dallas, for uncontrollable nosebleeds. Being in the hospital raised his priority — in no small part, he said, his mother lived in a mobile home in the Baylor parking lot, hoping for a liver before it was too late.

These agonizing waits have prompted some in the transplantation community to rethink the 1991 rules change. One alternative now discussed is a "super-regional" system where available organs would be allocated across two or three waiting lists. (Small centers are opposed to the idea.) Others have proposed a European-style program, where centers would get organs based on how many transplants they did in the previous six months. Under those proposals, patients like Mr. Voss would compete for organs based more on medical criteria than on the hospital they selected.

"The issue is fairness. Why should there be such disparity in waiting time?" asks Dr. Kintzmann, who is also a member of UNOS's liver subcommittee and is now advocating change.

Another idea floated by large centers is to set a minimum one-year survival rate: A program can transplant any patient it wants, but must achieve a one-year survival rate for 75% of its patients. This would force a broader balance between relatively healthy patients, who might have a 50% chance of surviving a year, and sicker patients with perhaps only a 10% chance. If a center fell below 75%, its access to organs would be curtailed.

Cruel Reminder

During Thanksgiving week, Mr. Voss was sent to the intensive-care unit and placed on emergency status. His arms and legs were so weak they turned mushy. His kidneys began to fail. A TV set over his bed rebounded during the transplant team's afternoon rounds with the theme song to "Jeopardy" — a kind of anesthesia for nurses from the constant beeping of monitors and pumps, but a cruel reminder of his plight as well. "What can you do?" his mother wondered later. "Maybe we should have stayed in Shreveport."

Placed with the current crisis, Dr. Kintzmann has decided to accept livers of marginal quality. For Mr. Voss, he would even have crossed blood-group lines and size criteria once he slipped into coma. While such stretches place patients at greater risk, Dr. Kintzmann has been forced to do it before and says the results to date have been adequate. "We'll take anything now," he sighs.

Meanwhile, Houston's two-year-old liver program, fed by the aggressive Houston organ bank, LifeGift, can be choosier. Last year, the organ bank discarded 17% of the livers donated because they didn't meet surgeons' standards, according to Rebecca Davis, director.

Dr. Kintzmann's team told Mrs. Voss that Ron would be listed for nationwide priority, but that they already had a patient in intensive care who was the same blood type and who would get the first available liver.

Another patient came into ICU soon after Mr. Voss. Without the UNOS emergency classification, and with the intense competition of the local allocation system, the odds were extremely long that all would get organs.

After several days of waiting, a debate began raging at Mr. Voss's bedside: Had he gone too far to transplant? His kidneys had failed and he was clearly too ill for a double transplant. Without kidney function, there was no point in giving him a liver, and no point in doing a liver-kidney combination and risking wasting two organs. The lack of livers had forced a choice: Who would live and who would die?

But Voss had missed his chance.

"These smaller centers are scarfing up livers while this guy crashes and burns," bristles Robert Goldstein, one of Dr. Kintzmann's surgeons. "I had to tell Ron Voss's family: 'He won't be a candidate and he will probably die.'" Mrs. Voss pleaded for another chance; Dr. Goldstein promised he would come by twice a day and check for improvement. The other person in intensive care did get a liver, flown in from Detroit. She recovered and returned home to south Texas. For the two others, there was nothing Dr. Kintzmann's team could do but stand by and watch.

Mr. Voss died Dec. 3. His obituary in the local newspaper asked people to sign up as organ donors.

THE WALL STREET JOURNAL THURSDAY, APRIL 1, 1993

Matching of Tissues In Organ Transplants Hurts Blacks' Odds

By Scott McCartney
Staff Reporter of THE WALL STREET JOURNAL

Statistically, blacks are more likely to suffer from kidney disease than whites. Unfortunately, they are less likely than whites to receive a kidney transplant.

The reasons for this lie in the genetically based tissue-matching system used to allocate kidneys harvested from cadavers. Proponents say this system provides the best chance for successful transplants. But a growing number of scientists argue that tissue-typing has proved to be medically insignificant in most cases, as well as racially discriminatory.

In a paper to be published in the medical journal "Clinical Transplantation," Nicholas Halasz of the University of California, San Diego, calls for a reworking of the computer-driven point system. He advocates instead a system based on who has been waiting longest. He has attracted some powerful allies, including transplant pioneers Thomas Starzl of the University of Pittsburgh and John Najarian of the University of Minnesota. "We feel it's unduly prejudicial," Dr. Najarian says of the current system.

How It Works

Under the current system, a donated kidney is tested for six types of antigens, substances that can stimulate an immune response. The more antigens that match antigens in the recipient, the less likely the patient is to reject it, the medical community maintains.

Where controversy erupts is in less-than-perfect matches, known as HLA matches. In the point system, those who match five of the antigens have the best chance of getting a kidney, followed by four matches and on down. Though length of wait counts, "very minor compatibilities weigh more heavily than two or three years waiting time," Dr. Halasz says.

But studies of HLAs haven't shown that they provide a statistically greater chance of success than transplants of kidneys without antigen matches, the critics say. Doctors suggest that the necessary suppression of the body's immune system with drugs after the transplant levels the playing field. Tissue typing "doesn't mean anything, and it is costing a tremendous amount," Dr. Starzl asserts.

Black kidney patients share very few of the six antigens with the white population. Which is why they now make up one-third of the nation's kidney-transplant waiting list. Blacks also donate organs at a lower rate than whites.

Drawing Blanks

Now, some black researchers contend that other antigens beyond the six have been identified and are ignored. What's more, within the current six-antigen system, types found in blacks still haven't been characterized, resulting in blanks on the matching scorecard and making a perfect match impossible. A federally funded program to identify antigens in blacks is under way.

"It's a numbers game," says Georgia Dunston of Howard University in Washington, one of the doctors working on the black-antigen study. "It's not so much a black-white issue as a genetic issue. If you're a minority, your chances of a match are less on the numbers if you have an antigen not common to the white population."

Critics also point to the lack of blacks on the 45-member board of the United Network for Organ Sharing, the non-profit group that runs allocation programs for the federal government. Last June, UNOS elected its first black director.

"There is very little input from the patients and the public. It is driven by the tissue-typing establishment and the clinicians who have good results in patients with very poor HLA matching," says Sami Gutmann, director of the McGill Centre for Clinical Immunobiology and Transplantation in Montreal.

At a medical conference in Arlington, Va., yesterday on blacks and kidney transplantation, Dr. Starzl offered another theory on why he believes tissue typing doesn't work: His latest research shows genetic material from donors migrates into cells of recipients, overpowering "the anticipated typing effect."

Despite calculations that their tissue-typing techniques don't produce significantly better results, proponents of the current system defend their results as better than nonmatches.

"It turns out it really is one of the strongest factors," claims tissue-typing pioneer Paul Terasaki of UCLA. "Six-antigen matches have finally been accepted. But five-antigen are second best, and [transplant surgeons] aren't willing to go the next step."

Dr. Terasaki says the current system offers a compromise between trying to find the best match and offering some aid to those who wait long periods.

"The solution is to increase black donors, not take away from good matches and prevent Caucasians from getting kidneys," he says.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington D.C. 20201

FACSIMILE

DATE MAY 27 1993

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Carol Rasco
Assistant to the President
for Domestic Policy

456-2216

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER) :

Kevin Thurm
Chief of Staff

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COMMENTS:



DEPARTMENT OF HEALTH & HUMAN SERVICES

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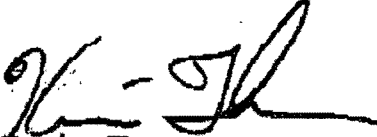
MAY 27 1993

MEMORANDUM FOR CAROL RASCO

As a follow-up to the meeting on May 5 with the attorneys and staff from the University of Pittsburgh on the United Network for Organ Sharing (UNOS) Liver Allocation policy, attached is a background paper on the National Organ Transplant Act as well as some data and other information related to liver transplantation.

The current liver allocation policy has been developed by a body comprised of representatives of the nation's liver transplant programs and continues to be reviewed by this group.

Department officials believe that, given the shortage of available organs and the need to make difficult decisions, the organ allocation system in place today is equitable.



Kevin Thura
Chief of Staff

Attachment

LIVER TRANSPLANT ALLOCATION POLICY

DRAFTNational Organ Transplant Act (NOTA)

NOTA was enacted into law in 1984. It was in response to the severe shortage of transplantable organs and the desire to ensure that the organs that were available were allocated fairly and equitably among transplant patients. Prior to implementation of NOTA there was a fragmented system of organ retrieval and distribution, paid for by Medicare, but with virtually no coordination or public oversight. This patchwork cost the taxpayers about \$100 million dollars per year, but relied upon media appeals by the families of terminally ill patients to promote organ donation and to seemingly decide who received a life-saving organ and who did not.

After months of careful study, Congress designed a national system built around an organ procurement and transplantation network (OPTN). The OPTN was conceived as a policy making body. It would not only maintain a single national list of patients waiting for organ transplants, but more important, it would establish an open, public process to decide difficult questions such as how organs should be allocated.

Congress, in particular, recognized two things about organ allocation. First, no matter how organ donation is improved, there will always be a critical shortage of organs that will result in the death each year of thousands of Americans on transplant waiting lists. Thus, the government has a duty to ensure that the decision of who lives and who dies be fair and equitable for patients.

Second, medical criteria alone will not be sufficient to decide who is next on the waiting list. The decision will need to balance utility and justice -- higher survival rates of the best transplant candidates against the urgent needs of dying patients who are likely to have lower survival rates. Congress designed the OPTN to address these difficult questions.

Policy Development for Organ Allocation

It was anticipated during Congressional deliberations on NOTA that the United Network for Organ Sharing (UNOS), a nonprofit entity with expertise in organ procurement and transplantation, would be the most likely organization to operate the OPTN. A contract for the OPTN was awarded to UNOS in 1986. Two subsequent three-year contracts (1987, 1990) have been awarded to UNOS. The current contract expires on September 30, 1993 and the Department is currently in the process of awarding a new contract.

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Policy making for the OPTN is carried out through representative committees which formulate policy recommendations for consideration of the OPTN Board of Directors.

If the Board approves a proposed policy, it is distributed for comment to the 3,500 individuals, organizations and media representatives that comprise the constituency of the OPTN. Following a 45-day public comment period, the committee reviews the comments and amends the policy as is appropriate. The committee then resubmits the policy to the Board for a final vote. In emergency situations OPTN policy permits the board to adopt a new interim policy and then send it out for public comment.

The 17 different OPTN committees are comprised of members who are geographically representative of the United States and are experts in the areas of their assigned committees such as Education, Ethics, Patient Affairs, Finance, and Organ Procurement and Distribution.

The Liver Subcommittee which developed the 1991 change to the liver allocation policy, is part of the full Organ Procurement and Distribution Committee. Its members are liver transplant surgeons and physicians. The current chairman is Dr. Ruud Krom of the Mayo Clinic, and members now include Drs. Roger Jenkins of New England Deaconess Hospital and John Fung of the University of Pittsburgh. A listing of the current membership of the Liver Subcommittee may be found in Appendix A.

The Liver Allocation Policy

The first liver allocation policy was approved by the OPTN Board of Directors in 1986. In 1987 it was changed largely to a system developed by Dr. Thomas Starzl of the University of Pittsburgh, the largest liver transplant program in the country.

The policy adopted in 1987 included a category known as UNOS/STAT. UNOS/STAT waiting list patients were those not expected to live 24 hours and were given priority for livers recovered throughout the country. Although there were minor changes made to the policy between 1987 and 1990, the UNOS/STAT category was retained.

In August 1990, the Liver Subcommittee recommended that the UNOS/STAT category be eliminated because some transplant centers were using it to acquire livers for patients who were not actually in the UNOS/STAT category.

The subcommittee further recommended that the four categories of patient Status remain (4, 3, 2, 1) but that Status 4 patients, the sickest patients, always be given first priority at the local level. A seven day limit, (as a Status 4)

DRAFT

renewable once, with provision for a longer extension, was implemented to ensure that only the sickest patients be placed in that category.

The policy was passed by the Board of Directors in November, 1990 and became effective January 1, 1991. It was unanimously supported by the Patient Affairs Committee in February, 1991.

Summary of Liver Data

Since the implementation of the liver allocation policy in January, 1991 both UNOS and HHS have been doing an ongoing analysis of the data showing trends in waiting list, allocation, transplantation and outcome. Since 1989, rates of deaths on the liver waiting list per 1000 patient waiting days have been dropping in the U.S. They have also declined at the University of Pittsburgh.

Outcome data clearly indicate that the survival of patients at home, but too sick to work is 81 percent at one year in contrast to the sickest patients (those on mechanical support) where the survival rate is 55 percent at one year.

Transplanting a high percentage of the sickest people results in the death/loss not only of the patient, but the organ that could have saved a person in need of a liver who was not so severely ill at the time of transplant. Some additional highlights of this data analysis, including information on numbers dying on waiting lists, may be found in Appendix B.

Steps Being Taken Regarding the Liver Allocation Policy

The OPTN Liver Subcommittee meets three times a year. Its primary focus is on the effectiveness of the allocation system.

Both UNOS, through the Liver Subcommittee, and HHS have begun work on simulation models designed to test the efficiency of different liver allocation strategies. Efficacy in this instance is defined as the balance between transplanting very sick patients and using the relatively small number of available livers most effectively.

Within HHS an article is being written which examines recent trends in liver transplantation and waiting list activity. The article will focus on the impact of the current allocation policy on liver transplantation. The paper will be reviewed internally by HHS staff knowledgeable about health registry data and analysis prior to being submitted to a peer reviewed journal for publication.

DRAFT

APPENDIX A

**ORGAN PROCUREMENT AND DISTRIBUTION
LIVER SUBCOMMITTEE MEMBERSHIP, 1992-93**

DRAFT**ORGAN PROCUREMENT AND DISTRIBUTION
LIVER SUBCOMMITTEE MEMBERSHIP, 1992-93**

Chairman **Ruud A.F. Krom, M.D., Ph.D.**
Surg. Dir., Liver Transplant
Rochester Methodist Hospital
Mayo Clinic
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REGIONAL REPRESENTATIVES

Region 1 **Roger L. Jenkins, M.D.**
Director, Liver Transplant Program
New England Deaconess Hospital
Boston, MA

Region 2 **John J. Fung, M.D., Ph.D.**
Director, Transplant Division
University of Pittsburgh
Pittsburgh, PA

Region 3 **Steven C. Poplawski, M.D.**
University of Alabama
Liver Transplant Program
Birmingham, AL

Region 4 **Goran B. G. Klintmalm, M.D., Ph.D.**
Director, Transplant Services
Baylor University Medical Center
Dallas TX

Region 5 **John P. Roberts, M.D.**
Assistant Professor of Surgery
U.C.-San Francisco Transplant Service
San Francisco, CA

Region 6 **James D. Perkins, M.D.**
Director of Transplantation
University of Washington Medical Center
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Region 7 **Mark B. Adams, M.D.**
Director, Kidney/Liver Transplant
Froedtertr Memorial Lutheran Hospital
Medical Collect of Wisconsin
Milwaukee, WI

Region 8 **Byers W. Shaw, Jr., M.D.**
Chief of Transplant Services
University of Nebraska Medical Center
Department of Surgery
Omaha, NE

DRAFT**Region 9**

Charles M. Miller, M.D.
Director, Liver Transplant Program
Mt. Sinai Medical Center
New York, NY

Region 10

Jeremiah G. Turcotte, M.D.
Director, Transplant Center
University of Michigan Medical Center
Ann Arbor, MI

Region 11

William C. Stevenson, M.D.
UVA Medical Center
Department of surgery
Charlottesville, VA

DRAFT

APPENDIX B
HIGHLIGHTS ON ANALYSIS OF LIVER DATA

DRAFT

HIGHLIGHTS ON ANALYSIS OF LIVER DATA

- In 1992, there were 3,053 liver transplants in the U.S. In 1990, the year before current liver allocation was put into effect, there were 2,682.

At the University of Pittsburgh, the number of liver transplants has been declining since 1990. There were 490 in 1990 and 316 in 1992. Their share of the total has fallen from 18.5 percent in 1990 to 10.6 percent in 1992.

- There were 4,710 new liver waiting list registrants in the U.S. in 1992 compared to 3,589 in 1990. Total patient waiting days was 705,000 in 1992 and 315,000 in 1990.

In 1990, the University of Pittsburgh had a 17 percent increase in new liver registrants over the previous year. In 1991, the number of new liver registrants dropped 3 percent and then another 26 percent in 1992.

- The number of U.S. deaths while on the waiting list was 494 in 1992, 316 in 1990 and 282 in 1989. For the University of Pittsburgh, the number of deaths has fluctuated: 70 in 1989, 57 in 1990, 86 in 1991 and 66 in 1992. The increase in the number of deaths on the liver waiting list nationwide is lower than the increase in the number of patients waiting for a transplant.

Number of Deaths While on Waiting List

	1989	1990	1991	1992
U.S.	283	314	435	494
Pittsburgh	70	57	86	66

- The risk of dying while on the liver waiting list has continued to decrease since 1989. The number of deaths per 1000 patient waiting days has decreased at a greater rate at Pittsburgh than nationally.

Risk of Dying on Liver Waiting List
(Deaths/1,000 Patient Waiting Days)

	1989	1990	1991	1992
U.S.	1.7	1.0	0.9	0.7
Pittsburgh	1.12	.66	.65	.38

- Nationwide, there has been a decline in the percentage of liver transplants for critically ill patients. In 1990, 29.2 percent of all U.S. liver patients transplanted were in the intensive care unit or on mechanical support.

DRAFT

This percentage (29.2) dropped to 25.4 in 1991 and to 24.7 in 1992. This follows a decline that began in 1989 when the percentage of sickest patients transplanted was 37.5.

The trend at Pittsburgh is different. In 1990, 24.7 percent of their transplanted patients were in the sickest categories. Thirty-four percent of patients transplanted in 1991 were the sickest, and 40.3 percent in 1992.

- In 1992, the percentage of least critically ill patients receiving a transplant (those working full- or part-time or at home but not able to work) was 53.8. In 1990, it was 49.1 percent. One-quarter of liver transplants went to the sickest patients in 1992, down from 29 percent in 1990. Also, about the same proportion of liver recipients were in the least sick category in 1992 as in 1990.

Therefore, the type of patients transplanted nationally since the current allocation policy was established in 1991 has changed little.

- The one-year survival rates for the sickest patients (those on mechanical support and most likely to be Status 4's) is 54.6 percent; for patients at home but too sick to work, the survival rate is much higher, 81.5 percent. Transplanting a high percentage of the sickest people results in the death/loss not only of the patient but the organ that could have saved a person in need of a liver who was not so severely ill at the time of transplant.
- Although a much greater proportion of Status 1 patients are alive after one year than Status 4 patients, the debate over the liver policy is not over the difference between Status 4's and Status 1's, but between Status 4's and Status 3's and 2's. The question is: should the sickest patients, who are least likely to survive, be transplanted, or should the emphasis be placed on transplanting Status 3's and 2's, who stand a better chance of surviving and of benefitting from what is a very scarce resource?

Do we have names
from HHS yet?
If not, call
Kevin Aume.

Brian Biles
+ 2 Public Health
Service Staff

→ they'll call back
with additional
names

EDWARD L. WRIGHT
(1903-1977)
ROBERT S. LINDSEY
(1913-1991)
RONALD A. MAY
ISAAC A. SCOTT, JR.
JAMES M. MOODY
JOHN G. LILE
GORDON S. RATHER, JR.
TERRY L. MATHEWS
DAVID M. POWELL
ROGER A. GLASGOW
C. DOUGLAS BUFORD, JR.
PATRICK J. GOSS
ALSTON JENNINGS, JR.
JOHN R. TISDALE
KATHLYN GRAVES
M. SAMUEL JONES III
JOHN WILLIAM SPIVEY III
LEE J. MULDRON
WENDELL L. GRIFFEN
N. M. NORTON, JR.
EDGAR J. TYLER
CHARLES C. PRICE
CHARLES T. COLEMAN
JAMES J. GLOVER
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April 29, 1993

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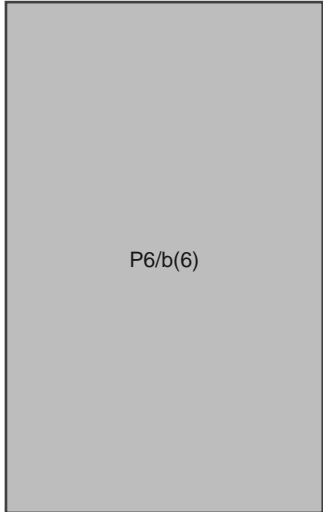
Re: Meeting with Representatives of the University of Pittsburgh Medical Center

Ms. Carol H. Rasco
Assistant to the President
for Domestic Policy
THE WHITE HOUSE
1600 Pennsylvania Avenue
Washington, D.C. 20500

VIA TELECOPIER: (202) 456-2878
CONFIRMATION COPY TO FOLLOW

Dear Carol:

Thank you very much for making room on your busy schedule to meet with representatives of the University of Pittsburgh Medical Center. I wanted to confirm my message to Rosalyn that we can meet with you on Wednesday, May 5, 1993 at 1:30 p.m. The persons who will attend the meeting on behalf of the University of Pittsburgh Medical Center and their birthdates are as follows:

- | | <u>Name</u> | <u>Birthdate</u> |
|----|--|--|
| 1. | John Tisdale |  |
| 2. | Isabel (Liz) Dunst
Hogan & Hartson | |
| 3. | Eugenia C. Stoner
University of Pittsburgh | |
| 4. | Dr. Andreas Tzakis
University of Pittsburgh | |
| 5. | Lazar M. Palnick
University of Pittsburgh | |

P6/b(6)

Ms. Carol H. Rasco

April 29, 1993

Page 2

In our conversation, you asked for suggestions about appropriate people from HHS to attend the meeting. In addition to Secretary Shalala, we believe Assistant Secretary of Health Designate Dr. Philip Lee and HHS Chief Counsel Ms. Harriet Rabb are key HHS personnel to be involved in the decisions relating to organ allocation issues.

There are two other persons in HHS who have some knowledge about this issue. Dr. Robert Harmon is the Administrator of the Health Resources and Services Administration. He is a holdover appointee from the prior administration and I understand that his tenure may be limited. He appeared at Congressman Waxman's hearing as the principal spokesman for the Administration to defend the current organ allocation policies. Ms. Judith Braslow is currently the director of the Division of Organ Transplantation at HHS. In that position she has been supportive of and has defended the current organ allocation policies. Given the prior involvement of these two persons in supporting the "heavily criticized" policy, I do not think they should be included.


As I mentioned to you in my earlier letter, Charlotte Hays in the Vice President's office has some knowledge of activities in this area. If you feel that it is appropriate, please invite her to the meeting.

To give you some additional background about the issues, I am enclosing a short summary of the written testimony submitted on behalf of the University of Pittsburgh Medical Center at Congressman Waxman's Committee hearing as well as a full copy of the Medical Center's statement. Dr. Tzakis from the Medical Center testified at those hearings and I enclose a copy of his remarks. I think they will help you understand his extensive background and knowledge in this area, prior to the meeting.

Again, thank you very much for making room on your schedule to visit with us. We look forward to seeing you on May 5th.

Cordially yours,

WRIGHT, LINDSEY & JENNINGS


John R. Tisdale

JRT/blm/Enclosures



University of Pittsburgh

UNIVERSITY OF PITTSBURGH MEDICAL CENTER

STATEMENT FOR THE RECORD

OF

DR. ANDREAS TAZAKIS

ASSOCIATE PROFESSOR OF SURGERY

UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

UNIVERSITY OF PITTSBURGH MEDICAL CENTER

HEARING ON THE REAUTHORIZATION

OF THE

NATIONAL ORGAN TRANSPLANT ACT

CONGRESSMAN HENRY WAXMAN, CHAIRMAN

HEALTH AND THE ENVIRONMENT SUBCOMMITTEE

HOUSE ENERGY AND COMMERCE COMMITTEE

APRIL 22, 1993

Chairman Waxman and Members of the Subcommittee, I am Dr. Andy Tzakis, an Associate Professor of Surgery at the University of Pittsburgh School of Medicine and a transplant surgeon at the school's Presbyterian University Hospital. I am submitting this testimony for the record of the Subcommittee on behalf of the University of Pittsburgh Medical Center.

With the passage of the National Organ Transplant Act (NOTA) in 1984 and its subsequent reauthorization in 1988 and 1990, the United States Congress required the development of a system for the allocation of organs used for transplant through a national list of individuals who need organs and through a national system developed in accordance with established medical criteria to match organs and individuals included in the list. Congress required that this system -- the Organ Procurement and Transplantation Network (OPTN) -- be developed through a contract with a private non-profit entity. The United Network for Organ Sharing (UNOS) has been awarded this contract since 1986. This contract is up for renewal again in 1993.

Since UNOS was awarded the original contract for the operation of the OPTN in 1986, UNOS has approved and

implemented a number of organ allocation policies, including liver allocation policies. According to the UNOS Policy Proposal Statement, Liver Allocation, dated January 21, 1991, the purposes behind the UNOS liver allocation policy are to:

- 1) establish equitable medical criteria to allocate organs;
- 2) maximize transplant opportunities;
- 3) increase the likelihood of successful transplants; and
- 4) minimize organ waste.

The first liver allocation policy was adopted by UNOS after UNOS Board approval in 1987 and modified in May 1988 and June 1989. Through 1990, livers were allocated in the local area first, based on a point system according to patient need and severity of the patient's condition. This policy, however, also included a patient priority designation called "UNOS/STAT" for patients not expected to survive more than 24 hours without a transplant. Under that policy, a substantial percentage of livers were allocated nationally, that is, to critically ill patients in areas other than the locale where the donor organ was obtained.

On August 19, 1990, UNOS announced to its members proposed changes to the then-existing policy which adversely affected transplant patients at Presbyterian University Hospital, as well as at many other medical facilities performing liver transplants on the most severely ill patients. The new liver allocation policy abolished the use of the UNOS/STAT designation and instead relied on four patient

status categories: Status 1 patients who were at home and functioning normally; Status 2 patients who require continuous medical care, but not constant hospitalization; Status 3 patients who must be continually hospitalized; and Status 4 patients who are in critical condition due to acute or chronic liver disease and are hospitalized in intensive care units. Status 4 included patients who would have otherwise been UNOS/STAT. The new allocation policy also relied on three geographic area factors (local, regional and national areas) that, with the elimination of UNOS/STAT, radically changed the "national" character of the allocation system.

Under the new liver allocation policy livers are allocated locally, and not on a "national system." Livers are first allocated to Status 4, then Status 3, then Status 2, and finally Status 1 patients in the local area; then from Status 4 to Status 1 patients in the region; and finally Status 4 to Status 1 patients nationally. Medical urgency based on the severity of the patient's condition is a determinant only within each of the three geographical divisions. For example, a Status 1 patient in a local area has a higher allocation priority for, and a greater chance of receiving, an available liver than a Status 4 patient in the region or nationally. Yet a Status 1 patient is functioning normally, while a Status 4 patient is considered to be within a week or two of death.

This new liver allocation policy not only is inconsistent with Congress' intent in passage of NOTA, but also the general goals and policies included in the very Policy Proposal Statement which announced the new policy. For example, in that Policy Proposal Statement UNOS states, "The allocation system is based on objective medical criteria that encompass the critical factors of medical urgency and time on the waiting list, factors deemed critical to successful liver transplantation." In explaining the Liver Allocation Criteria (Policy 3.6) in Section II, C (p. 4), UNOS made the following statement:

The distance factor is not relevant in the revised liver allocation policies (see Policy 3.6.7.1 below) because the current method of liver preservation (UW Solution) allows for long distance shipments. The committee believed that the donor livers available should be allocated to the most needy, irrespective of distance.

Notwithstanding these statements (and others in the same vein), UNOS adopted and implemented a liver allocation policy which provides that a local Status 1 patient (clearly one of the least urgent and least needy patients on the waiting list) will receive a compatible liver before an equally compatible Status 4 or Status 3 patient (clearly a more needy and more urgent patient) in another part of the U.S.

Recent data from UNOS confirms this trend. From 1990 to 1991 transplants for patients in Status 1 increased from

14.7% to 20.4% of all transplants, while transplants from Status 4 patients fell from 29.4% to 24.8% of all transplants.

Contrary to NOTA's express requirement that a national organ allocation system be developed utilizing a national organ list, under the new policy, the geographical location of a liver donor takes priority over the seriousness of medical need as a criterion for allocation. Inexplicably, this policy change has occurred at the same time that medical advances allow livers to be transported long distances without adverse effects. As a direct result of this new policy, organ waiting lists at many transplant centers, including Presbyterian University Hospital, have more patients than under the UNOS/STAT Policy, and patients on the waiting lists are required to wait longer for organs under the new policy.

The increased waiting period for Status 3 and 4 patients occasioned by this new policy carries with it significant costs. For example, after the new UNOS liver allocation policy was put into effect in 1991, the length of stay at transplant centers for pre-transplant patients on waiting lists and the pre-transplant medical charges increased drastically from prior years. In fact, at Presbyterian University Hospital the pre-transplant length of stay in 1992 doubled the pre-transplant length of stay in 1989, the pre-transplant time in ICU quadrupled from 1989 to 1991, and the pre-transplant charges in 1992 more than tripled the

pre-transplant charges in 1989, as more particularly set forth below:

Comparative Averages for Transplant Patients at PUM

<u>Year</u>	<u>Length of Stay (Days)</u>	<u>Pre-Transplant Length of Stay (Days)</u>	<u>Pre-Transplant ICU Length of Stay (Days)</u>	<u>Pre-Transplant Charges</u>	<u>Total Average Charges per Patient</u>
1989	42.3	6.7	0.8	\$21,948.90	\$273,476.69
1990	43.8	7.9	1.4	36,855.58	344,653.02
1991	46.8	9.3	1.8	53,705.64	433,585.27
1992	58.0	13.1	3.1	73,536.37	582,351.27

Furthermore, many seriously ill Status 3 and 4 patients waiting for organs now require increased recovery time since their health has seriously declined before transplantation, and they incur greater health care costs and more lost income as a result thereof.

Of greatest concern is the fact that the elimination of UNOS/STAT has increased the likelihood that patients in imminent danger of dying will, in fact, die. For example, the longer a Status 4, non-life support patient waits for a liver, the greater the chance that the patient's condition will deteriorate and the patient will end up being on life support by the time a liver becomes available. One of the most significant risk factors for a liver transplant recipient is the recipient's medical condition at the time of the

transplant, and patients on life support are four times more likely to die in the first year following a transplant than non-life support patients. Additionally, before a liver even becomes available to a transplant patient, the patient may become so ill while waiting that he or she will be removed from the candidate list altogether. This result is unconscionable, particularly in light of the fact that UNOS reported that prior to 1991 the percentage of Status 4 patients on waiting lists at any one time was generally between 3% and 15%. There are enough available livers, if allocated in accordance with medical necessity, to transplant all Status 4 and Status 3 patients and some Status 2 patients.

Because the new UNOS liver allocation policy has replaced the national system with a local and regional system, patients are, in effect, forced to engage in a lottery by selecting transplant centers with short waiting lists, or by trying to guess which locales are likely to have a greater supply of donor livers, rather than on the bases of quality, reputation, experience and cost. This outcome discriminates against the poor, who are limited solely to transplant centers close to where they live, and against veterans who are restricted to two VA-approved transplant centers, one of which is Presbyterian University Hospital.

The number of transplants and patients requesting transplants have consistently increased each year and more

patients are either dying at some transplant centers or their condition is deteriorating due to the inequitable allocation of organs as they wait for a suitable match. According to UNOS, in 1989 2,191 transplants were performed nationwide and 830 patients remained on a waiting list. Of the 830 waiting list patients, 300 were on life-support.

In 1990, the number of liver transplants increased to 2,555. Approximately 1,880 patients remained on a waiting list. Of those patients on the waiting list, 300 were life-support patients; 200 were non-life-support/intensive care patients; 480 were hospitalized patients; and 900 were home-bound patients.

The total numbers, and especially the number of Status 3 and 4 patients, increased drastically in 1991, the year of the policy change, when 2,954 liver transplants were performed and 4,860 patients remained on a waiting list. Of the waiting list patients, 800 were life-support patients; 600 were non-life-support/intensive care patients; 1,360 were hospitalized patients; and 2,100 were home-bound. Attempts have been made to obtain the waiting list statistics for 1992 from UNOS. However, UNOS has refused to provide these statistics at this time.

Presbyterian University Hospital at the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania, is the oldest and largest liver transplant program in the United

States. It is an internationally recognized center for human organ transplantation. Due to the expertise of Dr. Thomas Starzl and advances in transplantation research and surgical procedures, more patients from all over the country have sought to have their transplants, particularly liver transplants, performed at Presbyterian University Hospital than at any other transplant center in the country. The quality, skill and expertise of the hospital's program have resulted in a success rate for liver transplants that is above the expected rate, particularly considering the severity of the patients' conditions.

Because Presbyterian University Hospital is the largest transplant center, having performed more liver transplants than any other center, Presbyterian University Hospital patients have been severely and adversely affected by the new UNOS allocation policy and the resulting waiting list increases. For example, Presbyterian University Hospital performed 469 transplants in 1990. Of the transplant recipients, 66% were either UNOS/STAT or Status 4. The number of patients remaining on the waiting list at the end of 1990 totaled 277. Of those patients, 46 died while waiting.

In 1991, the number of transplants at Presbyterian University Hospital decreased to a total of 356. Of the transplant recipients, 40.9% were Status 4 patients. This indicates the deterioration of a patient's condition as a

result of the longer waiting period under the new policy. At the end of June 1991, the number of patients on the waiting list was 377, and the number of patient deaths doubled to 91.

As a result of the new UNOS liver allocation policy, major transplant centers, such as Presbyterian University Hospital, have experienced a significant decrease in the number of available livers and their patients have had to wait longer on a lengthened waiting list for organs for transplantation. Patients at Presbyterian University Hospital are now experiencing higher death rates. Overall, the waiting lists at transplant centers, such as Presbyterian University Hospital, have increased and the health status of those patients has become worse.

These patients are more than just statistics. They are real people whose chance of survival decreases with each day that passes without the receipt of a liver transplant. An article in the Wall Street Journal on April 1, 1993, tells of Rex Voss' unsuccessful fight for time, and ultimately life, waiting on a donor liver. In 1992, the 41-year-old Mr. Voss, who was also a father of four teenaged boys, contracted hepatitis C from an unknown source. Mr. Voss was evaluated and accepted as a liver transplant candidate at Baylor University Medical Center, and was placed on the waiting list. While waiting, Mr. Voss' condition deteriorated to a Status 4. He was placed in the intensive care unit and required a

life-support machine in order to breathe. Livers were available; however, they went to healthier patients as close as 40 minutes by air. Doctors eventually were forced to tell Mr. Voss' family that he was no longer a transplant candidate because of his deteriorated condition. Mr. Voss died on December 8, 1992.

Mr. Voss' story is just one of many tragedies which have resulted from the new allocation policy. However, a change can bring about happier endings, such as the story of Charlie Fourstar. Charlie Fourstar is a 4-year-old Sioux Indian girl from Montana who recently received a 5-organ transplant (including a liver) performed by surgeons at Presbyterian University Hospital. Fortunately, a liver became available to this Status 4 child in time to save her life. If the liver allocation policy is made more equitable on a national basis, more stories such as Charlie Fourstar's can occur.

The Committee should also be aware that this change of policy -- which has had such an enormous and devastating impact -- was not the result of any appreciable public comment or review. The new liver allocation policy was adopted by UNOS in October, 1990 and implemented on January 1, 1991, following only an internal approval process. Not until three weeks later, on January 21, 1991, were the changes sent to other interested parties for any comments. Even then, the "public"

comment procedure calls for the circulation to only a limited list of individuals and groups who have previously indicated an interest in UNOS policies and procedures. Presbyterian University Hospital reluctantly agreed with the merger of UNOS/STAT patients into Status 4, but vigorously objected to the "regionalization" of the new liver allocation policy.

Importantly, the U.S. Department of Health and Human Services -- charged with stewardship over the operation of the OPTN -- has also not approved this change in policy. Over 3 years ago in a letter dated September 22, 1989 the then appointed Assistant Secretary of Health announced that "effective immediately, policies that the OPTN contractor intends to be binding upon members of the OPTN are subject to the Secretary's review and approval prior to implementation," although existing UNOS policies could remain in effect pending the outcome of the Department's review. A December 18, 1989, notice in the Federal Register, published by the HCFA, required the approval of the HHS Secretary before a rule or requirement of the OPTN would be mandatory or binding on hospitals and OPO's participating in Medicare or Medicaid. As explained above, however, UNOS has changed organ allocation policies that affect patients, hospitals and organ procurement organizations effective January 1, 1991, without HHS approval. Indeed, in a May 24, 1991 letter to the President of the University of Pittsburgh Medical Center, the Assistant Secretary for Health

acknowledged that it had not determined which elements of the UNOS policy on liver allocation to adopt. It can hardly be said that this new allocation system -- which resulted in a redesign of the nationwide computer system to conform to the new allocation rules -- is anything but mandatory in its effect on the liver allocation policy of this county.

In conclusion, the current UNOS liver allocation policy was arrived at without the benefit of broad public participation and without the approval of the very government agency responsible for overseeing the program. The fact that the new policy gives primacy to geography and that a Status 4/life-support or intensive care patient in one region loses a liver to a Status 2 patient in another region clearly goes against the congressional intent behind the Act. Moreover, this result completely contradicts and defies the very purposes upon which UNOS bases its allocation policies.

Although the previous policy was not a perfect system, it was better than the current policy. The pre-1991 policy, with its UNOS/STAT classification, more closely approximated the "national" allocation system that is mandated by the Act. The pre-1991 system also more accurately accounted for UNOS' "critical factors" of medical urgency or need and time on the waiting list, than does the new policy.

The only effective remedy for this inequitable situation is to return temporarily to the UNOS/STAT Policy that

was based on patient medical necessity and a national priority system, and to require that HHS engage in notice and comment rulemaking that will create a truly national allocation policy using a national transplant list. The University of Pittsburgh urges this Subcommittee to adopt an amendment to existing law that accomplishes this result.

3103D



University of Pittsburgh

UNIVERSITY OF PITTSBURGH MEDICAL CENTER

PROBLEMS WITH THE UNOS ALLOCATION SYSTEM
FOR HUMAN LIVERS FOR TRANSPLANTATION:
RULEMAKING AND A RETURN TO THE PREVIOUS SYSTEM REQUIRED

- The National Organ Transplant Act, originally passed in 1984 requires the establishment and operation of an Organ Procurement and Transplantation Network ("OPTN"). The OPTN was required by statute to establish a national list of individuals who need organs, and to establish a national system in accordance with established medical criteria to match organs and individuals included in the list.

- Up until 1991, the United Network for Organ Sharing (UNOS), the Government contractor responsible for establishing and operating the OPTN, had adopted policies for liver allocation which, while not without problems because of an emphasis on local use of organs available for transplant, allowed the geographic limitation to be overridden to meet the urgent needs of the most seriously ill patients regardless of location (the so-called "UNOS/STAT" designation for patients at risk of dying within 24 hours).

- In 1991 UNOS revised this policy to abolish the use of the UNOS/STAT designation. The net effect of this policy change is that the geographic location of a liver donor now takes priority over the seriousness of medical need as the leading criterion for organ allocation. The new policy relies

on four patient status categories: Status 1 patients who are at home and functioning normally; Status 2 patients who require continuous medical care, but not constant hospitalization; Status 3 patients who must be continually hospitalized; and Status 4 patients who are in critical condition due to acute or chronic liver disease and are hospitalized in intensive care units. Status 4 includes patients who would have otherwise been UNOS/STAT. The new policy allocates livers geographically first to local Status 4 patients, then to Status 3's, then to Status 2's, and finally to Status 1 patients; then regionally from Status 4 to Status 1 patients; and finally nationally from Status 4 to Status 1. Thus, medical urgency based on the severity of the patient's condition is a determinant only as a secondary element within each of the three geographical divisions. For example, a Status 1 patient in a local area has a higher allocation priority for, and a greater chance of receiving, an available liver than a Status 4 patient in the region or nationally. Yet, a Status 1 patient is functioning normally, while a Status 4 patient is considered to be within a week or two of death. Recent data from UNOS confirms the effect of this policy. From 1990 to 1991 transplants for patients in Status 1 increased from 14.7% to 20.4% of all transplants, while transplants for Status 4 patients fell from 29.4% to 24.8% of all transplants.

- The new policy is ill-conceived and unsound because:
 - it extends unconscionably the waiting time for the most seriously ill patients resulting, at best, in the significant deterioration of patient status prior to transplantation, and, at worst, in the death of individuals who otherwise would have been viable transplantation candidates;
 - it is directly responsible for the dramatic escalation in the cost to transplant those seriously ill individuals who are able to get the needed organs; and
 - it runs counter to Congress' express direction that allocation policies be based exclusively on compelling medical criteria, and to UNOS' own policy rationale that clearly notes the irrelevance of geographic distance as an allocation factor.

• This policy change was not subject to any appreciable public comment or review. Moreover, HHS, charged with oversight of the OPTN, has not, to our knowledge, approved such change. Indeed, HHS has said that any such change should not be mandatory until it has reviewed and approved the policy, after going through rulemaking. Nonetheless, UNOS has gone ahead and adopted this change -- including revising its

computerized match system accordingly -- which effectively mandates compliance.

Based upon the above, we request that the Congress amend the Public Health Service Act to require that not later than 90 days after the enactment of this Act the Secretary publish in the Federal Register a notice of proposed rulemaking with no less than 60 days provided for public comment, to establish a national policy for allocation of livers which would include a national waiting list. Further, we request that Congress require the Secretary to publish a final rule establishing such policy not later than one year after the enactment of this Act. Until the publication of this final rule we urge that UNOS be required to reinstitute the liver allocation policy in effect before the amendments adopted by the UNOS on January 1, 1991.

3111D

Good morning Chairman Waxman and members of the subcommittee.

My name is Andy Tzakis and I am a transplant surgeon at the University of Pittsburgh where liver transplantation was largely developed and popularized. Most of the liver transplant surgeons practicing in the United States and around the world have been trained there.

We support the national allocation system which is provided for in the National Organ Transplant Act. However, today I would like to address current organ allocation practices, particularly as they pertain to liver transplantation. As you know, the fairness of organ allocation is the principle goal of this legislation.

Patients on the liver waiting list range from the slightly ill to critically ill. The sick patients should be transplanted first. There are three reasons: one is statistical, the second is financial, the third is moral.

If patients in dire need are not transplanted, 98% of them will be dead within a year. With transplantation, 68% of them will survive and this 68% is the net gain in life.

The best expected 1 year survival after transplantation for well patients is 89%. If not transplanted, ninety-five percent of them would have survived for a year if not transplanted. Transplantation of well patients provides an improvement in the quality of life but there is a net loss in life.

The financial reason comes next. There is nothing more expensive than sickness. If you have any doubt just look at a hospital bill. A program designed to take care of the sickest people first is bound to be cheaper than any program which ignores the fact that they are sick. Sicker patients do not die on cue when an organ goes to a healthier patient. Instead, they stay in our hospitals, often our intensive care units, and receive the most expensive kind of care in a desperate wait at a chance for life.

Then there is the most important, the moral reason. It is morally wrong to transplant the well patients first. With a ship on fire, the weak are evacuated first.

The patients should decide where they want to be treated and the organs should go where the patients are. In today's informed world, the patients know where their best chances are. They build or close down transplant centers according to results, and this is fair.

Transplant center survival statistics do not mean much. Centers which transplant difficult and high risk cases may not show the best survival statistics. Centers which select "boutique" cases, the healthier patients, may. The patients and their referring physicians know where chances are the best. Allowing the organs to follow the patients would enable the whole transplant system to autoregulate.

The current allocation policies adopted two years ago are based on logistics rather than medical need. According to existing policies, livers are first distributed locally and regionally and then leftovers go nationally. The problem is that if you transplant everyone on a local list first, including the patients who are relatively well, there are not enough livers left for patients around the country who will soon die without them.

There is no reason for artificial geographical boundaries because using current preservation methods, organs can be safely transported to every place in the United States using commercial aircraft.

What we propose is a single national transplant list as the act originally intended. Allocation of the organs should be according to medical necessity. If there is a tie, they should be allocated to the patient waiting the longest. Logistical factors should play a secondary role.

You can make this possible in your reauthorizing the act. When you do it give direction to the Administration and the contractor about your intent on having a national list based on medical need. Require them to engage in rulemaking or some other process which allows the patients and the public to express their view. In the meantime, require a return to the policy that provided for a national list for the critically ill. They need it urgently. I'm sure that if you do this, when you, your relative, your friend or your constituent have to come for help, we will probably be able to find an organ and save that life. Thank you.

3132D

INTER-OFFICE ROUTING SLIP

TO:

Carol Rasco

FROM:

NANCY HERNREICH

DATE:

24
3- -93

THE FOLLOWING MATERIALS WERE SENT TO YOU, PER THE PRESIDENT'S REQUEST. PLEASE TAKE APPROPRIATE ACTION. THANK YOU.

PRESIDENT COMMENTS:

(see attached)

3-10-93

CHRISTOPHER HYLAND

Submits proposal for Presidential Design Award to debut in 1994. Designers and architects can make environments, buildings, neighborhoods and cities that encourage productivity, provide safety and are accessible to all users. Good design affects every aspect of our material world. Proposal suggests that the award be named: The Jefferson Presidential Design Award.

Carol
Think
good idea
should be approved

Rasco

THE WHITE HOUSE

WASHINGTON

HHS

Brian Biles, Deputy Asst. Secty. for
Public Health Policy

Gerry Mande, Acting Assoc. Commissioner
for Legislative Affairs @
FDA

Dick Riseberg, Director of Public Health
Div. - Gen. Counsel

VP's Office

Charlotte Hayes

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DATE April 29, 1993

TOTAL NUMBER OF PAGES 3 (INCLUDING COVER SHEET)

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TO: Ms. Carol Rasco
 FIRM: THE WHITE HOUSE
 TELECOPIER: (202) 456-2878

FROM: John R. Tisdale

Our Teletcopy No.: (501) 376-8442

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Re: Meeting with Representatives of the University of Pittsburgh Medical Center

Ms. Carol H. Rasco
 Assistant to the President
 for Domestic Policy
 THE WHITE HOUSE
 1600 Pennsylvania Avenue
 Washington, D.C. 20500

VIA TELECOPIER: (202) 456-2878
CONFIRMATION COPY TO FOLLOW

Dear Carol:

Thank you very much for making room on your busy schedule to meet with representatives of the University of Pittsburgh Medical Center. I wanted to confirm my message to Rosalyn that we can meet with you on Wednesday, May 5, 1993 at 1:30 p.m. The persons who will attend the meeting on behalf of the University of Pittsburgh Medical Center and their birthdates are as follows:

	<u>Name</u>	<u>Birthdate</u>
1.	John Tisdale	P6/b(6)
2.	Isabel (Liz) Dunst Hogan & Hartson	
3.	<i>Jean</i> Eugenia C. Stoner University of Pittsburgh	
4.	<i>Andy</i> Dr. Andreas Tzakis University of Pittsburgh	
5.	<i>Transplant surgeon</i> Lazar M. Palnick University of Pittsburgh	

P6/b(6)

Assoc. Gen. Counsel - Med Center

WRIGHT, LINDSEY & JENNINGS

Ms. Carol H. Rasco

April 29, 1993

Page 2

In our conversation, you asked for suggestions about appropriate people from HHS to attend the meeting. In addition to Secretary Shalala, we believe Assistant Secretary of Health Designate Dr. Philip Lee and HHS Chief Counsel Ms. Harriet Rabb are key HHS personnel to be involved in the decisions relating to organ allocation issues.

There are two other persons in HHS who have some knowledge about this issue. Dr. Robert Harmon is the Administrator of the Health Resources and Services Administration. He is a holdover appointee from the prior administration and I understand that his tenure may be limited. He appeared at Congressman Waxman's hearing as the principal spokesman for the Administration to defend the current organ allocation policies. Ms. Judith Braslow is currently the director of the Division of Organ Transplantation at HHS. In that position she has been supportive of and has defended the current organ allocation policies. Given the prior involvement of these two persons in supporting the "heavily criticized" policy, I do not think they should be included.

As I mentioned to you in my earlier letter, Charlotte Hays in the Vice President's office has some knowledge of activities in this area. If you feel that it is appropriate, please invite her to the meeting.

To give you some additional background about the issues, I am enclosing a short summary of the written testimony submitted on behalf of the University of Pittsburgh Medical Center at Congressman Waxman's Committee hearing as well as a full copy of the Medical Center's statement. Dr. Tzakis from the Medical Center testified at those hearings and I enclose a copy of his remarks. I think they will help you understand his extensive background and knowledge in this area, prior to the meeting.

Again, thank you very much for making room on your schedule to visit with us. We look forward to seeing you on May 5th.

Cordially yours,

WRIGHT, LINDSEY & JENNINGS



John R. Tisdale

JRT/blm/Enclosures

Beverly
Kotell

Liver allocation (common also to other organs)

UNOS

Patient issue - not just a Pittsburgh or transplant issue BUT a patient issue

New system: focus ^{seems to be} on allocations to transplant centers not patient

UNOS STAT

Currently ^{proposed}

No rules adopted by feds on allocation.

What needs to be done?

Pre-'91 rule - should go back to it > need ASAP

Longer term > 4 HS needs to issue regs

① UNOS regs: organ allocation

② Organ procurement regs

At hearing > Congress very interested, UNOS plans coord work

From 90 to 91:

Status 1 up 6+%

Status 4 down 6+%

Reason for cancellation? No clear reason

Need national system w/ level 1 prioritized

ACFA - procurement law



University of Pittsburgh

SCHOOL OF MEDICINE
Department of Surgery

JUL 19 1993

July 15, 1993

Ms. Judy Braslow
Director, Division of Organ Transplantation
Room 11A-22
5600 Fishers Lane
Rockville, Maryland 20857

RE: (A) Liver Availability and Transplantation Data
(B) Benefits of Transplanting the "Sickest" Patients First
(C) No Medical Basis for Geographic Limits

Dear Ms. Braslow:

I am writing as a follow-up to your prior discussions with representatives of the University of Pittsburgh Medical Center and to my prior testimony. I wanted to share with you some of our data and some of my reasons for advocating allocation of livers to the sickest patients on a national list. I appreciate your willingness to consider our position as you formulate Regulations on organ allocation.

A. In evaluating the existing liver allocation policies established by UNOS and in formulating suggestions concerning appropriate allocation policies, we at the University of Pittsburgh Medical Center utilized certain data which indicates that, on an annual basis, there are sufficient donated livers to transplant all Status 4 and Status 3 patients and a substantial number of Status 2 patients on the recipient waiting list. The information relied upon by the Medical Center was obtained from UNOS, UNOS reports and OPTN reports. First, we looked at the available information concerning the recipient waiting list and the makeup of that list. Unfortunately, the number of persons on the waiting list and their status are available only on a "snapshot" basis, as of a particular date. From UNOS data we were able to determine the total number of persons on the waiting lists for livers at December 31 of the following years:

<i>TOTAL WAITING LIST FOR LIVERS @ 12/31 from UNOS or OPTN Data</i>					
<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>	<u>1992</u>
454	617	830	1242	1676	2526

Please keep in mind that some potential recipients are listed with more than one transplant center and the numbers provided by UNOS, in most instances, are not adjusted to eliminate multiple listings.

The number of persons on the waiting lists, broken down by Status category for years 1988, 1989 and 1990 were obtained from the UNOS Annual Report for the period January 1, 1990 through June 30, 1991 and from the Annual Report of the OPTN for 1990. The number and percentages of patients in each of the four Status categories are shown below and are adjusted for the change in Status codes which took place in 1989:

<i>PATIENT STATUS ON WAITING LIST FOR LIVERS @ 12/31</i>					
<u>Status</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>	<u>1992</u>
#1	84(14%)	345(42%)	514(41%)	NOT AVAILABLE	
#2	269(44%)	69(8%)	182(15%)		
#3	82(13%)	72(9%)	104(8%)		
#4	34(6%)	26(3%)	25(2%)		
#7(inactive)	148(23%)	318(38%)	417(34%)		

The Medical Center has been unable to obtain this information for the waiting lists as of the end of 1991 and 1992. The available statistics, however, indicate that less than 20% of the patients on the waiting list at any one time are in Status 4 or Status 3. Even assuming (as the Medical Center does) that there has been a slight increase in the number of Status 4 and Status 3 patients since the change in liver allocation policy on January 1, 1991, the Medical Center believes that the percentage of Status 4 and Status 3 patients on the waiting list at any one time does not exceed 20%.

The number of liver transplants each year has been increasing, but more people are seeking transplants than there are livers available. According to UNOS, the number of liver transplants for each of the years 1987 through 1992 was as follows:

<i>TRANSPLANTS FOR THE YEAR ENDED 12/31</i>					
<u>1987</u>	<u>1988</u>	<u>1989</u>	<u>1990</u>	<u>1991</u>	<u>1992</u>
1199	1714	2201	2695	2951	3057

In addition, in a publication entitled, "UNOS Update" dated August 1992, UNOS provided quarterly figures for the additions to and the removals from the liver waiting list for the period December 31, 1987 through and including December 31, 1991. Those numbers are attached as Exhibit 1. An analysis of those numbers indicates that for the years 1990 and 1991 between 32% and 45% of all the patients on

the liver waiting list during each quarter received transplants. These percentages are based upon the total number of persons on the waiting list including those persons shown as being in Status 7 (inactive). If those Inactive patients are factored out, the percentage of patients receiving transplants increases.

Thus, historically 20% or less of the persons on the waiting list at any one time are in Status 4 or Status 3. Statistics also indicate that there are sufficient livers available to transplant between one-third and 45% of the persons on the waiting list at any point in time. If those available livers (assuming they were otherwise compatible) were allocated first to Status 4 and Status 3 patients, all such patients could be transplanted and there would be livers available for many of the Status 2 patients. An example demonstrates this point. In 1990, 2695 transplants were performed and 1373 of those were for Status 4 or Status 3 patients. 129 patients on the waiting list at 12/31/90 were in Status 4 or Status 3. If you assume that 98% of the patients who died during 1990 awaiting transplants (total 316) were Status 4 or Status 3, that totals 310 patients. If all of these Status 4 and Status 3 patients had been transplanted, 1812 donated livers would have been used, and 883 donated livers would have been available for Status 2 and Status 1 patients. In 1990, 1334 transplants of Status 2 and Status 1 patients were performed. Under our proposal, 883 of those would still have been performed. In addition, 96% to 98% of those Status 2 and Status 1 patients who did not receive a transplant in 1990 would still be alive to be transplanted in later years. The same cannot be said for the Status 4 and Status 3 patients who did not receive a transplant.

Unfortunately, the current UNOS allocation system gives a higher priority to Status 2 and Status 1 patients in the locality and region where a liver is donated before making that liver available to a Status 4 or Status 3 patient on the national list. Allocating available livers to Status 4 and Status 3 patients first, without regard to locality, would give those patients a chance at life, yet still allow a significant number of transplants of Status 2 and Status 1 patients so that they never become Status 3 or Status 4.

B. When making decisions concerning whether donated livers or other available organs should be used to transplant the sickest first, it is always difficult to set aside the ethical and moral aspects of the question and focus only on the statistical analysis of survival rates. Typically, survival rates for transplant patients are reviewed three months after the transplant and one year after the transplant. By definition, one can say with certainty that most Status 4 patients will not survive three months without a transplant and virtually all of them will have died within one year from their classification as Status 4 if they have not received a transplant. Nevertheless, when allocating scarce natural resources such as donated livers, the government is obligated to balance the moral and ethical imperative of saving the life of a patient in imminent danger of death against the utilitarian concept of doing the greatest good with the available organs.

In looking at the statistics from UNOS and OPTN concerning survival rates of patients after transplant and the death rates for patients without transplants, the UNOS information is divided into seven (7) patient categories rather than the five Status codes used for liver allocation. A copy of those seven categories has been taken from OPTN 1990 Annual Report and is attached as Exhibit 2. In converting these seven categories to the Status codes used for allocation, Categories 1 and 2 equate with Status 1, while Category 3 equates to Status 2. Category 4 equates with Status 3 and Categories 5 & 6 equate with Status 4. The "not reported" category equates with Status 7 (inactive). Among the UNOS data, the

Medical Center has not been able to find any information which would correlate to a survival rate for Status 1 patients who do not receive a transplant. The Medical Center has done a study of its own patients during the period of January 1, 1989 through December 31, 1990. The results of that study and some observations based upon those results are included in a paper prepared by Dr. Thomas E. Starzl entitled, "Prioritization and Organ Distribution for Liver Transplantation." A portion of a draft of that paper is attached as Exhibit 3. Based upon that study, only 3% of those Status 1 patients died while waiting for a transplant. For Status 2, only 4% died while awaiting transplants. Information based on evaluation of the University of Pittsburgh waiting list, in other years indicated that Status 1 and 2 patients have a one-year mortality of only 2%. What is not known from any of the data available is whether these Status 1 patients died as a result of their liver disease or from other diseases or occurrences. In any event, the data demonstrates that between 96% and 98% of the Status 1 and Status 2 patients should be alive at the end of one year if not transplanted.

In viewing the data on Exhibit 2, the one-year survival rate for Status 1 patients who receive a transplant is somewhere between 84% and 86%. Likewise, the UNOS figures indicate that a Status 2 patient has a one-year survival rate of only 80% following a transplant. Thus, both Status 1 and Status 2 patients reduce their chances for survival for one year by undergoing a liver transplant. Obviously, considerations such as the opportunity for a better quality of life and the opportunity, if they survive one year, to have a greater life expectancy enter into the decisions to have a transplant.

A look at Status 3 and Status 4 patients from the University of Pittsburgh's study, however, indicates significantly different results for these patients if they are not transplanted. Among Status 3 patients only 6% were alive at the end of one year without a transplant, while 4% of the Status 4 patients had survived for one year without a transplant. In the Medical Center's study, they continued to track UNOS/STAT patients (Status 5) and found that only 3% of those patients were alive and still waiting for a transplant at the end of one year. Based solely upon their medical classification, the Status 3 and Status 4 patients would not be expected to survive in any large numbers for a year without a transplant.

The UNOS figures for years 1987 through 1989 indicate that Status 3 patients (Category 4) have a one-year survival rate after transplant of 73.6%, while those patients in Status 4 (but not on life support) had a one-year survival rate after transplant of 73.9%. The figures show, and reason would tell us, that those Status 4 patients on a life support system at the time of transplant would have the lowest one-year survival rate (52.6%).

As Dr. Starzl points out on pages 4-6 of his article, the benefits to be gained from transplanting the sickest patients first cannot be evaluated by comparing the percentage of transplanted patients in each status who do not survive. The benefit to be derived from liver transplantation is in part the increased life expectancy, and resulting increased productivity, of the transplant recipient. From the information in Dr. Starzl's paper, it is obvious that the increased years of life expectancy and productivity gained by a successful transplant of a Status 3 or Status 4 patient when compared with the life expectancy for that patient without a transplant is significantly greater than the increased life expectancy and productivity resulting to a transplanted Status 2 or Status 1 patient when compared with the life expectancy of that patient without a transplant.

Ms. Judy Braslow
July 15, 1993
Page 5

As demonstrated in the earlier part of this Memorandum, there are enough donated livers available to transplant all Status 4 patients and all Status 3 patients and a significant portion of the Status 2 patients on an annual basis. Based on the UNOS figures for 1987 through 1989, the difference in one-year survival rates between a Status 1 and a Status 4 patient (not on life support) is only 10 to 12%. The increased life expectancy and productivity gained by transplanting the Status 3 and Status 4 patients when compared to the increased life expectancy and productivity of a transplanted Status 1 patient far outweigh the difference in survival rates.

One other point needs to be considered when looking at survival rates for patients with and without transplants. There is continuing research and regular advances in the treatment of various types of liver diseases, some of which lead to cures while others lead to increased life expectancy. Those patients in Status 3 and Status 4 are, in many cases, beyond the point where they can benefit from current developments in the treatment of their disease. Likewise, they do not have the time to wait for the new treatment which might be available in six months or a year or two. On the other hand, in most instances, the Status 1 and Status 2 patients have a life expectancy which allows them the benefit of the continuing advances in treatment of liver diseases.

When you think about it, you will see that UNOS does not truly dispute the efficacy of transplanting the sickest patients first. In the UNOS allocation policy Status 4 patients are given priority over Status 3, 2 and 1 patients in each geographic area. If it is appropriate to transplant the sickest first in a local area, why is it not appropriate to transplant the sickest patient on the national list?

C. UNOS has admitted that transporting donated livers over long distances is not medically relevant to a successful transplant. In its Policy Proposal Statement which announced the new liver allocation policy, UNOS made the following statement:

The distance factor is not relevant in the revised liver allocation policies (see Policy 3.6.7.1 below) because the current method of liver preservation (UW Solution) allows for long distance shipments. The committee believed that the donor livers available should be allocated to the most needy, irrespective of distance.

Notwithstanding these statements, UNOS adopted and implemented a liver allocation policy which provides that a local Status 1 patient (clearly one of the least urgent and least needy patients on the waiting list) will receive a compatible liver before an equally compatible Status 4 or Status 3 patient (clearly a more needy and more urgent patient) in another part of the U.S.

It is the belief of the Medical Center (1) that the concept of transplanting the sickest patients first without regard to their location with respect to the donated organ is the correct response to the moral and ethical question "which patients should receive the donated livers?" and (2) that transplanting the sickest patients first without regard to their location with respect to the donated organ is the correct answer to the utilitarian question of providing the greatest benefit from the use of donated organs.

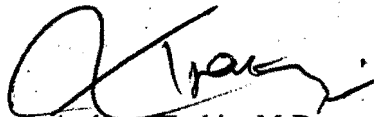
Ms. Judy Braslow
July 15, 1993
Page 6

At the very least, the regulations should allocate livers to compatible Status 4 and Status 3 patients on the local OPO list and then on the national list, before allocating the livers to any Status 2 or Status 1 patient.

Thank you for your hard work on this matter and your consideration of my thoughts.

Sincerely yours,

UNIVERSITY OF PITTSBURGH MEDICAL CENTER



Andreas Tzakis, M.D.

AT/blm
Attachments

cc: Brian Biles, M.D.
Deputy Assistant Secretary for
Public Health Policy
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Room 717H
200 Independence Avenue, S.W.
Washington, D.C. 20201

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Ms. Charlotte Hays
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UNOS Liver Transplantation Data Reviewed

The Organ Procurement and Distribution Committee's Liver subcommittee recently examined a selection of data analyses on liver waiting list additions and removals, liver sharing and Status 4 recipient outcomes. It was noted that the percentage of livers shared nationally has decreased significantly from 51 percent in 1988 to 21 percent in 1991. The subcommittee opined that this decline is largely due to the increasing number of U.S. liver transplant centers as well as the increased size of the waiting list. (See tables below and on page 9.)

Analysis of Additions and Removals to the Liver Waiting List Entire U.S.

Quarter Ending	List Size: Start	New Regs.	Total Waiting	Avg. List Size	Removed: Transplant	Removed: Died	Removed: Other	List Size: End	Number Transplants
12/31/91	1,519	1,091	2,610	1,600	716	123	92	1,679	762
09/30/91	1,504	1,051	2,555	1,495	788	148	100	1,519	799
06/30/91	1,338	1,041	2,379	1,436	643	132	100	1,504	720
03/31/91	1,242	986	2,228	1,293	627	126	137	1,338	658
12/31/90	1,081	1,024	2,105	1,174	638	101	124	1,242	685
09/30/90	971	909	1,880	982	622	90	87	1,081	695
06/30/90	936	895	1,831	961	640	97	123	971	705
03/31/90	829	848	1,677	881	548	89	104	936	571
12/31/89	754	776	1,530	775	518	89	94	829	563
09/30/89	747	689	1,436	747	521	67	94	754	575
06/30/89	721	723	1,444	739	512	79	106	747	567
03/31/89	610	749	1,359	667	462	82	94	721	495
12/31/88	518	652	1,170	568	443	54	63	610	470
09/30/88	450	583	1,033	494	387	61	67	518	429
06/30/88	456	498	954	469	413	50	41	450	435
03/31/88	449	446	895	459	343	38	58	456	380
12/31/87	381	420	801	415	276	34	42	449	322

(Based on UNOS OPTN files as of March 26, 1992)

Source of Transplanted Livers, by Year

Year	Organ Source			Total
	Local	Intra-Regional Share	Inter-Regional Share	
1988	467	367	880	1,714
	27.25	21.41	51.34	
1989	754	538	904	2,196
	34.34	24.50	41.17	
1990	1,072	658	911	2,641
	40.59	24.91	34.49	
1991	1,428	876	605	2,909
	49.09	30.11	20.80	
1992	316	146	90	552
	57.25	26.45	16.30	
Total	4,037	2,585	3,390	10,012

(Based on UNOS Donor Registration Records as of April 25, 1992.)

Appendix E-VI (cont'd)
Liver Transplants: October 1, 1987 - December 31, 1989
Three Month and One Year Patient Survival Rates
by Race, Citizenship, and Patient Description

	N	3 Month Survival %	Std. Error	1 Year Survival %	Std. Error
RACE					
White	3236	80.5	0.7	72.5	0.8
Black	338	74.8	2.4	67.2	2.6
Hispanic	240	74.2	2.8	68.7	3.0
Asian	128	78.8	3.6	59.6	4.4
Other	108	83.2	3.6	77.6	4.0
Not Reported	167	74.2	3.4	72.3	3.5
CITIZENSHIP					
U.S. Citizen	3909	79.7	0.6	71.7	0.7
Foreign National	142	79.5	3.4	68.7	3.9
Not Reported	166	73.4	3.4	71.6	3.5
PATIENT DESCRIPTION* AT TIME OF TRANSPLANT					
1	103	90.3	2.9	86.4	3.4
2	203	87.7	2.3	83.7	2.6
3	1384	87.5	0.9	80.3	1.1
4	1053	82.8	1.2	73.6	1.4
5	474	81.2	1.8	73.9	2.0
6	995	61.4	1.5	52.6	1.6
Not Reported	5	40.0	21.9	40.0	21.9
OVERALL	4217	79.5	0.6	71.6	0.7

***Patient Description Codes are:**

1 = Working/Attending School Full Time
 2 = Working/Attending School Part Time
 3 = Home-Bound/Failing to Thrive

4 = Hospitalized
 5 = In Intensive Care
 6 = On Life Support

SOURCE: SCIENTIFIC REGISTRY AS OF MARCH 3, 1992.

NOTES: N DENOTES THE NUMBER OF TRANSPLANTS FOR WHICH A SURVIVAL TIME COULD BE DETERMINED.

THE SURVIVAL RATES WERE COMPUTED USING THE KAPLAN-MEIER METHOD. STANDARD ERRORS WERE COMPUTED USING GREENWOOD'S FORMULA.

FOR REFERENCES, SEE THE DISCUSSION AT THE BEGINNING OF THIS APPENDIX.

**PRIORITIZATION AND ORGAN DISTRIBUTION
FOR LIVER TRANSPLANTATION**

Our professional and moral obligations are to make liver transplantation available by competent practitioners to those who need it and at an appropriate time --- neither at the brink of death, if this can be avoided, nor prematurely, if this service is not needed. It is obvious that we can not meet these obligations with the organ procurement and distribution systems now being used on either side of the Atlantic. Thus, the discussions at this meeting have centered on the wiser division of an allograft pie that is too small. The derivative implication is that livers must be rationed, and because rationing has a nasty ring to it, the word "prioritization" has been substituted.

CANDIDACY AND THE EFFICIENCY FACTOR

Single Disease Studies

The guidelines of candidacy were simple in the old days (before the American Concensus Conference of 1983 [1]), when liver transplantation still was classed as experimental. No adult on our candidacy list was considered who did not have chronic liver disease with a life expectancy of less

than 3 months. Fulminant hepatic failure was not yet a significant consideration although a few cases had been done in Denver (2).

Primary Biliary Cirrhosis --- The effect of such grave illness on post-transplant survival was defined decisively in the early cyclosporine era in patients with the uniform disease diagnoses of primary biliary cirrhosis (3). This study of our Colorado-Pittsburgh recipients from March 1980 through June 1987 was done in collaboration with physicians at the Mayo Clinic who independently stratified the patients into low, mid range and high risk categories by the combined factors of age, serum bilirubin, albumin, prothrombin time, and an edema index. The effect of liver transplantation on life survival was then compared with the outcome expected without transplantation.

This comparison was made possible in lieu of an actual randomized trial because the prognosis of patients had been shown previously to be highly predictable from a data base of 418 adults, including 106 who were eligible for transplant candidacy but declined it (4). These "control" patients had been given optimal medical treatment by Mayo Clinic physicians, and from their actual outcome a Cox

multivariant regression hazard prediction was constructed. This was called the Mayo model. From it, the 3 risk categories were defined for our transplant recipients (Table 1).

As a further notation, the policy at the time of the transplantation case accrual was not to operate on patients with PBC until the bilirubin increased above 10 mg% (171 micromoles/liter) unless there were exceptional additional features portending early death. Thus, virtually all patients who underwent transplantation in this earlier era had more severe disease than many (probably even the majority) of PBC patients now considered prime candidates for early intervention in many programs. The average bilirubin was 12 mg% in the good risk group 1 patients, 24 mg% in group 2, and 28 mg% in the high risk group 3. All 3 cohorts had significant hypoalbuminemia.

The one-year patient survival after transplantation was 76%, a 31% gain over the 45% predicted with medical treatment (Figure 1). Those who made it beyond 6 months had a relatively flat life survival curve thereafter. This study (3) and a similar one by Neuberger and Williams of London and Cambridge (5) constituted the first supreme

validation of the therapeutic efficacy of liver transplantation.

As to the efficiency of organ use, the sickest patients had the worst results after transplantation. Only 58% of the high risk category 3 recipients survived for one year, compared to 77% with an intermediate degree of illness, and 85% for those with the most favorable preoperative score (Figure 2).

These results have been used to illustrate a graded inefficiency of organ use. However, the studies had a deeper meaning that has been largely ignored --- namely the gain and loss of life years with transplant intervention at various disease stages. The greatest gain compared to the expectations of the Mayo model, actually was in the high risk patients. Of 100% of such patients, 58% (hereafter called life years) otherwise consigned to the loss column was the dividend after 12 months. The gain of life years during this time was almost as great in the intermediate severity group in which the average entry bilirubin was 24 milligrams percent. In contrast, the dividend was only 15 life years in the so-called good risk group in which the one year survival would have been 70% without surgical

intervention. The degree of rehabilitation of the survivors and the death rate after one year were the same no matter how sick the patients were at operation.

Sclerosing Cholangitis --- It could be contended that PBC was not representative of other chronic liver diseases. However, similar but even more pronounced trends were seen with the diagnosis of sclerosing cholangitis (6). Again, the stratification of disease severity was done blindly by the Mayo Clinic physicians, eliminating as before the seemingly universal charges of exaggeration of clinical gravity that each program directs at all others. Here, the parameters contributing a second Mayo prediction model (7) were: age, bilirubin, splenomegaly, and the histopathologic stage which was graded from 1 to a maximum severity of 4 (Table 2).

In this series compiled between 1981 and 1990, 3/4 of the transplantations were performed in Pittsburgh but almost 25% were contributed by the new Mayo Clinic surgical team whose first case was entered in March 1985. As with PBC, the best results were in patients with the lightest disease, and the worst with the most gravely ill recipients, with the cases of intermediate disease severity in between (Figure

3). But once again, the gain in life years that otherwise would have been lost was most modest in the so-called boutique (good risk) cases. In fact, even after 7 years, the difference in survival between the transplant recipients and that predicted without such treatment was less than 7% (60 versus 53%). In contrast, 30 life years was the dividend in the intermediate class 2 patients by the end of the first year, a gain that steadily expanded thereafter. Those in the high risk class 3 cohort achieved a stunning 40 life year gain by 12 months, an improvement that had grown to nearly 80 life years per/annum at 7 years by which time the best results belonged to the patients who originally had been most ill. There were no deaths after 18 months in this transplanted high risk group whereas all were projected dead by the Mayo model without such treatment.

Heterogeneous Diagnoses:

Disease Severity and Cost

A study of liver transplantation confirming the pervasive principle that sick patients are more apt to die at the time of initial treatment than well ones, and are more costly to take care of, will win no prizes for originality. However, because a study from the New England

Medical Center unites so well the issues of disease status, survival, and cost, it is unusually valuable (8). The investigation was of 124 adults and children who had a full spectrum of diagnoses and medical urgency. They were given 142 livers between 1984 and 1992. The rate of retransplantation (15%) well within national standards (9).

Urgency of need was determined with the 5-tier UNOS score that was used through 1990: 1) working, 2) home (many still working) but requiring close medical supervision and/or sporadic hospital care, 3) hospital bound continuously or the majority of time, 4) ICU bound usually with ventilator support, and 5) UNOStat, meaning a life expectancy of only a few days without transplantation. Fulminant hepatic failure accounted for 18 of the 31 patients in the UNOStat group.

Using the UNOS stratification, the New England results showed the expected impact of preexisting illness on graft survival (lower border of the shaded life survival) and patient survival (upper border) --- the difference between the 2 representing the benefit of retransplantation. The highly elective UNOS 1 and 2 recipients lived 35% more frequently than those in the UNOStat stage 5 (88 vs 53%)

(Figure 4). Even the UNOS 3 patients who were hospital bound but on the wards had only a 69% one year survival. Although this was a small program with a case accrual averaging less than 15/year, it was one of the first to be established on the east coast. The significant salvage of patients with catastrophic disease in spite of the minimal exposure of the transplant team to such cases was at least as noteworthy as the fact that the survival curve was degraded by their inclusion for candidacy.

What is missing in Figure 4 is an estimate of the survival expectations of the unoperated patient. However, what is apparent is that each higher level of treatment urgency piled on the dollar cost, reaching the median of nearly a quarter of a million dollars per case in the status 4 and 5 (UNOStat) categories. These figures included the expenditures before transplantation which presumably were considerable. In our own experience, these costs often exceed the expenses afterwards if recovery from transplantation is rapid and uncomplicated.

The Boston study also analyzed gravity of illness by different measures (8). One was the elective versus high risk classification of Blue Cross/Blue Shield consortium,

one of Americans leading health insurance corporations. High risk factors in this classification included several hepatic disease diagnoses (examples: fulminant hepatic failure, B virus hepatitis and prior transplantation), technical complexity such as previous portacaval shunt or other upper abdominal operations, extremes of age or body weight, abnormalities of other organ systems (particularly cardiovascular-renal), and infections.

In addition, the Boston patients were classified by their so called Apache score which expresses pretransplantation need for intensive care. With either the Blue Cross/Blue Shield or Apache stratification, the same trend of poorer and more expensive results was seen with the high risk patients as had been documented for the same patients with the UNOS system (Table 3).

Yet, no matter how sick or how high risk the patients were at the time of operation, those who lived and were tested one year later (and this was the majority in every subgroup) had the same degree of rehabilitation as judged by the Karnosky scores which were highly satisfactory in all (Table 4). These results were similar to those reported with the simpler rehabilitation yard stick of employment

used in our disease specific studies of PBC and sclerosing cholangitis. The meaning was clear. No matter how severe the disease, it was equally rectifiable by successful liver transplantation from the highest to the lowest score of preexisting disease gravity or treatment urgency.

Such complete and repeated reversal of fortune was without precedent in the history of medicine before the advent of our field of transplantation. This is the shimmering glory of what we can do. It explains the bitterness with which surgeons and physicians wrangle over the magic wands (the organs) without which these miracles can not be performed. Practically everyone who has performed one of these miracles has not been reminded by some Rabbi that "he who saves a single life has saved all the world". Of course, one also must ask "what is the penalty for losing a life that was not in jeopardy?" in the event of a death following a transplantation when it was not really needed.

The kind of data we have been discussing can not be taken lightly, because it has been used to argue against the treatment of patients who have entered the last days or weeks of their lives, or who have ancillary risk factors

such as those in the Blue Cross/Blue Shield list. However, at the so called favorable end of the risk scale, if such arguments are extrapolated to absurdity (Figure 4), the logic could be a recommendation that only asymptomatic (well) candidates be selected for operation because they are cheap and they yield predictably-good life survival curves, even by inexperienced teams.

THE TAIL AND THE DOG

Our mail is full these days of letters from full time employed patients with early liver disease, asking for a second opinion about the essentially prophylactic liver transplantation that has been recommended to them. No doubt such "candidates" would contribute, if they were foolish enough to go forward, to a good life survival curve. We also hear frequently from surgeons, boasting about a large volume of liver transplantations from a virtually non-existent waiting list. Not infrequently, their patients are called in for operation from their jobs or the golf course.

Perhaps, it is time to ask if liver transplantation has become the tail wagging the dogs of hepatology and hepatobiliary surgery. After all, there are other and often

TABLE 1

MAYO COX PROPORTIONAL HAZARD MODEL (PBC)

RISK FACTORS	RISK GRADE		
	1	2	3
Age (yr)	47	49	54
Bilirubin (mg/Dl)	12	24	28
Albumin (g/Dl)	3	2.7	2.5
Prothrombin (sec)	13.5	15	20
Edema score	0.4	0.8	0.9

(New Engl J Med 320:1709, 1989)

TABLE 2

MAYO MODEL (SCLEROSING CHOLANGITIS)

RISK FACTORS	RISK GRADE		
	1	2	3
Age	36	43	47
Bilirubin (mg%)	6	13	20
Splenomegaly (%)	37	66	86
*Histologic score	3.6	3.7	4.0

*1-4 (4 maximum)

Surgery, Gynecology, and Obstetrics, 1993

TABLE 3

PRETRANSPLANT STRATA VERSUS OUTCOME

STRATIFICATION	PATIENT SURVIVAL (%)	GRAFT SURVIVAL (%)	HOSPITAL CHARGE (MEDIAN \$)
APACHE II			
SCORE <10	80	73	137,407
SCORE >10	57	50	172,844
BLUE CROSS/BLUE SHIELD			
NORMAL RISK	84	79	124,779
HIGH RISK	67	59	162,246

TABLE 4

<u>STRATIFICATION</u>	<u>KARNOFSKY SCORE</u> (one year later)
Blue Cross/Blue Shield	
Elective	82
High risk	82
Apache II	
Elective	82
High risk	82
UNOS	
1	85
2	83
3	79
4	83
UNOStat	84

NEW ENGLAND MEDICAL CENTER 1993

FIGURE 1

Actual (Kaplan-Meier) Survival after Transplantation and Estimated Survival without Transplantation (Mayo Model) in Patients with PBC (n=161)

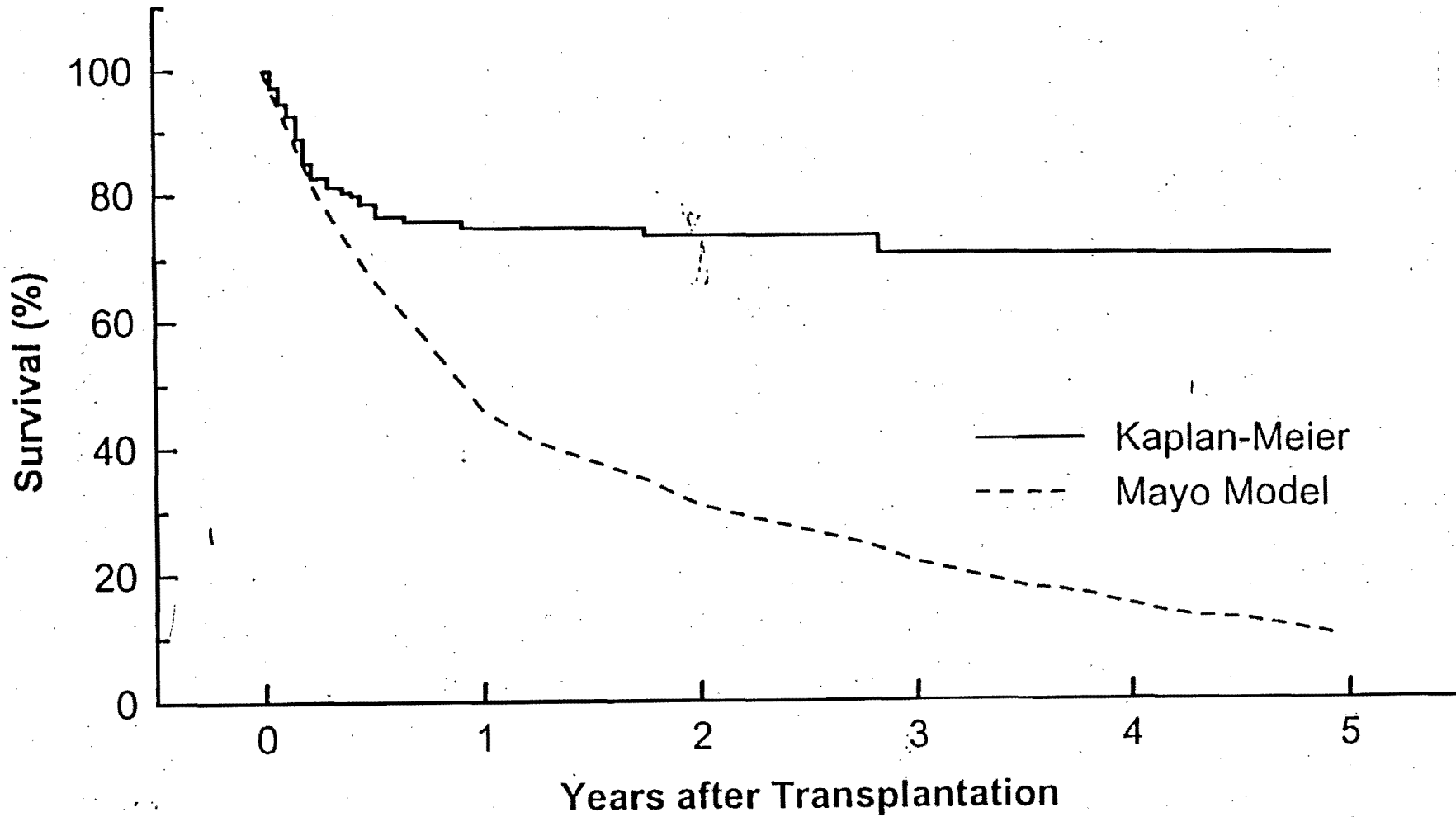


FIGURE 2

Actual (Kaplan-Meier) Survival after Transplantation and Estimated Survival without Transplantation (Mayo Model) in Three Risk Groups of Patients with PBC

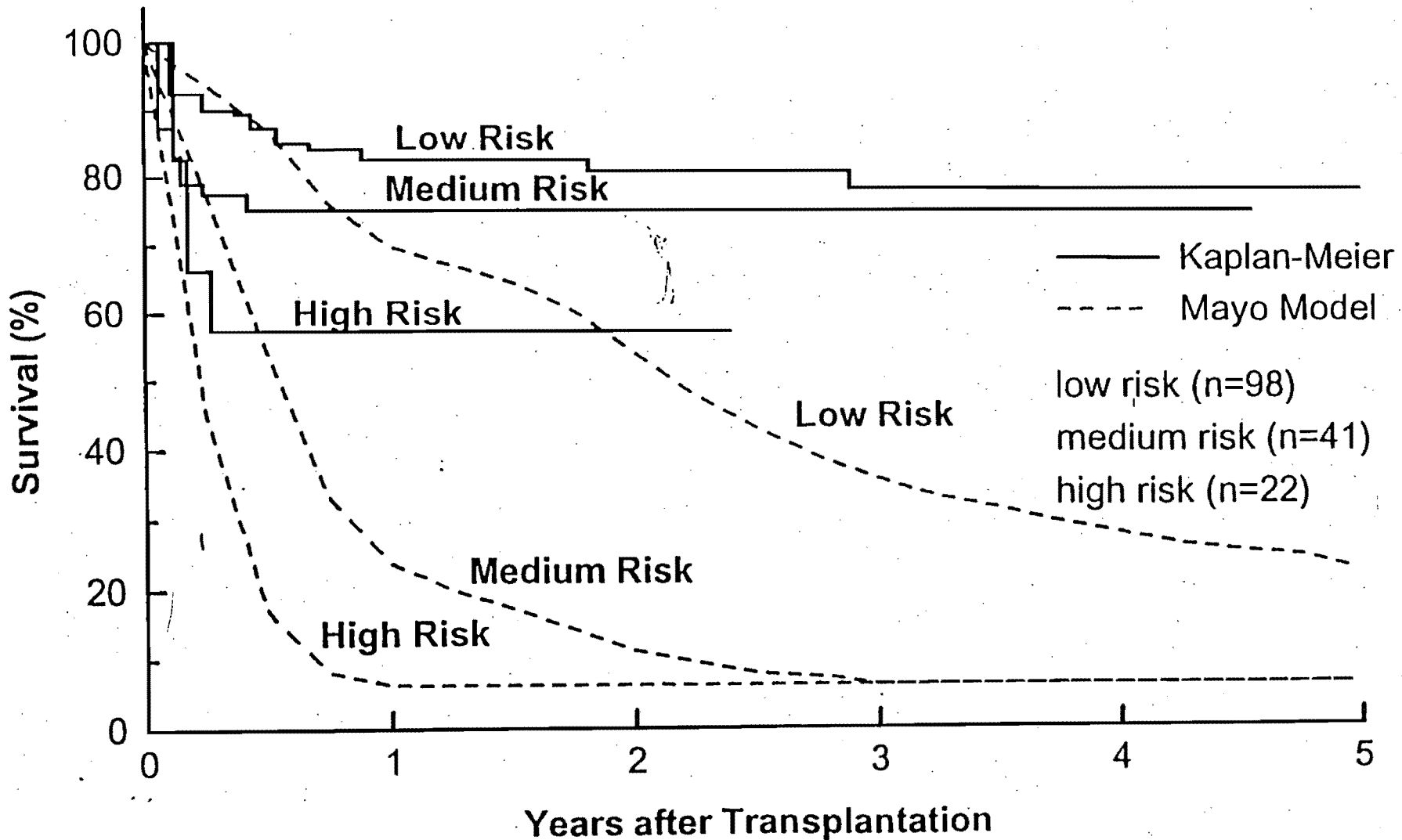
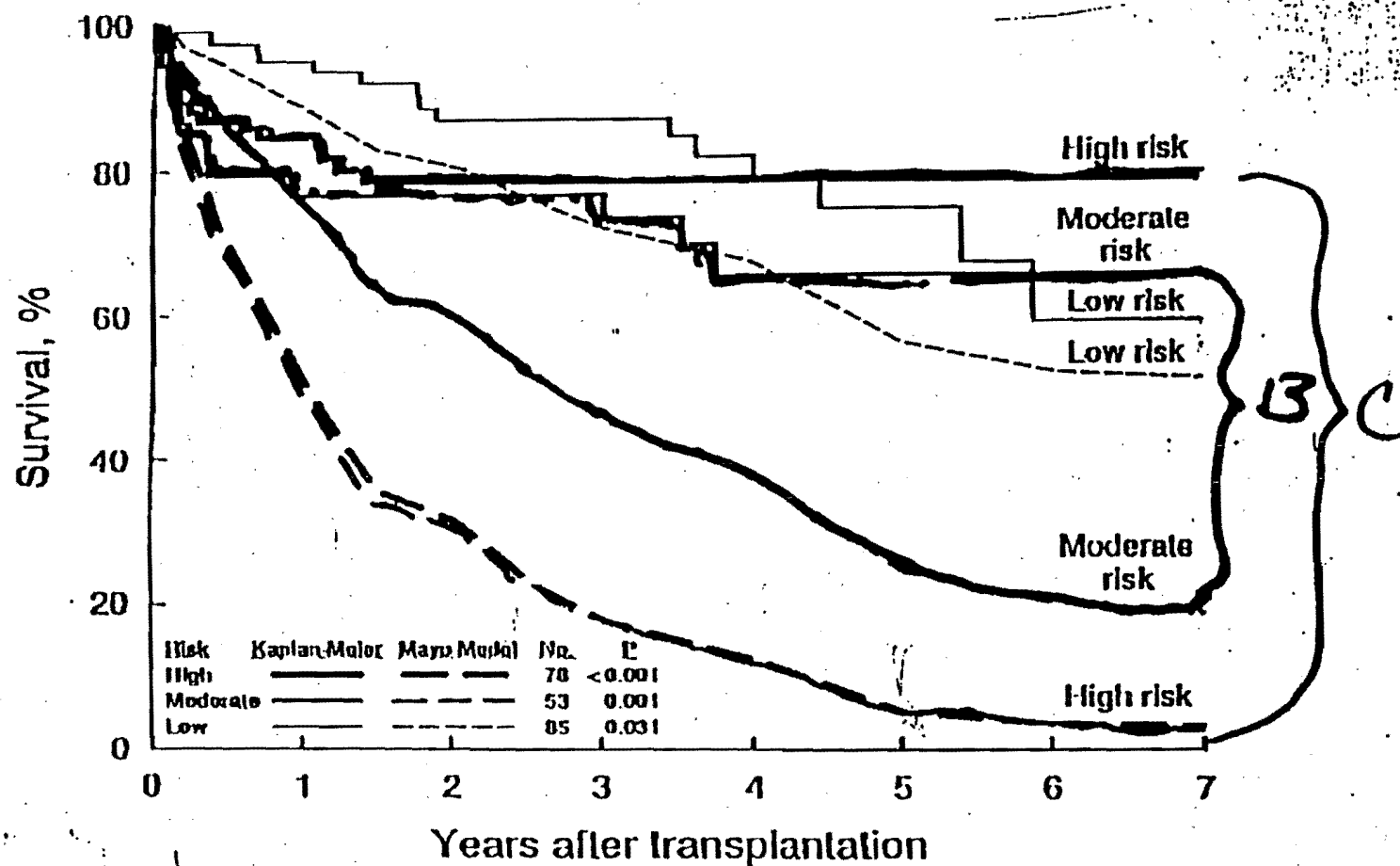


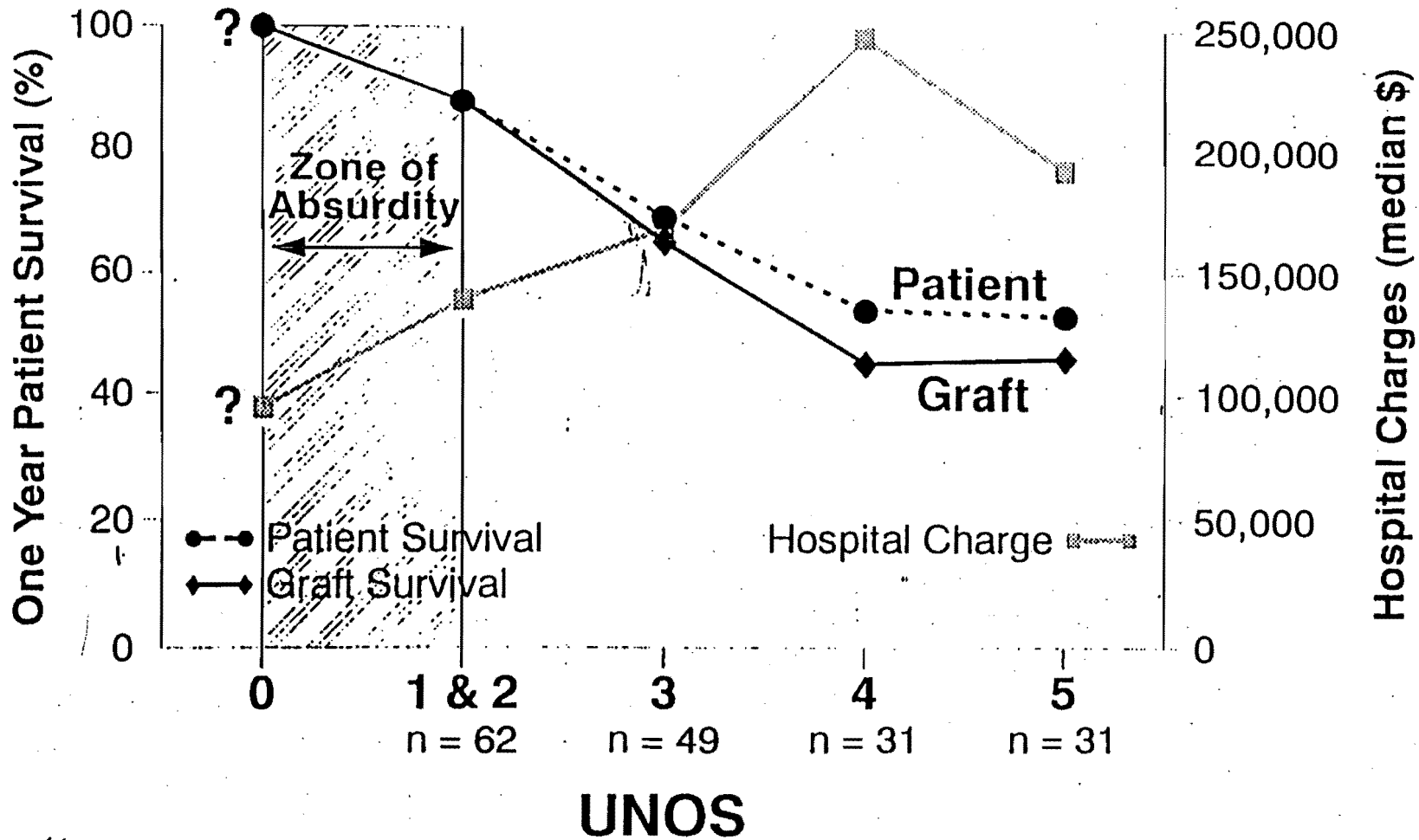
FIGURE 3



Actual (Kaplan-Meier) survival after transplantation in three risk groups of patients with primary sclerosing cholangitis and their estimated survival without transplantation as predicted by the Mayo natural history model. These risk groups were formed on the basis of pretransplantation Mayo-model risk scores with a cutoff value of 4.8 for the low risk and 5.4 for the moderate risk group.

FIGURE 4

New England Medical Center



FK506 Treatment of Autoimmune Hepatitis Patient Profile

