

**ORGAN PROCUREMENT AND TRANSPLANTATION
NETWORK AMENDMENTS OF 1999**

HEARING
BEFORE THE
SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT
OF THE
COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTH CONGRESS
FIRST SESSION
ON
H.R. 2418

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK AMENDMENTS OF 1999

WEDNESDAY, SEPTEMBER 22, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Burr, Bilbray, Ganske, Coburn, Bryant, Brown, Waxman, Pallone, Green, Barrett, and Eshoo.

Also present: Representative Klink.

Staff present: Marc Wheat, majority counsel; Clay Alspach, legislative clerk; and John Ford, minority counsel.

Mr. BILIRAKIS. The hearing will come to order. Good afternoon. I am pleased to convene this hearing on H.R. 2418, the Organ Procurement and Transplantation Network Amendment of 1999. I was pleased to introduce this bipartisan legislation with my colleague, Gene Green of Texas.

Last summer this subcommittee held a joint hearing with the Senate Labor Committee to review our Nation's system for organ allocation, and more specifically the changes proposed by the Department of Health and Human Services. The Department's proposed changes to the Organ Procurement and Transplantation Network and the policies that it sets for all patients have been, to say the very least, as we all know, controversial. A majority of the comments received by the Department were very critical of the regulation, and certainly we in Congress have heard from many experts in the field about the consequences, unintended or otherwise, of the Department's regulations.

We will have the opportunity to hear a range of views on these issues generally and H.R. 2418 in particular from our witnesses today.

Of course, many of us have already heard directly from our constituents. Recently, I received a letter from Kathy Gibson, a 49-year-old constituent who received two kidney transplants within the past year. The second transplant, which was a success, followed an unsuccessful first transplant using her husband's kidney. Kathy received her second kidney through Life Link Foundation, a non-profit community service entity in Tampa that operates four of the Nation's 62 organ procurement organizations. She wrote to tell me how grateful she was for Life Link's assistance saying, "I have

nothing but good things to say regarding my transplant team from Tampa General Hospital and Life Link Transplant Institute. They found me the gift of life.”

H.R. 2418 was drafted with people like Kathy Gibson in mind. The bill recognizes the decisions regarding organ procurement and transplantation are best left to the medical community, as Congress intended in passing the National Organ Transplant Act of 1984. Those experts at the forefront of changes in the medical profession are best suited to adjust policies in light of new technology and new medical understanding.

H.R. 2418 also addresses the underlying problem of an inadequate organ supply by promoting incentives to increase organ donation. For example, the bill includes innovative provisions to help reduce the financial burden on living donors. As the National Kidney Foundation has noted, these provisions will help increase the supply of organs needed for many men and women waiting for a matching organ to be transplanted.

I want to welcome all of our witnesses. I appreciate their time and effort in joining us and look forward to hearing their testimony. As you know, we changed the time for this from 2 to 2:30 for a very good reason. I appreciate your understanding in that regard.

I will now recognize the ranking member Mr. Brown for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman. I would like to also thank today’s witnesses for joining us and a special thank you to Representative Klink, who has joined us. He is not a member of the subcommittee, but he has a special interest and knowledge of this issue, especially in this western end of his State and his district.

I would like to commend you, Mr. Chairman, for bringing increased attention to a process within our health care system that is critical to the lives of so many Americans, the process of allocating an obviously scarce number of donated organs for those individuals throughout the country waiting for and praying for them. Your bill is intended to correct some important problems and forestall others. It addresses the lack of enforcement mechanisms to ensure that network participants comply with quality standards. It reflects a view I believe that we all share; that is, organ allocation decisions be shielded from political bias.

However, Mr. Chairman, I am concerned that in an effort to wall off organ donation allocation decisions from political influence, H.R. 2418 also shields the organ allocation contractor from the accountability and subordination to the public that it should have. The bill appears to deny the Secretary of Health and Human Services the right to exert any authority over any allocation decisions that are scientific, clinical or medical in nature. The private contractor that coordinates the organ allocation could not be challenged on decisions of that nature. Since no legitimate organ allocation decisions are made outside the context of scientific, clinical and medical considerations, this effectively undercuts the Secretary’s oversight of the contractor’s activities. The Secretary, charged with representing the public and the public interest, would be unable to hold the organ allocation contractor to its contract.

Let's explore a scenario, one we certainly hope would never happen. Let's say a private contractor hired to allocate donated organs determines, based on scientific and medical data, that malnourished children should be the last to receive donor organs because malnourishment is correlated with the rejection of donor organs. Even if that decision reflects the best science that medicine has to offer, is it the right thing to do from a public policy perspective? Obviously not. Malnourishment is not just correlated with rejecting donor organs, it is also correlated, obviously, with poverty, with the public agreeing to choose which child's life to save based on family income.

As I read it, under H.R. 2418 the public would in the end have no say in that matter. The organ allocation contractor could implement the rule without—regardless of public policy implications and without any public input. I am concerned that the organ allocation contractor would have more power than the entity it contracts with, particularly when the entity speaks on behalf of the public. I question the wisdom of setting a precedent like this when, for government contractor relationships, it advocates the government's responsibility and alleviates the contractor of accountability.

Mr. Chairman, I support the goal of ensuring an allocation system free of political bias and designed to deter internal breaches of quality. But the system as a whole and those who administer it must also be held accountable. The Institute of Medicine made a recommendation that I think would reconcile the need for public accountability and the importance of keeping politics out of organ allocation decisions. They recommended the establishment of an external independent scientific review board that would be charged with periodically assessing the organ allocation system. Starting there we can achieve our goals without compromising the integrity of the government/contractor relationship.

I look forward to hearing our witnesses' perspectives on this issues. I would like again to express my appreciation to the chairman for his efforts.

Mr. BILIRAKIS. I thank the gentlemen.

Dr. Ganske for an opening statement?

Mr. GANSKE. Thank you, Mr. Chairman. In the interest of hearing testimony from our first panel, I just want to say I appreciate you having the hearing, and I look forward to the testimony. Thanks.

Mr. BILIRAKIS. Mr. Waxman, opening statement?

Mr. WAXMAN. Thank you very much, Mr. Chairman. Only 5 months have passed since our last hearing on organ allocation, but a great deal has changed. For some time I have been deeply troubled by the debate over the Department's final rule. I have heard outright misrepresentations and gross misinformation aimed at scaring patients, communities of color and the poor into believing that the administration wanted to make it harder for them to obtain organ transplants. UNOS has spent nearly \$1 million lobbying Congress, dollars which should have gone toward saving lives.

Today we finally have the cure for this lobbying and rhetorical excess. The Institute of Medicine has provided us with a blueprint for a more equitable and efficient organ allocation system. They have reminded us that we must put patients, not UNOS, not trans-

plant centers, not transplant surgeons, first. The IOM concluded that the final rule should be implemented. They concluded that HHS should exercise legitimate oversight responsibilities articulated in the final rule. They documented how weak oversight has compromised accountability at all levels, and they found that broader sharing of organs won't hurt donation rates or close small transplant centers.

The IOM report reveals a national organ allocation system badly in need of reform, but H.R. 2418 ignores the IOM report. Patients across the country say that this bill would only make things or change things for the worse. It would strip the Secretary of her oversight authority over UNOS. It would insulate UNOS from competition and accountability. It would grant sole authority over life-and-death decisions to an organization that has fought to keep patient outcome data secret, shielded its decisionmaking from public input, and enforced its policies in a politically expedient manner.

Today a patient seeking a transplant has practically no idea how well our transplant centers are performing. The data is hidden somewhere in UNOS. After years of resistance, UNOS has finally made some patient outcome data available, but that data is for the years 1988 to 1994. That means that patients are still in the dark about the centers' current performance.

Yesterday at our request the Department provided myself, Mr. Dingell, Mr. Klink, and Mr. Stark with patient outcome data for every transplant center in the country. This data is up-to-date and was obtained under congressional mandate from UNOS. This data shows that a patient's chances of survival depends very much on where you get your transplant. Depending on the transplant center, a patient's likelihood of getting a liver transplant within a year of listing can range anywhere from 25 to 70 percent. Depending on the transplant center, if you are waiting for a liver transplant, your likelihood of dying within a year of listing can range from 7 to 22 percent.

This new data would help transplant patients make better decisions, but this data is blinded and the transplant centers are only identified by number. This afternoon I will formally request that the Department provide us with the identities of the transplant centers. When we receive this information, we will provide transplant patients with all of this recent information about every transplant center in the country, information which UNOS should have made public a long time ago.

I want to thank you, Mr. Chairman, for holding this hearing. I look forward to this afternoon's testimony.

Mr. BILIRAKIS. I thank the gentleman.

Dr. Coburn for an opening statement.

Mr. COBURN. Thank you, Mr. Chairman. I am not going to be able to stay for the whole hearing because of other obligations, but I wanted to make a couple points as we talked about the IOM study. The IOM study, the Institute of Medicine, is the same institute that said we shouldn't track HIV by partner notification. They are the same people who underestimated the sexually transmitted disease epidemic in this country. Although they are valuable in their input, what they say, in this physician's eyes, is not always 100 percent accurate. I think that needs to be said without de-

meaning or taking discredit for the efforts of those in the Institute of Medicine.

The second thing that I would say and offer is my own State has done a great job in terms of increasing the number of transplant organs available. I have a great deal of difficulty thinking that if families in Oklahoma have a loved one who lives in Oklahoma, and Oklahoma is working hard in their one good transplant center to perfect and improve survivability, that Big Brother should not have the right to tell Oklahomans that they can't direct an organ for their own State brothers and sisters.

That is what we are really talking about here. There is a States rights issue and a personal issue that has been ignored in this process. I raise that because it is a concern to me. I am not sure that it will be heated, but it is an important thing if we really want States to be active. And should all organ transplants be run by the Federal Government? That is where we are headed, and I am not sure that is a great idea. I am not sure it is great for innovation. I am not sure it is great for patient longevity. I am not sure it is great for people who are receiving transplants.

As a physician, I know transplant centers when they start don't have good rates. As they perfect and get better, they improve. So I would just hope that we would consider those thoughts as we hear this testimony and ask the questions. With that, I yield back and thank you, Mr. Chairman, for this hearing.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Green, for an opening statement.

Mr. GREEN. Thank you, Mr. Chairman, for scheduling this hearing on H.R. 2418 today. I am pleased to be an original cosponsor because I believe it ensures that medicine and science instead of Federal employees will develop our Nation's organ transplant policy.

The Department of Health and Human Services released their final rule on organ transplantation last year. They did so to equalize the waiting time differences for sicker patients around the country. They claim that a national waiting list would reduce some of the differences, which admittedly can be too long, and make the organ transplantation process fair. However, a recent Institute of Medicine report found that the current system is equitable for the most severely ill patients. While their report also found that broader sharing between OPOs and States in regions would be better, it is important to note that this initiative is already being implemented within the transplant community.

I agree with the intent of the promulgated HHS regulation. However, I believe that the regulation would leave small and medium-size transplant centers at a significant operating disadvantage, which would ultimately cause them to shut their doors, leaving thousands of needy patients with few options.

The problem with organ allocation policy is not the way they are allocated, but the number we have to allocate. Instead of trying to force new regulations on a transplant community that has nearly unanimously rejected them because they could harm patients, we need to focus on ways to encourage more people to donate healthy organs. I support creating the fair organ allocation system, not one that so many patient groups, transplant surgeons, and organ pro-

curement organizations believe would do more harm than good. I believe any policy needs to be dictated by the true experts in this issue, the transplant community. That is why I am proud to be a cosponsor. I would hope the administration recognizes the shortfall of their rule and would reach out to the transplant community and reach a compromise. Short of that, we have no choice but to pass legislation.

Again, Mr. Chairman, I appreciate your willingness to address this issue in a timely and equitable manner. I believe many of today's witnesses will express many concerns raised to me by both the Houston medical community and the Texas Medical Center in Houston. Thank you.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman, and I thank you for convening this hearing. I, too, am proud to be a cosponsor of H.R. 2418 because I believe it is a good bill and the right way to handle this matter. I think we are here today because—in large part because of HHS's final rule on Organ Procurement and Transplantation Network, which was published in April. Obviously, this has been a controversial issue since the beginning. In fact, we have as a Congress placed a 1-year moratorium on this. The moratorium is about to expire.

I think many of us do have serious concerns about this rule for several reasons; I think particularly its effect, potential effect, on local transplantation and small transplant centers. I think that we could go on, but I did want to incorporate as part of my statement and I will at this time ask unanimous consent to put the full letter that I am about to read a portion of—

Mr. BILIRAKIS. Without objection, so ordered.

Mr. BRYANT. [continuing] as well as the letter from the Tennessee Transplant Society, dated August 2, 1999.

Mr. BILIRAKIS. Without objection.

Mr. BRYANT. This is a letter—again, I will just take portions out—from a gentleman who has a great deal of credibility in this area. He is a donor father. His wife also was a kidney recipient. He has been on numerous organizations involving transplants, most particular a member of the national board of TRIO. He states in a quite lengthy letter that the policies that have come out of the National Organ and Transplant Act back in the mid-1980's, while not perfect, are good. He congratulates us or commends Congress on our wisdom, primarily because “it established a private partnership between the medical community and the patient population which is independent from undue political influence by government operatives however well they might be intended. Difficult decisions involving the allocation of scarce organ resources have been made by informed private partnership rather than by a core of government attorneys and bureaucrats.”

It goes on to say that there is a fear that a large transplant center with political clout would monopolize transplantation procedures by manipulating proposed rules dictated by HHS personnel. Proponents may dismiss such concerns as paranoia, but these worries are indeed genuine and have been supported by the monopolistic track record of certain large centers. Those of us who have

had the opportunity to experience that could tell you that some of the smaller regional transplant centers understand firsthand the excellence and talent available in many locations throughout the country. The benefit which I have seen countless times is under the existing system, families are able to provide local support for patients that do not have to travel long distances to receive life-saving transplant operations.

He goes on, if I might add, to say that "I can report to you that many of us who have been in the most difficult situation have been acutely concerned that hope be provided first to those in need in our local region. We do not want these precious gives to be treated as just some other government-owned part, shipped across country to a large center currently in favor with Federal rulemakers."

He closes by, "Keep transplantation a predominantly medical issue with rules established by the existing partnership of medical experts, patients, and donor families."

I agree with the sentiments of my constituent and would tell you further that I do look forward to the witnesses that we have here today. Like Dr. Coburn, I have another hearing that I have to jump back and forth between, so I apologize. I may not be here for your full testimony, I am going to try to come back and forth, but I would like to make that my way of explanation.

Again, Mr. Chairman, thank you for what you are doing in this area.

Mr. BILIRAKIS. I thank you, sir.

Mr. Pallone for an opening statement.

Mr. PALLONE. Thank you, Mr. Chairman. The National Organ Transplant Act reauthorization is long overdue. Increasing the supply of organs for transplantation is a critical policy issue in this Nation and an acute problem in my home State of New Jersey. The Federal Government can help realize this goal in two broad ways. First, it must maintain an equitable organ allocation system, and second, it must develop a new and improved process for evaluating the Nation's organ procurement program. In my opinion, H.R. 2418 of which I am a cosponsor along with the chairman and Mr. Green, ensures both of these points.

We must move swiftly to reauthorize the National Organ Transplant Act, and as we do so, however, we must keep some basic principles in mind. The recently completed Institute of Medicine report recommends creation of organ allocation areas independent of the current organ procurement organization population structure. An optimal population size of approximately 9 million is suggested for the organ allocation areas. They should be accomplished through new regional sharing agreements, not through consolidation of OPOs. The report notes that achieving optimum results and procuring organs for transplants is highly dependent on good working relationships at the local level among hospitals, OPOs, transplant centers and on others. The committee does not want its recommendations to detract from or interfere with present operations where they are working effectively.

I want to say that New Jersey's 6 transplant centers which service approximately 8.5 million residents already fits this model.

Congress specifically charged the Institute of Medicine with the review of access to transplantation services for low-income popu-

lations and racial and ethnic minority groups. This review included an examination of the impact of State policies regarding payments for services for patients outside of the States in which the patients reside. The report states the most important predictors of equity in access to transplant services lie outside the transplantation system; that is, access health insurance and high-quality health care services. The fact is that many minority and ethnic groups and low-income groups do not have access to health insurance and high-quality health care services. This fact of life cannot be divorced from a the review of how well organ donation transplantation works. This critical area must be given as much consideration and note as policies regarding allocations, or we will produce a caste system for organ transplantation with only the rich being able to afford transplants.

The IOM report noted that Federal oversight of the national transplant system is useful in some areas. I feel strongly that the medical community must be free to make critical clinical decisions regarding transplants, but I welcome Federal oversight in the area of appeals, enforcement of national organ transplantation policy, and imposition of sanctions when deemed necessary to further the operation of the national transplant system.

I have learned from constituents in my area that many variables affect organ donor rates. The current performance standards used by the Federal Government do not accurately assess OPO performance because they are based on total population and not the number of potential donors. In New Jersey, for example, the number of potential donors is significantly reduced by the State's high incidence of cancer and AIDS. The diverse nature of New Jersey's people also make organ donation education and procurement particularly challenging.

Adherence to the current performance standards without regard to these operations which occur from one area of the country to another may needlessly lead to the termination of OPOs with strong relationships in their communities which are addressing their coverage area donor potential in an effective manner.

Organ procurement organizations cannot fully concentrate on programs to increase the supply of organs when they are burdened by the mandate to meet unpredictable national average performance standards over a 2-year period. Such a short cycle does not help. OPOs implement best practices to increase the organ supply. The population-based performance measures used by HCFA has been widely criticized by the Institute of Medicine, the GAO, the Harvard School of Public Health and others as being significantly flawed for assessing OPO performance. Mr. Chairman, unless overturned, these inappropriate measures may very well result in the decertification of OPOs that are actually excellent performers. To that end I support the inclusion of language in the reauthorization calling on HHS to suspend the current OPO recertification process until a fair process that relates to true performance are developed in cooperation with the OPO community.

I believe that H.R. 2418 will allow organ procurement organizations the freedom to do their good work of educating and procuring precious organs in an efficient manner, and therefore I look forward to working with you, Mr. Chairman, to directly help those

Americans in need of transplantation by passing this good bill. Thank you.

Mr. Chairman, could I ask, I would like to ask unanimous consent to submit for the record a statement by Peggy Dreker of Kearny, New Jersey. Ms. Dreker is the cofounder of the New Jersey chapter of the Transplant Recipients International Organization. Her testimony recounts the hardship she and her family experienced when their 2-year-old son needed a liver transplant. And he had—both she and her husband had to travel back and forth to Pittsburgh for 3 years to save their son's life. No offense to my friend from Pennsylvania, Pittsburgh is actually a nice place, but it is unfortunate they had to travel back and forth to Pittsburgh during this time. Their testimony illustrates why we need to pass H.R. 2418, and I would ask that it be included in the record.

Mr. BILIRAKIS. Without objection that is part of the record.

[The prepared statement of Peggy Dreker follows:]

PREPARED STATEMENT OF PEGGY DREKER, NEW JERSEY CHAPTER, TRANSPLANT
RECIPIENTS INTERNATIONAL ORGANIZATION

Good Morning, I am Peggy Dreker. I live in Kearny, New Jersey which is located about 15 miles outside of New York City. I am the co-founder of the New Jersey Chapter of TRIO, Transplant Recipients International Organization. I serve on the Board of Directors of the New Jersey Organ and Tissue Sharing Network, the organ procurement agency in New Jersey, and I am currently the Treasurer of that board. I am here today in another role, that of a Mom who would like to share my experience with the transplant community. I am also here because I am concerned that part of the new HHS regulations will hurt many potential recipients and many New Jersey residents. I am concerned that these changes will limit patient access to transplant services which can add a tremendous financial and family burden to the transplant patient. I am also here today to tell you that the NJ chapter of TRIO strongly supports HR 2418 sponsored by Congressman Bilirakis and cosponsored by New Jersey's Congressman Pallone.

I would like to share with you my story which is typical of many families that have had family members transplanted and therefore, the tremendous need for local services.

In December of 1984, when taking my six week old son Daniel, for a regular check up, the pediatrician pointed out that he was bit jaundiced and recommended that he have blood work done. He referred us to a pediatric gastroenterologist, Dr. Lucy McLoughlin at United Hospital in Newark, New Jersey. Daniel was hospitalized immediately on Christmas Eve. One week later on new Year's Eve, Daniel was diagnosed as having liver disease. In my mind I thought, OK, they know what the problem is and we are in a children's hospital, let's get this thing fixed quickly. I was in for a rude awakening when Dr. McLoughlin informed us that the only way to "fix" Daniel's problem was through a liver transplant. In 1985, I considered this just another thing that needed to be done. Imagine my shock and surprise when I discovered that an organ would not be available "on demand" just because my son needed it. I was appalled, and shocked but mostly scared. During this time we began a relationship with the physicians and nurses that so lovingly cared for my son and in turn for me. I was glad we had this relationship with the staff of the hospital knowing a liver transplant would mean a long hospital stay. That's when the final blow came. The doctor informed us the closest place for Daniel to receive his transplant was Children's Hospital at the University of Pittsburgh. I was shocked that as a life-long New Jersey resident, my husband and I both worked in New Jersey and yet health care was not available in the State for my son. I immediately wrote to the Commissioner of Health in New Jersey who informed me that transplant services were only available regionally and we were fairly lucky that Pittsburgh wasn't too far away from New Jersey.

While trying to deal with a sick infant in the intensive care unit, the real world also went on. I decided to resign from my position working for the County. My employer had been very generous extending my maternity leave but I felt I could not ask for an indefinite leave. This also meant that I would lose my medical coverage. We had just purchased a home and were counting on our two incomes to pay the

mortgage. This plan was shot. We also realized that many of Daniel's expenses were not being covered by our insurance which we always thought was so inclusive.

When Daniel was two months old he was placed on the national transplant list from Children's Hospital in Pittsburgh. Daniel weighed under eight pounds and was literally starving to death. He was on a constant feeding tube and his color was changing from a glow in the dark yellow to a sallow shade of green.

Getting a bit desperate, I decided to call the White House seeking help for Daniel. We were referred to the Transplant Office headed by Michael Batten. The local media in New Jersey/New York picked up on this correspondence and within two days of Daniel's arrival home we were besieged by the media. We decided to go along with this attention hoping that it would raise awareness for Daniel's plight. A reporter from the New York Times followed us around for a week trying to put a diary together of what it was like waiting to get a transplant. The local communities in the area rallied together to raise funds and awareness for Daniel. This was a wonderful thing but it did take away from our privacy and family life. Little did we know how important those funds would become.

In August of 1985, we received a call saying there was an organ available for Daniel. This was after a false alarm in June where we used up all our favors of a free plane ride, ambulance and police escorts. In 1985, time was of the essence getting to the transplant center. Within one hour, my husband arrived home for work, we begged cash from anyone who had it, contacted the airline to get on a regular scheduled flight to Pittsburgh, and packed clothing for all of us not sure how long we would be gone. We made arrangements with the local police department and the State Police since we had under one hour to get to Newark Airport. All of this while handling a sick infant who was still on a feeding pump, special formula and who cried constantly. By the time we left our home, it finally dawned on me that we were leaving a lot more than a house; I would have no family, no friends, no familiar physicians and nurses and no husband who would have to come back home shortly to return to work. I would be handling Daniel's health on my own. My first view of the city of Pittsburgh was strapped on a stretcher in the back of speeding ambulance with my tiny son on my chest sleeping.

On August 5, 1985 my son Daniel received the gift of life from a total stranger, another infant who had died. Daniel's surgery lasted well over 10 hours as we were left standing in the waiting room of the hospital with everything we owned and no place to stay. We ended up showering at the University of Pittsburgh dorms. Daniel was blessed with the best medical and nursing care. Unfortunately, within three days it was determined that Daniel would need another liver. By this time my husband had returned to work in New Jersey. My family drove the eight hours out to Pittsburgh to locate a cheap furnished apartment for me to live. Paying rent is not covered under your insurance. The community fund-raising money came in handy for this. Daniel was hospitalized in Pittsburgh from August 5, 1985 through April 10, 1986 before he was released with the knowledge that a second transplant was still needed. During this time, I would stay with Daniel in the hospital six days and nights a week. On Saturday morning, my husband would fly out to Pittsburgh and stay about 24 hours before returning back home. Daniel did not recognize him and would cry whenever he walked into the room. The total feeling of isolation was relieved only by the wonderful nursing staff who quickly became my new family. During this long period of hospitalization we developed a dependence on the physicians, as they developed a familiarity with my son on a daily basis. Six months later, when my son was finally discharged, the sense of anxiety of leaving the transplant center was upsetting. We were now back to using our original physicians back home in New Jersey. At the time, my son was the first and only transplant patient Dr. McLoughlin cared for. As of today, she cares for 40 post transplant children.

For the next 18 months, Daniel and I would fly back to Pittsburgh every three weeks or so because of the tubes that were left in him while he was waiting for another liver. Imagine if you can, traveling with a baby with a liver drain coming out the right side, a feeding tube coming out of his nose and a broviac catheter coming from his neck. I would leave the plane in Pittsburgh airport, put Daniel in the stroller, put the feeding pump on my shoulder, drag a set of luggage wheels with a suitcase and a baby walker, and carry a pack with diaper, bottles and supplies I needed if one of his tubes happened to break loose, which they frequently did. That was just to get through the airport before I could hail a cab. I would then pack this into the cab and head to the hospital. Thirty dollars later we arrived at the hospital. By this time, Daniel was screaming and I had reached my wits end. This procedure went on for the next year or more.

On October 26, 1987 we received a call that a second liver was available for Daniel. This time all the commercial flights from the three surrounding airports had stopped for the evening. We ended up chartering a small private plane from a friend

of a friend that we had never even met. We again packed up our things and tried to put our lives on hold.

Daniel had been blessed with this second gift of life. Surgery went well. We quickly reverted back to our hospital routine as my husband left us again in Pittsburgh to go back to work. We used the money raised by the communities to pay the rent on our apartment so we still had that. Daniel spent about eight weeks in the hospital and another month in Pittsburgh before he was sent home on Christmas Eve 1987—three years after the original diagnosis.

Since Daniel's ordeal, New Jersey has worked very hard establishing quality transplant programs for its residents. The thought of returning back to a time where accessibility to a transplant center could impede a person getting a transplant is appalling. The three years that my son and I lived away from home hurt my family, my marriage, my finances and ended my career.

Today, Daniel is a healthy fifteen year old. In the last 15 years a lot has changed in New Jersey.

There are now more transplant centers and pediatric transplant programs are available. Someone in my position would not have to leave the state to get medical care for a child.

I fear that the new HHS regulations on organ allocation will send us back to 1985, back to a time when there was not easy access to transplants for many people. In New Jersey the state has allowed more transplant centers to open, but only when there is a proven need. So there are not too many centers and they all have reasonable waiting lists. We also have worked hard at the New Jersey Organ and Tissue Sharing Network to increase the number of organs procured. The New Jersey Organ and Tissue Sharing Network does an excellent job in procuring organs and its potential yield from New Jersey's population is very high. We need to continue this, please don't let it be taken away by regulations that threaten transplant services to New Jersey residents and unfair federal agency review regulations that fail to take into consideration population characteristics that inhibit donation. It just doesn't make sense to me to destroy a system that works so well, a system that provides good outcomes and that so many people rely on. People need transplant services in their states like they need cardiac services, obstetric services and cancer care. Don't set policy that consolidated transplant services to regional areas. Americans will suffer.

I am not the only one who feels this way. I am surrounded by people at the Sharing Network and organizations like TRIO where people, like me, have experienced what it is like to have to go out of state. We are appalled by the HHS regulations and strongly support HR 2418. In fact, the New Jersey Chapter of TRIO has actively opposed the HHS regulations, as have Arkansas, Ohio, Louisiana, New Mexico, Hawaii, Memphis/Nashville, South West Florida, Main and Rhode Island Chapters of TRIO. We support Congressmen Bilirakis and Pallone's legislation that will further enhance organ donation and transplantation for all Americans.

I know that the current system is not perfect and I think there are some aspects of the new regulations that are good that have been incorporated in HR 2418. We can not allow the unbridled hunger for organs by mega transplant centers to dictate organ allocation schemes. It is the responsibility of the federal government to support policy that encourages the decentralization of transplant services so that Americans in need do not have to experience the hardships I endured with Daniel. Regular people like me need access to transplants, preferably close to home. HR 2418 supports this policy.

Thank you.

Mr. BILIRAKIS. I might add at this point the opening statement of all members of the subcommittee will made a part of the record, and would now recognize Ms. Eshoo for an opening statement.

Ms. ESHOO. Thank you, Mr. Chairman. I can't help but think of the joint hearing on this very issue that this committee had with our Senate counterparts a year ago this last June, June 18, 1998. So I want to thank you and salute you for having yet another hearing on this issue. It is a very important one. It is one of literally life and death for people in our country, and it is a difficult issue to take on, but one that deserves the kind of examination that you are giving to it. So I thank you for having the hearing.

Very recently—my staff didn't put this in the written open commentary, but I can't help but think of it. Very recently a company,

I think within the boundary of my congressional district, had online the sale or the posting of an organ online. It is a company that does essentially public auctions. Now, the response to that was absolutely extraordinary and overwhelming. The company did say out of respect, please don't bid on this. But I think if we were to peel away some of the veil of that in terms of its high profile in terms of the news, what it underscores is not only the demand, but the urgency.

Any one of us that would need to have an organ replaced in order to live—just imagine that—would want to have that organ available right now. So what we are dealing with is how best and how fairly to do this. As we speak, I am sure that people are going to think, well, this one is from such and such a district, this is what they have in their district, that is why they are saying it. We need to rise above that because the American people obviously deserve to have a system that is going to speak to the urgency at hand. In fact, if this hearing lasts 2 hours, someone will die waiting for an organ. That, too, underscores the urgency. A mere one-third of the more than 60,000 Americans now on waiting lists will receive a donated organ this year. With today's technology, really, people shouldn't be dying because they can't get an organ in time. We know that the system can't feed the demand, so we have more to do than what we are just dealing with here.

But of those organ that are donated, what is the best system, how should they be disbursed, so to speak. I don't want to sound cold or bureaucratic about this, because we are talking about human beings' lives.

Last Congress we enacted a 1-year moratorium on the HHS proposed rule so that the Institute of Medicine, the IOM, could study its potential effect. That study, released in July, resoundingly supported HHS's proposed rule. They concluded that, "broader sharing is likely to result in more of the most medically urgent patients receiving first attention when waiting for donated livers."

The IOM study goes on to refute many of the criticisms that were raised about final rule. Broader sharing of organs does not require a national waiting list. Treating more medically urgent patients first does not mean wasting organs on patients too sick to benefit from a transplant. Broader sharing does not mean reduced services to minorities or closure of smaller transplant centers. The substantial health benefits of broader sharing would outweigh the marginal effects of cost.

We have the medical knowledge to do successful organ transplants. We need to make sure that we have in place a system, match that, and have a record that we have a system that makes the most of available organs.

Let me just close by saying the following: In the aftermath of the joint hearing that we had with the Senate, I was a fairly new member of the committee. And the message that went out across the country, the impact of just having the hearing, really astounded me. It was yet another underscoring of the need to do better.

Some have heavily criticized the organization that is in place and how they do their work. That is not what I am here for. I think that all of us together, wherever we come from, whatever we have in our districts, whatever take we have on this, have to really at

the end of the day be devoted to filling any kind of gap that exists. So I am looking forward to hearing from the panelists today.

What I drew out of that hearing was that we do have some shortcomings. It is not for a committee or organization to do—it is not good enough. I used to say when I was in local government, don't tell me about your organization, tell me how effective your organization is for the people I represent.

So with that, Mr. Chairman, I hope that the people that testify will inform and enlighten us as to the results of the study and how they can direct themselves toward what is being proposed. I think they are steps in the right direction myself, and I appreciate your having this hearing. I think it is timely and critical. Thank you.

Mr. BILIRAKIS. I thank the gentlelady.

Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman. I thank you also for holding this very important hearing.

This is an issue that I think combines so many different human elements and so many economic elements together at the same time that it is bound to raise emotions on all sides. As Ms. Eshoo said, I think all of us look at this issue a little differently depending upon where we come from, whether we have a large center, small center, no center, or how close we are to a center.

But I look at the issue, and notwithstanding all of the emotions, health issues, the urgency issues, I think frankly what we are talking about here is very much an economic issue. These centers are big money-makers. And each one of us who has a center wants for economic reasons to maintain the economic resource that we have located in our own communities. There is nothing wrong with that. For those people who represent large centers, I understand where they are coming from. From people like myself, who come from mid-sized centers, I trust that the people who represent the large centers also understand where we are coming from.

In the end, of course, we want to do what is right for the patient. But there is no correct answer written in the back of the book as to what is the right answer for the patient.

The part of the country that I represent, the upper Midwest, does very, very well in producing several things. Ironically, we are dealing with one on the floor right now. We do very well in producing milk in the State of Wisconsin, as does Minnesota. There is another product that we do very well in the Midwest, and that is organs. For whatever reason, the people in our part of the country are very generous when it comes to giving organs. I would like to think that it is because we have this down-to-earth group of people who care about other people and society and are willing to make that sacrifice. Others might have other explanations as to why that occurs, but the fact is that if you look at Wisconsin and Minnesota in particular, we remain relatively high in the number of organs we produce. Correspondingly, we have health care centers and transplant centers that use some of these organs.

I get back to the economic argument because I look at the report from the Office of the Inspector General fostering equity in patient access to transplantation, local access to liver transplantation, where the inspector general says that 80 percent of the liver transplants are done in 35 cities in this country. So right now people are

traveling to cities, 35 different cities, to get organ transplants. Now we are going to fight about which city they go to.

I am obviously of the school of thought to say, well, if we want regions of the country to continue putting their emphasis on procuring organs, it makes sense not to penalize those regions of the country that do a good job of procuring organs. We could have taken another approach in our part of the country and instead of trying to harvest organs, we could have tried to harvest a waiting list and get as many people as we could on a waiting list so that there would be a lot of sick patients that would be on our waiting list. I personally think that that in the big picture is counter-productive. To say that what we should be doing is having the transplant centers put all of their emphasis on developing waiting lists, I think, is inevitably going to mean is they are going to put less emphasis on recruiting new organs.

I certainly heard—or rather the analysis that said that people don't care whether they know who the person is who is receiving the organ, that it doesn't make any difference to them. Again, I might be living in not exactly in Garrison Keillor country, but close to it, where it does matter to people if they know somebody. We have stories in our community about somebody who donated this organ marrying someone who donated that organ, and there is this nice little storybook ending from people who have met through this network.

So it is not big east coast stuff, it is not big west coast stuff, it is corny Midwest stuff, but I think it works.

I think what happens is that we should be putting more emphasis on increasing the supply of organs and stop fighting over where people are going to go, because again, as the inspector general's report says, 80 percent of the people are traveling. Let's not fight among the hospitals to develop waiting lists. Let's work together to get more people to give organs.

I would yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentleman for his remarks.

Mr. Klink is not a member of this subcommittee, and that is the only reason that we passed over him in his opening statement. The rules state that I must do that. But in any case, he has a great interest in this subject, as he does in most health care subjects, and the Chair is pleased to invite him to make an opening statement if he wishes.

Mr. KLINK. I certainly thank the chairman for his courtesy. He has always been very courteous. Even in this case where he knows that he and I come down on different sides of this issue, he has gone out of his way to allow my voice to be heard, and I appreciate that.

If ever there was an issue that deserves to be protected from political maneuvering, it is indeed the issue of organ allocation. This is one of the few issues that we in Congress will deal with where there is no doubt about it, it is life or death. If you are the one that is waiting for the organ, you either get the organ, or you die. There is nothing abstract about it.

Regardless of how each of us approaches this issue, I hope that all of us agree the best thing for everyone is to get this dispute out

of the annual appropriations process by for once and all establishing the rules for how our organ network should operate.

As I have seen this and I have studied it, there are two issues that are before us today: One, how do we make the allocation system fair and equitable; and, two, who should be responsible for setting and enforcing the policies for sharing organs? Should it be HHS or a government contractor?

While the bill before us today is a sincere attempt by two of my dearest friends in the legislative body here to rewrite those rules, I must respectfully speak against H.R. 2418 because it does nothing, I think, to make the system more equitable because it delegates too much policymaking authority to a largely unaccountable government contractor. The fact is that every year people die unnecessarily because the current organ allocation system is broken. Whether or not you get an organ that can save your life will depend on where you live. But under the current system, depending on where the organ was harvested, it could be given to someone with years to live while someone in the next town across the wrong border may die while waiting for a transplant.

One of the most difficult organs to transplant is the liver. Pioneered at the University of Pittsburgh, upwards to 90 percent of all of the liver transplant surgeons today were either trained at the University of Pittsburgh or by doctors who were trained there. Yet facilities like Pittsburgh and other highly regarded transplant centers which take on the most difficult and riskiest transplantations are struggling because they have the longest transplant list in the country.

While these centers are highly regarded, many of their patients don't come to them because of their reputation. The fact is that many of the patients come there and only seek them out after they have been turned down by their local transplant centers. There is very strong evidence to suggest that many smaller transplant centers avoid the riskier transplants on the sicker patients because they are more difficult and would adversely impact their reputation should they not be successful. Without national standards for how people get listed or how organs should be shared, the organs do not follow the people that need them. This is not right, and it should be fixed.

Ever since the rule was announced last April, its proponents have argued that the Secretary should not be allowed to set organ allocation policy because it involves a medical question that should best be left to medical professionals in the transplant community. I have to tell my colleagues that this argument causes me great difficulty when I know that if we share organs more broadly, lives would be saved.

I agree with the views of those in the transplant community should be given great weight, but I disagree with the notion in this bill that the Secretary should totally refer to a contractor on questions that are, "scientific, clinical, or medical in nature." The biggest opponent of any change and the proponent of this bill is the OPTN contractor, UNOS, who has a vested interest in not having the Department of Health and Human Service looking over their shoulders. Sadly, UNOS has budgeted upwards to \$1 million of pa-

tients' fees to lobby against the proposed changes. That is money that should have been spent saving lives.

The argument that the Secretary is unqualified to deal with medical questions causes me great difficulty when I know that every year Medicare and Medicaid pay for more than 50 percent of the transplants in this country. I think it would be highly irresponsible for us as taxpayers to pay for those transplants without making sure that the money is spent equitably. Not only would we be delegating sole authority over allocation policy to a private contractor, which I think would be an unconstitutional delegation of legislative authority, but as the agency that oversees most of our health policy, I don't understand how the Secretary becomes less qualified to deal with allocation policy than she is in making scientific, clinical, or medical decisions as she oversees, Medicare, Medicaid, NIH, or the FDA. As the ranking Democrat on Oversight and Investigation, I fully agree with the Institute of Medicine that says "vigilant and conscientious oversight and the review of programs and policies are critically important to ensuring accountability on the part of the OPTN, and that the HHS final rule appropriately places this responsibility with the Federal Government."

Again, I would close by saying that I must oppose H.R. 2418 as it is currently written because I feel it fails to improve the allocation system, and it gives too much policy-setting authority to an unaccountable Federal contractor while severely restricting the Secretary's authority to oversee the transplant network. People are dying because they happen to live in the wrong zip code and because States don't want to share their organs. Nowhere else in society would we allow a monopoly like this to continue. We have to put an end to this craziness. The No. 1 priority of organ allocation has to be medical necessity, not geography, period.

Mr. Chairman, again, I thank you so much. I yield back my time, and I ask unanimous consent, to not prolong your hearing, I would like to submit questions for the witness in writing.

Mr. BILIRAKIS. Without objection that will be the case. Of course, written questions are always provided to the witnesses to be responded to.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF WYOMING

Thank you, Mr. Chairman, for holding this important and timely hearing on organ allocation. I think many people, myself included, are happy to see legislation introduced that will address the problems associated with the 1998 proposed rule on a new organ allocation policy.

I have grave concerns about Secretary Shalala's proposed rule. The "sickest-patient-first" standard, applied on a national basis, would result in more deaths and fewer successful transplants.

In rural states, where most of the population is spread over large areas and many people live in rural communities, the number of transplants would drop, decreasing access to care if the "sickest-patient-first" standard were applied.

A national list would give transplant programs in high-population areas access to more organs. Regions with small populations would have fewer. The northwestern region's success in supplying quality, cost-effective transplants to all regions of the country could be reversed under this standard.

I believe that decisions regarding organ procurement and transplantation policy are best left to the medical community, patients, and donor families. Local and regional distribution areas have many advantages including giving people local access to transplantation and shorter distances to travel with the transplant organ. Our

current allocation system achieves a balanced and fair distribution of organs for all who await a life saving transplant.

I would like to commend the chairman, the subcommittee, and those involved in the drafting of H.R. 2418. This bill recognizes the importance of maintaining the regional boundaries in the current organ allocation system, and ensuring that medical experts ultimately make the decisions regarding organ transplantation.

I would like to thank our witnesses for appearing here today, and look forward to hearing their testimony. Thank you, Mr. Chairman.

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

Thank you, Chairman Bilirakis, for convening this afternoon's hearing on H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999.

It has been well over a year since the Administration issued its regulation on the Organ Procurement and Transplantation Network. Some claim that the regulation changed the HHS Secretary's oversight authority into a policy-making authority. Policy control of the Network is not what Congress intended, and that is not what the law permits.

The Organ Procurement and Transplantation Network was authorized by Congress to make decisions without political interference. The decisions they make safeguard the interests of not just those who are presently on a waiting list, but those unknown persons who will be placed on a waiting list in the future.

Mr. Chairman, your bill would safeguard the independence of the Network. It also would increase the level of accountability of the Network by mandating timely reports on the performance of transplant centers within the Network. The bill includes an innovative enforcement mechanism that would mandate the payment of liquidated damages by transplant centers that try to cheat under the Network rules. You are also to be applauded for the provision that would offer assistance for living donors seeking to donate an organ to someone in another state.

It is evident that a great deal of work and consultation went into this bill, Mr. Chairman, and I congratulate you for bringing H.R. 2418 to this stage in the authorizing process. I support your bill, Mr. Chairman, and I look forward to the testimony this afternoon and to a mark-up in the near future.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, a hearing on the subject of organ allocation is timely and I thank you for scheduling it. I know that we have many other issues to discuss and hopefully resolve before this session ends.

Mr. Chairman, there are a lot of reasons why we must reach some kind of collective and durable agreement on the future course of organ allocation policy. Let me name a few. *First*, patients need and deserve an allocation program that is efficient and equitable. The ongoing struggle over the current organ allocation system is discouraging and harmful to the many persons across this country who are in need of an organ transplant. *Second*, the professional transplant community consists of talented and dedicated professionals. Their views and concerns are important and need to be weighed in any organ allocation policy we develop. *Third*, the public has an important interest in organ allocation policy. I think the point is sometimes overlooked that when we speak of the proper role of the Secretary, we are ultimately speaking of the public's interest in this matter. The Secretary is a steward of the public interest and is accountable as such. In my view, this is more so when we note the fact that a third or more of all organ transplants are paid for with taxpayer-funded health insurance programs such as Medicare and Medicaid.

Some will argue that organ allocation is purely a matter of medicine and science and that public officials have no business in such matters. This is a curious argument. We debate public policies on such medical and scientific issues as limits on stem cell and cloning research, pain management, the scope and direction of public research funded by the NIH, availability of FDA approved pharmaceutical products, reimbursement for medical procedures, protection of human research subjects, and so on. The argument that medicine and science are not proper areas for public scrutiny is a dangerous notion and therefore should be rejected.

Let me be specific. H.R. 2418 divorces the operations of a government contractor from any meaningful oversight by or accountability to the Department of Health and Human Services, the agency from which the contractor derives its authority to operate an organ allocation system. Without that government contract, the Organ Procurement and Transplantation Network would have no authority to operate. As

I have already noted, my concerns in this area are amplified by the fact that Medicare and Medicaid pay for a substantial percentage of all organ transplants. There simply must be greater accountability of the Network to the Secretary than H.R. 2418 would provide.

I am also concerned that H.R. 2418 does not do enough to alleviate the shortage of organs. One example that comes to mind is the cost of immunosuppressive drugs. A major reason for long term failure of transplants is a lack of compliance with the life long drug therapy that is required for transplant patients. The major reason for a lack of compliance with immunosuppressive drug therapy is the lack of resources to pay for them. The result is that the organ fails and another is needed. We should examine this question and determine whether providing drug coverage for those who need it would be cost effective and help reduce the shortage of organs.

We should also take a look at other ways to encourage donations. These include, for living donors, extended leave, expanded reimbursement for costs beyond that proposed in H.R. 2418, and expanded insurance coverage. More aggressive outreach by medical, educational, and legal professionals, as well as other community leaders, to promote awareness of the need for donations is also desirable.

Mr. Chairman, I support the concept of engaging in an effort aimed at trying to resolve the issues that have been so divisive. I see encouraging signs of movement from almost every direction. HHS has indicated that it is willing to repropose its allocation regulation in an effort to deal with some of the criticisms leveled against its earlier version. The study by the Institute of Medicine, particularly with respect to the role of waiting times, may also have had an influence on the Department's thinking. The transplant community, for its part, has in some cases shown a recognition of the merit of broader regions for sharing organs. There is not a complete meeting of the minds yet, but I sense that the differences may be smaller than a year ago.

I am certainly willing to work with you and my colleagues on this. I thank the witnesses for appearing here today, and look forward to continued progress in increasing the supply of organs and making their allocation more equitable.

PREPARED STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF GEORGIA

Thank you, Mr. Chairman for holding this important hearing regarding H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999. As a cosponsor of this legislation, I appreciate your efforts in addressing this issue and encourage the subcommittee to support this bill which is important to my constituents and the State of Georgia.

As you know, this legislation reinforces the original intent of the National Organ Transplant Act of 1984 that is responsible for developing and maintaining the medical criteria and standards for organ procurement and transplantation resting with the medical community. It is my belief that properly trained physicians should be responsible for transplant issues, and we must ensure that these functions remain the sole discretion of the Organ Procurement and Transplantation Network (OPTN).

Furthermore, it is vital that we increase the supply of donated organs around the country so that more people may receive transplants and we can achieve a just and equitable allocation system. To that end, H.R. 2418 includes provisions that require the OPTN to actively increase the supply of donated organs and authorize the Secretary of Health and Human Services to award grants related to increasing organ donation. Finally, the bill strengthens patient confidentiality safeguards and mandates that transplant centers provide specific information to the patients.

If implemented, the Department of Health and Human Services' Final Rule on this matter will harm the state of Georgia. Currently, Georgians employ one of the best organ procurement systems in the country that results in better access to transplants. I fear that Georgians will no longer be as likely to donate their organs if the Final Rule is implemented and find it troubling that my state would be punished for our successful organ procurement program.

Again, I appreciate your efforts in introducing this legislation. I look forward to hearing from our witnesses and recommend that the subcommittee move ahead in this process to pass H.R. 2418.

Mr. BILIRAKIS. The Chair calls the panel forward. Please come forward.

Dr. William Raub is the Deputy Assistant Secretary for Planning and Evaluation/Science Policy with the Department of Health and

Human Services. Dr. William Payne is the director of the liver transplant program, Fairview Medical Center, Minneapolis, Minnesota. Dr. Robert G. Gibbons, professor of biostatistics, School of Medicine, Department of Psychiatry, University of Illinois, Chicago; Dr. Joshua Miller, Division of Transplantation, Department of Surgery, University of Miami School of Medicine; Mr. Craig Irwin, president of the National Transplant Action Committee out of Portland, Oregon; and Dr. John M. Rabkin, chief of liver transplantation, Oregon Health Sciences University, Portland, Oregon.

Gentlemen, the committee welcomes you. Before we hear from the first witness, I unfortunately have a negative statement to make. I want to remind our witnesses, not only here but forevermore, that the committee expects to receive testimony 2 days prior to the hearing. The purpose of this rule, I think it is kind of obvious, is to allow members and their staffs sufficient time to review the statements and educate themselves on the testimony that will be at the hearing.

The testimony from the administration was not received until 1 p.m. Today. Now, anyone tell me that that is unfair. That is unacceptable, and it shows, I think, blatant disrespect for the members of the subcommittee. And I know that the administration had to be aware that a hearing like this was going to take place because of the controversy that is involved.

The committee noticed this hearing 1 week prior to the hearing date, providing ample time for invited witnesses to produce testimony. And please, Dr. Raub, this is certainly no reflection upon you personally, but I appreciate it if you would maybe pass the word on to the Department to give us the courtesy of submitting their testimony at least 2 days prior to the hearing. We have gotten complaints from the minority, too, in this regard so it doesn't come just from the majority. I think that you can understand that.

Mr. Brown, did you have anything that you wanted to comment in this regard?

Mr. BROWN. Only that I agree with your assessment, Mr. Chairman.

Mr. BILIRAKIS. All right. The committee ordinarily gives the administration witness 10 minutes to testify and the others 5 minutes. But I am going to—you are all busy people, have taken time away from your schedules to be here. Anywhere between 5 and 10 minutes would be appreciated because I know that you have an awful lot of valuable things to say to us.

Dr. Raub, we would ask you to kick it off, sir.

STATEMENTS OF WILLIAM F. RAUB, DEPUTY ASSISTANT SECRETARY FOR PLANNING AND EVALUATION/SCIENCE POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; WILLIAM PAYNE, DIRECTOR, LIVER TRANSPLANT PROGRAM, FAIRVIEW MEDICAL CENTER; ROBERT D. GIBBONS, PROFESSOR OF BIostatISTICS, SCHOOL OF MEDICINE, DEPARTMENT OF PSYCHIATRY, UNIVERSITY OF ILLINOIS AT CHICAGO, ACCOMPANIED BY MITCHELL W. SPELLMAN, PROFESSOR OF SURGERY EMERITUS AND DEAN OF MEDICAL SERVICES EMERITUS, HARVARD MEDICAL SCHOOL, AND SUSANNE STOIBER, EXECUTIVE OFFICER, INSTITUTE OF MEDICINE; JOSHUA MILLER, DIVISION OF TRANSPLANTATION, DEPARTMENT OF SURGERY, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE; CRAIG IRWIN, PRESIDENT, NATIONAL TRANSPLANT ACTION COMMITTEE; AND JOHN M. RABKIN, CHIEF, LIVER/PANCREAS TRANSPLANTATION HEPATOBIILIARY SURGERY, OREGON HEALTH SCIENCES UNIVERSITY

Mr. RAUB. Thank you, Mr. Chairman. Good afternoon, Chairman Bilirakis, Congressman Brown, other members of the subcommittee. I am William Raub, Deputy Assistant Secretary for Science Policy at the Department of Health and Human Services. I appreciate your invitation to testify.

I will discuss H.R. 2418 and also will testify in general about national organ transplantation policies and the constructive discussions we have had with our colleagues in the transplant community about those policies. With your permission, I will submit my full statement for the record.

Thanks in part to the passage of NOTA in 1984, organ transplantation now is a routine and widely endorsed procedure. Many organizations and individuals deserve high praise for this achievement: The United Network for Organ Sharing; surgeons, physicians, nurses and other health professional who have committed themselves to the practice of transplantation medicine; laboratory and clinical scientists who continue to generate new knowledge and technology that drives transplantation medicine to ever greater success; the staff of organ procurement organizations who work so diligently to acquire and transport organs to transplant programs; patients who provide invaluable insights as to how OPTN processes might be improved; and most of all, organ donors and their loved one whose decisions to share the gift of life enable transplantation medicine to flourish.

Through the efforts of the Organ Procurement Transplantation Network, organ transplantation has become available to more and more chronically ill patients. Last year more than 21,000 Americans received organ transplants, but more than 4,000 people on transplant waiting lists died because of the scarcity of donated organs. As these lists grow, many more will die as the system continues to strain under the demand for organs.

In light of this demand, we in the administration believe that our first priority must be to increase organ donation. To that end, in December 1997, the Department launched its organ and tissue donation initiative to foster partnerships between public and private-sector organizations, to enhance public education about the need for donation, and to recruit potential donors. We believe that we

must work to ensure that the OPTN operates equitably and provides the best possible outcomes for patients.

This role for the Federal Government was recently affirmed by the Institute of Medicine, "The Federal Government as well as the transplantation community has a legitimate and appropriate role to play in assuring that the organ procurement and transplantation system serves the public interest, especially the needs and concerns of patients, donors, and families affected by it. The IOM learned of numerous instances in which weak governance tends to undermine the effectiveness of the system. Weak oversight has compromised accountability at all levels, permitted poor procedures for data collection and analysis to persist, and allowed the system to operate without adequate assessment of performance."

Thus, in commending the OPTN for its accomplishments, we cannot ignore the persistent flaws and unfairness in the system. The most medically urgent patients do not always receive priority. Patients with similar levels of disease may have different outcomes depending on where they live or list. Distrust among transplant surgeons and hospital administrators sometimes impedes broader sharing of organs. True measures of equity to judge the OPTN do not exist.

In recognition of a need for public sector oversight of the OPTN, and in response to provisions of the Consolidated Omnibus and Emergency Supplemental Appropriations Act of 1999, the Department has increased its efforts to assess the performance of transplant programs. With the assistance of staff from UNOS, the contractor for both the OPTN and the scientific registry, the Department staff analyzed OPTN outcome data for liver and heart transplants with respect to three critical issues: One, the likelihood that, having been listed as a transplant candidate, a patient would receive an organ within 1 year; two, the likelihood that a patient will die within 1 year of listing while awaiting transplantation; and three, the likelihood that a patient would still be alive 1 year after listing irrespective of whether he or she underwent a transplant procedure.

After risk adjustment, that is adjustment for differences in the mix of patients' health status from program to program, the analysis revealed substantial differences in outcome from one transplant program to another. These findings warrant attention by the OPTN. In the course of performing these analyses, the Department staff identified gaps in the data currently collected by the scientific registry; for example, additional clinical details about patients' condition at the time of listing, which could improve risk adjustment, and additional data on clinical complications, which could help in assessing quality of life following transplantation.

The Department intends to encourage UNOS in its management of the OPTN and its operation of the scientific registry to broaden the scope of data collection and make increased use of program-specific performance analyses.

Many of the flaws in the OPTN are addressed in the final rule issued by the Department in April, 1998, after extensive public comment and 3 days of public hearings.

The rule requires the OPTN to develop policies that will result in standard listing practices and medically based definitions of pa-

tient status categories. The rule also requires policies that will encourage broader geographic sharing of organs so that the most medically urgent patients receive transplants based on sound medical judgment. The rule leaves the policy decisions to the OPTN with oversight by the Department.

I again quote from the IOM report: "Vigilant and conscientious oversight and review of program policies are critically important to ensuring accountability on the part of the OPTN and other participants in the organ procurement and transplantation system. The final rule appropriately places this responsibility with the Federal Government. The IOM believes that this is an important aspect of the final rule and charge that should be pursued by the Federal Government in close cooperation with the full range of participants in the transplant community."

The Department concurs with the IOM. This is the balance we sought in the rule.

Mr. Chairman, we have taken very seriously the charge we were given by the Congress last year to work cooperatively with the transplant community to clarify the intent and the effect of the rule. We very much appreciate the many hours that those in the community have spent meeting with us and their constructive approach in identifying apparent problems and potential solutions through oral and written comments. In addition, we have carefully reviewed the IOM report and recommendations and have met with representatives of the IOM expert committee on two separate occasions. Also we are fortunate to have additional data pursuant to the study provisions of the omnibus bill.

In response to these helpful comments and discussions, we have committed to revise the rule in important areas. For example, we intend to clarify the rule so that there is no doubt that the OPTN will develop allocation policies. We intend to ease any lingering concerns of the transplant community about the Secretary's regulatory authority by instituting an independent advisory committee, as recommended by IOM, to review major differences between the Secretary and OPTN on policy matters.

Other areas of potential clarification or revision have been discussed in detail with transplant community representatives. I believe our revisions will address the major concerns we have heard from the transplant community, yet maintain the essential framework of the rule requiring standardization of certain practices and encouraging broader geographic sharing of organs.

Consistent with the law, it is our intent that the rule once revised go forward to address inequities in the system identified by the Department and IOM. However, congressional review of the OPTN is essential; and the Department looks forward to working together with you, Mr. Chairman, and other Members of the Congress to develop legislation to reauthorize NOTA. Reauthorization should primarily address the needs of patients and also maintain the requirement of NOTA that there be a national, equitable system of organ allocation in the United States. We recommend that reauthorization reinforce the role of the Federal Government in overseeing the OPTN in accordance with the IOM recommendations and that the statute continue to leave management and policy development of the OPTN in the private sector.

The Department is concerned that H.R. 2418 does not do enough to preserve and strengthen many of the attributes of the OPTN that have placed transplantation firmly within the medical mainstream. Indeed in some instances the bill takes a step backward. The Department therefore opposes H.R. 2419 in its current form. My full statement contains comments on specific provisions.

In summation, Mr. Chairman and members of the subcommittee, the Department is committed to working with you and the members of the transplant community to create policies that improve the quality of care and the equity of our organ allocation system. While we have had our differences, our recent discussions with the transplant community have been quite promising. We hope that this spirit of cooperation can extend to our discussions on reauthorization of NOTA as well. Thank you for the opportunity to testify today.

[The prepared statement of William F. Raub follows:]

PREPARED STATEMENT OF WILLIAM F. RAUB, DEPUTY ASSISTANT SECRETARY FOR SCIENCE POLICY, OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good afternoon, Chairman Bilirakis, Congressman Brown, and other members of the Subcommittee. I am William Raub, Deputy Assistant Secretary for Science Policy at the Department of Health and Human Services. I appreciate your invitation to be here today to discuss H.R. 2418, a bill to reauthorize the National Organ Transplant Act (NOTA). I also will testify in general about national organ transplantation policies and the constructive discussions we have had with our colleagues in the transplant community about those policies.

Thanks in large part to the passage of NOTA in 1984, the transplant network is very different from the system that existed then. Organ transplantation is no longer experimental; it is routine. The figurative handful of centers comprising the network in 1984 has grown into an enterprise of 891 organ-specific transplant programs. Technological advances allow excised organs to last much longer and to be transported much farther than they could fifteen years ago.

In many respects, NOTA and the transplant network it spawned have served patients well. We have an organized national system requiring a structured approach to organ transplantation that did not previously exist. Allocation of scarce organs is done more cooperatively than in the past. Advances in drugs for immunosuppression and techniques for lengthening cold ischemic time have resulted in high survival rates for transplant patients.

Many organizations and individuals deserve high praise for the achievements of the Organ Procurement and Transplantation Network (OPTN): the United Network for Organ Sharing (UNOS); surgeons, physicians, nurses, and other health professionals who have committed themselves to the practice of transplantation medicine; laboratory and clinical scientists who continue to generate new knowledge and technology that drives transplantation medicine to ever-greater success; staff of the Organ Procurement Organizations (OPOs), who work so diligently to acquire and transport organs to transplant programs; patients, who provide invaluable insights as to how OPTN processes might be improved; and, most of all, organ donors and their loved ones, whose decisions to share the gift of life enable transplantation medicine to flourish.

Their efforts have made organ transplantation available to more and more chronically ill patients. Last year more than 21,000 Americans received organ transplants. But more than 4,000 people on transplant waiting lists died because of the scarcity of donated organs. As these lists grow, many more will die as the system continues to strain under the demand for organs.

We in the Administration believe that our first priority must be to increase organ donation. To that end, in December 1997, the Department launched its National Organ and Tissue Donation Initiative to foster partnerships between public- and private-sector organizations to enhance public education about the need for donation and to recruit potential donors. The centerpieces of this initiative are a rule, modeled upon legislation in Pennsylvania, requiring hospitals participating in Medicare to expand their reporting of imminent deaths and deaths to OPOs and a new \$5

million grant program to learn more about what works in organ donation. We are pleased to report that organ donation increased by more than 5 percent last year as a result of our collective efforts, and we are hopeful that the upward trend will continue. Nevertheless, we recognize that the need for transplantation is growing faster than the supply of organs and that continued emphasis on both organ donation and equitable organ allocation is necessary.

A second priority for the Administration is to ensure that the OPTN established by NOTA works equitably and provides the best possible outcomes for patients. The role of the federal government in this area was recently affirmed by the Institute of Medicine (IOM), which was directed by Congress last year to study the national organ transplantation network. Two months ago, IOM reported that:

The federal government, as well as the transplantation community, has a legitimate and appropriate role to play in ensuring that the organ procurement and transplantation system serves the public interest, especially the needs and concerns of patients, donors, and families affected by it. The [IOM] learned of numerous instances in which weak governance tends to undermine the effectiveness of the system... Weak oversight has compromised accountability at all levels, permitted poor procedures for data collection and analysis to persist, and allowed the system to operate without adequate assessment of performance.

As I said, the OPTN should be commended for its wonderful accomplishments. Nevertheless, we cannot ignore the persistent flaws and unfairness in the system. The most medically urgent patients do not always receive priority. Patients with similar levels of disease may have different outcomes, depending on where they live or list. Distrust among transplant surgeons and hospital administrators sometimes impedes broader sharing of organs. True measures of equity to judge the OPTN do not exist.

In recognition of the need for public-sector oversight of the OPTN and in response to provisions of the Consolidated Omnibus and Emergency Supplemental Appropriations Act of 1999, the Department has increased its efforts to assess the performance of transplant programs. With the assistance of staff from UNOS, the contractor for both the OPTN and the Scientific Registry, Department staff analyzed OPTN patient outcome data for liver and heart transplants with respect to three critical issues:

- the likelihood that, having been listed as a transplant candidate, a patient will receive a organ within one year;
- the likelihood that a patient will die within one year of listing while awaiting transplantation; and
- the likelihood that a patient will still be alive one year after listing, irrespective of whether he or she underwent a transplant procedure.

After risk adjustment (i.e., adjustment for differences in the mix of patients' health status from program to program), the analyses revealed substantial differences in outcomes from one transplant program to another. The principal findings for liver transplants illustrate this:

- ten percent of the programs have a risk-adjusted rate of transplantation within one year of listing of 71 percent or more; whereas, for another ten percent of the programs, the rate is 25 percent or less;
- the likelihood of dying within one year of listing while awaiting a transplant ranges from less than 8 percent to more than 22 percent; and
- the likelihood of surviving one year after listing as a transplant candidate or a recipient ranges from approximately 65 percent to almost 86 percent.

The analogous values for heart transplants are 36-72 percent (transplantation within one year of listing), 9-23 percent (death within one year of listing while awaiting a transplant), and 67-84 percent (survival for one year after listing irrespective of whether transplanted or not).

In the course of performing these analyses, Department staff identified gaps in the data currently collected by the Scientific Registry—e.g., additional clinical details about patients' conditions at the time of listing (which could improve risk adjustment) and additional data on clinical complications (which could help in assessing quality of life following transplantation). The Department intends to encourage UNOS, in its management of the OPTN and its operation of the Scientific Registry, to broaden the scope of data collection and make increased use of program-specific performance analyses.

Although these findings warrant further study to determine the precise reasons for such variances in patient outcomes, one thing is clear. Where a patient lives or lists often does more to determine whether he or she gets a transplant than do medical considerations. Patients in like circumstances are being treated differently, in

clear contradiction of the premise of NOTA that we have an equitable national system of organ transplantation in the United States.

Many of the flaws that I have discussed are addressed in the final rule for the OPTN that was issued by the Department in April, 1998, after extensive public comment and three days of public hearings. The rule requires the OPTN to develop policies that will result in standard listing practices and medically based definitions of patient status categories. The rule also requires policies that will encourage broader geographic sharing of organs so that the most medically urgent patients receive transplants, based on the sound medical judgment of physicians under this general rubric. The rule leaves the policy decisions to the OPTN with oversight by the Department.

In reference to the final rule, I again quote from the IOM report:

Vigilant and conscientious oversight and review of programs and policies are critically important to ensuring accountability on the part of the OPTN and other participants in the organ procurement and transplantation system. The Final Rule appropriately places this responsibility with the federal government. The [IOM] believes that this is an important aspect of the Final Rule and charge that should be pursued by the federal government in close cooperation with the full range of participants in the transplant community.

The Department clearly concurs with the IOM. There should be vigilant government oversight and close cooperation with the transplant community. This is the balance we sought in the HHS rule.

Mr. Chairman, we have taken very seriously the charge we were given by the Congress last year to work collaboratively with the transplant community to clarify the intent and effect of the rule. We very much appreciate the many hours that those in the community have spent meeting with us and their constructive approach in identifying apparent problems and potential solutions through oral and written comments. In addition, we have carefully reviewed the IOM report and recommendations and have met with representatives of the IOM committee on two separate occasions. As I have indicated, we are also fortunate to have additional data pursuant to the study provisions in the omnibus bill.

In response to these helpful comments and discussions, we have committed to revise the rule in important areas. For example, we intend to clarify the rule so there is no doubt that the OPTN will develop allocation policies. We intend to ease any lingering concerns of the transplant community about the Secretary's regulatory authority by instituting an independent advisory committee—as recommended by IOM—to review major differences between the Secretary and OPTN on policy matters. Other areas of potential clarification or revision have been discussed in detail with transplant community representatives. I believe our revisions will address the major concerns we have heard from the transplant community yet maintain the essential framework of the rule requiring standardization of certain practices and encouraging broader geographic sharing of organs.

Consistent with the law, it is our intent that the rule, once revised, go forward to address inequities in the system identified by the Department and IOM. However, congressional review of the OPTN is essential, and the Department looks forward to working together with you, Mr. Chairman, and other members of Congress to develop legislation to reauthorize NOTA. Reauthorization should primarily address the needs of patients and also maintain the requirement of NOTA that there be a national, equitable system of organ transplantation in the United States. We recommend that reauthorization reinforce the role of the federal government in overseeing the OPTN, in accordance with the IOM recommendations, and that the statute continue to leave management and policy development of the OPTN in the private sector.

The Department is concerned that H.R. 2418 does not do enough to preserve and strengthen many of the attributes of the OPTN that have placed transplantation firmly within the medical mainstream. Indeed, in some instances, the bill takes a step backward. The Department, therefore, opposes H.R. 2418 in its current form. The following paragraphs describe our principal concerns.

- While calling for a national system to match organs and individuals who need organ transplants, the bill does nothing to decrease the reliance on arbitrary geographic boundaries and the inequities that result. Commenting specifically on allocation of livers, IOM concluded that “the fairness of the organ procurement and transplantation system, and its effectiveness in meeting its stated goals, would be significantly enhanced if the allocation of scarce donated livers were done over larger populations than is now the case.” Medical outcomes, waiting time and the possibility of fatality should not depend on the geographic location of a transplant program at which a patient is wait-listed.

- H.R. 2418 does not ensure that patients and referring physicians can obtain the kinds of program-specific information they need to make decisions about whether, when, and where to seek transplantation. Although H.R. 2418 provides for program-specific data on such items as the probability of receiving an organ transplant, the waiting time for similarly situated patients, and the medical outcomes for similarly situated patients, the bill does not specify that this information also be timely and easy to use. Out-of-date information can lead referring physicians and patients to make less than optimal decisions.
- H.R. 2418 would erode the role of the federal government in providing oversight of the OPTN. The OPTN, by its structure, is not able to incorporate into its activities the public policy considerations that underpin the NOTA. The Department believes that it must continue to be an active partner with the private-sector in striving to fulfill the goals of the OPTN. Indeed, the overarching purpose of the OPTN rule is to clarify the nature and extent of oversight by the Department while ensuring a continued prominent role for transplantation professionals, patients / patient-advocates, and other organizations and individuals in the private sector.
- As you know, under the U.S. Constitution, a private entity cannot perform functions inherent to the federal government. Yet the bill does not stipulate that binding policies for the OPTN be approved by the federal government.
- Although H.R. 2418 requires that the Board of the OPTN have physician representation of no less than 50 percent, it makes no such percentage requirements for patients and donor families, who we believe should have a significant representation on the Board.

In summation, Mr. Chairman and members of the Subcommittee, the Department is committed to working with you and the members of the transplant community to create policies that improve the quality of care and the equity of our organ allocation system. While we have had our differences, our recent discussions with the transplant community have been quite promising. We hope that this spirit of cooperation can extend to our discussions on reauthorization of NOTA as well. Thank you for the opportunity to testify today.

Mr. GANSKE [presiding]. Thank you, Mr. Raub. By the way, why was your testimony so late?

Mr. RAUB. Sir, the invitation to the Department, as I understand it, arrived at the end of last week. We worked very hard over the—

Mr. GANSKE. The invitation I am told arrived last Tuesday.

Mr. RAUB. That is not my knowledge, sir, but I have no reason to dispute your statement.

Mr. GANSKE. Okay. If it arrived last Tuesday, why did we not receive your testimony until today? Will you take personal responsibility and find out what the delay was?

Mr. RAUB. Yes, sir, I will.

Mr. GANSKE. Thank you. Dr. Payne?

STATEMENT OF WILLIAM PAYNE

Mr. PAYNE. Thank you, Mr. Chairman and distinguished members of the committee. It is an honor to testify today as the current President of UNOS, the United Network for Organ Sharing. I am Bill Payne, a liver transplant surgeon and Director of the Liver Transplant Program at the University of Minnesota.

On behalf of UNOS I will be speaking in support of H.R. 2418. First, however, I would like to provide a brief report on three major improvements made since we last appeared before you.

In June, the UNOS board of directors voted to institute a major change to the liver allocation policy by establishing region-wide sharing for the most urgent patients. This new policy, which has been in development for several years, addresses many of the concerns that have been raised with regard to allocation over the last year.

Each year more than 4,000 people die needlessly because of the organ shortage. I am pleased to report that UNOS recently completed a pilot test of its new critical pathway for organ donor management developed under our contract with HRSA. The study revealed a 10.4 percent increase in the number of organs recovered per donor at pilot sites.

This is extremely important news. The organ supply has remained roughly the same for years despite everyone's best efforts. As this new organ recovery technique is implemented nationally we expect a 10 percent increase, the largest in a decade.

Finally, UNOS recently unveiled an impressive array of new on-line data for patients and the public. By updating our Internet site we have an all new section called "Transplant Patient Data Source." we are now providing the latest statistics on survival rates on every transplant program in the country, the size of waiting lists and waiting times at each center and OPO, and the supply of donated organs nationally by State and by transplant center.

This unique research tool offers patients the critical information they need to evaluate transplant centers in a user friendly format. Consumer information and scientific data of this kind is unprecedented, available nowhere else in medicine. In fact, we recently asked Arthur Andersen to conduct a study to evaluate the data published by leading major health organizations. Arthur Andersen polled 40 Federal public health agencies and national private health care organizations and found that other than the small bone marrow transplant registry, none of the organizations polled collects or analyzes center-specific data or health care-related outcome data and makes it available to the public to the extent that UNOS does.

With regard to H.R. 2418, I am proud to represent the UNOS membership in strongly supporting this legislation. Mr. Chairman, we very much appreciate your leadership on this issue and commend you for your hard work and the truly bipartisan support for this legislation. We support this bill for many reasons.

First, the bill reinforces the original intent of NOTA. It was Chairman Bliley and other members of this committee who designed the current public-private structure that keeps the delicate medical decisionmaking with doctors and the medical community. H.R. 2418 preserves the original intent of NOTA by restating that the responsibility for developing, establishing and maintaining medical criteria and standards for organ procurement and transplantation rests in the private sector and the medical community.

This inclusive and democratic policymaking process ensures that transplantation policy reflects the consensus of the community while addressing the issues facing practitioners and patients every day.

Second, the bill also updates NOTA by providing new direction in important areas such as enforcement, accountability, and patient confidentiality. It provides several new means by which the network can enforce its policies. It also includes new requirements improving the network's public accountability. Specific and detailed data reporting requirements will now be mandated by law. The bill also provides for a new periodic evaluation of the network's per-

formance by the GAO to be submitted to Congress for review. UNOS strongly endorses these new oversight measures.

The bill also ensures that in an effort to provide more information to the public, the confidentiality of patients pre and post transplant will not be compromised. We wholeheartedly support this important protection for patients.

Finally and perhaps most importantly, the bill provides new incentives for donation. Simply put, too few people give the gift of life. The medical community struggles daily with families torn with grief over the loss of a loved one who through fear or mistrust choose not to allow organs to live on. This bill represents further commitment by Congress to help us increase donation.

Mr. Chairman, we believe all of these provisions are great improvements to NOTA and that a reauthorization is timely and necessary. We urge the committee to pass it, and again thank you for the opportunity to appear before you today. I would be happy to answer any questions you may have.

[The prepared statement of William Payne follows:]

PREPARED STATEMENT OF WILLIAM PAYNE, PRESIDENT, UNITED NETWORK FOR ORGAN SHARING

Mr. Chairman, distinguished members of the Committee, it is an honor to be here today to testify as the current President of the United Network for Organ Sharing, or UNOS. My name is Bill Payne, and I am a liver transplant surgeon currently serving as Chief of Staff at Fairview University Medical Center in Minneapolis, Minnesota, where I also am Director of the Liver Transplant Program.

UNOS members elect a new president each June, and my predecessors have appeared before you in the past. Therefore, you know that UNOS has been the Organ Procurement and Transplantation Network—the OPTN, or Network—since the passage of NOTA in 1986, and continues to operate this national Network under contract with the Department of Health and Human Services. Because we have testified before you in the past, I will only briefly recount who UNOS is and what we do.

As a private membership organization, UNOS includes every transplant center and organ procurement organization in the United States. The corporation qualifies under federal law as a charitable, tax-exempt scientific and educational organization. Although we employ almost 200 full-time staff, the important clinical and scientific work of UNOS, as well as the critical establishment of national transplant standards and policies, is accomplished by thousands of volunteers.

UNOS incorporates and embodies the entire organ transplant community in this country. It comprises surgeons, physicians, nurses, ethicists, and allied health professionals, as well as patients, patient advocates, and donor family members, all of whom have dedicated hundreds of thousands of hours to the operation of this critical life-saving Network.

It has been a year since UNOS last appeared before this Committee to testify on issues relating to organ transplantation. And, as you know, much has happened since then. I want to take this opportunity to inform you of several significant changes that have been made since we appeared last. In the last year, UNOS has:

- Implemented new liver allocation policies;
- Increased the supply of organs; and
- Published new, extensive data for patients and the public.

NEW UNOS INITIATIVES

New Liver Allocation Policy

Today's liver allocation policy is significantly different than when this issue was last before the Committee. In June, the UNOS Board of Directors voted to institute a dramatic change to the liver allocation policy that has been in development for several years. The new policy establishes region-wide sharing for the most urgent patients—the subset of patients doctors agree have the best chance of a successful transplant. This policy is founded on broad community consensus because it achieves the benefits of broader sharing while avoiding the problems that many think are inherent in the distribution of livers over excessively large areas, such as

increased retransplants or decreased access at smaller centers. This action is a major step toward the goal of broader sharing of livers and addresses many of the concerns that have been raised with regard to allocation over the last year.

This new sharing policy is also consistent with the Institute of Medicine's (IOM) recent recommendation that livers be shared in areas with a base population of 9 million versus the much smaller organ procurement organization (OPO) service areas. Since UNOS' 11 regions range in population from 10 million to 40 million, these areas are significantly larger than those recommended by the IOM. Needless to say, we will still be examining the IOM's recommendations to determine its advantages or disadvantages over the current system.

Increasing the Organ Supply

Regarding organ donation, I am pleased to report that UNOS has developed a new technique that has the potential to increase the overall number of transplantable organs by more than 10 percent. As you know, the organ supply has remained roughly the same for years, despite the best efforts of everyone involved in transplantation. UNOS recently completed a pilot test of the new UNOS Critical Pathway for organ donor management developed under our contract with the Health Resources and Services Administration (HRSA).

The study revealed that use of this new protocol resulted in a 10.4 percent increase in the number of organs recovered per donor at the test sites. The study also demonstrated that use of the Pathway reduced costs and did not increase the time spent in donor management. As the Pathway is implemented across the country, we expect to see a nationwide increase in the organ supply on the order of 10 percent, the largest increase in more than a decade.

New Data Available for Patients

Another significant change that has taken place since we were before the Committee last involves new information and data that we have made available to the public. Two weeks ago, UNOS unveiled an online resource to provide the transplant community and the public with unprecedented access to organ transplant information by utilizing the latest in Internet technology.

Available on our web site (www.unos.org/patients), *Transplant Living* is a new site offering patients and their families a single, comprehensive source for everything they want and need to know to handle the often tough decisions involved in obtaining an organ transplant. It is designed to help those who have just discovered they need a transplant better understand the process, and help them feel they are making the best choices for their care.

Among its many resources, the web site features *Transplant 101*, designed to be a step-by-step guide for patients and their families for every stage of the organ transplant process. There is helpful information on financing transplants, local support groups, instructions on how to get on waiting lists, as well as past experiences from transplant recipients, professionals and family members of organ donors.

The UNOS Internet site has been updated with a new section called, *Transplant Patient DataSource*. This part of our web site provides the latest statistics on:

- Survival rates for every transplant program in the country;
- The size of waiting lists and waiting times at each center and OPO; and
- The supply of donated organs, nationally, by state, and by transplant center.

This unique research tool offers patients the critical information they need to evaluate transplant centers when making decisions about obtaining a life-saving organ. This kind of consumer information and scientific data is unprecedented because nowhere else in medicine is this level of detailed, institution-specific data available.

UNOS is extremely proud to have been able to step into this leadership role in medicine, not only for the United States, but for the entire world. Through our partnership with HHS, under our contracts with HRSA, and through other funding arrangements, we have been able to provide more extensive data for patients and the public than any other public or private institution in medicine.

Ask yourself this question: If your doctor told you today that you had a life-threatening condition, could you find information about where you could receive treatment, and the track record at each hospital where it is provided? Could you learn the number of similar cases and the results at each of those centers, including every center's survival rate?

Unless the treatment you need is an organ or bone marrow transplant, the answer is no.

Arthur Andersen Study

We recently asked the world's leading information and management consulting firm, Arthur Andersen, LLP, to conduct a study to evaluate the extent to which leading major health organizations collect outcomes data and provide center-specific information to the public.

Arthur Andersen polled 40 federal public health agencies and national private health care organizations and found that other than the bone marrow transplant registry, none of the organizations polled collect or analyze center-specific data or healthcare-related outcome data, or make it available to the public to the extent that UNOS does. Three of the organizations noted that they make efforts to track other types of data, e.g. number of cases, case demographics, etc., but that the data is not made publicly available.

We believe the findings of this survey by Arthur Andersen confirm the unique and unprecedented depth of information UNOS now makes available to anyone interested in organ transplants.

UNet

Beyond the new, improved outreach to patients and their families, UNOS is launching a similar, but secure, Internet-based transplant information resource to help doctors and the transplant community match donors to recipients faster and more efficiently. UNETsm replaces an older, less user-friendly computer system, and should eliminate many of the time-consuming telephone calls and faxes required to coordinate the donation, allocation, and transplantation of life saving organs. UNETsm is scheduled to go online next week, offering physicians and organ centers unprecedented, real-time access to the latest organ transplant information.

Both of these Internet-based efforts are a direct response to feedback and suggestions from UNOS' network of patients, families, doctors and medical professionals. With its lifesaving charter, UNOS continually evaluates different ways to improve the system and help make donation and transplant data readily available.

NOTA REAUTHORIZATION

With regard to H.R. 2418, the bill that is before the Committee today, I am proud to represent the UNOS membership in strongly supporting this legislation. As I stated in my July 14, 1999 letter to you, Mr. Chairman, we very much appreciate your leadership on this issue and commend you for your hard work in developing this legislation and the bipartisan support it has received.

Since 1990, when NOTA was last reauthorized, many of us in the transplant community have been anxious about the state of transplantation, and the Federal government's commitment to the public-private partnership established in NOTA. We are enthusiastic about the prospect of NOTA reauthorization and the opportunity to update and strengthen current law. Specifically, we support H.R. 2418 for the following reasons.

H.R. 2418 Reinforces the Original Intent of NOTA

It was Chairman Bliley and other members of this Committee who designed the current public-private partnership that we now know as the Organ Procurement and Transplantation Network. The beauty of this structure is that it keeps delicate and informed medical decision making in the medical and transplant community and out of the political realm.

We at UNOS, as the Network contractor since its inception, believe that the vision of NOTA's original authors has been a successful model of great service to patients. The current system serves as a check and balance system, producing the best medical decisions and the best transplant policies for current and potential organ donors and recipients.

H.R. 2418 preserves the original intent of NOTA by restating that the responsibility for developing, establishing and maintaining medical criteria and standards for organ procurement and transplantation rests in the private sector and the medical community. With doctors, patients, donor families, procurement coordinators, ethicists, government officials, and others participating in a democratic policy making process, transplantation policy can reflect a consensus of the community while addressing the issues facing practitioners and patients every day.

H.R. 2418 Creates New Enforcement and Accountability Requirements

Within the framework of the original NOTA, H.R. 2418 updates NOTA by providing new direction in important areas such as enforcement, accountability, and patient confidentiality.

Enforcement: Over the years, the transplant community has been concerned that the Network lacked any real mechanisms to enforce its policies. H.R. 2418 provides

for several actions that the Network may take in this regard. This approach is contrasted with what many have regarded as the only enforcement mechanism available to the Network under current law: the severe penalty of a hospital or OPO losing its eligibility to be a Medicare provider (so severe a penalty that it is unlikely to ever be invoked). The bill's proposed intermediate actions include:

- Payment of damages by Network participants who are found to be non-compliant with Network policies through a peer review process;
- Suspension of a transplant program's ability to receive organs for transplantation; and
- Public designation as a member not in good standing.

Accountability: In addition to new enforcement mechanisms, H.R. 2418 includes new important requirements designed to make the Network more accountable to Congress, the Secretary of Health and Human Services and the public. For the first time, specific and detailed data reporting requirements will be mandated by law. This ensures that the extensive data that UNOS has recently made available to the public will always be available in the future. The bill also provides for a new periodic evaluation of the Network's performance by the Comptroller General of the United States, which shall be submitted to Congress for its review. Never before have such oversight measures been required by law, and we support them.

Patient Confidentiality: As a significant new addition to NOTA, H.R. 2418 contains a specific provision to protect patient confidentiality. This provision ensures that, in an effort to provide more information to the public regarding transplant hospital waiting lists and outcomes, the confidentiality of patients—pre- and post-transplant—will be protected. Many people do not realize the depth of information that patients must disclose to be placed on a waiting list to receive an organ transplant. As with any medical information, disclosure of this information—even if unintended—can have devastating effects on people's lives. We wholeheartedly support this important protection for patients.

H.R. 2418 Provides New Incentives for Donation

Perhaps most important are the bill's provisions aimed at increasing donation. All of us involved in organ transplantation struggle regularly with our frustration over the shortage of donor organs. Each year, nearly 4,000 people die needlessly because too few people give the gift of life. The medical community struggles daily with families torn with grief over the loss of a loved one, who, through fear or mistrust, choose not to allow organs to live on.

We know that Congress is committed to helping us bridge the gap. There have been several recent steps taken such as the passage of the Organ Donor Leave Act. For the past several years, Congress has also been generous in appropriating more funds dedicated to educating people about organ donation. This bill continues that trend.

The bill also provides resources to HHS to seek out the "best practices" in organ procurement so they can be duplicated around the country. I, for example, come from a state that has a great success rate in recovering organs. These funds could help facilitate information sharing and training between OPOs, hospital personnel and others around the country, allowing for the best and most successful ideas to be replicated.

Summary

Mr. Chairman, we believe all of these provisions are great improvements to NOTA and that a reauthorization is timely and necessary. We support the bill and urge the Committee to pass it. Again, thank you for the opportunity to appear before you today.

Mr. GANSKE. Thank you. Mr. Gibbons?

STATEMENT OF ROBERT D. GIBBONS

Mr. GIBBONS. Good afternoon, Mr. Chairman and members of the committee. My name is Robert Gibbons and I am a professor of biostatistics at the University of Illinois in Chicago, and also a member of the Institute of Medicine's Committee on Organ Procurement and Transplantation. With me today is another member from the IOM committee, Dr. Mitchell Spellman, who is Professor of Surgery Emeritus and also Dean of Medical Services Emeritus for Harvard

University Medical School. And also with me is Susanne Stoiber, the Executive Officer of the Institute of Medicine.

We are pleased to have this opportunity on behalf of our fellow committee members and the Institute of Medicine to talk to you about our report on organ procurement and transplantation. Copies of the report's executive summary have been submitted for the record and preliminary print of the full report has been available to members of this subcommittee.

The IOM was asked by Congress to review the regulation published by the Department of Health and Human Services in April 1998. Congress asked IOM to review its potential effect on access to transplantation services, organ donation rates, waiting times, survival rates and cost of organ transplantation services.

Much of the public debate that led up to Congress asking for our report centered on the observation that the time it takes to receive a liver transplant varies greatly depending on the location of the transplant center where the patient was placed on the waiting list; namely, geographic heterogeneity. Our committee quickly discerned that on the one hand this claim was highly overstated, but on another it diverted attention from very real and very important issues.

The reason this view is misleading is that it aggregated data across all the levels of severity of patients. Patients in liver Transplantation are broken down into four status groups depending on the severity of their condition. The most severely ill patients, which are called status 1 patients, have a life expectancy of approximately a week. By contrast, the less severely ill patients, status 3 patients and sometimes status 2B patients, may wait months or even years for a transplant.

Among the status 1 patients, the severely ill patients, there is very little variation in waiting time. On average these patients who do get transplanted do so within 4 days. This is not the case for the less severely ill patients who can wait months or possibly years based on differing policies and practices among the transplant centers on when these patients are placed on the list.

It is these listing practices that gave the overall impression that there were large heterogeneity in the median waiting times. Important to note is that more than 50 percent of the patients are, in fact, status 3 patients accounting for the variation in the median.

In terms of our analysis, for a variety of reasons the IOM committee focused its attention on livers. We reviewed over 68,000 liver transplant records for every liver transplant patient on the list from 1995 through 1999. This was a huge data base.

Attached to my testimony is a map showing the configuration of the 63 organ procurement organizations, which I will call OPOs from here on, covering the U.S. and its territories. The populations covered by these OPOs varied from 1 million to 12 million people.

We determined in an important finding that OPOs serving larger populations are associated with improved access overall for those patients most in need of a transplant. The committee found specifically that for status 1 patients, those most severely ill patients most in need of a transplant, they would receive transplants—they wait a comparable period of time across the country, about 4 days on average. However, transplantation rates do vary for patients

who are not as ill, with smaller OPOs having a larger proportion of status 2B and status 3 patients receiving transplants relative to the larger OPOs. Consequently patients who are less ill sometimes receive transplants before more severely ill patients who are served by a different organ procurement organization.

Based on the data available and our analysis, these differences begin to disappear when the population served by the OPO reached 9 million people or more. For that reason, and because the probability of a suitable match between a donated liver and a status 1 patient increases as the size of the population covered increases, we concluded that liver allocation areas should be established to cover an area large enough to serve at least 9 million people.

There were many other findings by the committee, but I will highlight a couple. Our analyses indicated that the longer that status 2B and status 3 patients are on the list, the lower their likelihood is that they will die or receive a transplant. This finding also led the committee to the conclusion that the time on the waiting list is not an appropriate criterion for allocating organs among the less severely ill patients.

Finally, we also looked at existing sharing arrangements and we found that the existing sharing arrangements did, as we would expect, increase status 1 transplantation rates and decrease the rate of transplantation of the less severely ill patients without increasing their pretransplantation mortality rates.

There were several concerns expressed about the notion of broader sharing. The first was whether or not there would be a limitation on minority access or access to low-income patients. The committee did not find any evidence in support of these concerns.

Information available to the committee indicated that the smallest transplant centers are not a major source of access for racial and ethnic minorities. Moreover, we found the evidence that small centers would be forced to close under broader sharing arrangements to be inconclusive.

We also heard concern that distributing organs across a wider area would discourage donation and again we found no evidence in support of this idea.

Finally, we also found that broader sharing would significantly increase the cost of transplantation and although it will increase the cost, only marginally compared to the total expenditures for transplantations.

Finally, the committee concluded that achieving the goals of the National Organ Transplant Act requires an active Federal role in review and oversight and this should be done in collaboration with representatives of those involved in transplantation, including patients, donor families, physicians, nurses, OPOs and transplant centers. At the heart of this there should be an independent scientific review board that should assist with policies and procedures, making sure that they are well grounded in medical science; that there is a cohesive and strategic approach to the entire transplantation system; that the interests of transplant patients and donor families are given paramount concern; and credibility and trust are maintained with patients in the transplant community and the general public.

Thank you.

[The prepared statement of Robert D. Gibbons follows:]

PREPARED STATEMENT OF ROBERT D. GIBBONS, PROFESSOR OF BIOSTATISTICS,
UNIVERSITY OF ILLINOIS AT CHICAGO

Good afternoon Mr. Chairman and members of the Committee. My name is Robert D. Gibbons. I am a Professor of Biostatistics at the University of Illinois at Chicago and a member of the Institute of Medicine (IOM) Committee on Organ Procurement and Transplantation Policy. With me is another member of the IOM committee, Mitchell W. Spellman, M.D., Ph.D. Dr. Spellman is professor of surgery, emeritus, and dean for medical services, emeritus, at the Harvard Medical School. [Also with me is Ms. Susanne Stoiber, the Executive Officer for the IOM.]

We are pleased to have this opportunity—on behalf of our fellow committee members and the Institute of Medicine—to talk about our report on organ procurement and transplantation. Copies of the report's Executive Summary have been submitted for the record, and a preliminary print of the full report has been available to the members of this Subcommittee. I have a short oral statement and Dr. Spellman and I [OR, the three of us] will be pleased to answer any questions you may have about the report.

THE COMMITTEE'S ASSIGNMENT

The IOM was asked by the Congress to review a regulation published by the Department of Health and Human Services (DHHS) in April 1998. That regulation set forth various requirements and procedures to be followed by the Organ Procurement and Transplantation Network (OPTN) in carrying out its responsibilities under the National Organ Transplant Act (NOTA). The Congress suspended implementation of the regulation and asked the IOM to review its potential effect on several important issues, including:

- Access to transplantation services by low-income populations and racial and ethnic minorities;
- Organ donation rates;
- Waiting times for organ transplants;
- Patient survival rates and organ failure rates; and
- Costs of organ transplantation services.

Our report examines each of these issues, and sets forth several conclusions and recommendations.

THE INITIAL PUBLIC DEBATE

Much of the public debate, leading up to the Congress asking for our report, centered on the observation that the time it takes to receive a liver transplant varies greatly, depending upon the location of the transplant center where the patient has been placed on the waiting list. This geographic inequity was put forward as evidence that the current system is grossly inequitable. Our Committee quickly discerned, however, that this was not the best way to evaluate the data. One the one hand, it overstated the inequities, for reasons I will briefly explain; but on the other hand, it diverted attention from some very real and very important issues. The reason this view was misleading is that it aggregated the data for all patients awaiting a liver transplant, instead of breaking the data down into the four status groups into which patients are classified, depending on the severity of their condition. The most severely ill patients—those having a life expectancy of a week or less—are in status 1. There is very little variation in the waiting time for these patients; it is a matter of a few days for those who receive a transplant. The least severely ill patients—those in status 3—may wait months or even years for a transplant. Since more than half of all patients on the waiting lists are in status 3, the data for these patients are what determines the overall variation in median waiting times used in the arguments noted above. But this tells us very little about the equity or effectiveness of the system, since differing policies and practices among transplant centers on when status 3 patients should be placed on a waiting list means that these patients form a very heterogeneous group.

THE COMMITTEE'S ANALYSIS

For a variety of reasons, the IOM Committee focused its attention on livers. In order to review the issues in greater depth, the Committee obtained, from the OPTN, approximately 68,000 records covering all the patients awaiting a liver transplant during the period from 1995 to 1999. Of particular interest were the consequences of the current OPTN policies on allocating donated organs among pa-

tients, and the likely consequences of the changes in those policies called for by the DHHS regulation.

Organ Procurement Organizations (OPOs) are statutorily created entities responsible for the procurement of donated organs and for coordinating the allocation of those organs among patients on the waiting lists of transplant centers. Attached to my testimony is a map, showing the configuration of the 63 OPOs covering the U.S. and its territories. At the present time, with a few important exceptions, when these OPOs obtain an organ donated for transplantation, they seek to allocate it to a patient located within their own defined geographical area. Only if they cannot find a suitable patient within their own area do they seek to find a patient located in one of the other—typically adjacent—OPO areas. The populations covered by these OPO areas vary from approximately 1 million to about 12 million. **We determined that OPOs serving larger populations are associated with improved access for those patients most in need of a transplant.**

The Committee found that status 1 patients (those with the highest medical urgency for a transplant) who receive transplants wait for a comparable period of time all across the country—about 4 days on average. Moreover, the transplantation rates and the pre-transplantation mortality rates for status 1 patients do not vary significantly from one OPO to another, despite substantial variations in the size of the OPOs. (Size of OPO was defined either by the size of the population served or the number of transplants performed within the OPO service area.) However, only about one-half of the patients listed as status 1 receive a transplant.

Transplantation rates do vary for patients who are not as ill, with smaller OPOs having a larger proportion of status 2B and status 3 patients receiving transplants than larger OPOs. Consequently, patients who are less ill sometimes receive transplants before more severely ill patients who are served by a different organ procurement organization. Based on the data available to the Committee, these differences begin to disappear when the population served by the OPO reaches 9 million or more.

For that reason, and because the probability of a suitable match between a donated liver and a status 1 patient increases as the size of the population covered increases, we concluded that liver allocation areas should be established to cover an area large enough to serve at least 9 million people. Nine million is as far as our available data could take us. Logic suggests that larger areas would be even more effective in arranging a suitable match. These areas, however, should not be so geographically broad as to pose difficulties or delays in transporting organs, which could threaten the viability of the organ and the success of transplantation. The allocation areas for organs other than livers will differ depending on how long they can survive outside the body.

It is important to note that improvements in the rates of transplantation for status 1 patients do not appear to come at the expense of other patients. Our analysis indicated that the longer status 2B and status 3 patients are on the waiting list, the lower is the likelihood that they will either die or receive a transplant. This finding also lead the Committee to the conclusion that time on the waiting list is not an appropriate criterion for allocating organs among status 2B and status 3 patients.

There are currently in effect several arrangements under which two or more OPOs share donated organs on a statewide or regional basis, at least for status 1 patients. The Committee could make only a preliminary analysis of the data available for such sharing arrangements, but that analysis tends to confirm the Committee's view that broader sharing is beneficial. The analysis shows that that such sharing: (1) increases status 1 transplantation rates; (2) decreases status 2B pre-transplantation mortality rates; and (3) decreases the rate of transplantation of status 3 patients without increasing their pre-transplantation mortality rates.

CONCERNS EXPRESSED ABOUT BROADER ORGAN SHARING

The Committee heard some people in the transplant community express concern that broader sharing of organs might reduce access to organs for minorities and low-income patients. This would be true, they stated, if broader sharing resulted in the closure of some of the smaller transplant centers.

The Committee did not find any evidence to support these concerns. For low-income patients, regardless of their racial and ethnic backgrounds, there is an appropriate concern that they may not be referred to a transplant center for an evaluation for transplantation. This is because appropriate referral depends in large part on whether they have access to health insurance and high-quality health services. Once patients are referred for an organ transplant—again regardless of their race

or ethnicity—there appear to be no significant disparities either in their placement on a waiting list or in access to transplantation.

Information available to the Committee indicated that the smallest transplant centers are not a major source of access for racial and ethnic minorities. Moreover, we found the evidence that small centers would be forced to close under broader organ sharing to be inconclusive.

The Committee also heard concern that distributing organs across a wider geographic area would discourage donation and drive down organ donation rates. Organ donation rates are affected by many variables, including cultural attitudes about donation and transplantation, the age and race of the potential donor, the progression of illness in the potential donor, the manner in which families of potential donors are approached, and the various policies and practices of hospital staff and OPOs. The biggest shortcoming at present appears to be that many potential donors are not identified and their families not approached about the possibility of donation. The Committee found little evidence—if any—to support the notion that families would decline to donate, or that health professionals involved in organ procurement would be less diligent in their efforts, if they knew a donated organ would be used outside the donor's immediate geographic area. The Committee believes current efforts to increase donation should be sustained and that broader allocation arrangements should be made in a way that does not undermine current effective working relationships between OPOs and hospitals.

Another concern expressed to the Committee was that broader sharing would significantly increase the cost of transplantation. Based on data provided to the Committee by the General Accounting Office (GAO), as well as the published literature, the Committee concluded that total expenditures associated with organ procurement and transplantation are likely to increase as a result of broader sharing. OPOs and transplant teams may both experience higher transportation costs. In addition, a larger number of sicker patients will receive transplants and there will likely be more re-transplants' both of which would increase costs. The Committee was unable to estimate the magnitude of the increase, but believes it would be marginal compared to the total expenditures for transplantation.

FEDERAL OVERSIGHT AND REVIEW

The Committee believes that, when Congress passed the National Organ Transplant Act, it intended for there to be a cohesive, well-coordinated system encompassing all aspects of transplantation. The Committee also believes that we do not have such a system at this time and that we cannot have such a system without effective, comprehensive oversight. We therefore concluded that achieving the goals of the National Organ Transplant Act requires an active federal role in review and oversight, and that this should be in collaboration with representatives from all those involved in transplantation, including patients, donor families, physicians and nurses, OPOs, and transplant centers. The federal government, as well as the transplantation community, has a legitimate and appropriate role to play in ensuring that the organ procurement and transplantation system serves the public interest, especially the needs and concerns of patients, donors, and families affected by it.

At the present time, responsibilities are dispersed throughout the system, creating impediments to oversight and review, permitting poor procedures for data analysis and dissemination to persist, and allowing the system to operate without adequate assessment of performance. The Committee acknowledges that many aspects of organ procurement and transplantation require effective arrangements and decision making at a local level. However, a more centralized mechanism for oversight and review would improve the quality assurance that donors and recipients deserve. This is not to say that the federal government should be making medical judgments regarding individual patients, but rather that its responsibility is to ensure that the policies that guide the operation of the system are equitable and well-grounded in medical science. Vigilant and conscientious oversight and review of programs and policies are critically important to ensuring accountability on the part of the OPTN and other participants in the organ procurement and transplantation system.

To assist in this activity, there needs to be independent scientific review. The Committee recommends that an independent, multidisciplinary advisory board be appointed to assist in the oversight of the program. Such a board could help to assure that: (1) policies and procedures are well grounded in medical science; (2) there is a cohesive, strategic approach to the entire transplantation system; (3) the interests of transplant patients and donor families are given paramount concern; and (4) credibility and trust are maintained with patients, the transplantation community and the general public.

In addition, the Committee concluded that better performance measures should be developed for each of the components of the transplantation system, and that data about the system should be reliably and regularly gathered, independently assessed, and made widely available. The Committee's concerns about oversight and review cut across the individual issues specified in its charge and relate in general to all organ transplantation, not just liver transplantation.

COMMITTEE RECOMMENDATIONS

Based on its review and analysis of the data and information available to it, the Committee reached the following recommendations:

Recommendation 1: *Establish Organ Allocation Areas for Livers*

The committee recommends that the DHHS Final Rule be implemented by the establishment of Organ Allocation Areas (OAAs) for livers—each serving a population base of at least 9 million people (unless such area exceeds the limits of acceptable cold ischemic time). OAAs should generally be established through sharing arrangements among organ procurement organizations to avoid disrupting effective current procurement activities.

Recommendation 2: *Discontinue Use of Waiting Time as an Allocation Criterion for Patients in Statuses 2B and 3*

The heterogeneity and wide range of severity of illness in statuses 2B and 3 make waiting time misleading within these categories. For this reason, waiting time should be discontinued as an allocation criterion for status 2B and 3 patients. An appropriate medical triage system should be developed to ensure equitable allocation of organs to patients in these categories. Such a system may, for example, be based on a point system arising out of medical characteristics and disease prognoses rather than waiting times.

Recommendation 3: *Exercise Federal Oversight*

The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the Final Rule, in order to manage the system of organ procurement and transplantation in the public interest. This oversight should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN.

Recommendation 4: *Establish Independent Scientific Review*

The Department of Health and Human Services should establish an external, independent, multidisciplinary scientific review board responsible for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible.

Recommendation 5: *Improve Data Collection and Dissemination*

Within the bounds of donor and recipient confidentiality and sound medical judgment, the OPTN contractor should improve its collection of standardized and useful data regarding the system of organ procurement and transplantation and make it widely available to independent investigators and scientific reviewers in a timely manner. DHHS should provide an independent, objective assessment of the quality and effectiveness of the data that are collected and how they are analyzed and disseminated by the OPTN.

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Committee on Organ Procurement and Transplantation Policy

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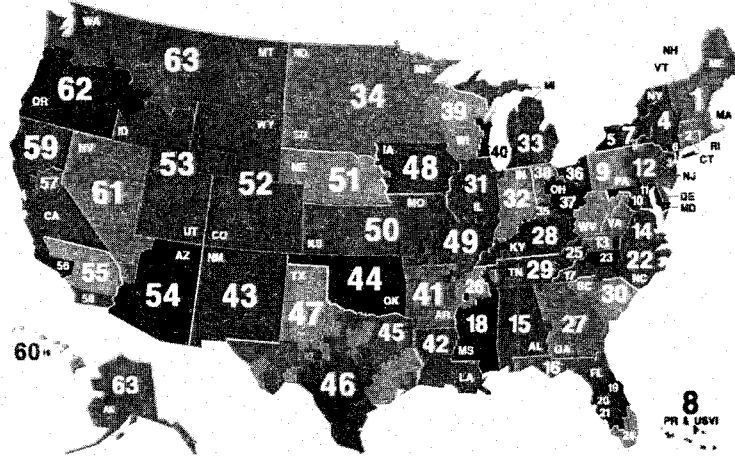
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|---|---|--|
| 1. New England Organ Bank, Inc. | 21. Lifelink of Southwest Florida | 45. Southwest Transplant Alliance |
| 2. Northeast OPO and Tissue Bank | 22. Carolina Organ Procurement Agency | 46. South Texas Organ Bank |
| 3. NJ Organ and Tissue Sharing Network | 23. Carolina Life Care | 47. Life Gift Organ Donation Center |
| 4. Center for Donation and Transplant | 24. University of Miami OPO | 48. Iowa State Organ Procurement Organization |
| 5. Upstate New York Transplant Services, Inc. | 25. Life Resources Donor Center | 49. Mid-America Transplant Association |
| 6. New York Organ Donor Network | 26. Mid-South Transplant Foundation | 50. Midwest Organ Bank |
| 7. Univ. of Rochester Organ Procurement Program | 27. Lifelink of Georgia | 51. Nebraska Organ Retrieval Systems, Inc. |
| 8. Lifelink of Puerto Rico | 28. Kentucky Organ Donor Affiliates | 52. Colorado Organ Recovery Systems, Inc. |
| 9. Center for Organ Recovery and Education | 29. Tennessee Donor Services | 53. Intermountain Organ Recovery Systems |
| 10. Washington Regional Transplant Consortium | 30. SC Organ Procurement Agency | 54. Donor Network of Arizona |
| 11. Transplant Resource Center of Maryland | 31. Regional Organ Bank of Illinois | 55. Southern California Organ Procurement Center |
| 12. Delaware Valley Transplant Program | 32. Indiana OPO, Inc. | 56. Regional Organ Procurement Agency of Southern CA |
| 13. Virginia Organ Procurement Agency | 33. Organ Procurement Agency of MI | 57. Golden State Transplant Services |
| 14. Life Net | 34. Upper Midwest OPO, Inc. | 58. Organ and Tissue Acquisition Center of Southern CA |
| 15. Alabama Organ Center | 35. Ohio Valley Life Center | 59. California Transplant Donor Network |
| 16. The OPO at University of Florida | 36. Lifebanc | 60. Organ Donor Center of Hawaii |
| 17. Life Share of the Carolinas | 37. Lifeline of Ohio | 61. Nevada Donor Network |
| 18. Mississippi Organ Recovery Agency, Inc. | 38. Life Connection of Ohio | 62. Pacific Northwest Transplant Bank |
| 19. Translife | 39. University of Wisconsin OPO | 63. LifeCenter Northwest |
| 20. Lifelink of Florida | 40. Wisconsin Donor Network | |
| | 41. Arkansas Regional Organ Recovery Agency | |
| | 42. Louisiana Organ Procurement Agency | |
| | 43. New Mexico Donor Program | |
| | 44. Oklahoma Organ Sharing Network, Inc. | |

Organ procurement organization service areas, 1997

Mr. BILIRAKIS. Thank you very much. Dr. Miller, when did you arrive? I was able to escape late yesterday after that storm which swerved from dead on Pinellas County down to your area.

Mr. MILLER. We ducked and it missed us. It went around the south tip of the State, so we were all fortunate.

Mr. BILIRAKIS. They are crazy, aren't they? In any case, sir, you are welcome. Please proceed.

STATEMENT OF JOSHUA MILLER

Mr. MILLER. I appreciate the opportunity to testify at this hearing on the important legislation that you have introduced, Mr. Chairman, which would reauthorize programs relating to organ procurement and transplantation. I am Dr. Joshua Miller, Co-director of the Division of Transplantation at the University of Miami School of Medicine in Miami, Florida. I am appearing today as the immediate past President of the American Society of Transplant Surgeons, the ASTS, a professional organization of surgeons, physicians and scientists who during the past 25 years of our existence have pioneered and continue to advance the frontiers of life-sustaining organ transplantation.

ASTS members have the responsibility for directing transplantation clinical and research programs at America's major medical centers. As part of this responsibility, we helped forge the National Organ Transplant Act, NOTA, into law in partnership with the U.S. Congress over a decade and a half ago.

We were instrumental in conceiving an organ procurement and distribution network and, in partnership with the Health Care Finance Administration of the Department of Health and Human Services, helped to organize it and to put it into action during the same period.

We are here now 15 years later to work with you in reauthorizing NOTA and providing a clear congressional guideline for how that network can provide the maximum benefit to our patients as we move into the 21st century.

Because of the explosive success of organ transplantation in the latter part of the 20th century there are now more than 65,000 Americans, an additional 3,000 since I last testified before your subcommittee in April, Mr. Chairman, with end-stage failure of hearts, livers, lungs, pancreases, and kidneys awaiting life-saving and life-sustaining transplants. This is a potentially explosive situation because as the number of patients on waiting lists climbs inexorably toward 100,000, concern and frustration over the allocation of these scarce organs is bound to grow. Our fear is that this mounting public concern is leading to increased efforts to politicize what is and ought to remain a medical decisionmaking process.

We strongly believe that Congress in enacting NOTA and establishing the Organ Procurement and Transplantation Network, the OPTN, in the private sector under government contract intended for this highly specialized and expert OPTN to make organ allocation policy based on sound medical and ethical principles and scientific data independent of political influence, and that is how it has essentially operated these past 15 years.

But as you are aware, Mr. Chairman, several sections of the final rule governing the OPTN published by the Secretary of Health and

Human Services a year ago April could be interpreted as setting the stage for the Secretary of DHHS to make specific allocation policy. This effort by the Department was the result of the fairly recent intense criticism by a vocal minority of one very specialized aspect of the OPTN, liver allocation. We have repeatedly expressed our concerns to DHHS in the course of a number of meetings this past summer. We have suggested changes in a rule that we largely agree with, this rule that we largely agree with, changes designed to prevent the baby that we jointly conceived from being thrown out with the bath water, changes that among other things would clarify that the Secretary must not dictate specific transplantation practices or medical judgments. We were also greatly concerned that the rule might unwittingly tamper with the very delicate but very real local influences on organ donation that we discussed in my last appearance before your committee.

We believe the legislation you have drafted makes it clear that there is a most legitimate oversight role for DHHS in ensuring that the policies which guide the operation of the system are adhered to, and we support that oversight role for DHHS.

We would also like to submit for the record a white paper our society issued just last Friday summarizing our views on the issues that we have been discussing with DHHS and on some of the recommendations included in the report delivered to Congress in mid-summer by the Institute of Medicine. We know Members of Congress have been provided with a variety of interpretations of this IOM report both by DHHS and by the OPTN contractor, UNOS, generally claiming vindications for their positions. And as is so often the case, we believe the truth falls somewhere in between.

I would like to just mention two important points that the IOM report makes what I believe go to the heart of our concern over leaving medical decisions in the hands of medical professionals.

Throughout 1998 and right up through this summer, DHHS, in urging Congress to allow the final rule to be imposed without delay, contended that significant regional differences in the length of time patients spend on waiting lists for livers demonstrated a fundamental unfairness of the current system. The ASTS testified before Congress more than a year ago as we repeatedly informed the Department that there really were only small differences in waiting times for patients in the most urgent categories and that median waiting times for all liver patients as used by the Department were really not a good measure of fairness.

The Institute of Medicine after analyzing data, and as was just mentioned, "Overall median waiting time, which has dominated the policy debate, is a poor measure of differences in access to transplantation."

It further suggested that differences in waiting time for less urgent patients are so, "misleading"—that was the word that the IOM used, misleading—that it proposed waiting time no longer be an allocation criteria in less urgent categories of liver patients.

The public focus on waiting time as the driver of the need for quick fix, quick change in the allocation of livers is exactly the kind of politicization of the medical decisionmaking process that concerns us.

And I would like to touch briefly on one other recommendation of the IOM that we move toward a system of broader sharing of livers for patients in most urgent need because we do believe that this recommendation has merit. In fact, less than a month after the IOM issued its report the OPTN put into effect a new policy of broader regional sharing for status 1 liver patients, the most urgent category, and this was already in the due process pipeline. This policy will hopefully ensure that those most critical liver patients to the best of our medical ability today have access to life-saving organs. This I believe is indicative that the establishment of allocation policies by the OPTN is a dynamic process through which change does take place in response to new information and analysis. Could this change have occurred earlier? Probably. Does the current system function perfectly? Of course not. Is there room for improvement in the performance of the current contractor? Absolutely. There is always room for improvement in the operation of the network through refinements like those suggested in our legislation.

Our society's interests lie in the structure and operation of the network and its relationship to DHHS. Our interest is not to be specifically protective of the incumbent contractor that is operating the network. We also very much believe that the OPTN should be responsive to independent external review and assessment. We would favor strengthening the section you already included in the legislation relative to General Accounting Office evaluations of the network.

We have a small number of other changes we would be pleased to discuss with you, Mr. Chairman, which we believe would further strengthen the NOTA reauthorization effort. But again let me conclude my prepared remarks by thanking you for the leadership you have demonstrated sponsoring this most important piece of legislation, and I would welcome any questions that I might be able to answer.

Thank you.

[The prepared statement of Joshua Miller follows:]

PREPARED STATEMENT OF JOSHUA MILLER, AMERICAN SOCIETY OF TRANSPLANT SURGEONS

I appreciate the opportunity to testify at this hearing on the important legislation that you have introduced, Mr. Chairman, which would reauthorize programs relating to organ procurement and transplantation.

I am Dr. Joshua Miller, Professor of Surgery, Microbiology, Immunology and Pathology, and Chief of the Division of Kidney and Pancreas Transplantation, at the University of Miami School of Medicine in Miami, Florida.

I am appearing today as the Immediate Past President of the American Society of Transplant Surgeons (the ASTS), the professional organization of Surgeons, Physicians, and Scientists who, during the past 25 years of our existence, have pioneered and continued to advance the frontiers of life-sustaining organ transplantation. ASTS members have the responsibility for directing transplantation clinical and research programs at America's major medical centers.

As part of this responsibility we helped forge the National Organ Transplant Act into law in partnership with the United States Congress over a decade and a half ago. We conceived of an organ procurement and distribution network, and, in partnership with the Health Care Financing Administration of the Department of Health and Human Services, helped organize it and put it into action during the same period.

Now, we are here—15 years later—to work with you in reauthorizing NOTA and providing clear Congressional guidelines for how that network can provide the max-

imum benefit to the maximum number of patients as we move into the 21st Century.

Because of the explosive success of organ transplantation in the latter half of the 20th century, there are now more than 65,000 patients—an additional three thousand since I last testified before your Subcommittee in April—with end-stage failure of hearts, livers, lungs, pancreases, and kidneys awaiting life-saving transplants.

This is a potentially explosive situation, Mr. Chairman, because as the number of patients on waiting lists climbs inexorably toward and passes 100,000 Americans, concern and frustration over the allocation of these scarce organs is bound to grow. Our fear is that, inevitably, this mounting public concern over who-gets-an-organ-and-when will lead to increased efforts to politicize what is, and ought to remain, a medical decision-making process.

We strongly believe that Congress, in enacting NOTA and establishing the Organ Procurement and Transplantation Network in the private sector under government contract, intended for the OPTN to make organ allocation policy based on sound medical principles and scientific data independent of political influence. And that is how it has operated these past 15 years.

But as you are aware, Mr. Chairman, several sections of the Final Rule governing the OPTN published by Secretary of Health and Human Services Donna Shalala a year ago April could be interpreted as setting the stage for the Secretary of DHHS to make specific allocation policy.

We have repeatedly expressed our concerns over this to DHHS, in the course of a number of meetings this past summer. We have suggested changes that, among other things, would clarify that the Secretary must not dictate specific transplant practices or medical judgments.

We believe the legislation you have drafted, Mr. Chairman, makes it clear there is a legitimate oversight role for DHHS in ensuring that the policies which guide the operation of the system are equitable, based on sound medical science, and are adhered to. We support that oversight role for DHHS.

But we do want to again express our appreciation to you, Mr. Chairman, for making it clear in this legislation that the responsibility for “developing, establishing, and maintaining medical criteria, and standards,” and policy concerning allocation, belongs with the Network. And those policies should be modified by the Network, as necessary, on the basis of sound medical science and developing medical practices.

We would also like to submit for the record, along with these remarks Mr. Chairman, a white paper our society issued just last Friday summarizing our views on a variety of the issues we have been discussing with DHHS. It also contains our views on some of the recommendations included in the report delivered to Congress in midsummer by a Committee of the Institute of Medicine.

We know Members of Congress have been provided with a variety of interpretations of this IOM report, both by DHHS and by the OPTN contractor, the United Network for Organ Sharing, among others, generally claiming vindication for their positions. As is so often the case, we believe the truth falls somewhere between.

I would like to just mention a couple of important points that the IOM report makes, however, that I believe go to the heart of our concern over leaving medical decisions in the hands of medical professionals.

Throughout 1998 and right up through this summer, DHHS—in urging Congress to allow the Final Rule to be imposed without delay—contended that significant regional differences in the length of time patients spend on waiting lists for livers demonstrate a fundamental unfairness of the current system.

We suggested in testimony before Congress more than a year ago—as we repeatedly suggested to the Department—there really were only small differences in waiting time for patients in the most urgent categories, and that median waiting times for all liver patients, as used by the Department, were really not a good measure of fairness.

The Institute of Medicine—after analyzing years of data—concluded, and I quote: “Overall median waiting time, which has dominated the policy debate, is a poor measure of differences in access to transplantation.” It further suggested that differences in waiting time for less urgent patients are so “misleading”—that was the word the IOM used—that it proposed waiting time no longer be an allocation criterion in less urgent categories of liver patients.

The public focus on waiting times as the driver of the need for quick change in the allocation of livers is exactly the kind of politicization of the medical decision-making process that concerns us.

I would also like to touch briefly on another recommendation by the Institute of Medicine—that we move toward a system of broader regional sharing of livers for

patients in most urgent need—because we do believe that this recommendation has a great deal of merit.

The IOM committee concluded, after crunching the data, that the most urgent liver patients—Status 1 patients—would be more likely to receive an organ expeditiously if contiguous OPOs were grouped into what it called Organ Allocation Areas each serving a population base greater than nine million.

Less than a month after the IOM issued its report, the OPTN put into effect a new policy of broader regional sharing for Status 1 liver patients—the most urgent category—which hopefully will insure that these most critical liver patients have access to a life-saving organ sooner than might have been the case.

I believe this is indicative, Mr. Chairman, of the fact that the establishment of allocation policies by the OPTN is a dynamic process through which change does take place in response to new information and analysis, and changes in medical science and medical practice.

Could this change have occurred earlier? Probably. Does the current system function perfectly? Of course not. Is there room for improvement in the performance of the current contractor? Absolutely.

There is always room for improvement in the operation of the network through refinements, like some suggested in your legislation.

And I might add that our Society's interests lie in the structure and operation of the network, the composition of the network and its relationship to DHHS, and the composition and authority of the network board of directors and committees, which establish policy for the network. Our interest is not to be specifically protective of the incumbent contractor that operates the network.

We also very much believe that the OPTN should be responsive to independent external review and assessment. We would favor strengthening the section you already included in the legislation, Mr. Chairman, relative to General Accounting Office evaluations of the network.

We have a small number of other changes we would be pleased to discuss with you, Mr. Chairman, which we believe would further strengthen the NOTA reauthorization effort. But again, let me conclude my prepared remarks by thanking you for the leadership you have demonstrated in sponsoring this most important piece of legislation.

Thank you.

Mr. BILIRAKIS. Thank you, Mr. Miller. You heard the bells, and the bad news is that there is no good news. The bad news is that we have a 15-minute vote followed by two 5-minute votes, so we are talking probably 35, 40 minutes. I would have liked to have been able to get through at least the witnesses, but we just won't really have time to do that because I hate to cut you off at 5 minutes. So I am just going to have to ask you to be as patient—continue to be as patient as you have been. We are going to break probably until about 4:30 or shortly thereafter.

Mr. GANSKE. Mr. Chairman?

Mr. BILIRAKIS. Yes?

Mr. GANSKE. I ask unanimous consent for 1 minute.

Mr. BILIRAKIS. One true 1 minute? Without objection.

Mr. GANSKE. Thank you, Mr. Chairman. As probably one of the few Congressmen who has scrubbed with Dr. Starzl and also did my general surgical training at the University of Oregon Health Sciences Center, I have some understanding of this issue.

I am disturbed with the administration on this. I think you have put your foot in a tar baby where you shouldn't be. Mr. Chairman, I see that on your bill you have cosponsors Gene Green, Bill Jefferson, Ken Bentsen, Peter Deutsch, Carlos Romero-Barcelo, Ralph Hall, Bart Gordon, David Wu, Jim Clyburn, Frank Pallone, Martin Frost, Sheila Jackson Lee, Jerry Kleczka, Peter DeFazio, Maurice Hinchey, Earl Hilliard, Tammy Baldwin, and a whole bunch of Republicans, and guess what, Mr. Chairman? You can now put my name on your cosponsor list. Thank you very much.

Mr. BILIRAKIS. I thank the gentleman and I believe that there are some that are probably not on that list.

Thank you for that. Dr. Gibbons, you have heard some of the comments made by Mr. Miller. I know that Dr. Payne, I am sorry I was called out by a large group of people that wanted to see me about another matter. That is the life up here but hopefully you all can talk about some of the comments that you have heard. We are trying to do the right thing. Granted, there is parochialism here. There is no question about it. But at the same time I think for the most part we do want to do what is right.

Well, anyhow, maybe you can have a little bit of interplay among yourself until we return. Thank you.

[Brief recess.]

Mr. BILIRAKIS. We are back. Mr. Irwin, President of the National Transplant Action Committee. By the way, thanks again for your patience and your understanding. Please proceed, sir.

STATEMENT OF CRAIG IRWIN

Mr. IRWIN. Thank you, Mr. Chairman. I am here today speaking on behalf of not only The National Transplant Action Committee but also TRIO, Transplant Recipients International Organization, and MOTTEP, the Minority Organ Transplant and Tissue Education Program. Collectively we represent thousands of transplant patients throughout the United States.

Unfortunately, Dr. Clyde Calendar of MOTTEP nor Mr. Bruce Weir, President of TRIO, were able to be here today but I am joined by Lisa Kory, President of TRIO.

I am here to speak in opposition to H.R. 2418, the Organ Procurement and Transplantation Network Amendments of 1999. This legislation comes amid considerable debate over the rules promulgated by the Department of Health and Human Services last year. Those rules are scheduled to go into effect on October 21.

Our three organizations believe that transplant patients and their families must be the focus of our public policy in this area of health care. Patients should be able to access critical information about the transplant system and the quality of care in our Nation's transplant hospitals. Patients deserve to be treated fairly by the organ allocation system. Some patients have choices among transplant centers, however, many don't. A patient's chance of finding a suitable donor shouldn't be a matter of who you are or where you live. And patients and their families either directly or through HHS deserve to have a significant role in the development of public policies impacting the Nation's transplant system.

These beliefs are consistent with the goals and intent of the National Organ Transplant Act. To quote the intent of Congress: The organ procurement and transplantation network was created in order to facilitate an equitable allocation of organs among patients. The OPTN's responsibilities are great and the purpose of the act will be served only if the policies of the OPTN are sound and are soundly developed. The allocation of organs may well be a life or death decision for patients.

And although the act gives the contractor authority to develop medical policies regarding the safe allocation and transportation of

organs, it does not give the contractor public policy authority. Instead it gives administrative authority to the Secretary.

Unfortunately, what has evolved is a patchwork system of organ allocation designed to meet the expectations and needs of transplant centers instead of the patients. Many patients and advocates who have worked hard to help others and have much to offer are often left out of the OPTN policy setting process because of their views. And critical data is often difficult to obtain and is often old and useless.

I am pleased to hear of Mr. Waxman's remarks regarding the availability of comprehensive data, and we look forward to reviewing that data and making it available to patients around the country.

These problems have continued to surface throughout the years. The concerns of patients have been echoed by the Congress and reflected by changes to the act in 1988 and 1990.

In 1990, Congress eased the minimum qualifications that must be met by an entity seeking the OPTN contract stating that, "By modifying this requirement, the committee intends to provide the Secretary with the opportunity to seek out the best possible potential applicants for this critical role."

This change along with changes the committee has made to the OPTN board of directors reflect deep concern on the part of the committee in the manner in which the OPTN has functioned. That same year, Congress amended the act to mandate that the OPTN assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients.

The bill now before this committee represents a complete reversal from these patient-driven policies and statements. H.R. 2418 would make dramatic changes to the manner in which organs are allocated to patients on the waiting list. New factors could now be considered in addition to equity. Fairness would no longer be the benchmark. Secretarial oversight would essentially be eliminated with no recourse to change or amend policies which might be detrimental to patients. The right of patients and the public to become members of the OPTN would be eliminated. There would be no further competition for the OPTN contract. UNOS would be the only organization meeting the contract criteria.

H.R. 2418 contradicts the past actions by this committee. The bill also ignores the recommendations of the recent report by the Institute of Medicine, which was required by Congress, submitted to this committee. The report contains key recommendations impacting transplant patients. The IOM calls for more oversight, not less, of the OPTN. In addition, the report calls for independent comprehensive review by a body reporting to the Secretary and not affiliated with the OPTN contractor.

The IOM concluded that broader sharing as called for by the regulation would have the net effect of saving more lives by increasing transplantation rates for those with the greatest risk of dying, decreasing pre-transplant mortality rates for the next level of patients on the waiting list and decreasing the number of the healthiest patients transplanted without increasing their risk of dying.

Finally, the report dispels the many myths promoted by the opponents of the regulation, many of which we have heard today.

Paramount is the myth that minorities would be hurt by the regulations.

Although the IOM found that there is essentially parity and equity in liver allocation, the report also concluded that minorities would not be hurt by the regulations. The HHS regulations will move the system toward greater fairness and a more patient-driven system. H.R. 2418 will move us in the opposite direction.

Mr. Chairman, when the committee last took up the reauthorization in 1993, you took exception to the full committee's desire to simply call for a study of organ allocation. You were quite eloquent in recognizing that sick people will continue to die merely because of UNOS-created geographic boundaries. You asked the Secretary to do what the committee would not, operate the program closer to the original congressional intent when the act was passed in 1984.

Mr. Chairman, you were right then. Your conclusions apply equally today and your views have been validated by the IOM. On behalf of the 65,000 patients now waiting for transplants in the United States, we ask that you not change directions now.

Thank you.

[The prepared statement of Craig Irwin follows:]

PREPARED STATEMENT OF CRAIG IRWIN, PRESIDENT, NATIONAL TRANSPLANT ACTION COMMITTEE

National Transplant Action Committee (NTAC) is a consumer advocacy organization founded in 1992. We currently have approximately 1500 members across the United States. NTAC has been a leading advocate for organ transplant patients and their families as directed by our Patient Public Policy Committee.

ANALYSIS AND COMMENT ON HR 2418

NTAC strongly opposes HR 2418, the "Organ Procurement and Transplantation Network Amendments of 1999. The bill now before the Committee would make drastic changes to the National Organ Transplant Act (NOTA) and the management of the nation's Organ Procurement and Transplantation Network (OPTN).

1. The bill establishes the private contractor as an "independent partner" with the federal government. It requires the Department of Health and Human Services (HHS) to "cooperate" with the contractor as well as eliminates the oversight role of HHS. It reduces the role of the Secretary to taking and reviewing comments but grants no authority to HHS to protect or promote the public health interest through an administrative role.

2. Eliminates the independent Scientific Registry

3. Gives the OPTN contractor greater authority over which information is released to patients and the public. Grants the contractor new "authority" by which to withhold vital information from the public.

4. Excludes members of the public and patients from being members of the OPTN. Membership is only permitted to "entities" in the transplant field.

5. The bill would eliminate the release of center specific data and replace it with less helpful OPO specific data.

6. Gives the contractor broad judicial authority and the right to penalize transplant centers. Such penalties may include the withholding of organs from transplant centers that do not adhere to network rules.

7. Administrative and procedural activities between the Secretary and the contractor would now have to be conducted on a mutually consensual basis. Gives the contractor sole discretion over "scientific, clinical, and medical decisions" regardless of the impact of such decisions on the public health interest.

8. Any subsequent contractor must be approved by the OPOs and transplant centers. Requires the OPTN contractor to have "experience" in organ transplantation.

9. Changes the criteria for the allocation of donated organs. Expands consideration of allocation policies to include issues of equity and ethics. It also eliminates the requirement that organs be distributed on a "nationwide" basis "equitably among patients on the waiting list."

NTAC believes that each one of these provisions would have an adverse impact on organ transplant patients and the public's health care interest. We support the

current National Organ Transplant Act and the Final Rule promulgated by HHS governing the OPTN. We are concerned that HR 2418 is aimed at derailing the HHS rules before they go into effect on October 21, 1999.

The OPTN is currently operated by the United Network for Organ Sharing (UNOS) based in Richmond, VA. UNOS has operated the network since its inception in 1986. HR 2418 as written would eliminate the Secretary's discretion to contract with the best possible candidate to operate the OPTN. Under the Bill, UNOS could essentially operate the OPTN without regard to the public health interest and without oversight by HHS and still not jeopardize its standing as the OPTN contractor.

Throughout the years, patients, transplant centers, the Administration, and the public have raised concerns about the manner in which UNOS has operated the OPTN. These concerns have been echoed by Congress and reflected in amendments to the National Organ Transplant Act in 1988 and 1990. Although the Act has not been formally amended since 1990 congressional hearings in 1993 and 1995 have resulted in similar actions attempting to address troubling concerns over UNOS activities.

Timely, accurate, and useful information is critical to the public, policy makers, and especially transplant patients. UNOS has shown a blatant disregard for the public interest in this area and has resisted attempts to obtain vital information. In 1997 a request for data on organs turned down by transplant centers was made available only after an exhaustive process that culminated in a Freedom of Information Act request. Only then did UNOS make the data available. In its attempt to block the information UNOS used similar defenses to those proposed in HR 2418. However, no patients were ever identified, directly or indirectly, as a result of the data release. Information currently available with respect to center specific performance and OPO performance is outdated when it is published. The current HHS regulations would require the OPTN contractor to update its data every six months.

The UNOS governance and policy setting process is highly politically charged and greatly influenced by transplant center self interest. There is no opportunity given for public testimony at UNOS board meetings or committee meetings. Public members and patient advocates are excluded from participating in UNOS because of their viewpoints. Recently, the UNOS patient affairs committee attempted to censure a UNOS public member because his positions and public statements were critical of the organization.

Not only is the UNOS policy setting process corrupted, its enforcement of policies is based upon political expedience and appeasement. Recently, the UNOS board of directors implemented a policy to create regional sharing for liver transplant candidates in the most urgent health care status. However, transplant centers in Wisconsin refused to abide by the new policy, adversely affecting patients in nearby Illinois. UNOS currently has at its disposal some of the same penalties available to it that are created in HR 2418. However, instead of enforcing its policy, UNOS opted to endorse a special agreement insisted on by the Wisconsin transplant centers.

However, the most critical decisions impacting organ transplant patients center on the allocation of donated organs. As stated in a Congressional conference report "The Organ Procurement and Transplantation Network (OPTN) was created by the 1984 Act in order to facilitate an equitable allocation of organs among patients." "The allocation of organs may well be a life-or-death decision for patients." (Senate Report 100-310, P.L. 100-607). In 1990 UNOS changed liver allocation rules to eliminate the priority status given to the most medically urgent patients on the national waiting list. The policy was enacted before public comment was sought. Since then, organ allocation has been hotly debated in the organ transplant community.

The organ allocation issue is exacerbated by the fact that there are approximately 65,000 patients on the national waiting list and the number of transplants has continued to hover around only 20,000. Over ten patients die each day waiting for organs.

The manner in which UNOS has managed the policy setting process in this critical illustrates the shortcomings of the current system and UNOS's ability to promulgate policies that serve the public interest. After exhaustive debate and efforts on the part of patients and the public UNOS began considering the liver allocation issue. The result was a policy where patients with chronic liver diseases would be eliminated from the highest priority status. It was only after HHS intervention and overwhelming public outcry at a three-day hearing that the policy was reversed. Recommendations made by the UNOS Liver and Intestine Committee to expand liver allocation in order to improve equity were ignored by the UNOS board, which focused on regional and local interests instead of promulgating a fair public policy. In the meantime, patients have needlessly died as a result of UNOS's failure to act in a responsible manner.

These issues highlight the grave concerns with the function of the OPTN and the manner in which UNOS has managed the transplant network. Throughout the years, Congress has acted to limit the authority of the OPTN contractor, attempted to improve the internal operation and management of UNOS, and has called upon HHS to exert greater authority of the Act and the OPTN to protect the public interest. In 1990 Congress eased the minimum qualifications that must be met by deleting a prior requirement that an entity seeking the OPTN contract must not be engaged in any activity unrelated to organ procurement. The Committee Report stated “By modifying this requirement, the Committee intends to provide the Secretary with the opportunity to seek out the best possible potential applicants for this critical role.” The Committee went on to state “This change, along with changes the Committee has made in the OPTN board of directors, reflect deep concern on the part of the Committee in the manner in which the OPTN has functioned.” The Congress should continue to be concerned.

It is in this context that NTAC opposes the proposed OPTN reauthorization bill. We believe that UNOS has failed to carry out the mandates of the National Organ Transplant Act and that undue political influence and rampant self-interest characterize the UNOS process. The welfare of patients should be at the forefront of the OPTN policy setting process but that is not the case.

In lieu of HR 2418, we believe that the Committee should give serious consideration to the recent report of the Institute of Medicine on Organ Procurement and Transplantation. Congress requested the report as part of a one-year delay in the HHS regulations.

The IOM has emerged from its deliberations in support of the final rule which, together with its own recommendations, “*could go a long way toward facilitating the development of improved principles of [organ] allocation and improving what everyone agrees should be a patient-centered system.*”

HIGHLIGHTS OF THE IOM COMMITTEE REPORT:

1. Impact of the Final Rule on Access

The IOM Committee found that the Final Rule would not adversely impact patient access to organ transplantation. It has been claimed that small transplant centers would close as a result of changes to the nation's organ allocation system imposed by the Final Rule. “*The committee was not persuaded*” by the arguments stated by the opponents of the Final Rule. In fact, the IOM report states that, “*there is some preliminary information that counters the argument that broader sharing [of organs] under the Final Rule would adversely affect small transplant centers.*” “*Broader organ sharing may well increase the prospects that a patient listed at a low-volume transplant center will obtain a suitable matching organ.*”

The committee also examined the impact of the Final Rule on minorities and low-income populations. The committee found that “*African Americans do not receive kidney transplants as quickly as whites*” and that the rule would not exacerbate this problem. The committee also found that “*broader sharing of organs resulting from implementation of the Final Rule is not likely to have a significant adverse effect on those who are dependent on Medicaid for their health care.*”

2. Impact of the Final Rule on Organ Donation

The IOM committee found no evidence to support claims that organ donation rates would decrease as a result of the Final Rule, stating that “*the committee found no convincing evidence to support the claim that broader sharing would adversely affect donation rates or that potential donors would decline to donate because an organ might be used outside the immediate geographic area. In fact, there is some evidence suggesting that broader sharing is associated with increased rates of donation.*”

3. Analysis of Waiting Times

Disparities in waiting times for liver transplant candidates have been at the center of a heated debate over the allocation of scarce donor organs. Therefore, the Committee concentrated its research on the current liver allocation policies. The IOM Committee concluded that aggregate-waiting time is not a good measurement of the equity and effectiveness of the transplant system. However, the Committee made other key observations about the transplant system.

a. The system is basically fair for the sickest patients (Status 1). However, the IOM Committee recommends improvements: “*Although the current system appears equitable, with respect to status 1 patients receiving transplants at similar rates among OPOs and having similar mortality and outcomes, the equity of the current system might be improved for all patients if it were possible to identify a minimum OPO population size or transplant volume that would promote both greater consist-*

ency in transplantation rates across OPOs and a higher rate of transplantation for needier patients.”

b. Some of the healthier patients on the waiting list do not die while on the list nor do they move up in priority, suggesting that some patients are inappropriately put on the list for a liver transplant. The IOM found that there are patients on the waiting list who “have little likelihood of receiving a transplant and are also at little risk of dying.”

c. More “healthier” patients die on the waiting list in OPOs with smaller transplant centers. “Of concern was evidence of a statistically significant increase in the risk of pretransplant mortality in those OPOs with smaller transplant volumes.” Relatively healthy patients in small-volume OPOs “had a significantly increased risk of pretransplant mortality while on the waiting list.”

d. Larger OPOs transplant the sickest patients while smaller OPOs and transplant centers transplant a greater percentage of healthier patients. The IOM concluded that “smaller OPOs, by generally transplanting more status 2B and 3 patients than larger OPOs, may contribute to a situation in which more severely ill patients are required to wait longer for organs at increased risk of death.”

e. There are fewer patients waiting in smaller OPOs so that they can transplant healthier patients. “Although smaller OPOs have lower transplantation rates than larger OPOs, their listing rates are even further reduced relative to larger OPOs.” “This means that smaller OPOs are able to allocate organs to patients farther down their shorter waiting lists than are larger OPOs.”

f. Increased sharing of organs would save more lives. “A reasonable improvement in the current allocation scheme could be achieved by creating allocation areas of sufficient size to shift some of the transplants from status 3 to statuses 1 and 2.” “It seems apparent that patients on liver transplant waiting lists will be better served by an allocation system that facilitates broader sharing within larger populations.” Greater sharing will have the effect of “increasing transplantation rates for status 1 patients, decreasing pretransplantation mortality for status 2B patients, and decreasing transplantation rates for status 3 patients without increasing mortality.” The net effect is that more lives would be saved through broader sharing of donor organs to those patients with the greatest need.

4. Patient survival

The IOM found that the medically acceptable ischemic time (time that organs can travel without a blood supply) for donated livers was 12 hours. However, more significantly, the IOM Committee found that larger transplant centers had better patient survival rates than smaller centers, despite the fact that larger centers also transplant the sickest patients. “Patients located in smaller-volume OPOs had increased risk of posttransplant mortality relative to those in larger-volume OPOs.” In reviewing UNOS data the IOM Committee found that “several of the transplant centers doing 25 or fewer liver transplants had 1-year graft survival rates significantly lower than expected, given the health status of their patients.”

5. Costs

The IOM Committee concluded that increased sharing would have a slight increase in the overall costs of liver transplantation. However, the committee stated “The committee was unable to estimate the magnitude of the increase, but believes that it would be marginal compared to the total expenditures for transplantation. The committee also believes the health benefits of implementing broader sharing will be substantial and outweigh any net increase in expenditures.”

6. Federal Oversight

The report of the IOM Committee supports the HHS Final Rule, “In the end, the committee emerged from its deliberations generally supportive of the Final Rule.” In addition, the committee called for more, not less, federal government oversight of the nation’s organ transplant system. “Weak [government] oversight has compromised accountability at all levels, permitted poor procedures for data collection and analysis to persist, and allowed the system to operate without adequate assessment of performance.”

The report recommends that HHS “should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act in order to manage the system of organ procurement and transplantation in the public interest.” Furthermore, the committee recommended “a process for periodic, independent and comprehensive review by a body reporting to the Secretary and not affiliated with the OPTN contractor is needed to help provide objective information and advise for the future directions of the system.” The board would include “a broad spectrum of medical and scientific experts, including epidemiologists and health services researchers,

as well as representatives from the community of transplant patients and donor families.”

CONCLUSION

National Transplant Action Committee opposes HR 2418 and hopes that the Committee will not vote in favor of legislation which we believe will have a devastating impact on organ transplant patients throughout the United States. We encourage the Committee to focus on sound public policies as opposed to parochial self-interests. We hope that the HHS regulations will be permitted to move forward and that a fair and equitable system soon becomes established for the 65,000 Americans currently waiting for transplants in our nation's hospitals.

Mr. BILIRAKIS. Thank you, Mr. Irwin. Dr. Rabkin.

STATEMENT OF JOHN M. RABKIN

Mr. RABKIN. Mr. Chairman, distinguished members of the committee, I am John Rabkin. I am a surgeon and the Chief of Liver Transplantation at the Oregon Health Sciences University. I am here today on behalf of the 31 organ transplant programs and 1,300 patients that currently make up the Patient Access to Transplantation or the PAT Coalition. I respectfully request submission into the hearing record along with my testimony the August 28, 1998, PAT Coalition comments on the health and human services final rule and a recent PAT Coalition policy paper from this September which delineates our views on several critical issues in the legislative and regulatory debate.

The PAT Coalition strongly supports H.R. 2418, the Organ Procurement and Transplantation Amendments of 1999, the reauthorization of the National Organ Transplant Act, or NOTA, introduced by Representatives Bilirakis, Pallone and Green. We appreciate their commitment to this issue and that of Commerce Committee Chairman Tom Bliley and other members of this committee.

The PAT Coalition urges Congress to pass this legislation because we feel strongly that enactment of this bill is the best way to settle controversy over organ transplantation resulting from the HHS rulemaking. Moreover, we think it is imperative to stem the erosion of public faith in the transplant system which has occurred since HHS issued its controversial rule in April 1998.

We believe that the current organ transplant system is fair and that it does a good job of acquiring and allocating organs for transplantation. We all must recognize the extremely dynamic aspects of the transplant system as medical developments occur on practically a daily basis. Like any system, there is and always will be room for ongoing improvement and this is how our current system operates. A recent study by the Institute of Medicine came to the same conclusion, “The committee found that the current system is reasonably equitable for the most severely ill status 1 liver patients since the likelihood of receiving a transplant is similar across organ procurement organizations, or OPOs, for these patients.”

The IOM study contradicted the underlying rationale for the controversial final rule on organ allocation proposed by the Department of Health and Human Services. In an analysis of 68,000 liver patient records, the IOM panel said, “The overall median waiting time that patients wait for organs, the issue that seems to have brought the committee to the table in the first place, is not a useful statistic for comparing access to or equity of the current system of

liver transplantation, especially when aggregated across all categories of liver transplant patients.”

HHS always maintained that reducing these regional differences in waiting time was the primary goal of the rule on organ allocation. The PAT Coalition has actively supported the two moratoriums on the HHS final rule implemented by Congress because we think that the final rule usurps the authority of the transplant community under NOTA to determine organ transplant policy. Stated most simply, Congress in NOTA vests the private sector OPTN with the authority to determine organ allocation policy.

We strongly support this NOTA directive and agree with Congress that the private sector entity is far better equipped than the government to make medical policy judgments and adapt to changing technological developments and scientific and medical advances.

NOTA simply does not provide the Secretary with authority to substitute her judgment if she or her staff disagree with a medical transplant community with respect to policymaking, yet the Secretary’s final rule usurps this authority by regulatory fiat and claims the ability to reverse OPTN policy.

Among our other concerns we also recognize that the transplant policy suggested in the final rule would result in more of our patients dying while waiting for transplant and a significantly higher rate of retransplantation and possible organ wastage. We are also concerned that the core HHS policy is a design to direct more organs to a few larger transplant centers, which would result in a loss of access to transplantation services for those patients who could not travel long distances for financial or family reasons.

The rule itself applies to all organs and cannot withstand medical scrutiny. For example, another serious effect of this policy would be to increase the cold ischemic time, or the time that organs are stored outside of the body, since organs would travel farther to the large centers. The IOM study pointed out, “That a 4.2 percent reduction in retransplantation by using livers with lower ischemic times would necessitate less retransplantation and would mean that 170 additional patients could receive a liver transplant.”

The HHS policy is also short sighted in its wholesale preemption of State laws regarding organ transplantation. Many of the beneficial policies that have served to improve organ procurement and donation were based on State laws such as the organ donor check-off on driver’s licenses. The HHS preemption fails to recognize that fact. In addition, this preemption clearly exceeds the authority granted by Congress.

During the moratorium period we have worked actively with the transplant community to try to form a consensus on how best to deal with the HHS position. We have been involved in discussions with HHS officials who have promised the transplant community a revised proposal that would take into consideration our objections to the final rule. We are still waiting for a response from HHS as the clock ticks down on the current moratorium scheduled to expire October 21.

We are also still waiting for the HHS to publish an analysis of the thousands of public comments filed in response to the final

rule. We understand that more than 85 percent of these comments stated strong opposition or concerns about the rule.

The best solution to the problem is for Congress to reiterate the long-held statutory premise that organ transplant policy should be left to the private sector transplant community through passage of new authorizing legislation. Short of that, Congress should continue the moratorium until a new authorization bill can be passed.

H.R. 2418 recognizes that scientific and medical decisions about organ transplant policy should be left to the private sector transplant community rather than to the Federal Government bureaucracy, a concept that the PAT Coalition enthusiastically supports. The legislation's construct has worked successfully historically and we continue to believe that the private sector is better equipped than the government to sort through the complex medical, specific, and ethical challenges presented by organ transplantation.

H.R. 2418 correctly places a strong emphasis on the real solution to the organ shortage problem, which is increasing organ donation. With your permission, Mr. Chairman, I would like to submit a report of Kansas State University researcher and professor of psychology James Shanteau's recent summary of research on what motivates people to donate organs and a press release article which expressed serious concern that the HHS new organ policy may result in a donation decline.

Mr. BILIRAKIS. Without objection, that is made a part of the record Dr. Rabkin. Proceed.

Mr. RABKIN. Thank you, Mr. Chairman. Most importantly, H.R. 2418 would restore the public's confidence in the transplant system. Congress should expeditiously take this positive step forward building on a truly unique and successfully working transplant system and pass H.R. 2418, the organ procurement and transplantation network amendments of 1999. We appreciate the opportunity to testify here today. Thank you.

[The prepared statement of John M. Rabkin follows:]

PREPARED STATEMENT OF JOHN M. RABKIN, OREGON HEALTH SCIENCES UNIVERSITY
REPRESENTING THE PATIENT ACCESS TO TRANSPLANTATION COALITION

Mr. Chairman, distinguished Members of the Committee, I am John M. Rabkin, M.D., a surgeon and Chief of Liver Transplantation at the Oregon Health Sciences University.

I am here today on behalf of the 31 organ transplant programs and 1300 patients that currently make up the Patient Access to Transplantation (PAT) Coalition. I respectfully request submission into the hearing record, along with my testimony, a recent PAT Coalition policy paper (September 1999) which delineates our views on several critical issues in the legislative and regulatory debate.

The Patient Access to Transplantation (PAT) Coalition supports H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999," the reauthorization of the National Organ Transplant Act (NOTA), introduced by Reps. Bilirakis, Pallone, and Green. We appreciate their commitment to this issue and that of Commerce Committee Chairman Tom Bliley, and other Members of this Committee.

The PAT Coalition urges Congress to pass this legislation because we feel strongly that enactment of this bill is the best way to settle the controversy over organ transplantation resulting from the HHS rulemaking. Moreover, we think it is imperative to stem the erosion of public faith in the transplant system that has occurred since HHS issued its controversial Rule in April 1998.

We believe the current organ transplant system is fair and does a good job of acquiring and allocating organs for transplantation. We all must recognize the extremely dynamic aspects of the transplant system as medical developments occur on practically a daily basis. Like any system, there is, and will always be, room for on-

going improvement, and there are several proposals that the PAT Coalition supports to increase the numbers of transplants.

A recent study by the Institute of Medicine came to the same conclusion: "The committee found that the current system is reasonably equitable for the most severely ill (Status 1) liver patients, since the likelihood of receiving a transplant is similar across organ procurement organizations (OPOs) for these patients."

The IOM study contradicted the underlying rationale for the controversial Final Rule on organ allocation proposed by the Department of Health and Human Services. In an analysis of 68,000 liver patient records, the IOM panel said "the 'overall median waiting time' that patients wait for organs—the issue that seems to have brought the committee to the table in the first place—is not a useful statistic for comparing access to or equity of the current system of liver transplantation, especially when aggregated across all categories of liver transplant patients." HHS always maintained that reducing regional differences in waiting times was the primary goal of the rule on organ allocation.

The panel also found that enlarging the current organ allocation areas—a broad, regional sharing concept that the PAT Coalition generally supports—would improve the chances of Status 1 and 2 patients being transplanted.

The PAT Coalition has actively supported the two moratoriums on the HHS Final Rule implemented by Congress because we think that the Final Rule usurps the authority of the transplant community under NOTA to determine organ transplant policy. Stated most simply, Congress in NOTA vests the private sector OPTN with the authority to determine organ allocation policy. We strongly support this NOTA directive and agree with Congress that the private sector entity is far better equipped than the government to make medical policy judgments and adapt to changing technological developments and scientific and medical advances. NOTA simply does not provide the Secretary with authority to substitute her judgment if she or her staff disagree with the medical transplant community with respect to policymaking—yet the Secretary's Final Rule usurps this authority by regulatory fiat and claims the ability to reverse OPTN policy.

Among our other concerns, we also recognize that the transplant policy suggested in the Final Rule would result in more of our patients dying while waiting for a transplant, and a significantly higher rate of retransplantation and possible organ wastage. We are also concerned that the core HHS policy is a design to direct more organs to a few larger transplant centers, which would result in a loss of access to transplantation services for those patients who could not travel long distances for financial or family reasons.

The Rule itself applies to all organs and cannot withstand medical scrutiny. For example, another serious effect of this policy would be to increase the "cold ischemic time" for organs since organs would travel farther to the large centers. The IOM study pointed out that "a 4.2 percent reduction in re-transplantation...by using livers with lower ischemic times would necessitate less re-transplantation and would mean that 170 additional patients could receive a liver transplant."

The HHS policy is also shortsighted in its wholesale preemption of state laws regarding organ transplantation. Many of the beneficial policies that have served to improve organ procurement and donation are based on state laws, such as the organ donor check-off on driver's licenses. The HHS preemption fails to recognize that fact. In addition, this preemption clearly exceeds the authority granted by Congress.

During the moratorium period, we have worked actively with the transplant community to try to form a consensus on how best to deal with the HHS position. We have been involved in discussions with HHS officials who have promised the transplant community a revised proposal that would take into consideration our objections to the Final Rule. We are still waiting for a response from HHS as the clock ticks down on the current moratorium scheduled to expire October 21, 1999. We also are still waiting for HHS to publish an analysis of the thousands of public comments filed in response to the Final Rule. We understand that more than 85% of these comments stated strong opposition or concerns about the Rule.

The best solution to the problem is for Congress to reiterate the long held statutory premise that organ transplant policy should be left to the private sector transplant community through passage of new authorizing legislation. And, short of that, Congress should continue the moratorium until a new authorization bill can be passed.

H.R. 2418, the "Organ Procurement and Transplantation Network Amendments Act of 1999" recognizes that scientific and medical decisions about organ transplant policy should be left to the private sector transplant community rather than to the federal government bureaucracy, a concept that the PAT Coalition enthusiastically supports. The legislation's construct has worked successfully historically, and we continue to believe that the private sector is better equipped than the government

to sort through the complex medical, scientific, and ethical challenges presented by organ transplantation.

H.R. 2418 correctly places a strong emphasis on the real solution to the organ shortage problem: *increasing organ donation*.

But most importantly, this bill would restore the public's confidence in the transplant system and would serve to recognize the contributions made by the donors, patients, OPOs, doctors and volunteers who have actively participated in the development of a transplant system that results in 21,000 life-saving transplants each year.

Since the passage of NOTA in 1984, the number of people receiving organs has increased annually and survival rates are steadily improving.

Congress should expeditiously take a positive step forward, building on a truly unique and successfully working transplant system, and pass H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999".

We appreciate the opportunity to testify here today.

Thank you.

PATIENT ACCESS TO TRANSPLANTATION COALITION

POLICY PAPER

September 1999

The Patient Access to Transplantation (PAT) Coalition supports an organ allocation system that balances fairly "equity" with "utility." Organ allocation policy must seek to achieve the greatest good for the greatest number of people. Organ allocation policy must avoid futile transplantation, excessive retransplantation, decreased viability of organs and other waste adversely affecting the supply of organs.

Local access to transplantation must be preserved both for the sake of patients nationwide, especially minorities and medically underserved populations, and in order to improve donation.

NOTA

The PAT Coalition strongly supports NOTA's current delineation of authority. The National Organ Transplant Act (NOTA), as initially passed by Congress and as amended, establishes and clearly delegates policymaking authority to the Organ Procurement Transplantation Network (OPTN), a private sector entity comprised of physicians, patients and other transplant community representatives.

- NOTA's legislative history explicitly provides that the private sector OPTN should decide medical criteria for allocating organs, and should resolve issues regarding the fair distribution of organs.
- NOTA grants the Secretary oversight authority. Under NOTA, the Secretary is responsible for contracting with the OPTN and for soliciting comments on the OPTN's performance of its duties.
- The PAT Coalition strongly supports retention of medical decisionmaking in the private sector, and opposes HHS' involvement in developing, modifying or vetoing organ allocation policy unless specifically directed under statute.

PREEMPTION

NOTA currently does not contain federal preemption statutory language. The Secretary's Final Rule should avoid any attempt to preempt by regulation authority of the states or authority in the area of organs which the Congress has not granted explicitly to the Department. The federal preemption issue should be reserved for NOTA reauthorization. Otherwise, HHS invites a lawsuit on the preemption issue.

HHS ROLE

The Pat Coalition supports a strong federal leadership role in organ *donation*. Intractable problems in allocation can never be fully resolved as long as the dire shortage of available organs remains and we urge the federal government to assume affirmative responsibility and make this its highest and primary priority. To that end the PAT Coalition supports:

- Substantial increases in federal funding available for organ donation initiatives, including a national educational campaign which covers living donor organ donation as well.
- Direct financial support and matching grants to states who are willing to mount donor education and awareness campaigns within their states, establish donor

registration programs, and test other innovative approaches such as contributions for funeral expenses.

- Substantial increases in the National Institutes of Health (NIH) budget for targeted institute intramural and extramural research initiatives directed at increasing donations and making scientific and medical progress in organ transplantation (*e.g.*, NIDDK, NHLBI, etc.).
- Continual expansion of the HRSA extramural research support funding to test, evaluate and replicate creative research projects developed nationwide, including a directive to cover living donation initiatives.
- Seed money to explore the feasibility and logistics of establishing a national organ donor registry.

The PAT Coalition supports the oversight role given to the Secretary of Health and Human Services in the National Organ Transplantation Act (NOTA) regarding oversight of the Organ Procurement Transplantation Network (OPTN). HHS has no policy role in organ allocation.

- The PAT Coalition supports strong enforcement of OPTN policies by the OPTN. The Department may exercise its oversight responsibilities to seek input on the OPTN's exercise of this authority.
- Any independent review board created to assist or advise the Secretary (as suggested by the IOM) must be fully autonomous and independent. The appointment, composition and responsibilities of any such group must be wholly independent of any political process and the Department and Administration. We do not support using the Federal Advisory Committee Act ("FACA") construct because it would vest the Secretary with appointment authority and the role of a committee or advisory board chartered under this authority would be advisory and non-binding. This review group should not be charged with any policy-making responsibilities which belong in the private sector OPTN.

LISTING CRITERIA AND PRACTICES

The PAT Coalition believes that the private sector medical community, including surgeons, transplant physicians and scientists, should be solely responsible for development and ongoing refinement, where appropriate, of organ-specific *listing and de-listing* criteria based on standardized medical assessments.

- In balancing equity and utility considerations, the PAT Coalition recognizes that transplantation of the "sickest" patient is not always the best or most appropriate use of an organ, given higher survival rates and lower retransplantation rates of less sick patients.
- The PAT Coalition supports an independent process of prospective and ongoing concurrent review of patient status and application of medical listing and delisting criteria through chart review of all transplant centers within a given region.
- The PAT Coalition supports imposition of significant monetary penalties by the OPTN to enforce standardized listing and de-listing practices, and adherence to OPTN policy.

REGIONAL SHARING

The PAT Coalition supports broader regional sharing of organs based on private sector initiatives and arrangements. The PAT Coalition supports flexibility in the size of the population base utilized to achieve broader regional sharing, such as a population range of 6-11 million lives. Working relationships and arrangements between and among transplant centers in specific regions must drive the development of broader sharing. We do not perceive a "cookie cutter" approach to broader sharing will succeed because successful sharing must be based on relationships, which reflect regional considerations and availability of transplant centers and other resources within these regions. The PAT Coalition opposes development of a national waiting list and any centralized allocation system administered or structured by the federal government.

IMPORTANCE OF LOCAL ACCESS

- The PAT Coalition continues to believe that the policy mandated by HHS will impair access to transplantation services, especially for low-income and minority patients. Lack of access to organs may drive some regional transplant centers out of business, inflicting a fundamental blow to patient access and patient choice. Any Final Rule adopted by HHS must ensure access to transplantation and prevent unnecessary transplant center closings. The OPTN must assure

that allocation policies developed will not harm patient access to local transplantation services.

- The PAT Coalition concurs with the independent research finding that for a significant number of individuals, there is a greater willingness of people to donate if they can be assured that their organs will remain in their own local community or at least in their state (source: 12 years of independent research conducted by Kansas State University researcher James Shanteau).

ADDITIONAL CONCERNS

- OPO performance and effectiveness must be measured in a more meaningful way. HHS should develop alternative and outcome performance measures for OPOs as recommended by the General Accounting Office and endorsed by the Institute of Medicine.
- The Medicare and Medicaid statutes should be amended to ensure coverage to transplantation for beneficiaries who are uninsured. Such costs should not be borne by transplant centers.
- Models should be developed and disseminated nationally from careful screening of procurement and utilization practices and subsequent clinical outcomes.

CONGRESSIONAL OVERSIGHT

The PAT Coalition supports strong Congressional oversight of both the federal Department of Health and Human Services and the Organ Procurement Transplantation Network (OPTN). To that end, the General Accounting Office (GAO) should be charged with periodic oversight reviews of both the Health Resources Services Administration (HRSA) and Health Care Financing Administration (HCFA) program responsibilities and the OPTN contractor.

Mr. BILIRAKIS. Thank you very much, Doctor. There is a package here, testimony of the National Kidney Foundation and various letters—Shands Health Care and University of Texas, et cetera, which has been handed to the minority, and I would ask unanimous consent that it may be made a part of the record. Without objection. That will be the case.

I very much appreciate Dr. Rabkin emphasizing so very much the donation area, because without adequate organs being donated we can have all the allocation systems in the world, change this, change that, and it is just not adequate.

And that is what concerns me an awful lot. Granted we are concerned about allocation and that sort of thing. And Mr. Barrett said it as—I am not going to paraphrase and I may even be wrong in paraphrasing, but he referred to the people in his area wanting to know basically who was getting the organ and at least that there would be an easier donation type of a situation if they knew that it was sort of local, if you will, or at least regional. And I have made those comments before and I feel very strongly about that.

I don't have any trouble putting myself in the shoes of the public back in my region in terms of—and we do well, particularly in Florida, we do well as far as donations are concerned. And someone said something about if it ain't broke don't fix it, and that concerns me.

I want that to be a part of the record because I know Mr. Irwin referred to prior comments on my prior positions on my part.

But I will tell you and anyone who says differently is lying in my opinion, that we are, as I said earlier, parochial. We have to be. We represent people in our congressional district. And I dare say that if the University of Pittsburgh were not at the forefront of this national allocation system, that some of the people in Pennsylvania and eastern Ohio might maybe not change their positions but at least look at it a little more objectively. And the same thing is true

if Florida and the University of Florida and Miami and whatnot had a different position, that certainly would have an effect on me, and I am going to be the first one to admit that.

But we are concerned about equitable—to use the terms that I think Mr. Irwin used—equitable allocation. And we are concerned about the sickest receiving the organs as against those who are not in that category.

I understand that the IOM report concluded the current system of liver allocation is not only fair for the sickest patients, but to everyone in urgent need of a transplant receives—and I believe Dr. Rabkin touched on this—receives one, status 1 and 2A.

And if that is the case, it makes me wonder, Secretary Shalala in a January 20, 1999, press release said: “These findings make clear that changes are urgently needed to produce better and fairer outcomes for our Nation’s organ transplant patients” and that, “further delay can only needlessly injure patients.”

And yes, the IOM, which has been quoted so very much by the administration and by others and certainly has made the news, basically is being held out as having said that unfairness exists and that sort of thing. So Dr. Gibbons, would you care to expand?

Mr. GIBBONS. Love to. Let me first state that there is a difference between equitable and optimal.

Mr. BILIRAKIS. Equitable and?

Mr. GIBBONS. And optimal.

Mr. BILIRAKIS. Okay.

Mr. GIBBONS. Our findings were that the status 1 patients were treated equitably in the sense that there was not significant variability across the organ procurement organization for those status 1 patients, meaning that the rates of transplantation were fairly similar and there weren’t these large geographic heterogeneous distributions. This was not true for the status 2B and 3 patients. There was considerable variability from one OPO to the other and beyond just that, the smaller OPOs were transplanting large numbers more of these less severely ill patients relative to the larger organ procurement organizations.

Mr. BILIRAKIS. Are the sickest patients receiving the organs even though—I mean, and if that is the case, are some of those organs, many of those organs, whatever the proper term is, coming from outside of those regions?

Mr. GIBBONS. That is an excellent point. First of all, all status 1 patients are not receiving organs. By our comments about it being equitable it means that the rates are fairly similar, but only 54 percent of the status 1 patients are ever receiving an organ across the country.

Now, what happens to the other 46 percent, which is a very important question? 8 percent of those status 1 patients die while waiting for an organ. Again, those rates are comparable across the system.

Mr. BILIRAKIS. Doctor, forgive me, are you saying that appropriate organs are available in other regions and that they are being used for people who are nowhere near as sick and for that reason these category 1 people are not receiving the organs?

Mr. GIBBONS. That is one of the reasons, yes, sir.

Mr. BILIRAKIS. That is one of the reasons.

Mr. GIBBONS. Absolutely.

Mr. BILIRAKIS. And you pointed—you have detailed that in your report in terms of evidence of that and that sort? I am not trying to be difficult, don't get me wrong, I just want to be sure. I know that you have used terms like "inconclusive" and that sort of thing, and I just want to know is this conclusive? I am assured in Florida particularly, Mr. Miller can speak to this—nobody is under oath here—but I am assured that many organs are shipped, if that is the proper term, out of the State to be used by recipients who are sicker. Is this true, Mr. Miller? If it is not true, please feel free—

Mr. MILLER. Well, it just so happens that we have a very, very busy transplant program in Florida, many status 1 patients. So if I were to say what the net would be, the balance of trade for status 1s would probably be into the State. On the other hand, were there a status 1, let's say, in Emory in Atlanta, and we have the donor in Miami, that status 1 would be sent to Atlanta.

As a matter of fact, Dr. Payne just testified that the new algorithm for status 1 sharing was already in the pipeline as the Institute of Medicine was deliberating. So there was a more broader sharing of status 1s—

Mr. BILIRAKIS. You said that. I suspect that Dr. Payne said that, too, and I apologize for not hearing his testimony. But Dr. Gibbons heard that. Is that true, were these changes in the pipeline during the times that you were deliberating and working up your report?

Mr. GIBBONS. There were changes that were made during the course of—towards the end of our report that were to some degree consistent with our recommendations. Our recommendations were broader sharing all across the board, not just for status 1 patients.

Also, what you are saying and what Dr. Miller is saying is completely consistent with our findings; that is, those States and those regions that started to institute broader sharing of one form or another had an increase, a statistically significant increase, in the overall transplantation rates of status 1 patients, making it more optimal, despite the fact that it was already quite equitable. There are status 1 patients who are not receiving organs, and there are small organ procurement organizations in existence that are transplanting much higher rates of 2Bs and 3s that could ultimately go to status 1 patients in other organ procurement organizations within the limits of cold ischemic time.

Mr. BILIRAKIS. My time is well up. We might—depending on how many more people return, we might go a second round here.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Dr. Rabkin, in your testimony you said that the organ transplant policy should be left to the private sector transplant community. You basically argue, if I understand transplantation, communities should make virtually all or basically all allocation distribution decisions, correct?

Mr. RABKIN. I think if you define the transplant community as it is currently structured, the answer yes would be correct.

Mr. BROWN. How would you define it?

Mr. RABKIN. Well, the transplant community currently doesn't just consist of transplant surgeons and transplant physicians. It includes, most importantly, patients, patient families, donor families.

It includes members of the community. So I think it is a very broad net. But I think all of these individuals have an interest and a knowledge and a commitment to the transplantation process. They understand the nuances, and they therefore—what has historically happened is they have derived an allocation policy that has been very effective and has brought transplantation to the point that it is today. It is a dynamic process, continuously evolving and improving.

Mr. BROWN. If those transplants are paid by Medicare or Medicaid, FEHP, the Federal health system, does that change the position that you take in terms of who should make these decisions?

Mr. RABKIN. By the same token that we don't discriminate on a payor to decide who gets a transplant. It doesn't matter who is paying for it who should be making the decision on who should get a transplant.

The answer is no. We are trying to help as many patients as we can with the limited resources that we have available.

Mr. BROWN. So with these decisions, spending taxpayer dollars, there should be no real public role of government and of representing taxpayers when taxpayers are paying huge amounts of money in a very profitable system, a system that has huge—all kinds of for-profit entities in this system, from doctors being very well paid to hospitals using it as profit centers, for-profit hospitals and in some cases not-for-profit hospitals, for other kinds of people in this allocation system which you describe very well. There should be no role for taxpayer government involvement in these decisions?

Mr. RABKIN. No. That is not, in fact, what we believe. There is a role for government oversight.

What I stated was that the allocation policy is a medical decisionmaking policy. It is similar to all other policies that take place currently in other medical fields. There is not a government bureaucracy deciding necessarily who gets treated with a particular illness and in what fashion. I think that there is a level of decisionmaking and oversight that does take place at the Federal level, but the allocation policy per se needs to be in the hands of the transplant community.

Mr. BROWN. Even though the allocation decisions affect large numbers of people, even people that—affects large numbers of people beyond perhaps what you very narrowly define as the transplant community, those decisions shouldn't be overseen by the HHS or shouldn't be formed or formulated in any way by HHS?

Mr. RABKIN. I am not sure I really understand your question. I think that I have stated as best I can state that I try to segregate what we feel ought to be left in the hands of the transplant community, which is really the medical decisionmaking involved, as opposed to some of the—

Mr. BROWN. Let me take another direction for a moment. Adding that UNOS in this bill has an appropriation of \$6 million, so there is always government involvement when it comes to paying for it, the section, page 15 of the bill, this is my concern. I don't disagree with you in terms of the medical decisions. Clearly, the physicians and the nurses and the hospitals and the transplant—the patients all should have major roles in all of this. But on page 15, there is

a section on gifts. “this section does not prohibit the network from accepting gifts of money or services including gifts to carry out activities to provide for increase in organ donation.”

On page 20 of the bill, “Prohibition against organ purchases,” insert after, “does not include—does not include”—inserting after, “does not include the following: A benefit, the exchange of which is expressly contemplated by organ distribution policies, demonstration projects.” it goes on and on and on.

My concern and a concern of a lot of us on both sides is the enormous profits that come from the terrific services that you as surgeons and the people that work with you—enormous profits generated in many cases. What drives this whole issue in part, I am not sure that we—I am not sure that we have protected the public when things like gifts are expressly allowed. Those gifts could take the form—some cases a gift to encourage people to donate perhaps, but in other cases gifts to steer people into major centers or to encourage—maybe if I am a wealthy potential beneficiary, recipient of a transplant, then I make a gift to a hospital and get moved up on the list, or my family does. We have to be extremely careful that—while you certainly want to do the right thing from your testimony, all of you do, that are physicians and nonphysicians alike, we need to be especially careful to not allow the for-profit drive in this to overwhelm what should become good public policy.

Did you want to say something, Mr. Irwin, just a minute ago?

Mr. IRWIN. I just wanted to comment that I believe there are two levels of decisionmaking that go on here, or policy setting. One certainly is medical. From our perspective I don’t think that we have an issue with that. For the most part, the medical allocation policies that distinguish status 1 patients from 2As, 2Bs, and 3s we feel is pretty well thought out. The problem is the public policy issue. With that medical criteria, how big of an attachment area do you use?

The problem with the system today is you have—because of a varying number of factors, you have relatively small allocation areas where relatively healthy patients are being transplanted, where sicker patients are not being transplanted in fairly close proximity, which really is contrary to the medical allocation decision that the sickest patients should be given priority.

The other concern that we have in our experience is just the way these decisions are made by the OPTN contractors’ board. There seems to be a lot of self-interest that comes out in the discussions at the board level to the point where sometimes recommendations from committees that explore this issue are overlooked or overruled despite the fact from our perspective they make pretty good sense from a public policy perspective.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. I apologize to this panel for being a little bit late. We were involved in another committee, and I have missed some of the testimony. For that reason I would ask Mr. Irwin, if you have a microphone handy there, you represent NTAC. Is that the correct—

Mr. IRWIN. Yes, the National Transplant Action Committee.

Mr. BRYANT. Does NTAC in any way coordinate its activities with the University of Pittsburgh?

Mr. IRWIN. Mr. Bryant, we coordinate our activities with a lot of institutions and patients around the country. We have—we speak with and work with Mount Sinai Medical Center, with the University of North Carolina. We have received a contribution last year from Jackson Memorial Hospital in Miami. I work with Stanford and University of California, San Francisco. And yes, we coordinate our activities with all of these institutions, including the University of Pittsburgh.

Mr. BRYANT. Thank you.

Mr. Chairman, if I could, with unanimous consent I have a six-page document that is various memoranda from the University of Pennsylvania and a one-sheet, two-sided letter from Mr. Livingston, our former Member, former Chairman of the Appropriations Committee. I would like to——

Mr. BILIRAKIS. Is that University of Pennsylvania or Pittsburgh?

Mr. BRYANT. It could be Pennsylvania, UPMC. I think that is University of Pittsburgh.

Mr. BILIRAKIS. Okay. In any case, without objection, but that is a part—well, I am not sure. Anyhow, that is part of the record.

Mr. BRYANT. Thank you.

[The information referred to follows:]

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Government Relations*

800 Lathrop Street
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FACSIMILE TRANSMITTAL MEMO

TO: Dr. John Roberts
Dr. Gerson Klitbaum
Dr. Charlie Miller

FAX: 415-885-3832
214-820-4827
~~212-688-6688~~
212-289-0857

FROM: Dr. John Fung ←
Jeanne Stoner
Director, Federal Government Relations
Phone: 412/647-4481; Fax: 412/647-9387

DATE: May 8, 1998

SUBJECT:

PAGES: 3, including this page.

*If there is a problem with this fax transmission,
please call Suzanne Ricketts at (412) 647-5815.*

MESSAGE:

We are drafting a letter to Secretary Shalala that we hope can be signed by Dr. John Roberts, Dr. John Fung, Dr. Charlie Miller and Dr. Gerson Klitbaum describing what occurred at the Liver Committee meeting yesterday and criticizing UNOS' latest press releases which indicate that last year's changes in Liver Allocation System have fixed all the problems. Attached is drafted the critique of last year's changes. Draft cover letter to Shalala will arrive early this afternoon.



UPMC HEALTH SYSTEM

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A member of the UPMC family

CONFIDENTIAL MEMORANDUM

To: Members of the "Government Relations" Transplant Team
From: Jeanne Stoner *JCS*
Date: May 6, 1998
Re: Targeted List of Legislative Contacts--Call for Action

There is clearly increasing Congressional opposition to the OPTN final regulation (e.g. the Livingston amendment now signed into law and the newest "Dear Colleague" letter). As Charlie and Craig mentioned on our last call, it is more critical than ever for legislators to hear from their constituents who are supporters of the OPTN regulation. These individuals may be candidates, recipients, family members, or simply interested parties, but the patients and their family members have the strongest messages.

Craig and Charlie have identified the following members of the House and Senate Appropriations Committees as initial targets because of their views and their districts or states.

House Appropriations Committee

Bob Livingston (R-LA)
John Porter (R-IL)
Ralph Regula (R-OH)
Louis Stokes (D-OH)
Marcy Kaptur (D-OH)
Blaney Yates (D-IL)

Senate Appropriations Committee

Ted Stevens (R-AK)
Arlen Specter (R-PA)
Christopher Bond (R-MO)
Judd Gregg (R-NH)
Ben Nighthorse Campbell (R-CO)
Lauch Faircloth (R-NC)
Kay Bailey Hutchison (R-TX)
Robert Byrd (D-WV)
Daniel Inouye (D-HI)
Patrick Leahy (D-VT)
Dale Bumpers (D-AR)
Frank Lautenberg (D-NJ)
Tom Harkin (D-IA)
Barbara Mikulski (D-MD)
Harry Reid (D-NV)
Byron Dorgan (D-ND)
Barbara Boxer (D-CA)

*Write out
sample letter
and addresses
for - UMD
- TRIO
- NIOSIV*

The states represented by the legislators on the list are:

Alaska	Ted Stevens (R)
Arkansas	Dale Bumpers (D)
Colorado	Ben Nighthorse Campbell (R)
California	Barbara Boxer (D)
Hawaii	Daniel Inouye (D)
Illinois	John Porter (R) (Suburban north of Chicago), Sydney Yates (D) (North side of Chicago and Evanston, IL)
Iowa	Tom Harkin (D)
Louisiana	Bob Livingston (R) (Suburban New Orleans, including Metairie, LA)
Maryland	Barbara Mikulski (D)
Missouri	Christopher "Kit" Bond (R)
Nevada	Harry Reid (D)
New Hampshire	Judd Gregg (R)
New Jersey	Frank Lautenberg (D)
North Carolina	Lauch Faircloth (R)
North Dakota	Byron Dorgan (D)
Ohio	Ralph Regula (R) (Canton, OH), Marcy Kaptur (D) (Toledo, OH), Louis Stokes (D) (East suburban Cleveland, OH)
Pennsylvania	Arlen Specter (R)
Texas	Kay Bailey Hutchison (R)
Vermont	Jim Jeffords (R)
West Virginia	Robert Byrd (D)

The supportive transplant centers, including UPMC, are identifying patients at their centers, candidates or recipients, from the states represented on the list who can be contacted and asked to write the Appropriations Committee member.

If you have not already done so, as soon as reasonably possible:

- 1) Please identify any of your patients pre- and post-transplant list from the states listed above.
- 2) Please contact them and ask whether they would be willing to contact their legislator(s) and Secretary Shalala AND provide a copy of the letter or a postcard to you and to National Transplant Action Committee. Craig Irwin is developing a postcard tear-off which should be available very shortly to make it easier for patients. Sharon Tomazic has prepared a draft patient letter which could also be used as a sample. A copy of our advocacy package is attached which you may wish to use. Also attached are the House and Senate membership rosters and the maps of the state Congressional districts above. The information will be faxed and sent overnight.
- 3) Also, please ask them for permission to pass along their name and telephone to National Transplant Action Committee for further advocacy.
- 4) Patients and families who may have relationships with Members of Congress should be encouraged to also call the legislators to weigh in on the issue. They may wish to request a meeting in the state or district. All Members of Congress are up for reelection this year, so they are trying to spend as much time in the districts as possible prior to the primary and general elections. A number of the Senators are also up for reelection. Please give me a call if you want this information.
- 5) Pending further Congressional action, the comment deadline is now moved back to August 31, 1998, which gives us--and UNOS--additional time to pursue advocacy. HHS reportedly had received 1,000 letters or cards supporting UNOS and the status quo. While the numbers of letters are not the only measure looked at by the Department, they are one index of public opinion. So, getting as many comments as possible (letters and/or cards) as well as the substantive comments is so important.
- 6) In light of Congressman Barrett's bill, Congressman Boswell's bill, the newest "Dear Colleague" letter appealing the regulation, and Congressman Livingston's efforts, advocacy on behalf of patients and their needs and interests couldn't be more important. If some of these Congressional efforts are successful, patient lives and fairness in the system will again be relegated to a priority behind that of transplant centers. Craig's call for a "Fight for Fairness" takes on new meaning with the newest Congressional initiatives.

Many, many thanks.

Attachments:

The Honorable Donna Shalala
 Secretary of Health and Human Services
 United States Department of Health and Human Services
 200 Independence Avenue, S.W.
 Washington, D.C. 20201

Dear Secretary Shalala:

As liver transplant surgeons from some of the largest medical centers in the country, we wanted to take this opportunity to let you know of our views concerning some of the information which has been communicated to you and to the public by the United Network for Organ Sharing with respect to the Regulations for the Organ Procurement and Transplantation Network and actions taken at a recent meeting of the Liver and Intestinal Organ Committee of UNOS on May 7, 1998.

First, we support you in your issuance of the Regulations as a means of giving some guidance to the transplant community on public policy issues involved in organ transplantation and of exercising some oversight over the operation of the OPTN. As indicated in your Regulations, we believe that the medical decisions inherent in issues relating to organ transplantation should continue to be made by trained medical personnel.

Second, you have recently received correspondence from UNOS transmitting certain statistical data about the effect of implementation by UNOS of its new guidelines (January 20, 1998) to define objective patient health status categories. We believe the information provided to you by UNOS is not an accurate portrayal of the whole picture resulting from implementation of the new UNOS status definition categories.

- There is no data showing any improvement in the wide disparity in waiting times.
- The data presented by UNOS fails to disclose that the percentage of patients in Status 1 and Status 2A (the urgent patients) who die while waiting for a transplant remains at 20%, while the percentage of deaths while waiting among Status 2B patients has decreased from 11% to 8% and the death rate for Status 3 patients has remained approximately the same at 1.6%. Without wider geographic sharing and equalized waiting times, the Status 1 and Status 2A patients will continue to die at unacceptably high rates while waiting for transplants.
- The increase in the aggregate number of transplants for patients in Status 1 and Status 2A occurred not because of UNOS' new health status definitions, but because patients who are listed at centers with long waiting times are more likely to enter the most urgent health status before receiving a transplant.
- The new status definitions reclassified a significant number of formerly Status 3 patients as Status 2B patients, thus increasing the number of transplants recorded for Status 2B patients. *very large and*
St. 2B is more readily compatible

- In its January 20, 1994 guidelines, only Status 1 and Status 2A patients were to be classified as "urgent" or "critical". In the numbers presented to you, UNOS has also included Status 2B patients as "urgent" or "critical". Moreover, UNOS has inaccurately described Status 2B patients as having a life expectancy "between one week and two months", despite the fact that such limitation has never been included in any UNOS policy.

→ No data, specious.

Attached to this letter is a more detailed analysis prepared by CONRAD Research Corporation with respect to the recent statistical information provided to you by UNOS.

Finally, at the recent meeting of the Liver and Intestinal Organ Committee of UNOS, the committee members were critical of the computer modeling used to justify UNOS' arguments against the Regulations. Committee members took issue with the fact that the modeling was based upon data going back to 1991. Improvements in organ transplantation have resulted in better patient survival rates and a decrease in the number of retransplants performed on sicker patients. The Committee members agreed that UNOS could comply with the terms of the Regulations and propose an allocation and distribution system which meets the policy goals in the Regulations, without some of the practical difficulties attendant to distribution pursuant to a single national waiting list. We intend to work actively with that Committee to develop and propose to the Department a proposed liver allocation system which will accomplish the goals in the Regulations and be fair to patients regardless of their location.

Thank you very much for your support of the OPTN.

Sincerely yours,

Goran S. Kintzheim, M.D.
Baylor University Medical Center

Charles Miller, M.D.
Mount Sinai Medical Center

John R. Lewis, M.D.
UCSF—Stanford Medical Center

John Fung, M.D., Ph.D.
University of Pittsburgh Medical Center



Congress of the United States
House of Representatives
Washington, DC 20515-1801

October 20, 1998

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The one-year moratorium on new HHS organ transplantation regulations in the Omnibus Appropriations Bill is the right thing to do.

First, let me say that I am deeply saddened by the loss of Jordan Rosebar. I express my condolences to the Rosebar family for having to endure a tremendously difficult loss.

But the regulations proposed by Secretary of HHS Donna Shalala will not improve the current climate for organ transplantation; and may well make it much worse. For example, distributing organs from a national list and in more centralized locations jeopardizes the health of the organ and diminishes the incentive for people to donate in the first place.

The National Transplant Action Committee's assertions that the one-year moratorium on HHS organ transplantation regulations will result in increased patient deaths is totally unfounded. The moratorium will save lives by preventing ill-conceived regulations from going into effect thus preserving a nationwide system of over 270 transplant centers that provide everyone, including low income patients, the opportunity to receive life saving transplants close to home. Implementing HHS' one size fits all national system for allocating organs will not make transplant accessibility easier for low income and other patients who will otherwise have to travel farther to fewer transplant centers and who may not be able to transfer Medicaid or other health insurance coverage across state lines. The moratorium on HHS regulations was not a back room deal. These regulations have been subject to both House and Senate hearings and have generated so much controversy that 85% of the many people who submitted formal comments to HHS were opposed to the regulations.

The case of Jordan Rosebar demonstrates very clearly the critical need to increase the number of organs available for transplantation by increasing the number of organ donors nationwide. That is why the Omnibus Appropriations conference agreement provides funding significantly higher than the Administration's request to increase organ donation efforts.

In order to answer some of the assertions made about the Rosenberg case, I have provided some facts as I know them now on the reverse side of this page.

Sincerely,

Robert L. Livingston
Member of Congress

- The organs from the New Orleans donor could not have saved Jordan Rosebar because she died during the donor's organ recovery surgery.
 - There were two other status 1 patients ahead of Jordan Rosebar.
 - The recovery of the donor liver began at 3:00 a.m. (CDT). According to the Times Picayune, the child died at 4:17 a.m. in Pittsburgh, which would be 3:17 a.m. local time, if the listing was Pittsburgh time. If not, it still would have taken 3-4 hours for the liver to have traveled to her.
 - Jordan Rosebar was not listed in Florida when the Louisiana Organ Procurement Agency (LOPA) ran the list looking for suitable patients awaiting a liver transplant. Even so, Miami requested that LOPA run the list again on behalf of a Pittsburgh patient, a request that most organ recovery centers would not have granted. Transplant doctors around the country feel that running the list more than once opens the door to favoritism and potential manipulation of the system.
 - After Miami turned down the liver, Pittsburgh called LOPA directly and asked that it be diverted to them. As per the current policy that the transplant community developed, LOPA told Pittsburgh that the liver would go to a patient in its region—in Georgia. LOPA informed the Georgia center that Pittsburgh wanted a liver for a status 1 patient and that Pittsburgh would call. Pittsburgh chose not to call the physician in Georgia to discuss the status of their respective patients. The Georgia physician may well have been willing to divert the liver to Pittsburgh.
 - Between 1995 and 1997, 22 Louisiana livers went to Pittsburgh. In 1995, LA sent 13; in 1996, LA sent 6; in 1997, LA sent only 3. (Pittsburgh's organ supply is dwindling from Louisiana and other OPOs. Transplant technology has become diffuse with local and regional centers around the country now providing access to many patients in their own geographic areas.)
 - Pittsburgh has not sent any livers to the Louisiana transplant centers LOPA coordinates.
 - Less than 4% of Pittsburgh's transplanted patients are African-American.
 - In 1996, the rate of African-Americans in Louisiana receiving liver transplants was nearly 3 times the national average, with more than 23% of Louisiana's liver transplants being performed on African-American patients and nearly 27% were Medicaid.
 - Transplant pioneer Dr. Michael DeBakey wrote, "...the regulations (issued by Sec. Shalala) would unintentionally reduce the number of people who get transplants and thus cause more patients to die—all because of a change in policy that sounds logical initially, but would actually have devastating consequences."
- He continues "There is a vital medical reason that the sickest patients are not always at the top of the list for transplantable organs. Many of these patients are so sick their bodies would reject a transplant, and they would require a second or even a third transplant to survive. This would reduce the number of organs available to other patients, and over time, cause hundreds more to die."
- Ronald Busuttil, M.D., President-elect of the American Society of Transplant Surgeons, testified that "Giving priority to sickest first over broad geographic areas would be wasteful and dangerous, resulting in fewer patients transplanted, increased death rates, increased re-transplantation due to poor organ function, and increased overall cost of transplantation."
 - The regional sharing system gives the patient an advantage because the sooner an organ is transplanted, the more successful the transplant.

Mr. BRYANT. The concern I had, quite frankly, Mr. Irwin, is that in this confidential memorandum, it is discussing various strategies in lobbying Congress and getting people to write letters, which I assume would be taking a position consistent with the University of Pittsburgh.

It mentions that Charlie and Craig mentioned it is more critical than ever for legislators to hear from their constituents. And then Craig and Charlie have identified the following members of the House and Senate Appropriations Committees as initial targets because of their views in the district.

So it looks to me like you have been coordinating strategies that I assume would make NTAC consistent with taking the position consistent with the University of Pittsburgh?

Mr. IRWIN. Certainly, Mr. Bryant. The same thing is happening on the other side of this issue with the opposition.

Mr. BRYANT. I have no doubt. I just want to be transparent.

Mr. IRWIN. In addition, I would like to state that we do have membership around this country, and we rely on volunteers and that membership to also help us in a variety of areas.

Mr. BRYANT. Does—do you—you are an active lobbyist for the year 1998. During this particular year, and including the year that you wrote the letter about former Chairman Livingston, were you officially lobbying? Were you registered as a lobbyist in 1998?

Mr. IRWIN. The National Transplant Action Committee has not filed as a lobbyist. The work that I do I do through a private company. And as directed by law, this is a company that I started with Mr. Charlie Fisk that does a variety of services in the transplant field. As appropriate, we have filed papers with respect to the lobbying act.

Mr. BRYANT. For year 1998?

Mr. IRWIN. Mr. Bryant, off the top of my head, I can't tell you exactly. I think we filed in 1997 because we did have some considerable expenditures, but I know in the last year I can't tell you whether or not we met the criteria or not.

Mr. BRYANT. Could you tell me if either you or Mr. Fisk are being paid by the University of Pittsburgh to testify?

Mr. IRWIN. No. I have never been paid by the University of Pittsburgh to testify.

Mr. BRYANT. And Mr. Fisk?

Mr. IRWIN. No.

Mr. BRYANT. Dr. Raub, if I might ask you some questions also. At last year's hearing there was a great deal of concern that the regulations would force the closure or have a severe negative impact on small and medium-size transplant centers who are performing these vital services. The Secretary at that time assured this committee that she would make certain that regulation would not have that effect. Specifically, the Secretary was asked by Senator Frist, "Would you be willing to provide assurances and regulation if possible that you are not asking the UNOS or whoever the contracting agency might be for a policy that would result in the center's closing," end of question.

The Secretary responded, "The answer is yes. As best I can tell, the IOM report was less than convincing that these regulations would not have such an impact citing conflicting studies."

My question is are you willing to give this subcommittee the same assurances that the Secretary did last year?

Mr. RAUB. Sir, the final rule as published in April includes the provision that, when the OPTN develops the proposed allocation policies, it take into account and make an assessment of the likely impact on those small centers. The basis of that provision is to fulfill the Secretary's assurance. It is not our desire to close small centers.

Mr. BRYANT. That would be then—you feel that would adequately protect the small centers?

Mr. RAUB. We do, sir.

Mr. BRYANT. Mr. Chairman, is my time up?

Mr. BILIRAKIS. It is. If you would like an extra minute or so, with unanimous consent, we will be glad to grant it. I do want to finish. Hopefully, we will finish up before the vote comes up on the last amendment on this particular bill on the floor. Please proceed if you would like.

Mr. BRYANT. If I could have unanimous consent for one additional question?

Mr. BILIRAKIS. Without objection.

Mr. BRYANT. Dr. Raub, we are all aware of the substantial debate generated by the Department's April 2, 1998, final rule. I understand that you have conducted a series of meetings with the transplant community aimed at identifying a reasonable compromise all parties can live with. It is also my understanding that as part of the process, the Department has indicated on several occasions its intent to reissue modifications to the April 2, 1998, final rule, but has not yet actually done so. Specifically, your letter of August 30, 1999, to the transplant community stated that "I intend to move vigorously in cooperation with the transplant community to put a modified final rule in place—"and this is important—"and to bring about the changes in the regulation that could and should be made."

Why then, when we find ourselves less than 1 month from the expiration of the current moratorium, has the Department not yet issued anything in writing to indicate the proposed modifications of the final rule? Are we running out of time?

Mr. RAUB. Sir, in considering the public comment, the IOM report, and the meetings with the representatives of the transplant community, the Department has made several determinations. One is that the core principles and provisions as embodied in the rule are sound. Second, these interactions have helped us identify a number of areas where some refinement or revision or other clarification in the rule would make it better and would be responsive to many of the concerns. I indicate two examples in my prepared testimony.

Third, the intent of the Department, by the time of the date of the end of the moratorium, is to have those revisions in place and be prepared for that revised rule to go forward.

Mr. BRYANT. If I might follow up, on a time line, when would we see this?

Mr. RAUB. I can't state a precise time line other than that our intent is to meet the end of the moratorium and to have these revisions in place at that time.

Mr. BRYANT. Can you identify for this subcommittee those aspects of the rule that you plan to change?

Mr. RAUB. Just elaborating on one of the examples in the testimony, both the IOM report and a number of the public comments indicate a desirability of some sort of scientific expert independent advisory panel. We believe that is an intriguing idea. We are considering the number of variants that have been proposed for that. We are looking at that in the context of the Federal Advisory Committee Act. That is an area that we are pursuing very seriously.

Also, our colleagues on the outside have pointed to the various sentences in either the rule or the preamble that have caused them to conclude, incorrectly, that the rule calls for a national list, that it overrides the decisions of physicians with respect to which patients to transplant. We are looking hard at that language. That was not the intent of it. To the extent that we identify an ambiguity and can clarify that, we will do so.

Mr. BRYANT. Thank you, Mr. Chairman.

Mr. RABKIN. Mr. Chairman, would it be out of order for me to just ask a question?

Mr. BILIRAKIS. Who asked that? A question of whom, of Dr. Raub?

Mr. RABKIN. Yes.

Mr. BARRETT. Mr. Chairman, there is 10 minutes until the next vote.

Mr. BILIRAKIS. If you are going to ask questions, sir, without—this is out of the ordinary, but do it quickly. And respond to very—

Mr. BARRETT. I would like to object until we are done with our questioning, if I could.

Mr. BILIRAKIS. Okay. The objection is heard, so you can't do it. Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman. I don't mean to be rude. If we have time, I would be happy to let you do it.

Mr. Irwin, you begin your testimony by saying you are a consumer advocate of the National Transplant Action Committee as a consumer advocacy organization; is that correct?

Mr. IRWIN. Yes.

Mr. BARRETT. What percentage of your funds comes from consumers?

Mr. IRWIN. Off the top of my head, I couldn't tell you.

Mr. BARRETT. Would it be fair to say that over 90 percent comes from hospitals?

Mr. IRWIN. Not that much.

Mr. BARRETT. Can you give me a ballpark figure?

Mr. IRWIN. It is like moving—a moving target. What I can tell you is we recently did a fund-raiser in our community with about 200 volunteers that raised about \$30,000. I would say maybe 60 percent.

Mr. BARRETT. Dr. Rabkin, the Patient Access Coalition, I assume the lion's share of your money comes from hospitals as well?

Mr. RABKIN. That is correct.

Mr. BARRETT. I say that because we are all on our best behavior, and we are all trying to be nice to each other, but we are fighting about money, and we shouldn't forget that.

I would like to sort of invite you in and have you sit with me and pretend for a moment that I am a hospital administrator that is affected by this rule. We have been spending \$200,000 on an organ procurement outreach network in our community. This new rule comes down that says from here on in the organs will not stay in our region, they will be shipped across the country. Correct me if I am wrong, but as I am sitting here with my surgeons, my nurses, and my other hospital administrators, I am going to say, zero out that \$200,000 in organ procurement, that is no longer a priority. Put that \$200,000 into developing a waiting list of the most critical patients. Won't I do that, Dr. Raub?

Mr. RAUB. I see that as a possible decision, sir, but I couldn't state it with certainty that it would or wouldn't be.

Mr. BARRETT. Dr. Gibbons, what would you do if you were administrator of that hospital? Would you put money into organ procurement, or would you put it into developing a waiting list, if you were running a hospital?

I am asking what you would do. Data shmata. What would you do?

Mr. GIBBONS. I only do data, sir.

Mr. BARRETT. You look remarkably like a human being, so I am asking you what you would do if you were the hospital administrator.

Mr. GIBBONS. If I were the hospital administrator, sir, I would note that increased broader sharing has actually increased donation rates, and that to ship an organ across the country doesn't make an awful lot of sense given cold ischemic times and the—

Mr. BARRETT. \$200,000, where would you put that money, putting patients on a waiting list or procuring organs that might be shipped across the country?

Mr. GIBBONS. I would put it into procuring organs because I don't believe that those organs would be shipped across the country. I think broader sharing is a good thing, and 9 million people is not so large that it reaches—

Mr. BARRETT. Okay. Mr. Gibbons.

Mr. GIBBONS. That is me.

Mr. BARRETT. Mr. Irwin, what would you do?

Mr. IRWIN. It doesn't make sense to try to buildup your waiting list if you don't have the donors to service it.

Mr. BARRETT. But aren't we putting together a beautiful system for a free rider in pure economic terms, someone who says, well, I am not going to worry about organ procurement because I gain nothing. I gain nothing from organ procurement—in the most selfish way. Maybe in the global picture we do, but I am concerned about my center here. And so the ticket to success under this system is to develop a waiting list.

Wouldn't we agree with that, the ticket to guaranteeing patients under this new system—guaranteeing patients under this new system is not getting organs, the ticket is getting sick patients. So if I am a rational economic actor, I am going to be putting my effort into getting sick patients. I think that has a devastating impact on the supply of organs.

Mr. IRWIN. If you still want to hear from me, let me make a couple of comments.

First of all, organ donation rates certainly vary throughout the country. I don't see any evidence that transplant centers or OPOs with larger waiting lists are less aggressive or more aggressive in trying to find donors. I think everybody in this system works hard to maximize organ donation.

Second of all, I think you will find that in many cases patients who do end up—who are sick patients who end up in a larger center, they are there because they are turned down by another center who doesn't have the expertise or the willingness to transplant them.

Third of all, I think if you look at the data, transplant centers that do transplant fairly sick patients in many cases have survival rates that are on a par or even better than transplant centers that transplant healthy patients.

Mr. BARRETT. If I may, Mr. Chairman, I know that time is short. I also want to make this point. This is from Mr. Irwin's testimony commenting on the IOM study. Quoting, "Broader sharing of organs resulting from implementation of the final rule is not likely to have a significant adverse effect on those who depend on Medicaid for their health care."

I don't read that as a ringing endorsement that we are going to improve access to the poor. That is one of the things that we have had discussions here. To say that it is not going to have a significant adverse effect certainly leaves the door open that it is going to have an adverse effect. With minorities in particular, the committee found, "that African-Americans do not receive kidney treatments as quickly as whites," and that the Department's rule would not exacerbate this problem. It doesn't say it will improve the problem, it simply says it is not going to make the problem worse.

So again, I think as we talk about minorities, about the underserved, that no one should leave this room thinking that the Department's rule is somehow helping minorities and the poor based on IOM's own statement.

I would yield back the balance of my time.

Mr. BILIRAKIS. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and I will be as quick as I can.

My first question is for Dr. Miller and Dr. Payne. I am concerned that OPOs have not shown a willingness to share organs with other OPOs or States within their closed region unless they do not have any match within their own area. This practice is—the Institute of Medicine found it could have a negative impact on all patients who may lose the opportunity to receive a life-saving organ based solely on their location.

In your testimony, you mentioned that the OPTN had already begun to implement some of the IOM recommendations as they relate to organ sharing. Would you comment in greater detail on the steps that have been taken? Are there plans to take or encourage or require broader sharing of organs by OPOs within reasonable geographic boundaries?

Remember, I am from Texas. We are pretty big. We have three OPOs in our own State, and geographically there is no relation to their areas.

Mr. MILLER. Dr. Payne is going to be able to do this better than I. I would like to comment, though, if I might. The reason is he is the president of UNOS this year. I think that is important. That is where this process occurs.

However, we have felt the impact and are going to feel more of this impact because of broader sharing, and it has to do with the most urgently ill patients needing it. It is going to be regionalized rather than localized so that in a region—for instance, we are in a very large region in Florida that consists of Florida, Alabama, Georgia, Louisiana, Mississippi. We are talking about a large region that has much more than 9 million people. That region has developed methodologies now to attempt to share status 1—liver status 1 patients.

May I make one comment about this local effect on organ donation, because there has been actually statements made by both the esteemed Congressmen here as well as some of my colleagues at this table that have actually put words into the IOM's mouth, so to speak. IOM came out with a statement that was very perceptively stated by Congressman Bilirakis, our chairman, that said that it was inconclusive as to whether there would be an effect or not on local organ retrieval or closure of local programs. Inconclusive. They did not say that there would not be an effect.

Now, if you were to ask experts in this field, the majority of the American Society of Transplant Surgeons feel that there would be an effect. We came out with a white paper about that. That word is very important because it is a word that is used by—if you will forgive me—statisticians who do not wish to make mistakes. It is very important that they don't.

Mr. BILIRAKIS. Doctor, would you submit that white paper for the record?

Mr. MILLER. It has been submitted, and we will do so again. It was our first paper on this when the—

Mr. BILIRAKIS. Please do so. The staff is not certain.

[The information referred to follows:]

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS

ON EFFORTS TO RESOLVE THE CONTROVERSY OVER THE ORGAN PROCUREMENT AND
TRANSPLANTATION NETWORK

Introduction:

On October 21, 1998, a Congressionally ordered moratorium went into effect on implementation by the U.S. Department of Health and Human Services (DHHS) of the Final Rule published by HHS Secretary Donna Shalala in the Federal Register on April 2, 1998 (42 CFR Part 121). This one-year moratorium is scheduled to end on October 21, 1999 unless further extended by the U.S. Congress. In imposing the moratorium, Congress asked the Institute of Medicine (IOM) and the General Accounting Office to conduct a study of current policies of the Organ Procurement and Transplantation Network (OPTN) and the potential impact of the Final Rule. An IOM Committee was formed to conduct this study in early 1999, and it published a report, entitled "Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule," on July 20, 1999.

The American Society of Transplant Surgeons (ASTS), as the professional organization representing the surgeons, physicians and scientists who lead the transplant programs at the major medical centers across the United States, is committed to the continuing refinement of organ allocation policies to meet the needs of our patients. During the past 18 months, we have expressed both strong support for and strong opposition to various aspects of the Final Rule. We have met repeatedly with leaders of DHHS, have testified on this subject at hearings conducted by the U.S. Senate

and the U.S. House of Representatives, and have both testified before and provided voluminous written information to the Institute of Medicine during its deliberations in the spring of 1999.

We believe, based on numerous conversations, that an increasingly broad consensus exists among members of the transplant professional community on many of the most contentious aspects of the Final Rule. We believe if a new Final Rule were to be published today, it would not contain some of the elements that ASTS has most vigorously opposed. DHHS itself has stated that it intends to publish some number of unspecified changes to the Final Rule at some unspecified time prior to implementation. We are increasingly apprehensive, however, that the transplant community—and Members of the U.S. Congress, which is concluding its 1999 Session—will not see the proposed changes in a timeframe that would enable Congress to again legislatively defer implementation of the Final Rule if the changes are not found to be sufficiently responsive to our concerns.

While we do not propose in this position paper to repeat all of the points ASTS has made in published position statements and testimony, we would like to highlight the major concerns we have been discussing with DHHS—and our views on recommendations of the IOM Committee. We also urge Secretary Shalala to immediately publish the changes she proposes to make in the Final Rule. Given that the one-year moratorium is near an end and we still have not seen any proposed changes, we believe that when publication of changes by DHHS finally does occur, a reasonable period of time for consideration of, and reaction to, these changes by the transplant community—and Members of Congress—*prior to implementation* is both fair and essential.

NOTA and Secretarial Authority:

The most difficult area to resolve in our discussions with representatives of DHHS has been the question of Secretarial authority. We strongly believe the National Organ Transplant Act (NOTA), which was passed by Congress in 1984 and established the OPTN in the private sector under government contract, intended for the OPTN to make organ allocation policy based on sound medical principles and scientific data independent of political influence. This important principle is reaffirmed in the NOTA reauthorization legislation introduced this summer in the U.S. House by Chairman Michael Bilirakis and we hope that the legislative consideration of NOTA Reauthorization will move forward in the coming year.

Let us be clear that ASTS supports preservation of the Secretary's legitimate oversight role. Three of the five specific recommendations included in the IOM Committee's report addressed the area of oversight and review. The committee concluded that "oversight and review of the nation's organ procurement and transplantation system needs to be enhanced to improve the system's accountability to the public and to ensure that it operates effectively in the public interest." We endorse Recommendation 8.1 (Exercise Federal Oversight) and we stand ready to assist DHHS in defining and updating performance standards for the OPTN, OPOs and transplant centers.

We simultaneously recognize and support the responsibility of the OPTN to make specific organ allocation policy based on sound medical principles and scientific data. We have expressed to DHHS our concerns that sections 121.4 (b) and (d) could be interpreted as setting the stage for the Secretary of DHHS to make specific allocation policy, and have suggested changes in these sections to clarify the respective roles. DHHS's oversight responsibility should be to ensure that the policies that guide the operation of the system are equitable, based on sound medical science, and are adhered to. However, the Secretary must not dictate specific transplant practices or medical judgments. The OPTN's responsibility is to make specific policy concerning allocation and to modify that policy on the basis of sound medical science and developing medical practices.

Independent Scientific Review:

We believe IOM Recommendation 8.2, that the Department "establish an external independent, multidisciplinary scientific review board," has great merit. We agree with the committee that the organ allocation system should be reviewed periodically by an independent body separate from the OPTN. Obviously, a number of key issues remain to be addressed, including the makeup of this board, how members would be appointed, and what issues the board would review.

To be truly independent, we believe it important that the independent scientific review panel not be appointed at the sole discretion of the Secretary, and since this panel will be reviewing issues of medical judgment, we believe it imperative that this panel consist of not more nor less than 50 per cent transplant surgeons and physicians active in the field of transplantation. We believe an appropriately com-

posed body could bring medically sound resolution to difficult or contentious problems through careful objective review. We would then expect the Secretary and the OPTN to work together to develop solutions based upon recommendations of this body. We are prepared to suggest appropriate scientific experts to participate in these reviews.

Standardized listing and de-listing criteria:

The transplant community currently recognizes the need for standardized listing criteria, de-listing criteria and criteria for determining medical status. It is clearly within the purview of the OPTN to develop these criteria, and to continually refine them based upon changes in clinical care resulting from advances in medical science. We believe the Final Rule should instruct the OPTN to develop standardized listing and de-listing criteria, and to develop a process for both prospective and retrospective review for compliance. It should also provide a mechanism for funding prospective review, such as an increase in listing fees. In this area, we would expect that DHHS would be in a position of enforcing sanctions for non-compliance, and we urge that the language of the Final Rule be changed to clearly reflect this.

Evaluation and Enforcement:

We totally agree that allocation and other policies, such as standardized listing and de-listing criteria, must be enforced. However, as noted in section 121.10, the only enforcement currently specified would involve relatively harsh penalties, including termination of a transplant hospital's participation in Medicare or Medicaid, or termination of a transplant hospital's reimbursement under Medicare or Medicaid.

We believe the Rule should direct the OPTN to make recommendations on graduated enforcement options, and work with DHHS to develop a process for corrective action prior to imposition of severe sanctions. Among the issues to be addressed is due process, including at what level of enforcement Secretarial approval is required prior to imposition of penalties.

Organ specific allocation policies:

We have previously emphasized the important principle that different organ transplants require different allocation policies. The IOM report is careful to make recommendations about liver transplantation only. Objective criteria of disease severity may be relevant to organs in which there is no suitable life support system, such as livers or hearts. These types of criteria may have no relevance to other organ transplants, such as kidneys or pancreata, for which there are suitable support techniques. We urge the Secretary to review the Final Rule and indicate that other principles may apply to such organs.

Reducing Socio-Economic inequities:

We are encouraged by the IOM report's conclusion that "the most important predictors of equity in access to transplant services lie outside the transplantation system—that is, access to health insurance and high-quality health care services. Thus we are concerned that Section 121.4, subsection (3) of the final rule may seem to place a too-heavy burden on transplant hospitals and OPOs. Specifically, we propose that subsection (3) be changed to: "(i) Ensuring that patients in need of transplant are listed without regard to source of payment. (ii) Procedures for transplant hospitals to make reasonable efforts to obtain from other sources ..."

OPTN Board Composition:

The final rule in Section 121.3 mandates an OPTN Board with a minimum of 30 members. Two seats are specifically allocated to transplant surgeons and two to transplant physicians. It provides that "transplant candidates, transplant recipients, organ donors and family members" shall comprise "at least 25 percent" of Board members; and that transplant surgeons and transplant physicians shall comprise "no more than 50 percent." We strongly believe that because of the technical and scientific as well as ethical and social problems continuously occurring in this field, transplant physicians and surgeons should comprise no more nor less than 50 percent of the membership of the Board.

Allocation of Organs:

In 1998, DHHS contended that differences in the median time that patients spent waiting for a transplant at various centers demonstrated a fundamental unfairness of the current allocation system, and argued on that basis for immediate implementation of the Final Rule.

ASTS has always taken the position that waiting times as used by DHHS were not a good indicator of fairness, and totally agree with the data analysis performed

by the IOM Committee which clearly indicates that waiting time is not a reasonable measure of equity of allocation for patients nor is the disparity of overall median waiting time a reasonable measure of fairness of the current system.

But while we do not believe that waiting times as currently used are an appropriate performance measure, we are not—in the absence of a better methodology—prepared to totally endorse the IOM Recommendation to “discontinue use of waiting time as an allocation criterion for patients in Status 2B and 3.” We believe waiting times might continue to be one consideration in the triage of liver patients in Status 2b and 3 when all other medical criteria are equal.

Thus, we recommend that certain sections of 121.8 be revised. As we have previously stated, neither time waiting nor medical urgency can be considered absolute measures of equity for allocation of all types of organs for transplantation. For these reasons, we would suggest that the final rule contain general principles of equity, and suggest that it be left to the OPTN to develop the specific policies that achieve equity.

Record Maintenance and Reporting Requirements:

We endorse IOM Recommendations 8.3 (Improve Data Collection and Dissemination). We strongly agree that physicians, patients and the public should have access to accurate, understandable, and timely information regarding performance of the OPTN, OPOs and transplant centers. However, the provisions in Section 121.11 mandating that updated data be made available to the public “no less frequently than every six months . . . and shall be presented no more than six months later than the period to which they apply” are not currently realistic. We propose that data be collected annually. The one-year border will likely lead to more accurate and efficient reporting. We also propose that data made available within one year after the period to which it applies, but that it be made available more quickly at a time when implementation of improved systems make this possible. Within two years of the date of implementation of the Final Rule, we believe it should be possible to make data available no more than six months later than the period to which the data applies.

It is extremely important that the Secretary assure that any release of data be done in a manner that preserves the confidentiality of individual patients and donors. Understanding that organ transplantation is performed infrequently even in the busiest centers, identification of the date and location of a procedure could simultaneously identify the donor and recipient. Thus, in some circumstances, appropriate coding of some information may be necessary.

Organ Allocation Units:

We believe that Recommendation 1 (Establish Organ Allocation Areas for Livers) is deserving of further study and would urge the Secretary—even prior to issuance of the Final Rule—to direct the OPTN to present an analysis on those areas where broader geographic sharing is now in effect and possibly even conduct tests in certain geographic areas based on this recommendation. Although the report of the IOM committee found no evidence that supports the concerns that wider sharing—or disassociating organ retrieval from organ allocation—would lead to decreased donation or closure of small programs, further study is required before such a conclusion can be drawn. There is no question that several OPOs serving relatively small population areas have achieved some of the best donation rates, while other OPOs do not have comparable rates of donation. This would suggest that local factors may well influence organ donation, a very complex and delicate system, and that changes should be made with extreme care. Therefore, to the extent that steps are taken either to broaden organ allocation areas or disassociate organ retrieval from organ donation, we recommend that any change in policy be reviewed by the OPTN within one year, and at yearly thereafter, for its impact on patient outcomes, organ donation rates and transplant center volumes. We suggest that the OPTN might also undertake studies to determine whether the same principle of population-based allocation areas might improve the system of allocation of other organs.

DHHS and OPTN:

The report of the IOM committee clearly supports complementary roles of DHHS and the OPTN in the transplant system. Unfortunately, a variety of issues have led to substantial discord between the two organizations. While we understand the positions of the two parties and have commented on them previously, we believe it is critical to the transplant community that these disputes be ended. We are encouraged by Secretary Shalala’s announcement that DHHS is prepared to make alterations in the Final Rule, and urge her to publish those changes for consideration by the transplant community and the U.S. Congress at the earliest possible date.

September 16, 1999

Mr. BILIRAKIS. Please proceed, Mr. Green. I am sorry for interrupting.

Mr. GREEN. Dr. Payne?

Mr. PAYNE. My comments regarding wider sharing—

Mr. GREEN. Wider sharing within the region. I am not familiar with southeast Texas, but I am in the Southeast of the United States but understand Texas and sharing within the region, if not nationally.

Mr. PAYNE. If I could just preface the answer with a little explanation about OPO boundaries, because I would hate for UNOS to be saddled with the present OPO boundaries. Those boundaries were established by HHS at the point that they were established through HCFA. They were approved by HCFA. So those OPO boundaries were out of the purview of UNOS at the time.

Mr. GREEN. My concern, though, is that the goal, I think, was to regionalize it; not nationalize it, but regionalize it.

Mr. PAYNE. One of the first policies that UNOS adopted that extended sharing beyond OPO boundaries was that of identically matched kidneys. That truly is a national program where if a kidney is made available anywhere in the country, and it is a so-called perfect match with anybody on the waiting list, every effort is made to get it to that particular patient. If more than one patient is identified, the patient waiting the longest gets that organ. That is a long-standing program that is available and takes it—expands all OPOs in the country. That is an extraregional sharing agreement.

Mr. GREEN. That is for kidneys. That sounds like what HHS might be wanting to do. I am a cosponsor of the bill, and I am concerned about what may happen in my own State.

Mr. PAYNE. The point there is that there is efficacy in doing that. There is demonstrated improvement in outcome, so there is an effort made to do that, plus it is possible to do that with kidney transplants because the cold ischemic time that we heard about is not as critical in kidneys. They can go longer, so you have the time to do it. In a liver transplant, it is much more difficult to set up some sort of that broad sharing scheme.

So there have been stepwise attempts in regions around the country to broaden sharing agreements across OPOs. Many of them, they have been permitted by UNOS. Now, most recently the policy that has been put in place nationally is that it will mandate regional sharing, meaning the 11 UNOS administrative regions for status 1 liver transplant recipients. Again, that is because of the effectiveness of that for that particular patient population. Those patients have a demonstrated benefit.

Earlier on, Dr. Gibbons was talking about the differences between equity and effectiveness, and in that case there is a real effective change in going from that 4 days that people average down to 2 days. Everybody moves together. There is no change in equity. Everybody waits the same amount of time, but everybody wins in terms of effectiveness in terms of that patient.

Mr. GREEN. Thank you, Mr. Chairman. I see my light on. Since we haven't had a call for a vote, I have one question—

Mr. BILIRAKIS. Without objection, I have no problem with you asking that additional question.

Mr. GREEN. Thank you, Mr. Chairman.

Dr. Raub, you mentioned that proposed provisions, we won't have to wait much longer. But again, this legislation and Congress is going to have to act before October. It concerns me that we don't have those revisions now so that we can look at them and see what may need to be done. But that leads into, both for the administration and UNOS and the rest of the panel, that we have been dealing with this in delaying the effectiveness of the final rule. There has been—in earlier hearings there was effort to have both sides sit down and work together to see how we could come up with something that would be, and to this date I guess we haven't.

Has there been efforts between the administration and HHS and UNOS and the various groups to actually sit down and see how this could be worked out?

Mr. RAUB. Sir, repeated discussions and meetings have been held with both oral and written comments. As I indicated in my testimony, the Department has considered very seriously all of those comments and has identified some areas where, while not modifying the core principles or provisions of the rule, we think some refinements would improve it. And we are working hard to get those formulated before the moratorium date ends.

Mr. GREEN. Thank you, Mr. Chairman. Any other comments from—everyone else has a dog in the fight, so to speak.

Mr. MILLER. The American Society of Transplant Surgeons has met with the Department very recently. My colleague, the president of the society, Dr. Busuttil, met with Dr. Fox.

We are concerned that we will not see this rule until the very last minute. There may be language in the rule that still might be improved upon. This is of great concern to us.

Mr. RABKIN. Mr. Green, I would like to echo that thought and say that after having such a long period where we have had an opportunity to meet with the HHS and failed up to this date to have any concrete proposal for change, it troubles us as well in the PAT Coalition that we will not have the opportunity to weigh in and make suggestions for refinement. As an example, Dr. Raub pointed out that the IOM suggested an independent panel to be set up to look at some of these issues. In fact, then he went on to mention implementing the Federal Advisory Committee Act.

Well, the problem that we would immediately recognize is that under that act it is directly under the Secretary's discretion, it is advisory, and, frankly, we don't understand how that would add any benefit if it is not an independent panel. I think if you read the IOM report, they are very explicit, it needs to be an independent panel. So again, as an example, if the HHS comes forward at the 11th hour with a proposal, but has these nuances of the interpretation that it would be put forward in policy, that would be clearly objectionable to the members of the PAT Coalition.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Well, Mr. Green, you brought up a point certainly that I have been concerned with. We had all hoped—again, we are an ivory tower here. We use that term an awful lot, but it is true. We are required to make these tough choices and these tough deci-

sions when, in fact, people are better capable of doing it than we are.

So this is why we had hoped that the transplant surgeons, HHS would get together and work something out, and you haven't. I haven't been privy to those conversations, but frankly, in my mind, I really wonder whether HHS is willing to bend at all or just dead set on their ways. Again, I am not trying to belittle any efforts that HHS made in trying to work out these things and not resolving it and not having to pass legislation to do something that you all should be able to do, particularly when we hear of a bending on the part of UNOS in terms of some of these areas that have been pointed out.

Can you, Dr. Raub—would you furnish to the committee a copy of those areas that you are contemplating changing that Mr. Bryant went into that somewhat? Will do you that?

Mr. RAUB. Yes, sir.

Mr. BILIRAKIS. Can do you that within the next couple of days?

Mr. RAUB. I will do it as soon as we can, sir.

Mr. BARRETT. Mr. Chairman, just for my education, the 1-year moratorium, when does that expire? Do we know the day that expires?

Mr. BILIRAKIS. October 21.

Mr. BARRETT. I just want to say that I share the concern that we are going to see that about the same time we saw the Department's testimony.

Mr. BILIRAKIS. Well, Dr. Raub, you indicated you have been working on this. Is there any reason why you can't furnish at least where you are at this point within the next few days? You will furnish it when you can. That might not be until late October.

Mr. RAUB. Some of the items are still in the early stages of crafting.

Mr. BILIRAKIS. The moratorium is almost over, and they are still in the early stages of drafting. I sometimes wonder if—well, sir, we need that information. I frankly think that the industry out there, the transplant industry, needs that information, and I think they need it long before to give them an opportunity—I mean, I don't think that they should be left with what we have been here today, not having seen the testimony until an hour before the hearing started.

I say that with all due respect, but you should also realize that—well, I am going to ask that that information, whatever is available—and whatever isn't available, I guess you can't furnish—be submitted to this committee within—let's say within 7 days of today?

Need 48 hours? Why?

I am told that you have that information, and you are—all right, 48 hours. I am going to ask that it be furnished in 48 hours. I don't think that we should have to go through any legal proceedings or whatnot in order to get that.

Can you do that, what you have?

Mr. RAUB. I will convey that request, sir.

Mr. BILIRAKIS. Please, Dr. Raub, do that. We want to do this the right way, the nice way.

All right. A vote is being called on the floor. We have a number of questions—oh, yes. A statement here submitted by Charles Fisk; a statement here by Bruce Weir, Transplant Recipients International Organization, Inc., and a statement by Congressman Pete Stark. I would ask as the Chair unanimous consent those be made a part of the record.

There are a number of questions as per always, as per usual that have not been asked, and we would like to furnish those to you in writing and request that you respond to them as quickly as you can, because, again, we are trying to do the right thing. I know there has been more adversarial taking place at that table there than frankly usually takes place up here, but believe it or not, we are trying to do the right thing. Whatever information you furnish to us could be helpful.

The hearing is adjourned. Thank you. Thank you for your patience.

[Whereupon, at 5:45 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF CHARLES FISKE, UNOS GENERAL PUBLIC MEMBER

Mr. Chairman and Members of the Subcommittee: Thank you for allowing me to submit written testimony on the reauthorization of the National Organ Transplant Act. I came before this committee in April of 1990 and also April of 1993 to address issues about the national transplant system. My involvement in organ transplantation began in 1982 when my then nine-month old daughter, Jamie needed a liver transplant. At that time there was not much of a system in place for matching donors with recipients. In addition liver transplants had not been performed on anyone as young as Jamie and since there were only two liver transplant centers in the country our family faced a difficult ordeal. Jamie was successfully transplanted in November at age eleven months at the University of Minnesota Hospital.

The following Spring (April 1983) we came before then, Congressman Al Gore who was conducting hearing on the problems transplant patients faced. In the fall of that year Senator Orrin Hatch held hearings to learn of the ordeals that we and other families encountered while waiting for an organ to be found in time. Senator Hatch was familiar with Jamie's situation since the donated liver came from Jesse Bellon of Alpine, Utah. In 1984, President Reagan signed the National Transplant Act calling for a Task Force to study the issue. The task force concluded that a single national system would ensure that these national resources—donated organs—could be effectively allocated fairly to all needing an organ transplant. Since then, I have been actively involved in the issue and served on the UNOS (United Network for Organ Sharing—the federal contractor) Board of Directors for four years. Currently, I am one of only nine UNOS general public members. My observations and conclusions today are similar in some respects to my testimony previously presented before this same committee. We've come far but still have a long way to go to encourage the transplant system to be responsive to patients no matter who they are or where they live. The implementation of the HHS transplant regulations will take the care of patients to the next level. Passage of H.R. 2418 will be a step backwards in this process and should not be passed. Congress has directed that the single national system be response to all medically urgent patients especially those with the least access.

Congress must again encourage and demand that the National Transplant System reflect the needs of the patient population first before serving the unique interests of any transplant center. I've always advocated that the system be fair so that those patients who are medically most urgent receive first attention. Patients should not have to chase organs but rather be assured that when their time comes for transplantation they, given their medical status, will have a fair chance of receiving an organ. Currently the system is based on local preference so that the available organ is given locally even if there is another more medically urgent patient in the next local area. If the organ can't be used it is distributed regionally and then nationally. Recently UNOS passed a resolution to have organs shared with status one patients (most medically urgent with seven days to live) within each of the eleven regions in the country. This is a good first step. Allocation determined primarily through geographic boundaries rather than medical urgency makes little sense especially if

those organs can be safely transported greater distances. The wider allocation of organs needs to be expanded to include status 2A and 2B patients as well. There has been a marked increase in the number of transplant centers. As a result, with more patients needing transplantation the supply of available organs cannot meet the current demand.

Congress needs to require that the national transplant system take the following steps:

1) There should be *greater oversight* on the system to protect patients from the self-interests of transplant centers. The UNOS Board is comprised of many individuals who represent various transplant centers throughout the country. Often they are voting on policies that directly affect the financial interests of their own institutions. On the one hand the contractor is a membership organization and on the other a regulatory body. Over the course of years this has been a difficult task for the contractor. Greater oversight would assure the general public that the system is in operating the best interest of all patients whether they lived in New England or on the West Coast. That oversight involves the establishment of specific standards that not only protect the public but also assure the transplant community that there is a mechanism in place to encourage compliance with public policy directives. Only the Secretary can issue public policy that has the effect of law. Much of current debate over the NOTA reauthorization has to do with the confusion between the development of public policy and the practice of medicine. The current contractor and a number of transplant centers have determined that all transplant issues are considered the practice of medicine and are unwilling to respond positively to standards that have been established for the public policy purposes. Much energy has been spent circling the wagons to keep the Department at bay when in reality the public strongly supports a system that meets the needs of its most medically urgent. The transplant system is not the private domain of a certain select group within the transplant community but directly connected to all our citizens on whom we depend for organ donation. It is the general public through its patient registration fees and tax dollars that is fueling the system. To suggest that the National System can fairly operate on its own is both unrealistic and shortsighted. The recent border war over organ allocation between Wisconsin and Illinois is a prime example of special interests winning out over patients' interests.

2) *The most medically urgent patients must receive organs first.* Distribution for organs for the most urgent category could be realistically done beyond the boundaries of our current systems at both the local level and the regional level. The recently completed Institute of Medicine studies found that the current system now operating could be greatly improved so that organs may be reaching to most medically urgent. The Institute of Medicine did find that the less urgent patients (Status 3) were being transplanted at the expense of those who are most medically urgent (Status 1).

3) *Data should be made available in a timely fashion.* This data is not the private property of the federal contract and should be accessible to physicians and patients who make decisions on which center to approach for treatment. Data must be used to help drive public policy decisions so that parochial interests of the various transplant centers cannot come before the interests of patients.

4) *Patient registration fees* should reflect the cost of helping run the transplant system rather than fuel the special interest and lobby efforts of the contractor.

5) Greater steps need to be taken so that the "*green screen*" (no dollars, no transplant) affect is adequately understood as a major impediment preventing some patients from receiving care.

Congress has the ability to require this be done. The public needs to have confidence in the system so that when organs are distributed each patient can receive an organ in a timely fashion when their turn becomes available.

I'll submit copies of my prior testimonies from 1990 and 1993. Issues that were raised then are yet to be resolved. I would urge this Committee to look forward not only in fully supporting the HHS regulations but also encouraging the current contractor to take the immediate steps necessary to put an allocation system in place that is responsive to current needs of the general public. The clear and astute recommendations that have come forward from the recently published Institute of Medicine report on the transplant system have supported the Department's efforts to encourage the contractor to be more responsive to the needs of patients. Once the changes have been enacted a full reauthorization of NOTA is in order. A more comprehensive bill to include the recommendations of the IOM report, the OIG report (August 1999) and the April 1998 HHS regulations should be considered in the spring of 2000.

Again I thank the Committee for the opportunity to present this information and I am available at anytime to review this matter with you.

PREPARED STATEMENT OF BRUCE WEIR, PRESIDENT, TRANSPLANT RECIPIENTS
INTERNATIONAL ORGANIZATION, INC.

I am submitting this testimony today on behalf of a vital segment of the national transplant system that has been, and still is, quite under-represented...the patients.

In April of 1998, the Secretary of the Health and Human Services (HHS) issued a "Final Rule" that addressed certain areas in the present system that need improvement (allocation of organs, oversight of the system, to name a couple).

United Network of Organ Sharing (UNOS), who holds the contract of the Organ Procurement and Transplant Network (OPTN), decided to fight these changes and the two sides became polarized. No gain for either side; and even worse...the patients lost. Many of the changes would have helped a patient's chances of being transplanted sooner. When things got to an impasse, UNOS then successfully lobbied Congress to issue a moratorium for one year, asking the Institute of Medicine (IOM) to study the Rule and the issues having been raised to see if the Rule had any merit. The IOM Report was issued on July 20, 1999 and generally supported the reasons the "Final Rule" was issued and debunked the untruths spread by its opponents. The moratorium expires October 21, 1999.

The very Congress that ordered the moratorium, not having yet studied or evaluated the IOM report, is now embarking on a mission to rewrite the law that established the OPTN, how it operates and what, if any oversight and authority the Secretary of HHS might or should have over the national organ transplant system.

What I have seen of the proposed changes only heightens my concerns. This bill is greatly skewed in favor of OPTN and lessens the power and authority of HHS. There needs to be balance. This bill would create imbalance.

I urge you all to seriously consider whether this is the time to even consider such changes. Transplant centers may feel these changes are necessary to help insure their future. This is not the time for patients—for while *they* are waiting, they have no future.

PREPARED STATEMENT OF HON. PETE STARK, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF CALIFORNIA

Mr. Chairman: Thank you for holding this hearing today which will help educate Members concerning the need for a more effective and fair system of organ allocation.

Every day 10 people die in this country waiting for an organ transplant. At least 65,000 Americans are currently awaiting an organ transplant. There is no disagreement about the problem—there aren't enough organs to meet the needs of patients. This Congress, I introduced legislation, H.R. 941, the "Gift of Life Congressional Medal Act of 1999." This legislation encourages donations thereby making more organs available for potential donation. I hope Members would consider this effort to increase donations.

In April of last year, after extensive public debate, the Department of Health and Human Services issued regulations intended to provide oversight for the nation's organ transplant system and to help guide the transplant community to create a fairer transplant system. The FY '99 Appropriations bill included a moratorium on the regulations until October 21 of this year. Congress also directed the Institute of Medicine (IoM) to report on the current organ allocation system.

The Secretary's regulation will let medical people make medical decisions about the best way to allocate the limited number of donated organs within a framework that, as set forth by the IoM, will improve the function of the system. The Secretary's regulation is urgently needed by patients across the country.

I believe there is a great deal of evidence of the need for timely implementation of the Secretary's regulations concerning organ allocation policies.

For example, a recent report from the HHS Office of Inspector General found that the Secretary's new transplant rules would not impose new hardships on patients from small communities who need transplants. According to the OIG, most transplant centers are clustered around major cities and it is a "myth" that most Americans now have access to transplants virtually in their backyard. Thus the regulation won't hurt "local access" because such local access doesn't truly exist.

Also, the Institute of Medicine has issued its report with conclusions that are very supportive of the Department's regulations. The IoM supports having the Federal government exercise its legitimate oversight responsibilities under the National Organ Transplant Act, instead of allowing a federal contractor essentially make the rules. The report also declares that the current system would be significantly en-

hanced if the allocation of scarce organs were done over larger populations than is now the case.

The IoM report stated that “Vigilant and conscientious oversight and review of programs...are critically important to ensuring accountability on the part of the OPTN and other participants in the organ procurements and transplantation system.” The report also concluded that the Department’s Final Rule appropriately places oversight responsibility with the federal government. Yet H.R. 2418 would set allocation policies different than those contained in the Department’s regulations.

Among other flaws, H.R. 2418 provides unreasonable protections for the current contractor (UNOS), removes the Secretary’s legitimate oversight authority over the program, while simultaneously making data less available to the public. It is a significant step backward from even current law. And, in its delegation of power to private parties, it is probably unconstitutional.

I can think of no better way to put patients first than to make the system fair for all. This issue is about putting patients first—not putting transplant bureaucracies first.

Mr. Chairman, armed with the strong support of the IoM report, Congress should oppose another moratorium and should not enact H.R. 2418.

PREPARED STATEMENT OF THE NATIONAL KIDNEY FOUNDATION

On behalf of the thousands of individuals who are on waiting lists for an organ transplant, we wish to thank you for introducing legislation to reauthorize the National Organ Transplant Act (NOTA). The Mission of the National Kidney Foundation (NKF) is to prevent kidney and urinary tract diseases, improve the health and well-being of individuals and families affected by these diseases and increase the availability of all organs for transplantation. NKF represents 30,000 lay and professional volunteers from all walks of life and every part of the country.

The NKF has long held that NOTA should be reauthorized in an effort to expand organ donation and we are pleased that H.R. 2418 addresses the problem of the shortage of organs available for transplant in this country. In addition, we are supportive of the effort to clarify the responsibility for developing, establishing, and maintaining medical criteria and standards for organ procurement and transplantation as a function of the OPTN. Further, we believe that the transplant community at large should play an integral role in the development of these policies. The NKF agrees that the OPTN shall make available timely information on outcomes at specific transplant centers, as you have provided for in Sec. 3(d)(2), so as to help transplant candidates make informed choices.

Research supported by the NKF Council of Nephrology Social Workers shows that unreimbursed expenses serve as a disincentive to living organ donation. As such, we are very appreciative and supportive of Sec. 5 of H.R. 2418, “Payment of Travel and Subsistence Expenses Incurred Toward Living Organ Donation.” However, we urge you to remove the provision that the donor must reside in a different State than the recipient. Certain expenses, such as the need for temporary day care, are incurred regardless of where the donor resides and a transplant center in-state could be at a greater distance from the donor than one in a State different from that in which the donor lives. We also urge you to remove the provision that restricts payments to situations in which the annual income of the organ recipient is less than \$35,000. It is our belief that it is more appropriate for States, transplant centers, organ procurement organizations and voluntary health agencies to determine who should be eligible for assistance in each particular instance. Furthermore, any means test might be more appropriate for the donor rather than the recipient. We also believe Sec. 4(c) will be useful toward increasing organ donation, specifically as this would facilitate demonstration projects on the efficacy and acceptability of financial incentives to families for cadaveric organ donation.

We have additional specific suggestions regarding H.R. 2418. With regards to the composition of the OPTN Board of Directors (Sec. 3(a)), we believe a more specific designation is warranted for transplant recipients, candidates for transplants, donors and donor families, rather than the “reasonable proportion” cited in the bill language, and we recommend that transplant surgeons and transplant physicians should comprise *not more than* 50% of the members of the OPTN Board. We also suggest that “transplant patients” be added in the list of groups with which the Comptroller General be required to consult in preparation of the General Accounting Office’s evaluation of the Network (Sec. 3(i)(2)).

Thank you for holding this hearing and for the opportunity to provide written testimony. We look forward to working with you to improve the efficiency and effectiveness of our nation’s organ procurement and transplant system.

LOUISIANA STATE UNIVERSITY MEDICAL CENTER
OFFICE OF THE CHANCELLOR
September 21, 1999

The Honorable THOMAS J. BLILEY, JR.
Chairman
House Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515-0106

DEAR CHAIRMAN BLILEY: I am writing on behalf of the Louisiana State University Health Sciences Center to express my deep concern that implementation of the DHHS Final Rule regarding organ allocation will jeopardize access to life-saving organ transplants needed by Louisiana's working poor and indigent. These are the very patients most dependent upon our institution's organ transplantation programs. However, H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999" appears to be in the best interest of these patients as it would provide them with continued access to organ transplantation. Introduced by Chairman Michael Bilirakis of the Health and Environment Subcommittee, Congressman Gene Green and Congressman Frank Pallone, H.R. 2418 is supportive not only of the organ transplantation programs at the LSU Health Sciences Centers in New Orleans and Shreveport, but also of most other medical centers across the country. For example, the bill specifies that functions "scientific, clinical or medical in nature" are within the "sole discretion" of the Organ Procurement and Transplantation Network (OPTN). Further, it restricts the Secretary of the Department of Health and Human Services from using provisions in the Social Security Act to exert broad oversight authority relative to the OPTN. These two provisions would effectively prevent DHHS from going forward with its OPTN Final Rule which, as I have stated, is not in the best interest of many of our patients.

As you know, Congress, through the appropriations process, thus far has blocked DHHS from implementing the Final Rule. However, on October 21, 1999, the current congressional moratorium will expire. My colleagues and I feel it is imperative for the future well-being of our patients that H.R. 2418 be considered by the appropriate authorizing committees in Congress.

Sincerely,

JOHN C. McDONALD, M.D., *Professor and Chairman*
Department of Surgery, LSU Health Sciences Center-Shreveport
PHILIP BOUDREAUX, M.D., *Professor of Surgery, LSUMC*
Division of Transplantation, President, Louisiana Organ Procurement Agency

cc: Louisiana Congressional Delegation
The Honorable Richard Ieyoub
Mervin L. Trail, M.D.
Bonnie J. Hymel

UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY
OFFICE OF THE VICE PRESIDENT
September 20, 1999

The Honorable THOMAS J. BLILEY, JR.
Chairman, House Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515-0106

DEAR CHAIRMAN BLILEY: As Acting Chief Executive Officer of UMDNJ-University Hospital in Newark, New Jersey, I am writing to lend my institution's strong support to the passage of H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999." Introduced by Chairman Michael Bilirakis of the Health and Environment Subcommittee and cosponsored by Congressman Frank Pallone of New Jersey, this legislation supports the interests of New Jersey's sole transplant program and other programs throughout the country. Provisions contained within the bill would effectively prevent DHHS from going forward with its OPTN Final Rule, which we strongly oppose as it threatens the continued viability of our outstanding liver transplant program.

As you know, the moratorium blocking DHHS from implementing the final rule is scheduled to expire on October 21 without any measure of compromise or consensus having been reached between the transplant community and the Administration. We believe that a strong show of support for H.R. 2418 in the House will send still another clear signal to the Secretary and the Administration that the Final

Rule as written is not acceptable and that DHHS should seek to accommodate the concerns held by most transplant centers throughout the nation.

Accordingly, I urge you to support H.R. 2418 and ask that you encourage your colleagues to do the same.

Sincerely,

DANIEL L. MARCANTUONO, FACHE
Acting Chief Executive Officer

CLARIAN HEALTH
September 22, 1999

The Honorable THOMAS J. BLILEY, JR.
Chairman
House Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515-0106

DEAR CHAIRMAN BLILEY: On behalf of Clarian Health Partners located in Indianapolis, Indiana, I am writing in support of H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999." Introduced by Chairman Michael Bilirakis of the Health and Environment Subcommittee, along with Congressmen Gang Green and Frank Pallone, this legislation is supportive of the interests of the organ transplantation programs at Clarian Health Partners and at most other medical centers across the country. For example, the bill specifies that those functions that are "scientific, clinical or medical in nature" are within the "sole discretion" of the Organ Procurement and Transplantation Network (OPTN). Further, it restricts the Secretary of the Department of Health and Human Services from using provisions in the Social Security Act to exert broad oversight authority relative to the OPTN. These two provisions would effectively prevent DHHS from going forward with its OPTN Final Rule, which Clarian Health and others strongly oppose.

As you know, Congress through the appropriations process has thus far blocked DHHS from implementing the Final Rule. However, on October 21, 1999, the current congressional moratorium will expire, and we feel it is imperative that this legislation be afforded the opportunity to be considered in the appropriate authorizing committees in Congress. We believe a strong show of support for H.R. 2518 in the House will send a clear signal to the Administration that the Final Rule is not acceptable and that DHHS should seek to accommodate the concerns held by most transplant centers by modifying the regulations. Accordingly, I would urge you to support H.R. 2418, and also ask that you encourage your colleagues to do the same.

Thank you for your consideration.

Sincerely,

BRUCE M. MELCHERT
Vice President, Government Affairs

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
OFFICE OF THE PRESIDENT
September 20, 1999

The Honorable THOMAS J. BLILEY, JR.
Chairman
House Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515-0106

DEAR CHAIRMAN BLILEY: On behalf of the University of Alabama at Birmingham (UAB), I am writing in support of H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999" introduced by your colleague Michael Bilirakis, Chairman of the Health and Environment Subcommittee. As you know, this legislation is supportive of the interests of the organ transplantation programs at UAB and at most other medical centers across the country. It specifies that those functions that are "scientific, clinical or ethical in nature" are within the "sole discretion" of the Organ Procurement and Transplantation Network (OPTN). Further, it restricts the Secretary of the Department of Health and Human Services from using provisions in the Social Security Act to exert broad oversight authority relative to the OPTN. These two provisions would effectively prevent DHHS from going forward with its OPTN Final Rule, which we and others strongly oppose.

As you know, Congress through the appropriations process has thus far blocked DHHS from implementing the Final Rule. However, on October 21, 1999, the cur-

rent congressional moratorium will expire, and we feel it is imperative that this legislation be afforded the opportunity to be considered in the appropriate authorizing committees in Congress. Accordingly, I would urge you to lend your strong support to H.R. 2418. In this regard, I am pleased to report that we anticipate all of the House members from Alabama will be supportive of this important legislation.

Sincerely,

W. ANN REYNOLDS
President

THE UNIVERSITY OF TEXAS
HEALTH SCIENCE CENTER AT SAN ANTONIO
September 2, 1999

The Honorable JOE BARTON
2264 Rayburn HOB
Washington, DC 20515-4306

DEAR REPRESENTATIVE BARTON: I am writing to request that you become a cosponsor of Representative Michael Bilirakis's bill, H.R. 2418, which relates to transplant oversight by the Secretary of Health. I feel strongly that the government should have oversight of this process, but should not dictate the process as is suggested in the final rule, written by Secretary Shalala. I also feel that a dramatic overhaul of the current system is not in the interest of patients waiting for implantation in the United States. The current system works well. It can be improved upon, and UNOS has been taking progressive steps, including the recent sharing of organs, regionally for Status I patients, which are consistently improving the system.

The recent Institute of Medicine study indicated the current system was a good system, and suggested small changes to modify it, rather than a traumatic change, which in my opinion would be a total disaster. Most of Secretary Shalala's effort to change the system has been based on the political consideration of the inequality of waiting times, and the Institute of Medicine's study clearly concluded that waiting times should not be a measure of transplant equity. Therefore, I urge you to please not support the final rule, which is supported by Secretary Shalala, and I request that you call Representative Bilirakis's office, 202-225-5735 to add your name as a cosponsor on this bill.

Best regards,

GLENN HALFF, M.D.
*Associate Professor of Surgery,
Director, Division of Organ Transplantation*

SHANDS HEALTHCARE
September 21, 1999

The Honorable THOMAS J. BLILEY, JR.
*Chairman
House Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515-01066*

Dear Chairman Bliley: On behalf of Shands HealthCare at the University of Florida, I am writing in support of H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999." Introduced by Chairman Michael Bilirakis of the Health and Environment Subcommittee, along with Congressmen Gene Green and Frank Pallone, this legislation is supportive of the interests of the organ transplantation programs at Shands and at most other medical centers across the country. For example, the bill specifies that those functions that are "scientific, clinical or medical in nature" are within the "sole discretion" of the Organ Procurement and Transplantation Network (OPTN). Further, it restricts the Secretary of the Department of Health and Human Services from using provisions in the Social Security Act to exert broad oversight authority relative to the OPTN. These two provisions would effectively prevent DHHS from going forward with its OPTN Final Rule, which Shands and others strongly oppose.

As you know, Congress through the appropriations process has thus far blocked DHHS from implementing the Final Rule. However, on October 21, 1999, the current congressional moratorium will expire, and we feel it is imperative that this legislation be afforded the opportunity to be considered in the appropriate authorizing committees in Congress. We believe a strong show of support for H.R. 2418 in the

House will send a clear signal to the Administration that the Final Rule is not acceptable and that DHHS should seek to accommodate the concerns held by most implant centers by modifying the regulations. Accordingly, I would urge you to support H.R. 2418, and also ask that you encourage your colleagues to do the same.

Sincerely,

J. RICHARD GAINTNER, M.D.
Chief Executive Officer

SAINT LOUIS UNIVERSITY HOSPITAL
September 21, 1999

The Honorable THOMAS J. BLILEY, JR.
Chairman
House Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515-0106

DEAR CHAIRMAN BLILEY: On behalf of Saint Louis University Hospital, I am writing in support of H.R. 2418, the "Organ Procurement and Transplantation Network Amendments of 1999." Introduced by Chairman Michael Bilirakis of the Health and Environment Subcommittee, along with Congressmen Gene Green and Frank Pallone, this legislation is supportive of the interests of the organ transplantation programs at Saint Louis University Hospital and at most other medical centers across the country. For example, the bill specifies that those functions that are "scientific, clinical or medical in nature" are within the "sole discretion" of the Organ Procurement and Transplantation Network (OPTN). Further, it restricts the Secretary of the Department of Health and Human Services from using provisions in the Social Security Act to exert broad oversight authority relative to the OPTN. These two provisions would effectively prevent DHHS from going forward with its OPTN Final Rule, which Saint Louis University Hospital and others strongly oppose.

As you know, Congress through the appropriations process has thus far blocked DHHS from implementing the Final Rule. However, on October 21, 1999, the current congressional moratorium will expire, and we feel it is imperative that this legislation be afforded the opportunity to be considered in the appropriate authorizing committees in Congress.

We believe a strong show of support for H.R. 2418 in the House will send a clear signal to the Administration that the Final Rule is not acceptable and that DHHS should seek to accommodate the concerns held by most transplant centers by modifying the regulations. Accordingly, I would urge you to support H.R. 2418, and also ask that you encourage your colleagues to do the same.

Sincerely,

JAN BLOMFIELD
Administrator for Transplant Services, Saint Louis University Hospital

LIFECENTER
August 6, 1999

Representative ROB PORTMAN
United States Representative, Ohio
238 Cannon Building
Washington, DC 20515

RE: NOTA Reauthorization

DEAR REPRESENTATIVE PORTMAN, I am the Executive Director of Ohio Valley LifeCenter (LifeCenter). LifeCenter is the federally designated, non-profit organ procurement organization serving the Cincinnati area. Recently, Congressmen Bilirakis, Pallone, and Green introduced a bill to reauthorize the National Organ Transplant Act (NOTA). I would like to bring to your attention the importance of this bill to the Greater Cincinnati area. As you are aware, there has been considerable focus on the issue of organ allocation in the United States. At the heart of the matter is who is most capable of deciding national implant policy: those involved in the field or the federal government.

The bill has several key components:

- Increase organ donation.

- Reaffirm that authority for transplant policy decisions and medical/scientific judgment/decision-making reside in the transplant community, with the government's role being one of oversight.
- Preserves the Organ Procurement Transplant Network (OPTN) as a private entity.
- Requires that administrative/procedural functions of the OPTN be established by mutual agreement through a contract between the OPTN and HHS.
- Updates NOTA to reflect recent medical advances in the field of transplantation. LifeCenter fully supports this bill. I would request that you consider being a co-sponsor of this much-needed legislation.

Last year, Congress enacted a one-year moratorium on the organ allocation regulations proposed by the Department of Health and Human Services. This moratorium expires in October. This would be to the detriment of those Greater Cincinnati residents awaiting a life-saving organ transplant. The expiration of this moratorium heightens the need for NOTA reauthorization or, at the very least, an extension of the moratorium.

Please feel free to contact me, if I can provide additional information or assistance.

Sincerely,

DAVID D. LEWIS
Executive Director

LIFECENTER
August 6, 1999

Representative JOHN A. BOEHNER
United States Representative, Ohio
1011 Longworth HOB
Washington, DC 20515

RE: NOTA Reauthorization

DEAR REPRESENTATIVE BOEHNER, I am the Executive Director of Ohio Valley LifeCenter (LifeCenter). LifeCenter is the federally designated, non-profit organ procurement organization serving the Cincinnati area. Recently, Congressmen Bilirakis, Pallone, and Green introduced a bill to reauthorize the National Organ Transplant Act (NOTA). I would like to bring to your attention the importance of this bill to the Greater Cincinnati area. As you are aware, there has been considerable focus on the issue of organ allocation in the United States. At the heart of the matter is who is most capable of deciding national implant policy: those involved in the field or the federal government

The bill has several key components:

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- Requires that administrative/procedural functions of the OPTN be established by mutual agreement through a contract between the OPTN and HHS.
- Updates NOTA to reflect recent medical advances in the field of transplantation. LifeCenter fully supports this bill. I would request that you consider being a co-sponsor of this much-needed legislation.

Last year, Congress enacted a one-year moratorium on the organ allocation regulations proposed by the Department of Health and Human Services. This moratorium expires in October. This would be to the detriment of those Greater Cincinnati residents awaiting a life-saving organ transplant. The expiration of this moratorium heightens the need for NOTA reauthorization or, at the very least, an extension of the moratorium.

Please feel free to contact me, if I can provide additional information or assistance.

Sincerely,

DAVID D. LEWIS
Executive Director

LIFECENTER
August 6, 1999

Representative STEVE CHABOT
United States Representative, Ohio
129 Cannon Building
Washington, DC 20515

RE: NOTA Reauthorization

DEAR REPRESENTATIVE CHABOT, I am the Executive Director of Ohio Valley LifeCenter (LifeCenter). LifeCenter is the federally designated, non-profit organ procurement organization serving the Cincinnati area. Recently, Congressmen Bilirakis, Pallone, and Green introduced a bill to reauthorize the National Organ Transplant Act (NOTA). I would like to bring to your attention the importance of this bill to the Greater Cincinnati area. As you are aware, there has been considerable focus on the issue of organ allocation in the United States. At the heart of the matter is who is most capable of deciding national implant policy: those involved in the field or the federal government.

The bill has several key components:

- Increase organ donation.
- Reaffirm that authority for transplant policy decisions and medical/scientific judgment/decision-making reside in the transplant community, with the government's role being one of oversight.
- Preserves the Organ Procurement Transplant Network (OPTN) as a private entity.
- Requires that administrative/procedural functions of the OPTN be established by mutual agreement through a contract between the OPTN and HHS.
- Updates NOTA to reflect recent medical advances in the field of transplantation. LifeCenter fully supports this bill. I would request that you consider being a co-sponsor of this much-needed legislation.

Last year, Congress enacted a one-year moratorium on the organ allocation regulations proposed by the Department of Health and Human Services. This moratorium expires in October. This would be to the detriment of those Greater Cincinnati residents awaiting a life-saving organ transplant. The expiration of this moratorium heightens the need for NOTA reauthorization or, at the very least, an extension of the moratorium.

Please feel free to contact me, if I can provide additional information or assistance.

Sincerely,

DAVID D. LEWIS
Executive Director

LIFESOURCE
July 29, 1999

The Honorable BILL LUTHER
House of Representatives
Washington, DC 20510

DEAR REPRESENTATIVE LUTHER: On behalf of LifeSource, the Organ Procurement Organization serving Minnesota, I am writing to ask your support for legislation reauthorizing the National Organ Transplant Act (NOTA). This bill, H.R. 2418, was introduced on July 1, 1999. Your leadership in signing on as a co-sponsor of this legislation is important in maintaining the organ procurement and transplantation system.

The bill seeks to increase organ donation, and it reaffirms that authority for transplant policy decisions and medical/scientific decision-making will reside in the transplant community. This will maintain the appropriate administrative oversight of the Department of Health and Human Services while allowing the patients and medical professional to develop appropriate donation and allocation policies. The bill will also maintain the Organ Procurement and Transplantation Network's (OPTN) status as a private entity and will update NOTA to reflect medical advances in the field of transplantation. NOTA has not been re-authorized since 1990.

I also anticipate that additional language will be proposed via amendment which will address the process for designation and certification of Organ Procurement Organizations by the Health Care Financing Administration. LifeSource and other members of the OPO community, supported by findings of the General Accounting Office, believe that the current process and standards used to assess OPO performance are flawed and should be discontinued until a new process is developed. I am

enclosing a letter to Jeffrey L. Kang, M.D., M.P.H., HCFA, from the Association of Organ Procurement Organizations which further outlines OPO concerns.

We believe it is vitally important that the NOTA reauthorization move forward at this time and encourage you to sign on as a cosponsor. Please do not hesitate to contact me if I can provide any additional information.

Sincerely,

SUSAN GUNDERSON
Chief Executive Officer

UNIVERSITY OF FLORIDA
COLLEGE OF MEDICINE
August 11, 1999

The Honorable KAREN THURMAN
440 Cannon HOB
Washington DC 20515
ATTN: Jeff Cohen

RE: Institute of Medicine Report

DEAR CONGRESSWOMAN THURMAN: I have reviewed Congressman William Coyne's letter dated July 29, 1999 that he sent to his colleagues in Congress regarding his interpretation of the Institute of Medicine's (IOM) report on organ allocation. Congressman Coyne's interpretation of the report is a rather limited one and does not, in the opinion of most transplant professionals, truly represent the content of that report. I thought it might be helpful to you and your staff to clarify some of these issues.

The most important point that Congressman Coyne fails to understand is that the IOM determined that geographic differences and waiting times are "not an appropriate measure of the fairness of the system." The claims made by the proponents of the HHS regulation are that waiting times vary from region to region. While this is true, it reflects the listing practices of centers in those regions and not the availability of organs. In fact, the waiting time for liver transplantation for all Status 1 patients is remarkably similar in every UNOS Region across the country (two to four days). The IOM clearly recommends that the use of waiting time as an allocation criterion for statuses 2B and 3 be discontinued. The IOM noted that the heavy emphasis placed on waiting times by HHS created the perception that the system was unfair.

The IOM report does not, as Congressman Coyne states, suggest that the Health and Human Services (HHS) regulations should be implemented. The IOM in fact determined that the liver organ allocation system is "reasonably effective and equitable" and that no system will ever function perfectly when the need for organs vastly exceeds the demands. The IOM does suggest that sharing of livers for the Status 1 (sickest patient) Category be done over areas consisting of approximately 9,000,000 people. This is, however, similar to the geographically based system already in place. In fact, all of the UNOS Regions currently share livers for this patient status category. No changes need to be effected in order to fulfill this recommendation.

Congressman Coyne neglected to mention that the IOM found that the institution of these regulations would increase the overall cost of transplantation. Congressman Coyne's letter states that the IOM concluded that the new regulations would not cause small transplant centers to close or negatively impact access for minority populations. The IOM was unable to come up with any firm evidence based conclusions regarding these issues, but they did recognize that a consensus existed in the transplant community that the implementation of these regulations would lead to these problems.

In summary, the findings of the IOM challenge the medical basis of the regulations suggested by the HHS. While they do endorse a note for federal oversight, I do not believe that it is their intention that anyone other than the medical community determine the rules for organ allocation.

I do not believe that Congressman Coyne's interpretation of the IOM report accurately reflects the content of that report. I hope that this letter is helpful and I would be happy to discuss this with you at your leisure.

Thank you for your ongoing concern regarding the organ allocation issue.

Sincerely,

ALAN REED, MD
Associate Professor of Surgery

UNIVERSITY HOSPITALS OF CLEVELAND
26 August, 1999

Congressman THOMAS C. SAWYER, Ohio
1414 Longworth House Office Building
Washington, DC 20515

DEAR CONGRESSMAN SAWYER: I am writing you to urge you to extend the moratorium on the HHS Organ Procurement and Transplantation Network Final Rule.

As you know Secretary Shalala and HHS have repeatedly sought to implement rules that would effectively nationalize organ acquisition. While effectively spun as a means to equalize access and ameliorate regional inequities, the real purpose of the proposed rule is to restore oligopoly in transplantation to a few centers, such as The University of Pittsburgh, which have seen volume disappear, have suffered financially, and which seek to repair that damage through use of friends and lobbyists to obtain governmental relief. The citizens of Ohio among others will see access to transplantations reduced as a result and those without means may lose it altogether.

The Institute of Medicine was asked to provide an evaluation of this controversial issue, and issued their report earlier this month.

Recently a letter from Secretary Shalala to Members of Congress cast the Institute of Medicine report—a neutral assessment of the problem—as an endorsement of her position.

It is nothing of the sort. In fact the IOM report is evenhanded. It notes that there are no real differences in waiting times for the sickest liver patients—the core argument of the Secretary's position and the *casus belli* of the dispute—but that there are differences among less ill patients, and that these could be erased by establishing catchment areas of 9 million or so. This is similar to what we have already in Ohio, and we can live with it. But it is not an endorsement for the very broad catchment areas necessary to afford the few HHS-favored centers what they seek. What the Secretary wants on their behalf is in effect a private bill.

Failure to extend the moratorium is certain to lead to a massive export of organs, recipients and ultimately skilled professionals from Ohio to other states. I cannot see how this pernicious policy change is in the interest of Ohioans and I think it both unwise and unfair.

Sincerely,

D. ALLAN GRAY, *Senior Vice President and General Manager*
Medical/Surgical Services, University Hospitals of Cleveland

MISSISSIPPI ORGAN RECOVERY AGENCY, INC.
July 14, 1999

Representative CHIP PICKERING
427 Cannon House Office Bldg.
Washington, D.C. 20515

Re: Organ Procurement and Transplantation Network Amendments of 1999

DEAR REP. PICKERING: As you are aware over the last two years there has been much discussion of the organ allocation process and who determines distribution of this scarce resource. Since the inception of the Organ Procurement and Transplant Network (OPTN), the United Network for Organ Sharing (UNOS) has been charged with overseeing allocation of organs for transplant in the United States. UNOS has done an excellent job over the years dealing with the very difficult task of determining how the precious gift of life of an organ transplant should optimally be shared to ensure maximal lives saved.

Currently Representative Michael Bilirakis (FL), Chair of the Subcommittee on Health and the Environment of the House Commerce Committee, is looking for co-sponsors for legislation he is introducing to ensure that efforts continue to allocate organs optimally. This legislation will ensure that Mississippians will continue to have fair and equitable access to transplantation. If this legislation is not passed, many Mississippians may die of organ failure and never get the opportunity of transplant, particularly minority Mississippians and those in the lower socio-economic strata.

Please support this legislation that should enable every Mississippian in need access to transplantation.

Please call if we can be of any further service or answer any questions.

Sincerely,

KEVIN STUMP,
Executive Executor
SHIRLEY SCHLESSINGER, M.D.
Medical Director

CENTER FOR DONATION & TRANSPLANT
September 16, 1999

Hon. MICHAEL R. McNULTY
House of Representatives.
2161 Rayburn
Washington, DC 20515

DEAR CONGRESSMAN McNULTY: I am writing to ask for your support in cosponsoring the National Organ Transplant Reauthorization Bill, H.R. 2418. It is my understanding that there will be a hearing on this bill on September 22. For additional information or to be added as a cosponsor, the contact person in Congressman Biliarakis's office is Michael Reilly. The phone number is 202-225-5755.

As in the past, thank you for your support.

Sincerely,

FRANK TAFT
Director

TENNESSEE TRANSPLANT SOCIETY
August 2, 1999

The Honorable BILL FRIST
SD-567 Dirksen Senate Office Building
Washington, DC 20510-4205

DEAR SENATOR FRIST: The Tennessee Transplant Society (TTS) consists of all seven transplant centers, all of the transplant professionals (physicians, nurses, transplant coordinators), and all organ procurement organizations within the state of Tennessee. At the July 26 meeting of the TTS, there was a vote taken following discussion of the Institute of Medicine (IOM) Report and the continuing saga of the HHS final rule regarding the allocation of organs for transplant. The IOM report did not support the basic premise of the HHS rule, that is, waiting times for patients needing transplant are valid measure and should be equalized.

The Tennessee Transplant Society unanimously requests you to cosponsor Congressman Biliarakis' Bill H.R. 2418 "Organ Procurement and Transplantation Network Amendments of 1999." Additionally, if it does not look like H.R. 2418 is going to pass in this session of Congress, we would strongly encourage you to support an extension of the moratorium on the implementation of the HHS final rule (current effective date 10/1/99) while we study the ideas brought forward in the IOM report.

Sincerely yours,

C. WRIGHT PINSON, M.D., M.B.A.
President

JACKSONVILLE TRANSPLANT CENTER
July 26, 1999

The Honorable CORRINE BROWN
2444 Rayburn House Office Building
Independence Ave. and S. Capitol St., SW
Washington, DC 20510

DEAR REPRESENTATIVE BROWN: I write regarding H.R. 2418 (Organ Procurement and Transplant Patient Network amendments of 1999), a Bill before the House of Representatives. Since I serve patients in your District, I encourage your support of this Bill.

H.R. 2418 allows for the general functions of day-to-day organ donation and transplantation to continue throughout America. It maintains the truly excellent administrative structure and self governance of the Organ Procurement and Transplantation Network. Important in the latter is the fact that the Board governing the Network is inclusive not just of medical professionals, but of patients and public members. Further, the Bill establishes a workable and reasonable relationship of

oversight between the Secretary of Health and Human Services and the Network contractor.

Important new features of the Bill relate to access to transplantable organs and tissues, recognition that organs and tissues from certain animal sources may soon be applied to human disease, and enabling sections on provision of benefits for cadaveric organ donation should demonstration projects to increase organ donation be developed around survivor benefits. Finally, an important aspect of the Bill is that expenses of living organ donors be reimbursed through mechanisms similar to other aspects of organ transplant reimbursement.

May I thank you in advance for considering support of this important Bill which may so positively affect your constituents and my patient.

Sincerely,

THOMAS G. PETERS, M.D.
Clinical Professor of Surgery, University of Florida HSCJ

JACKSONVILLE TRANSPLANT CENTER
July 26, 1999

The Honorable CHARLES T. CANADY
*2432 Rayburn House Office Building
Independence Ave. and S. Capitol St., SW
Washington, DC 20510*

DEAR REPRESENTATIVE CANADY: I write regarding H.R. 2418 (Organ Procurement and Transplant Patient Network amendments of 1999), a Bill before the House of Representatives. Since I serve patients in your District, I encourage your support of this Bill.

H.R. 2418 allows for the general functions of day-to-day organ donation and transplantation to continue throughout America. It maintains the truly excellent administrative structure and self governance of the Organ Procurement and Transplantation Network. Important in the latter is the fact that the Board governing the Network is inclusive not just of medical professionals, but of patients and public members. Further, the Bill establishes a workable and reasonable relationship of oversight between the Secretary of Health and Human Services and the Network contractor.

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Sincerely,

THOMAS G. PETERS, M.D.
Clinical Professor of Surgery, University of Florida HSCJ

JACKSONVILLE TRANSPLANT CENTER
July 26, 1999

The Honorable TILLIE FOWLER
*106 Cannon House Office Building
Independence Ave. and S. Capitol St., SW
Washington, DC 20510*

DEAR REPRESENTATIVE FOWLER: I write regarding H.R. 2418 (Organ Procurement and Transplant Patient Network amendments of 1999), a Bill before the House of Representatives. Since I serve patients in your District, I encourage your support of this Bill.

H.R. 2418 allows for the general functions of day-to-day organ donation and transplantation to continue throughout America. It maintains the truly excellent administrative structure and self governance of the Organ Procurement and Transplantation Network. Important in the latter is the fact that the Board governing the Network is inclusive not just of medical professionals, but of patients and public members. Further, the Bill establishes a workable and reasonable relationship of oversight between the Secretary of Health and Human Services and the Network contractor.

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May I thank you in advance for considering support of this important Bill which may so positively affect your constituents and my patient.

Sincerely,

THOMAS G. PETERS, M.D.

Clinical Professor of Surgery, University of Florida HSCJ

JACKSONVILLE TRANSPLANT CENTER

July 26, 1999

The Honorable CLIFF STEARNS
2227 Rayburn House Office Building
Independence Ave. and S. Capitol St., SW
Washington, DC 20510

DEAR REPRESENTATIVE STEARNS: I write regarding H.R. 2418 (Organ Procurement and Transplant Patient Network amendments of 1999), a Bill before the House of Representatives. Since I serve patients in your District, I encourage your support of this Bill.

H.R. 2418 allows for the general functions of day-to-day organ donation and transplantation to continue throughout America. It maintains the truly excellent administrative structure and self governance of the Organ Procurement and Transplantation Network. Important in the latter is the fact that the Board governing the Network is inclusive not just of medical professionals, but of patients and public members. Further, the Bill establishes a workable and reasonable relationship of oversight between the Secretary of Health and Human Services and the Network contractor.

Important new features of the Bill relate to access to transplantable organs and tissues, recognition that organs and tissues from certain animal sources may soon be applied to human disease, and enabling sections on provision of benefits for cadaveric organ donation should demonstration projects to increase organ donation be developed around survivor benefits. Finally, an important aspect of the Bill is that expenses of living organ donors be reimbursed through mechanisms similar to other aspects of organ transplant reimbursement.

In your capacity as a member of the Commerce Committee, may I ask that you especially regard this Bill as an important step in serving patients in need of an organ transplant. I stand ready to provide further information or assistance to your office should that be necessary. May I thank you in advance for positively considering H.R. 2418.

Sincerely,

THOMAS G. PETERS, M.D.

Clinical Professor of Surgery, University of Florida HSCJ

THE UNIVERSITY HOSPITAL

September 3, 1999

The Honorable STEVE CHABOT
United States Representative, Ohio
129 Cannon Building
Washington, DC 20515

RE: House Bill: H.R. 2418

DEAR REPRESENTATIVE CHABOT: I am the Administrator of Transplant Services at The Health Alliance of Greater Cincinnati. Recently, Congressmen Bilirakis, Pallone, and Green introduced House Bill H.R. 2418 to reauthorize the National Organ Transplant Act (NOTA). I would like to bring to your attention the importance of this bill to the Greater Cincinnati area. As you are aware, there has been considerable focus on the issue of organ allocation in the United States. At the heart of the matter is who is most capable of deciding national transplant policy: those involved in the field or the federal government?

The bill has several key components:

- Increase organ donation.
- Decrease disincentives for living organ donation.
- Reaffirm that authority for transplant policy decisions and medical/scientific judgment/decision-making resides in the transplant community with the government's role being one of oversight.
- Preserves the Organ Procurement Transplant Network (OPTN) as a private entity.
- Requires that administrative/procedural functions of the OPTN be established by mutual agreement through a contract between the OPTN and HHS.
- Updates NOTA to reflect recent medical advances in the field of transplantation.

Last year, Congress imposed a one-year moratorium on the organ allocation regulations proposed by the Department of Health and Human Services. This moratorium expires October 21, 1999. Enactment of the HHS organ allocation regulation would be detrimental to the Greater Cincinnati residents awaiting a life-saving organ transplant. The expiration of this moratorium heightens the need for NOTA reauthorization or, at the very least, an extension of the moratorium.

I fully support the House Bill H.R. 2418. I am requesting that you consider being a cosponsor of this important and critical legislation.

Please contact me for additional information or assistance at (513) 584-1811.

Sincerely,

EDWARD Y. ZAVIA, M.B.A.
Administrator, Transplant Services

405 OWENDALE DRIVE
ANTIOCH, TN 37013
June 24, 1999

The Hon. ED BRYANT
408 Cannon House Office Bldg
Washington, D.C. 20515

DEAR MR. BRYANT, I am writing to you today concerning important pending legislation which will affect organ and tissue transplantation policy in the United States for years to come. I speak from the perspective of a donor father (both of my sons were organ donors following tragic accidents in 1990-91) and as the spouse of a kidney recipient in 1994. Tragically, my wife has since passed away, but I have been so energized by her determination and courage throughout her wait of over 25 months for an organ that I have been actively involved in organ donation matters since that date. Specifically, I have been a member of the national Board of Directors of Transplant Recipients International Organization (TRIO) and also the President of the Music City (Nashville area) TRIO local chapter. In addition, I have worked extensively with Rotary International, the National Kidney Foundation (NKF), Tennessee Donor Services (TDS), the Minority Organ Tissue Transplant Education Program (MOTTEP) and several other organizations to promote increased organ donation awareness.

I provide you with this detailed background information so that you can understand the depth of my frustration concerning the ongoing debate in the Congress over national transplantation policy. While there is general agreement that the existing policies developed by the National Organ and Transplant Act during the mid-80's are not perfect, it is the feeling of most of the "non-professionals" within the transplant community (recipients, donor families, and those currently waiting) that the system in operation today has served us well. It has proven to be remarkably adaptive to changing conditions as medical advances have taken place, and has resulted in a transplantation record that is the envy of the world. This has taken place primarily because of the wisdom of the Congress to establish a private partnership between the medical community and the patient population which is independent from undue political interference by government operatives, however well intentioned. Difficult decisions involving the allocation of scarce organ resources have been made by this informed private partnership, rather than by a corps of government attorneys and bureaucrats.

I do not want to sound harsh in the above assessment, but it is imperative that you understand that the current system has indeed served us well, and that any improvements should be made on the margins by legislation to strengthen, rather than dismember, the Organ Procurement Transplant Network (OPTN). This really should not become a partisan issue, as both sides should have an intense interest in insulating the organ transplant process from the political whims of whichever party is in control of the Executive Branch or the Congress. It is critical that you

insist that the current “firewall” be maintained so that transplantation policies are predictable, just, and institutionally immune from political tampering.

I would also like to address comments which have been made publicly by those purporting to represent all transplant patients and donor families. This is simply a myth. There are, in fact, many different viewpoints throughout this large and diverse community. As you can imagine, there are some who view the current system as “unfair” and in need of massive government intervention, if not outright total control. It is my experience that these folks, however vocal, are in a distinct minority, but their opinions are nonetheless real.

What I see is a vast majority of those Americans who are interested in transplant matters wanting the existing partnership of medical professionals and transplant patients to remain in charge of transplant policy. **Those who argue otherwise as “spokespersons” for transplant groups simply do not represent the views of the majority of their membership.** I say this with absolute certainty in the case of Transplant Recipients International Organization (TRIO), because as a Board member I asked repeatedly that our entire membership be polled on this key issue, and such never happened.

When we did poll our local chapter here in Tennessee, the results were overwhelming in support of the current non-political, private partnership (the OPTN). [The actual vote was 131-4]. In speaking with other TRIO chapter Presidents, I noted differing levels of support due to local factors, but the overall fact is that there is NOT unanimity in support of either side. Some of the other organizations which purport to speak for the transplant community (e.g., National Transplant Action) are simply ad hoc “fronts” which have been chartered by interested parties to lobby for passage of proposed HHS regulations which will financially favor them. The bottom line is that **no one** speaks for the *entire* transplant community and that there are mixed feelings about the issue throughout the U.S. I can report, however, that the vast majority of the TRIO members to whom I have personally spoken are opposed to government intervention and want the existing system to have simple improvements.

There is also a fear that large transplant centers with political clout will monopolize transplantation procedures by manipulating proposed rules dictated by FMS personnel. Opponents may dismiss such concerns as paranoia, but these worries are indeed genuine and have been supported by the monopolistic track record of certain large centers. Those of us who have had the opportunity to experience the expertise of some of the smaller, regional transplant centers understand first hand the excellence and talent available in many locations throughout the country. The benefit, which I have seen countless times, is that under the existing system families are able to provide local support for patients who do not have to travel long distances to receive life saving transplant operations.

As a two-time donor father I would like to comment personally on one aspect of organ donation which is frequently misstated by proponents of a “national” system. It is often stated by these people that donor families “do not care where organs of their loved ones go.” This may be correct in some cases, but I can report to you that many of us who have been in this most difficult situation have been acutely concerned that hope be provided first to those in need in our local region. We do not want these precious gifts to be treated as just some other government owned part shipped cross country to a large center currently in favor with federal rulemakers.

Obviously there are many other issues which are associated with this pending legislation, but I encourage you to focus on one thought: patients do not want a working, viable process with a proven track record to be dismembered and displaced by policies dictated by government bureaucrats subject to political pressure. Keep transplantation a predominantly medical issue with rules established by the existing partnership of medical experts, patients, and donor families.

Sincerely,

THOMAS L. MEREDITH

TENNESSEE DONOR SERVICES
September 21, 1999

The Honorable ED BRYANT
United States Representative
408 Cannon House Office Building
Washington, DC 20515-4207

Attention: Carrie Dawson, Legislative Aide

DEAR REPRESENTATIVE BRYANT: Tennessee Donor Services (TDS) is the federally designated Organ Procurement Organization (OPO) serving the vast majority of

Tennessee. On September 22, 1999 the House Commerce Committee will conduct hearings on H.R. 2418, the National Organ Transplant Act (NOTA) Reauthorization Bill. The bill has a significant number of bipartisan sponsors,

Last year, Congress extended a moratorium on the implementation of a federal rule that would have had a serious negative impact on the centers and patients we serve. This moratorium is set to expire October 21, 1999. On behalf of transplant centers, transplant physicians, donor families, and recipients that we serve, I request your support and urge you to cosponsor H.R. 2418, "Organ Procurement and Transplantation Network Amendments of 1999."

H.R. 2418 protects the integrity of organ procurement organizations and transplant centers all across the country. It reiterates the original intent of the National Organ Transplant Act of 1984 which was to create a national system that promotes and supports a central network in the private sector serving all of the citizens of the United States,

H.R. 2418 is unanimously supported by all Tennessee OPOs and ten transplant centers. In the area served by TDS, H.R. 2418 has the support of Vanderbilt University Medical Center, St. Thomas Hospital, Centennial Medical Center/Parkview, UT Medical Center, Johnson City Medical Center and Erlanger. H.R. 2418 is also unanimously supported by Mid-South Transplant Foundation and its affiliated centers.

We also encourage you to send a letter to the Secretary of HHS asking that the final rule be withdrawn in the meantime. If the Secretary fails to do so, we urge you to extend the moratorium until such time as a solution in the best interests of the patients we serve can be achieved.

Please contact Michael Reilly with Congressman Bilirakis' office at (202) 225-5755 to be added as a cosponsor, I thank you for your support of H.R. 2418. You may contact me at (615) 327-2247, if you have any questions or need additional information.

Sincerely,

LAWRENCE D. COCHRAN
Executive Director

UNIVERSITY OF ILLINOIS AT CHICAGO
Chicago, Illinois

The Honorable DIANA DEGETTE
1339 Longworth Building
U.S. House of Representatives
Washington, DC 20515-0601

DEAR CONGRESSWOMAN DEGETTE: Thank you for your letter requesting additional information in connection with the testimony I gave recently at a hearing of the Subcommittee on Health and the Environment relating to organ procurement and transplantation. I apologize for not getting back to you sooner; however, I have moved offices and mail has been delayed in reaching me.

You asked several questions relating to liver transplantation for pediatric patients, particularly in response to recent studies done by researchers at Pittsburgh Children's Hospital and the Medical University of South Carolina. Those studies apparently raised questions whether pediatric patients are receiving appropriate access to donated livers.

The Institute of Medicine Committee that prepared the report "Organ Procurement and Transplantation" was not specifically requested to investigate the issue of pediatric patients' access to transplantation and we did not do so. We did not have copies of the research you cite and I have not read them. Some of our analysis of transplant waiting times and mortality does, however, bear on one of the points raised in your letter and I am happy to share that with you.

According to your letter, the research studies you cited found that children are "55% more likely to die waiting for an organ transplant than adults." (Presumably this refers to liver transplants.) Our analysis yielded somewhat different conclusions. Although the most severely ill (status 1) children, aged 0-5, had a significantly lower rate of transplantation than status 1 adults, they also had a lower rate of pretransplant mortality. This finding suggests young children in status 1 are capable of living longer than adults in this status as they wait on the list. Less severely ill (status 2B) children (aged 0-5) actually had a higher rate of transplantation than status 2B adults and the least severely ill (status 3) children in all ages (aged 0-17) had transplantation rates that were significantly higher than adults. In both of these status groups, there was no difference between children and adults

in their pretransplant mortality rates. In addition, age was not a significant determinant of post-transplantation mortality.

There could be a variety of reasons why our findings differ from those cited in your letter, but without having read those studies I cannot pinpoint what they might be. The time period covered by the data, the comprehensiveness of the data, and whether patients were classified by severity of illness would be some of the things to look at. Our analysis reflects the experience of all liver transplant patients who were on waiting lists anywhere in the nation from the start of 1998 through the first quarter of 1999 and we stratified these patients by severity of illness (status level).

Finally, I would note that the recommendation of the IOM Committee that donated livers be allocated over larger populations would appear to improve the likelihood that a suitable organ would be found for a child awaiting a transplant. Furthermore, the Committee's recommendation to eliminate waiting time as a criterion for allocating organs to status 2B and status 3 patients and to substitute more medically relevant criteria to bring about a better match (e.g. pediatric versus adult) would also appear to benefit children.

I hope this information is useful to you in your review of this important issue.

Sincerely,

ROBERT D. GIBBONS, *Professor of Biostatistics*
University of Illinois at Chicago

IOM Organ Procurement and Transplantation Committee Member

cc: The Honorable Michael Bilirakis

RESPONSES OF WILLIAM F. RAUB, DEPUTY ASSISTANT SECRETARY FOR PLANNING AND EVALUATION/SCIENCE POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, TO QUESTIONS OF HON. DIANA DEGETTE

Question: Recent studies by researchers at Pittsburgh Children's Hospital and the Medical University of South Carolina reveal some rather disturbing trends with respect to pediatric transplantation. The studies indicate that: Two-thirds of liver donations by children go to adults; and Pediatric liver donations have increased through the 1990's. And yet—The number of children who received a donated liver from another child decreased dramatically from 1990 to 1996; and, Children are 55% more likely to die while waiting for an organ transplant than adults.

According to American Medical News, "Europe has virtually eliminated deaths of children while on liver waiting lists by giving them priority over adults for pediatric organs..."

The Administration's Final Rule, H.R. 2418, and the IOM report all fail to directly address this issue.

To all the members of the panel, what are we as a nation doing to address this growing and unacceptable problem for children in need of organ transplantations and what additional steps need to be taken to reduce pediatric mortality rates?

Response: The current liver allocation conventions of the Organ Procurement and Transplantation Network (OPTN) give priority to children 18 years of age and under, who account for 10 percent of transplant candidates. The 1998 HHS regulation made clear that the Department intended the OPTN to address the special needs of children as it developed fairer allocation policies:

"...current OPTN policies take into account the special medical needs of children. The Secretary endorses this approach and expects that the OPTN will continue to take these needs into account as it develops new medical criteria and allocation policies." (63 FR 16315; also discussed at 63 FR 16304)

The recent amendments to that regulation reaffirm this intention:

"The Department wishes to emphasize, however, that these changes are not intended to limit the ability of the OPTN to address special situations such as the unique needs of young children." (64 FR 56657)

Based on the OPTN's actions, the guidance provided in the HHS regulations, and our expectations for continued improvement in split-liver techniques (whereby an adult donor liver that is too large for a child can be divided surgically to transplant two individuals in need of a smaller liver), the Department is optimistic that children will have a growing new source of opportunities for transplantation.

Children have the following outcomes under current OPTN liver allocation policies: they receive liver transplants at a higher rate (60%) than do adults (45%); their survival at one year with or without transplant (21%) is similar to all other age groups; and they die awaiting a transplant at a slightly lower rate (12.5%) than do adults on the waiting lists (14%).

Despite these generally favorable data, room remains for improvement. The Department—through its efforts to increase organ donation generally (its National Organ and Tissue Donor Initiative), its research to improve transplantation procedures, and its oversight of the OPTN—will continue to strive to meet the needs of children 18 years of age and under who are candidates for liver or other organ transplantation. The Department intends to highlight this issue as it seeks comments from the public and advice from the Advisory Committee on Organ Transplantation on new allocation policies developed in response to the amended HHS regulation.