OVERSIGHT OF THE NATIONAL ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES

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REFORM AND OVERSIGHT
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OVERSIGHT OF THE NATIONAL ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

WEDNESDAY, APRIL 8, 1998

House of Representatives,
Subcommittee on Human Resources,
Committee on Government Reform and Oversight,
Milwaukee, WI.

The subcommittee met, pursuant to notice, at 11 a.m., in the Alumni Center Auditorium, Medical College of Wisconsin, 8701 Watertown Plank Road, Milwaukee, WI, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays and Barrett.

Staff present: Lawrence J. Halloran, staff director and counsel; Anne Marie Finley, professional staff member; Teresa Austin, clerk; and Cherri L. Branson, minority counsel.

Mr. Shays. Good morning. My name is Christopher Shays. I represent the Fourth Congressional District in Connecticut. My Midwest experience found me in college in Illinois, so I have a little bit of if, if you call that the Midwest in Wisconsin, and to tell you that I am very excited that our committee is here. This is the first hearing that we've had on this issue, and we decided to have our hearing here at the request of Tom Barrett, who serves on the committee as a very active member, and we're going to have a very interesting, I think, and informative day.

I want to first say before I read my statement to you that I come with no preconceptions, at least I'm not aware that I have preconceptions on this issue. And this is a hearing of Congress. We swear our witnesses in. The testimony that we will have from this hearing will lead to potential changes in regulations, potential legislation. It will be referred to other committees, but as all the witnesses know, we swear them in. This is a big deal. And it's a very important hearing, and I'm delighted that so many of you decided to come, and I would like to welcome our witnesses and all of you who are here as guests.

The people of Wisconsin and the medical institutions serving them have been leaders in making life-saving organ transplant safer and more available. As we begin our assessment of current and proposed organ allocation policies, our Wisconsin witnesses offer the subcommittee an important perspective. We appreciate the opportunity to be here today.

How do you ration miracles?

With each advance in transplant medicine, the gift of life can be more widely shared, miraculously transported in a donor's heart, lung, liver, kidney, pancreas, or other organ. But the unimagined possibilities of science and surgical skill remain cruelly bound by the very real shortage of donor organs. Need already far exceeds supply. The need is growing far faster than supply.

How can so precious yet so scarce a resource be shared? These questions confront us today as they did in 1984 when Congress stepped in to end glaring inequities in organ allocation and passed the National Organ Transplant Act, NOTA. The act charges the Department of Health and Human Services, HHS, to ensure an adequate supply of organs and to oversee a national allocation system based on fair, objective factors, not accidents of geography or wealth. Today, as part of our oversight responsibilities, we ask how the Department is meeting these important national goals. On both fronts, organ donation and organ allocation, HHS concedes a lack of progress against stubborn obstacles. Less then one-third of potential donors contribute. Wide disparities in waiting times between transplant centers and regions invite gaming of the listing system, produce inequities for those unable to travel and feed a perception that the system is arbitrary and unfair.

The Department recently issued two new regulations to address these issues. The first conditions hospital Medicare participation on implementation of strengthened donor organ procurement activities. The second requires the modernization and standardization of the Organ Procurement and Transplantation Network, OPTN, the statutorily mandated but privately run association of physicians, transplant centers, patients, and procurement organizations that establishes and implements organ allocation policies. Pointing to the wide variation in waiting times, the Department believes the current local first policy of distributing organs within relatively small geographic boundaries artificially constrains broader organ sharing in the interest of protecting transplant centers, but to the detriment of patients.

The Department's call for greater standardization of Medicare criteria and broader geographic organ sharing has generated considerable concern among transplant physicians, transplant centers and patients. We will hear many of those concerns expressed by our witnesses today, to the extent broader organ allocation practices might work as a disincentive to donate, might diminish patient outcomes or might increase organ waste. The subcommittee shares these concerns. Both physical and fiscal realities limit the reach of any allocation scheme. Yet it appears relatively minor adjustments to the current geographic boundaries could produce significant benefits for patients in terms of waiting times and access to a greater number of potentially suitable organs. We look forward to hearing how OPTN, operator, the United Network for Organ Sharing, UNOS, plans to address these.

Last month U.S. Surgeon General David Satcher told this subcommittee that the silent epidemic of Hepatitis-C is destroying the livers of more than 4 million Americans. HCV is already the leading cause for liver transplant. Over the next decade and a half many of those 4 million will need transplants as well. Will there be enough miracles to meet that national public health crisis?

To help the subcommittee answer these profound, often controversial questions our witnesses today bring impressive expertise and passion. We thank them again for their time and insights and welcome all of them.

At this time I would like to recognize Tom Barrett.

Mr. BARRETT. Thank you, Chairman Shays. And I would like to welcome you to Wauwatosa and to the Milwaukee area, and I would like to thank you for agreeing to hold this hearing to review this important issue.

Mr. Chairman, it is fitting that we are holding this hearing in Wisconsin. Wisconsin is recognized nationally as a leader in organ donation and an example of efficient donor recruitment. Transplant centers in Wisconsin have made organ donation a priority and have turned their efforts into a successful system of providing organs to patients with a serious need for them. Despite the efforts of transplant centers like ours in Wisconsin, there remains a dire shortage of organs nationally. The waiting list of organs grows by 500 names per month, and more than 3,000 patients each year die while waiting for organs. Clearly the supply is not meeting the demand.

In an attempt to improve their chances for transplantation, patients sometimes move to a different part of the country or try to get their names on a recipient list at a transplant center in another State. In some cases, patients go to great lengths and considerable expense in order to receive an organ transplant and some patients, without the resources to fly around the country, remain on the list at their local transplant center, waiting for an organ to become available. Sometimes the wait is too long. Today, we will hear from two witness panels made up of people who have firsthand experience in how the organ transplant system works. We will discuss new regulations on organ allocation developed by the Department of Health and Human Services. These new regulations call for an allocation system based on providing available organs to the sickest patients, which I think we would all agree is a noble sentiment, but as we will hear today, it may not be the most effective means of distributing organs and improving survival rates. I'm not a doctor, but there are doctors on our witness panels who will speak about the pros and cons of these new regulations, so I look forward to that discussion. What is apparent to me is that there is a serious deficiency in the organ donor recruitment system in this country. I understand that HHS is currently developing additional regulations to improve organ donor recruitment nationally. I believe this is the most important issue facing the transplant system.

Some regions like Wisconsin have been very successful in recruiting donors, but other areas have not been as successful. Without a commitment to improve donor recruiting nationally, there will be no significant progress in treating more patients and improving survival rates. At best, all that will be accomplished with these new regulations is that the same number of organs will be available to the same number of patients, but the organs will be distributed differently.

I believe the system of organ allocation should be fair. I also believe that the success or failure of any organ donation system depends on the level of donations. I am concerned that these new regulations may adversely affect organ donation levels and thereby jeopardize the well-being of the patients as well as the stability of some transplant centers.

My concern is if these new regulations with their emphasis on allocating organs nationally instead of the current system of allocating locally first will force transplant centers to focus their resources on recruiting the sickest patients to get organs instead of recruiting organ donors to treat their sickest patients. We need to examine if these new regulations will serve as a disincentive to recruiting donors.

I don't think Secretary Shalala or the Department intended for these new regulations to serve as a disincentive, and I don't think any transplant centers are out to close the doors of any other centers. But as we listen to the testimony presented today, we must keep in mind that transplant centers have a responsibility to recruit donors and that without donors there will be no organs to transplant. We can hold up Wisconsin as an example of a successful organ donor recruitment program and as a model that other transplant centers should follow.

Thank you very much.

Mr. SHAYS. Thank you, Mr. Barrett. Let me just get some housekeeping out of the way and ask unanimous consent that all members of the subcommittee be permitted to place any opening statement in the record and that the record remain open for 3 days for that purpose. I'm going to say 5 days for that purpose and without objection so ordered.

And I ask further unanimous consent that all witnesses be permitted to include their written statement in the record and without objection so ordered.

I'm also at the request of Mr. Barrett—our committee does something a bit unique in Congress. If time permits we are going to invite testimony from the audience. They will not be sworn in, and we won't be asking questions, but we will try to provide at least an hour for some of you who are here as witnesses who might like to share some comments. So we're going to try to do that.

And at this time we have six people on the panel. Three are going to deliver testimony, but all six will participate in responding to any questions or comments that others have said, and I'm going to ask the six first to introduce—you're going to go in the order in which I announce you, and if there's anyone who's accompanying you that is not at the table but might provide some documentation, we will be asking them to stand up and be sworn as well.

So our first speaker will be Dr. Claude Earl Fox, Acting Administrator, Health Resources and Services Administration, HRSA, that's U.S. Department of Health and Human Services, accompanied by Dr. William Raub, Science Advisor to the Secretary at HHS, and Marc Smolonsky, who is the Senior Policy Advisor at HHS.

Our second panel will be Dr. Mark Yessian, Regional Inspector General, Office of the Inspector General, U.S. Department of Health and Human Services, HHS.

And our third panel will be Dr. Lawrence Hunsicker, president, United Network for Organ Sharing, UNOS. And he's accompanied by Walter Graham, executive director from UNOS.

I'd invite you all to stand up to be sworn in, and if there is anyone else who you think is with you that needs to be sworn in.

[Witnesses sworn.]

Mr. SHAYS. For the record all have responded in the affirmative, and we will start with you, Dr. Fox.

Dr. FOX. Mr. Chairman, Congressman Barrett——

Mr. SHAYS. Let me just ask a question before—I want to make sure that the audience can hear. Are you picking up the mics at the top here in the very back? Are you able to hear? Not as great as it could be. Is that on? I don't think yours is on, is it? Is the switch there? No. OK. This is going to be interesting. I want you to speak and let's see how——

Dr. FOX. Mr. Chairman, can you hear me?

Mr. SHAYS. No. Not well. Are we picking it up back there? We need to resolve that before we start. I find that if the audience can't hear, they start to talk, and then we end up with chaos. I do want you to be happy, but I also want the system to work. Is someone here to adjust—OK. Let me just test first, are you able to pick up—Sir, you in the dead center in the back in the suit. I'm going to ask you, can you hear me when I speak right now?

VOICE. Yes.

Mr. SHAYS. I meet the test here. Mr. Barrett.

Mr. BARRETT. Can you hear me?

VOICE. Yes.

Mr. SHAYS. OK. When you lean over, he can. OK, now, I'm going to just test your mic first. Would you speak into it?

Mr. SMOLONSKY. Yes. Can you hear me?

Mr. SHAYS. No, but you're not going to speak—when you're reading—just bring the mic a little closer but don't lean over. It should pick it up without——

Mr. SMOLONSKY. Is this better?

Mr. SHAYS. Yes. Can you hear that in the back? No. OK. We're going to have a problem here. We'll resolve it. Sorry. I should have thought to ask that it be tested. Let me ask you this: Is it a factor that we have too many mics on? If we turn off some mics, does that improve the—who is the expert?

VOICE. Tom is adjusting——

Mr. SHAYS. Tom, let me ask you a question. If we turn off some mics, does that make a difference? I may have to ask you to hold the mic, which will be an inconvenience, and put it much closer to you. Now, we're trying to get their mics. That's——

Is that a little better?

Can you hear me? OK. Let me just—I need to have you just pick it up to see what happens. Can you pick it up in the back when he does that? Even that is not great. So I'm going to ask you to do something else. I'm going to ask you to really project a lot louder. OK? I'm going to ask you to speak loud. I'm going to ask—Sir, as long as you're back there, I'm going to say this to you: If people in the back cannot hear, I just want you to raise your hand. You deserve to hear the testimony as well as us, so if I see some hands going up, I will just ask you to speak up. All righty? OK.

Dr. Fox, we'll start with you.

STATEMENT OF CLAUDE EARL FOX, M.D., ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. FOX. Mr. Chairman, Congressman Barrett, we're very pleased to be here on behalf of the Department. As you've already alluded, Wisconsin has an excellent record in organ donation and obviously has some of the finest transplant surgeons in the country and, of course, the breakthrough in transplant technology, the Belzar solution developed here really has allowed for longer preservation of organs, and so we think this is a very appropriate issue to discuss here because it obviously affects not only the citizens of Wisconsin, but citizens all over this country. As you've already alluded, the National Organ Transplant Act of 1984 created a national system for organ procurement known as—by its acronym OPTN, managed under a contract with the Department by the United Network of Organ Sharing, or UNOS.

HHS has the responsibility to oversee the OPTN and to ensure that its policies conform to the technologic advances and are consistent with the intent of the statute. Our review indicates that there are still many challenges to optimal patient care. The greatest challenge as you already mentioned is the shortage of organs available for transplantation. About 4,000 individuals died in 1996 while waiting for a transplant that probably would have saved their lives. The gap between the demand and supply of available organs is growing and will continue to expand as medical innovations make transplant more and more feasible. Approximately 10 to 15,000 deaths in the United States each year could result in more viable organ donation, but only about 5,500 cadaveric donors, about a half to a third of potential organ donors, contribute organs for transplantation. While the number of cadaveric organ donors has increased from 4,000 in 1988 to about 5,400 in 1996, the number of deaths among people on transplant waiting lists has grown. There were about 1,500 deaths in 1988, and the number jumped to over 4,000 in 1996.

While some 20,000 Americans received transplants in 1996, more than 55,000 individuals were on the waiting list, and of those on the waiting list, 10 people die each day because there are not enough organs to go around.

The Nation's failure to obtain optimal donation rates for transplantation is unquestionably the biggest problem facing the transplant community and a concern of the administration. Last December the Vice President announced a nationwide initiative to increase organ donations. This initiative, as you've also alluded, includes proposed Medicare regulations designed to ensure that deaths are reported to organ procurement organizations whenever there is a potential for donation. We are also working with providers, consumers, organ procurement organizations, and tissue banks, and hospitals to develop the final regulation. The proposal is based on approaches that have been successful elsewhere, and in Pennsylvania organ donations have increased dramatically under a State law that requires reporting of deaths to OPO's. The Department estimates that the number of donations nationwide could increase by as much as 20 percent over the next 2 years after the final publication of the rule. Although the country's mixed record on organ donation is our primary concern, there are other questions that pose concerns for the Department. How do we ensure that organs are allocated fairly and with sufficient efficiency that available organs are used to prolong the lives of people in the greatest need? How do we guarantee that the OPTN operates primarily in the interest of patients?

Our best answers to these questions are contained in the new regulations for the OPTN which were published last week. There are six principles that underly the regulations. First, that transplant patients are best served by an organ allocation system that functions equitably on a nationwide basis.

Second, that the Secretary of HHS should represent the public interest by setting broad goals for the OPTN and by overseeing OPTN policy development and operation with a view toward ensuring that the goals being addressed are done so in a reasonable manner.

Third, that the OPTN must exercise leadership in performing its responsibilities under the Transplant Act, in particular by devising specific policies assigned under the regulations and by adapting its policies and procedures to reflect the changes in medical science and medical technology.

Fourth, that organs be equitably allocated to all patients, giving priority to those patients in most urgent medical need of transplantation in accordance with sound medical judgment. And I emphasize that last phrase. And, fifth, that thorough, timely and easy to use information about transplant centers, including center-specific performance data is essential for measuring the quality of care and should be readily available to help patients and physicians in choosing transplant centers. And, finally, potential conflicts of interest should be minimized for those who are responsible for the OPTN.

The statute that created the OPTN requires the Secretary to provide timely information to patients, families and physicians about transplantation. We think that current OPTN policies make it impossible to fulfill this requirement because the Department has been denied current and thorough information. Under existing policies, for example, we can't provide Americans with current 1-year survival rates for patients and organ grafts. We can't compare the performance of transplant programs, and the data available to patients today is 4 years old and so out of date that in many instances not usable. Given that the data made public is outdated and incomplete, patients and their doctors cannot review the performance of prospective transplant programs. And we find this situation unacceptable and seek to obtain timely, useful data for patients through the pending regulation.

The regulation also addresses the issue of broader sharing of organs and intends to spur a debate within the OPTN about the suitability of the local-first policy that's currently in place for the allocations of organs. We believe that there is solid evidence that the current system is unfair and that patients may be dying unnecessarily because they happen to live in the wrong place at the wrong time. Secretary Shalala believes that everyone in need of a transplant should have equal access to an organ regardless of where they live or list. We believe broader sharing of organs will reduce current geographic inequities in the OPTN. Our view is supported by prominent and enumerous medical authorities and experts who have proposed broader sharing of donated organs. For example, according to the AMA's Code of Ethics, "Organs should be considered a national rather than a local or regional resource. Geographic priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transportation."

The OPTN we feel has not met the mandate of the statute that created it. The allocation system is not fair nor is it a national network. By allocating organs primarily at the local level, OPTN policies give the sickest patients a substantially lower chance of being properly matched to a suitable organ. Current OPTN policies create enormous geographic disparities in the time patients must wait to receive transplants.

For example, based on the latest data, if you live in New England and need a kidney transplant, you'll wait as long as 3 years, but in the upper portion of the Southeast, a patient in need of a kidney transplant will wait as little as 200 days.

The Department recognizes that there is tremendous controversy over the subject of organ allocation. We understand that there is division in the transplant community about the distribution of organs and that while many want the current system changed, others do not. The OPTN must not be so paralyzed by controversy and division that it does not act to change a system that we think is unfair to patients and that may be allowing patients to die unnecessarily. Through the pending regulation the Department we believe is putting patients first. What is best for patients in our view overrides concerns about the individual needs of transplant centers, whether they be large or small.

In its pursuit of justice for patients, the Department does not intend to substitute its own medical judgment for the judgment of the members of the OPTN. Although the pending regulations require changes in current allocation policy, the regulation does not contain a specific policy. The regulation leaves it to the OPTN to perform the policy and present its recommendations to the Secretary. I reiterate HHS will not be setting any new allocation policy. It's up to the medical experts of the OPTN to set the new policy. We ask only that the policies conform to the three basic performance goals.

One, that the criteria for placing patients on waiting lists be standardized. Two, that criteria for determining medical status of patients be standardized. And, three, that medical urgency, not geography, be the main criteria for allocating organs.

I've described what the pending regulations will do. Now let me tell you what the regulations will not do. We believe the regulations will not adversely affect patients who are on waiting lists at the time it takes affect. There is a transition provision allowed in the regulations. The regulation states that no one currently on a waiting list will be disadvantaged by changes in the allocation policy. The regulation will not deprive any locality of organs. Broader sharing we believe will mean that patients have more access to organs, not less. Our goal is that patients be better off as a result of the policy reforms.

I'd like to conclude by saying that the Department has solicited widespread public comment on this regulation. It was published as an NPRM in 1994, and we received extensive public comments in the process. In December 1996, the Department conducted 3 days of public hearings on issues pertaining to the regulation. Everyone connected with the transplant community from patients to surgeons was invited to testify. The pending regulation also has a 60-day public comment period and a delayed effective date. Should the Department learn anything during the public comment period that required change, the effective date of the regulation can be delayed further to accommodate these changes. We encourage public debate on the regulation, whether it be at a hearing like this or within the confines of the OPTN.

Thank you very much for the opportunity to be here, and I look forward to answering any questions you might have.

Mr. SHAYS. Dr. Fox, thank you. This is a nice way to introduce the issue, and I appreciate you putting all those issues out in front of us.

[The prepared statement of Dr. Fox follows:]

Mr. Chairman and members of the Subcommittee, thank you for inviting the Department of Health and Human Services to participate in this very important hearing on national organ transplantation policy. I am Doctor Claude Earl Fox, Acting Administrator of the Health Resources and Services Administration. I am accompanied by Doctor William Raub, the Secretary's Science Advisor and Marc Smolonsky, Senior Policy Advisor in the Office of the Assistant Secretary for Legislation.

We are delighted to be here in Wisconsin, a State with an outstanding record of organ donation. Wisconsin has some of the finest transplant surgeons in the country. And one the great breakthroughs in transplant technology, the Belzar UW solution, was developed in Wisconsin. This is an appropriate issue for discussion here or anywhere else in the United States, because organ transplantation policy affects all Americans, regardless of where they live.

As you know, the National Organ Transplant Act of 1984 created the national Organ Procurement and Transplantation Network, commonly known by its acronym, OPTN. The OPTN is managed under a contract with the Department by the United Network for Organ Sharing, or UNOS. The Act was amended twice, in 1988 and 1990, each time with language clarifying that the OPTN should direct an equitable nationwide distribution of organs. In the construction of a national organ allocation network, Congress recognized that there is a shortage of organs available for transplantation, and that the shortage was likely to continue into the foreseeable future. Congress further recognized that medical urgency and equity should be the main criteria for access to available organs and that no one should be allowed to unfairly game the system.

Prior to passage of the National Organ Transplant Act, the distribution of organs was often unfair. Wealthy people or persons with special connections reportedly were able to manipulate the system so that they received organ transplants instead of people who were sicker and had been waiting far longer. Patients from foreign countries sometimes received life-saving transplants while Americans died. After hearings and media reports had confirmed many of these allegations, Congress acted swiftly to establish a national system.

I am pleased to report that the system envisioned by Congress works very well. It is a much more efficient and equitable system than what existed prior to its creation. It has allowed dedicated surgeons and organ procurement professionals, and many others who work with them, to routinely save lives in cases where death would have been certain only twenty years ago. It has, to a very large extent, eliminated the kinds of abuses that occurred before passage of the 1984 law.

HHS has the responsibility to oversee the OPTN to ensure that its policies conform to technological advances and are consistent with the intent of the statute. Our reviews indicate that there are still many challenges to optimal patient care. The greatest challenge is the shortage of organs available for transplantation. About 4,000 people died in 1996 while waiting for a transplant that probably would have saved their lives. The gap between the demand and supply of available organs for transplantation is growing, and will continue to expand as medical innovations make transplantation an option for more and more patients.

Approximately 10,000 to 15,000 deaths in the United States each year could result in viable organ donation. But only 5,500 cadaveric donors, one half to one third of potential organs, contribute organs for transplantation. While the number of cadaveric organ donors has increased, from 4,084 in 1988 to 5,417 in 1996, the number of deaths among people on organ transplant waiting lists has also grown. There were 1,507 deaths on the waiting list in 1988, a number that jumped to 4,022 in 1996.

Some 20,000 Americans received organ transplants in 1996, but more than 55,000 people were on the waiting lists. Of those on the waiting lists, ten people will die every day, mainly because there are not enough organs to meet their needs.

The Nation's failure to make optimal use of available organs is unquestionably the biggest problem facing the transplant community. Addressing the shortage of organs is a priority of this Administration. Last December, the Department announced a nationwide initiative to increase organ donations. The initiative is focused on known barriers to donation by creating a national partnership of public, private and volunteer organizations. The partnership emphasizes the need to share personal decisions on organ donation with one's family. Even if an individual agrees during his or her lifetime to be an organ donor, the agreement is not always honored without family consent. As part of the initiative, HHS convened a conference on best practices last week, with experts from throughout the country discussing successful solutions for increasing organ donations.

The initiative includes proposed Medicare regulations designed to ensure that deaths are reported to organ procurement organizations whenever there is potential for donation. HHS is working with providers, consumers, organ procurement organizations, eye and tissue banks and hospitals to develop a final regulation. The proposal is based on approaches that have been successful in other areas. For example, organ donations increased dramatically in Pennsylvania as the result of a state law that requires the reporting of deaths to organ procurement organizations. The Department estimates that the number of donors nationwide could increase by 20 percent within two years of the publication of a final rule.

Organ procurement is one of the most sensitive issues in American society. Asking a family to donate an organ from a loved one who just died is a wrenching task, which is done most effectively by people who are trained organ procurement specialists. There are many heroic individuals who are in the business of saving lives every day by convincing people to donate organs. But as a nation, we must do a better job.

Although the country's mixed record on organ donation is our primary concern, there are other problems that pose vexing questions for the Department. How do we ensure that organs are allocated fairly and with sufficient efficiency that available organs are used to prolong the lives of people in the greatest need? How do we guarantee that the OPTN operates primarily in the interests of patients? Our best answers to these questions are contained in the new regulations for the OPTN, which were published last week.

Six principles underlie the regulation:

1. Transplant patients are best served by an organ allocation system that functions equitably on a nationwide basis.

2. The Secretary of Health and Human Services should represent the public interest by setting broad goals for the OPTN and by overseeing OPTN policy development and operations with a view toward ensuring that the goals are being addressed in a reasonable manner.

3. The OPTN must exercise leadership in performing its responsibilities under the National Organ Transplant Act, in particular by devising the specific policies assigned under the regulations, and by adapting its policies and procedures to changes in medical science and technology.

4. Organs should be equitably allocated to all patients, giving priority to those patients in most urgent medical need of transplantation, in accordance with sound medical judgment.

5. Thorough, timely, and easy to use information about transplant centers, including center-specific performance data, is essential for measuring quality of care and should be

readily available to help patients and physicians in choosing among transplant centers.

6. Potential conflicts of interest should be minimized for those who are responsible for operation of the OPTN.

The statute that created the OPTN requires the Secretary of Health and Human Services to provide timely information to patients, their families, and physicians about transplantation. Current OPTN policies make it impossible to fulfill this requirement because the Department has been denied current and thorough information. Under existing policies, for example, we cannot provide Americans with the current one-year survival rates of patients and organ grafts. We cannot compare the performance of transplant programs. Data available to patients today is four years old, so it is out of date. Given that the data made public is outdated and incomplete, patients cannot review the performance of respective transplant programs. We find this situation unacceptable and seek to obtain timely useful data for patients through the pending regulation.

The pending regulation also addresses the issue of the broader sharing of organs and intends to spur debate within the OPTN about the suitability of the current local-first policy for the allocation of organs. We believe there is solid evidence that the current system is unfair and that patients may be dying unnecessarily because they happen to live in the wrong place at the wrong time. Secretary Shalala believes that everyone in need of a transplant should have equal access to an organ, regardless of where they live or list.

We believe broader sharing of organs will reduce current geographic inequities in the OPTN. Our view is supported by numerous prominent medical authorities and experts who have proposed broader sharing of donated organs. For example, Dr. Lawrence Hunsicker, the current President of the United Network for Organ Sharing, said in 1986:

> "In principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography."

According to the American Medical Association's Code of Medical Ethics:

> "Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."

In 1991, the HHS Inspector General reached the following conclusion:

> "...current organ distribution practices fall short of congressional and professional expectations," and that "there has been substantial progress in developing a national organ distribution system grounded in uniform policies and standards. However, organ

> distribution remains...confined primarily within the individual service areas of the...Organ Procurement Organizations."

In passing the National Organ Transplant Act, Congress clearly intended that the OPTN act as a nationwide system, free of geographic bias. In 1990, when Congress amended the statute to emphasize the importance of a truly national allocation system, the Senate reported, "because the demand for transplantable organs is expected to continue to be considerably greater than the supply, a fair and equitable organ sharing system is critical to the future of a national transplant program that the public will support."

The OPTN has not met the mandate of the statute that created it. The allocation system is not fair, nor is it a national network. By allocating organs primarily at the local level, OPTN policies give the sickest patients a substantially lower chance of being promptly matched to a suitable organ. Current OPTN policies create enormous geographic disparities in the time patients must wait to receive transplants. For example, based on the latest data, if you live in New England and need a kidney transplant, you will wait as long as three years. But in the upper portion of the southeast, a patient in need of a kidney transplant will wait as little as 231 days.

We find the disparity in waiting lists across the country to be unacceptable. Americans in need of organ transplants will live or die on the basis of where they live. The policy that allows this to happen is contrary to the intent of Congress and in violation of the American Medical Association's Code of Ethics.

It would be illegal to deny an organ to patients because of their race, gender, and in the case of suitable transplant candidates, their age. Yet organs are denied to patients because of where they live. Geographic discrimination is no better than any other sort of discrimination. It is flat out wrong and should no longer be tolerated.

The Department recognizes that there is tremendous controversy over the subject of organ allocation. We understand that there is division in the transplant community about the distribution of organs, and that while many want the current system changed, others do not. The OPTN must not be so paralyzed by controversy and division that it does not act to change a system that is unfair to patients, and that may be allowing patients to die unnecessarily. Through the pending regulation, the Department is putting patients first. What is best for patients, in our view, overrides concerns about the individual needs of transplant centers, whether they be large or small.

In its pursuit of justice for patients, the Department will not substitute its own medical judgment for the judgment of transplant professionals. Although the pending regulation requires changes in current allocation policy, the regulation does not contain a specific policy. The regulation leaves it to the OPTN to reform the policy and present its recommendations to the Secretary. I reiterate, HHS will not be setting any new allocation policy; it is up to the medical experts of the OPTN to set the new policy. We ask only that the policy conform to three basic performance goals: One, that criteria for placing patients on waiting lists be standardized; two, that criteria for determining medical status of patients be standardized; and three, that medical urgency, not geography, be the main criterion for allocating organs.

The OPTN agrees with the first two performance goals. In fact, the network is already working toward those aims. It is the third performance goal, the one that is designed to end discrimination in the allocation system, that the OPTN is struggling with. But I am confident that if the OPTN puts patients first and pushes the individual concerns of transplant centers to the side, it will accomplish this goal as well.

I have described what the pending regulation will do. Now let me tell you what it will not do. The regulation will not adversely affect patients who are on waiting lists at the time it takes effect. The regulation states that no one currently on a waiting list will be disadvantaged by changes in the allocation policy. The regulation will not deprive any locality of organs. Broader sharing will mean that patients have more access to organs, not less. Our goal is that all patients be better off as a result of policy reforms.

I will conclude by saying that the Department has solicited widespread public comment on this regulation. It was published as an NPRM in 1994, and we received extensive public comments in response. In December 1996, the Department conducted three days of public hearings on issues pertaining to the regulation. Everyone connected to the transplant community, from patients to surgeons, was invited to testify. The pending regulation has a 60-day public comment period and a delayed effective date. Should the Department learn anything during the public comment period that requires change, the effective date of the regulation can be delayed further to accommodate the changes. We encourage public debate on the regulation, whether it be at a hearing like this one or within the confines of the OPTN.

Thank you for the opportunity to testify. I will be pleased to answer any questions you may have.

Mr. SHAYS. Dr. Yessian.

Dr. YESSIAN. Good morning.

Mr. SHAYS. Good morning. I'm sorry to ask you to take that out, but I'm assuming we are able to hear in the back, maybe not as well as we'd like, but you are able to hear?

Dr. YESSIAN. How is this?

Mr. SHAYS. You've got to talk a little louder. You want to get a little more wire there and just give yourself a little more flexibility. Thanks.

Dr. YESSIAN. Good morning, Mr. Chairman and——

Mr. SHAYS. Good morning.

STATEMENT OF MARK YESSIAN, PH.D., REGIONAL INSPECTOR GENERAL, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. YESSIAN. Congressman Barrett. It's a pleasure to be here this morning and to testify before you. I'm Mark Yessian. I'm the Regional Inspector General of the U.S. Department of Health and Human Services.

Our work in this area of organ allocation systems has led us to focus, to emphasize two important points about how those systems should operate. One is that they should focus on equity among patients, not among transplant centers. And, two, that they focus on common medical criteria, not the circumstances of a patient's residence or transplant center affiliation.

Our work in this area—my testimony this morning is based on a report that has had a pretty good shelf life for Government reports. It's 7 years old, but we think it's relevant to today's discussion. That report focused on expectations and practices of organ allocation systems. It concentrated on kidneys because back in 1991 about 81 percent, I think 84 percent of those awaiting a transplant were awaiting a kidney transplant. I think that percentage would be more like two-thirds now.

A few quick highlights from that study that are most pertinent to today's——

Mr. SHAYS. Let me just tell you, we want your testimony in the record and you have about 10 minutes, so feel free.

Dr. YESSIAN. OK. We found looking back at the congressional trail of legislation here and after a lot of discussions with a lot of the professional leaders in the field we identified three major sets of expectations governing all the organ allocation. One is that there be an equitable system with each person on a transplant list having an equal opportunity to receive a transplant subject to established medical criteria. Second point is that it be a national system based on uniform policies and standards. And the third is that it be a system based on cooperation, cooperation focused on doing what is best for the transplant patients that are on those waiting lists. In each case we found that the actual reality, the actual practices fell well short of these congressional expectations.

Let me take the issue of equity first. We found at that time that for patients awaiting a kidney, a cadaver kidney transplant we found widespread variation not only among regions and service areas, but among transplant centers. From as low as 1 month, one—median of 1 month waiting list at one center to as much as

6 years at another. Even more profound than that we found major differentials according to race. And that's why this report got an awful lot of attention at the time, mainly because of this finding. And we found that blacks tended to wait twice as long as whites for a first cadaver kidney transplant and that this differential held even when we took a blood type, age, and sensitivity level into account.

The second expectation, a national system. We found that the way the system operated was a long way from operating in the sense of being a national system in accord with uniform criteria and standards. In fact, organ allocation was heavily controlled and heavily influenced by individual transplant centers, not the organ procurement organization and not even the Organ Procurement Transplantation Network. The individual centers at that time had substantial influence on the equal allocation decisions.

The third issue of cooperation. Among transplant centers and many transplant professionals we found a strong sense of local ownership toward organs that we found really impeded the development of an equitable national system for distributing organs. One manifestation of that at the time was what was called keep one, share one arrangements whereby the team going out and procuring a couple of kidneys would get to keep one for their own center and another one would go into the common pool to be distributed often on the basis of a rotational arrangement among the centers, not a patient-based equity system.

The mismatches between expectation and reality led us to make a number of strong recommendations at the time. Perhaps the one that was most important was our recommendation that—and these were directed to our Department of Health and Human Services, and we had a recommendation that each Organ Procurement Organization be required to establish a single unified list of patients awaiting transplantation and that they distribute organs to patients on a first come, first serve basis subject to established medical criteria.

We also, I might note, had a recommendation that when a patient gets on a list can make all the difference in the world and how fair the first come, first serve system is we emphasized a need at that time, 7 years ago, for practice——

Mr. SHAYS. Could you turn the mic this way rather—yeah, that way.

Dr. YESSIAN. Can you hear me OK? OK. Sorry. We emphasized the need at that time for practice guidelines geared to the issue of access to waiting lists in the first place.

Since our report there has been progress in dealing with some of the gaps that we've talked about, yet it's clear also that there's room for much further progress as these wide differentials among transplant centers waiting times indicate. With three times as many people now awaiting a transplant as was the case when we did our study—there were 20,000 on the list, national list then, only 7 years ago. There are about close to 60,000 now. We believe this growth, this increased scarcity makes it even more crucial that there be close accord between practices and expectations as we've defined them and that there be publicly accountable guidance on how best to deal with this situation.

The performance goals that Dr. Fox issued that are reflected in the HHS rule that was announced earlier this year on March 26 move in the direction of our findings and recommendations as we set those forth in that 1991 report. It remains essential, we believe, Mr. Chairman, that we continue to move in developing organ allocation systems that are grounded in equity among patients, not among transplant centers and that focus on common medical criteria, not the circumstances of a patient's transplant center affiliation or the patient's residence. Thank you.

Mr. SHAYS. Thank you, Doctor.

[The prepared statement of Dr. Yessian follows:]

Good morning. I am Mark R. Yessian, Regional Inspector General for Evaluation and Inspections in the U.S. Department of Health and Human Services (HHS). I am pleased to testify at today's hearing on the effectiveness of organ allocation practices.

Our work in this area has led us to call for an organ allocation system that focuses on: (1) equity among patients, not among transplant centers, and (2) common medical criteria, not the circumstances of a patient's residence or transplant center affiliation.

I will concentrate my testimony on a report we issued 7 years ago. That report is relevant to today's discussion because it makes the case for a more equitable organ allocation system that is based on common medical criteria. The HHS rule issued on March 26, 1998 moves in a direction that is responsive to the thrust of our findings and recommendations.

Background on the Report

Our 1991 report is entitled "The Distribution of Organs for Transplantation: Expectations and Practices," and is attached. It was issued at a time when the national transplant waiting list had grown to more than 20,000 people. That was less about one-third of the current level, but was large enough to heighten concerns about the fairness of practices being used to allocate donated organs for transplantation.

In the report, we focused on the organ distribution process, from the point that a cadaver organ is procured to the point that it is transplanted. We concentrated on the distribution of kidneys because at that time about 84 percent of those on transplant waiting lists were awaiting a kidney transplant. When our report was issued in 1991, the Medicare program had just recently covered liver transplants for adults and had certified only 20 liver transplant centers in the country.

The basic purposes of our inquiry were threefold: (1) to clarify expectations governing organ distribution practices in the United States, (2) to determine the extent to which actual practices were in accord with expectations, and (3) to offer recommendations that facilitated closer accord between expectations and practices. We recognized the sensitivity of the issues under examination and gave great emphasis to the presentation of objective, factual information that could contribute to constructive policymaking.

Our methodology was based on four major lines of inquiry: (1) a statistical analysis of a data base consisting of all individuals who were waiting for or received their first kidney transplant between October 1, 1987 and March 31, 1989; (2) case studies of organ procurement organizations and affiliated transplant centers in California, Florida, Wisconsin, and Pennsylvania; (3) a review of key literature and Federal documents; and (4) interviews with representatives of national organizations involved with organ transplantation, government policymakers, public and private researchers, and transplant professionals.

In the sections below, I will present the three sets of expectations governing organ allocation that we found were held by Congress and professional leaders. In each case, I will then contrast the expectation with the actual practices that we found to be operative at the time. Finally, I will review the recommendations we offered and their relevance to the current HHS rule.

Expectations

An Equitable System, With Each Person on a Transplant Waiting List Having an Equal Opportunity to Receive a Transplant Subject to Established Medical Criteria.

There is a clear trail of congressional and professional expressions that provide the foundation of this expectation. The National Organ Transplant Act of 1984 specified that an Organ Procurement Organization (OPO) must "have a system to allocate donated organs among transplant centers and patients according to established medical criteria." In an accompanying report, the Senate Labor and Human Resources Committee added the following: "An equitable policy and system is necessary so that individuals throughout our country can have access to organ transplantation when appropriate and necessary."

Two years later, the Task Force on Organ Transplantation, established by the 1984 legislation, defined this expectation more specifically, as follows:

> The Task Force recommends that selection of patients both for waiting lists and for allocation of organs be based on medical criteria that are publicly stated and fairly applied. The Task Force also recommends that the criteria be developed by a broadly representative group that will take into account [redacted] Selection of patients otherwise medically qualified should be based on length of time on the waiting list.

In 1988, amidst some concerns that its initial expectations concerning equity were not being adhered to, Congress amended the 1984 legislation to clarify that in allocating organs according to established medical criteria, an OPO must focus strictly on the allocation among patients, not transplant centers. In an accompanying report, the House Committee on Energy and Commerce urged the HHS Secretary to monitor the allocation of organs closely to make sure that allocation schemes remain based on equity among patients, [redacted].

In the 1984 legislation, Congress did single out one group that it felt needed special attention if it were to receive a fair opportunity for a transplant. In calling for the Organ Procurement and Transplantation Network (OPTN) to develop "a national list of individuals who need organs" and a "national system . . . to match organs and individuals on the list," it indicated that particular attention should be given to "individuals [redacted] them to receive organs." In calling for this special attention to highly sensitized individuals, it implicitly recognized that for these individuals, the opportunity to receive a medically suitable organ increases as the size of the available pool of donors increases.

A National System Adhering to Uniform Policies and Standards.

Congress called for the OPTN to establish one nationwide list of individuals awaiting transplantation and a "national system" that would allow for donated organs to be quickly matched with medically suitable candidates on that list. Yet, it did not mandate national distribution per se. It specifically stated that a national list and a national system could be established in regional centers instead of one central location.

The Task Force, in its final report, reinforced the importance of a national system with [redacted]." The Task Force noted that while diverse practices and protocols were to be expected during the pioneering years of transplantation, "at this point in the evolution of organ transplantation, sufficient data have been developed to allow for the establishment of [redacted]" (This observation was 12 years ago, in 1986.)

A Cooperative System Based on the Best Interests of Patients Waiting for Transplantation.

This expectation is obvious enough. But it is important to set forth because cooperation among diverse parties is so integral to the transplant field. From the earliest efforts to enlist support of potential donors and donor hospitals to the post transplant efforts to improve patient outcomes, successful performance requires the cooperative efforts, often under strict time pressures, of a wide range of professionals. These include but are no means limited to transplant coordinators, nurses, social workers, neurologists, nephrologists, transplant surgeons, immunologists, and OPO administrators. While each of these participants have their own particular interests, they must work together effectively as trustees of organs for all the persons awaiting a transplant.

It was in recognition of the complex nature of this collaborative effort that Congress called for the unusual approach of a private body, the OPTN, having a strong role in shaping the national system. Congress and professional leaders saw the OPTN and, to a lesser degree, the OPOs as forums for developing approaches buttressed by broadly based consensus.

Realities

In our 1991 report, we pointed out that while progress had been made, actual practices fell well short of each of the above-noted expectations. I point out those shortfalls below.

Equity

- **The access of patients to donated organs remained unequal in some important respects.**

One important inequality was that among transplant centers. For the period we studied, the median patient waiting time for a first kidney transplant ranged from a low of less than 1 month at one center to a high of 71 months at another. Among the 202 centers we reviewed, the median waiting time at 79 was less that 6 months for non-highly sensitized patients; at 15 it was over 18 months. [redacted]

A second major inequality was with respect to race. We documented that blacks on kidney waiting lists waited almost twice as long as whites for a first transplant, 13.9 months compared with 7.6. This differential remained even when blood type, level of sensitization, and age were taken into account. It was especially significant because blacks have much higher rates of kidney failure. We examined various possible causes for the wide difference, but did not have any overriding explanation.

Finally, we found that highly sensitized patients had considerably less access to transplants than did others on waiting lists. During the 18 month period we examined, the median time that highly sensitized patients waited for donated kidneys was almost 4 times that of all others, 32. 4 months compared with 8.6.

What stood out in our considerations of equitable access was that in OPO service areas, few transplant centers had joined together to develop a common list of transplant candidates and to distribute donated organs to those candidates on a first come first served basis, subject to medical criteria. Some had formed a common list, but the sharing criteria they developed were apt to devote more attention to the distribution of organs among centers than among patients. Along this line, many transplant centers participated in an OPO approved arrangement whereby for each pair of cadaver kidneys they retrieved, they kept one for one of their own patients and gave one to a common pool. The kidney donated to the pool was then made available to another transplant center in the service area, usually in accord with some rotational arrangement

This practice did not appear to us to be fair from the perspective of the overall pool of patients awaiting a transplant. Also unfair from that broader perspective was that individuals seeking a transplant could register at different centers both within and across OPO service areas, thereby increasing their own chances of a transplant but reducing those others who did not have the resources and/or information to get themselves multiple-listed.

National System

- **Organ distribution remained heavily controlled by individual transplant centers and confined primarily within the individual service areas of organ procurement organizations.**

Notwithstanding some progress in developing a national system grounded in uniform policies and standards, the actual distribution of organs from donors to recipients remained highly localized. This local orientation, we found, applied in two very important respects. First of all, through the OPTN's "local use" policy, transplant centers were allowed to retain almost all of the organs that they had retrieved. ***They entered into cooperative agreements with an OPO or other centers only at their own will.*** If they so wished, they could make arrangements concerning the distribution of organs with a donor hospital and/or an OPO in a service area other than the one in which they were located.

Secondly, as follows from this local use policy, most organs procured within a service area never left that area. Only about 22 percent of kidneys retrieved were shared nationally.

Cooperation

- **Among some transplant centers and professionals, a sense of local ownership towards organs they had procured impeded the development of an equitable national system for distributing organs.**

It is this sense of local ownership, we found, that sustained the "keep one-share one" arrangements, whereby a transplant center that retrieved an organ kept one for one of its patients and donated one to the common pool. It also sustains the "renal payback system," whereby a transplant center that provided a perfect match kidney to the national pool was entitled to a payback kidney from the receiving transplant center.

Such practices contributed substantially to the uneven playing field across the country, with access to organs being much greater in some geographic areas and in some transplant centers than at others. Many transplant professionals, we noted, would justify this unequal situation by noting that any system that sought to level the playing field across regions or transplant centers would discourage donations since, they alleged, families were more likely to donate if they knew the organ is being used in the local area.

In our review, we found no statistical basis for this contention. In fact, we found that in a national public opinion poll commissioned by the OPTN itself, over 75 percent of the respondents disagreed with the statement that "donor organs should go to someone in the area where the donor lived."

A number of transplant surgeons we learned also disagreed with the notion of local ownership. One, who was also the medical director of an OPO, commented as follows in a letter sent to the OPTN:

> Establishing a payback system also creates the illusion that a kidney is the property of a given OPO. Clearly, we need to foster the notion that organs for transplantation are a national resource which should be used in the most efficient and successful manner possible. They are not anyone's individual property.

Recommendations

We found the mismatch between expectations and reality significant enough for us to make a number of strong recommendations to HHS. In making the recommendations, we recognized that many organ allocation decisions are essentially medical in nature and ought to be made by medical professionals on the basis of the best available evidence and objective criteria. At the same time, we held that [redacted].

Thus, we grounded our specific recommendations on actions that could be taken to help close the gap between actual practices and the expectations clearly set forth by Congress. We did not seek to impose our own or others' judgments about what those expectations should be.

Below, I present the recommendations we made that are most pertinent to the March 26, 1998 HHS rule:

Issue regulations to require that each OPO (1) establish a single, unified list of patients awaiting transplantation and (2) distribute donated organs to those patients on a first come first served basis, subject to established medical criteria.

It was time, we argued, to preclude transplant centers from operating as if they "own" the organs that they or others have procured. Each center, we recommended, should have to register its own transplant candidates on one unified list maintained by the OPO. Each cadaver organ that then becomes available for transplantation in that service area (except for those mandated by the OPTN to be distributed nationally) would be offered to patients on that list in the order that they have registered. ([redacted]) The only basic exceptions here would be those warranted in accord with established medical criteria.

This approach, we emphasized, would make for more equitable access for patients within OPO service areas. It would reinforce the notion of equity among patients rather than among transplant centers and would establish a system more in accord with congressional intent.

Issue regulations to require that each transplant center and donor hospital in an OPO service area adhere to the centralized organ distribution policies of the OPO governing that area.

Transplant centers, we indicated, should not be allowed to violate the first come first served approach by making organ distribution arrangements, as some did, with donor hospitals and/or OPOs outside their own service area. We sought to reinforce the point that OPOs, not transplant centers, be regarded as the engines of the organ distribution system. They should have the authority to shape and oversee distribution policies in their service areas, in accord with guiding Federal requirements, and they should be held accountable for the exercise of this authority. In overseeing the distribution of organs, they must assure that the focus is on the equitable access of patients, not transplant centers.

Support the development of medical practice guidelines addressing organ transplantation.

We fully recognized that without more uniform and explicit medical criteria, equitable access as we call for would be difficult to achieve. Widespread differences among professionals in the field have inhibited the development of such criteria. The differences relate to the degree of emphasis that should be given in allocating organs to such matters as age, sensitivity level, and HLA matching. Even more fundamentally, they relate to the criteria that determine whether or not one is a suitable candidate for a transplant and should be placed on a list in the first place. Different practices in placing candidates on waiting lists clearly affected the equity we aimed for with our first come first served recommendations.

For these reasons, we urged the Department to support the development of transplant practice guidelines, based on medical outcomes, that would serve as an authoritative and useful reference point for practicing professionals and for oversight bodies responsible for assuring that organs are in fact being distributed equitably.

- **Fund a demonstration effort incorporating the following two features: (1) the establishment of a single, unified waiting list including all patients awaiting an organ transplant in a number of OPO service areas and (2) the mandatory distribution of donated organs to those patients on a first some first served basis, subject to established medical criteria.**

We recognized that even with the development of equitable, patient-based allocation systems within OPO service areas, the unequal patient access across service areas would not be diminished. Thus, we called for demonstration efforts that would develop larger pools of donors. Such efforts could enhance equity across the established regions, allow greater opportunities for highly sensitized patients, and enable better overall understanding of the pros and cons of operating larger scale distribution systems. The demonstration effort, we believed, would foster progress toward the national system envisioned by Congress.

Update and Conclusion

Since 1991, some progress has been made in closing the gaps we identified between expectations and practices. The OPOs now must establish a single unified list of patients awaiting transplants and use it as the basis for allocation, in accordance with OPTN rules. Further, the differential in black-white waiting times for cadaver kidneys appears to have been reduced somewhat. The OPTN has served as a vital forum for addressing issues and making decisions that contributed to this progress in organ allocation practices.

At the same time, there is still much room for progress, as is most clearly exemplified by the substantial differences that remain in waiting times across OPO service areas. Further, with three times as many individuals awaiting a transplant as there were 7 years ago, it is even more imperative that Congressional expectations of the organ allocation system and actual practices be in close accord. The increased scarcity heightens the urgency of the situation and, we believe, the importance of public guidance on how best to deal with the situation. Our recommendations offered general directions on how that might be done. The March 26 HHS rule follows along the same line, presenting broad directions for the OPTN and medical professionals to apply, using the best of the medical evidence available to them.

By calling for performance goals for standardized criteria for listing patients on transplant waiting lists, for standardized criteria for medical status of those on waiting lists, and for organ allocation policies that give priority to those whose needs are most urgent, with less attention to geographic factors, the HHS rule provides an opportunity for continued progress toward the kind of system we called for 7 years ago. The OPTN, of course, has a key role to play in carrying out that opportunity.

It remains essential, we believe, for HHS and for the OPTN to exert leadership to help develop organ allocation systems that are grounded in ([redacted]ters and (2) in [redacted]plant c[redacted]on.

Mr. SHAYS. Our final testimony will be from Lawrence Hunsicker and we welcome your testimony.

STATEMENT OF LAWRENCE HUNSICKER, M.D., PRESIDENT, UNITED NETWORK FOR ORGAN SHARING [UNOS]

Dr. HUNSICKER. Mr. Chairman, Congressman Barrett, good morning. I'm Dr. Larry Hunsicker. As you just heard, I'm the medical director of Organ Transplantation at the University of Iowa and currently also the president of the United Network for Organ Sharing, or UNOS. UNOS is a private corporation that is the contractor to HHS as both the Organ Procurement Transplantation Network, or the OPTN, as you've heard it abbreviated, and the operator of the Scientific Registry of Transplantation. Our members are transplant centers, doctors, recipients, donor families, and others who comprise the transplant community.

Today, I will try to put to rest several misconceptions regarding organ allocation and the HHS regulations. First, let me emphasize that while the great majority of the transplant community feels that these regulations are ill advised, we do wish to continue to work with HHS to improve the system as we have done for the past 11 years.

I want to point out that Federal law provides that organ allocation policy will be made in the private sector, not at HHS. Congress wisely insisted on this in an effort to shield the formulation of these vital policies from the effects of special interests in politics. In doing this, over time UNOS has been able to develop consensus among the medical experts and the other community members to resolve almost every difficult issue except liver allocation, and we've made substantial progress recently in that area.

Much of our concern with the recent HHS action is based on our understanding of the profound, sometimes heart-wrenching complexities of the relatively new branch of medicine. Policy changes as radical as those contained in the regulations need to be thoroughly reviewed, debated and consensus reached before they are implemented.

The system being mandated by HHS will not save more lives. Our computer models indicate that in the long run more patients will die under the HHS regulation. There's no scientific or medical evidence to support the assertion as argued by HHS that technology now permits all livers safely to be shipped to any part of the country without detriment to the organ or the patient. Increased time without a blood supply still significantly decreases the viability of the organ, especially an organ from a less than perfect donor, and it increases likelihood that it will fail, thus requiring yet another organ to be used for the same patient. Under the new regulations we project increased wastage of precious organs due to excessive transit times, organs that could have saved a life if they were used promptly in a local setting.

Of equal concern to UNOS is that the new policy requires the sickest patient in the country to be transplanted first no matter where that patient is in relationship to a recovered organ. This means that most patients already suffering from the effects of end stage liver disease will have to become yet more severely ill before being transplanted than is the case today. Survival rates for this complex surgery are significantly worse for those who are on life support. It is important to note that current UNOS policies already make livers available to the most seriously ill patients at a very similar rate, about 4 to 6 days, no matter where in the country they are hospitalized. Another potentially devastating problem is the predictable decrease in organ donation that would result from the closing of smaller local transplant programs. Many of these will be unable to transplant a sufficient number of patients to maintain the proficiency of their staffs. Donation, like politics, is a local phenomenon, and as the best professional advocates of donation leave a community, donation will decrease. We have seen the converse of this effect repeatedly as new centers have opened and caused significant increases in local donation.

Also a significant ethical question is raised by the new regulations. After many committee meetings and several public hearings involving representatives of HRSA or the branch of HHS that deals with transplantation, UNOS in 1992 unanimously adopted basic ethical allocation principles that are designed to guide us in our policymaking. The basic message is that there is a fundamental ethical obligation to balance justice and medical utility in crafting allocation policies. HHS has focused solely on fairness and in doing so we fear has promulgated a policy that will have tragic practical consequences.

We are also concerned about the cost implications of the new policies. The HHS regulation will result in many millions of dollars of increased costs for the care of critically ill patients in Intensive Care Units who never had to be there.

I feel sympathy for the patient who is unable to afford to travel from his home to the remaining transplant centers or whose spouse has to quit her job to accompany him. Who will pay for their temporary lodging far from home sometimes for months while they wait for their surgery in strange surroundings and ever-failing health. Some Medicaid programs will not cover this expense, which means that there will be no transplants for many poor or rural citizens. The HHS regulation require that UNOS implement policies to encourage transplant centers to pay the costs of transplantation, but then what is to stop insurance companies from dropping coverage for this expensive procedure.

In closing, I urge you to give careful thought to the effects of these regulations and to their underlying implication for future transplant patients. I urge you to direct the Department not to implement them as they are and to require a meaningful dialog with the Congress and the transplant community before making any changes in the current program. I appreciate the opportunity to testify and will be happy to answer your questions.

[The prepared statement of Dr. Hunsicker follows:]

Opening Comments of Lawrence G. Hunsicker, M.D.
before the House Government Reform and Oversight Committee
Subcommittee on Human Resources
April 8, 1998

Mr. Chairman, good morning. I am Dr. Lawrence G. Hunsicker, president of the Unite Network for Organ Sharing. UNOS is a private corporation that, among other activities is the contractor to HHS as both the Organ Procurement and Transplantation Network (OPTN) and the operator of the Scientific Registry of Transplantation. Our members ar the transplant centers, doctors, recipients, donor families, and others who comprise the transplant community.

You are all aware of the controversy that has surrounded the issuance of interim final regulations by HHS regarding organ transplantation policy. In my brief appearance her today I will try to illustrate a number of reasons for this controversy, and put to rest several misconceptions. First, let me emphasize that, while the great majority of the transplant community feels that these regulations are ill advised, we do wish to cooperat with HHS to improve the system.

I want to point out that Federal law, the National Organ Transplant Act, provides that organ allocation policy will be made in the private sector, not at HHS. Congress wisely insisted on this in an effort to shield the formulation of these vital policies from the effects of special interests and politics. In doing this, over time UNOS has been able to develop consensus among the medical experts and other community members to resolve almost every difficult issue except liver allocation, and we have made substantial progress recently in that area, as well. The amount of effort expended in fulfillment of this responsibility has been considerable- UNOS just surpassed one million hours of volunteer time that have been invested by the community in an effort to make the system as fair, as just, and as medically sound as it can be.

Much of our concern with the recent HHS action is based on our understanding of the profound, sometimes heart-wrenching complexities of this relatively new branch of medicine. Policy changes as radical as those contained in the regulations need to be thoroughly reviewed, debated, and consensus reached before they are implemented, but despite repeated written requests from the community and Congress, HHS did not follow this path.

The system being mandated by HHS will not save more lives. Our computer models indicate that in the long run, more patients will die under the HHS regulation. There is no scientific or medical evidence to support the assertion, as argued by HHS, that technology now permits all livers safely to be shipped to any part of the country without detriment to the organ or the patient. Increased time without a blood supply still significantly decreases the viability of the organ, especially an organ from a less than perfect donor, and increases the liklihood that it will fail, thus requiring yet another organ to be used for the same patient. Under the new regulations we project increased wastage of precious organs due to excessive transit times- organs that could have saved a life if used promptly in a local setting.

Of equal concern to UNOS is that the new policy requires the sickest patient in the country to be transplanted first, no matter where that patient is in relationship to a recovered organ. This means that most patients, already suffering from the effects of end stage liver disease, will have to become more severely ill before being transplanted than is the case today. Survival rates for this complex surgery are significantly worse for people who are on life support (status 1 liver patients). It is important to note that current UNOS policies already make livers available to the most seriously ill patients at a very similar rate (i.e., 4-6 days) no matter where in the country they are hospitalized. The great differences in waiting times for livers that HHS cites are for the least ill, not the most ill patients.

Another potentially devastating problem is the predictable decrease in organ donation that will result from the projected closing of smaller local transplant programs. Many of these will be unable to transplant a sufficient number of patients to maintain the proficiency of their staffs. Donation, like politics, is a local phenomenon, and as the best professional advocates of donation leave a community, donation will decrease. We have seen this effect repeatedly as new centers have opened and caused significant increases in local donation.

Let me also emphasize that a significant ethical question is raised by the new regulation After many committee meetings and several public hearings, UNOS unanimously adopted basic ethical allocation principles that are designed to guide us in our policy making to treat patients fairly and save the greatest number of people. I have submitted its text for the record, but the basic message is that there is a fundamental ethical obligation to balance fairness, justice and medical utility in crafting allocation policies. HHS has focussed solely on fairness, and in so doing, we fear, has promulgated a policy that will have tragic consequences.

We are also concerned about the cost implications of the new policies. In an era when health care costs are of such great concern, the HHS regulations will result in many millions of dollars of increased costs for the care of critically ill patients in intensive car units who never had to be there. The cumulative cost of caring for increasing numbers c people in the final months of end stage disease will dwarf the costs currently associated with transplanting them at an earlier stage of disease. In addition, the costs incurred by increased transportation of both patients and organs will be enormous.

I feel sympathy for the patient who is unable to afford to travel from his home to the remaining transplant centers, or whose spouse has to quit her job to accompany him. Who will care for their children? Who will pay their bills? Who will pay for their temporary lodging far from home, sometimes for many months, while they wait for their surgery in strange surroundings and in ever failing health? Some Medicaid programs wi not cover this expense, which means that there will be no transplants for many poor or rural citizens. The vocal but very small minority in favor of these new regulations claim that this will be better for patients, but you can be the judge of their objectivity. The

HHS regulations advise UNOS to implement policies to encourage the transplant centers pay these costs, including the costs of the transplant, but then what is to stop insurance companies from dropping coverage for this expensive procedure, making matters much worse for future patients.

In closing, I urge you to give careful thought to the effect of the regulations and to their underlying implications for future transplant patients. I also urge you to direct the Department to not implement them as they are, and to require a meaningful dialogue with the Congress and the transplant community before making any changes in the current program. I appreciate the opportunity to testify and will be happy to answer any questions.

Mr. SHAYS. Let me just make a request of the audience. We will show, I think, some significant flexibility here. It's clear to me that you were not clapping for all three speakers. So now that's clear to us and so we know where you are coming from, but it's important for us to be able to make all the speakers here feel comfortable that they can answer questions and expose us to their view, and if we are not exposed to their view, we are not going to be able to judge this issue fairly. So I really thank all the speakers here. I particularly thank the first two as well as Mr. Hunsicker because they have stated the case in a way that we now can have some meaningful dialog. And I will say to some of you in the audience that you will get an opportunity, some of you, not all of you. Some of you will get an opportunity to make comment to what you are hearing, and that's another way that you'll be able to express yourself.

I'm going to ask Mr. Barrett to go first, and we are going to go back and forth. Before I do, the three who have accompanied, if you'd like to just make a comment before we start.

Mr. Smolonsky, I note for the record that you spent most of your time at the Chicago airport last night instead of a nice place to sleep, and we thank all of you for being here, but would you like to just make a comment or you, Mr. Graham, or, Doctor, any comment before we begin?

Dr. HUNSICKER. I think we'll just be ready to answer your questions.

Mr. SHAYS. OK. Mr. Barrett.

Mr. BARRETT. First of all, I want to thank all of you for your testimony. I think that everyone who is involved in this issue is operating in good faith. I don't question the motives of anyone who is here today, because I think everyone is concerned about doing the best that they can for the people in this country and the people who deserve the gift of life. My concerns come in translating the best intentions to the practical impact that it's going to have. And my perception, and, Dr. Fox, I would like you perhaps to comment on this, my perception is that there are some medical centers or some hospitals who have put an emphasis on developing a patient list and have done so quite well. There are other hospitals who have put their relative resources on developing an organ donor list. My concern is that these rules will create an incentive for all hospitals to no longer put any emphasis on organ donations but to put all of their emphasis on finding the sickest patients that they can. And the reason I say that is—again, I think that all of us are here because we care about the patients, but I will say to everyone in this room I think there is along with that concern for patients, there is from every one of these transplant centers a high degree of economics involved here. And we can sort of dress it up and dance around it, but I think that's a reality that centers are concerned about being closed, they're concerned about losing patients. But if you could respond to my concern, please.

Dr. FOX. Let me just say that——

Mr. BARRETT. It's not on.

Mr. SHAYS. I believe the switch might have come off. OK.

Dr. FOX. Well, several things. One, in regard to the patient list, one of the problems and one of the things that we think contributes to the inequity is that the listing criteria, the way you get on the list, how early you get on a list really varies across this country, and so that if a particular physician is aggressive for his or her patient, they may get on the list much earlier in one part of the country than another. And, again, that provides some inequities, and we think that should be standardized in some way or other, so that is a problem.

The donations, as you've also alluded, there's tremendous variation. Some hospitals have contributed virtually no donations to the national donations and other that do quite well. So there is a disparity in each one right now. I think that what we hope will happen out of this will be that because now today we have between a 75 and 85 percent survival rate for people in this first, schedule 1, 2, the ones that are ill enough to be in a hospital, that those people deserve a chance. We are not saying in this regulation, I would like to point out that this regulation is only eight pages long, but it has in it on several occasions comments around sound medical judgment. And, in fact, the allocation part of this regulation is prefaced with sound medical judgment and also a caveat that whatever policy that the OPTN brings forward be based on sound, efficient management of the organs that are vital. Then there is also a specific section around wastage. So we do not stipulate what the policy should be. And, in fact, we don't say, or I hope in this regulation, that organs will necessarily go coast to coast, but that whatever policy is provided would be based on what makes sense. What makes sense is to try to transport those people, and it's not sickest first, it's medical urgency. And obviously a patient who is ill enough today that they would not benefit by transplant that in a physician's judgment would not be transplanted, would also not transplanted under this new policy. So we think there are caveats in the regulation that lay out a framework for the transplant community as they put these forward to use medical judgment, to not waste our precious national resource and to come forward with a policy that operates in that guideline. But it is a problem because now there are disparities on both waiting list and donation across the country and tremendous variations depending on where you live.

Mr. BARRETT. But again let me ask the question, does not this rule create a disincentive for a hospital to put economic resources, this hospital to put its own economic resources into procuring organs if—and I'm talking about an economic disincentive, because it will believe that those organs will not stay here.

Dr. FOX. We don't believe that's the case. I would point out right now today nationally one-third of all organs go outside of the area they're collected. It varies again by area. For the OPO we're sitting in, about 20 percent of the livers currently go outside this OPO we're in today. In Connecticut 70 percent, 68 percent of the livers go outside of the Hartford OPO. So I think there is a misconception that organs are not moving. Today they are, and if one-third nationally, if you take the average one-third of organs moved today, what we don't know, and we've asked UNOS to provide this information, how many organs come in, and how many organs go out. We think that that's today what happens. It will also be what happens under a revised policy. To what extent that occurs really is going to depend on the policy, which is not laid out, and I think that that's what we are certain that it's part of.

Mr. BARRETT. Let me go down that road for a second, if I could.

Mr. SMOLONSKY. Congressman Barrett, excuse me. If I may respond to your question about this being a disincentive for hospitals to invest in organ procurement.

Mr. SHAYS. I'm going to ask you to put the mic a little closer to you. I'm sorry.

Mr. SMOLONSKY. I'll try.

Mr. SHAYS. Just pull it right up.

Mr. SMOLONSKY. Is this better?

Mr. SHAYS. Yes. I think these mics are designed to be close, unfortunately.

Mr. SMOLONSKY. As you know, we have a two-pronged attack here. One is an earlier regulation, the Hospital Conditions of Participation Regulation. Under that regulation a hospital will not be allowed to deemphasize organ procurement.

Mr. SHAYS. A little louder. A little louder.

Mr. SMOLONSKY. It will be required to do more. All hospitals in the country under this regulation, in order to participate in Medicare and Medicaid, will be required—regardless of what the final allocation policy is, all hospitals will be required to do more for organ donation. So the disincentive that you are worried about has been dealt with in the Hospital Conditions of Participation Regulation. It will not happen. And if a hospital chooses to do that, they risk jeopardizing their Medicaid or Medicare eligibility.

Mr. BARRETT. And I appreciate that answer. Dr. Yessian, did you want——

Mr. YESSIAN. On that point, let me emphasize this first, that in speaking for the Inspector General, speaking as an independent oversight entity here, so we haven't cleared our testimony or comments with the Department in this case, but obviously much of what we found is supportive of the direction of these policies.

On your point about the disincentive——

Mr. SHAYS. Just lower your mic just a speck. Just lower it down below you.

Mr. YESSIAN. OK. How's this?

Mr. SHAYS. Yes.

Mr. YESSIAN. That disincentive—the leading responsibility for organ donation in each area is the organ procurement organization, which clearly involves hospitals or transplant centers in a leadership role, but also other parties in the service area in the region. In the Department of Health and Human Services Medicare continues to fund those organ procurement organizations on a cost reimbursement basis for whatever their expenses are. That's a pretty unusual way of funding these days, so that's an incentive to do what it takes to be very active in procuring organs. So I just wanted—I think that's an important point.

Mr. BARRETT. Dr. Fox, if I could go back to you for a second. As I listen to your statements, it sounds like there could be different policies for different organs based on viability of the organ or time for transportation. Isn't this going to create rules and subrules and create more confusion that way?

Dr. FOX. Again, we have laid out the broad parameters. We know that the current technology around the viability of how long organs can go prior to transplantation varies and is going to continue to change over time. And we fully expect any policies that the OPTN brings back would reflect that. And again, that's one of the reasons that we left it flexible, because as technology changes, it allows the OPTN through its deliberations to change the policies to make sense with medically what's available at the time, so we think that's rational, we think that's the approach that ought to be taken, and again, it'll change as the technology changes.

Mr. BARRETT. Dr. Hunsicker, I think in your testimony you alluded to the waiting list, in particular for those in level I. And I guess I have been under the impression that maybe there are some regions of the country where someone who's on level I would wait longer than others, but your testimony seems to rebut that. Can you amplify that, please?

Dr. HUNSICKER. In both level I and actually level II, the differences in waiting times amongst the different regions are really——

Mr. SHAYS. A little louder.

Dr. HUNSICKER. I'm sorry. The differences in waiting times amongst the regions, the 11 regions of UNOS between level I or status I and status II are quite small. So it is primarily to the—with livers to the extent that there are differences in waiting it is primarily in the least urgent category.

Mr. BARRETT. OK. Let me check with the other panel members to see if they agree with that because I think that's significant.

Dr. FOX. By region I would agree except to say that if you—that waiting times, and there's two caveats; that one, if you look at the individual OPO areas, there is a significant variation. By definition status I is patients only expected to live 7 days, and what it doesn't take into account is the patients who die while waiting in status I, and we don't have those numbers.

Mr. BARRETT. If I could interrupt. Again, his testimony is that a patient at level I waits 4 to 6 days? Is that——

Dr. HUNSICKER. The median waiting time in the 11 regions——

Mr. SHAYS. Doctor, I'm going to ask you to really project. You've got a beautiful voice. I want to hear it.

Dr. HUNSICKER. The median waiting time in the 11 regions of UNOS ranges from about 4 to 6 days.

Mr. BARRETT. OK. And so what are you saying?

Dr. FOX. I'm saying, one, the definition of category I is patients who only—to get in category I you have to be expected not to live more than 7 days. So that in itself is limiting. What it doesn't tell you is that people drop off the list because they die.

Mr. BARRETT. So you're saying that they die before they get to level I.

Dr. FOX. I'm saying that some die. Some die. But the second thing I'm saying is that by looking at it by region, you lost waiting times, and I think we provided this to the committee. If you look at it by OPO, which is a much smaller area, there is a fairly significant difference in the waiting times.

Mr. BARRETT. Does your policy have the effect of telling someone come back when you are sicker?

Dr. FOX. Again, we are not saying how ill—I mean what we are saying in the regulation is use medical judgment, set up a process that looks at those medically urgent. That may be different than sickest. Sickest may be so sick as to not survive a transplant. What we are saying is use medical urgency.

One of the other misconceptions is medical urgency is currently the policy within the OPTN right now, it's just applied on a local basis. And what happens is, for instance, in I believe it was 1996 of the 950 some odd people who died waiting for a liver transplant, 400 of those died while in the hospital, but the same time almost half of the transplants that took place for liver patients took place on people who were not ill enough to be in a hospital. And the effect would be that if you have two OPOs that are right adjacent to each other and divided by a river, you could have one person living on one side of the river who because the—there's no people in status I or status II could get a liver and could be an outpatient while someone living a mile right across the river on the other side in another OPO who is ill and in the hospital does not get that liver. And, again, that is an arbitrary geographic distinction and one we think is unfair.

Mr. BARRETT. Dr. Hunsicker, do you want to respond to that?

Dr. HUNSICKER. Yes. I think that the issue with respect to the sickest first is one that requires clarification. I don't think that there is any dispute about the patient who has gotten so ill that he or she will not benefit from a transplant. Neither the Government nor UNOS nor any responsible surgeon or physician would recommend that a liver be put into a person who cannot survive the procedure. That's silly. The issue comes up with the balance in the degree of severity of illness of the patients who will get the transplants. There are patients who are so ill that the risk for their surviving is reduced, nonetheless had I a liver, I would offer it to this person, but it might better be put into another person whose condition had not deteriorated so far, and so that the likelihood of benefit is better.

Now, we have tried to balance in UNOS the issues of care for the most seriously ill so that we don't write off anybody who could benefit but so as to try to maintain the balance so that a larger fraction of patients who are in a more stable condition. All of these people are people who are seriously ill and need a transplant. You talked about death on the waiting list. It's worth noting that almost half of the deaths on the waiting list occur in patients who are not in hospitals, who are in the least urgency category because they are all sick. We are trying to suggest that a balance in which we transplant patients relatively earlier probably is a more efficient use of this extremely valuable, scarce resource.

Mr. BARRETT. Mr. Chairman.

Mr. SHAYS. Thank you. I realize almost everyone here knows more than I do on this issue because this has been your life in some cases and you've learned a heck of lot about it. I'm going to ask a few questions that are going to illustrate my ignorance, but I want to at least have this established before I go on.

I look at the, I guess the 63 procurement organizational service areas, and I make the assumption that these are the smallest areas and that they are trying to identify donors and receive organs. I make an assumption that the OPTN regions are basically the regions in which these organs can be provided. As a general rule. Is that—am I still on target here?

Dr. FOX. No. They're generally shared within the OPO's.

Mr. SHAYS. Within the OPO's.

Dr. HUNSICKER. The first level of sharing——

Mr. SHAYS. Let me just say, just make sure that we don't go too fast for our recorder here. Let me just say, Dr. Fox, your comment, and then I'll go to you.

Dr. FOX. The local area is considered for the most part the OPO.

Mr. SHAYS. What is the significance of the OPTN region?

Dr. HUNSICKER. As Dr. Fox said, the first level of sharing is the OPO. As he also said before, a significant number of livers are actually shared outside their original OPO, and those would be if they cannot be effectively used within local OPO, then they are shared second level within the region, which is a smaller geographic area than the entire United States.

Mr. SHAYS. Right.

Dr. HUNSICKER. The large majority are used either within the local OPO or within their region. Only a small number are shared nationally. That is to say between regions.

Mr. SHAYS. But I make the assumption then that most donors are identified within the smallest area, the service area, and most of the organs are then provided in those small areas. Is that correct? I mean there's consensus there?

Dr. HUNSICKER. The majority.

Mr. SHAYS. Yes. OK.

Mr. GRAHAM. Could I add one point?

Mr. SHAYS. Sure.

Mr. GRAHAM. When the National Organ Transplant Act established the system by which we have been discussing this, it said that the OPO service area——

Mr. SHAYS. Let me ask you a little louder.

Mr. GRAHAM. OK. The OPO service area is required by law to be large enough to provide for efficient organ procurement as well as equitable organ allocation. So that's how Congress set this up back in the beginning, and that was the basis for our distributing organs locally to begin with.

Mr. SHAYS. OK. The other assumption I make is that the OPTN is basically the network and UNOS is the contractor. Because sometimes we use them interchangeably and I just—you want to respond?

Dr. FOX. Well, UNOS is the contractor and operates the network as a part of that contract.

Mr. SHAYS. Right. They operate the network.

Dr. HUNSICKER. Yes. UNOS actually does at this point effectively only two things. It operates the OPTN under one contract in the Scientific Registry, which is a closely related thing which deals with the data management under a separate contract. We are, however, a private corporation with a life independent from the two contracts.

Mr. SHAYS. Let me just throw something on the table. I find myself reacting to your statement, Dr. Hunsicker, and feeling there is a bit of what I think is a little disingenuous and so let me just put it out on the table. You basically are a private organization, but you are a monopoly; correct?

Dr. HUNSICKER. That is—yes. We are not a monopoly. We are the only organization that does that. I'm being told not to say that.

Mr. SHAYS. Well, you may be told not to say that, but you are a monopoly.

Dr. HUNSICKER. We are the only organization that does this because the——

Mr. SHAYS. Well, I'm not arguing about the validity of it. The bottom line is monopoly means to me one player, and you are the player.

Dr. HUNSICKER. Although the Government could switch the contract if it wanted to do so.

Mr. SHAYS. I understand that. I understand that. But just so we——

Dr. HUNSICKER. So long as we hold the contract, we are the people that do the job.

Mr. SHAYS. Right. And I'm not arguing that you have one organization doing that. I'm not arguing that it shouldn't be your organization. But it's a little disingenuous to me just to tell you to talk about how the public and private sector do things and don't have the public sector tell the private sector what to do. If you only have one player, the public sector better be in there regulating that monopoly. And then the question to me is if we can get beyond that. The question is, are these logical regulations? But if you were to get to the level that "the public doesn't have any right telling us what to do," you know, "we are the private sector," then you and I are going to be having a long dialog for a long time on that.

Dr. HUNSICKER. We have never had any problem with the Government participating in the process and exercising oversight. They do this through the contract. They've done it for 11 years, we've worked with them for 11 years and we think that that is an appropriate way for things to happen.

Mr. SHAYS. OK. Now tell me——

Dr. HUNSICKER. It's important for me to say that the board of directors of UNOS does in fact have—one-third of its members are either patients or patient families or donor families. The method for selecting the candidates for the board of directors is that they are nominated by a nominating committee which reflects the composition of the board of directors, and so there is in a sense, at least in part UNOS is a self-perpetuating board that is selected from the community of transplantation. It involves representation from all the aspects of transplantation.

Mr. SHAYS. It's just important for me to tell you up front that I believe the issue is what kind of regulations should the Federal Government be imposing on this monopoly to make sure that the public's interest is dealt with fairly. You want to make a comment?

Mr. GRAHAM. Back in 1984 when this law was passed, the Congress created a new way of approaching this kind of relationship, and so I thought it would be important to point out that the National Organ Transplant Act says that the Secretary shall establish and operate the OPTN by contract and that the OPTN shall be a nonprofit entity. And that this is to be done in the private sector, so it's done by contract as opposed to the traditional regulatory route that had been done before in other areas of medicine. So the oversight that's been provided to us by HHS for the last 11 years has been through the contract.

Mr. SHAYS. Well, it's both—Mr. Graham, I don't want to nitpick here, but I'm happy to pursue this. It is done both by regulation and contract; correct?

Mr. GRAHAM. It has not been today. It has been done by——

Mr. SHAYS. There are no regulations governing?

Mr. Graham. I'm talking about these that are out today. This is the first time the OPTN regulations have been promulgated.

Mr. SHAYS. There are no regulations on the books right now dealing with how UNOS operates? It is all done by contract; is that your testimony to the Court?

Mr. GRAHAM. Yes.

Mr. SHAYS. Dr. Hunsicker.

Dr. HUNSICKER. There are many regulations, of course, that are swept into the contract to which we are subject.

Mr. SHAYS. Well, yes. So, I mean the contract trying to implement certain regulations that exist that HHS has imposed. I don't want to go too far here. We were talking about federalization, and I need to know what that means. But I just need to know how HHS views this. And I would love to know how the Inspector General views this. It's not a big point in the dialog here, but it's just like if we can't establish certain things between reasonable people, then I can't get to the next point.

Dr. FOX. Ask Mr. Smolonsky.

Mr. SMOLONSKY. Thanks, Dr. Fox.

Mr. Chairman, there is a regulation, a 1988 regulation that gives the Secretary the authority to approve all UNOS policies and all OPTN policies—I'm sorry, not UNOS policies, but OPTN policies. It's a standing regulation. In addition to that, Congress amended the Social Security Act, section 1138, which gives HHS the authority to deny Medicare or Medicaid eligibility to any hospital or transplant center that does not abide by the rules of the OPTN. It's our legal view that it would be impossible to enforce that provision without binding regulations. You can't very well kick an entire hospital out of the Medicaid or Medicare Program on the basis of voluntary or informal guidelines, and that is our view.

Mr. YESSIAN. Mr. Chairman, if I could just add to that point that in 1988 when Congress passed an amendment to the law here, there had been some concerns at that time about how the Congress' intentions on inequity were being transferred in a way that emphasized equity among transplant centers and not patient and the law clarified its intent to focus on patients and in an accompanying House report by the Committee on Energy and Commerce specifically called for the HHS Secretary to monitor the allocation of organs closely to make sure the allocation schemes remained based on equity among patients, so there is a trail here of congressional expectations about oversight.

Mr. SHAYS. Doctor.

Dr. HUNSICKER. I'm not a lawyer and I'm not going to try to answer a legal question, Mr. Chairman. I think the sense of your question is, has there been previous instruction from HHS on allocation policy.

Mr. SHAYS. No. My question, bottom line, is this. My question is this; Congress passes a law and gives HHS the ability to establish regulations. In the law and in the regulations HHS has the ability to contract out to your organization or somewhere else, and to me it is extraordinarily disingenuous to suggest that there haven't been regulations and that there shouldn't be. The issue is what kind of regulations. I mean I haven't passed judgment on what kind of regulations. You've got to trust me on that one. But bottom line I just think it's a little disingenuous to say, "we are the private sector, you Federal Government don't tell us what to do." They are going to tell you what to do because you are a monopoly and you maybe don't want to be called that, but you are, and you are an important monopoly, in my judgment. And I'm not arguing that there shouldn't be a monopoly. But once we can at least understand the relationship here, then we can, it seems to me, talk about what logical regulations should happen. And with that in mind, I just want to ask you in the letter that I have here, it's a sample letter to Congress. It's from your web site. I'm going to quote a paragraph here. It says:

> As a transplant center, our concern has been, always has been and always will be with the outcome and well-being of our patients. We are convinced, however, that the impact of the regulations would be to lengthen the amount of time sick people must wait for transplants and reduce the number of people who are able to get them. The proposed federalization of the current system would take away control of the transplant system from doctors and patients and hand it over to the Federal regulators.

I need you to explain that one to me. I don't understand what that means.

Dr. HUNSICKER. I assume you're referring to the last sentence and not to——

Mr. SHAYS. Yes, the federalization. Yes.

Dr. HUNSICKER. I actually understand the sense of the law that was passed, the NOTA, N-O-T-A, perhaps differently from you. And I don't want to argue with you because that is not my point.

Mr. BARRETT. Speak up a little more.

Dr. HUNSICKER. We believe that it was quite intentional by Congress at that time to stipulate that these rules concerning the allocation of organs were not in fact to be made within the Government but were to be made in a private organization under contract to the Government. That is my understanding of what was the intent of Congress at that time. Should the Secretary have the ability unilaterally to say no, the rules that you have adopted have to be changed to different rules without the communities being able to respond to that or to say, gee, we think that's really a very bad idea, we believe that that would be contrary to the intent of the people who passed the law in saying that these rules should be made by the community under the general supervision of or the general whatever you want to call it. Supervision is as good a word as any of the Government and not that the Government itself was supposed to have the ability ultimately to set what the rules were.

Mr. SHAYS. Could you define to me what the community is?

Dr. HUNSICKER. The community in this case is the—very specifically the community is represented by UNOS because it's the UNOS board of directors, I should say the UNOS Board of Directors that has the authority to make rules for UNOS and then for the OPTN.

Mr. SHAYS. Is UNOS given an unlimited contract or does it get——

Dr. HUNSICKER. No. It's renewed every, it's been every 3 years.

Mr. SHAYS. But the community is basically the centers.

Dr. HUNSICKER. The membership of UNOS includes centers, OPOs, individuals with an interest in transplantation and I may have missed one category or another. I don't think so.

Mr. SHAYS. So how does an individual who has an interest become part of UNOS?

Dr. HUNSICKER. They have to be approved by the board of directors, by the—well, ultimately by the board of directors, but by the Membership Professional Standards Committee. That particular thing is made—is put in explicitly to make it possible for people who do not have any kind of affiliation with any other organization to be on the board of directors because you've got to be a member to be on the board of directors.

Mr. SHAYS. But admittedly it's a pretty small group.

Dr. HUNSICKER. It's a small group.

Mr. SHAYS. It's a small group of people.

Dr. HUNSICKER. The large group of members are hospitals; however, I want to reiterate that the way in which the members of the board of directors, which ultimately has the only operative voice, if you will, the only ultimate authoritative voice for UNOS, is selected by nomination by a nominating committee that represents the membership of the board of directors.

Mr. SHAYS. How many members are part of UNOS?

Dr. HUNSICKER. What's the number? There's 600 members.

Mr. SHAYS. Are those individuals or organizations?

Dr. HUNSICKER. No. The vast majority of the members are transplant hospitals because transplant hospitals must. The second category is——

Mr. SHAYS. So the vast majority of the transplant centers.

Dr. HUNSICKER. Yes, sir.

Mr. SHAYS. Right. OK.

Dr. HUNSICKER. But the nomination to the board of directors is to the ones nominated by the nominating committee, so there is a strong element here of a self-perpetuating board. In other words, the members—we have to have a certain fraction of public representatives. We have to have certain categories. Those are in the contract. We cannot select people just any way we want.

Mr. SHAYS. The bottom line for me, not for you, and I'm not going to try to convince you that I'm right on this, I'm just going to tell you what I think. The bottom line is this: The Federal Government decided that we had to have a system of encouraging donors and to provide for a system where we could disseminate the organs in the fairest and best way. We passed laws, we passed regulations, we gave HHS the ability to contract with UNOS, and your organization is a very small organization. We are a country of over 260 million people, and we're not going to let a very small organization dictate every policy. We're going to have that be through a representative body. Now, Mr. Barrett and I know we are not doctors and we're going to stay out of the way as much as we can. We're going to allow for expertise in the Federal Government to play a role. Now, their role, it seems to me, right now, is to say, "We don't like what we are seeing," and let me ask you that. Should I feel comfortable with the existing—and we got the same message from the Inspector General. In fact, the report that the Inspector General has he can basically take out from 7 years ago. So would it be your testimony before this committee that things are working well and that we don't need any changes?

Dr. HUNSICKER. You have two separate pieces——

Mr. SHAYS. It's not on now.

Dr. HUNSICKER. You have two separate pieces to your question.

Mr. SHAYS. Let me say something to all of you. We're going to go until we establish a certain point. There's no rush in time, and I'm just trying to get some answers here.

Dr. HUNSICKER. There are two separate pieces to your question. One is are things going well, and the second is do—is there any need for changes. Well, I think it's a function of what part of this you are talking about. I think that UNOS has done an extraordinary job. I, of course, am a biased observer here, I'm a part of the system. But I think we've come a long way in an area that has not ever been tackled in medicine before.

Do I think we have reached the ultimate——

Mr. SHAYS. What is going well and what isn't going well. I think if we can all agree where it's working well and where it isn't, then we can go to the next step.

Dr. HUNSICKER. For one, when the NOTA was passed back in 1984, formation of any kind of transplant policy, allocation——

Mr. SHAYS. We had no policy.

Dr. HUNSICKER. There was none. It was all local. Like most other parts of medicine, it was whatever you do at your hospital is your policy.

Mr. SHAYS. Correct.

Dr. HUNSICKER. In the interim since that time there is really in effect now a true national transplant policy. Dr. Yessian commented on some of the things that he felt that needed to be done 7 years ago, and, in fact, we quite on our own, and I think to our great credit, have done many of those things. We agree that there need to be uniform listing criteria. We agree that there need to be urgency criteria. And these things have been done by UNOS that have not been done in any other part of the medical area. We have national agreement of these things. So I think that that is a system that is going very well.

Do I think that the policies we have today are the last policies we will have? No. I don't think so.

Mr. SHAYS. Now, I need to ask you more specifically, then I'm going to go to you, Mr. Barrett, in about 5 minutes here. I need to know, are we getting enough donors?

Dr. HUNSICKER. No. You've given me a chance to say something. One area where everybody in this field agrees, the Secretary, all of the members of UNOS, the ones who are unhappy with the current, everybody agrees that the issue is donation.

Mr. SHAYS. OK. So we all agree pretty much on that issue. The second issue is based on your testimony. I gather from you that you are pretty comfortable with how we are allocating the organs, that you think the system works pretty well. And I gather from both Dr. Fox and Dr. Yessian that we have some problems here, but I want to understand you first. Do you think the way we are allocating organs is working well?

Dr. HUNSICKER. I personally have my thoughts about that. We are evolving as an institution. I don't want to sidestep you, Mr. Chairman. It's not my intent to do that. The policies will change over time, and I don't want to substitute my opinions for the opinions of the organization.

Mr. SHAYS. Let me just say you are here representing the organization, and I am going to pin you down unless you are telling me that the organization simply doesn't have an opinion.

Dr. HUNSICKER. No. The organization's opinion is that where we are is reasonable as a step in the direction that we need to be going. We need to base our decisions on hard scientific facts as best we can. We have looked at the scientific evidence. We have evolved in that direction. I don't imagine this is the end of the road for us or for any group with respect to this issue.

Mr. SHAYS. What I am struck with, though, is that you basically have used your organization to try to communicate that you don't like the rules and regulations and it's eight pages. I'm going to come back next round. I'm just going to tell you where I am coming from so you can think about it.

Basically, I believe that since one of the key issues is getting enough donors, that anything that we do that discourages donors would not be a particularly positive thing, and so I kind of lean toward what I perceive concerns Mr. Barrett. But I then see that your regulations are about eight pages; correct? I mean that's a first for Government. I mean usually they're 800 pages, and they'd be telling you every I to dot and every T to cross. They didn't tell you, it strikes me, unless I'm incorrect—let me ask this question. Dr. Fox, you haven't told UNOS how large the region has to be, how large you have to distribute. You are still leaving that up to UNOS.

Dr. FOX. That is up to the transplant community to come back and tell us how it should happen.

Mr. SHAYS. Yes; and so I'm just going to say to you I think that they have done the minimum and they have left you the opportunity to have to deal with their concern. And I'm also struck by the fact that you weren't prepared to say to me quickly, "well, there are solutions and we should do one, two, three, four, and five," and that you didn't want to speak as an individual. But I asked you to speak as an organization, so I'm going to go to Mr. Barrett, but I'm just left with the feeling right now that the Federal Government said, "we've got to expand the area in which we donate"—excuse me, "in which we provide the organs." They're leaving it up to you, the private sector, through a monopoly, but the private sector, to debate, and I'm left mostly with your testimony you're saying what you don't like. I want to also know before this hearing is over what you want. So, Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman.

If my wife or one of my kids, any family member or friend needed a transplant, I wouldn't care what list they were on, I wouldn't care what level they were on, I would want them to get that transplant. And the problem that we face and the problem that you face is that person might get a transplant and die 2 weeks later. But if it were my wife or my kids or my mother, I would still want that transplant. I wouldn't care. I wouldn't care, and I hate to say that, but that is a family member, that's somebody I love, and I think probably every person in this room probably feels the same way. But as you look to the greater good and where you can do the most good for the most amount of people, the greatest number of people, that is where it starts getting sticky.

And one of the concerns that I have, Dr. Fox, looking at your testimony, you state under existing policies, for example, we cannot provide Americans with the current 1-year survival rates of patients and organ grafts. We cannot compare the performance of transplant programs.

It seems to me that we are going down a road here where we are saying even though we don't know whether we are going to do the most good for the most amount of people or the greatest amount of people, we are going to take this step. And it concerns me. It concerns me if we are going to all of a sudden start putting those organs in the people who would not live past a year anyway, are we doing the greatest amount of good? And again, I'll stress if it's my wife or my kids, I want it anyway. But what are we doing as a society if that's where we are going? And we don't know, and, again, this is what concerns me. You say in your testimony we don't know.

Dr. FOX. Congressman, let me say first that we know that for those people that get a transplant, they generally do well, and the system works for those people that get a transplant. Survival rates are the highest even in status category I and II. The problem is that I have a cousin in California, I have a daughter in Alabama, I have a sister in Nashville, I live in the District of Columbia. And whether or not my chance or any family members of mine who are all over this country have a chance to get a transplant should be at least the same within the general sense if our medical conditions are pretty much the same. And that is what we are saying.

The data, the data that was issued in the 1997 report was 1994 data. And that data was pooled with data back to the late 1980's. We feel that there is better information available. One of the things that can happen is that doctors and patients we think should know center-specific survival, they should know deaths on waiting list by facility, they should know, we should have available the public organ wastage, we should have the survival rates by specific setup.

Mr. BARRETT. But we do not have that, really.

Dr. FOX. We do not have that now. And we believe that that data can be put out there, that it should be available and that people can make up their own minds.

Mr. BARRETT. But shouldn't we be doing that first? Isn't this just a crap shoot? Dr. Fox. And this is part of what we think the regulations clarify as to make that information available. But the data that we have available that again, and what we are asking, Congressman, is UNOS has the data as a part of the contract, Scientific Registry, and we're asking them as they put forward whatever the new allocation policy is, to use that data.

Mr. BARRETT. So you're saying that they have the data even though you don't?

Dr. FOX. Yes, sir.

Mr. BARRETT. OK. Dr. Hunsicker.

Dr. HUNSICKER. I actually think that there is relatively little trouble between UNOS and the Government with respect to the data. We have actually played a leading role in terms of developing center-specific information. We are doing what we can to shorten the interval between collecting the information and presenting it, and in fact, we have just recently taken an action at the board of directors level to try to shorten that substantially by——

Mr. BARRETT. Let me read his statement again and ask whether you agree with it then.

Dr. HUNSICKER. Yes.

Mr. BARRETT. Under existing policies, for example, we cannot provide Americans with the current 1-year survival rates of patients and organ grafts. We cannot compare the performance of transplant programs. Do you agree with that statement?

Dr. HUNSICKER. No. We can do it better than in any other area of medicine in the world. We can do it yet better than we are doing it. His concern is that the data are older than they need to be, but they are more current than any other analyses that have been done anywhere else.

Mr. BARRETT. Can you define "better?" We do it better?

Dr. HUNSICKER. Yes. I think we can shorten the time between collecting the information and doing the analyses by about a year, something we've already taken to do, and we do this by eliminating one step in the process, which is the separate validation step. This is a technical——

Mr. SHAYS. Could I ask—I'm just not clear as to your answer. He asked you if you agreed with the statement. You said we could do it better. But the issue is is the statement true or isn't it true.

Dr. HUNSICKER. Well, ask me the statement again, because I'm still not sure I understand your question.

Mr. BARRETT. Under existing policies, for example, we cannot provide Americans with the current 1-year survival rates of patients and organ grafts. We cannot compare the performance of transplant programs.

Dr. HUNSICKER. If by current you mean data that are more current than the 1994 report, based on the data up to 1994, we have not done an analysis on the data since that time. That will be part of the next report. If you ask can we compare centers, yes, we can compare centers, and that information has been available in UNOS since the first report, which was what, 1992, I think or something like that, the first one we did.

Mr. BARRETT. OK.

Dr. HUNSICKER. So I think we can compare centers.

Mr. BARRETT. All right. I'd like to go down a different road here. One of the concerns that has been raised to me is that we are seeing an increase in the number of managed care contracts that will direct a patient to a particular center.

Mr. Yessian, you raised the issue of racial minorities, which is an issue that concerns me greatly. I'm concerned that if we have a policy that allows a managed care organization to refer me to, or an African-American or a poor person or an elderly person, I don't care who they are, in Milwaukee to the University of Pittsburgh, the University of Alabama, UCLA, whatever, that is a pretty nifty way to weed out some people if they can't afford to go there and sit. What impact does that trend have, first of all, on the underserved poor, and second, what is that going to do to smaller regional centers that do not have a contract with the managed care company?

Mr. YESSIAN. I think that is a very crucial question, and I think we need to carefully watch the data on how things operate that way. I think that the differential has improved somewhat since we did our study, but here again, I would say that how the Organ Procurement Transplantation Network defines the rules that govern allocation can significantly influence that and can limit what kinds of policies apply in that way. Those rules have facilitated, have been responsible, I believe, somewhat in the last few years to help reduce the differential by virtue of the kind of point system they have.

Mr. BARRETT. So you read these rules to allow UNOS——

Mr. YESSIAN. Well, UNOS can——

Mr. BARRETT [continuing]. To prohibit a managed care contract that would take a person out——

Mr. YESSIAN. No; I doubt—I don't see how they could be that specific. No.

Mr. BARRETT. How could it do that? And again, this is—when you are talking about a profit motive, when you are talking about incredibly expensive procedures, I think that one of the most dastardly and hidden ways to control costs is to say, yes, you are on this list, you are on your way out of town and the family, the family knows they can't go wait in another locale for a long period of time. And all of a sudden we are back to the pre-1984 days where this becomes an economic asset that few people can afford. Again, I want you to address what specifically in these rules will prohibit that from happening, and if not, what needs to be added to these rules to make sure that doesn't happen.

Mr. YESSIAN. The rules as I understand them would give the OPTN substantial flexibility in determining how the allocation would proceed thereby—and tracking that such that if that kind of unfortunate effect happened, it would be really obvious to the HHS and we would bring that to light. I think that that's not a tenable situation. But the rules would govern allocation regardless of the payment source. And if the effect of those rules is to add to the differential, then clearly it's not a system that is working in accord with the HHS policy, which is to move on a patient-based system. And as I read those rules, I read them carefully, they're only eight pages, but they did call for bringing attention to onerous transportation practices or other factors. As I understand it, those would be within the prerogative of the Organ Procurement Transplantation Network to address. It would not be tenable to have a system that would allow that kind of lack of access.

Mr. BARRETT. Again, that goes back to my concern about subrules and regulations.

Mr. YESSIAN. Yes.

Mr. BARRETT. And all a sudden these eight pages start ballooning.

Dr. Fox—maybe I will ask any of the six of you here what is the trend right now, with the managed care organizations or any other insurance companies for that matter, what is the trend, who are they entering into contracts with, are they entering into contracts more likely with large ones, which again could ultimately have the impact of taking away smaller regional ones, which in the long run would mean that people would have to leave their communities and go to these larger centers, which again gets us back to pre-1984?

Dr. FOX. I would think there's no blanket answer to that, that it really depends on the part of the country you are in. Part of our concern in this whole issue is that right now, again depending where you live, and it's certainly not true in Wisconsin because of the shorter waiting time, but the patients have to often go to the organs. Witness the man in New York who recently chartered a Lear jet to take him to Florida to have a transplant, and what we think will happen under a policy that tends to equalize waiting times is that hopefully the organs are going to come to the patients, that a patient that happens to be in a small transplant center is more likely to get a match because there is going to be a bigger pool of organs to match from. And as it is now, to turn that around a little bit, a managed skill organization may prohibit you, may prohibit you under your plan from flying you two States or three States over to get a transplant and because they will not allow that and there is no match available in your local area, you die. And we think that—so this, we believe, again depending upon how the policy is put forward by OPTN, may very well improve patients' chances both getting a match and being able to stay in their local area.

Mr. BARRETT. Dr. Hunsicker.

Dr. HUNSICKER. The different insurance companies behave differently. There is some consortia there.

Mr. SHAYS. Louder, Doctor.

Dr. HUNSICKER. I'm sorry. Different insurance companies and consortia handle this issue differently. Some contract with many and some have a very narrow list of centers with which they deal in order to try to get large numbers of transplants at one center. The ones that do the latter do tend to draw patients away from their homes, and if the livers or the organs in general did follow those, those would tend to put at risk the local centers that might not be able to compete for those and that could in fact in my opinion put at risk the access to transplantation locally by patients either who could not travel or who are poor or otherwise need to get their care within their State. But I think that it is only fair to say that different insurance companies handle this issue quite differently.

Mr. BARRETT. Chairman Shays.

Mr. SMOLONSKY. Excuse me, Mr. Barrett. I just wanted to address one of your points. You were concerned about possible discrimination along racial lines because of——

Mr. BARRETT. A little louder.

Mr. SMOLONSKY. You were concerned about possible discrimination along racial lines because of trends in managed care. I can't address that, and I cannot tell you that we know of any specific discrimination that occurs in the OPTN along racial lines. But I can tell you that in Milwaukee if you are waiting for a liver, blacks wait three times as long as whites. And if you are waiting for a kidney, blacks wait twice as long as whites.

Mr. BARRETT. In Milwaukee.

Mr. SMOLONSKY. In Milwaukee. Just in Milwaukee, not Madison.

Mr. BARRETT. And what do you attribute that to?

Mr. SMOLONSKY. That is just what the raw data shows. There may be some explanation for that, but it is something to be concerned about. It is something to be looked at.

Also, there are differences in the waiting times between the Madison transplant center and the Milwaukee transplant center. In Madison generally you have to wait much longer for a transplant than you do in Milwaukee, and part of that may be attributable to the fact that you have two OPO's here with two allocation regions. But these kinds of data are what needs to be explored by the OPTN, and the final point I wanted to make is that there's been a lot of discussion here, particularly in Dr. Hunsicker's open comments, about what the regulation would do. He said that the regulation—he has evidence, he said, that the regulation would cause more deaths. He has evidence, he said, that the regulation would cause longer waiting times. Well, he may have some evidence and we would like to see it, but the truth is, as Chairman Shays pointed out, it's a minimal regulation. It prescribes no medical decisions. It leaves all medical decisions up to the OPTN. There is no allocation policy in the regulation. We are asking the OPTN to come up with an allocation policy, and we don't have one that is in place.

Mr. BARRETT. OK. Very briefly, Mr. Chairman. I agree with you that he made that statement. At the same time Dr. Fox made the following statement: The OPTN must not be so paralyzed by controversy and division that it does not act to change a system that is unfair to patients and that may be allowing patients to die unnecessarily. So I think he uses the word "may." Maybe he uses the word "does," but I think that we are seeing countercharges as to which policy would deny or would lead to more deaths. I am concerned, and I don't know, Dr. Yessian, if you have any views, again on the rational disparity, and I would ask your office to do an update on that if you could, please, because I think that that is something that's, that under any standpoint can't be acceptable. What is your analysis as to why we see that disparity, that racial disparity?

Mr. YESSIAN. Oh, it's such a complicated factor, and I would certainly not tend to sound authoritative that I have any one answer. In our report of 7 years ago we reviewed the various possible causes. Many of them are very technical and medical in nature. Clearly, one is the rate of donations among minorities is important, and the more donations you have among blacks and other minorities, the more they're apt to find organs that will be suitable, and that has improved somewhat, I understand. But there's a series of other factors, including income, including living style, if you will, including what the—and this is what generated a lot of controversy at the time, but the American Medical Association Council on Judicial Ethics itself said could be subconscious bias in various ways. There's no one factor here, but I think it would help to have a clear tracking of what is happening there and whether we've had progress, and to have that be a fair system it seems to be on a national basis would be one where that gap closes significantly.

Mr. SHAYS. Let me just say I'm prepared to go on a speck longer. Does the recorder need any——

The REPORTER. I need to change my paper.

Mr. SHAYS. OK. Just for those of you here, we are going to have about a 20-minute break from the first panel to the second, in part because we have one recorder. The one thing I'm certain of is there is one person in this room that is working every second and that is the recorder, and we're going to make sure that she has some time off. And then it's going to be my intention to go to panel II, and then we're going to have a slight break for the recorder again, and then we are going to go and invite the audience to make comments.

What we're going to do, it's basically—this isn't for the record, so you don't have to record this.

[Discussion held off the record.]

Mr. SHAYS. I'd like to just ask a few questions. The bottom line is we have an eight-page regulation that in my judgment allows for a lot of flexibility, but it does say you give way to I over III. Correct? I mean that we have to provide—the ones who are in the greatest need are the ones that should have the first opportunity to get an organ; is that correct?

Dr. FOX. Again, with the caveat, Mr. Chairman, that's actually stated in the reg that there be an efficient use of the organs that are available.

Mr. SHAYS. OK. Dr. Hunsicker, do you think that is an unreasonable request?

Dr. HUNSICKER. Actually, I was going to quote the section from the thing, but you probably have it up there.

Mr. SHAYS. A little louder.

Dr. HUNSICKER. I was going to quote the actual section from the regulations, which is to allocate organs among transplant candidates in order of decreasing medical urgency status with waiting time used to break ties. That is an explicit part of the regulation.

Mr. SHAYS. Right.

Dr. HUNSICKER. That would require us—by my reading that would require us to transplant the patients in the most urgent category first all the time, a requirement that I think is medically unwise.

Mr. SHAYS. OK. If you don't mind, I would like just to——

Dr. FOX. If I could comment and then Dr. Raub. Obviously this is going to vary by organ, Mr. Chairman.

Mr. SHAYS. Right.

Dr. FOX. Kidneys where you have dialysis, there are rescue techniques if someone is ill. It doesn't mean that someone can't be at death's door, but it's going to play out we think differently as opposed to livers where there is no rescue technique. So we fully anticipate that the policies are not going to be identical.

Dr. RAUB. Mr. Chairman, just to add that the current policy is based on medical urgency and the regulation reinforces that, that idea. The regulation does, however, require that the same——

Mr. SHAYS. Let me ask you, the present regulation or the present contract?

Dr. RAUB. The regulation.

Mr. SHAYS. The regulation right now on the books——

Dr. RAUB. No, no. The one that has been issued here with the delayed——

Mr. SHAYS. Right. But you said, I thought you said the present law or something. I want to understand——

Dr. RAUB. This regulation. What you're addressing.

Mr. SHAYS. Yes. It has not yet been implemented.

Dr. RAUB. Correct.

Mr. SHAYS. But it has a comment period, but it will be implemented. It's not a potential rule, it is the rule.

Dr. RAUB. And that was why I was referring to it as the regulation. It endorses the current principle of medical urgency in the allocation.

Mr. SHAYS. So it is a current principle but not a regulation? I just want to understand.

Dr. RAUB. Yes.

Dr. FOX. The current policy, the current UNOS policy is medical urgency that is applied now. It's just applied within a local area, so that is the current policy of the OPTN.

Mr. SHAYS. All right. OK.

Dr. HUNSICKER. Could I comment on that?

Mr. SHAYS. Let me just make sure, any other comment?

Dr. RAUB. Well, where I was going with that point, Mr. Chairman, is that the regulation that you are now considering does not even go so far as to require that the same four current categories in the policy be continued. That is there is 1, 2A, 2B and 3. It leaves the discretion to the transplant community in coming back with its proposal to, among other things, assess whether more or fewer categories.

Mr. SHAYS. Now, this is a rule that would take effect in about 60 days from now?

Dr. FOX. Thirty days.

Mr. SHAYS. About 30 days.

Dr. FOX. It was 30 days after the end of comment period, which was 60 days. So from the date of publication it would take affect in 90 days.

Mr. SHAYS. Right. OK. And the bottom line is that then UNOS comes back and says this is what we think lives up to the spirit of the regulation and you would then be able to respond and say yes, it does or doesn't?

Dr. FOX. Yes, sir.

Dr. RAUB. And that was my point, Mr. Chairman, that the regulation calls for a proposal to come back addressing these principles.

Mr. SHAYS. God works in strange and mysterious ways here.

OK. Yes.

Dr. HUNSICKER. What I wanted to say about the issue of the current policy is that the current policy has grown up in the setting of extensive computer modeling of what the outcome is in terms of allocations. The current policy does assign the organ within a local region to the most seriously ill or the patient in the most serious category but is still capable of benefiting. But it was recognized that if the sharing areas were widely changed, that that would lead to a much larger fraction of patients being transplanted in this most severe category, and that was one of the major reasons why the group chose not to go down that route. There could be other ways of approaching this.

Mr. SHAYS. I'm missing your point. Since this is your point, make it again.

Dr. HUNSICKER. Yes. The point is that the current policies do in fact locally allocate the organ to the most severe category, but it does that in the understanding of what the overall distribution is amongst patients in the most severe category and the lesser severe categories. Changing to a much larger list, irrespective of exactly how that is defined, will change——

Mr. SHAYS. Determined by your organization, by the way.

Dr. HUNSICKER. Which we would presumably determine based on what he said. That's—I don't want to get into that issue right here. That's not relevant for the moment.

Mr. SHAYS. With all due respect, it is very relevant.

Dr. HUNSICKER. OK. The issue——

Mr. SHAYS. And it may be off the point you want to make and——

Dr. HUNSICKER. Yes; that's what I meant. Off the point.

Mr. SHAYS. I don't mean to distract you. Make your point. I'm sorry.

Dr. HUNSICKER. The point is that if we go in fact with a policy that requires transplanting uniformly, the patients in the most severe category first, in a very wide or a much wider sharing area, the consequence will be to shift the fraction of patients in the different severity areas, something that the community looked at and believed was unwise. So it's the two pieces together. It's the sharing area and the sickest first or the most severe category first that determines the distribution of patients.

Mr. SHAYS. Thank you. Let me just tell you the two other areas I want to get to. It is surprising to me that statistics are not available on a current basis, and I really want to ask you, Dr. Fox, what took 13 years to get HHS to ask UNOS to provide better documentation?

Dr. FOX. Well, one, this has been an evolutionary process, as we've already mentioned, that the congressional intent has changed over time and as recently as 1990, 1990, there was specific language charging the Department to look at a national system that was equitable to patients. I think that is the exact language. The NPRM was issued in 1994. This is a tremendously complicated issue as I think everybody, I think that's another thing that everybody would agree on. There are very few things that we probably all would agree on, but I think that is one of the others in addition to donation. And there's been a lot of discussion both within the Department and outside the Department. We had hearings, there was public input in 1994, again in 1996. The OPTN was moving toward some different allocation policies in liver in 1996 and that did not happen, and it's a combination of the fact that we have had a lot of deliberation on what would be the best approach. And we think we have come down, quite frankly, Mr. Chairman, as a result of the time and tremendous amount of attention that this has received in and outside of the Department to the best approach we could take, and I think that is why we are here with eight pages today because of its relevance of specifying allocation policy in regs because it is something that will change over time. It is something——

Mr. SHAYS. Well, you're going a little beyond. You're trying to make another point. I just wanted to know about the statistics themselves. The bottom line to me is that—You want to make a comment, Doctor?

Dr. FOX. I'm sorry. I thought you alluded to the regulation, not the statistics.

Mr. SHAYS. No. I'm sorry. I didn't make it as clear as I should have. It seems to me it's taken a heck of a long time to ask UNOS to provide statistics that are a little more reliable.

Dr. FOX. Let met defer to Bill but just to say that we've—there's been a lot of discussion within the Department with UNOS over the years about trying to get data, and this has been a very problematic area for us, for the Department.

Mr. SHAYS. This would be one thing that our committee will really address because this should be a no-brainer.

Dr. RAUB. I would make two points, Mr. Chairman. One is in hindsight, it would have been desirable to move earlier in terms of getting this kind of information, but also this is part of a larger trend with respect to medicine of putting more emphasis on getting timely, accurate information for patients and their physicians rather than imposing Government requirements of volumes of transplants or particular outcomes, and as we were developing this regulation, it seemed to us that information——

Mr. SHAYS. Just lower your mic a little bit. It picks up at the top rather than the bottom.

Dr. RAUB. It seems to us that information, timely, accurate, center specific, was the best thing we could do for the community of patients and their referring physicians. Under the current policies, the center-specific information is available every 3 years, and it's 3 years old when it comes out. The performance goal in the regulation is that it come out every 6 months and be no more than 6 months old when it comes out.

Mr. SHAYS. Let me ask you, that seems reasonable, Dr. Hunsicker. You should be able to provide that data within 6 months; is that——

Dr. HUNSICKER. The providing the analysis within 6 months actually is a bit of a push. This actually is my area of medical specialization, if you will. You will understand that if you are going to collect data on a patient, on patients let's say in the calendar year 1994, the patient hasn't even been transplanted until the end of 1994, let's say, so you've got then some of those patients are already a year out of date. You then want 1-year followup. You're already a second year out of date. You then have to get the data through the system and get the analyses done. That gives you a total of about another year, and that is about the state-of-the-art.

There is no group that turns around their data faster in this respect than UNOS.

Now, I agree with HHS that we can shorten that time, and we have in fact just done that or made that step in that direction at the UNOS board meeting by agreeing to delete a separate data validation step, and that should speed up the turnaround by a year. I don't think that there is a substantial disagreement in the intent of the data issues between HHS and UNOS. I would say that doing it every 6 months on a center-specific risk-adjusted basis would be quite an undertaking.

Mr. SHAYS. Do the rules say 6 months or do they say—OK.

Dr. HUNSICKER. It's—the rules say that they should be updated every 6 months, but they don't say exactly what——

Mr. SHAYS. What update means.

Dr. HUNSICKER. Well, or what pieces. And so——

Mr. SHAYS. There's a little bit of flexibility in dialog.

Dr. HUNSICKER. Yes; I don't think that's an area of real dispute.

Mr. SHAYS. Well, there's one area that's not for real dispute, and we haven't even gotten into this, and it's the whole issue of how we increase the number of donors.

Dr. HUNSICKER. I agree with you. We don't have much dispute on this.

Mr. SHAYS. And I will say that in the end that whatever regulation is adopted, excuse me, if this rule goes through, however the rule is implemented, it better do something to encourage more donors rather than less. I'm a little confused by your comment on, Dr. Fox, on page 5 of your statement. Maybe it's relating to something else. The Department estimates the number of donors nationwide could increase by 20 percent within 2 years of the publication of the final rule. What inherently is in there in your rule to increase the number of donors?

Dr. FOX. OK. We're alluding to the hospitals, the conditions of participation.

Mr. SHAYS. The other rule.

Dr. FOX. Right, the other rule. They're tandem, they're not the same rule, but they were issued——

Mr. SHAYS. Fair enough.

Dr. FOX. And in Pennsylvania there's actually more than a 20-percent increase. They have done it as a State law. So we think that that will really help nationwide. It's not the only thing we need to do, but it certainly will have a significant impact.

Mr. SHAYS. And that's your Department's contribution on how we could increase——

Dr. FOX. It's one—actually there was initiative that was lodged by the administration by the Vice President back in December. We are partnering with AMA, with the Coalition on Donation, with black churches, with the bar association, with a number of different groups, professional and public, trying to look at ways we can both increase the visibility. There's been a lot of work done with Federal employees as well, and so there's a lot that's happening in that area. We think there's not any one thing that we need to do on donation, it's probably a whole series of things of which the conditions of participation will have a significant impact, but we need to do more than that, and it may have a broad initiative that's already underway.

Mr. SHAYS. I always make my staff uneasy when I say this, but that may be another hearing just on how we do increase the number of donors. I realize they relate to this, but I'm basically done other than allowing you, Dr. Hunsicker, or Mr. Graham to respond, and then do you have something Mr. Graham?

Mr. GRAHAM. I would, if I could, I would like to come back to a point that we were talking about earlier.

Mr. SHAYS. Not about donors?

Mr. GRAHAM. No.

Mr. SHAYS. OK. I do want to make sure—I'll let you come back. I just want to understand UNOS' suggestions on how we increase the number of donors. Not in great depth. I just want to know——

Dr. HUNSICKER. Very briefly, UNOS supports pretty strongly the other set of rules which have to do with increasing donation. We have no problems there. The concern we have with respect to this set of rules we are looking at today is that if the impact were to reduce the number of local transplant organizations, that the secondary consequence of that is likely to be a decrease in donations. The reason for that is that every time we have seen a transplant center open we have seen the rate of donation increasing. We believe that the presence of transplantation in a community, what size I don't know, is important to motivating the awareness of the citizens about organ transplantation and donation and that losing local transplant centers would have a very adverse effect on donation.

Mr. SHAYS. Let me just come back to you just to pursue this. I mean would there be a consensus, Dr. Yessian or Dr. Fox, that local transplant centers do have a role in increasing the number of donors?

Dr. FOX. I would say they do, along with all transplant centers, but all organizations. The problem is basically the people don't think about donating, or they do think about it and as I have, put it on their driver's license, but they don't tell their family, so that when something happens, a surgeon may be hesitant to take the organs because the family doesn't consent, so there's a role there. There's definitely a role, and we support that.

Mr. SHAYS. Yes.

Dr. RAUB. I think we have to be very careful, though, with the notion that the motivation for donation is essentially geared for organs going locally.

Mr. SHAYS. You say motivation is essentially what?

Dr. RAUB. Geared to organs that are donated being used locally. UNOS' own data through commissioned studies has not shown that to be the case. Let me also say on that point that we're in an area here that has an exemplary record in terms of organ donation. I think few, if any, exceed what is being accomplished in this area.

Mr. SHAYS. Right. In Milwaukee.

Dr. RAUB. In Milwaukee and in Wisconsin generally, I believe. And maybe, and we have made the point in the past, too, that more attention can be focused on holding organ procurement organizations around the country accountable for their performance so that some are clearly lagging, why is that, and should they continue to be Medicare certified. And maybe we can do more in learning from the Wisconsin situation that can help the performance of others.

And I point out in that regard, too, one of the things we noticed, you mentioned on the black/white issue before, and I don't know if this has improved, but as simple as it may sound, one of the reasons it seemed that there weren't as many black donations were that few organ procurement organizations had black procurement coordinators. Hopefully that's improved significantly.

Mr. SHAYS. Bottom line, about 50 percent of all transplants are paid for by the Federal Government one way or the other?

Dr. FOX. Close to that.

Mr. SHAYS. Yes. Let me say to you I'm going to go to Mr. Barrett, and then I'll make my comments, but you have the floor.

Mr. BARRETT. Oh, thank you.

With respect to the other rule, was that issued as a final rule or proposed final rule?

Dr. FOX. Proposed. It's proposed for public comment.

Mr. BARRETT. I have to acknowledge that and, Mr. Yessian, maybe I'll ask you first, how unusual—maybe this does not fall under the purview of the Inspector General, but we have here a final rule that has been promulgated. In the other case we have a proposed final rule. What significance do you read into that?

Mr. YESSIAN. I'm not sure that I read any. I don't know. This proposed rule, the final rule here, that we are talking about here today to me has been something that's had a long gestation so that——

Mr. BARRETT. How unusual is it for an agency to issue a final rule as opposed to a proposed final rule?

Mr. YESSIAN. I would defer to Dr. Fox on that.

Dr. RAUB. The final rule that you're considering falls on a proposal.

Mr. BARRETT. A proposed final rule?

Dr. RAUB. No. Yes. A notice of proposed rulemaking is the official term.

Mr. BARRETT. A proposed final rule?

Dr. RAUB. Well, that's not the term, sir.

Mr. BARRETT. OK. Well, what is—compare and contrast what's done and—we've got two rules here. I want to know the——

Mr. SMOLONSKY. Excuse me, Mr. Barrett, but if I may, there actually is no difference in the process between the two rules. Both of them have started out as an NPRM. The hospital conditions of participation reg is in the NPRM status now. The second reg is now in the final status pursuant to being in an NPRM status. So as far as we are concerned, there's absolutely no difference in the process between the two rules. I'm just talking about process. Obviously there is difference in content.

Mr. BARRETT. So you are saying that they are identical?

Mr. SMOLONSKY. In terms of process, yes.

Mr. SHAYS. The bottom line is the proposed rule can be changed. This rule will not be changed. There is a distinct difference.

Dr. FOX. Well, this rule is issued with a 60-day comment period and I think it's the intent of the Department, and correct me if I'm wrong, but that during this comment period, even though this is a final rule, that if there are compelling reasons to change or modify this rule, that the Department has expressed an unwillingness to do so.

Mr. SHAYS. So the bottom line is that I can almost make an assumption it has almost the sense of a proposed rule. The bottom line is you have the legal ability to go with this rule without change and move it along quicker, but you are making the point—I'm sorry to interrupt. You're making the point that you have an open mind to changing the rule if you think there is merit to it.

Dr. FOX. The dilemma is this, Mr. Chairman: The proposed rulemaking that this rule went through earlier, there was a prolonged comment period. We're down to final rule now. What we want to do is get this rule out, get it into effect and get going with it, but there is a provision issued, and the way this rule was issued, even though it was issued as a final rule, that, one, there can be a comment period, but the Department also can, it can go with the rule as written, but if there's a sense of desperation that there are compelling reasons, we can also change that rule, make modifications in it prior to it going into place.

Mr. BARRETT. OK. Again, I'm going to apologize for following up on this, but I want to make sure I understand it. Has there been between—or has there ever been opportunity for this language to be commented on by the—this language to be commented on by the public prior to this final decision?

Dr. FOX. The major provisions of this rule were published in 1994, and there was public comment during that time and again in 1996.

Mr. BARRETT. Dr. Hunsicker, do you agree with that?

Dr. HUNSICKER. I believe that there is some significant parts of this rule that have come out that were not in the prior period.

Mr. BARRETT. Specifically what?

Mr. SHAYS. Please speak a little louder.

Dr. HUNSICKER. I'm sorry. I believe that there are some parts of the present rule which were not contained in the prior proposed, notice of proposed rulemaking that are really the, some of the areas——

Mr. BARRETT. The geography?

Dr. HUNSICKER. The issue of a specific statement about the sickest patients first and the geography.

Mr. BARRETT. Was the geography in the 1994?

Mr. SMOLONSKY. Mr. Barrett, Congressman Barrett, if I may, they were both issued, both rules were issued——

Mr. BARRETT. Was the geography in the 1994 rule?

Mr. SMOLONSKY. Mention of geography and the allocation issue was mentioned in the 1994 NPRM.

Mr. BARRETT. In the same way that it's mentioned here?

Mr. SMOLONSKY. No. But whenever you issue an NPRM and it's out for public comment, the final rule can change in response to that comment.

Mr. BARRETT. I think you understand what my concern is. I don't want the Department pulling a fast one on this one.

Mr. SMOLONSKY. Well, it's not a fast one. In fact, we have bent over—we have done something unusual in the opposite direction with this rule. We have allowed an additional 60-day public comment period, which we do not usually do. We have allowed a 30-

day delayed effective date to the final rule which we do not usually do. And we have taken the extraordinary step of saying that if anything, if we learn anything during the comment period, we will delay the effective rule even further. So we're not only not trying to pull a fast one, we are doing the exact opposite. We are trying to go as slow as possible to achieve as much consensus as possible. We have responded at every turn I think to outcries of unfairness, and if there is anything we have done in this process, it's been to be fair and open. And I think our record would stand on that.

Mr. GRAHAM. Mr. Barrett. Could I comment on that question?

Mr. BARRETT. Yes.

Mr. GRAHAM. From UNOS' perspective looking back at the proposed rule and comparing it to what we are seeing today, we are seeing a fairly significant change in how it plays out. And that goes back to something I wanted to say earlier, and that is that we have been operating under a contract with HHS. HHS has been overseeing the activities of the OPTN through that contract for the last 11 years. We went through an elaborate process in which we evaluated over 100 different organ allocation proposals and put them through the modeling system that Dr. Hunsicker described earlier to evaluate their relative merits. This was done by the entire transplant community. At the same time that the proposed rules were being published—those proposed rules were published with what we understood to be that the Department would receive the recommendations from the community and determine whether or not to accept those. These rules have a fundamentally different approach. It is that the Department has decided what the rules should be in general and have given general guidance and then the OPTN has to make a proposal and they will determine, the Department will determine whether to accept those or whether to issue rules that the Department might develop. And that's a fundamentally different change in how the whole process was seen to be done in the notice of public rulemaking before.

Mr. BARRETT. OK. I think probably the best way for us to proceed is if the Department could simply get us copies of the 1994 and 1996 proposals and we can look——

Mr. SMOLONSKY. Yes. Someone actually—someone just has handed me, I will admit it's a selected page from——

Mr. SHAYS. A little louder.

Mr. SMOLONSKY. Someone just handed me a selected page from the NPRM from 1994, but I will read you one section which in discussing changes in policies says that some policies intended to maximize transplant outcomes and based on sound scientific data may have adverse implications for one ethnic group in particular or for residents of particular geographic areas. So we definitely sounded the alarm in 1994 that we were concerned about geographic inequities.

Mr. BARRETT. OK. I'm just about done, Mr. Chairman.

Mr. SHAYS. Sure.

Mr. BARRETT. One of the concerns that has been raised, and that I think there is also agreement on is the criteria for placing people on different levels. My understanding is that along with these rules or the interim rules is that no one who is on a list right now will be essentially bumped. Have we rewarded medical centers who have inappropriately put people on lists by doing that?

Dr. FOX. Well, I think that the way we would like to think about it, Mr. Barrett, is that we have protected and not adversely impacted people that because of timing might be impacted otherwise. And we feel it's appropriate to have a grandfather provision. That is really what this is. It can be of length determined by the OPTN. We've not said how long that grandfather provision should apply. We've not said exactly how the grandfather provision should be put in place, but we've not even mandated that for all organs there be a grandfather provision. We've left that up to the OPTN. And I think again we've applied a principle that we think protects people that are on the list now but not said how to do that and left that up to the transplant community.

Mr. BARRETT. Do you see that as a problem, Dr. Hunsicker?

Dr. HUNSICKER. I don't believe that there's any substantial disagreement between the Secretary and ourselves with respect to listing criteria or severity criteria. We actually were the ones that, how shall I say, developed this idea. It was largely an idea that came from the community——

Mr. BARRETT. I understand. That's not my question. My question is——

Dr. HUNSICKER. We have no problem with those parts of——

Mr. BARRETT. OK. And, again, that is not my question either. My question is, and maybe I'm wrong here, that there is an interim, there's an interim period——

Dr. HUNSICKER. Yes, there is an interim transition——

Mr. BARRETT. And if I'm a smart transplant center, I'm going to have that baby backed up to 2020 with people who are on my list.

Dr. HUNSICKER. Is there the potential for doing that? I suppose. I don't know. I don't like to put myself into the heads of other people. Are the interests of the patients protected? Yes. The rule that it has here has the mechanisms in it so that we can protect the interests of patients that are currently listed. I don't know that that again directly answers your question.

Dr. FOX. Congressman, if I could just also add one other point. It was the individuals on the list on the date the regulation was published, so it doesn't continue on.

Mr. BARRETT. Right. I guess that's why——

Dr. FOX. It's a point, specific point in time.

Mr. BARRETT. I understand that.

Dr. FOX. Yes, sir.

Mr. BARRETT. OK. Thank you. Mr. Chairman.

Mr. SHAYS. I'd like to thank this panel. I know that a number of you, if not all of you, don't live in Milwaukee and you came here and it's important that we be here rather than in Washington, I think, for this hearing. And I'm really happy we came. I find this issue more intriguing than I imagined. I honestly don't think that our differences are as great as some may feel. I think that an eight-page regulation gives UNOS a lot of flexibility. And I have this one remaining concern that whatever regulation is implemented that it not discourage donors, so that is an issue that we will be looking at as well, but I think all of you have been very candid with us and told us what you believe, and it's been extraordinarily helpful.

So I am grateful that you all came. And I will say to you that, I will say to the audience that we are going to adjourn for a half hour. We will start promptly—and Congress is capable of being prompt.

Mr. BARRETT. When there's two of us.

Mr. SHAYS. We will start promptly at 5 of, in fact maybe a few minutes before because it's not yet 25 after, and I don't envision that we will ask as many questions of our next panel because I think that we are here more to listen to their testimony. And then we will get into the audience who wants to participate. And the rules again for that will be we'll have a microphone for the third panel. We will invite you to speak. We will have a few stand up in line. When you are done you will give your name and address for the recorder. And we will go from there. So we stand at recess until no later than 5 of and maybe a few minutes before.

[Recess.]

Mr. SHAYS. I'd like to call this hearing to order and to announce our witnesses for the second panel. It's Susan Heitman, the mother of a 13-year-old cystic fibrosis patient who died in December 1997, while awaiting a lung transplant. Patricia Aschbacher, who received a liver transplant. Patricia Hodgson, a donor family representative. Paul Volek. Am I saying your name correctly? Director, Wisconsin Donor Network. Anthony D'Alessandro.

Dr. D'ALESSANDRO. D'Alessandro.

Mr. SHAYS. D'Alessandro. I'm sorry. Dr. D'Alessandro.

Dr. D'ALESSANDRO. That's correct.

Mr. SHAYS. Excuse me. A transplant surgeon. Robyn Shapiro, director of Center for Bioethics of Medical College of Wisconsin. And John Fung, director, Starzl Transplant Center. Am I saying that correctly?

Dr. FUNG. Yes.

Mr. SHAYS. University of Pittsburgh Medical Center.

It's wonderful to have you all here. We will now swear you in, and then we will, I think, just go down the row. Is that basically how you lined them up?

If you would all stand, please, and raise your right hands.

[Witnesses sworn.]

Mr. SHAYS. Thank you. The record will note that everyone has responded in the affirmative. Now, we're going to try to accommodate the media to some extent. I think they have a microphone that projects as well, but is this the one that we——

VOICE. Yes.

Mr. SHAYS. And let me just see if that's—can you just talk——

VOICE. Yes.

Mr. SHAYS. Are you hearing back there? OK.

VOICE. A little louder, please.

Mr. SHAYS. Yes. We will be a little louder. She hasn't said anything yet. But if you can't hear—Ms. Heitman, it's wonderful to have you here, and I know you are here as a mother who lost her child, and I particularly thank you for your willingness to testify. It's very important we hear your testimony. Thank you for being here.

STATEMENTS OF SUSAN HEITMAN, MOTHER OF 13-YEAR-OLD CYSTIC FIBROSIS PATIENT WHO DIED IN DECEMBER 1997 WHILE AWAITING A LUNG TRANSPLANT; PATRICIA ASCHBACHER, LIVER TRANSPLANT RECIPIENT; PATRICIA HODGSON, ORGAN DONOR FAMILY REPRESENTATIVE; PAUL VOLEK, DIRECTOR, WISCONSIN DONOR NETWORK; ANTHONY D'ALESSANDRO, M.D., TRANSPLANT SURGEON, UNIVERSITY OF WISCONSIN-MADISON; ROBYN SHAPIRO, J.D., DIRECTOR, CENTER FOR BIOETHICS, MEDICAL COLLEGE OF WISCONSIN; AND JOHN FUNG, M.D., DIRECTOR, STARZL TRANSPLANT CENTER, UNIVERSITY OF PITTSBURGH MEDICAL CENTER

Ms. HEITMAN. Thank you. Thank you.

Thank you for the opportunity to share my son's journey.

Mr. SHAYS. Let me just say that I'm going to require you hold it up even closer. I'm sorry. It makes it a little more difficult.

Ms. HEITMAN. My name is Susan Heitman. My son Nathaniel Benjamin was a 13-year-old. He died due to complications of cystic fibrosis.

Mr. SHAYS. OK, I'm going to have you start over again. I'm having a few people raise their hands. It's important we hear your testimony. I'm going to ask—there seems to be a little movement here. We're going to just quiet down a bit. Is the other mic—no, that's the mic, but it just doesn't project as well as we'd like. We need you to hold it almost like this and——

Ms. HEITMAN. Like this?

Mr. SHAYS. And then you also need to talk a little louder. Your testimony is very important and we'd love people to hear it. You can start all over again.

Ms. HEITMAN. Thank you for the opportunity to share my son's journey. My name is Susan Heitman. My son Nathaniel Benjamin was a 13-year-old. He died due to complications of cystic fibrosis while awaiting a lung transplant.

In March 1997, we were told that Nathaniel was a candidate for a transplant. He had been getting sicker more frequently and was requiring higher oxygen.

After the initial shock I began to plow through the insurance maze. Nathaniel's primary pediatrician assured me that if the transplant was medically necessary, the insurance would cover it. The insurance company was not that clear. They offered us a number of options during the next 4 months.

One option was to move to Pennsylvania, North Carolina, or Missouri as each of these States had facilities that had performed more lung transplants than Children's Hospital of Wisconsin. That would mean that I would have to quit my job, lose the insurance coverage, as I was the carrier, and split my family up for 1 to 2 years. This was not possible. So we entered into the process of review. We met with the medical director of the insurance company. He appeared to share our concern regarding our son's health. He led us to believe that the insurance company would cover the procedure, but that we should go to the hospital that had the most transplants, the best possible care in our State. At this time we were offered the option of going to the University Hospitals in Madison. He promoted their "Service of Excellence" as the place to go. As we explored Madison, we discovered they had not done a lung transplant on a child. This "Service of Excellence" was a title that did not necessarily mean superior care for my child. It appeared to be a money link.

The Madison evaluation was scheduled and done on July 7. After brief introductions the doctor told me that Nathaniel was not a candidate for their facility. He made soft remarks about him not being a good candidate and he added that Nathaniel did not need a transplant at that time and therefore would not be listed. As this option was dissolving, we waited anxiously for the medical director of the insurance company to contact us. We left numerous messages. We needed a summary of the Madison visit so that we could pursue the final option, which was the Title 19-Katie Beckett insurance.

The next hurdle was incredible. The medical director would not release this document. He conveyed we needed to write a letter to absolve the company from further responsibilities regarding Nathaniel's care. He gave us specific information and what to have in the letter and told us to fax it to him. Again, we were compliant with this request.

I thought I would then get the information that we needed to proceed; however, the medical director stated that he would not be able to get us this paperwork for a number of days. I felt as if Nathaniel was a pawn in a game and the game was all about who would get stuck with the financial responsibility. The insurance company appeared to make sure that it was not going to be them. We were finally able to get a copy of the evaluation after I contacted our attorney.

I want to impress upon you that families who are suffering with a loved one who has a chronic illness do not have great stores of energy. This entire saga was a great struggle for the family.

We then completed the comprehension application process for the Katie Beckett-Title 19 coverage and Nathaniel was listed on this program as of July 18.

The autumn proved to be a difficult time for him. Nathaniel was hospitalized four times in 3 months. In October, we were told that he would be considered for a transplant sooner than originally estimated. We were issued a beeper. Nathaniel had contracted a bacterial sepsis. He had high blood sugars and his kidneys were not functioning properly. After much prayer we decided not to place Nathaniel on a ventilator. We continued to hold on to the hope that he would be blessed with a miracle. We were told that if he had 3 days of negative cultures, he would continue to be considered for the lung transplant. My husband and I were told nonverbally that we didn't need to worry about the availability of an organ. When Nathaniel needed one, there would be one available.

Nathaniel did respond to the treatment. Unfortunately, he went into kidney failure and contracted another sepsis, this time of a fungal origin. Again, we were told that he was still a candidate for a lung transplant if he again would have 3 days of negative cultures. This did not happen. Nathaniel's condition worsened and he died at 5:30 on Sunday, December 7.

I think that the insurance company should work with us and for us in funding the organ transplants. The 4 months in this case might not have made a difference for Nathaniel, but it brought our family unnecessary stress and anxiety. Transplants are a risk and necessitate difficult decisions for both patients and families. However, they are a reality of today's medical technology.

As my story indicates, there are many hardships involved beyond procurement and distribution of organs. Please remember to focus on what is best for the patient and their family. Thank you.

Mr. SHAYS. Thank you, Ms. Heitman. When was Nathaniel born?

Ms. HEITMAN. In 1984, when all of these things started with——

Mr. SHAYS. Yes.

Ms. HEITMAN [continuing]. Decisions for transplants. Thank you.

[The prepared statement of Ms. Heitman follows:]

Thank you for the opportunity to share my son's journey.

My name is Susan Heitman, my son, Nathaniel Benjamin was a 13 year old. He died December 7, 1997 due to complications of Cystic Fibrosis while awaiting a lung transplant.

My son demonstrated a lot of courage each day of his life. Each day he tolerated three hours of treatment. When hospitalized, that number could double.

I hope that I can offer you a piece of his courage in a clear fashion so you may have a glimpse into the life challenges he met.

Our story consists of a review of events that occurred from March of 1997 through Nathaniel's death. The focus is on the hurdles that we were forced to go through as a result of our insurance mandates. I will share the emotional component that my family endured and offer a plea to simplify the process, allow the physicians, medical teams and families make choices. Please remember to focus on what is *best* for the patient.

In March of 1997, we were told Nathaniel was a candidate for a lung transplant. He had been getting sicker more frequently and his oxygen requirements were increasing.

After the initial shock, I began to plow through the insurance maze. My policy did not list lung transplants as a covered benefit, however, Nathaniel's primary pediatrician assured me that if the transplant was medically necessary, the insurance would cover it. The insurance company was not that clear. They offered us a number of options during the next 4 months.

Option 1: accept their fact that lung transplants are experimental and always flawed. Do not consider this treatment option. Essentially, go away and don't come back.

Option 2: move to Pennsylvania, North Carolina or Missouri as each of these states had facilities that had performed more lung transplants than Children's Hospital of WI. This would mean that I would have to quit my job, lose the insurance, as I was the carrier and split my family up for 1-2 years. This bizarre option was provided after the administration became aware that we were not going away and that we knew that the transplant was not experimental.

Neither option was acceptable.

We entered into a process of review. We met with the medical director of the insurance company. He appeared to share our concern re. our sons health. He led us to believe that the insurance company would cover the procedure but that we should go to the hospital that would provide us with the best possible care in the state. At this time the medical director offered us option 3, the University Hospital in Madison. He promoted their "Service of Excellence". It sounded great, we would not have to relocate, split the family up and would be able to draw on our social supports. This positive feeling lasted ever so briefly. As we explored Madison, we discovered they had not done a lung transplant on a child. This "Service of Excellence" was a title that did not mean superior care for my child. It appeared to be a money link. The medical director told us we must complete a second opinion in Madison.

On July 7, 1997, Nathaniel and I drove to Madison. Nathaniel was most upset. He did not want to go through more tests or medical evaluations. He had been in the hospital on numerous occasions. He did not want to go through more to please the insurance company. He was comfortable with the C.F. team at Children's Hospital. He trusted these people as a result of his 12 year history with them. The CF team at Children's Hospital were acutely aware of Nathaniel's strengths and limitations. They knew all of us and as a result we were able to communicate well together. Nathaniel was unable to understand why he had to go through MORE. Nathaniel was unable to comprehend the importance of the coverage, Thank God. I was compliant and literally begged him to endure this day. My son needed the transplant, I wanted the nsurance company to provide coverage, I wanted my son to survive, I wanted my family to survive.

We arrived in Madison. The non-invasive appointment quickly turned into a painful, heart wrenching experience. Our insurance provided case manager, whom I had only spoken to on the phone, promised me that Nathaniel would not have to endure any painful procedures. She stated we would have lung functions and speak with the doctor. I had in turn told Nathaniel this plan. He trusted me, I had never lied to him. And here we were, in a strange place with somebody poking him with a large needle in his arm, trying unsuccessfully to obtain an arterial blood gas! This was very traumatic, the technician did not prepare Nathaniel verbally or physically. The technician was unable to access the artery, I can still see the needle bobbing back and forth in my son's arm, I can still see the tears running down his cheeks. In the background, another technician was standing behind me saying "Who wants this transplant anyway?" the tone was sarcastic, condescending and cold.

Somehow, Nathaniel was able to pull strength from his soul to complete lung functions before being seen by the doctor.

After brief introductions, the doctor told me that Nathaniel was not a candidate for their facility. He made soft remarks about him not being a "good" candidate. The doctor also conveyed Nathaniel had organisms that were resistant to antibiotic treatment. This news was quite upsetting. I had not heard this before. He added that Nathaniel did not need a transplant at that time, and therefore would not be listed.

I needed to investigate the information regarding resistance. I also had to keep my wits about me regarding the message that Nathaniel did not need a transplant at that time. I knew this, the waiting list for lungs can be 1-2 years. The whole point of going through the evaluation was an attempt to be ready when he was in need. It is common knowledge regarding listing anyone for any transplant that there are no guarantees to health, conditions can improve or decline rapidly.

The CF team at Children's had sent Nathaniel's cultures to Columbia to make sure he did not have a resistance issue. Unfortunately, the physician in Madison did not review this study.

I want you to understand the importance of having continuity of care. We were blessed to work with a group of professionals that knew my child and cared for him in a holistic manner. The CF team was connected to our family, as they become connected to all CF families due to the chronic nature of the disease.

At that point, I knew then that I could not trust the insurance company. It became clear that the medical director did not plan on following through with authorizing Nathaniel's transplant. My heart was being pierced. We had battled for 4 months to get to the point of being allowed to go to Madison for the second opinion at their "Service of Excellence". The medical director had told us that their "service of excellence" was the place to go for the best treatment. Due to my compliance and desire to play by the rules, 4 months that Nathaniel could have been on the waiting list was wasted. My perception of reality was that Madison had never transplanted a child and they wanted to have a perfect first candidate. My son was not a perfect candidate, but to tell us that he had resistant organisms and that his lungs were good enough were unprofessional statements to share with me.

As option 3 was dissolving, we waited anxiously for the medical director of the insurance company to contact us. We left numerous messages. We needed a summary of the Madison visit. I felt pressured to get this document so we could pursue option 4: the Katie Beckett-Title 19 program.

The next hurdle was incredible. The medical director would not release this document. He conveyed we needed to write a letter to absolve the company from further responsibilities regarding Nathaniel's care. He gave us specific information to include in this letter and told us to FAX it to him. Again, we were compliant. I thought we would then get the information we needed to proceed. But, there was more game to be played. The medical director stated he would not be able to get us the paperwork for a number of days.

The entire event was emotionally charged, however, this drama was most stressful. The energy required to contend with daily medical care and 'regular' life responsibilities was minimal. We had done everything the insurance company had dictated. Time was passing. Our goal to have our son listed for a transplant was not becoming a reality

I felt as if Nathaniel was a pawn in a game. And the game was all about who would get stuck with the financial responsibility. The insurance company made sure it was not going to be them.

We were able to get a copy of the evaluation after I had contacted our attorney. Again, I want to impress upon you that families with a loved one suffering from a chronic illness do not have great stores of energy. This entire saga was a struggle. I am grateful for the family love and support that we had. We needed that support to proceed with the insurance battle.

A social worker at Children's Hospital was helpful in assisting us in the comprehensive application process for the Katie Beckett/Title 19 coverage. Nathaniel was accepted into this program and listed July 18, 1997 at Children's Hospital of WI. Katie Beckett Title 19 would cover expenses. God Bless.

Once listed, Nathaniel had to endure preparatory sinus surgery in an attempt to keep his lungs as healthy as possible before and after transplant.

The autumn proved to be a difficult time for him. Nathaniel was hospitalized 4 times in 3 months. In October he was told that he would be considered for transplant sooner than originally estimated. We were issued a beeper.

It was most difficult to know what questions to ask about the transplant. We were issued a rough draft of a booklet regarding the procedure. Nathaniel began working with a psychologist in preparation for the surgery.

The family was always hopeful that Nathaniel would be a successful transplant recipient. We made tentative plans for family and friends to make meals, help care for my other son, etc. so things would be as organized as possible when the transplant would take place.

Nathaniel would have a few good days after a hospitalization and then he would begin to have increased fatigue and shortness of breath. He was hospitalized for the final time on November 21, 1997. He was admitted through the emergency room and then quickly transferred to the intensive care unit. We were told to decide whether or not to put our son, Nathaniel, on a ventilator. Fear, anxiety, and grief surrounded us.

Nathaniel had contracted a bacterial sepsis. He had high blood sugars and his kidneys were not functioning properly. After much prayer, we decided not to place Nathaniel on a ventilator. We continued to hold on to the hope that he would be blessed with a miracle.

We were told that if he had 3 days of negative cultures, he would continue to be a candidate for a lung transplant. My husband and I were told non-verbally, that we didn't need to worry about the availability of an organ, when Nathaniel needed one, there would be one available. At the time, I was so grateful. I did not understand what had changed in the listing process, but I was feeling as if prayers were being answered. I held tightly to this powerful message. Nathaniel did respond to the treatment, unfortunately, he went into kidney failure and contracted another sepsis, this time of a fungal origin.

Again, we were told that he was still a candidate for transplant, but he had to again have 3 days of negative cultures. This did not happen. Nathaniel's condition worsened, and he died at 5:30am on Sunday, December 7, 1997.

The whole point behind this testimony is that insurance companies should work with and for us towards funding organ transplants. The 4 months wasted in this case might not have made the difference for Nathaniel. But it brought our family unnecessary stress and anxiety. Transplants are a risk and necessitate difficult decisions for both the patients and families. They are also a reality of todays medical technology. As this story indicates, there are many hardships involved beyond procurement and distribution of organs. Please remember to focus on what is *best* for the patient and families.

Mr. SHAYS. I'm going to—Ms. Aschbacher, I'm going to ask you to hold the mic. I'm sorry. You really have to almost put it like an inch away from your mouth. Why don't you take it off the platform. The platform can get out of your way there a little bit. Take your time to get set. I'm going to ask you to really speak up. OK? Thank you.

Ms. ASCHBACHER. Thank you for inviting me to this hearing. I am happy to share my story. My name is Pat Aschbacher. In April 1975, I had a hysterectomy and during surgery, I needed a blood transfusion. I became very sick 5 weeks later and was hospitalized at that time for 2 weeks. I was told that I had hepatitis. In 1983, my doctor told me that my hepatitis was now called non A, non B.

Mr. SHAYS. Called C.

Ms. ASCHBACHER. Pardon?

Mr. SHAYS. Called C.

Ms. ASCHBACHER. Not yet, sir.

In 1990, my disease was renamed Hepatitis C. And it was determined that because of my liver problems, cirrhosis, portal hypertension, varices in the esophagus and ascites, I would need a liver transplant. My doctor referred me to the hepatologist at Froedtert Hospital, and in January 1991, I was evaluated for a liver transplant.

After 17 years of struggling with Hepatitis C, I was put on a liver transplant waiting list in 1992. It was a difficult decision that I initially resisted. I thought that I would just try to live that way. But when my doctor said, "Pat, I'm afraid we are going to lose you," I knew that I had much to lose as well—my family. On August 21, only 16 days after being listed, and only a few days shy of my 65th birthday, I received a call that a liver with my blood type had been donated, and I received a transplant. For 5½ years now, I have had a wonderfully normal life.

I know this hearing is about waiting and allocation. I waited 16 days and I understand that many others have waited longer, but when you are faced with death, 1 day can be an eternity. On August 21, 1992, I was not the sickest person in the country, but like every other recipient on the day of my transplant, I was the luckiest and most grateful person in the country.

I love my husband, Jim. He is my greatest supporter. This July, we will celebrate our 50th wedding anniversary. We have four terrific kids and seven beautiful grandchildren. In May, we will see our granddaughter get married. At the time of my transplant, my husband was retired from a 37-year career at Harnischfeger. Our health care coverage would have enabled me to go to other transplant centers, but I was happy with the high quality transplant center here. I would never have considered relocating for my transplant. The financial and emotional cost to my family would have been overwhelming.

I have been very blessed and want to give back to my community. My husband and I give time to organ donor awareness projects in our area with the Wisconsin Donor Network. We distribute posters and information and I talk at health fairs, churches, and hospitals. In fact, my donor, Donnie, was a patient at St. Mary's Hospital in Racine. I have gone there twice with the donor network to share my experience with the ICU nurses that cared for him. In our own way, every day, I know that my family and I do something to promote the benefits of donation and transplant. Unfortunately, there is still a long way to go to increase organ donation.

Some time ago when I was talking about donation at a health fair, a woman commented that she would like to donate anything she could to save someone's life, but she would never donate her liver. She said she wouldn't want to help someone who had ruined their health because of drinking and those patients didn't deserve a transplant. That really hurt me.

I calmly explained that I had gotten a liver transplant because of a disease that I had acquired through no fault of my own. After a few minutes of sharing my story, she apologized and told me I had changed her mind. But that incident still bothers me. I felt that I had been judged badly because I had a liver disease. There are some who may think that organs shouldn't go to alcoholics, or to people who are almost 65 years old, or to people without the best insurance. What really makes me angry is any talk about who is worthy to be transplanted. My doctors determined I had a very good chance of success with a transplant and they were right.

Tragically, donor organs are scarce. Until there are enough organs available for transplant, recipients and patients will have to endure discussion of who is most worthy. All of us are worthy, but all of us won't make it until the organ shortage is solved. Won't you please help to do what you can?

I could not end my testimony without telling you about the event that has touched my heart the most. Over the years I had written letters of thanks to my donor family. They don't live far away. In December, my prayers were answered and I received a letter from my donor's sister. Donnie's mother and his sister have come to our home twice since then and we phone and send notes. I am very grateful to them. They have become a second family to me.

I am grateful to God, my donor Donnie and his family, and to the doctors, nurses, and transplant coordinators at Froedtert Hospital. I am grateful for this indescribably wonderful gift that I have been given. Thank you.

Mr. SHAYS. Thank you very much.

Ms. Hodgson. Now, we have—that mic is an amplifying mic, I believe, so let's pull it out and let's see. Yeah. You just need to put it real close to you.

Ms. HODGSON. Can you hear me OK?

Mr. SHAYS. We hear you great.

Ms. HODGSON. I thought you would.

Thank you for this opportunity to submit testimony to this committee on behalf of all donor families. It is given in special loving memory of my late husband, Jim, and all who have given the ultimate gift of love, the gift of life, through organ donation.

My name is Patricia Hodgson. I am a registered nurse with 12½ years experience in critical care. I'm also a former EMT. That is an emergency medical technician.

Death can be sudden or painfully slow. It can be expected or it can be the worst of surprises. I am familiar with death and dying and grieving families.

At 10 p.m., March 30, 1992, as I was about to leave for work I found my 37-year-old husband, Jim, semiconscious, slumped in his favorite chair in front of the television. After cursory assessment, I established that he had suffered some neurological catastrophe. My son helped me lift his limp body to the floor while my daughter dialed 911.

Upon arrival in the emergency room, I informed the nurse that I was pretty certain of this outcome. I told him Jim was a potential organ donor and that everything should be done to put him on life support. After valiant or in spite of valiant efforts by the neurosurgeon to stop the cerebral hemorrhage he had suffered, Jim was placed on life support. Throughout the night his two young children, his other family members and friends said their goodbyes. And I held fast to our mutual decision throughout our 5-year marriage that he would become an organ donor.

The next morning after Jim was declared brain dead, I was introduced to my procurement coordinator, Don. He compassionately and patiently answered all my questions and explained the donation process. He said that it takes a while to match organs and waiting recipients in need, to alert those patients and the transplant teams and to get the recovery teams in place. One by one he asked if I would donate his corneas. I said yes. His heart. Yes. His kidneys. Yes. His pancreas, liver, and bones. Yes. Yes. Yes. I signed the papers.

Mr. SHAYS. Take your time.

Ms. HODGSON. I didn't ask or care if Jim's organs went north, south, east, or west or stayed in Wisconsin. My intent was that someone was to be given a chance to live. Because of Jim, two people can now see. A 23-year-old man who received one of his kidneys now doesn't need dialysis three times a week. Three other people in their twenties received his pancreas, his liver, and his other kidney. His heart now beats in the chest of another man named Jim, who has been able to walk his daughter down the aisle and see his grandchildren.

Donor families give without strings attached. We place our trust in medicine to make the right choice. Obviously that would be to the sickest patient or actually the one who has the best chance of recovery with this very precious resource.

In my experience as a nurse, I have observed that doctors differ in their opinions. Although they have the same facts, five cardiologists may look at one electrocardiogram and come away with five different interpretations.

A patient who has undergone bypass surgery may be managed one way by his cardiologist and another way by his cardiac surgeon. This can produce a rather significant conflict. I know. I have been in the middle of it. They both want what is best for their patient.

My point here is to identify the probability that in some transplant centers, the patient who is from out of State may be placed higher on the waiting list because he is hospitalized. Another patient who may be sicker but capable of being managed medically at home, under the direction of a physician may be placed lower on the list. Remaining at home with the support of family and friends certainly lowers the cost of medical care. In addition, it lowers the risk of infections they can get through hospitalization and depression due to separation and waiting, risks which certainly have an adverse effect on the transplantation outcome. What we all must agree on here today is there is a shortage of organs for the ever-growing population that requires them.

Advanced techniques in preservation and transportation of organs across the country and the precision of transplant experts are useless without the organs.

I suggest education for the promotion of organ donation as the starting point in this maelstrom. It belongs in the curriculum for medical school, nursing school, taught in—I have taught it in high school. And the list goes on. I have seen organ donation advertised on billboards, in newspapers and on TV here in Milwaukee. What about buses? What about shopping carts? What about radio spots during rush hour? Since my husband's death I have crusaded in his honor to promote organ donation by speaking for the Wisconsin Donor Network. I've spoken to nurses, clergy, doctors, morticians, EMT's, and the general public. Through lectures, seminars, media appearances, and dissemination of literature I've tried to raise awareness of the importance of organ donation. Last year our Governor honored recent donor families with a special ceremony at the capitol. I was privileged to represent them as their speaker. One by one they walked up to receive an engraved metal, some tearfully, most with pictures of their loved ones in hand. They were all such brave, courageous miracle workers.

Personally for me, and I know I speak for other donor families, organ donation has been beneficial in the grieving process. It gives us some small sense of control. It helps us fulfill our loved ones' very last wishes, and it helps us make the best out of the worst situation.

We need organs. We are spending all this time and money traveling. Traveling here and then back to Washington and still talking. People are dying. People will be grieving while you are all still talking.

As a donor wife I would urge this committee, rather beg this committee to spend an equal amount of time and money on a program to promote organ donation. We are all part of this shortage. Demand definitely is exceeding supply. This comes first. If we had more organs, we wouldn't have to change our allocation practices.

I challenge everyone present. Have you signed your driver's license? Have you filled out a uniform donor card? If the answer is no, you have no business being here today. Thank you for this opportunity to speak.

[The prepared statement of Ms. Hodgson follows:]

Thank you all for this opportunity to submit testimony to this Committee on behalf of all donor families. It is given in special loving memory of my late husband, Jim, and all who have given the ultimate gift of love - the gift of life - through organ donation.

My name is Patricia Hodgson. I am a registered nurse with 12½ years experience in critical care and I am a former EMT.

Death can be sudden or painfully slow, expected or the worst of surprises. I am familiar with death and grieving families.

At 10 p.m. on March 30, 1992, just before I left for work, I found my 37 year old husband, Jim, semi-conscious, slumped in his favorite chair in front of the TV. After cursory assessment, I established that he had suffered some neurological catastrophe. My son helped me lift his limp body to the floor, while my daughter dialed 911.

Upon arrival in the emergency room, I informed the nurse that I was pretty certain of what the expected outcome would be for my Jim. I told him that Jim was a potential organ donor and after valiant efforts by the neurosurgeon to stop the massive cerebral hemorrhage he had suffered, Jim was placed on life support.

Throughout the night, as his 2 young children, other family members and friends said their good-byes, I held fast to our mutual decision throughout our five year marriage that we would be organ donors.

The next morning after Jim was declared brain dead, I was introduced to my procurement coordinator, Don. He compassionately and patiently answered my questions and explained the donation process. He said that it takes awhile to match organs with waiting recipients in need, to alert those patients and transplant teams and dispatch recovery teams. One by one, he asked if I wanted to donate his corneas - "yes;" his heart - "yes;" his kidneys - "yes;" his liver, pancreas and bones - "yes!" "yes!" "yes!" I signed the papers.

I didn't ask or care if Jim's organs went north, south, east, west or stayed here in Wisconsin. My intent was that someone was to be given another chance to live. Because of Jim, two people can now see. A 23 year old man who received one of his kidneys no longer needs dialysis after three years. Three other people in their twenties received his other kidney, his liver and his pancreas. His heart now beats in the chest of another man named Jim, who has since walked his daughter down the aisle and has lived to see his grandchildren.

Donor families give without strings attached. We place our trust in medicine to make the best choice. Obviously that would be not only to the sickest patient; but, the patient who has the best chance of recovery with this very precious resource.

In my experience as a nurse, I've observed that doctors differ in their opinions. Although they have the same facts, five cardiologists could review one electrocardiogram and might have five slightly different interpretations.

Burn specialists may estimate percentage and degree of burns just a bit differently. Though they all agree a patient needs skin grafts - it's a questions of how much or how soon or for how long a period of time. A patient who has undergone bypass surgery may be managed one way by his cardiologist; with a differing approach from the cardiac surgeon. This can produce significant conflict, (I know, I've been in the middle of it) but they both want what's best for their patient.

My point here is to identify the probability, that in some transplant centers, the patient who is from out of state, may be placed higher on a waiting list because he's admitted to the hospital. Another patient, who may be truly sicker but capable of being managed medically in his home, under the direction of a physician and home care professionals may be placed lower on the waiting list. Remaining at home with the support of family and friends certainly lowers the cost of medical care. In addition, it lowers the risk of nosocomial infection and depression due to separation and waiting - risks which may have an adverse effect on the transplantation outcome.

What we all must agree on here today is that there is a shortage of organs for the ever growing population that requires them.

Advanced techniques in preservation and transportation of organs across the county, and the precision of transplantation experts, are useless without organs.

I suggest education for the promotion of organ donation as the starting point in this maelstrom. It belongs in the curriculum for medical school and nursing school - I've taught in high school. Include it in training for emergency medical services, fire and police training and basic training for the armed services. Make it a part of driver's education and part of license applications for hunting and fishing. I've seen organ donor awareness ads on TV, billboards and in newspapers in Milwaukee. Why not on buses or grocery carts? Radio slots during rush hour?

Since my husband's death, I have crusaded in his honor to promote organ donation by speaking for the Wisconsin Donor Network. My audiences vary: registered nurses, M.D.'s, clergy, emergency medical services, morticians, high schools and the general public. Through lectures, seminars, media appearances and dissemination of literature, I've tried to raise awareness of the importance of organ donation.

Last year, Governor Tommy Thompson honored recent donor families with a special ceremony at the capitol. I was privileged to represent them as a speaker. It was with great honor, awe and a personal understanding of their loss that I watched each surviving family (almost 200) some tearfully, many with portraits of their loved ones in hand, walk up and receive an engraved medal from our Governor. They were all such brave, courageous miracle workers.

Four months from now, August 8, will mark the introduction of the organ and tissue donation stamp which encourages you to "share your life". We can all become part of the crusade to raise the visibility of this critical health care issue.

Personally, for me - and I know I speak for the other donor families - organ donation has been beneficial in the grieving process. It permits us to fulfill our loved ones' last wishes, it gives us some sense of control and, it allows us to make the best of the very worst of situations.

We need organs! We're spending all this time and money. Traveling here - then back to Washington or wherever to talk some more. People are dying! People will be grieving while you're still talking!

As a donor wife, I would urge this Committee - no, I beg this Committee to spend an equal amount of time and money on programs to promote organ donation. We are all part of this shortage. Demand exceeds supply. This comes first. If we had enough organs available, we wouldn't need to change allocation practices.

I challenge everyone present: Have you signed your driver's license or a uniform donor card? Has your family? If the answer is no, you have no business being here.

I thank the Committee for the opportunity to testify today.

Mr. SHAYS. Mr. Volek.

Mr. VOLEK. Mr. Chairman, Congressman Barrett, I'm Paul Volek, director of the Wisconsin Donor Network, a division of Froedtert Memorial Lutheran Hospital. I'd like to thank you for the opportunity to provide testimony before this committee regarding the impact of the recent changes in organ allocation policy proposed by the Department of Health and Human Services.

Wisconsin has a tradition of excellence in organ procurement and transplantation. Both the Wisconsin Donor Network and the University of Wisconsin OPO rank among the top OPO's in the country and are leaders in every measure of OPO performance. Our success is directly attributable to the relationships we have maintained both with our health care providers and our local communities. Our mission is to extend the benefits of transplantation to our community through increasing the availability of transplantable organs and tissues. To this end we've achieved a high degree of success. For calendar year 1997, the HCFA OPO performance report ranked University of Wisconsin OPO and the Wisconsin Donor Network No. 1 and 3 respectively for organs recovered and transplanted per million population.

By design and regulation, OPO's are constituent based. Our boards are composed of public members and represent recipients, donor families and the general public residing in our service area. Each transplant center is represented on our board as well as other physicians from our community. The purpose of this structure specified under section 371 of the Public Health Service Act is to ensure the OPO is responsive to the unique needs of its community. This structure flows directly from the historical precedent for utilizing locally procured organs for transplantation into local recipients. This closed loop of donating to benefit the community has been a consistent theme in Wisconsin for over 25 years, and I believe this accounts for our success in organ donation.

HHS should be commended for breaking the log jam which has prevented publication of rules governing the OPTN. Although we disagree with the decision to publish these rules in the final form without significant opportunity for public comment, we are pleased that the voluntary rules which have governed the OPTN will now carry the weight of Federal regulation. On the issue of organ allocation policy, however, we have a mixed reaction.

The adoption of minimum listing criteria and uniform criteria for assigning patients and status are consistent with efforts currently underway by the United Network for Organ Sharing.

Unfortunately, the third element of the regulations in question today goes directly to and attacks the very heart of our program. The redistribution of organs away from Wisconsin so as to ostensibly benefit the sickest patients seems to satisfy a business agenda of a few transplant centers which have encouraged unlimited growth in their waiting list 'til they've outstripped the capacity of their community to meet their organ needs. Unfortunately, in the competition for local organs, local residents are frequently the ones disadvantaged by waiting lists heavily populated with out-of-area patients, many of whom could be transplanted quicker and with better outcomes in their home community. One might suggest the issue is as much a misallocation of patients as it is an issue of organ allocation.

Of concern in our area is the plight of the indigent patient or those patients who lack mobility and rely on access to a local provider. Over the past 3 years, 52 percent of the liver transplants, of our liver transplant recipients had their medical care paid through Medicaid or Medicare programs. Today these patients are well served. Double or quadruple waiting times and the cost burdens of extended periods of transplant, medical—pre-transplant medical management, increased acuity and comorbidity will fall squarely on the shoulders of the taxpayers.

We recently commissioned a Wisconsin public opinion pole to assist preferences for organ allocation; 82 percent of respondents affirmed the view that their organs should go to the sickest patients first, but only when the threat of death was eminent. Among patients who are equally sick, 56 percent of Wisconsin residents felt preference should be given to patients at Wisconsin hospitals and 32 percent were undecided. When asked who should make decisions about who receives organs, the overwhelming majority of residents, 76 percent, say that the decision should be left to organ donation and transplant professionals. Only 1.3 percent felt decisions should be made by the Federal Government.

Organ donation exists in an environment of trust. Trust on the part of families and care providers that we will be faithful stewards of this precious gift. When we speak to families at the time of great loss, we try to assure them this gift will save the life or improve the quality of life of someone in their community.

Organ transplantation is not a foreign concept in Wisconsin. We've followed the growth of this life-saving technology and are immensely proud of our outstanding program. On an intellectual level, we know the value of organ donation is realized wherever the gift is used. However, the decision to donate is an emotional one, and when families agree to permit donation, they're often giving to their friends and neighbors in need. Based on the findings of our public opinion poll, we believe the act of passing over local recipients so as to achieve some level of national equity may have a detrimental impact on donation and lead care providers and the public to adopt a more ambivalent attitude toward this important issue.

If a fraction of the resources and public attention which has been devoted to furthering changes in our current allocation policies were themselves allocated to improving local OPO performance in those very communities with the longest waiting times, much of the immediacy of the organ shortage in those areas would be diminished.

On one hand we're pleased that the Secretary has finally issued OPTN regulations. On the other hand, we see a decision to radically depart from the system which has successfully supported one of the fastest evolving areas of medical technology. This shortsighted approach to addressing a highly complex issue and the creation of policy in the absence of any consideration of the impact this will have on patients, providers and the communities they represent is an example of the worst kind of policymaking.

We genuinely appreciate the interest of this committee, the interest this committee has taken in this issue and respectfully request that you exercise your influence in support of the majority of transplant patients in our country. Thank you for your consideration.

[The prepared statement of Mr. Volek follows:]

TESTIMONY BEFORE THE HUMAN RESOURCES SUBCOMMITTEE

April 8, 1998
Paul J. Volek, M.P.H.
Wisconsin Donor Network
Milwaukee, Wisconsin

Mr. Chairman, Congressman Barrett, I would like to thank you for the opportunity to provide testimony before the Human Resources Subcommittee regarding the impact of the recent changes in organ allocation policy proposed by the Department of Health and Human Services. I am Paul Volek, Director of the Wisconsin Donor Network, a division of Froedtert Memorial Lutheran Hospital located in Milwaukee, Wisconsin. The Wisconsin Donor Network is the organ procurement organization (OPO) designated by the Health Care Finance Administration to serve the 2.2 million persons residing in southeastern Wisconsin. WDN supports three transplant centers and is affiliated with 38 local hospitals.

Wisconsin has a tradition of excellence in organ procurement and transplantation. Both the Wisconsin Donor Network and the University of Wisconsin OPO rank among the top OPO's in the country and are leaders in every measure of OPO performance. Our success is directly attributable to the relationships we have maintained with both our health care providers and our local communities. Our mission is to extend the benefits of transplantation to our community through increasing the availability of transplantable organs and tissues. To this end, we have achieved a high degree of success. For calendar year 1997, the HCFA OPO Performance Report ranked the Univ. of Wisconsin OPO and Wisconsin Donor Network numbers 1 and 3 respectively, for organs recovered and transplanted per million population in the United States.

By design – and regulation – OPO's are constituent based. Our Boards are composed of public members, and represent recipients, donor families and the general public residing in our service area. Each transplant center is represented on the Board, as well as other physicians from our community. The purpose of this structure, specified under Section 371 of the Public Health Service Act, is to ensure that the OPO is responsive to the unique needs of its community. This structure flows directly from the historical precedent for utilizing locally procured organs for transplantation into local recipients. This closed loop, of donating to benefit the community, has been a consistent theme in

Wisconsin for over twenty-five years and I believe accounts for our success in organ donation.

The Department of Health and Human Services should be commended for breaking the log jam which has prevented publication of rules governing the OPTN. Although we disagree with the decision to publish these rules in final form without significant opportunity for public comment, we are pleased that the voluntary rules which have governed the OPTN will now carry the weight of a federal regulation. On the issue of allocation policy, however, we have a mixed reaction.

The adoption of minimum listing criteria, assuming they are defensible and provide opportunity for exceptions on the basis of a physician's clinical judgment relative to an individual patients medical condition, is consistent with efforts currently underway through the United Network for Organ Sharing. These criteria should limit access to the transplant waiting list to those patients who are in genuine need of transplant rather than inflating the list with patients with progressive organ failure who may not be suitable candidates at the moment, but will accrue waiting time priority through early listing.

Uniform criteria for assigning patients to the appropriate clinical status is equally important and has been implemented by UNOS. Regional Review Boards currently conduct documentation reviews to verify the appropriateness of patient assignment to the highest status's.

Unfortunately, the third element of the regulations in question today goes directly to, and attacks the very heart of our program. The redistribution of organs away from Wisconsin so as to ostensibly benefit the "sickest "patients, can be perceived to satisfy the business agenda of a few transplant centers which have encouraged unlimited growth in their waiting list till they have outstripped the capacity of their community to meet their organ needs. This situation is exacerbated when those lists are heavily populated with out-of-area patients, many of whom could be transplanted quicker and with better outcomes in their home community. Unfortunately, in the competition for local organs, local residents are frequently the ones disadvantaged. One might suggest that the issue is as much a misallocation of patients as an issue of organ allocation.

Of concern in our area is the plight of the indigent patient, or those patients who lack mobility and rely on access to a local provider. Over the past three years, 52% of our liver transplant recipients had their medical care paid through the Medicaid or Medicare programs. Today these patients are well served. Double or quadruple their waiting times and the cost burden of extended periods of pre-transplant medical management, increased acuity and co-morbidity falls squarely on the tax payers shoulders. Similarly, jeopardizing the financial viability of local programs through significantly reduced volume may result in their closure, the impact of which will again be felt by the least advantaged in our community.

We recently commissioned a Wisconsin public opinion poll to assess preferences for organ allocation. Eighty-two percent (82%) of respondents affirmed the view that their organs should go to the sickest patients first -- but only when the threat of death is eminent. Among equally sick patients, 56% of Wisconsin residents felt preference should be given to patients at Wisconsin hospitals before organs are shared out-of-state and 32% were undecided. When asked whether organs from Wisconsin donors should be given to Wisconsin patients first, given death could result without a transplant, slightly more respondents want organs to stay in Wisconsin rather than given to an out-of-state patient. Finally, when asked who should make decisions about who receives organs, the overwhelming majority of residents (76%) stated the decision should be left to organ donation and transplant professionals. Only 1.3% felt decisions should be made by the federal government. These are not anecdotal comments or speculation, but a statistically-valid, randomly-drawn, representative sample of Wisconsin residents (95% confidence level).

Organ donation exists in an environment of trust. Trust on the part of families and care providers that we will be faithful stewards of this precious gift. When we speak to families at the time of great loss, we try to assure them that this gift will save the life or improve the quality of life of someone in their community.

Organ transplantation is not a foreign concept in Wisconsin. We've followed the growth of this lifesaving technology and are immensely proud of our outstanding programs. We know people who have received transplants - maybe a friend or neighbor. On an intellectual level, we know the value of organ donation is realized wherever the gift is used. However, the decision to donate is an emotional one and when families agree to permit donation, they're often giving to those friends and neighbor in need. Based on the findings of our public opinion poll, we believe the act of passing over local recipients so as to achieve some level of national equity may have a detrimental impact on donation and lead care providers and the public to adopt a more ambivalent attitude toward this important issue. The resulting loss of donation opportunities hurts everyone – especially those in the greatest need.

If a fraction of the resources and public attention which has been devoted to furthering changes in our current allocation policies were themselves allocated to improving local OPO performance in those communities with the longest waiting times, and if those programs were able to achieve success comparable to both our Wisconsin programs, much of the immediacy of the organ shortage in those areas would be diminished.

Gentlemen, on one hand we're pleased that the Secretary of HHS has finally issued the OPTN regulations. On the other hand, we see a unilateral decision to radically depart from the system which has successfully supported one of he fastest evolving areas of medical technology. This shortsighted approach to addressing a highly complex issue and the creation of policy in the absence of any consideration of the impact this will have on patients, providers and the communities they represent is an example of policy making at its worst.

We genuinely appreciate the interest this Committee has taken in this issue and respectfully request that you exercise your influence in support of the majority of transplant patients in our country. Thank-you for your consideration.

Mr. SHAYS. Dr. D'Alessandro.

Dr. D'ALESSANDRO. Good afternoon, Mr. Chairman, Congressman Barrett. My name is Dr. Tony D'Alessandro and I'm a transplant surgeon from the University of Wisconsin in Madison. I'd like to thank the Human Resources Subcommittee for the opportunity to present testimony today on the implications of changes to the organ allocation system proposed by the Department of Health and Human Services. In Wisconsin, many patients, donor families, and transplant professionals have serious concerns about some of the changes proposed by HHS. These are changes with life or death implications for some of our friends and neighbors who will be hoping desperately over the next several years that they will be joining fortunate Wisconsin residents who have been given a wonderous new chance at life. Projecting out the numbers from the UNOS modeling, the cruel reality is that nearly 800 Americans who would have been among the fortunate recipients of a transplant under the current rules, will not receive a liver under the new formula. Perhaps a dozen or more of these 800 real people waiting, hoping, praying for this new chance at life now under the new rule to be disappointed will be Wisconsin men and women, friends, neighbors and patients of those of us in this room. Real people. So we are very concerned that a major impact of the new rule will be that fewer patients benefit from the current limited supply of precious organs. That's why a number of us in this room have worked so hard to increase organ donation, so more of our friends and neighbors would have a chance at a new life. As you heard, the organ donation rate here in Wisconsin is quite high. A second, very major concern of ours over the impact of this new rule is that Americans, as the men and women of Wisconsin, see the new system not working as well as it has in recent years may have an obviously unintended, negative impact on support for organ donation.

The proposed HHS sickest-first policy will in the future mean that 95 percent of patients receiving liver transplants will be those who are either desperately ill in an intensive care unit or are sick enough to be continuously hospitalized. Is it sound medical policy to require that patients become as sick as possible before we administer to their needs? A policy of this kind has several extremely worrisome implications.

First, it is clear that under the proposed changes of transplanting only ICU-bound or hospitalized patients, the number of patients requiring more than one liver transplant will almost double from 10 to 19 percent. Under the proposed changes, fewer patients will receive a transplant, thereby increasing the waiting list size, and fewer patients who receive a transplant will actually survive. When three of these precious livers are used in a 6-month period to keep a desperately ill person alive, that means two other people, perhaps friends and neighbors of those in this room, will not receive a liver, will not receive a chance at a new life. More importantly, the number of patients who return to productive, rewarding lives will be fewer if they are required to become desperately ill before they can benefit from the miracle of transplantation.

How can we ask the American people to accept a policy that is not based on sound medical and ethical principles? Is this how we manage a scarce precious resource, we make it more scarce for fewer patients?

In my remaining time this morning, I would like to briefly introduce to you by way of photographs three patients who had been anxiously waiting at home for a liver transplant at the time an organ became available. As you may or may not know, the majority of patients who died on the waiting list last year were at home and were not even hospitalized. Mr. Chairman, these patients all were facing the prospect of death and some of them might well have not received this miraculous chance at a new life if the new HHS rule had been in effect.

Eugene Scott is a 48-year-old who received his liver transplant 5 years ago. He went back to work—back to school, excuse me, after his transplant and now works as a full-time mortician.

Ross Larson is a healthy 12-year-old sixth-grader who received his liver transplant 2 years ago. He is accompanied today by both his mother and father.

The third photograph, and that's——

Mr. SHAYS. Excuse me. You say he is here now?

Dr. D'ALESSANDRO. Yes. He is.

Mr. SHAYS. Does he want to stand up and introduce himself?

[Applause.]

Dr. D'ALESSANDRO. Annette Stebbins is a 51-year-old mother of two grown children who in this photograph celebrated the fifth anniversary of her liver transplant. She is also here today. These are our Wisconsin friends and neighbors who will be affected by this new policy. And what is perhaps most tragic of all, the policy with its increased transportation requirements, as shown in this poster, means that an increased number of precious livers provided through the generous spirit of donors and their families will tragically be wasted and will not provide a new life for people like these or sadly for anyone at all.

In closing we believe the proposed changes will result in fewer lives saved, fewer patients transplanted, increased organ wastage, and decreased organ donation, perhaps the worst side effect. Until enough organs are available to everyone in need, transplant policies must ensure that the precious organs presently available provide the maximum benefit for the maximum number of Americans. Thank you.

Mr. SHAYS. Thank you very much.

[The prepared statement of Dr. D'Alessandro and the information referred to follow:]

TESTIMONY BEFORE THE HUMAN RESOURCES SUBCOMMITTEE

April 8, 1998

Anthony M. D'Alessandro, M.D.
Associate Professor of Surgery
University of Wisconsin-Madison

I would like to thank the Human Resources Subcommittee for the opportunity to present testimony today on the implications of the changes to the organ allocation system proposed by the Department of Health and Human Services (DHHS). In Wisconsin, many patients, donor families, and transplant professionals have serious concerns about some of the changes proposed by HHS. To us, these are not abstract refinements of regulations that one reads about in the Federal Register. These are changes with [redacted] for some of our friends and neighbors who will be hoping desperately over the next several years that they will be among those fortunate Americans who receive this miraculous gift of a new organ, and are given a wondrous new chance at life. Projecting out the numbers from the UNOS modeling that has been done, the cruel reality is that nearly 800 Americans who would have been among the fortunate recipients of a transplant under the current rules, will NOT receive a liver under the new formula. Perhaps a dozen or more of these 800 – real people, waiting, hoping, praying for this new chance at life, now under the new rule to be disappointed, will be Wisconsin men and women, friends, neighbors, and patients of those of us in the room. Real people. So we are very [redacted]. That's why a number of us in this room have worked so hard to increase organ donation, so more of our friends and neighbors would have a chance at a new life. The organ donation rate here in Wisconsin is quite high. And a second, very major concern of ours over the impact of this new rule is that as Americans – as the men and women of Wisconsin – see the new system not working as well as it has in recent years, this may have an obviously unintended, negative impact on support for organ donation. And that in turn means more friends and neighbors will be disappointed. So these are very real, personal concerns to us.

Let me address our first concern. The problem that HHS has stated that it is trying to solve with these proposed changes is that under the current allocation system, some of the sickest patients are not receiving livers because they are going instead to patients in less urgent need. The sickest category consists of patients hospitalized in intensive care while the second highest category are those patients who are hospitalized continuously. Despite HHS's concerns, waiting times for these two groups of patients are short and are on average 4 days for the most urgent and 12 days for the next most urgent categories. The least urgent category consists of patients on the waiting list who are not hospitalized. So essentially, what HHS has said is: "Here you've got people in intensive care, and they are the ones that are at imminent risk of dying, and you've got livers instead going to people at home – who obviously could wait – while the people in intensive care are dying. We've got to change this." And superficially, that sounds like it makes sense. So I wonder if members of this Committee would be surprised to learn that nearly half of the patients waiting for a transplant who die before they receive this gift are not in intensive care when they die, are not in fact, in the hospital at all when they die. They are in the category of those waiting for a liver transplant at home. Nearly half. So we are concerned, because [redacted] – takes away some flexibility that has been very important in our trying to maximize the number of patients who benefit from the limited number of precious organs that are available.

And that brings me to a second aspect of this concern. The proposed HHS "sickest first" policy will [redacted] be [redacted] be [redacted]. Is it sound medical policy to require that patients become as sick as possible before we administer to their needs? A policy of this kind has several extremely worrisome implications. First, it is clear that, under the proposed changes of transplanting only ICU-bound or hospitalized patients, the number of patients requiring more than one liver transplant will almost double – increasing from 10% to 19%. Under the proposed changes, fewer patients will receive a transplant, thereby increasing the waiting list size and fewer patients who receive transplants will survive. When three of these precious livers are used in a six-month period in a high-risk effort to keep a desperately ill person alive, that means that two other people – real people, perhaps friends and neighbors of those in this room – will not receive a liver, will not receive a chance at a new life.

More importantly, the number of patients who return to productive, rewarding lives will be fewer if they are required to become desperately ill before they can benefit from the miracle of transplantation. The sicker the patient gets, the more complications of various kinds can be expected – and some of these are irreversible. How can we ask the American people to accept a policy that is not based on sound medical principles. Is this how we [redacted]? We make it more scarce and help fewer patients?

The primary focus of our energy and resources should be spent on increasing organ donation. And certainly HHS has recognized the importance of this in its National Organ and Tissue Donation Initiative. But this rule has the unfortunate potential of seriously undercutting that effort. Until there are enough organs available for every American who needs them, we believe America's national policy should be to seek to maximize the benefit of the precious number of organs available for the maximum number of Americans, wherever they live. This is exactly what the transplant community – which includes patients, donor families, and professionals -- has been striving to achieve in [redacted].

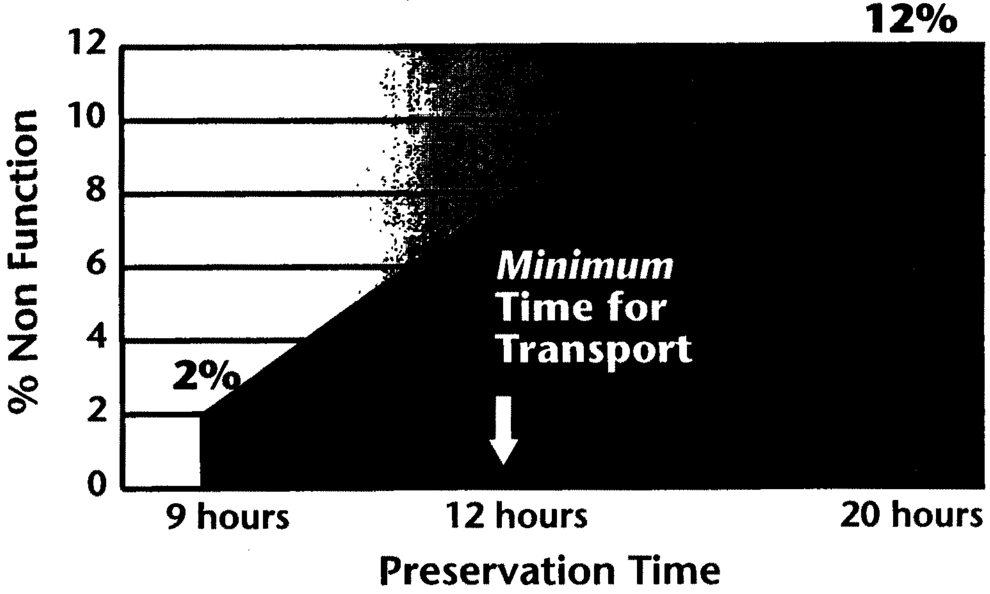
Finally, I would like to address another aspect of the "sickest first" policy that will also decrease rather than increase the number of Americans, some friends, some neighbors – who will benefit from a transplant in the next few years. That is the requirement that organs go to the sickest patient, even where that means significantly increased time in transit. HHS has made the assumption in its proposed changes that preservation technology has progressed to the level where it is safe to transport livers anywhere in the country. Since the University of Wisconsin developed the solution that is currently used to preserve organs, we are also keenly aware of its limitations. Every minute of increased preservation time results in worse liver function and an increase in the number of livers that never work leading to patient death or the need for a second or third transplant.

We believe in order to maximize the number of organs that can be successfully transplanted, preservation times must be kept to a minimum. We have done just that over the last 5 years and have reduced the need for multiple liver transplants from over 6.0% to 2.0%. Our center has previously shown that livers preserved between 12 and 17 hours, the minimum time necessary to transport livers across this country, resulted in 8% of livers – one out of 12 of these precious gifts – never function. Tragically, wasted. Even increasing the average transportation time from 9 hours to 11.5 increased the likelihood of the liver not functioning by 4%. Since patients receive priority for another liver in cases of nonfunction, the number of scarce donor livers would be further reduced. Again, our goal should be to maximize the benefit of transplantation for the maximum number of Americans. Our very serious concern is that the proposed changes will actually reduce the benefits of transplantation by increasing the number of livers that never function. And of course, from the standpoint of encouraging organ donation, how are families of donors going to feel about the increased chance that the organ will not actually provide some friend or some neighbor with a new chance at life.

In closing, we have several concerns about the proposed HHS changes in organ allocation. We believe the proposed changes will result in fewer lives saved, fewer patients transplanted, increased organ wastage, and decreased organ donation. This is not what patients want, it is not what donor families want and it is not what the majority of the transplant physicians and surgeons wants. I assure you, it will not be what the American people will want.

The proposed changes do not have their basis in sound medicine. Until enough organs are available to everyone in need, transplant policies must ensure that the precious organs presently available provide the maximum benefit to the maximum number of Americans. As members of the Human Resources Subcommittee, you are uniquely positioned to hear our concerns. I urge all of you to examine these proposed changes closely and to take seriously our concerns.

Precious Donated Livers Wasted When Transportation Time Increases



Mr. SHAYS. Ms. Shapiro.

Ms. SHAPIRO. Mr. Chairman, Congressman Barrett, thank you for the chance to be here with you today and to share my thoughts about ethical considerations relevant to organ allocation regulations proposed by the Department. I'm a professor of bioethics here at the Medical College of Wisconsin, director of the College's Center for the Study of Bioethics, a practicing health law attorney, and chair of the American Bar Association's Coordinating Group on Bioethics and the Law and its Health Rights Committee.

We have heard much today about the critical and chronic shortage of donor organs in this country which requires ethically sound procedures for organ allocation, not only to fairly distribute a scarce and precious community resource, but also to maintain the public's trust in the allocation system, which is essential for successful organ procurement.

The two ethical principles that are most relevant to organ allocation analysis are these: Utility, or doing the most good for the most people; and justice, or fairly distributing the attendant benefits and burdens among transplant patients.

From these two ethical principles, specific objectives for our organ allocation system can be derived. So that from utility, we see that we get enhancement by maximizing the availability and efficient use of organs; by maximizing long-term patient survival overall, both before and after transplant; by maximizing graft survival; by maximizing quality of life both before and after transplantation; by minimizing the need for retransplants and by minimizing overall transplantation-related costs.

From the principle of justice, which, again, requires a fair distribution of benefits and burdens, we get these objectives: accommodating medical urgency, which we have heard about today, by giving appropriate priority to patients for whom the consequences of not being transplanted are most severe; giving appropriate priority to same status patients who have waited the longest for a transplant, provided that objective medical criteria for listing patients and for assessing status are consistently applied; giving appropriate priority to categories of patients who are medically disadvantaged because they have a special medical or biological condition that inordinately reduces their ability to receive a suitable organ; preventing patients from being disadvantaged on account of nonmedical problems such as access or geography problems; and, finally, by assuring the accountability of the system within the system.

These are the specific objectives which flow from the ethical principles that are most relevant to our discussion today. So that evaluation of the proposed rule requires analysis of its impact on satisfaction of these ethically based organ allocation system objectives. Let's look at that.

What is the impact of this rule on utility-based objectives? Well, there are some concerns that the new rule could result in fewer numbers of available organs because of its impact on donation decisions as well as procurement efforts, and we have heard something about this already. Data remain unclear, but there are some who suggest that potential donors and families are more likely to give permission to donate their organs if they are assured that someone in their community will benefit. Some say that keeping organs for patients in the donor's local area encourages local professionals like trauma specialists and emergency room personnel to identify and to refer potential organ donors more often. There are also some who say that with local use, procurement professionals are more highly motivated. There are also concerns about the proposed rule's impact on the prevalence of retransplants and on patient and graft survival. With the new rule, most believe that the average organ transplant patient will be sicker with more advanced disease, with more co-morbidities and therefore more likely to reject an organ graft after transplantation and therefore to require a second or even third transplant to survive; and as a result, fewer individuals overall will be transplanted and fewer lives will be saved.

An additional concern again relating back to utility has to do with overall cost. It's less expensive to use a donated organ within shorter distances from the donor facility because transportation costs are lower and travel arrangements are less complicated than when longer distances are involved and we have more concerns about assuring organ viability. In addition, hospitalization costs of patients who are sicker before transplant may be higher, and the adverse effects of ischemia of the organs during the longer transit times from donor to recipient could prolong the transplanted patients' intensive care or overall hospital stays at increased cost or, worse yet, result in loss of a substantial number of organs altogether.

What is the impact or the likely impact of this rule on the justice-based objectives that I talked about earlier? I think we probably have agreement in this room, and it does seem clear, that the rule's call for the development of uniform and objective criteria for placement on the waiting list and for status determination would enhance justice-based objectives by making it easier to objectively compare the medical need of patients awaiting transplant, thereby helping to assure a level playing field in selecting among patients. In addition, the provisions which seek to ameliorate local allocation preference do, I believe, attempt to favorably impact justice-based objectives by eliminating the impact of where a patient lives or lists on his or her chance of getting an organ. But in terms of this geographic factor, some fear that the rule would actually have a negative impact on justice-based objectives because it would divert organs from smaller centers to larger ones, perhaps result in the closure of smaller transplant programs, force sick patients then and their families to leave supportive home communities and travel long distances for their transplants, or deprive them of the opportunity for a transplant altogether if they can't afford or are too ill to travel or temporarily relocate.

In light of these lingering questions and concerns about the rule's impact on the availability and efficient use of organs—the utility-based objectives—and on the possibility of unjust burdens being placed on potential recipients, it seems to me that it may be advisable to implement more modest changes while more data about the likely impact of the rule on patients, on institutions and on the public are gathered and analyzed.

First, standard, objective, measurable medical criteria for listing those who need transplantation and for determining medical status should be developed and should be implemented by all transplant centers, and the resulting impact of that on equalizing currently disparate waiting time should be evaluated. We should start there.

Second, if disparate waiting times still persist even after the adoption of standardized medical criteria for listing and medical status determination, medical need should be emphasized over geographic location as an allocation factor by making organs available on a broader regional basis for patients in the most serious condition. Regional as opposed to national sharing could avoid some of the jeopardy to the utility-based objectives of our allocation system that I talked about earlier; and modeling suggests that even modest geographic sharing could greatly reduce disparities in waiting times.

Third, in order to evaluate the changes, to reduce the ability of patients and institutions and payers and/or providers to game the system, and to preserve the public trust and confidence in organ allocation, public oversight and accountability provisions should be implemented. We should have uniform, timely, accurate records kept by transplant centers and OPO's; we should have periodic audits to assess record accuracy, and data should be analyzed and evaluated in light of system objectives.

There is a final issue that requires attention and invokes separate ethical consideration; and that issue is respect for patients and for patient welfare in this process of contemplated change of our system. We have heard many times today that organ transplantation is about patient welfare; and organ donation is grounded in the public's trust that patient welfare will be promoted fairly. The best interests of patients has to inform and guide not only the laws and regulations that we come up with, but the process through which we evaluate and change policy. And this means, first, that the catalyst for change has to be an honest and thorough consideration of relevant medical, social and ethical factors, not political contributions or pressure by individuals or groups with a vested interest, as has been alleged. To maintain the public's confidence in the integrity and patient welfare goals of our organ allocation system, there should be full disclosure of any such contributions that may have been made or any such pressure that may have been asserted.

Respect for patients and patient welfare also means that if change is to be implemented, transition policies have to be developed so that patients on the list don't get less favorable treatment than they would have received under previous policies. Such transition policies are contemplated in this rule.

And, finally, respect for patients means that as proposed changes are evaluated, prospective transplant candidates can't be unduly alarmed or pressured by ungrounded or exaggerated and incendiary reports of possible consequences for them disseminated by either proponents or opponents of the rule in efforts to gain political or public opinion advantage. Thank you.

Mr. SHAYS. Thank you very much, Ms. Shapiro.

[The prepared statement of Ms. Shapiro follows:]

Mr. Chairman and distinguished subcommittee members, thank you for this opportunity to share my thoughts regarding the ethical considerations relevant to organ allocation regulations proposed by the Department of Health and Human Services. I am a Professor of Bioethics at the Medical College of Wisconsin, Director of the College's Center for the Study of Bioethics, a practicing health law attorney, and Chair of the American Bar Association's Coordinating Group on Bioethics and the Law and its Health Rights Committee.

The critical and chronic shortage of donor organs in the United States results in a tragic number of potentially preventable deaths; and the discrepancy between supply of, and demand for, transplantable organs continues to worsen at an accelerating rate. Under these circumstances, ethically sound procedures for organ allocation are crucial--not only to fairly distribute a scarce and valuable community resource, but also to maintain the public's trust in the allocation system, which is essential for successful organ procurement.

The two ethical principles that are most relevant to organ allocation analysis are:

(1) Utility--doing the most good for the most people; and

(2) Justice--fairly distributing the attendant benefits and burdens among transplant patients.

From these general ethical principles, specific objectives for our organ allocation system can be derived.

Utility clearly is enhanced by:

(1) maximizing the availability and efficient use of organs, which in turn is accomplished by:

  (a) promoting consent for donation;

  (b) improving procurement efficiency;

  (c) minimizing organ discards; and

  (d) promoting efficiency in organ distribution and allocation;

(2) maximizing long term patient survival overall (pre-and post-transplant);

(3) maximizing graft survival by promoting the transplantation of organs that function successfully for as long as possible;

(4) maximizing patients' quality of life before and after transplant;

(5) minimizing the need for retransplants when the likelihood for such a need can be predicted; and

(6) minimizing overall transplantation-related costs.

The ethical principle of justice, which requires a fair distribution of benefits and burdens, translates into these objectives:

(1) accommodating medical urgency by giving appropriate priority to patients for whom the consequences of not being transplanted are most severe;

(2) giving appropriate priority to same-status patients who have waited the longest for a transplant, provided that objective medical criteria for listing patients and assessing their status are consistently applied;

(3) giving appropriate priority to categories of patients who are medically disadvantaged because they have a special medical or biological condition that inordinately reduces their ability to receive a suitable organ;

(4) preventing patients from being disadvantaged on account of non-medical access problems, e.g. inability to travel long distances; and

(5) assuring accountability within the system.

The new rule calls on the Organ Procurement and Transplantation Network:

(1) to develop revised allocation policies that will reduce current geographic disparities in the amount of time patients wait for an organ by allocating organs first to those in the highest medical urgency status, with reduced reliance on geographic factors; and

(2) to develop uniform criteria for determining a patient's medical status and eligibility for placement on a waiting list.

Evaluation of the proposed rule requires analysis of its impact on satisfaction of the ethically based organ allocation system objectives set forth above.

Impact of the Proposed Rule on Utility-Based Objectives

There are some concerns that the new rule could result in fewer numbers of available organs because of its impact on donation decisions and procurement efforts. While data remain unclear, there are some who suggest that potential donors and families are more likely to give permission to organ donation if they are assured that someone in their local community will benefit. In addition, some contend that keeping organs for patients in the donor's local area encourages local professionals, such as trauma specialists and emergency room personnel, to identify and refer potential organ donations more often, and that with local use, procurement professionals are more highly motivated.

There are also concerns about the proposed rule's impact on the prevalence of retransplants and on patient and graft survival. Under current policies, since matching organs are made available to listed patients in a local organ procurement area before they are made available to patients outside the area, local patients may receive a transplant while patients with more urgent medical needs in another area continue to wait. Under the new rule, the average organ transplant patient will be sicker, with more advanced disease and more co-morbidities, and therefore more likely to reject an organ graft after transplantation and to require a second or third transplant to survive. As a result, fewer individuals would be transplanted and fewer lives would be saved.

An additional concern about the proposed rule's impact on utility-based objectives relates to overall costs. It is less expensive to use a donated organ within shorter distances from the donor facility because transportation costs are lower and travel arrangements are less complicated than when longer distances are involved and assuring organ viability is more challenging. In addition, hospitalization costs of patients who are sicker before transplant may be higher. Furthermore, the adverse effects of ischemia of organs during longer transit times from donor to recipient could prolong transplanted patients' intensive care and/or overall hospital stays, at increased cost, or result in a loss of substantial numbers of organs altogether.

Impact of the Proposed Rule on Justice-Based Objectives

It seems clear that the rule's call for the development of uniform, objective criteria for placement on the waiting list and for status determination would enhance justice-based objectives of our allocation system. These changes would make it easier to objectively compare the medical need of patients awaiting transplantation, thereby helping to assure a "level playing field" in selecting among patients.

The rule's provisions which seek to ameliorate local allocation preference also could favorably impact justice-based objectives. Eliminating the impact of where a patient lives or lists on his or her chance of receiving an organ would guard against disadvantage related to non-medical access problems.

On the other hand, some fear that the rule would have a negative impact on justice-based objectives because it would divert organs from smaller transplant programs to large centers, which would result in closure of smaller transplant programs. This would force sick patients and their families to leave supportive home communities and travel long distances for their transplants, or deprive them of the opportunity for a transplant altogether if they are too ill or cannot afford the expenses related to travel and temporary relocation, or if their insurance carrier will not cover transplantation at the center where the procedure would be performed. It should be noted, however, that these fears about access limitations are rejected by others who point out that currently approximately half of liver patients must travel outside their local area to obtain a transplant.

Recommendations

In light of lingering questions and concerns about the rule's impact on the availability and efficient use of organs, and the possibility of unjust burdens placed on potential recipients, it may be advisable to implement the following more modest changes while more data about the likely impact of the rule on patients, institutions and the public are gathered and analyzed.

First, standard, objective and measurable medical criteria for listing those who need transplantation and for determining medical status should be developed and implemented by all transplant centers, and the resulting impact on equalizing currently disparate waiting times should be evaluated.

Second, if disparate waiting times persist even after the adoption of standardized medical criteria for listing and medical status determination, medical need should be emphasized (over geographic location) as an allocation factor by making organs available on a broader regional basis for patients in the most serious condition. (This is particularly important with respect to livers, because hearts already are shared regionally in many areas, and kidney patients have dialysis options.) Regional, as opposed to national sharing could avoid jeopardy to the utility-based objectives of our allocation system; and modeling suggests that even modest geographic sharing could greatly reduce disparities in waiting time.

Third, in order to evaluate the changes; to reduce the ability of patients, payers and/or providers to "game" the system; and to preserve public trust and confidence in organ allocation, public oversight and accountability provisions should be implemented. Uniform, timely, and accurate records should be kept by transplant centers and OPOs; periodic audits should be undertaken to assess record accuracy; and data should be analyzed and evaluated in light of system objectives.

A final issue that requires attention and invokes separate ethical consideration is respect for patients and patient welfare in this process of contemplated change in our organ allocation system. Organ transplantation is about patient welfare; and organ donation is grounded in the public's trust that patient welfare will be promoted fairly. The best interests of patients must inform and guide not only law and regulations governing organ transplantation, but also the process through which we evaluate and change policy. This means, first, that the catalyst for change should be honest and thorough consideration of relevant medical, social and ethical factors, not political contributions or pressure by individuals or groups with a vested interest, as has been alleged. In order to maintain the public's confidence in the integrity and patient-welfare goals of the organ allocation system, there should be full disclosure of any such contributions that have been made or pressure that has been asserted.

Respect for patients and patient welfare also means that if change is to be implemented, transition policies must be developed so that patients on transplantation waiting lists do not receive less favorable treatment than they would have received under previous policies.

Finally, respect for patients means that as proposed changes are evaluated, prospective transplant candidates should not be unduly alarmed or pressured by ungrounded or exaggerated and incendiary reports of possible consequences for them, disseminated by proponents or opponents of the rule in efforts to gain political or public opinion advantage.

Mr. SHAYS. That mic, let me just see, I think the mic in front of you is—which one—OK.

Dr. FUNG. Good afternoon.

Mr. SHAYS. Good afternoon, Dr. Fung. Nice to have you here.

Dr. FUNG. Thank you. Mr. Chairman.

Dr. FUNG. Mr. Chairman, Congressman Barrett, ladies and gentlemen in the audience, my name is John Fung, and I'm a transplant surgeon.

Mr. SHAYS. Doctor, I'm really sorry, but you're going to have to hold it real close to you. These mics are designed to——

Dr. FUNG. I'll try better. I'm the director of Transplantation Services at the University of Pittsburgh. And I come from a unique perspective, primarily because the University of Pittsburgh has a very long history in transplantation, has one of the largest experiences in the world. We have performed transplantation for citizens in every State of the union, including the territories and commonwealths of——

VOICE. Speak up.

Mr. SHAYS. Let me just say this to you. No noise from the audience, please, but hands are appreciated. Doctor, evidently you've got to be like this. OK? Think of yourself as a singer or something.

Dr. FUNG. Contrary to some beliefs, the University of Pittsburgh Medical Center has no managed care contracts. We do not go out and recruit patients to our center, yet 60 percent of our patients on our waiting list are outside of our local area.

Now, I have been involved in organ transplantation since 1984, and I have been active in transplantation policy issues over the past 8 years. I've been involved in a number of UNOS committees, including the Liver and Intestine Subcommittee, and I currently serve as the region 2 representative to the UNOS board. I would like to thank the subcommittee, as everyone else on the panel, to have the opportunity to provide testimony today.

In short, I do want to express to the subcommittee how important I believe this effort to be and that I endorse very strongly the principles announced on March 26 by Secretary Donna Shalala because it embodies in its final regulation a truly patient-driven system with the emphasis on saving patient lives as its highest criteria for organ allocation. I would commend her for taking a strong stance in favor of increasing equity and increasing access for patients which support the objectives of NOTA. She has already stressed that it is important to maintain the physician-patient relationship as well as a policymaking function of the transplant professionals of UNOS. The Secretary has stated that these regulations provide policy guidelines and a policy framework which performance objectives but not the policies themselves are crafted upon. Originally I had intended to spend the few minutes I had to detail the history of allocation controversies, the status of liver transplantation in the United States, limitations of UNOS. Obviously this would take too long, so what I would like to do is to review some of the issues that were brought up today and a brief summary of my own comments, but I would also——

Mr. SHAYS. Let me ask you a question. Are you all hearing in the back? Let me just say, the reason is, you've got to project a little with what you have to say. First off, we could have had this hearing in Pittsburgh, and then we could have had people from Wisconsin go there. You were good enough to come here. We are having the hearing here and so I know the audience is very interested to know what you have to say, but I do want to make sure that you are projecting. And you have—we gave Ms. Shapiro about 10 minutes. You have a bit of time here. I want to make sure we cover this information.

Dr. FUNG. Well, thank you. I have submitted written testimony and some appendices to that which I think will be informative and provide you with some factual data. I believe that UNOS has worked under the mistaken belief that it alone, without Government and adequate patient and family involvement, can decide really what is best for transplant candidates. Regrettably, the long delay at the issuance of final regulations by HHS has only fostered that myth of really almost uncontrolled authority and autonomy. We recognize that UNOS created a unique public/private relationship with the OPTN, but even as late as 1996——

Mr. SHAYS. Doctor, I'm going to just get on your back here. You just need to get that mic much closer to you. If you hold it, because I notice you want to rest your arm down, just hold it down like this and you will get it. Your testimony is very important, and we'd like people to hear it.

Dr. FUNG. I'm sorry.

Mr. SHAYS. It appeared that that mic is not as good. Yes, let's see if that mic is better.

Dr. FUNG. Is that better? Hello. Hello.

Mr. SHAYS. It's really the same mic.

Dr. FUNG. Right. Well, let me try, if I can just set it up here, maybe that will help.

I would say even as late as 1996, the Senate Labor and Human Resources Committee, which was chaired by then Senator Nancy Kassebaum, identified that there was a need for the Government to provide oversight to OPTN policies. Now, we had hoped a long time ago that HHS would have issued OPTN regulations. We have heard today that perhaps these regulations are not necessary. We have heard that UNOS has made an earnest effort and made great strides in trying to move forward with some of the principles that they elucidated, but I really would argue with that fact. I would say that the failure to increase donation rates significantly, the failure to weed out poorly performing programs, the reluctance to provide data to HHS as specified in contract, failure to mediate a solution to the allocation policy and their failure to adopt public attitudes into UNOS policies really suggests that there is much work that needs to be done.

I believe that Secretary Shalala should be complimented on getting the final rule right for patients. It is a long-awaited and much needed re-orientation of the OPTN, and the priorities which are specified in NOTA.

We have all heard what the laudible principles are. There are really five of them: Equity for patients on the waiting list, access to transplant center data for patients, a level playing field as defined by standard listing and status criteria, reaffirmation of the Government oversight role, and encouragement of patient participation in transplant policymaking. Some people credited this to be

HHS' creations, but in fact, these principles have been with organ transplantation for over 20 years. The 1977 AMA Council for Ethical and Judicial Affairs, as we heard before, confirmed that organs should be considered a national rather than a local or regional resource and that geographic boundaries in the allocation of organs should be prohibited. This concept was further reaffirmed in 1984 by NOTA, in 1986 by the U.S. Task Force on Organ Transplantation, and more recently in 1991 by the Offices of the Inspector General, which we heard this morning.

The GAO, in 1993, recognized that the OPTN and their policymaking capabilities created a potential conflict of interest. In addition, when we talked about reauthorization of NOTA in 1993 and 1996, both of the panels recognized that there was a problem with geographic inequity and recognized it was an importance for the Government to provide oversight to OPTN policies. We know that the public has views. The question is are these views being implemented? In 1994 UNOS commissioned their survey in which over 1,700 randomly selected members of the general public, recipients and candidates were asked to address questions about organ donation and allocation. The majority of patients, of recipients, candidates assigned the lowest priority to keeping organs locally, and we heard that from Mr. Volek today, when the majority of them would assign the highest priority to patients who had the least amount of time to live. Only 22 percent of recipients and 20 percent of candidates assigned top priority to the patient who had the "best chance at survival." One-third of patients felt that top priority should be to make equal waiting times. And we believe these have not been incorporated into UNOS policies. Now, we recognize that organ shortage is the driving force here. And I support all possible initiatives to increase organ donation. I have some ideas of my own, but we can discuss that later. But I really do believe that it's important to engender the trust of the public and only by doing that can we increase donation. Sixty-six percent of the respondents in that survey, the general public, said they would be more strongly influenced to sign a donor card if they were sure that the policy favored a national distribution rather than a local distribution.

I would like to emphasize also that even if there were more organs available for transplantation, the issue of fairness to all patients must be the foremost principle in allocation policies. In my opinion, I believe that HHS and the Secretary have weighed all the arguments, they have examined the evidence, they have listened to all the testimony and have arrived at the conclusion that fairness is the most important guiding principle.

We believe that in the short period of time that the Secretary and the HHS has allotted for the development of these policies that UNOS should begin to earnestly work on setting these policies up. But instead all we see is a flurry of media and lobbying activity which is only—whose only goal is to influence legislators to intervene on UNOS and the transplantation program behalf. We are also—it's also unfortunate that there are many superficial statements I consider half truths that are being sent out into the media. For example, we had heard today that the very sickest patients who are in the Intensive Care Unit, for instance, have equal waiting times. Now, Dr. Fox recognized and had tried to explain to you that this is really an artifact and really meaningless. Why? Because in that status there is only a 7-day maximum with a 7-day extension. So excluding the patients who are dying, you can't really have a tremendous variation from region to region.

I think that UNOS has a fiduciary responsibility to provide the patients and the public with accurate, complete, and useful information that is based on fact and science, not a cursory examination and a cursory summary. If they were really factual, UNOS actually would be doing the public a service. They would be educating them, but in fact, that is not happening. Instead, the use of scare tactics projecting that the final rule would "make it more difficult for the majority of patients to get a transplant, for centers to close, likely need to decrease in donation, result in fewer patients receiving transplants." There is no data to support these contentions, these claims.

HHS regulation in no way affects the patient's freedom to choose the center that he or she wants to go to. Does not force patients to travel to a center that they do not wish to. Does not call for closing of transplant centers. It does not force transplant programs to transplant patients in extremis.

Dr. D'Alessandro has stated that it's not, that transplanting the sickest patients may not be the optimal utilization of donor organs, but the Secretary has already stated that it is the OPTN's medical policies that will determine what constitutes a futile effort at transplantation. And I actually believe that the Secretary and her staff recognize there is a concept of greatest net benefit. Net benefit is a difference in survival between those that are transplanted and with those that there is survival without a transplant. And in fact, the greatest net benefit are for the patients in the Intensive Care Unit and hospital, a 50 percent increase in survival versus no net benefit in survival for 2 years in the other group.

Mr. SHAYS. Thank you, Doctor.

Dr. FUNG. I will just conclude, I am just going to say I really believe that the final rule does not impinge on UNOS. I believe that UNOS has wide latitude to make policies that will eventually be viewed by the HHS as seeing whether or not it achieves the principles that they've elucidated. I thank you.

Mr. SHAYS. Thank you.

[The prepared statement of Dr. Fung follows:]

Introduction

Good morning, Mr. Chairman and Congressman Barrett. My name is Dr. John Fung and I am the Director of Transplantation Surgery at the University of Pittsburgh Medical Center, where I have been involved in organ transplantation since 1984. Our transplant center is unique in that we are the largest and most experienced center in the world. We have performed liver transplants for citizens from every state in the Union and from its territories and commonwealths. Contrary to some beliefs, the University of Pittsburgh Medical Center has no managed care contracts for liver transplantation, yet over 60% of the patients on our liver waiting list are outside of our catchment area.

I have been actively involved in UNOS affairs since 1990, serving on a number of UNOS committees, including:

1) Scientific Advisory Committee
2) Liver and Intestine Transplantation Committee
3) Liver Allocation Modeling Sub-Committee
4) Membership and Professional Standards Committee
5) UNOS Board of Directors.

In addition, I have been involved both nationally and internationally in numerous academic and transplantation societies, including serving as the current President of the International Liver Transplantation Society. I have served as an advisor to state and federal agencies on transplant related issues. I am enumerating these organization to emphasize that my experience in transplantation spans a number of years and that I have diligently and responsibly represented the transplant community on issues of scientific and academic interest.

I would like to thank the Subcommittee for the opportunity to provide testimony today in considering the effectiveness of current organ distribution practices and the implications of the proposed changes from the Department of Health and Human Services to the organ allocation system.

In short, I strongly support the principles announced on March 26, 1998 by Secretary Donna Shalala as embodied in the final regulation because they truly place patient benefit and the saving of patient lives as the highest criteria for organ allocation. I commend her for taking a strong stance in favor of increasing equity and access for patients to support the objectives of the National Organ Transplant Act of 1984. She wants to maintain the important physician-patient relationship as well as the policy-making function of the transplant professionals in the OPTN. The Secretary has clearly stated that these regulations provide policy guidance and a policy framework with specific performance objectives but not the policies themselves.

It should be emphasized that this regulation in no way affects the freedom of patients to select the transplant center of their choice; it does not force patients to travel any farther to a transplant center than they wish to; it does not call for the closing of any transplant centers; and it does not force transplant centers to transplant patients in extremis. You may hear such conflicting testimony today that you will perhaps wonder how the witnesses can possibly be talking about the same issues. I am knowledgeable about the process UNOS uses to develop organ allocation policies and I can assure you that the concerns expressed by the Department about the OPTN in the Preamble are accurate and valid. The original commitment to the welfare of all patients has been replaced by a mistaken belief that the OPTN alone, without government involvement or adequate patient and family involvement, can decide what it thinks will be best for patients. The bureaucratic trappings of the OPTN and the long delay in the issuance of final regulations by the Department have fostered the myths of unlimited authority and autonomy. The final rule is a long-awaited and needed reorientation of the OPTN and its priorities within the objectives of NOTA.

Status of the Government's Efforts to Realize the Goals of NOTA

The National Organ Transplant Act of 1984 created the unique public-private partnership of the OPTN. NOTA specified "a national list" and a "national system for the allocation of organs," although the details of the list and system were to be developed by the transplant professionals in the OPTN. As recently as 1996, the Senate Labor and Human Resources Committee chaired by Senator Nancy Kassebaum Baker clearly recognized the role of the transplant community with regards to developing OPTN membership criteria and medical aspects of transplantation. However, these deliberations also identified the need for the government to provide oversight of OPTN policies.

Many of us, quite frankly, hoped that HHS would issue OPTN regulations much sooner than it has. The OPTN has developed transplant policies without significant federal input ever since UNOS successfully bid for the first OPTN contract in 1986. The amendments to the Social Security Act in 1986, the General Notice in 1989, the Notice of Proposed Rulemaking in 1994, the 1996 notice of the HHS hearings, and now the final rule with comment period tantalized the community with the prospect of the Department issuing regulations. Secretary Shalala should not be faulted with the lack of progress of her predecessors in issuing the final regulation. She should be complimented for getting the final rule right for patients at long last.

Defining the Principles in Organ Transplantation

The Secretary has clearly defined noble principles, namely: 1) equity for patients awaiting organ transplantation as measured by waiting time and medical urgency; 2) access to transplant center data for patients; 3) a "level playing field" by defining standard listing and status criteria; 4) reaffirmation of the government oversight role as a public advocate; and 5) encouragement of patient participation in transplant issues.

Contrary to some beliefs, these elucidated principles did not originate at HHS. Advocacy groups, ethics committees, governmental agencies, consultant groups and various task forces have all arrived at similar recommendations over the past 20 years. Starting in 1977, the American Medical Association Council on Ethical and Judicial Affairs affirmed that "Organs should be considered a national, rather than a local or regional, resource. Geographical priorities in the allocation of organs should be prohibited...." In 1984, the National Organ Transplant Act called for the fair and equitable national allocation of organs among patients in accordance with medical criteria established by the OPTN. An accompanying report from the Senate Labor and Human Resources Committee stated: "An equitable policy and system is necessary so that individuals throughout our country can have access to organ transplantation when appropriate and necessary." As called for by NOTA, the U.S. Task Force on Organ Transplantation in its recommendations in 1986 clearly stated the need to avoid using geography as the basis for organ distribution. The 1991 report of the Office of the Inspector General cited the deficiencies which existed in the OPTN with regards to equitable organ distribution practices. The 1993 General Accounting Office report recognized the potential for conflict-of-interest in the policy making abilities of the OPTN with its membership and structure. Finally, two separate attempts to reauthorize NOTA, in 1993 and 1996, also pointed to the need to minimize geographic differences in access to transplantation and further recognized the importance of government oversight in OPTN policies.

Voice of the Public

It is clear that transplant policies greatly affect the public, but their involvement in policy making has been minimal. There is ample evidence that UNOS represents the transplant programs rather than the transplant patients. For example, UNOS commissioned a survey in 1994, to determine the opinions of those who are affected by the allocation policies. A sample of 1,752 randomly selected members of the general public, recipients and candidates were asked to answer questions about organ donation and allocation. Sixty percent of recipients and 58 percent of candidates assigned the lowest priority to keeping organ locally. Fifty four percent of recipients and 50 percent of candidates assigned top priority to the patient who has the least amount of time to live. Only 22 percent of recipients and 20 percent of candidates assigned top priority to the patient who has the best chance of survival. Making waiting time "about the same for all patients nationally" was a top priority in over one-third surveyed. Sixty six percent of the general public would be more strongly influenced to sign a donor card by a policy that favored national distribution rather than local distribution. It is apparent that UNOS has not adequately integrated these viewpoints into its policies.

Other patient organizations, such as the American Liver Foundation, Transplant Recipients International Organization, National Transplant Action, and the Minority Organ and Tissue Transplant Education Program, have all endorsed the Secretary's position and affirmed the rights of the patients and public in providing input into transplantation policies.

How Will UNOS Respond?

It is my belief that the Secretary and HHS have adequately weighed the arguments, examined the evidence, listened to the testimony, and arrived at the conclusion that fairness for patients is the most important guiding principle in organ transplantation. Given the time allotted by the Secretary to devise policies to achieve these goals, one would expect UNOS to begin committee deliberations. Instead, we have seen a flurry of media and legislative activity to attempt to influence legislators to intervene on behalf of UNOS and transplant programs. UNOS and the transplant programs have already shown that they cannot be objective parties in these deliberations. UNOS' press releases emphasize the impact of these regulations on their transplant program constituency, primarily the smaller transplant programs, which UNOS has pledged to support. As voiced by a member of TRIO, "Individuals need to have the option to be transplanted at the institutions of their choice according to the greatest medical need without ignoring the great number of patients that await at larger institutions. Neither group can be ignored...".

Half-truths and superficial statements are the public relation tools of choice for UNOS and some of its members. For instance, UNOS states that the "very sickest patients - those who are in intensive care units" have relatively equal waiting times across the country. When one appreciates that a patient can only remain in this status for seven days, with one seven-day renewal, the claim that there are "relatively equal waiting times" is artifactual and meaningless. Rather the chance of dying in this status is much more revealing - this varies five-fold amongst the 11 UNOS regions. Both computer models show that the waiting times for the Status 1 patients will be reduced to 1 or 2 days, if policies which comply with the regulations are implemented. The difference in waiting times for Status 2A and 2B patients are substantially greater than for Status 1 patients. Status 2A patients suffer from chronic rather than acute conditions, but they also have a life expectancy without a transplant of 7 days or less. Both computer models show that broader geographic sharing of livers will reduce and equalize the differences in waiting times for these 2A and 2B patients.

If the UNOS releases were factual, they would provide a service to the public by way of educating them. Instead, UNOS has chosen to employ scare tactics in projecting that the final rule: "would make it more difficult for the majority of patients to receive a transplant"; "force many smaller transplant centers to shut their doors"; "likely . . . cause a decrease in donations"; "result in fewer patients receiving transplants"; "individuals . . . will have to travel great distances and be separated from their loved ones"; and "20 percent of transplant patients who are on Medicaid might find it impossible to receive a transplant because of the need to travel to a distant center." <u>There are no data to support any of these claims</u>. As the administrator of the OPTN, UNOS has a fiduciary responsibility to patients to provide accurate, complete, and useful information which should be based on science, not wild speculation.

UNOS and some of its members have argued that transplanting the sickest patient is not the optimum use of donor organs. The Secretary has stated that the intention of this regulation is not to transplant patients whose outcomes are futile. However I believe that HHS recognizes that the greatest net benefit of liver transplantation is for those patients whose outcomes without transplantation are poor. The net benefit is the difference in survival between those who are transplanted and those who are not. UNOS data have already shown that this difference is greatest for the sicker patients (on the order of 50% at one year) as compared to the most elective patients (no difference in survival for more than 2 years). Any program (whether large or small) will have the same likelihood of performing transplants should they choose to transplant patients in the higher risk categories. Unfortunately, some programs currently perform greater than 90% of liver transplants as an elective procedure, while others are forced to transplant more than 90% of their transplants as inpatients. Under the "one center-one vote" policy, UNOS policies represent the interests of its membership, the majority of which perform <u>less</u> than the Medicare minimum requirements. Since many Medical Assistance programs require Medicare certification to provide transplant services, the current system does great disservice to the underprivileged population (if one were to believe this argument). In the United States, many transplant candidates travel outside their "home" area to receive a transplant. Fourteen states have no in-state liver transplant program, and almost one-half of the country's citizens do not live in a Metropolitan Statistical Area with any liver transplant program. With broader geographic sharing of organs, those patients who are required to travel for a transplant (because of insurance requirements or the lack of a local transplant program) or those who choose to travel for a transplant (because of specific treatment needs or low mortality rates) will have a fair and equal chance to receive a donated organ. The latter point is important when one considers that the number of poorly performing programs outnumbers the number of excellent performing centers by a two to one margin.

Some critics of the regulations prophesy that "many transplant centers" will close as a consequence of these regulations. There is no evidence to support such predictions of doom and gloom. Transplant centers usually house more than one different transplant program (kidneys, heart, liver, lungs, etc.), but not all centers have transplant programs for all organs. In fact, some very good transplant centers have programs which specialize in transplant of only one or two organs. There is no evidence that closing a heart program, or never starting one, reduces the number of donor families in the area who consent to donate a loved one's heart. The two studies described earlier found that donor families donate organs to help patients who are close to death. There is no evidence that donor families say "yes" to donating a heart and liver, but "no" to donating lungs because the lungs may go to an out of state patient.

Conclusions

The final rule with comment period does not encroach on either the OPTN's authority to establish membership and medical criteria as set forth in NOTA or the OPTN's policy-making function. To the contrary, HHS is offering UNOS wide latitude to restructure its system of allocating organs, demanding only that the final product achieves the principles set forth in the HHS regulations. We applaud the HHS regulation in its broadest applications, for all solid organ transplants, enhancing organ donation, taking into account patient interests as the primary objective, and defining the role of the government in OPTN policy-making.

We believe that OPOs should not be involved in organ distribution matters; they should concentrate on increasing donation. Patients should not be held accountable for OPO efficiency, nor should they be forced to consider anything but where they can expect the best service or outcomes. The entire transplant system will benefit by enhancing fairness in the system. These have been the principles that we have long argued in the OPTN forum. The salient points are included in a manuscript, which is attached for your information, and a statement addressing the issues in a UNOS release.

While much public attention has been focused on the organ allocation sections of the final regulation, the Secretary has included a number of provisions other than allocation that are extremely supportive of patients:

- Center-specific transplant data will be available to patients and families in an easier and far more timely way to help them in making their treatment decisions;
- The OPTN Board and Executive Committee will have expanded patient and family representation, in more balanced proportion to the number of transplant physicians and surgeons;
- HHS will examine more closely the patient registration/waiting list fee for fairness and appropriateness;

- The standardized listing criteria and standardized medical status criteria will also contribute to greater patient equity across the country, at all transplant centers. In addition, they will provide medical guidance as to the medically appropriate times when candidates may be removed from the waiting list because of their condition.

These provisions and the organ allocation sections are set in the context of an OPTN policy development process that will benefit patients and save more patient lives.

We hope that this subcommittee will set aside the politics presented here today and focus only on the perspectives of patients. We hope that the decisions reached by this committee will be based on the facts, not on media hype. Thank you for allowing me to speak today. I am ready to answer any questions that you may have.

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UNIVERSITY OF PITTSBURGH RESPONDS TO ADDITIONAL CRITICISMS OF THE NEW ORGAN ALLOCATION POLICY

Health and Human Services Secretary Donna Shalala announced on March 26, 1998, new regulations to reform the nation's organ allocation system. Under these new regulations, organs will go to patients who are the sickest regardless of their geographic location. The regulations also call for much-needed government oversight.

The University of Pittsburgh and other transplantation centers throughout the country along with patient advocacy groups applaud the Secretary's action. All believe the new regulations will improve the prospects for patients awaiting organ transplantation.

On March 25, the day before the federal announcement, the United Network for Organ Sharing (UNOS) issued a statement criticizing the new regulations. (UNOS is the private agency that holds the government contract for organ allocation.) Following the issuance of the UNOS statement, the University of Pittsburgh issued a response to all points made in their document.

While praised by most, there remain a few who are critical of the new regulations. Because it is necessary for the public to be well informed, following is a rebuttal of issues that have been raised since the Secretary's announcement.

Critics of the HHS regulations argue that a system that shares donor livers more widely and gives priority to sicker patients would increase the number of patients receiving second and third liver transplants. This criticism is not necessarily true.

Under the current allocation system, which results in more than 50 percent of organs going to the least sick patients, a large number of organs that become available to the sickest patients often have been rejected for use by the transplant surgeons within the local or even the regional areas where they originated. Those organs, thus, are relatively low in quality and when transplanted into the sickest patients (who have no other choice), often fail. With a system that provides broader sharing, the sickest patients would be offered higher quality organs, resulting in fewer transplants.

Offering organs to the most medically urgent patients first will, therefore, decrease their retransplant rate and increase their survival rate.

Critics contend that, with the current allocation system, the waiting time for the patients does not differ materially among the UNOS regions. The average amount of time such patients wait in their last episodes in Status 1 before they obtain liver transplants ranges from four to six days among the 11 UNOS regions.

This statistic does not consider those who die while waiting. Current policy dictates that patients can only be listed in the most urgent status if they are expected to die within seven days. Thus, a typical waiting time of four to six days makes sense because these patients must either be transplanted within that period or die before a donor organ becomes available.

With the current system, among the patients in Status 1, 33.4 percent die before obtaining a transplant. This percentage ranges from 17.1 percent in one region to 49.1 percent in another. Analysis indicates that with alternative systems that provide broad geographic sharing, only about 4.0 percent of these sickest patients would die pre-transplant. In addition, the typical waiting times would be one or two days shorter than they are with the current system.

Critics say organ donation will decrease because organs may go outside the local area.

Based on current knowledge about the donation process, there is no factual basis for claiming the changes in allocation policy sought by the HHS regulation will adversely affect donation rates. To the contrary, increasing the equity of the national organ allocation system may improve public trust in the system, which can only have a beneficial effect on donation.

Surveys conducted by UNOS and HHS have found that both the general public and donor families themselves wanted donated organs to go to the patients who need them the most regardless of where they might be in the United States. In one survey, 75 percent of the respondents disagreed with the statement: "donor organs should go to someone in the area where the donor lived."

People generally agree that donated organs are a national resource, and do not belong to the organ procurement organization, a transplant program or a state. They assert that all patients, regardless of where they live or choose to have their transplants, should have equal opportunity to benefit from organ donation.

It, therefore, follows that, so long as organs are a scarce resource, they should be allocated equitably. If the public perceives that the allocation system is fair, people will be more likely to support organ donation and to choose to donate organs themselves.

At the time that the family of a potential organ donor is approached to provide consent, it is not known whether the donor organs will be provided to a recipient in their community or elsewhere. This is true with the current system, and will continue to be true with any alternative policy. It is important to realize that, on the average, three organs are recovered from each donor. It is not reasonable to believe that a donor family will donate a liver or kidneys but say no to a heart donation because it may be used in another state.

Critics say that all organs will go to large centers because they have the sickest patients.

With broader geographic sharing, after an initial transition period, patients at centers with long waiting times will be offered donor livers after the same waiting time that patients at smaller programs experience. All programs will obtain donor livers on an equitable basis. Transplant programs will receive organs in proportion to the numbers of patients who register with them. Programs will therefore maintain their access to donor organs to the degree that they can attract patients to register with them on the basis of their medical proficiency, their accessibility, their cost, and any other factors that patients value. Even with broader sharing, so long as programs are successful in attracting patients, they will be successful in obtaining donor organs when their patient becomes the next compatible patient on the waiting list.

Clinical Transplants 1996. Eds. Checka, J.M. and Terasaki, P.I.,
Los Angeles, CA, UCLA Tissue Typing Laboratory, 1997.
pp. 325 - 332.

The Rationale for Equitable Liver Allocation

John J. Fung, MD, PhD and John P. Roberts, MD

Prior to 1967, when the first human liver transplant was successfully performed, end stage liver failure was synonymous with death. Advances in immunosuppression, preservation solutions and techniques have significantly improved the results after liver transplantation. In June 1983, the National Institutes of Health held a consensus development conference on liver transplantation and concluded: "Liver transplantation is a therapeutic modality for end stage liver disease that deserves broader application."

As the need and application of liver transplantation has grown, the pressure exerted on a limited donor pool continues to increase. In principle, livers are allocated to patients with the greatest need, since they derive the maximum benefit from this procedure. In practice, patients with years of life-expectancy are being transplanted in large numbers, even though needier waiting patients are dying without access to these livers. This disturbing practice has been perpetuated due to the resistance of the Organ Procurement and Transplantation Network (OPTN) to eliminate artificial geographic boundaries, which have created obvious inequities in access of patients to liver transplantation. This can best be seen by an examination of the increasing disparity of median waiting times across the county. This discrepancy is particularly important when examining the likelihood of patients dying while waiting for a liver transplant. In spite of public opinion denouncing these inequities, OPTN procedures make it extremely difficult, if not impossible, to make mid-course adjustments. This will seriously hamper any future attempts at increasing organ availability. Since these are not only medical issues but also public policy issues, there is strong justification and need for government oversight and intervention.

Getting Back to the Fundamentals - The National Organ Transplant Act (NOTA)

In 1984, the National Organ Transplant Act (NOTA - P.L. 98-507) was passed by the Congress of the United States, and the intent was to develop a fair and efficient national system for the distribution of organs. The cardinal principle of NOTA was stated simply: "Patient welfare must be the paramount consideration". NOTA called for the formation of the OPTN, which is responsible for determining means to maximize organ procurement and develop equitable allocation algorithms, and creation of a Scientific Registry, which would allow for evaluation of outcomes for transplantation. In addition, it called for the establishment of a 25-member Task Force on Organ Transplantation, whose recommendations were published in April 1986. This report described a national organ-sharing network that had national standards for organ procurement and distribution, patient prioritization and broad public representation.

In 1987, the United Network of Organ Sharing (UNOS) was awarded the contract from Health Resources and Services Administration (HRSA) to maintain both the Scientific Registry and the OPTN. This subcontract was renewed in 1990, in 1993, and again in 1997. Unfortunately, NOTA has not fared as well. NOTA was reauthorized in 1990, but failed to be reauthorized in 1993 and again in 1996. In these reauthorization attempts, the principles of NOTA were reaffirmed and deemed worthy, but its failure to be reauthorized was, in part, linked to a provision, calling for the Comptroller General of the United States to study and recommend changes regarding equitable allocation of organs. In the most recent version of the Reauthorization Act of 1995, the authors were noted as stating: "...the Network contractor ... has a monopoly. The integration of the policy-making body (the Network) with the Network contractor ... allows the Network contractor to function in a manner which poses a threat for a conflict of interest. ... we believe that the elected government of the people should, in partnership with the private sector, be the ultimate steward of this special gift, ensuring that this gift is properly cared for, adequately regulated, and distributed equally.." The original supporters of NOTA clearly envisioned a list spanning the country that provided organs equitably and justly to candidates based upon greatest medical need (as determined by established medical criteria), regardless of location. Geography - whether on the basis of where the patient chooses to have his or her transplant or where the organ was retrieved - should be irrelevant.

The OPTN policies dictating organ allocation clearly affect the patient population, yet the patients input into the policy making process has been limited, as evidenced by their minority voice in the OPTN. The 1986 Report of the Task Force on Organ Transplantation concluded: "It is implicit in the framework of such a national network that the transplant community views donated organs as a public resource..." In addition, they also stated: "...the public must participate in decisions of how this resource (donated organs) can be used to best serve the public interest." In an attempt to express the opinions of those who are affected by the allocation policies, UNOS commissioned a survey in 1994, in which 1,752 randomly selected members of the general public, recipients and candidates were asked to address questions about organ donation and allocation. Sixty percent of recipients and 58% of candidates assigned the lowest priority to keeping organ locally. Fifty-four percent of recipients and 50% of candidates assigned top priority to the patient who has the least amount of time to live. Only 22% of recipients and 20% of candidates assigned top priority to the patient who has the best chance of survival. Making waiting time "about the same for all patients nationally" was a top priority in over one-third surveyed. Of the general public, 65% would be more strongly influenced to sign a donor card by a policy that favored national distribution rather than local distribution. It is apparent that the current OPTN policies have not adequately integrated these viewpoints.

Grading NOTA - Has It Measured Up to Its Expectations?

It is evident that the current system does not effectively increase the availability of and access to donor organs. HRSA envisioned the purpose of the OPTN to: "... improve the effectiveness of the nation's organ donation, procurement, and transplantation system by increasing the availability of and access to donor organs for patients with end-stage organ failure." Since the implementation of the OPTN in 1987, the number of cadaver organ donors have increased from 4,083 to 4,846 (18% increase), while the number of patients awaiting organ transplantation have increased from 16,028 to 33,352 (108% increase) in 1993. Most of the increases in organ donation have come from donors who were once considered too old for use. The increased disparity between available donors and patients on the waiting list has resulted in increased annual deaths while waiting from 1,481 to 2,889 (95% increase). It has been assumed that one of the principal explanations for the failure to significantly increase donation is a lack of public awareness. As a result, over the past few years, millions of dollars have been channeled into educational efforts. In spite of these efforts and resources, there has not been any substantial increase in organ donation or in consent rates. More recently, studies have suggested that the perception of inequities in the organ transplant field may play a significant role in the refusal to donate.

Procurement activities are an important component of increasing organ donation. Organ Procurement Organization (OPO) efficiencies (measured by organ procurement rates) vary considerably. In 1994, OPO's reported their efficiency of procurement, expressed in donors/million. The figures ranged from a low of 10.8 donors/million population to a high of 33.9 donors/million, with a national average of 19.5 donors/million. These figures are far short of the potential donor pool of 80 donors/million. In another analysis of OPO performance, the percentage of donors from whom a liver was obtained, ranged from 0% to 92%, with a national average of 73%. These ranges of OPO efficiency suggest that different OPO's have varying degrees of commitment to organ donation. As noted in the 1993 GAO report, which was mandated to study the effectiveness of the organ procurement: "HRSA and the Network contractor, UNOS, are responsible for overseeing the effectiveness of the organ procurement organizations in increasing organ supply. Neither, however, has monitored the organizations' procurement efforts or adopted a measure for assessing procurement effectiveness." In September 1994, an interim Final Rule with performance standards for OPOs was published in the Federal Register. However, recent consideration to enhance ineffective OPO outcomes by merging them with efficient ones were met with a great legislative outcry, resulting in only remedial action being taken.

An Overview of the Allocation Policies

There are two elements which determine the allocation of organs for transplantation. The first is the system of prioritization, which incorporates principally medical determinants, such as medical urgency and time waiting. The second element affects the distribution of organs among the different areas of the country. The distribution system offers the organ first to patients in the local area who are waiting, then to a regional area, and finally to the nation at large. The decisions that affect both prioritization and distribution are made by OPTN members and approved by their Board of Directors. Under the terms of NOTA, the OPTN policies are to be reviewed and approved by the Secretary of the Department of Health and Human Services (HHS) before becoming binding. Unfortunately, none of the OPTN policies have yet been approved by the federal government. In 1993, the GAO report cited the lack of HHS role in assessing the impact of changes to UNOS allocation criteria with respect to the "impact on the equitable distribution of organs nor the merit of incorporating these changes into UNOS allocation criteria." Nevertheless, these operational policies determine the fate of almost 50,000 patients that are listed for transplantation at any time, as well as the fate of approximately 20,000 patients that undergo transplantation each year in the United States.

The relative weight given to prioritization and distribution varies among the various organ transplants. Because the elements of prioritization and distribution are so closely linked, the distribution scheme may act as a de facto prioritization scheme. Although the prioritization scheme may decide that the sickest patient will be offered the organ first, only in the instance where the distribution scheme is a national one, will there be the greatest probability of this patient receiving an organ. If the number of distribution units increases, the probability of having the sickest patient within the unit of distribution becomes smaller, and thus will impact on prioritization. Thus, the effect of the current geographically-restricted distribution scheme overrides the medical prioritization scheme, at least when viewed on a national basis. This situation is inequitable since all patients are not given similar opportunities to participate in the overall organ distribution system. The fact that the variations cannot be attributed to objective or medical criteria, lends support to criticisms that some patients are being systematically disadvantaged by arbitrary distribution arrangements. This was highlighted in the 1993 GAO report: *"... broadening the number of patients considered for an organ may result in selecting a patient who is better suited for the organ or has been waiting longer."*

The Liver Controversy - Allocation of Livers in the United States

The principles of liver allocation were first described in 1987 and adopted by UNOS, but have changed from their original intent. Originally, overwhelming weight for liver distribution was given to urgency of need, because there is no treatment option comparable with the artificial kidney. This is in keeping with the original intent of liver transplantation, that is, to provide a life-saving procedure for those who had failed all medical and surgical options. The appropriate timing of liver transplantation requires a national donor pool from which the recipient population can be served, as called for by NOTA. The introduction of the University of Wisconsin solution in 1987, and prompt delineation of its capabilities by the end of that year, made it possible for safe shipment of livers between most locations in the United States. In August, 1990, a meeting of the Liver Subcommittee of UNOS passed a motion to alter the allocation policy, by removing the most urgent category (UNOS STAT), and creating a second tier of liver distribution to the 11 UNOS regions, in which organ movement was discouraged. This policy was adopted by the UNOS Board of Directors later that year, and took effect on January 1, 1991.

Prior to 1991, the majority of liver transplants were performed in more urgent categories (25% on life support, 35% hospitalized or ICU bound, 31% homebound, and 8% functional patients). Since then, the trend has been to exclude the more urgent status patients resulting in an increase in the percentage of "elective" transplants (1993: 12% on life support, 28% hospitalized or ICU bound, 35% homebound, and 24% functional patients). This is responsible for the high proportion of waiting list deaths which are comprised of hospital-bound and ICU candidates.

As analyzed in 2 manuscripts (Bronsther O, et al, JAMA, 1994, 271:140, and Eghtesad B, et al, Hepatology, 1994, 20(SI 1):56), "electively transplanted" patients had an overall 80-90% one-year survival without liver transplantation, and thus, these studies suggest that these patients would have an even higher survival without liver transplant intervention (national survival of 77%) at one year. A recent analysis performed by UNOS revealed that the relative risk of dying for "homebound" (Status 3) liver transplant candidates and those that underwent "elective" liver transplantation, was not different up to 2 years after initial listing. They concluded: "there is no net survival benefit of liver transplantation for Status 3 patients within the first 2 years following transplantation." On the other hand, liver transplantation is most efficient in the setting of transplantation of hospitalized or ICU-bound patients, as determined by the "life years gained" analysis. This type of analysis has been accepted by the Consensus Conference on Indications of Liver Transplantation (Bismuth H, Hepatology, 1994, 20(SI 1): 63).

One intent of UNOS to keep organs locally is to enhance the survival of low volume, but local centers. This shift of organs from a national resource to that dictated by local programs is readily apparent. In 1988, 44% of the livers transplanted were from nationally "shared" organs. By 1994, this had fallen to 10%, and the number of locally used organs increased from 26% in 1988 to 60% in 1994. The emphasis on local use has led to a loss of oversight on the quality of liver transplants being performed. A recent analysis by UNOS revealed that the volume of transplants performed by a center is directly correlated with results (UNOS Update, 1994). Survival after liver transplantation has been shown to be related to center effects, with centers performing fewer than 11 cases per year having a 2.4 times greater likelihood of death, and centers performing 10-34 transplants per year having a 1.6-1.8 time greater likelihood of death, as compared to those that perform 35 or more liver transplants per year. A similar analysis was also completed by the Cleveland Plain Dealer, which revealed a higher mortality at centers that perform less than 12 transplants per year, the minimum yearly requirement for Medicare certification. As noted in the Paris consensus document: "The competence of liver transplantation teams, which varies widely from center to center, depends largely on the number of operations carried out; there should thus be a yearly minimum to ensure uniform quality." Unfortunately, patients are enticed to move to centers with shorter waiting times, with less emphasis on the quality of the program.

Justification of UNOS Policies - The "Managed Care Mentality"

In order to obtain the credibility (and profitability) associated with "good" results, some programs, under the present UNOS policies, can systematically exclude candidates because of: the nature of the liver disease, the added risk of age extremes, advanced disease, extrahepatic complications, previous abdominal operations, history of social behavior, or other less well defined factors, which are known (or assumed) to degrade results or increase costs. This mentality was the impetus for a recent controversial change in the assignment of priorities for patients awaiting liver transplantation (see following section). Most such rejected candidates are currently deprived of the right to treatment, because if they go to other regions, where good facilities abound, organs are scarce. Even worse, the insurance carriers (including government agencies, such as Medicaid), may refuse to allow treatment outside the region, on grounds of non-candidacy pronounced by a team (or teams) in the originating region. More experienced centers already face a growing stream of rejected candidates, who have resources, or are championed by their own physician, to seek second opinions. These centers have reported excellent results following transplantation of these candidates, rejected by the patients' own local programs.

While only economically efficient transplant programs will survive in a managed care environment, we must insure that transplant centers are gauged on cost efficiency on a level playing field. Those centers that may be efficient but accept only inappropriately "blue ribbon" candidates must not be compared to those that are efficient but accept critically ill patients. This issue has been recently addressed by the Health Care Finance Administration (HCFA), that stated: "The posttransplant mortality rate must take in account the contribution to the risk of death and the condition of the patient ... If it is to reflect accurately the proficiency of the center. If it does not, it will serve as an incentive for centers to avoid the sicker patients who might well be the ones who benefit most from a liver transplant." (Klipa VE, et al, Transplantation 1993; 56:564) Some will argue that transplanting sicker patients will cost the healthcare system more. But what greater waste of healthcare dollars than transplanting patients who do not yet need the procedure, or the costs associated with watching a hospitalized candidate deteriorate and possibly die from lack of a liver for transplantation?

In the arena of oversight, little has been done to review the quality of the transplant programs which managed care designates as "centers of excellence". There is a perception that "excellence" refers only to cost containment and not medical outcomes. Managed care plans examine factors which may increase hospital stay and costs, such as the risk profile of the center's transplant candidates, the median waiting time, retransplantation rates, and immunosuppressive and antimicrobial prophylaxis regimens, but do not seem to factor in medically related outcomes. In the 1994 UNOS Center Specific Report, an analysis of the 88 liver transplant programs revealed that the majority of liver transplant programs (73%) had an actual patient survival similar to the *calculated survival rate*. Only 8% of programs had an actual survival statistically better than the calculated survival rates. Twenty percent of the liver transplant programs had statistically significantly worse actual survival as compared to calculated survival. These statistics have not changed in the 5 years that UNOS has been collecting and analyzing this data. Clearly, the public must be informed about the issues of quality as well as cost. Competition has become intense in response to the designation of "centers of excellence". In the most recent UNOS Center Specific Report, one center was quoted as stating "The reduced survival ... stems from a combination of factors ..., a policy discouraging retransplantation, and early withdrawal in patients requiring prolonged intensive care", clearly a reflection of cost considerations impacting patient care.

Failure of the OPTN Policy Development Procedures

In 1989, a public notice by HHS mandated that OPTN policies be reviewed and receive formal approval of the Secretary in order to be enforced. Congress made it clear that the 1990 amendments "reflect deep concern on the part of (Congress) in the manner in which the OPTN has functioned. It is the intent that this bill will assist in a midcourse correction." (Senate Report #101-530). Unfortunately, the midcourse correction never came and since then there have been numerous examples in which major changes in OPTN policies have been implemented without safeguards, resulting in drastically altered practices in transplantation. For example, the current inequities in liver allocation can be traced back to a single change in liver allocation made by UNOS and implemented on January 1, 1991 (see above). The impact of this change in policy, was predicted, shortly after the policy took effect. In a letter to the Executive Director of UNOS, dated March 1991, Dr. Thomas Starzl wrote: "With the reform (the 1991 liver allocation change) ... the pattern has drastically changed. The one criterion which was the universal condition of equity, greatest need, no longer counted for anything. ... The reform is contrary to the principle of equity to patients, which is our foremost mandate."

The lack of oversight in passing UNOS policies was cited in the 1993 GAO report. "...the policies of UNOS, a private contractor, are advisory. HHS must develop these policies as federal regulations for them to become requirements with which organ procurement organizations and transplant centers must comply." This emphasizes the need for UNOS policies to be approved by the Secretary of HHS in the usual regulatory manner, to assure compliance with federal regulations. Over 6 years after the original public notice publication, there still are no final rules which have been approved, although a Notice of Proposed Rule Making was published in the Federal Register on September 8, 1994.

The structure of the OPTN and the procedures adopted by the OPTN have also been an area of controversy. UNOS is a membership organization which is comprised of mostly representatives with involvement in transplantation activities. Currently, less than 30% of the voting Board of Directors of the OPTN consist of members from the "general public." Nevertheless, this governing board approves the policies which govern the welfare of transplant patients centers and OPO's. This poses a potential (if not real) conflict of interest, by possibly influencing Board members to consider the possible impact of those decisions on their transplant centers. As stated in the 1993 GAO report: "Favoring transplant centers over the needs of patients is contrary to federal law." Failure to address these conflicts of interests, and to address the concerns of the patients, will only serve to heighten the suspicions raised in current surveys showing a reluctance to donate because of perceived inequities.

As if the 1991 assault on the fairness of the transplant system was not enough, UNOS dealt the concept of "justice" another blow at the November 1996 UNOS Board of Directors meeting. UNOS opted to eliminate a large group of high-risk candidates from being considered in the highest priority class (Status 1), thus removing the onus of responsibility of transplant surgeons to decide which patients would benefit the greatest from liver transplantation. UNOS based this action on the rather dubious assumption that patients with acute liver failure have a "greater chance of survival" than patients with chronic liver failure. At a recent NIH conference on acute liver failure, it was determined that "severly ill patients with either acute liver failure or chronic liver failure have the same chance of survival when diagnosis independent factors are taken into consideration". Analysis of the UNOS Liver Registry shows that the magnitude of survival difference is only 10% at 2 years after transplantation (acute Status 1 - 67% vs *chronic Status 1* - 57%). To put this into perspective, Afro-American kidney transplant patients have a 9% worse outcome than

Caucasian kidney transplant patients. Pediatric heart transplant patients under the age of one have up to a 20% worse outcome than older patients, but still are given the highest priority for heart transplantation. It would be unconscionable to deny transplantation on the basis of age, sex or race.

In 1993, both UNOS and an independent consulting group developed computer models to predict the effects of changes in organ allocation in liver transplantation. These computer models revealed that the policies actively considered by UNOS will result in: 1) no improvement in the inequities in waiting times; 2) an increased number of patients dying while waiting; 3) no significant increase in the number of transplants performed; and 4) a continued policy which allows elective transplants to be performed when a more needy patient exists elsewhere. UNOS has defended this policy: "*A small group moved up to a higher category, as opposed to moving some people down.*" This is inconsistent with the results of the computer model, which shows that the number of patients transplanted in the previous chronic Status 1 group will actually decline by 50%, resulting in increased deaths of patients on the waiting list.

Policies that emphasized equity were eliminated from consideration by UNOS membership. Supporters of UNOS justify their actions by claiming that transplantation should attempt to "maximize patient survival" and "maximize the benefit of transplantation." At face value, these seem to be the epitome of the UNOS concept of "utility." Under the UNOS policy that prevents severely ill, chronic liver failure patients from gaining top priority, the national survival rates after liver transplantation may improve by 1.5%. However, the transplant community could triple the improvement in survival by simply eliminating poorly performing transplant programs. It is of interest to note that the majority of programs that responded to a recent UNOS questionnaire did not favor consideration of center performance in the allocation of organs. Similarly, the argument that the current trend of transplanting elective patients provides the "maximum benefit" is also flawed. Studies have shown that transplanting elective patients residing at home, does not provide a net survival advantage following transplantation. On the other hand, patients who are sick enough to require hospitalization (including ICU-bound patients) have a net survival benefit of 50-60% in the first year following transplantation, because of their poor prognosis without transplantation.

UNOS has stated that their policy development relies on a "perceived benefit" for a change; but for whose benefit? It appears that the most important principle has been lost, namely that patient benefit should be the primary criterion for the national liver allocation policy. UNOS has acted without due consideration to the scientific method, that is, one based on data. UNOS should first correct the disparities in "equity" by providing transplants to more medically needy patients (e.g. inpatients before outpatients) and simultaneously minimize geographic barriers to the extent permitted by organ viability, so that organs could flow to the sicker patients, wherever they are located.

Proposed Modifications to the Liver Allocation Policies

In developing a rational and equitable policy governing liver allocation policies, and also for other organ allocation policies (such as heart, lung, intestine, pancreas, and even kidney), the following should be taken into account:

1) Require that any allocation scheme be based upon principles set forth by the 1984 National Organ Transplant Act and accepted principles of transplantation. These include:
   a) Provide priority to transplantation of the most medically urgent candidates (those with the shortest amount of time to live without transplantation, and therefore those who stand to gain the most from transplantation),
   b) List candidates on a national list so that access to transplantation is equitable,
   c) Allow patients to choose the center where they will be transplanted (influenced by reputation, quality of program, networks and "centers of excellence", and not by differences in length of waiting times). If a center fails to recruit candidates (either because of cost or outcomes), it will be an expression of dissatisfaction by potential recipients who should have the right to join the waiting lists in other regions, rather than be captive to the organ supply at a transplant center. If not incarcerated by regional boundaries, organs will go to patients listed in regions where there is center excellence, even in smaller population areas, and good centers will be able to build their own recipient lists and compete with the traditional tools of quality service and the improvements of care

then can be engendered by effective research and development programs.

   d) Enhance developmental programs in transplantation which will improve organ utilization, and increase the population which transplantation will benefit. For example, the use of "split-livers," which allows an adult liver to be split into a right half and a left half, could potentially increase liver availability by up to 30% (Rogiers, et al, Ann. Surg 1996;224:331). A policy which encourages the wider sharing of livers would increase participation in such a venture, thus benefitting many more patients than UNOS predicts by restricting access to liver transplantation. Maximizing "split-liver" transplantation could potentially increase the number of transplantable livers from 4,000 a year to over 5,000 a year.

2) Insist on proactive governmental oversight to assure the public that appropriate policies are in keeping with the interests of patients and the field of transplantation. Policies put forth by the OPTN should not be approved as regulations by default. The government should not substitute its judgment on purely medical transplant issues, but organ transplantation and organ allocation are certainly significant issues on which larger public policy concerns should be brought to bear. Since substantial taxpayer dollars are spent on transplantation through Medicare and Medicaid, it is important that the government evaluate how the transplant policy process and the contractor's policies maximize the proper use of scarce organs, whether the policies promote patient interests as strongly as possible, whether the policies are sound, and whether the policies are in compliance with the law and any pertinent regulations. HHS should also seek to implement review of the quality of transplant programs, and should be directed towards:

   a) Ongoing review of transplant programs, reviewing both current (past year) and cumulative (1987-present) experiences. The programs falling below a given level for one-year survival (taking into account factors which have been identified by UNOS) should be reviewed by HHS, and where appropriate, corrective action should be taken.

   b) Developing criteria to evaluate the benefit of transplantation, taking into account: cost, impact on survival according to status, and deaths on the waiting list. This is particularly true for transplantation of a life-saving organ (e.g. liver, heart, lung) for those who failed all other medical and surgical options. For example, liver transplantation is most efficient in the setting of transplantation of hospitalized or ICU-bound patients, as determined by the "life years gained" analysis.

   c) Reviewing the impact of policy changes on the availability of organ transplantation to candidates of all races and socioeconomic classes, and with respect to severity of medical condition. For example, the tendency to endorse listing of patients with liver disease at an earlier stage in the course of their disease, will only serve to lengthen waiting times, provide fewer incentives to utilize alternative medical and surgical therapies, and decrease the net benefit associated with liver transplantation.

   d) Providing access to the Scientific Registry database, with appropriate safeguards for patient confidentiality, for the purposes of bona fide scientific inquiries.

3) Restructure the OPTN Board of Directors to include a significant group of patient representatives and donor families, to avoid potential of conflicts of interest.

CONCLUSIONS

The concept of a patient-driven allocation requires restoration of the original emphasis on medical urgency and equity. The emphasis placed on allocating organs by OPO and UNOS regions, within which boundaries, life saving organs could be used without consideration of patient need on a national basis, toppled the fundamental purpose of NOTA, and has encouraged an increasingly divisive center-driven mentality. A unified movement within UNOS has made it harder, if not impossible, for profoundly sick patients to obtain transplantation, so that these organs could be used preferentially for less medically urgent, and therefore "elective" patients. A patient-driven allocation system would provide organs to patients with an urgent need, but not for elective candidates, if there is an overriding need elsewhere in the country. For patients of equal medical urgency, significant weight should be given to time waiting. Considerations of organ allocation should emphasize equity measures first and utility measures second. Survival concerns must take precedence over quality of life measures, including cost/benefit measures. The allocation system must be based upon principles, among which patient concerns are primary. The guiding philosophy of a national policy should be the prompt transplantation for, not avoidance of, bonafide candidates, thought most certain to die without such intervention.

It is only now that the whole range of public policy consequences of allocation of scarce resources are starting to be examined critically, including the operation of the OPTN, as well as its organ allocation policies. While the transplant community supports all possible initiatives to increase the rate and number of organ donors so that as many organs as possible can be available to the patients who need them, this can only be done in the setting of support garnered by trust in those that allow the whole field of transplantation to exist, namely the altruistic donor. The transplant community must strive to earn this trust by insuring equity and access to transplantation.

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Mr. SHAYS. I think that mic did work better, actually, and thank you for that suggestion. When we take questions, I'm going to have you, rather than bring the mic back and forth, just use that mic and just speak loudly. We really have seven witnesses, one who wanted to be a recipient and lost her sor, one who was a recipient, and one who lost her husband who was a donor. And then four of you who have gotten into the whole issue of this but have not had a personal relationship with this issue. That is a fair summation. And we'll start with Mr. Barrett, Congressman Barrett. I'm pretty certain that we will just ask a number of questions, then go on to inviting the audience to address this issue as well, but Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman. First I want to applaud all the members of this committee, in particular those who have been affected by this on a personal—I am amazed by your courage and in the way you have handled what's obviously a crisis in your life. And I don't know that everybody could be as strong as you have. So my compliments to all three of you.

And to the other four witnesses, I will state at the outset what I stated at the outset of the last panel. And I think we have an issue here where good people are disagreeing with the best of intentions. I think that all of us in this room are concerned about patients. During the break I talked to a couple people who have been here, and the complaint I got was what about the patients, let's get to the patients first. Unfortunately, there are patients in Wisconsin, there are patients in Pennsylvania, there are patients in Alabama, and they are all good people. That's what makes this so difficult.

I'd like to start with you, Ms. Heitman, because you talked about your insurance company. Do you feel that the insurance company's attitude toward you was based on economics? If you could just elaborate on that. And I'd frankly be interested in knowing what insurance company you dealt with, if you'd be willing to share that with us.

Ms. HEITMAN. Initially——

Mr. SHAYS. No, that mic is not a great one either. We can't go too far down the line here with it. We're just waiting for—let me just say that since we don't have a company here to defend itself and so on, if it's not necessary, I think we—are we all set or—take your time. Our court reporter is Colleen Reed, and we're just very grateful that—you're a Milwaukee-based person now, we didn't bring you out from Washington here?

The REPORTER. No; I'm from Milwaukee.

Mr. SHAYS. From Milwaukee. We could give you a hand for participating. Thank you very much. [Applause.]

Are we all set? All set. Ms. Heitman. Thank you.

Ms. HEITMAN. Initially it did appear that it was finances that were driving the decisions. When we first contacted the insurance company, they said that a lung transplant was an experimental procedure and we should just basically go away, that this was just stupid for us to think of putting our son through this. And then after they realized we weren't going to go away, then they offered us the various States to go to. They had no answer for us when I said, well, then I would have to lose my job, lose the insurance, and relocate and what about my other son, who also has a chronic illness, and my husband, they, you know, sorry, kind of too bad kind of things, those are my options. And then they offered the final option, which was their service of excellence, and that was linked with the HMO.

Mr. BARRETT. And what was your understanding as to why they asked you to move to those other States?

Ms. HEITMAN. Because they really promoted that the other States would have better opportunities for the transplant itself, that they were, the numbers that they were telling us, the numbers were better.

Mr. BARRETT. Do you know whether they had an economic relationship with any of the hospitals in those States?

Ms. HEITMAN. No. I don't know that.

Mr. BARRETT. OK. I was—I found it interesting, Dr. Fung, if I can go to the other end of the table here, because of the experience I think you have heard here in Wisconsin where the majority of the patients are from this area, that 60 percent of the patients that go to the University of Pittsburgh are from outside that area. I want to applaud the University of Pittsburgh, maybe because my father went there for a year, but I find it interesting. Can you tell me how that's developed, how such a high percentage has come from outside your area?

Dr. FUNG. Well, if you look at the United States, they have these things they call metropolitan statistical areas, and half of the country does not live in an MSA that has a transplant program. Fourteen States don't have transplant programs. Only one-half of the transplant programs in this country are Medicare approved. So patients are already forced, one-quarter of patients have to travel outside their own State to get a transplant. Some programs don't have pediatric services, so patients are already forced to move, regardless whether or not their insurance company forces them to do it, don't have the access, either turned down by smaller, less experienced programs or whatever reason they travel; have to go somewhere else. I think what we are advocating is because the patients have to travel for whatever reason, they shouldn't be penalized.

Mr. BARRETT. You're a doctor from Wisconsin. Is the University of Wisconsin a Medicare-approved facility?

Dr. D'ALESSANDRO. Yes, it is.

Mr. BARRETT. Why the vast difference between University of Pittsburgh, University of Wisconsin?

Dr. D'ALESSANDRO. I can't explain the total difference. I do know what I'm concerned about is what you mentioned earlier in the first panel, is that there will be intense and fierce competition for the recruitment of recipients, and despite what Dr. Fung says about not recruiting recipients, every hospital attempts to recruit recipients. Even though the HHS people have mentioned that there will be ways that hospitals are forced to increase organ donation, that does not eliminate the fact that many centers will indeed attempt to recruit as many patients as possible, because if you recruit as many patients as possible in a system that is totally equity based, and has eliminated utility from the equation, livers will go to the largest centers who are able to have the largest lists, and that is one of my very serious concerns. And the second concern that I mentioned earlier, a consequence of that will be that organ donation from the local communities will decrease.

In Madison, 95 percent of our patients are from Wisconsin. We have about 15 percent Medicare, Medicaid. I believe Milwaukee has about 20 or 25 percent.

Mr. BARRETT. Is there a disagreement among—within the medical community about the mortality rates? Are large centers better than medium centers?

Dr. D'ALESSANDRO. The only data that exists and that is published is that a center that performs less than nine transplants per year, and there are very few at this point, I don't know the exact number, but those are the only centers that are shown to have any decrease in survival with the procedures.

Mr. BARRETT. Would you agree with that, Dr. Fung?

Dr. FUNG. Well, unfortunately, the median number of transplants performed in this country for liver programs is 10. That means almost 50 percent of the programs fall in that realm. And actually, the study was one less than 11, 11 and less per year, and a higher mortality rate on the order of 2½ times greater. Half the programs in this country don't fulfill minimum Medicare requirements, which are 12 per year.

Mr. BARRETT. OK. So you would argue that there is a higher mortality rate for those that——

Dr. FUNG. It's a conglomerate. I'm not saying——

Mr. BARRETT. I understand.

Dr. FUNG [continuing]. It isn't right. There are good small programs. I'm just saying in general the whole package, which represent more than 50 percent of the programs in this country.

Mr. BARRETT. And your response to that, Doctor?

Dr. D'ALESSANDRO. I would like to see the actual numbers of centers that perform less than that. Dr. Fung has alluded to the fact that small centers and medium centers are good. There have been through UNOS Committees ways to look at very small, I mean very small percentage of centers that haven't performed up to expectation. I think we don't want to get sidetracked from what we believe is best for our patients in looking at large centers, small centers. The overwhelming majority of centers in this country have results that are equivalent, if not better, than the large centers. Large, medium, small, the majority have equivalent results. The technology to perform liver transplantation is not something that needs to be performed in regional centers. This is something that can be performed in every State that has a transplant program.

Mr. BARRETT. Again, I want to state though that I—even though I think everybody in this room is concerned about patients first, I also feel very strongly that there is a strong economic element as to what is going on here. I'm not saying that is good, I'm not saying that is bad. I'm saying that economics plays a part in what we are doing today. It's my belief that the donations in a given location will increase if there's, if there is a tie to the area. This morning Congressman Shays and I talked to a woman who had received a transplantation, a transplant 10 years ago, I think it was, and she talked about the television coverage and how her friends got involved and there was real sense of community when she had the transplant and she had it here. My concern is if we move to more concentrated areas, that you are going to see less of that sort of local tie, what's the good news. And people sort of lose the tie to it. And it becomes more of a, OK, it's a good thing, but it doesn't have an impact on my life. Do you think that I have a real concern there, Dr. Fung?

Dr. FUNG. I think just in principle I believe that the——

Mr. SHAYS. I want the mic a little closer.

Dr. FUNG. Just in principle I believe OPO's have a job. They are to educate and enhance donation. They shouldn't be involved in the distribution of organs or deciding who should get organs. That should be the OPTN with the transplant program, determination based on medical policy. The problem is that OPO's get involved with all these controversies. Half the time that is spent in an OPO director's day deals with organ allocation and distribution which——

Mr. BARRETT. So you're saying they should be concentrating exclusively on obtaining organs?

Dr. FUNG. Yes. I do.

Mr. BARRETT. Shouldn't we then be putting our concentration on punishing, disciplining, encouraging those OPO's who have done a poor job?

Dr. FUNG. Well, that's part of the HHS regulations. That was published in the Federal Register. There are minimum performance criteria for OPO's. The problem is that, again, it's a political potato. About 2 years ago there were a number of OPO's that were identified as being suboptimal. They were going to be reviewed and appropriate changes were going to be made. They were either being incorporated by another OPO or something. New administration. But, in fact, what ended up happening is nothing happening.

Mr. BARRETT. Do you have people on staff, paid people on staff to encourage the procurement of organs?

Dr. FUNG. We have in-hospital, in our own hospital in our health system, we have people that are volunteers that are usually part of the hospital nursing, physician center.

Mr. BARRETT. I understand.

Dr. FUNG. No, but the OPO's——

Mr. BARRETT. No, that is not my question. My question is, do you have employees at your hospital that are involved in trying to increase organ donations?

Dr. FUNG. In the community or in the hospital?

Mr. BARRETT. Either.

Dr. FUNG. Well, I would say they are all volunteers.

Mr. BARRETT. No paid employees at all?

Dr. FUNG. They're not paid to do that. The OPO is paid, the OPO coordinators are paid to do that.

Mr. BARRETT. OK, I understand that. But I wanted to know on staff whether you had any—nobody—Dr. D'Alessandro, at the University of Wisconsin is anybody——

Mr. SHAYS. Can I say something? The audience is going to have an opportunity to make comment, but it's not now. Now it's the witnesses up here.

Mr. BARRETT. Is there anybody paid at the University of Wisconsin?

Dr. D'ALESSANDRO. Only people who are in our OPO, of which we have five employees.

Mr. BARRETT. Who pays them, the OPO or the hospital?

Dr. D'ALESSANDRO. In our situation we have a hospital-based organ procurement agency, as opposed to an organ procurement agency that is independent from the hospital. So our hospital, they are employees of the hospital, and they are paid from the hospital.

Mr. BARRETT. And that's different from Pittsburgh then.

Dr. FUNG. Most of them are independent OPO's in the country. Few of them are hospital based.

Mr. BARRETT. OK. Mr. Volek, you are an OPO director. What I'm driving at, because I believe that there's an economic incentive for hospitals to go out and procure organs, especially if they believe that those organs are going to be used within their region. Conversely, I believe that there is a disincentive and that if you have an OPO that is a hospital-based OPO or with any relationship to the hospital, that if there is no longer an incentive to bring those organs into that hospital, that that will decrease the incentive for them to go out and get them. Am I off base? What is your response to that?

Mr. VOLEK. Well, I believe that—first of all, we are a hospital-based OPO here. We're based at Froedtert Hospital. And last year Froedtert had 32 organ donors, which puts us among the top donor hospitals in the United States in terms of actual numbers. I think it's very difficult and from the community perspective to decouple the value of having a local transplant center from the organ donation process. I would have to say I believe here in Wisconsin that organ donation has benefited because of the growth in the visibility of two very strong transplant programs, and so the public hears daily from the transplant center's side from a marketing perspective and promotion the success and the benefits of transplantation and the need for transplantation. And so you have, we have Wisconsin patients or, patients or individuals in our area who are hearing about it. The OPO goes out and carries the message to the community and says look at it. We have got excellent programs in our State. We need to support them, and the public gets on board and gets behind it.

I would say that regardless, from my perspective as an OPO director, albeit we have, we're sitting here in the middle of a transplant center, I would say regardless of the outcome of this debate, our efforts to identify potential donors will not diminish in the slightest. In fact, I think if we need to fight sort of on a handicap because of some perceived inequities locally in terms of donation, we are going to work all the harder.

So, no, from the OPO perspective, I think it's—I don't expect to see a lack of or a loss on enthusiasm. I think we have to do it, and as Dr. Fung said, we have a job to do. And that is why we have, for lack of a better term, the franchise to provide organ donation services in this area. But, again, I would reiterate that I don't think we can decouple the value of having a local transplant center and local recipients in closing that loop on organ donation with our community from the overall donor awareness effort.

Mr. BARRETT. Mr. Chairman.

Mr. SHAYS. Thank you. For the record, GAO has provided testimony we will put in the record. It's entitled, "Assessing Performance of Organ Procurement Organizations." So it's appropo to this question.

[The information referred to follows:]

Mr. Chairman and Members of the Subcommittee:

We are pleased to contribute this statement for the record as part of the Subcommittee's review of issues concerning organ donation. Our comments will focus on the current standard for assessing the effectiveness of organ procurement organizations and alternatives to this standard.

Advancements in organ transplant technology have increased the number of patients who could benefit from such transplants. The supply of organs, however, has not kept pace with the growing number of transplant candidates, continuing to widen the gap between transplant demand and organ supply. With the passage in 1984 of the National Organ Transplant Act, the Congress sought to increase the organ supply. To some extent, this has succeeded: the number of cadaveric[1] organ donors increased 33 percent between 1988 and 1996–from 4,083 to 5,416–and the number of organs transplanted from cadaveric donors rose from 10,964 to 16,802 in the same period. Nevertheless, the organ supply has not kept pace with demand, and over 54,000 patients are now on the waiting list for a transplant.

The Department of Health and Human Services (HHS) has just published a new regulation to change the allocation of organs from what is now a largely regional approach to a more national approach.[2] Under current policies, matching organs are usually made available to all listed patients in a local organ procurement area before they are made available to other patients. Today we will discuss a key element of the current system, the local organ procurement organizations (OPO), rather than the impact of the change in policy.

To help the Congress better understand the operation of the organ allocation and procurement system, we have issued several reports over the last few years examining the equity of organ allocation decisions, variations in patient waiting times, and the lack of adequate measures to assess organ procurement effectiveness.[3] Most recently, in November 1997, we reported on our examination of the approaches for assessing the effectiveness of OPOs in increasing the organ supply.[4] Our statement will focus on this

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[1] Some patients receive organs, particularly kidneys, from living donors. In 1996, 3,524 people donated organs.

[2] 63 Federal Register 16296 et seq., Apr. 2, 1998 (to be codified at 42 CFR Part 121).

[3] Organ Transplants Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs (GAO/HRD-93-56, Apr. 22, 1993) and Impact of Organ Allocation Variances (GAO/HEHS-95-203R, July 31, 1995).

[4] Organ Procurement Organizations Alternatives Being Developed to More Accurately Assess Performance (GAO/HEHS-98-26, Nov. 26, 1997).

most recent work, in which we examined (1) whether the current standard for assessing OPOs' effectiveness appropriately measures the extent to which OPOs are maximizing their ability to identify, procure, and transplant organs and tissue and (2) alternatives to the current standard that could be more effective.

OPOs play a crucial role in procuring and allocating organs.[5] They provide all the services necessary in a geographical region for coordinating the identification of potential donors, requests for donation, and recovery and transport of organs. OPOs work with the medical community and the public through professional education and public awareness efforts to encourage cooperation in and acceptance of organ donation. Although they have similar responsibilities, OPOs vary widely in the geographic size and demographic composition of their service areas as well as in number of hospitals, transplant centers, and patients served. The Health Care Financing Administration (HCFA) administers section 1138 of the Social Security Act,[6] which requires, among other things, that the Secretary of HHS designate one OPO per service area and that OPOs meet standards and qualifications to receive payment from Medicare and Medicaid. Section 371(b)(3)(B) of the Public Health Service Act[7] provides that an OPO should "conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors."

HCFA regulations set performance standards for OPOs.[8] These standards assess OPOs according to their achieving numerical goals per million population in their service areas in five categories: (1) organ donors; (2) kidneys recovered; (3) kidneys transplanted; (4) extrarenal organs, that is, hearts, livers, pancreata, and lungs recovered; and (5) extrarenal organs transplanted. HCFA assesses OPOs' adherence to the standards and qualifications every 2 years. Each OPO must meet numerical goals in four of the five categories to be recertified by HCFA as the OPO for a particular area and to receive Medicare and Medicaid payments.[9,10] Without HCFA certification, an OPO may not

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[5] OPOs are nonprofit private entities that facilitate the acquisition and distribution of organs.

[6] 42 U.S.C. 1320b-8.

[7] 42 U.S.C. 273(b)(3)(B).

[8] 42 CFR Part 486, Subpart G.

[9] During the 1996 designation period only, HCFA redesignated OPOs that met numerical goals in three of the five categories and submitted an acceptable corrective action plan.

[10] According to HCFA regulations, certification or recertification refers to HCFA's determination that an entity meets the standards for a qualified OPO; designation or redesignation refers to HCFA's approval of an OPO to receive Medicare and Medicaid

continue to operate. In 1996, HCFA assessed OPOs for the first time using the population-based standard with 1994 and 1995 procurement and transplant data.

Whether the HCFA population-based standard appropriately measures the extent to which OPOs are maximizing their ability to identify, procure, and transplant organs and tissue was the subject of our recent report. We determined the strengths and weaknesses of the current standard and identified and assessed alternatives to that standard.

In brief, HCFA's current performance standard does not accurately assess OPOs' ability to meet the goal of acquiring all usable organs because it is based on the total population, not the number of potential donors, within the OPOs' service areas. We identified two alternative performance measures that would better estimate the number of potential organ donors: measuring the rates of organ procurement and transplantation compared with either the number of deaths or the number of deaths adjusted for cause of death and age. Both these approaches have limitations, however, in data availability and accuracy. Two other methods for assessing OPO performance--medical records reviews and modeling--show promise because they could more accurately determine the number of potential donors. Because OPOs must meet the performance goals to continue to operate, approaches that more accurately differentiate between OPOs that achieve greater or lesser proportions of all possible donations in their service areas can help increase donations.

BACKGROUND

Although the number of donors is growing more slowly than the demand for organs, the number of donors has steadily increased since 1988. The major reason for this increase is because many more older people are becoming organ donors than in the past. Nearly two-thirds of cadaveric donors were between the ages of 18 and 49 in 1988, but by 1996 only about one-half of donors were in this age group. The proportion of donors aged 50 and older doubled from about 12 percent in 1988 to about 26 percent in 1996. Another reason for the increase in donors is because more minorities are consenting to donate organs. Between 1988 and 1996, the percentage of organ donors who belonged to racial and ethnic minority groups increased from about 16 to 23 percent.

The organ donation process usually begins at a hospital when a patient is identified as a potential organ donor. Only those patients pronounced brain dead are considered for organ donation.[11,12] Most organ donors either die from nonaccidental injuries, such as

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payments. These terms are usually used interchangeably.

[11] States set the legal standard for determining death. "Brain death" is defined as the irreversible cessation of all functions of the entire brain, including the brain stem.

a brain hemorrhage, or accidental injuries, such as a motor vehicle accident. Other causes of death that can result in organ donation include drowning, gunshot or stab wound, or asphyxiation.

Once a potential organ donor has been identified, a staff member of either the hospital or the OPO typically contacts the deceased's family, which then has the opportunity to donate the organs. If the family consents to donation, OPO staff coordinate the rest of the organ procurement activities, including recovering and preserving the organs and arranging for their transport to the hospital where the transplant will be performed.

One donor may provide organs to several different patients. Each cadaveric donor provides an average of three organs. In 1996, OPOs procured kidneys from 93 percent of organ donors and livers from 82 percent of them; other organs were procured at lower rates.

Role of OPOs

The national system of 63 OPOs currently in operation coordinates the retrieval, preservation, transportation, and placement of organs. For Medicare and Medicaid payment purposes, HCFA certifies that an OPO meets certain criteria and designates it as the only OPO for a particular geographic area. OPOs must meet service area and other requirements. As of January 1, 1996, each OPO had to meet at least one of the following service area requirements:

1. It must include an entire state or official U.S. territory.

2. It must either procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation, or it must request and receive an exception to this requirement.

3. If it operates exclusively in a noncontiguous U.S. state, territory, or commonwealth, the OPO must procure organs at the rate of 50 percent of the national average of all OPOs for both kidneys procured and transplanted per million population.

4. If it is a new entity, the OPO must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

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[12] Organs are recovered from a small number of donors declared dead by traditional cardiac death criteria. Some have termed these donors as "non-heartbeating."

In addition, an OPO must be a nonprofit entity and meet other requirements for the composition of its board, its accounting, its staff, and its procedures. To ensure the fair distribution and safety of organs, OPOs must have a system to equitably allocate organs to transplant patients. In addition, OPOs must arrange for appropriate tissue typing of organs and ensure that donor screening and testing for infectious diseases, including the human immunodeficiency virus, are performed.

OPOs use a variety of methods for increasing donation such as raising public awareness of organ donation and developing relationships with hospitals. The goal of public education is to promote the consent process, giving people the information they need to make decisions about organ and tissue donation and encouraging them to share their decisions with their families. Such public education campaigns include mass media advertising; presentations to schools, churches, civic organizations, and businesses; and informational displays in motor vehicle offices, city and town halls, public libraries, pharmacies, and physician and attorney offices.

In addition, education efforts help hospital staff clarify organ and tissue recovery policies to ensure that potential donors are consistently recognized and referred. OPOs also conduct hospital development activities to build strong relationships with service area hospitals to promote organ donation.

PROBLEMS WITH THE CURRENT STANDARD

HCFA chose a population-based standard to assess OPO performance after considering the availability and cost to the OPOs of obtaining and analyzing various types of data. When HCFA first applied this standard in 1996, five OPOs were subject to action for failing to meet the standard. This resulted in two OPOs' service areas being taken over by adjacent OPOs, a portion of one OPO's service area being taken over by an adjacent OPO, and the merger of one OPO with another. The fifth OPO that failed the standard was determined to be a new entity and not subject to meeting the performance standard.

A population-based standard, however, does not accurately assess OPO performance because OPO service areas consist of varying populations. Although potential organ donors share certain characteristics, including causes of death, absence of certain diseases, and being in a certain age group, OPO service area populations can differ greatly in these characteristics.

For example, motor vehicle accidents, the cause of death for about one-quarter of organ donors in 1994 and 1995, ranged from about 4.4 to about 17.9 per 100,000 population among the states and the District of Columbia. In addition, the rates of acquired immunodeficiency syndrome, a disease that eliminates someone for consideration as an organ donor, differ among the states and the District of Columbia–from 2.8 to 246.9 cases per 100,000 people in 1994. Furthermore, although most organ donors were between 18 and 64 years of age in 1994 and 1995, this age group constitutes from 56 to 66 percent of the population in different states. Thus, the number of potential organ donors can vary greatly for OPOs serving equally sized populations.

ALTERNATIVE STANDARDS COULD MORE ACCURATELY ASSESS OPO PERFORMANCE

We identified several performance measures as alternatives to the current population-based standard. The alternatives we examined included measuring organ procurement and transplantation compared with (1) the number of deaths, (2) the number of deaths adjusted for cause of death and age, (3) the number of potential donors based on medical records reviews, and (4) the number of potential donors based on modeling estimates in an OPO service area.

In developing its current OPO performance standard, HCFA considered using the number of service area deaths as the basis for assessing performance. Although some organs, typically kidneys, are obtained from living donors, OPOs recover organs from cadaveric donors. Therefore, the number of deaths in an OPO's service area more accurately reflects the number of an OPO's potential donors. In 1994, the United States had about 2.3 million deaths out of a population of about 260 million. Although using total deaths fails to consider other factors about and characteristics of potential donors, it would eliminate considering a portion of the population that an OPO clearly could not consider for organ donation.

HCFA also considered using an adjusted measure of deaths for the performance standard. Measuring OPO performance according to the number of service area deaths adjusted for cause of death and age more accurately reflects the number of potential donors than measuring performance according to the number of all service area deaths. The number of service area deaths adjusted for cause of death and age better estimates the number of potential donors because it accounts for the small subset of the deceased that may be suitable organ donation candidates. Adjusting for cause of death and limiting consideration to deaths of those under age 75, we found that in 1994 about 147,000, or 6 percent, of the 2.3 million U.S. deaths involved these causes of death or were of people in this age group. This estimate, however, is much larger than the estimates some have made of a national donor pool of from 5,000 to 29,000 people per year.

We found that both the death and adjusted-death measures have drawbacks that limit their usefulness, however, including lack of timely data and inability to identify those deaths suitable for use in organ donation. We ranked the OPOs, using 1994-95 OPO procurement and transplant data, according to the current population-based measure and these two alternative measures–number of deaths and adjusted deaths. Although three OPOs would not qualify for recertification under any of these measures, according to our review, the number of and which OPOs would not qualify vary depending on the measure used. More OPOs would have been subject to termination under either of these alternative measures.

HCFA did not consider two other methods for determining the number of potential donors–medical records reviews and modeling–that show promise for determining OPOs' ability to acquire all usable organs. Reviewing hospital medical records is the most accurate method of estimating the number of potential donors in an OPO's service area. A medical records review involves reviewing all deaths at a hospital with an in-depth examination of those meeting certain criteria. Reviewing the records of these patients reveals the patients' suitability for organ donation based on several factors, including cause of death, evidence of brain death, and contraindications for donation such as age and disease. Such reviews can identify that subset of deaths in which patients could have become organ donors–the true number of potential donors for an OPO service area.

Most OPOs do conduct medical records reviews but at varying levels of sophistication. For records reviews to be useful for assessing OPO performance, the reviews would have to be conducted consistently among OPOs and the results would need to be available for validation. Such reviews, however, are labor intensive and therefore expensive. Although most OPOs are conducting some form of medical records reviews and therefore already incurring the costs of these reviews, HCFA must consider its own and the OPOs' additional expense involved in standardizing such reviews. Other considerations include the extent to which the reviews would add to the cost of organs and whether these costs would outweigh the benefit of more accurately measuring the number of potential donors.

Another alternative, modeling, shows promise and would be less expensive than medical records reviews. At least one group is developing a modeling method using substitute measures to provide a valid measure for estimating the number of potential donors. The goal of this effort is to design an estimating procedure that will be relatively simple to execute, inexpensive, and valid. This approach uses information from hospitals in the OPO's service area on variables, such as total number of deaths, total staffed beds, Medicare case mix, medical school affiliation, and trauma center certification, to predict the number of potential donors. Using existing data would make this alternative less costly than medical records reviews; however, the accuracy of such a model has yet to be established. If the number of potential donors for an OPO can be reasonably predicted using a set of variables, this could eliminate concerns about the cost of implementing medical records reviews.

RECOMMENDED FUTURE STEPS

HCFA believes its current standard identifies OPOs that are poor performers. When publishing its final rule, however, the agency stated that it was interested in any empirical research that would merit consideration for further refining its standard. The approaches we identified in our report merit HCFA's consideration.

More specifically, our report recommended that to better ensure that HCFA accurately assesses OPOs' organ procurement performance and that OPOs are maximizing the number of organs procured and transplanted, the Secretary of Health and Human Services direct HCFA to evaluate the ongoing development of methods for determining the number of potential donors for an OPO. These methods include medical records reviews and a model to estimate the number of potential donors. If HCFA determines that one or both of these methods can accurately estimate the number of potential donors at a reasonable cost, it should choose one and begin assessing OPO performance accordingly.

HCFA has concurred with our recommendation. It has indicated that when the ongoing research on medical records reviews and modeling are complete and it receives the studies, it will review the results to determine if it can support a better performance standard.

HCFA's continuous monitoring of the developments in approaches to identifying potential organ donors is important. Because the demand for organs surpasses the supply, OPOs are required by law to conduct and participate in systematic efforts to acquire all usable organs from potential donors. As we have reported, unless HCFA measures OPO performance according to the number of potential donors, the agency cannot determine OPOs' effectiveness in acquiring organs.

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Mr. SHAYS. There's just so much we can touch on, and so some of it's going to be a little superficial because we're really not going to get into the essence of it, but I would like to ask a few kind of general questions, not that I'm going to be able to get into the full extent of it.

For instance, Ms. Heitman, your son Nathaniel had cystic fibrosis. My understanding is that that clearly is life threatening, but was there ever a debate that if he had a lung transplant, that he might only live so much longer and that he would have to have another one or that he would have problems with other organs? Was that ever a dialog, and was that ever a factor in deciding whether he would have an organ transplant? Do you understand my question?

Ms. HEITMAN. In the family deciding whether or not——

Mr. SHAYS. No. With the medical treatment. First let me ask this question: If he had had a lung transplant, was his prognosis good that he would live a long and healthy life, or would he have been faced with other physical challenges?

Ms. HEITMAN. Long and healthy, no. The research is not wonderful because things have just been—with cystic fibrosis transplants have not been used for that long of a period, but the research is very encouraging. Those folks who have had transplants that suffer with cystic fibrosis are having their quality of life improved by leaps and bounds.

Mr. SHAYS. Did that ever get into the dialog? Was it ever introduced as an issue, that your son may not be considered as good a candidate for the transplant because of cystic fibrosis? Was that ever an issue? With the insurance company or the doctors?

Ms. HEITMAN. I think that it was when we were in Madison. I think that some of the soft answers that I was given and also that in July we were told that Nathaniel didn't need a transplant, that his lungs were good enough and, you know, a number of months later he had died. I don't know if they were thinking that it would have been a waste of an organ. I don't know that.

Mr. SHAYS. Let me just ask other panelists. First, I don't want to get in big detail because we're just not going to be able to wrestle with this issue, but it's interesting so far with all the people who have spoken, none have really addressed the issue of the viability of the patient after the operation. Is this a factor that—I mean you alluded to it in terms of the issue of age. But is that a factor? Dr. Fung, is that a factor in deciding whether a patient, besides what stage they are, I, II, or III, the viability, the prognosis of how they will be afterwards?

Dr. FUNG. I think it's taken into consideration, although it depends, for instance, on the original diagnosis. It may depend on how old the particular patient is. Each center has its own criteria. I know that this idea of standard listing criteria is important to try and make sure everybody gets on the list at the same time. But the other end, the other end of the spectrum, which is the patients that become a little bit questionable, they may be higher risk, each center develops its own principles or philosophy as to how aggressive that particular center wants to get. Some programs don't want to get aggressive because they know they don't have the resources to care for that kind of a patient. Other programs may feel that they have the experience to do so. I think that that's not the issue we are talking about in terms of regulation.

Long-term outcomes for all the transplants actually are quite good. Lungs probably are one of the more difficult ones because the rejection process is still difficult to control. But for livers, you are looking at a 10-year survival of 50 percent. That is after the—that's really only about a 2, 1 to 2 percent patient death per year after the first year. That is not too bad.

Mr. SHAYS. Thank you.

Ms. Hodgson, from your testimony I got the sense that where your husband's organs went did not matter to you at all as long as they went to someone who would be helped by them. Is that a fair assessment of your statement?

Ms. HODGSON. At the time that I made the decision to donate organs you have to understand that you are still in a total state of shock, stunned that you have irretrievably lost your spouse. You—at that time I wasn't even aware that organs can be shipped across the country. I suspected that they would stay within Wisconsin. It did not occur to me nor did it make any difference to me. What I wanted was for his organs to help somebody else to live. As the years have gone by and now this discussion, I see that it becomes, in my own opinion it becomes a point of issue as to not only who the sickest patient is, but you want the best, the best recovery available. I'm concerned with the transportation of organs across the country and transplanting those into the very sickest patient and what that outcome might be, the viability of that organ by the time it reaches its destination.

Mr. SHAYS. Could I say, though, I mean I realize you're a nurse, but that's left to people other than you and me to decide, the viability.

Ms. HODGSON. That is true.

Mr. SHAYS. But if in fact the viability is good, I'm just trying to—I haven't met many individuals who were faced with the incredible decision you were faced with and so I'm taking advantage of that. But I'm gathering there are all kinds of donors. You were a donor who—your husband was obviously, your husband's organs were being donated. You made the decision in a sense. I mean he allowed for it, but you made that ultimate decision. You could have stopped it, correct?

Ms. HODGSON. Yes.

Mr. SHAYS. As the spouse. Even if he had wanted his organs to be donated. Am I correct here? Maybe I need to—my understanding is that someone can say "Yes, I want my organs to be donated," but, they are in an automobile accident and have to make a decision fairly quickly. A family can stall that process if they themselves don't want their family member's organs to be donated, then they don't get donated; is that correct?

Ms. HODGSON. If somebody with more expertise than this can correct me, it's my assumption that if a driver's license is signed, then there is no argument in the emergency room when that patient——

Mr. SHAYS. OK. I get the sense——

Ms. HODGSON. OK. I stand corrected.

Mr. SHAYS. Let me ask Mr. Volek. OK. I'm sorry, Ms. Shapiro. We'll come to you.

Mr. VOLEK. There's a fair amount of confusion in that Wisconsin is one of the few States that the signed, properly executed anatomical gift document takes precedence over the wishes of the next of kin. That is matter of State law, and so technically on the basis of a donor card, the organ procedure staff can go ahead and proceed with recovery. Practically speaking, we sit down and we talk with the family and we know that the vast majority of families will go along with the wishes of their family member. So, yes, the donor card does take precedence here, but practically speaking, it's important to the family that they know and concur with this, so we sit and work with the family.

Mr. SHAYS. And so the—the legal answer is yes, the practical effect is the family is consulted and the family's wishes do come into play.

Ms. Shapiro.

Ms. SHAPIRO. From what I know, most, if not all, State laws or organ donation are patterned after the Uniform Anatomical Gift Act. And that provides just as you said, which is that it's a contract. It's a decision on the part of the donor, if he or she signs a paper, that that organ is to be recovered. But in practice, from what I hear and what I read, if there is an objecting family member who, after all, will be around to sue, who objects, the organ won't be taken.

Mr. SHAYS. Yes; which kind of gets me to—I have a sense that people would like to think that the organs being donated are being donated to people that they interact with, not directly, but in a sense in their community. And I think I almost accept that intuitively, but—and so I can see that, but in a sense I wonder if it's just intuitive and if there's any science to back it up one way or another. I mean has this been an issue that has been thoroughly researched?

Dr. Fung, you basically responded that the statistics don't seem to support that. I would be interested if anyone else in this panel can—and, Mr. Volek, maybe you can respond to it and then——

Mr. VOLEK. Well, we did conduct a public opinion poll for exactly that reason. There's a lot of speculation and anecdotal information and intuition about how it ought to be, and not surprisingly, if you lay out to the public the sickest person where death is eminent versus a patient who is stable and could otherwise live for several months, the majority of public says, yes, we ought to be providing the opportunity for the transplant to that sickest patient. And that is a very simplistic view, and it's—I mean, again, in a survey, you can't get into a whole lot of detail. Probably what was the most telling here, though, is all things being equal, patients that are sort of an equal medical status, there was a preference in Wisconsin, 56 percent of the respondents said that they would prefer that that organ was used in a Wisconsin resident; 32 percent were undecided and 12 percent took the other thing, which is we really don't care where that organ is used. And so clearly for the folks that had a preference, they preferred that it was used locally.

If you take the 32 percent, the don't knows or won't answers and force an answer, typically in surveys of this nature they usually fall pretty much along the same lines as the ones that had a strong opinion. So yes, I mean that is a real fair question.

Mr. SHAYS. It seems that the statistics could almost support either position, which is welcome to public life.

Dr. D'Alessandro, you made a comment to me and I triggered—and I responded somewhat negatively and I want to tell you why, and then I'd be curious to know how you'd respond. It's my sense that within an OPTN region you really seek out the one who is in the greatest need first, and so basically level I over level III in a particular region. And yet you spoke out against that concept being projected out by the rule. And you made an argument that it should go to level III, who have the best likelihood of, who are the least at risk. And it seems to me you are almost playing both sides of the argument.

Dr. D'ALESSANDRO. I think the balance which has tried to be achieved is for sick patients and for—actually all patients are sick. I would like to say that again. Both outpatients and inpatients are very sick. And as I mentioned, the majority of patients on the waiting list last year who died were not hospitalized. They were in the least urgent category. I'm very concerned that the Department of HHS has weighed in only on the equity side of this issue and has not looked at or has discounted the utility of these organs. From a personal point of view, and I know patients don't think of this, but I would like to think that if I were an organ donor, that the organ—or my son or daughter were an organ donor, that had the maximum benefit, that could really help someone in the long term.

Mr. SHAYS. Do you think you are addressing my question, though? My question is this: If the logic is that within a region you choose the one who has got the greatest need, why then do you speak out against an argument that by the rule that says where there is the greatest need, and by the way we may have to go from one region to another to satisfy that? I could just make the point. I could see where you would object to it going from one region to another, but I don't think you could use the argument that it shouldn't go to the one who is the sickest because you do it right here.

Dr. D'ALESSANDRO. We've tried to maximize the benefit of the precious organs that we have for as many patients as we can. The current allocation system which is in place and has evolved and is continuing to evolve has actually looked at these both, both of these issues, equity and utility, and in many parts of the country there has been broader sharing of organs in the higher status patients within a region. And as I mentioned with my poster on preservation times, you have to take into the effect, and if I could show that poster one more time, if we transplant livers in Wisconsin and we put the livers in immediately and we don't have any time where we preserve them for extended periods, the average preservation time is 9 hours. Only 2 percent of those livers fail to function. If you go out to 12 hours, which is the minimum time that's necessary for transport of organs, we are talking a 6-percent increase. We're probably talking more about 10 to 12 percent. Now, this 6 percent of 4,000 donors last year is not a small number.

Mr. SHAYS. I think that is a very valid argument. The transportation is a valid argument. I don't think it's a valid argument that—if it is, I think then every region is talking on both sides of its mouth because I bet every region seeks to help the person who has the greatest need.

Dr. D'ALESSANDRO. What does the Department and what would families say if the Department is weighed in on the favor of equity for sick patients? How are the changes fair to nearly half or more than half of the sick patients who die without ever getting to a hospital? These patients are not well. These are sick patients. These patients are in need.

Mr. SHAYS. That's a very valid point. It's just not—I'm just readdressing one argument that you made. And I'm making the argument to you that you can't argue within your own region that it should go to those who have the greatest need and then argue conversely that it is wrong to have a Federal rule that says it should go to the people in greatest need. That's all. I'm just making that point. And I think that point still stands.

I'm interested to know, this hospital basically services the VA; correct?

Dr. D'ALESSANDRO. Yes. We have a VA contract.

Mr. SHAYS. I'm sorry. The University of Wisconsin.

Dr. D'ALESSANDRO. That's correct.

Mr. SHAYS. And you practice there as well.

Dr. D'ALESSANDRO. Yes.

Mr. SHAYS. Now, there you bring patients down from Alaska and a whole host of different places; correct?

Dr. D'ALESSANDRO. We have only five patients, we have five patients who are VA contract patients. And we have one patient each from five other States. The majority of our patients are Wisconsin residents. Not 60 percent. This is somewhere between 90 and 95 percent of our patients on the list are Wisconsin residents.

Mr. SHAYS. But the basic logic is that you have to service a region that is quite extensive.

Dr. D'ALESSANDRO. I don't know that we have to service a quite extensive region.

Mr. SHAYS. What I'm trying to understand is that you service patients from Alaska, from Hawaii. Correct?

Dr. D'ALESSANDRO. That is true. There are five patients on our list from five other States.

Mr. SHAYS. OK. I'm sorry. Oh, so your point—I am missing this. And the five constitutes a small minority of——

Dr. D'ALESSANDRO. That's correct.

Mr. SHAYS. One last question. Ms. Shapiro, maybe you could respond to this. Is the only way to address utility through geographic boundaries? I mean that seems like what we are doing. And it seems so rigid and arbitrary in a sense.

Ms. SHAPIRO. They do. Whenever you are getting—well, let me not answer your question and go back to comments that you made to him.

Mr. SHAYS. No; you're going to answer my question, but——

Ms. SHAPIRO. They're rigid and arbitrary, but they're drawn in an attempt—and this does go to some of the comments that you were addressing toward Dr. D'Alessandro—the challenge that we have, as you have so acutely identified, is to strike a balance between utility and justice. And they are at odds. I mean, it's true that if you are going to go for the sickest, you are looking at justice. You are trying to rescue people who otherwise are going to die and you can identify them, they are on your list, they're the worst off, and you need to get to them. But if we want to enhance utility, which is the most good for the most people——

Mr. SHAYS. Right.

Ms. SHAPIRO [continuing]. Then we have to look at other things. So while equity or justice would say, let's not get, let's not let geographic or any other nonmedical criteria get in the way of rescuing the identifiable individual, the necessity to accommodate some of the other utility-based objectives cuts the other way. What this rule would result in, I think, is a wholesale shift toward rescuing sicker patients with a resulting dramatic impact on some of the utility-based objectives.

Mr. SHAYS. Can I put it in my simple words, justice says go to No. 3. Excuse me. The most sick, No. 1. Utility says go to No. 3.

Ms. SHAPIRO. May——

Mr. SHAYS. In the most simplistic way of looking at it.

Ms. SHAPIRO. Yes.

Mr. SHAYS. I tell you now reacting to two panels, I think the thing that I have the most sympathy probably with many in the audience is that if Wisconsin is doing a better job of getting people to donate their organs, they should not in a sense be penalized by seeing the organs go somewhere else. I have that sense. [Applause.]

But that is a different issue than we have been debating back and forth. I mean I think there's got to be an incentive. Because I don't like fighting over scarce resource. I like to make the pie bigger rather than argue who is going to get a smaller and smaller pie. And I do accept the potential though it contrasts with your testimony, Ms. Hodgson, because in the end you just wanted them to go anywhere. But I do think intuitively that you are more likely to get more donors if people can see a firsthand benefit so and so donated from the community and so and so was blessed by the organ. And so that's the thing that we still need to, you know, it's still on the table as far as I'm concerned.

Ms. SHAPIRO. I agree. And with all due respect to Paul Volek, my colleague here, I think it's counterintuitive to presume that an OPO will not be less motivated to answer the call in the middle of the night to retrieve an organ if they don't know that one of their patients will be benefited.

Mr. SHAYS. Right. That is an issue, though, of their—no. I'm almost certain, I don't even think he would suggest that. Honestly.

Ms. SHAPIRO. No; he wouldn't. He said in fact the opposite. But I think that it's just human nature to be more motivated to get an organ that you can see put to use.

Mr. SHAYS. Right. But if there is an organ available, the medical community is going to get it. The question is, is someone going to be putting on their license that they want to donate.

Ms. SHAPIRO. I think it's both. I think getting out there and really trying to find that this is a suitable organ, to try to make arrangements that it remains a suitable organ, to make travel—I mean there's all sorts of things that I think go into motivation of OPO's to increase numbers.

Mr. SHAYS. Go back to Mr. Barrett. And I think I am concluded. I just want to say that I have seven hospitals, now six in my district and visit them quite often, but I was very impressed with visiting the hospitals here, the attitude of those who are providing the service, just the atmosphere that exists here, and I think you all have very strong reason to be proud of these many facilities here, and it was wonderful this morning to be able to visit them.

Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman. I want to stick with you, Ms. Shapiro, if I could, since you are the ethical guru. I want to toss a couple of ethical questions at you that sort of range at different ends of the pendulum here, probably neither of which would come to fruition. Should we be paying people to donate organs?

Ms. SHAPIRO. No.

Mr. BARRETT. Can you elaborate on that? What's the problem with that? The problem here is lack of organs. Why aren't we paying people?

Ms. SHAPIRO. I think there are two big problems. One is that part of the preciousness of our system now is that we do see organs as community resources, and the system is based on altruism. And there is something about that in and of itself that I think is a real tribute to our country. But the other concern is the possible abuse. Some people may feel pressured to donate where others might not. And this may be particularly true when we're talking about living donors who will jeopardize their own health in order to receive compensation pursuant to that system.

Mr. BARRETT. Does the rest of the panel share that view? Does anybody disagree with that? Doctor?

Dr. D'ALESSANDRO. I don't disagree with that view, but we are currently looking in one of the committees in UNOS at disincentives for organ donation. And we are also looking at is it possible to provide through a third party reimbursements for funeral expenses. I think everyone benefits from organ donation perhaps except the donor family. And not—we want to avoid any abuse, we want to maintain altruism, but are there ways that we can remove disincentives without actually paying for organ donors. And we're looking very closely at that in one of the organ allocation—not allocations, one of the other committees in UNOS.

Mr. BARRETT. Ms. Hodgson, what's your view on this?

Ms. HODGSON. As far as——

Mr. BARRETT. Paying.

Ms. HODGSON [continuing]. Paying. I have always been against paying for organs. It then becomes whoever is the highest bidder, and I don't even want——

Mr. SHAYS. We can't hear right away. I just want to make sure you speak a little louder.

Ms. HODGSON. I have never been in favor of payment for organs. I think it becomes a situation where the person that receives the organ will go to the highest bidder and that is against my beliefs.

Mr. BARRETT. Again from Ms. Shapiro. Going to the other end of the extreme, should we prohibit hospitals from going out and trying to attract patients or marketing on the patient side?

Ms. SHAPIRO. Any kind of patients?

Mr. BARRETT. Transplant patients.

Ms. SHAPIRO. Transplant patients.

Mr. BARRETT. If the problem here is that we have hospitals that are suddenly competing with each other, and, again, I will keep harping back to the economic issue, that there are a lot of jobs and prestige involved in this, are we distorting our medical system and ultimately perhaps resulting in a more concentrated delivery system where people have to travel farther lists.

Ms. SHAPIRO. A couple things. I think that there may be a fine line between educating patients and marketing or pressuring patients; and I think that it is a good thing to raise consciousness about being an organ donor. So to the extent that we go out and promote donation via education, we see some of the benefits that flow to families when they are aware of that option and actually participate. So I see nothing wrong with that.

In terms of creating a list of sick patients who are prospective recipients, one of the concerns that I have with this rule is are we going to make patients sicker or make them look sicker in order to up them on the list? And there are, from what I understand, things that can be done to make it appear that someone is sicker and therefore more eligible for an organ transplant, and that does give me concern.

Mr. BARRETT. But the ethics of a hospital going out and trying to recruit patients, what is your feeling on that?

Ms. SHAPIRO. That is health care delivery today. And I can't believe that health care professionals are going to, in the end, recommend a procedure on any basis other than true analysis of needs.

Mr. BARRETT. Doctor.

Dr. D'ALESSANDRO. I think there are two sides of this coin which you don't have in most other medical professions and that is you have a recipient side and you have donor side. No, there is nothing wrong with recruiting patients and that is health care today. But if you recruit patients because you know that organs will come your way if you have a large list and a large—and sick patients, well, you are recruiting patients and indirectly you are benefiting because you will be able to direct the flow of organs to your center by way of the system that is totally equity based. And that is the concern that we have. I don't know that you should or could stop that, but this is a concern that—and until there are enough organs for everyone—the system will be set up in such a way that if you know that you could do more transplants because of the number of patients on your list, that you will make every effort to recruit patients. And I'm afraid that some of the interest in organ donation will go down because you know the livers will come to you. Or you know the organs will come to you because you have done your recruitment job.

Mr. BARRETT. Dr. Fung, you see the graph over there pertaining to transportation. Do you agree with that? Do you take issue with that, or is that something that there's agreement in the medical community?

Dr. FUNG. Well, we have actually done our own analysis.

Mr. SHAYS. The mic needs to be closer. I'm sorry.

Dr. FUNG. I'm sorry. We have done our own analysis. We've examined 3,000 grafts, and the numbers don't quite look like that.

There is a break point, but ours is 14 hours. And in fact, when you go from 14 to 20 hours, we go from about a 4 percent at 14 hours to about 10 percent at 20 hours. There is an increase. The question is where is the cut point, break point for that.

Mr. BARRETT. Doctor, do you want to comment on that?

Dr. D'ALESSANDRO. Well, from a paper in 1991 from Pittsburgh, let me quote;

> The trend to a higher retransplantation rate with longer preservation was unmistakable and significant. The dominant contribution of primary non-function to retransplantation need was also evident. Caution should be exercised and undue procrastination in the use of these livers.

Mr. BARRETT. Sounds like that was written by an academic. Can you tell us what that said?

Dr. D'ALESSANDRO. In other words, every minute that you preserve an organ, every minute that it doesn't have blood supply results in worse liver function.

Mr. SHAYS. I would think there would be agreement between the two of you on this.

Dr. FUNG. Well, I think in theory there is. I'm not sure that I would—that was a study that wasn't done with much experience. We now have a lot more.

Mr. BARRETT. Go ahead, Doctor.

Dr. FUNG. I just want to say one thing and——

Mr. SHAYS. Doctor, I know your mic is the worst mic, but you——

Dr. FUNG. I'm sorry. Yes. I just wanted to say one thing about the issue of the local use and local donor. You know, each—the average donor gives about four organs per donor. Already in the country about 20 percent of kidneys are shared for a number of reasons, so one out of five kidneys actually travel outside of your OPO. With four organs, and if we're talking about one of those organs having to go out for whatever reason to a more medically urgent patient or for some antigen match or something, does anybody at this table really think that that's going to adversely affect the other, the procurement of that, of the other three organs from that donor? You know to me I don't really think that somebody is going to say yes, I'm going to give you kidneys, yes, I'm going to give you liver, but no, I'm not going to give you the heart because the heart is not going to stay in——

Mr. BARRETT. But I don't hear anybody making that argument here today.

Dr. FUNG. Maybe I'm stretching it.

Mr. BARRETT. OK. Just a couple more questions so we can move on. Limitations on insurance companies. Is there a problem here? Are we seeing a trend toward insurance companies going with particular centers which could have the impact again of driving a certain center out of business? Is this something we should be concerned with? Mr. Volek.

Mr. VOLEK. I think that insurance companies who have managed care, particularly large national ones, have established what they call centers of excellence. They are typically not limited to 4 or 5 centers, but most often represent 15 or 20 centers. Typically those centers are located where the insurance company has a large enrolled population, and so there will be companies here that choose to, large national companies that choose to do business in Milwaukee rather than go to Madison because this is where their patients live. So I think the insurance companies are looking for quality programs in communities where they have a large enrolled population. They then will go in and attempt to negotiate the best rates they can using their leverage in that.

One piece on the insurance that I think gets overlooked many times is that it's not just the episode of care where you put the organ in and do the transplant. The insurance companies are on the hook for the entire amount of time that that patient, for that entire patient, including any time that patient is waiting for transplant. So I'm actually frankly surprised that the insurance companies and managed care organizations haven't weighed in on this issue.

This summer I believe UNOS is releasing center-specific, actually OPO-specific waiting times, and it will be kind of interesting to see what the response from the payroll community is on this particular issue, because clearly if you can get your patient into, back into their own community at a transplant center with an appropriate outcome and a short waiting time, I would be surprised if the insurance companies didn't jump in terms of starting to redirect some of the patients back in consistent with where the shorter waiting times are.

Mr. BARRETT. And, finally, Ms. Aschbacher, I think your experience shows us the need for increased supply, and, Mrs. Hodgson, I guess for you I think your plea was that we put more effort on increasing the number of donations. And, again, I don't know that there is any disagreement. Do either of you have any specific suggestions on how we could better accomplish that?

Ms. HODGSON. I just think a lot more time and money needs to be spent on figuring out programs to promote organ donor awareness, and there isn't enough time and money being spent on that right now.

Mr. BARRETT. And Ms. Aschbacher, did you have any suggestions?

Ms. ASCHBACHER. No. I just agree with Patty here. And I just feel that our Wisconsin Donor Network is so great in the work that they do here, you know, the transplant coordinators. Somehow if the other transplant centers could get some of that knowledge and success, that is the way we could go and get more organs.

Mr. SHAYS. Maybe we should export them out so they can teach other people to get organs.

Mr. BARRETT. I want to thank each of the panel members. Again, this is very beneficial, I think, to all of us. And I want to thank you for taking the time out of your lives to be with us today.

Mr. SHAYS. Let me just tell you what we we're going to do. We're going to have a 10-minute break. We're going to have cards in the corner desk over there. We're going to have people sign cards. We're going to have you in groups of 1, 2, 3, and 4. A group is going to consist of five. I'm not going to call off the names, I'm going to just say group 1 now come up, line up and give their testimony. What I'm going to ask is please raise you hand high when I ask this question, because we want to get a sense of time here. How many people would like to make a statement before this subcommittee?

Just keep them up for a second. I have about 20. We'll accommodate you. And so we're going to have a 10-minute break. We're going to start at about 3 after 4 o'clock, a 10-minute break. We look forward to your testimony. I want to thank panel II. You were outstanding and very helpful and thank you very much.

[Recess.]

Mr. SHAYS. What we have, we have 30 speakers. And we are going to allow each speaker 2 minutes, and Tom and I for the most part are going to do some good listening. We may jump in, but hopefully we'll keep our side down to allow for testimony. We have 30 speakers and we're not going to increase the list. I hope everyone understands. So we have the list. It's 30. That is what we're going to go with. And so we'll be out of here in about 1 hour and 15 minutes, I think, by the time it takes to—and we have, I think we have six groups? We have six groups of five, and so the first group, if you don't mind, we'll call the first group up, and we will have—if you know who you are, you can just, in that first group you can give your name, and then we're going to have you—I'm going to just give you a sense. This is going to be the clock right here. I mean obviously if you're 1 or 2 seconds over I'd appreciate it if you could be under, but I won't cut you right off, but pretty close to it. And then you'll just bring the card to Joyce. OK? It's great to have you here.

Mr. CORROW. My name is Johnny Corrow (phonetic spelling). I'm a kidney-pancreas recipient for 8 years down at the University of Wisconsin-Madison. In your comments earlier I heard you wanted—you said that you would like some information or some proof that if the organs went national instead of regional, how it would affect the outcome or the donor situation. When I went on a donor list 7 years ago, almost 8 years ago, we had 300 of my friends, my family, my race car fans, I drive a race car, they all signed their donor cards. You're talking about a community coming together. We run ads in the newspaper. My local newspaper ran a big ad. They had a whole day of donor awareness day. Everything was pointed toward local donors and that the organs were going to be donated and if something ever did happen, barring was going to happen to anybody we knew, that it gave me another chance at life. I received my transplant. Ever since then I have been involved in going around and talking every single day, every day of my life since my transplant. I talk to people about donor awareness and how it changed my life and how it changed my wife's life. This year in 1998 the Race For Life that we're going to be racing at the Slinger Speedway is made for awareness and opportunity, awareness of the need of organs, opportunity to give people a chance to sign their donor card at the race track. They save a dollar. Your organ's already made you a buck, so, you know, you're money ahead. And these are our shirts.

Mr. SHAYS. Join the——

Mr. CORROW. Join the Winner's Circle.

Mr. SHAYS [continuing]. The Winner's Circle. All right.

Mr. CORROW. And I'd like to say that I hope that everything that we have done in Wisconsin, I mean our organ procurement center, University of Wisconsin organ procurement center, these people work their butts off, and I know deep down in my heart if you had your job and you worked your butt off and your boss said, "Well, you know, Tom, I'm going to cut your pay back 10 bucks, you're working hard but I'm cutting your pay back," you know deep in your heart you are not going to work as hard. You may think they are people who make sure that you are working that hard, but I think that is what is going to happen with organ procurement with the donors. I mean you are penalizing Wisconsin for their hard work. You're taking our organs and sending them all over the Nation. We're working hard—if they go that way, I know my heart is not going to be into it because when I go to Madison, I see all my friends, we're like a fraternity.

Mr. SHAYS. OK. Let me just say, since you're the first, I've got to set a fairly good example of sticking with the 2 minutes, otherwise I'll probably lose control here.

Mr. CORROW. OK. I just want to say that we'd like to, you know, hopefully maybe be able to keep them here and——

Mr. SHAYS. Fair enough.

Mr. CORROW. Go to the Race for Life June 14.

Mr. SHAYS. Thank you. If you'd give Teresa your card. That's great. Thanks. This is for the recorder. That is why we are doing this. Thank you.

Ms. LARSON. Hi. How close?

Mr. SHAYS. Yes. Up close.

Ms. LARSON. OK. My name is Michelle Larson. That great kid you saw in that picture is mine. I don't think that picture will fit in my wallet, but as Dr. D'Alessandro stated, Ross was not hospitalized as he awaited his transplant, but that is not to say he was not ill. We lived with the transplant cloud hanging over our heads for 10 years since Ross was born. We followed with intense interest the progress in medical technology in organ transplantation, and we felt extremely fortunate that we lived in Wisconsin where we knew that when the time came, our son would get the best of medical care. In 1990, we moved from northern Wisconsin to Madison as Ross' health started to deteriorate. We wanted to be in the best location possible. Finally, in early 1996, it was time to have him evaluated for transplant. We were so fortunate that Ross only waited 4 months and had his transplant just before he turned the corner to being critically ill.

Ross went home after only 10 days in the hospital after a liver transplant. This is not to say that it has been easy, these almost last 2 years. It has been a very rocky road, and because of that we truly feel that if we had waited until Ross was critically ill, Status I, we probably wouldn't have our son with us today. He probably wouldn't be here. We're very thankful to Dr. D'Alessandro, Dr. Stuart Knechtle, UW Hospital for their great care. Most of all we are thankful to God and the family of Samantha who bravely donated her organs. Sam's picture smiles down from us every day from our refrigerator. She was a beautiful 14-year-old girl who lost her life in a traffic accident. Interestingly, she died in the same hospital that our younger child was born in in northern Wisconsin. And to go one step further, the week after our son had his transplant, my sister realized that she went to church with Samantha's grandmother and they held each other and cried with each other. So when you talk about community, this is community. This is sharing life. They gave us the most precious gift that they could give us, the life of our son, and we keep in touch with them. And they are wonderful people. And they are happy that they can be a small part of our lives, too. So I just want to say that—I guess that's all I want to say.

Mr. SHAYS. Well, your son should be very grateful to have two great parents.

Ms. LARSON. Thanks.

Mr. BARRETT. Thank you.

Mr. SHAYS. Thanks. Ma'am, we need you—ma'am, I'm sorry.

Ms. LARSON. That's all right.

Ms. SHINSTINE. Hi. My name is Lori Shinstine, and I'm a nurse working with the University of Wisconsin organ procurement program. First and foremost I'd like to say that it's an honor and a privilege to work with donor families, for they really are the nucleus of organ transplantation. Without them no lives are saved. In my work with them, it has become very apparent that keeping organs in our community is essential. They want to meet the recipients. They want to share with the recipients, and they want their loved ones to be honored. They want the pictures on the refrigerator. They want the community support. I think we owe that to donor families, to give them the opportunity to share life right here in their local community. Thank you.

Mr. SHAYS. Thank you.

Ms. JENSEN. My name is Cindy Jensen, and I'm a liver recipient. I realize that Government regulations are absolutely necessary. It's really unfortunate that everyone in the Government that is making all the decisions cannot walk the walk and does not face a life-threatening illness and waiting for a transplant and then actually going through it.

I am from Rockford, IL, the second largest city in Illinois, and I had my transplant in 1996 at UW. I think an issue that hasn't been brought up is the fact that I was an hour away from home. Unfortunately, I had many complications and I was there for 4 months. Had I not been in a location where my family and friends could have visited me on a regular basis and given me all their support and love, I really don't believe I would have survived. That was a real determining factor in my survival. I can't imagine being that sick and having to be a long distance away from home and not have all of that support.

Another thing is one of our television stations followed my story, as did all our media in Rockford. Consequently, I became a household name for 4 months. It's really amazing. No matter where I go, people are aware of my story. And they feel, it's like anything, you know, when we know someone that has been faced with something, it's more our issue, also. And because of that I feel our community has really taken a different look at organ donation, and not a day goes by that I don't hear from people saying what a difference it made in their life where they never would have considered donation before. After following my story, they definitely are now a donor. I have even experienced people dying and their families donating saying it was because of me. It's very important.

Mr. SHAYS. Sounds to me like the media as well deserves a lot of credit.

Ms. JENSEN. Oh, absolutely. Absolutely.

Mr. SHAYS. Thank you very much.

Ms. JENSEN. Thank you.

Mr. MEDLAND. Mr. Chairman, Congressman Barrett, I'm Mike Medland. I happen in professional life to be a single client attorney specializing in administrative law and insurance law. And my immediate reaction probably should be to stand here and discuss all of the things about the administrative agencies that I didn't like that I heard this morning and the insurance questions that came up that I didn't like, but more important than all of that, I am recipient of a liver transplant 4½ years ago, and I can't be dispassionate about this. I got my liver transplant at the University of Wisconsin. I live in Madison, only 5 minutes away from the hospital. It was great to be able to do that.

I do want to share with you some things that have happened over the years to me that will tend to support your intuitive feeling, Mr. Chairman, that people—it is important to donors and to other people in this whole process to see the results and that therefore they must be local.

When I got diagnosed with my problem, I had prior to that on a tentative basis not been properly diagnosed. After the proper diagnosis came down, one of the surgical nurses stopped in my room and said I need something to pick me up, and I just heard that the diagnosis that we initially had on you wasn't correct and I'm so happy to hear it and I had to stop down to see you. Now, there is somebody who wants to see good results from what is being done.

Second one is a donor family. The family of my donor, the donor was a 14-year-old boy, unfortunately, who died in a motor vehicle accident. The parents were divorced, both remarried. One parent did not want to know any of the donees—any of the recipients. The other parent did want to know the recipients, has met at least two of them that I know of, including myself, and has expressed disappointment in not meeting the others, but they all live in the area, within a couple hundred miles of the donor family. I live less than 100 miles away from the donor family.

The third one is the staff, professional staff and nursing staff at Theda Clark Hospital where my liver came from. And I have met some of that staff, including the neurosurgeon. And they were anxious to meet me. They were anxious to see the good results of all of the hard work that they went through on that case or any other case where organs were donated. It is important to these people to be able to see those results. And this importance for some may make the difference between whether there is a donation or not. It may make the difference between whether the hospital staff really approaches donation with a positive attitude or they just fulfill the law by saying you wouldn't be interested in donating, would you? Those are important, and they result in additional donations, and we will lose some of those donations. Thank you very much.

Mr. SHAYS. Thank you.

If we could have group 2 now come forward. I think Mr. Barrett would agree that this is a very important part of our day. We really appreciate you all staying and willing to testify.

Mr. HULNICK. Congressman Shays, Congressman Barrett, my name is Warren Hulnick, and I'm a liver recipient of 11½ years.

Fortunately, I received my transplant before the current regional barriers were in place. At the time of my transplant I was a resident of New York and was referred to the University of Pittsburgh Medical Center for my transplant, and my donor liver came from Alabama. Today that wouldn't happen. I wouldn't be here. Currently I volunteer with the University of Pittsburgh Medical Center Liver Transplant Service at the Candidate Evaluation Clinic, and I have met—I have been doing that now for almost 5 years, and I've met patients from all over the country. They're referred to Pittsburgh and to the other larger centers probably because of the reputation of excellence. And I don't see any reason why since the larger centers, probably a lot of the centers, not only the larger ones, are treating patients from, away from their local area that these organs can't follow the patient to the center. And I think these new regulations are finally patient-based rather than center-based, and I think they should be supported. Thank you.

Mr. SHAYS. Thank you very much, sir.

Ms. FLASHER. My name is Jennifer Flasher, and I am a cystic fibrosis patient who had a double lung transplant 3 years ago March 27th, so I've just experienced my third anniversary. Because of that I have been able to go back for a second degree. I'm going for dietetics at the University of Wisconsin. I have worked continuously except for the 3 months post-transplant. I worked up until the day of my transplant. I was able to stay out of the hospital, mainly because of my own whatever, just drive that I had to keep myself out of the hospital.

Also, I do want to say that I do think insurance companies have a play in what is being done with patients and the organs. I had a friend who died 2½ years ago because of an insurance decision. She got all of her pretransplant care for cystic fibrosis at the University Hospital in Madison. She was ironically able to have all her post-transplant care at the University of Madison. However, she could not have her transplant at the UW because she lived right over the border in Rockford. I think that insurance companies and just basic general knowledge of organ donation does need to be stressed to everybody. I mean and the TV shows that are depicting organ donation as negative ought to be told that that is not exact—that their representation of organ donation is definitely false. That's all I have to say.

Mr. SHAYS. Thank you very much.

Mr. TOEWS. My name is Bob Toews. My wife——

Mr. SHAYS. Bob, just lift the mic up for you. You can just point it right up to you. Thanks.

Mr. TOEWS. My name is Bob Toews up from Illinois. My wife is Cindy Jensen that had the liver transplant.

Four items I would like to talk on are selection, shortage, promoting livers, and the KISS method.

Selection is when we found out that Cindy needed a liver transplant in 1990. We reviewed all the transplant regional units, hospitals, and we also looked at location. By the numbers we chose UW for those two reasons.

Shortage. We started, Cindy did, started an organ fair in Rockford at one of the largest—largest what, Honey?

Ms. JENSEN. Mall.

Mr. TOEWS. Mall there in Rockford. And we had a fair of the year to promote organ donation. It worked out real well.

As far as the KISS method that I would like to address, ladies and gentlemen, Wisconsin has one of the best in the country. Select the top 10, find out how they do it and proceed that direction.

Mr. SHAYS. What is the KISS method?

Mr. BARRETT. What is the KISS method, if you could really quickly tell us?

Mr. TOEWS. Keep it simple, shithead.

Mr. SHAYS. Now, in my refined area of New England, we say keep it simple, stupid. But then again, I'm in farm country; right?

Ms. SURLAS. Have I lost——

Mr. SHAYS. You have not lost any time.

Ms. SURLAS. OK, thank you. My name is Debbie Surlas. I am a registered nurse. I had a kidney-pancreas transplant 4½ years ago at the University of Wisconsin. I'm also vice chairman of Patient Affairs Committee of UNOS. I'm on a UNOS subcommittee for patient access to transplantation. And I'm also the immediate past president and executive director of Organ Transplant Support, which has about 800 members on our mailing list, and we're one of the largest independent support groups in the country. We are not financially supported by any transplant center.

I would like to say that I am both honored and privileged to work with an organization like UNOS where I cannot only bring my opinions, but the opinions of the support group, the patients that are on it, the candidates, donor families, and recipients to the Patient Affairs Committee. All the policies of UNOS come through our committee for our input, our opinions, and our vote. I don't know of any other organization where I would have the opportunity to represent this many patients the way I do with UNOS.

I'd also like to say that my organization, my support organization, is extremely active in organ promotion, organ donation promotion awareness. We've also set up programs in the high school to teach children about organ donation.

I'd also like to say that because I was transplanted when I was not extremely critical, that my quality of life post-transplant is what it is today. Most people looking at me have no idea I was as sick as I was. And if I was transplanted at a much more critical stage, I don't think that I would be possibly alive or in the shape I'm in today to be able to touch as many lives as I do touch. All my—almost all my waking hours I'm promoting organ donation, helping patients on the Internet, in our support group. I have been teaching insurance companies about organ donation and transplantation and the effects of the whole thing to help them understand the payment system, et cetera. Thank you.

Mr. SHAYS. Thank you very much.

Ms. CONRAD. Hi. I'm Joan Conrad with the Wisconsin Donor Network. And I have been a procurement coordinator for the last 9 years and have worked as a nurse for 12 years. And I want as a professional just to acknowledge the work that is being done here on allocation is very important, yet, again, we cannot lose sight of the fact that we do not have enough organs to go around. One of the most limiting factors in my profession is access to the donor family, and one of the things that can be so very beneficial is an opportunity for hospital administration and physicians to let the donor professional staff interact with those families at the time of grief and loss. We have done in the procurement world extensive studies that show that families need to be approached in a sensitive manner at the appropriate time with the appropriate terminology and in an environment that promotes a decision that's best for them, yet oftentimes we're not allowed to participate in that discussion due to a fear that we are going to be too coercive or as the TV show "ER" portrays us as the vulture coming in and not actually being on the side of that family making the decision. So we need to focus again on physician education, letting the physicians know that we are there to help and if they are not able to do so, we can approach those families. And if they choose to do so, give them the information so they can do so in a compassionate and sensitive manner. So we can't lose sight that we need to help our physicians and our hospital administration realize that this is an important issue. Thank you.

Mr. SHAYS. Thank you very much.

If we could have group 3 come up.

Mr. DUMEZ. My name is Duane DuMez. I'm a heart recipient 3 years ago, just about 3 years ago. To preface it, I'd like to say I've met the family, and the importance of having it done locally, that's been one of the biggest events in my life. We have gained some dear friends. When we met them we talked to them collectively and individually. When I talked to the youngest daughter alone, she said to me she had been very opposed to her mother donating a heart. But she said the rest of the family wanted to do it, and I knew that was my mother's wishes, so I went along with it very reluctantly. She said would you mind if I listened to my mother's heart? I said no. And she put her head on my chest and she said I've changed my mind. She said that part of my mother is here in you. And she said I've changed my mind on the donor program. I will be promoting it.

As far as another thing goes with the Government, yesterday Russell Feingold was in Sheboygan, and he usually gets crucified on the partial birth abortion issue there, and he defended it by saying legislatures have no business getting in the medical field. That is why they should leave that up to the medical people that are good at it. And now here we are on the other end, we're getting legislation and the Government getting involved in something the medical people should be dealing with. It scares me a little bit because we are not dealing with a rash or anything like that. That's dealing with my life, and I don't want a bureaucrat in Washington deciding what to do with it. I want the people that are dealing with it right here, right now and that can see me and check me, not somebody somewhere else. And it scares me a little bit whenever the Federal Government gets involved in things. Usually things are done very inefficiently and expensively, so I ask you to keep out of it.

Mr. SHAYS. Thank you, sir.

Mr. HACKBARTH. Mr. Barrett, Mr. Shays, my name is Elmer Hackbarth, and my wife is a recipient of a liver transplant. Just stand up there. That's my bride of 36 years. And we have five children. And let me tell you this was a real blessing from the Lord, I would say, that the liver became available for us here. And I have just put down a couple comments here. First of all, with the, all the controversy about Social Security going broke and Medicare having all kinds of trouble, is there a successful program that you can tell us about that the Federal Government instituted that is successful? I can't really think of anything decent.

Mr. SHAYS. Well, let me just say that 60 percent of all the transplants that take place are paid for by your Federal Government. In fact, Medicare, so I do want to say I think Medicare is an outstanding program.

Mr. HACKBARTH. That transplant there was not paid for one dime by the Federal Government money. By Government money. It was all insurance, which I paid the bill for. OK. I have a suggestion for procuring organs. Most of us have a driver's license. What is wrong with saying—we'd probably have to have it come through the State, but let's say let's make a free license renewal if you would put on your driver's license that you would be a liver, I mean an organ donor. People would get out of paying, what is it, $7 or $15 whatever it is. Yes. Whatever it is. I've forgotten what it is. It's been a year or two. But just something that simple you probably could get a lot of people signing up for organ donors.

And my final point is apparently since other areas of the country are envious of Wisconsin's success, why don't they—why don't you guys tell them to come to Wisconsin, study us.

Mr. SHAYS. Before Mr. Barrett asks you a question, I will tell you that is why we are here.

Mr. HACKBARTH. Don't dismantle our system here. We have something that is working.

Mr. SHAYS. Well, that's why we're here, to see how you do it.

Mr. BARRETT. Let me ask you a question, if I could, please. Did you say you had five children or five children so far?

Mr. HACKBARTH. Five children.

Mr. BARRETT. OK.

Mr. HACKBARTH. My friend is kidding me every once in awhile that an 18-year-old liver is hard to keep up with.

Mr. BARRETT. OK. Another point, I'm obviously on the side of the Wisconsin hospitals, but I don't think it advances our cause, frankly, to say that the Federal Government hasn't done anything well because the system is frankly a, it's a contract with the Federal Government, but in essence as Mr. Shays was saying, because of the monopoly conferred upon it, it is an extension in some ways of the Federal Government even though it's operated privately, and I think that our goal for all of us in our community should be to try to get across our belief that this system will work better if the organs stay here. So I don't think that this is one of those issues, and I realize there are issues out there where the Federal Government does this well or doesn't do this well. I don't view this as that type of issue, just so you know that.

Mr. SHAYS. But I do think we both agree that the Government should stay out of it to the extent possible. I mean I do think that it's very clear.

Mr. HACKBARTH. I think that's better left off to a private enterprise, to the individuals of the State of Wisconsin and, hey, let's keep our organs here. We need them here.

Mr. SHAYS. OK, sir.

Mr. HACKBARTH. Hey, if you've got problems in Connecticut, rouse the people up there, do something a little more better.

Mr. SHAYS. We also have problems in Connecticut. OK, thank you, sir.

Ms. STEBBINS. My name is Annette Stebbins. I'm going to be celebrating the sixth anniversary of a liver transplant this Easter. Dr. D'Alessandro had my picture up there, and he gave me the credit for being 51 years, but, however, I got my liver for my 50th birthday, and I thank you and I'll give you a little kiss later on.

Mr. SHAYS. That is a different kind of kiss.

Ms. STEBBINS. Write that down.

I would like to say that I think we are fortunate to have so many wonderful transplant centers across the country, Pittsburgh, Alabama, Wisconsin. I was very fortunate to be living in Madison, WI, which is my umbilical cord for my liver. But I hate to see the system being bureaucratized, and I would like to be able to see rather than punishing the groups that do really well on procurement, why can't we bring up some of the smaller groups. I have people from all over the country call me because they ran into so and so on the airplane who, gee, do you know someone in Madison, WI. I know this, I have people in Florida and Texas and California and on the east coast that I talk to about kidneys, about livers and whomever would call, and I'm happy to do that. The woman I received my liver from happened to be a 26-year-old woman who died in the closing of a C-section after delivering a health baby girl, and I happened to be the very fortunate recipient of it. I'm delighted to have been here today. It was a great education for me. Every day is an education. I don't complain about the rain or the snow. I would like to congratulate our procurement department, and all over Wisconsin they take the time to go to the smallest group in the smallest church, the smallest town, whether it's 5 people, 10 people or 100 people and talk to them about organ donation.

I happened to have a background in marketing and design, and when I received my organ, when I received—had to have a liver transplant and be put on the list, I had terrible insurance problems. Insurance is the problem, and my heart goes out to the woman who lost the young child. When you are not well and your family is involved in emotional, financial trauma, it is very difficult to make decisions. We need the insurance people to listen to us. They said you have to have so many refusals, you go back to them and they say, "Well, we will get back to you in six weeks," you say, "I will be dead in six weeks." I just finished a 4-year stint on the Hurst (phonetic spelling) Board Health Insurance Risk Sharing Program for the State, so I can tell you that it's a very difficult situation with insurance for all of you. I wish everyone here well. I thank you for coming and talking to us. And I wish we'd kind of look into an implied consent even in some way for our country. I realize that's another pail of worms, but it's something to talk about.

Mr. SHAYS. OK. Fair enough.

Ms. STEBBINS. Thank you.

Mr. SHAYS. Yes, sir.

Mr. JONES. Mr. Chairman, I received my heart in November 1993, from the University of Wisconsin. I think you are doing an investigation of this problem that is admirable, but I also think that it's rather obvious and that anybody with common sense, with the exception of Ms. Shalala possibly, can see what the effects of her proposals will be on this program. It is obvious to me that the effects will be a net outflow of organs from low population areas to high population areas. Areas such as Wisconsin, North Dakota, Iowa, et cetera, will end up in a period of time with a net outflow of organs. I being a resident of Wisconsin naturally don't think this is a good situation. I've got so many thoughts that I find it hard to correlate them at this point, but one of the things that was brought up during the day was the possibility of racial discrimination in the process. I don't know about that, but I don't think that that exists to a very great extent. If there is discrimination that exists, it's economic discrimination. The fact is that in most cases, with the exception of the people that the Government pays for, the only people that can get a transplant of any kind are the people that can afford it, either through their insurance or through their personal finances.

In my case, as an example, before I was put on the list, there were two requirements to be put on the list. You either had to deposit 100,000 in cash or you had to have a letter in writing from the insurance company stating that they would pay the bill when it was all done. In my case it turned out I had a number of complications, so in my case it amounted to a figure somewhere between 450 and 500,000, and to this day it's still adding up. So, again, as far as, now as far as the donors, another thing that——

Mr. SHAYS. Try to wrap up just a little bit.

Mr. JONES. OK. One of the things that I wanted, that the donors' families, I think one of the things that they are primarily interested in is that their gift is going to somebody and is going to do some good. And if you give it to the sickest, that is not always the case. It will be wasting many organs, and from the donor's standpoint, it will be a loss to their heart that they have donated something and it's gone to a person that didn't survive and in that way they have a loss. Thank you for your time.

Mr. BARRETT. I just want to make a comment. I don't know to the extent that the new rules deal with this, but I talked to one other person today that talked about the lists and the inability for people who don't have the resources to get on the list. I am concerned that there should be no financial barrier whatsoever to get on the list. And that is something I'm going to look into further. Thank you.

Mr. ENK. Good afternoon.

Mr. SHAYS. Good afternoon.

Mr. ENK. Congressperson Shays, Congressperson Barrett, friends, my name is Scott Enk. I'm a life-long resident of the city of Milwaukee and the State of Wisconsin who, like many people, used to be very passive about organ donation. I really believed that signing my donor card and talking it up to people who seemed resistant was enough. It's not. It's very obvious that when you look at organ donation from perhaps an economic standpoint, which is perhaps the most dispassionate way to look at a scarce good, there is a supply side and a demand side and as people like Mr. Vorus (sic) of the Adult Wisconsin Donor Network, and—Volek, Mr. Volek, and Ms. Little-Conrad both pointed out, the real problem, as many speakers also point out, is with the supply of organs. I would hope that you and other Members of Congress start taking a very close look at how to increase the supply of organs by considering some of the suggestions you have heard today, perhaps going if not all the way, too, in the direction of a presumed or implied consent system, but that's a completely different set of issues.

What we are looking at here is the demand side. When it comes to that, we know what works. You have heard it reported here that the vast majority of Wisconsin residents felt that—56 percent, felt a preference should be given to patients at Wisconsin hospitals. Now, the people in Pennsylvania, some of the people in Washington, DC, might call that provincial, but it works. Wisconsin has one of the better organ donation programs in the country. And we do not think—instead of exporting livers to States which do not have as good an organ donation programs as we, why not export our ideas. Why not bring them up to our standards rather than be penalized for our success, because otherwise you have no incentive for those other States to really improve.

We have all heard about the concerns expressed about other transplant centers closing, about people having a hard time traveling, about the possibility of livers being wasted on retransplantation. As long as these serious concerns exist, and they are very legitimate concerns, should we follow the basic medical maxim, first do no harm. Let's not rush into this, these changes. Let's take a very good close look at them, and if need be, go very slowly, if at all, before destroying a system that we know works.

Mr. SHAYS. Thank you, sir.

Mr. ENK. Thank you.

Mr. SHAYS. All right, sir.

Mr. LAMM. Yes; my name is Frank Lamm. I'm a kidney transplant recipient and I also have four children, three of whom stand a 50 percent chance of having the same kidney disease that I have. Under the new proposal I'm not sure that I would be standing here because after my kidney transplant, I had a series of rejections that if I was a lot sicker, I probably wouldn't have survived. There is a lot more that goes into a doctor's determination and the whole assessment as to whether or not an individual is ready to be transplanted than a series of numbers or filling in a few blanks that might be the cases in a Federal procedure. I really believe that decisions like this should be made closer to home. I also believe that if there is—there's an old saying that if something ain't broke, don't fix it, and at least in Wisconsin, this system is not broke. This works fine. This works as—about as well as one could hope, and I was somewhat disappointed to hear the Federal testimony to the fact that they felt that this was unfair. I think that this system is as fair as a system, a human system could be, and regulations would not necessarily make a more fair system. Of course, the problem is there aren't as many organs as are necessary to solve the problem, and until that case and until the day comes that there are more organs, everybody who doesn't get one is going to feel that the system is unfair. So I think efforts should be placed someplace other than trying to fine tune and manipulate the system that we have right now.

I do also think that if the subcommittee is interested in making some changes, they should consider maybe reducing the impact that a large center has such as Pittsburgh and give more emphasis to the regional systems and create in fact more regional systems throughout the country that can be as good as the one here in Wisconsin.

Mr. SHAYS. Thank you, sir.

Mr. LAMM. As far as tax incentives are concerned, I really think—or as far as other incentives are concerned, I think they should consider tax incentives and perhaps something in the form of paying for burial benefits also. Thank you.

Mr. SHAYS. Thank you very much. I think we're with group 4; is that correct? I appreciate everybody's patience in waiting. This is very interesting.

Mr. FISKE. My name is Charlie Fiske. I'm from Boston. The last time I was in Milwaukee was November 5, 1982. My plane had stopped here just briefly as I was on my way to the University of Minnesota because my daughter who was the most needy patient and the youngest liver transplant patient in the country was waiting for an organ to be flown from Primary Children's Hospital in Utah, so she could receive a life-saving organ transplant.

In 1983, I was in front of Congress twice. In 1990, I was in front of Congress. In 1993. I testified at the HHS hearings in December 1996. Also served on the UNOS board for 4 years. I'm also one of nine general public members of the UNOS Corp. I thoroughly support the Department's initiative to make it a level playing field. I cannot say that enough times. I have said that publicly, I've said it privately. I have always advocated for a level playing field.

Under the current system my daughter, who is now age 16 and a testament to the fact that liver transplantation works under the current arrangements, would not be alive. Under the current system that's being proposed, she would have an equal chance and we came from Boston, went to Minnesota and the organ came from Utah. That was 1982. The Department has made the right step and, again, I thoroughly support and encourage the members of the committee to look at what the Department has said because I as a patient and a father of a patient advocate thoroughly support what the Department has done. Thank you very, very much.

Mr. SHAYS. Thank you very much, sir.

Mr. OLDAM. My name is Paul Oldam. I'm chairman of the UNOS Patient Affairs Committee. More importantly, I'm also a heart transplant recipient. I'll try to be very ecumenical in my comments today because I received my transplant at St. Luke's Medical Center in Milwaukee. My wife's family is from Pittsburgh. And my father was born in Beacon Falls, CT. So I think I've got all three bases covered. There seems to be some concern expressed here that there is perhaps insufficient patient input into UNOS' activities and that perhaps it operates in a partial vacuum. In my opinion, that's extremely far from the truth. My committee is made up of patient recipients from each of the 11 regions of UNOS. They are not paid by UNOS, they're not employees, they're purely volunteers, and they are interested in furthering transplantation. That's their sole motivation. We consider every policy which is proposed to change in UNOS or any new policy. We review it thoroughly and I report personally to the Board of Directors of UNOS. There is, I think, ample patient access into these problems and into this discussion, and it's certainly not operating in a vacuum, I can assure you.

At our last meeting, which preceded by about a week and a half, the actual regulations which were just published by the Secretary, we discussed what we knew of the regulations at that point in time, and I can tell you that the committee unanimously feels that UNOS should be the principal allocator of organs in the United States. Not to say there shouldn't be some appropriate Government overview, but UNOS is made up of patients, professionals, transplant professionals, physicians, surgeons, and I think in our opinion is far better suited and more able to determine organ allocations than any Government entity is. Thank you.

Mr. SHAYS. Thank you, sir. Thank you very much.

Ms. WAGNER. Good afternoon. My name is Virginia Wagner. I'm a physician assistant. I work at Children's Hospital in the emergency room. I'm also a patient, and in 1979 my dad, 1973, excuse me, my dad was a patient at the VA Hospital here in Milwaukee. He was in renal failure, and my sister and I were both in our early twenties. As my dad's health declined, we were told by the doctors at the hospital that a committee at the hospital had met. We didn't know this committee existed. They had met. They had reviewed my dad's case, and they had decided at that time that he was not a candidate for dialysis or the experimental process of transplantation. At that time dialysis was not covered by the Federal Government. There were few machines and a process had to be decided on, who was chosen, and who was not. My dad was not chosen and he died that summer.

That summer our whole family was checked for kidney disease, and I was determined to have adult onset polycystic disease. It is now 25 years later. My kidneys are failing. I will be on dialysis probably in the next few months. And now I'm faced with the fact that another committee is deciding my fate, a committee that by happenstance I happen to run across today. I didn't even know you were meeting here until I came in the building. So I'd just like to have that input.

I can't tell you how to make these rules. It's above my statistical knowledge to figure out what is going to work out best for patients. I can just tell you it's very hard sitting here having someone else decide. It's like you are in front of a giant slot machine and the wheel is pulling down and you watch those wheels spin and you wonder are the three balls going to come up for me or not. The odds are not great, and if you start playing around with the system, you upset everyone's lives, and you don't know how it's going to turn out either. So just be aware that our lives hang in the balance when those wheels are spinning, and I don't like committees deciding what happens to my life. I have been through that once already. Thank you.

Mr. SHAYS. Thank you, ma'am.

Mr. JONES. I'm Alvin Jones. I'm from Mount Horeb. And I had a liver transplant. It will be 2 years, May 22. And I was in the hospital for the month of March, and the first few days I wasn't expected to live, and on the 5th of April I got the word that I was on the transplant list, and on May 21, I got the call for a liver. And, anyway, my liver came from the Swedish American Hospital down in Rockford, and when I went in that night, I went in with a smile and a positive attitude and God was behind me. Thank you.

Mr. SHAYS. Thank you, sir.

Mr. CRONCE. Chairman Shays, Congressman Barrett. My name is John Cronce. I'm from Milwaukee. My daughter works at St. Luke's Hospital. My wife, however, is a patient at the UW Hospital in Madison. She received a heart and kidney 2 weeks ago. For the past 5 months I have lived with a community. It is a community composed of three major components at the moment. Heroic doctors who practice an art of medicine. She was not listed at some institutions. Her heart was too strong, her kidney was too weak, her heart was too weak or whatever. She was listed there. A heart surgeon began an operation when others thought he shouldn't. He was willing. He succeeded. The art of medicine.

The patients that I have lived with, we have lived with for 5 months. Do you know what they do when the word is out so and so's got their heart? They lined the halls on either side and they clap and applaud and cheer that patient on. Then they return to their rooms and wonder should I be happy? Why am I sad? That roulette wheel I just heard about, I know that wheel.

A day or two later these patients, Frank and Maynard, who have been there over a year, have watched 70 people come and get hearts while they have waited. Their number has not come up. Others were sicker. The blood type wasn't right. They understand this. They understand maybe it will be their turn, maybe. They understand it might not.

The donors. 10:30 in the morning I received a call about what happened between 6 and 10 that morning someplace. A nurse approached a family at the moment of death and found generosity, light, life for another family, nurses whose names turned out to be Teresa. I don't know Teresa. A nurse manager who worked with an organ procurement organization that worked years and years to develop a relationship so that this could happen. There are, there's a family out there. Attorney Shapiro talked on why don't you pay for organs. Because there's something altruistic about this. This is the most human, humanizing experience. This is the most personal experience. Public interference in this personal activity must be done with extreme caution. Thank you.

Mr. SHAYS. Thank you, sir.

I really appreciate the cooperation of everyone who's—do you need a second here?

[Discussion off the record.]

Mr. SHAYS. I will call on group 5. I appreciate the cooperation of everyone. You've made this work very nicely. If group 5 could come forward. Are we all set? Thank you.

Welcome, sir.

Mr. KRALL. Hi. My name is Dan Krall. I received a heart July 1, 1994, and I waited on a transplant list for over a year, and the last month or so I spent in the hospital waiting for the heart in critical condition. And breathing my last gasp and waiting to die and having a hose sewn into my body so that I could wait for fluids to come in to make my heart function more properly is a ghastly experience. And probably the most terrifying part was when the nurse came in and told me that there was a heart available. It was understanding that I would live and the other side of that was understanding that someone else had to die for that that I could be alive. And the important thing was to me not where it came to, not where it came from, but that it was going to be available to me. And since then I have worked a lot with donor awareness groups and I've spent a lot of time and I've asked probably hundreds of people to sign their donor card. And the most important part I think is that there's a great deal of education necessary to educate the people of this country, this community and this country that donor awareness, donating organs is a good thing, it's a good thing for everybody. People fear that, people are afraid that their bodies are going to be disfigured, that they're not going to be OK, that it's going to cost them money. It's a very simple educational process that I think we need to work more on, more on to—there we go again. To—so that people will sign their donor cards and this problem would then be eliminated.

In the interviewing of all of those people, no one asked me where the organs were going. They wanted to know how they were going to be and if they were going to be OK and if their family was going to be OK with it. And that's the—the reality of it is giving the blessing and the people that I know that have signed their donor cards in that conversation, it's the blessing that we can give to someone else in our passing. Thank you very much.

Mr. SHAYS. Thank you very much.

Ms. MOORE. My name is Kathleen Moore, and I received a heart transplant January 1, 1993. So I'm technically 5 years old. I also am a health care professional, and so I am aware of many of the medical and ethical issues that surround transplantation and also the other health care issues.

Because I have had a heart transplant, I did very well, I was able to return to work 6 months after my transplant and I continue to work full time. I also do try to volunteer and promote organ donation and do talks at schools, schools of nursing and also different groups. I'm promoting organ donation. And like Dan said, it's a wonderful thing to be able to wake up in the morning and to know that you are alive and to pass that information on to other people.

I think one of the important factors also is that not only to communicate to sign your donor card, but also to communicate that decision to your family and to your loved ones because as it was brought out in the panel, that many of these decisions sometimes families can reject because they do not understand.

Also, I think it's important that there is good communication on the outcome and the effect and the quality of life of a heart transplant. I know many times when I talk to people, they will say you are a heart transplant? You don't look like one. I'm not quite sure what they expect to see. But, anyway, I think people need to know that we do have quality of life and that we are worth the time, the effort, the gift of life and the financial moneys and efforts that are put into us.

One of the other points that I would like to talk about or mention that I thought about very much during the panel discussion was the issue of the insurance coverage. I was very fortunate that when I had my transplant, my insurance company did not give me much grief before my transplant. Now I go through continuous grief. I have had to change insurance companies three times because they raised the rate. My employer nor the employees can continue to absorb that. I have to continuously fight for the proper care in the transplant community and with the hospitals and physicians because there is a lack of understanding of the need for continuous, accurate and professional follow-up.

So I guess in closing I would like to say I feel that there needs to be some more consideration and work done in those areas, not only to promote transplantation, but to keep those of us who have had transplants alive and well. Thank you.

Mr. SHAYS. Thank you very much.

Ms. MAYES. Hi. My name is Barbara Mayes. I received a heart transplant 3 years ago when I was 24. I just wanted to point out the fact I used to live in Texas and I relocated up here to Wisconsin, mainly because I have family up here and everything, but when I was in Texas, they wouldn't put me on a waiting list. And I knew I was getting worse and worse and, of course, no one would admit it. So I decided to take my son, he is 8 now, but he was younger then, and we uprooted everything that we ever knew and moved up here to Wisconsin, mainly because I had family up here, but I knew the hospitals up here and their qualities and they put a lot of work into them. So I felt comfortable being here.

When I got here, unfortunately, I got pregnant, but—so we had to wait, but as soon as I had my son, my heart gave out having him and I was immediately put on a transplant list, and I was blessed that I was only on the transplant list for 10 days. Everybody is amazed by that, including myself. And the thing that I attribute that to is the work that the Wisconsin Donor Network does up here and everything that the volunteers do. Of course, I volunteer now and it's just, my feeling is that if we mess with it, it's going to take the lives around here and I don't—it's not that I don't feel sympathy for the other places, because I do because I was there, but I think we need to use Wisconsin as an example and not tear it apart, is my main concern that we are messing with something that is proven to be good, so I just don't want to see that torn apart. And that is about all I have to say.

Mr. SHAYS. Thank you very much. May I ask you a question?

Ms. MAYES. OK.

Mr. SHAYS. Do your relatives who live here have that same wonderful accent that you have?

Ms. MAYES. No; I was the only one that was down there long enough to get it. I just can't get rid of it.

Mr. SHAYS. Thank you.

Mr. BARTER. I'm Elianor Barter. I had my transplant, my heart transplant January 11, 1995. I wasn't a good candidate and that I don't know how anybody can decide that for you. I got my transplant and developed deomberay—phonetic spelling—which left me paralyzed from the neck on down. With a lot of work at Froedtert Hospital, about 5½ months of therapy, I now talk, walk, do everything that the rest of you take for granted. So I also am a volunteer for Wisconsin Donor Network and they do such a wonderful job in the State of Wisconsin. I would like them to be used as an example by the other States. Thank you.

Mr. SHAYS. Thank you very much.

We're with our last group.

Ma'am, we need you to bring the card in. We need you to give Teresa the card. Thank you. That's for our transcriber.

Our last group now, our group of six, we will be concluding with this group because we have a plane to catch. We're going to Kansas for another hearing, and the staff has to take things down. So we have group 6 now?

Let me at this time—well, people are here, so we're all set.

Sir, you didn't butt in line, did you? I'm teasing. I'm teasing. I'm teasing. You come right up. I couldn't resist because you looked a little guilty.

Mr. BLEVINS. I just wanted to show off my T-shirt.

Mr. SHAYS. I like your T-shirt. And I like your smile.

Mr. BLEVINS. OK. My name is Daniel Blevins. I'm from Madison, WI, here. I received my transplant in January this year and I'm doing really good. I feel really good, and everybody has been behind me. My family has been behind me. They came all the way from California when I was sick and everything just turned over like over night. And I'm good and healthy now. Thank you.

Mr. SHAYS. Great. Thank you, sir. Thank you for testifying.

Ms. BAUMGART. Hi. I'm Marie Baumgart and I had a liver transplant December 27, 1997, and I'm doing quite well. I think one thing that has not been mentioned very much is the continuous care that is necessary after a transplant. It's not just the transplant and the hospitalization that occurs immediately after, but the followup which is so very, very necessary, and I have had some problems with that, so I know having to come back and have a little more surgery, to suffer rejection and to catch that right away so that it can be done on an outpatient basis, which is also physically economical. Then I would also like to say that as far as regional areas, very important as far as the support system, the husband and the family, because they need help as much as the patient themselves and they need to have people around them who are supportive in this real trying situation emotionally for them. Thank you very much.

Mr. SHAYS. Thank you very much.

Ms. RATHER. Hi. My name is Nancy Rather. I had my liver transplant here at Froedtert on Halloween of 1996. I was fortunate to be able to work up until the time I received my call to come in, which helped keep me, my mind off of this cloud that was hanging over me for a transplant. I was in the hospital for 10 days. I was back to work full time 3 months later. And I believe that we should keep the system we have but educate the Nation to sign your donor cards so we can have enough organs for everybody that needs one. Thank you.

Mr. SHAYS. Thank you very much, ma'am. Now——

Mr. ZIEHR. I'm going to speak, OK.

Mr. SHAYS. OK. Well——

Mr. ZIEHR. My name is Jim Ziehr and this is my wife Colleen and this is my son Michael.

Mr. SHAYS. Hello, Michael. What is your name?

Mr. ZIEHR. We have been doubly—Jim Ziehr.

Mr. SHAYS. Jim. Nice to meet you.

Mr. ZIEHR. We've been doubly blessed, we have two children that have had liver transplants, so we have been through the situation several times.

First of all, I'd like to start off by saying I listened to some of the statistics this morning, and if I was running my business the way I heard the 7-year-old statistics that we are making decisions on here, I think I'd be out of business. And that kind of appalls me because I'm a taxpayer. So I didn't realize the numbers were that old. Let me just tell you a little about our background. Michael and Benjamin—we have three boys and the middle boy doesn't need a transplant, were born with Alpha 1 antitrypsin deficiency, and they were, we were taken to Madison, WI, and we were diagnosed that we needed a transplant down the road sometime in late grade school. Benjamin, our oldest, who is 9 years old now, received his transplant in August 1995.

One month later Michael got an opportunity to go through it. He was 2 years old at the time. However, due to complications with his first liver, which brings me to one of my other points, which is the fact that we talk about regional and national donation. There are different procurement methods that occur across the country by the procurement doctors who go out. And my concern is that if we don't standardize some of those practices—Michael's liver came from a regional donation. He had problems with the artery that goes into his liver, and we feel that the reason that it had problems was because the liver wasn't procured by the doctors who were actually going to use the liver, so there has to be some consideration of if the doctor who gets it knows exactly what organ is going into Michael's body, knows the size of the cavity, knows exactly what he is looking for. Michael needed a second transplant because of that situation. The second time around Dr. Kaloyoglu in Madison specifically asked for an artery to be taken out of the boy's leg that was the donor the second time so that they could make compensation for that.

If you are doing organ donation from out in Utah or California, bringing it to Wisconsin, those doctors in that 12-hour period of time will not have time to do those kind of quality decisions in their medical decision, and that is a concern of mine that you need to take into consideration there.

The other thing that I'd like to bring up is, along with that, we need to stress organ donation. Everybody talked about it. And the reason is because statistically one-third of all the people who are organ donators, donation people, aren't even asked. The situation in Pennsylvania, when they put their program in that Donna Shalala and President—or Vice President Gore is now pushing forward, their model program had 44 percent donation increases during that time. I didn't hear that statistic at any of the panels. Forty-nine percent of people had, organ donations went up during that time, 44 percent more donors, 49 percent more. So if we are short and 4,000 people died, that would mean 2,000 more people a year wouldn't die because of it. So we really do need to stress that procurement is the issue. And I apologize for rambling on about this. That is very important to me.

Second, I believe in democracy. As we educate young men and woman who come out of these transplant centers, my concern is that where are they going to go practice if we put out—the smaller transplant units go out of business? We need to continue to develop those young doctors, and as we push them out, with the current UNOS program, the number of transplant programs have gone up 124 during that same timeframe during the last—since they put those rules in. But what is interesting is the University of Pittsburgh's number of organ transplants that they have done has gone down by half. So I have a question about that. Why would they go down by half? Is it because they don't have a procurement program that is present for them? And I think that that needs to be brought forward from that standpoint.

Mr. SHAYS. Thank you very much.

Mr. ZIEHR. Yes. Do you have anything to add? Thanks.

Mr. SHAYS. Let me just ask, Michael, I have this gavel, and I would love to end this hearing in a second and would love you to be the one to hit the gavel here if you want to come on up here. If you want. You don't have to. But first Mr. Barrett just wants to make a comment and then I'll——

Mr. BARRETT. I just want to say that I'm very humbled and proud to be a Representative in Congress, and just as all of you who have had organ transplants feel lucky when you get up, I feel lucky to have this job, but there are some days when you feel luckier, and I think today's hearing is a time when I'm going to leave and feel good about the community, the greater community that I represent because I think if there is a message that has come through today, it's that the people of Wisconsin care about other people, and what we would like to see is we would like to see other States emulate the job that we have done, and so I want to thank everybody. I think that my friend Christopher Shays saw a good glimpse of Wisconsin and what good people we have here. So I want to thank all of you for coming and being a part of this hearing today. Thank you.

Mr. SHAYS. Thank you. Let me say that I'm always proud to be an American, and when I come to a community like this, I feel even more proud. What a great Nation we have, and how nice you were to participate in this hearing and to be so attentive and so cooperative, and I learned a tremendous amount. I want to first thank your Congressman. I happen to be a close friend of Tom's. He and I work on a lot of issues together, not just these issues, one of them happens to be campaign finance reform which he and I have worked long and hard on. Other reforms like getting Congress under all the laws that we impose on the rest of the Nation and lobby disclosure and gift ban legislation. All of this I worked with Tom on, and I just have a tremendous appreciation for the job he does.

And I also want to thank our court reporter, Colleen Reed, for her cooperation today. You can put that in the record. And to our clerk, Teresa Austin. Thank you very much, Teresa. Our subcommittee staff. Anne Marie Finley, by the way, is a home product.

She's a Milwaukee lady. Her mom is here, I think. Is your mom still here?

Ms. FINLEY. She had to go to work.

Mr. SHAYS. She had to go to work. OK. People in Wisconsin work. But I just love the fact that she was here and she is our key person on health care issues. And Cherri Branson and—also on the committee. And thanks—Cherri, rather. And Tama Mattocks and Terry Perry and Ed Walz from Mr. Barrett's personal staff. I also want to thank Donna Gissen—phonetic spelling—who is assistant vice president of Office of Planning and also Sandra Terra Nova—phonetic spelling—and with that I would say the hearing is adjourned. Would you like to hit the gavel on that?

[Whereupon, the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

Dear Honorable Donna Shalala, Secretary of U.S. Health and Human Services:

We, the undersigned, feel the Organ Procurement and Transportation Network (OPTN) should remain as it was established under the 1984 National Organ Transplant Act (NOTA).

We, along with all major professional societies, including The American Society of Transplant Surgeons and American Society of Transplant Physicians, as well as recipient and donor organizations, feel the current allocation policy regarding donated organs should not be changed.

Name	Address
[illegible]	W248 S1620 Scotland Dr. Waukesha 53182
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GERALD HERZBERG	10240 S. YOUNG ST WIS. RAPIDS 54494
Richard H Mosey	3030 S 56 Mil, Wis 53219
Paul Ingram Jr.	3718 N 53rd Milwaukee 53216
[illegible] McWhorter	7405 No. 38th Milw. 53209
[illegible]	527 [illegible] Dr Sun Prairie 53590
Terry Woodward	109 Belmont Rd Madison 53714
[illegible]	W9005 Brazelton Dr Kewaskum WI 53040
Donna Buczek	W3766 Midland Dr. Campbellsport Wi 53010
Carol [illegible]	1808 Plymouth St New Holstein WI 53061
Carolyn Werth	8113 W Greentree Rd Milw 53223
Irma Koscielak	609 Menomonee Av So Milw Wi 53172
[illegible]	2314 ATWOOD AVE MADISON WI 53704
Claude Carpenter	817 Doty St. Eau Claire WI 54701
David Vaughn	2120 S. HAWTHORNE PK DR JANESVILLE WI 53545
[illegible]	128 WINESAP DR JANESVILLE WI 53545
[illegible]	240 State Rd 73 Bancroft WI 54921
[illegible]	920 North 58th St Mil WI 53213
[illegible]	6597 W County Line Rd Brown Deer 53223
[illegible]	2251 E. Broadway Dr. Appleton WI 54915

The United Auto Workers Region 4 Wisconsin Community Services Council hopes that we have provided you with a helpful and appropriate form of public comment.

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Helen Miller	3201 S. 68th Milw WI 53219
John Weinkauf	5412 W. National Ave West Milw 53214
Mike Bink	3207 S. Pine Avenue Milw. WI 53207
[illegible]	4425 N 53rd st 53218
Bradley Schurz	5268 S 13 MILW 53201
Mary Hawkins	4970 N 58 St Milw WI 53218
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Bonnie L. Dunford	4380 S. 46 Greenfield 53220-3644
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Sam Francis	1217 Burton Beloit Wi 53511
Helen Miller	3201 S. 68th Milw, WI 53219
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Elaine C. Bastone	E1156 Rodlley Rd. Waupaca, Wi 54981

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Arthur [illegible]	N64W24385 Ivy Ave Sussex WI 53089
Cheryl [illegible]	1010 E. Stonegate Dr, Oak Creek, Wi 53154
[illegible]	9137 W. Capitol Dr. Milw., WI. 53222
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Rowdy H. [illegible]	1442 State Road 83 Hartford, WI 53027

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Glenn P. [illegible]	380 Cardigan Ct. Wales Wi 53183
Alan D. [illegible]	S30W20838 Sunset Dr. Waukesha WI 53188
Robert [illegible] Jr.	W. 5884 Sum Rd. Juneau, Wis 53039
[illegible]	3998 Kingsway Slinger Wisc. 53086
Edward A. [illegible]	N72 W13906 GOOD HOPE Rd. MENO. FALLS, WIS 53051-4661
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Betty Phillips	3060 N 28th Milwaukee Wi 53206

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04-14-98 12:29PM P013 #36

MEDICAL
COLLEGE
OF WISCONSIN

M. B. Adams, M.D., M.S.
Professor & Chairman

C. P. Johnson, M.D.
A. M. Roza, M.D.

Department of Transplant Surgery

April 8, 1998

The Honorable Congressman Thomas Barrett
135 West Wells Street
Milwaukee, WI 53203

Dear Congressman Barrett:

I am writing in opposition of the proposed plan final rule put forth by Donna Shalala in HHS regarding organ allocation. I am a transplant surgeon and run the Abdominal Organ Transplant Program here at the Medical College of Wisconsin in Milwaukee. We do liver, kidney, and pancreas transplants in our program and service the people of Southeastern Wisconsin.

While most of what is published in the final proposed rule is what has been developed painstakingly by UNOS over many years, there is a radical departure regarding the issue of organ allocation. As you are aware UNOS has been a voluntary organization which has consumed hundreds of thousands of hours of time of health professionals over the years working painstakingly at many issues relating to transplantation and organ allocation and distribution in the United States. Our current system, while not perfect, has been carefully designed and is in constant evolution based on hard data which has been carefully accumulated over many years and analyzed and reanalyzed many times.

I find it puzzling and alarming that while HHS is delayed so long in coming out with a proposed interim role and has only apparently been stimulated to do this through political pressure of a few large centers doing liver transplantation in this country which will essentially result in several very detrimental forces coming into play in the United States. As you are aware, the rule charges UNOS with first coming up with a system to reallocate livers within a very short time frame but then to be followed by other organs within a year.

Although many people have been led to believe that the sick patients do not get an equitable chance of getting liver transplants in a short time frame, this is in fact not true. Patients at the highest statuses who are in immediate danger of loss of life without a transplant are transplanted within a very short time, and the time does not vary across the country. Patients in status 2A, which is the next sickest group, also have a relatively short

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time frame which does not vary that much. Also, as you may not be aware, the number of people who die while waiting for a liver transplant is to a large extent people who are at home stable who die suddenly and unexpectedly and are not in fact that sick prior to their deaths. This accounts for almost half of the deaths on the list, i.e., in status 3.

Shipping of livers to the sickest patients would substantially increase cost and decrease the chances of success because these livers would have prolonged ischemic times and would more often fail and require re-transplantation. Although the University of Wisconsin solution was an advance in terms of our ability to preserve livers, a heavy price is paid if preservation extends beyond 6 to 10 hours which would almost always occur when organs are shipped.

A second issue which is even of greater concern to me is that myself and my colleagues in the State of Wisconsin have worked tirelessly for almost 30 years now to promote organ donation in Wisconsin. We speak to this issue every chance we get and have given innumerable talks to hospital staffs, ICU's, Emergency Rooms, etc. regarding the need for organ donation and referral for potential donors

We feel, as do most transplant professionals in the United States, that organ donation is largely a local phenomenon. This is borne out by the fact that states with the best organ donor rates, of which Wisconsin leads the country, have put considerable effort into accomplishing this while the states that have lower donations have less of a history of this type of effort. Donor families largely donate because they feel that there are people in their community that need organs to survive. If this stimulus is removed, we feel that organ donor rates will drop and there will be less incentive for donor families to consider this life saving gift at the time of their greatest sorrow.

While the transplant operation is important in the overall picture, an additional more important factor is the availability of health care for these transplant recipients following the actual operation. It is difficult to obtain quality health if a patient is far from a center that knows them and is used to dealing with them as a patient and their individual problems and concerns. Additionally, requiring families to travel far distances as is frequently mandated by HMO's and insurance companies based on where they can obtain the services at the lowest price, and this puts a huge stress on families and patients' support structure as well as ruling out that possibility for people without adequate financial resources.

While Donna Shalala has publicly stated that HHS has no intention of taking these decisions out of the hands of medical professionals, in fact, the rule does just that. The system would be best served and would result in the most successful transplants if it was truly left to medical professionals and it should continue to be so into the future.

This rule would result in closure of a significant number of programs of which mine is one. This would result in not having those vital services available to people at a local level. A state such as Wisconsin with a smaller population but excellent records in organ donation and transplantation would be severely disadvantaged by this change.

I appreciate your willingness to consider these views. I will be at your disposal if you would like further conversation or documentation of these issues.

Sincerely,

Mark Adams

Mark B. Adams, M.D.
Professor of Surgery

MBA:kml

SA

SURGICAL ASSOCIATES, S.C.
GENERAL AND VASCULAR SURGERY

JAMES P. BINDER, M.D., F.A.C.S.
CHARLES R. ALDEN, M.D., F.A.C.S.
MARK W. ASPLUND, M.D., F.A.C.S.
SALLY S. MATTINGLY, M.D., F.A.C.S.
TODD M. BAYER, M.D.

April 1, 1998

Subcommittee on Government
Reform and Oversight
ATTN: Christopher Shays, Chairman
c/o Tom Barrett
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

To Whom It May Concern:

I read in the paper recently of Donna Shalala advocating announcing the new rules for organ allocation and sharing. This raised some red flags in my mind, and then this was further raised by a letter I received (copy enclosed) from Dr. Mark Adams, Professor of Surgery, at the Medical College of Wisconsin. I know Dr. Adams professionally as a very fine transplant surgeon at the Medical College.

My interest and opinions in this are more than just casual. I have completed a multi-organ transplant fellowship at the University of Pennsylvania and headed for a time a transplant program at the Iowa Methodist Medical Center in Des Moines, Iowa. I am fully aware of the politics behind this situation.

I have agreed with Dr. Mark Adams's assessment of this new rule, although I am not familiar entirely with it. His points I would agree with. Regarding point #1, I am concerned about outcome. Our program in Des Moines had a very short waiting time, and we were very active and efficient in a private setting with obtaining organs, especially in liver transplants. I believe that transplanting earlier in the disease process may actually be a more successful way to transplant these people, and funneling organs to centers who have the sickest patients lined up in their intensive care units would have lower overall success rates, increased costs, and increased rates of failure.

WAUSAU HOSPITAL / 425 PINE RIDGE BOULEVARD, SUITE 200 / WAUSAU, WISCONSIN 54401 / (715) 848-9090

I strongly agree with point #2 that having the organs not used locally would significantly decrease local incentive for donations and reward to the local institution. The donation rate in Des Moines, I believe, was increased by the fact that the organs were going to be used locally.

Point #3 is clearly present as we had much conflict with the University of Iowa, as before our center was opened, the patients and the donors came from that large population based area.

Regarding point #4, my experience with UNOS is nothing short of professionalism. I perceive that government involvement and mandating of this as doing nothing, but usurping their long term commitment to fair organ procurement and sharing.

On a more personal note, I believe that my father would not be alive today without the current organ procurement system. He received a heart transplant at the University of Wisconsin approximately two years ago. He had progressive heart failure from ischemic cardiomyopathy. He waited as an outpatient, I believe, about two years on the list. His health deteriorated to the point of needing hospitalization and chronic Dobutamine infusions. His in-house hospital stay lasted, I believe, about three months waiting for an organ.

The University of Wisconsin system, according to the statistics I have seen, has the shortest wait for a heart transplant and, hence, procuring the freshest organs. In any other system, I believe he would not have survived long enough to obtain his heart which was provided, I believe, just in the nick of time. I think to have the Federal Government step in and force local OPO to ship their viable organs away from local needy recipients would be a crime, and I would guess that if this system would be intact, my father would not be alive today.

Therefore, I have very strong opinions about any new rules that Donna Shalala plans on implementing. The guise of price cuts at centers of excellent, I have seen in several areas of medicine, and I find all too concerning that this now becoming an issue with transplantation.

Sincerely,

Mark W. Asplund, M.D., F.A.C.S.

MWA:ja

cc: Mark Adams, M.D.

SA

SURGICAL ASSOCIATES, S.C.
GENERAL AND VASCULAR SURGERY

JAMES P. BINDER, M.D., F.A.C.S.
CHARLES R. ALDEN, M.D., F.A.C.S.
MARK W. ASPLUND, M.D., F.A.C.S.
SALLY S. MATTINGLY, M.D., F.A.C.S.
TODD M. BAYER, M.D.

April 6, 1998

Subcommittee on Government Reform and Oversight
ATTN: Christopher Shays, Chairman
c/o Tom Barrett
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

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Continued...

Subcommittee on Government Reform and Oversight
Page 2
April 6, 1998

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Sincerely,

Mark W. Asplund MD FACS

Mark W. Asplund, M.D., F.A.C.S.
General & Vascular Surgeon

MWA:ja

cc: Mark Adams, M.D.

MIDWEST
NEPHROLOGY
ASSOCIATES, S.C.

James Brandes, M.D.
Amir Daniel, M.D.
Claire Fritsche, M.D.
William Kraklow, M.D.
Todd Muche, M.D.
Gregory V. Warren, M.D.
Paul J. Warren, M.D.

April 1, 1998

Christopher Shays, Chairman
2157 Rayburn House Office BLDG.
Washington, DC 20515-6143

RE: UNOS changes

Dear Mr. Shays:

I am writing in opposition to the proposed UNOS changes. I care for a number of kidney transplant, heart transplant and pancreas transplant patients. I think it unwise to look only at equalization of waiting time, instead of factors such as outcome.

Unfortunately, when we allocate organs to the sickest patients first, we will have fewer successful transplants and this will certainly be a waste of these precious organs. The changes might result in lower organ donations since the local organ drives, which have made such a difference in increasing donation, may not have a reasonable outcome. People will realize that organs may be shipped out of their local area.

This new change is not based on scientific data and will not allocate the organs appropriately. There will not be completely equal access and the number of successful transplants will decrease.

UNOS has been a very effective organization in allocating organs. Should the rules be changed, UNOS will have very little say. This would be a travesty especially considering how many transplant professionals, patients and families have been involved in developing a sound and fare organ allocation system.

I am very much opposed to the changes as proposed by Donna Shalala and I think that the changes must be re-thought so that we don't waste organs.

Sincerely,

James Brandes, M.D.
(dictated not read)

JB/lj

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7701 WEST CLINTON AVENUE • MILWAUKEE, WI 53223 • (414) 760-3090 • FAX: (414) 760-3068

N2437 Brattset Lane
Jefferson, WI 53549
16 April 1998

Congress of the United States
House of Representatives
Committee on Government Reform and Oversight
2157 Rayburn House Office Building
Washington DC 20515-6143

Dear Committee Members,

Last week we attended the congressional hearing in Milwaukee which was chaired by Representative Shays. The subject of this hearing was the proposal by Donna Shalala to modify the organ allocation system within our country.

Here in Wisconsin we have an excellent donation and transplantation system that works. We believe this is due to the sense of community we have in Wisconsin, the sense of social responsibility, and the very real work ethic shich has enabled us to work hard at spreading the word about organ donation--often on a very personal level. One needs only visit the transplant unit at University Hospital in Madison to realize the almost super-human dedication the staff there exhibits. Yes, we Wisconsin people have a wonderful system because we work so very hard at having a wonderful system!

For many people in our culture donating the organs of a loved one represents a sort of desecration of that loved one's body. Thus, the act of organ donation requires an emotional sacrifice. In an area such as ours with such a good rate of transplantation success this emotional sacrifice becomes easier because we know there is an excellent chance that these organs will save lives. If the integrity of these organs is to be compromised by being transferred long distances and given to those "Most in need", you may be sure the rate of donation will decline.

Although common sense would tell us that the correct path to a sound nation-wide organ allocation system would be to study successful systems and work diligently to model others after them, knowing that the whole is only as sound as its parts, this does not seem to be Donna Shalala's approach. Instead, she prefers the path of least resistance and, in the name of fairness, prefers to reduce everyone to the lowest common denominator--what a shame!

Please, Committee Members, do not yourselves be guilty of such a faulty decision.

Sincerely,
Weenonah Brattset
Harold Brattset (organ recipient)
Weenonah Brattset

cc: all appropriate agencies

LEONARD L. BOSWELL
3rd District, Iowa

Committees
AGRICULTURE
Subcommittee on Risk Management
and Specialty Crops
Subcommittee on Livestock,
Dairy, and Poultry

TRANSPORTATION AND
INFRASTRUCTURE
Subcommittee on Aviation
Subcommittee on Water Resources
and Environment

Congress of the United States
House of Representatives
Washington, DC 20515–1503

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(202) [illegible]

JOHN R. NORRIS
Chief of Staff

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Osceola, Iowa 50213
(515) 342-[illegible]
Toll Free Iowa Number
1-[illegible]

April 6, 1998

Chairman Christopher Shays
Committee on Government Reform and Oversight
Subcommittee on Human Resources
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Shays:

I would like to take this opportunity this morning to bring forth the perilous condition of one of my youngest constituents, Mekenzie Lee of Ottumwa, Iowa, to your attention.

Enclosed please find a letter written by her father Bryan Lee, expressing the human costs associated with the implementation of proposed rules by the Department of Health and Human Services. I have also enclosed a copy of a letter from the University of Iowa Hospitals and Clinics (UIHC), express their concerns regarding the effects of this rule. The UIHC is a renowned organ transplant facility.

Little 5-year-old Mekenzie has liver cancer and desperately needs a liver transplant. The rules your committee are reviewing make a major modification to how this system works.

While the stated purpose of the rule is admirable and I strongly support efforts to increase the donations, I fear this rule may in fact result in a number of unintended consequences.

It will take the decision making process away from the physicians, those who are the most skilled and proficient to able to deal with this, who have got the expertise, and put it into the hands of some bureaucrats. Forcing a one-size-fits-all is questionable to me.

I would ask that members join the efforts to save Mekenzie and every transplant patient like her who may be harmed by this proposed rule by becoming a cosponsor of H.R. 3584, a bill delaying this process for one year to give Congress and the public time to review it, to receive input from the physicians and facilities around the country that perform this life-saving work.

I respectfully request the enclosed letters and my comments be included in the written record of your Subcommittee field hearing on April 8, in Milwaukee, Wisconsin.

Sincerely,

Leonard L. Boswell

Leonard L. Boswell
Member of Congress

LEONARD L. BOSWELL
3RD DISTRICT, IOWA

COMMITTEES:
AGRICULTURE
SUBCOMMITTEE ON RISK MANAGEMENT
AND SPECIALTY CROPS
SUBCOMMITTEE ON LIVESTOCK,
DAIRY, AND POULTRY

TRANSPORTATION AND
INFRASTRUCTURE
SUBCOMMITTEE ON AVIATION
SUBCOMMITTEE ON WATER RESOURCES
AND ENVIRONMENT

Congreſs of the United States
House of Representatives
Washington, DC 20515–1503

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JOHN R. NORRIS
CHIEF OF STAFF

709 FURNAS DRIVE
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(515) 342–4801
TOLL FREE IOWA NUMBER
1–888–432–1984

April 1, 1998

TRANSPLANT PATIENTS ARE RUNNING OUT OF TIME

Dear Colleague:

I hope you will give serious consideration to join my efforts to delay the adoption of a rule proposed by the Department of Health and Human Services (HHS) regarding the system by which transplant organs are allocated to patients. In the past several days I have heard from concerned patients as well as transplant centers about the possible implications of this proposed rule. My concern for the well being of those in need of organ transplants has prompted me to introduce H.R. 3584, prohibiting HHS from implementing the proposed rule for one year.

While the stated purpose of this rule is admirable and I strongly support efforts to increase organ donation, I fear this rule may in fact result in a number of unintended consequences which will have devastating consequences on many people in need of a transplant.

These regulations will take the decision making process out of the hands of the medical community, who are properly trained to make these life saving decisions, and shift it to administrators. The current system allows those closest to the patients to be most involved in these decisions. Forcing a one-size-fits-all system on our transplant centers and hospitals will ultimately hurt patient care.

The current system allows patients to receive this life saving care closer to their communities. The proposed national system may force many of the nation's smaller transplant centers to close their doors, forcing patients and families to travel great distances to receive the medical care they require.

H. R. 3584 will prohibit HHS from implementing the rule for one year, allowing Congress and the public to hold hearings on these proposed rules to determine their effects on patient care and the collateral effects of these rules on smaller transplant centers and hospitals. I appreciate your consideration of this important legislation and hope you will join in this effort to provide the best possible care to those in need of organ transplants. If you would like to become a cosponsor of H. R. 3584, or would like any further information, please contact Eric Witte in my office at 5-3806.

Sincerely,

Leonard L. Boswell

Leonard L. Boswell
Member of Congress

Rep Shays

From: KSBurton[SMTP:KSBurton@aol.com]
Sent: Thursday, April 09, 1998 5:02 PM
To: Rep Shays
Subject: SUPPORT the DHHS Changes to Organ Allocation Regulations

Dear Representative Shays -

Recently, the Department of Health and Human Services published new federal regulations for transplant organ allocation among the nation's transplant centers. I support those changes and urge you and the Human Resources Subcommittee to do the same – but not without being FULLY informed of the FACTS.

The United Network for Organ Sharing (UNOS), a DHHS contractor, has embarked on a PR campaign to kill the new regulations. I believe that UNOS is misinforming and misleading both the American public and its political leaders.

I have a website and have included links to relevant information on this important issue. I hope you will visit that website; it is designed to allow the visitor to view as much, or as little, information as he chooses. The web address is:

http://members.aol.com/shuckskbee/

Though the site has a "tongue-in-cheek" appearance, I believe you will discover that the information presented is solid.

Sincerely,

Karen Burton
735 Rundell Street
Iowa City, IA 52240

FROEDTERT
Memorial Lutheran Hospital

9200 West Wisconsin Avenue
P.O. Box 26099
Milwaukee, WI 53226-3596
Telephone: 414 259 3000

Primary Affiliate of the
Medical College of Wisconsin.
Member, Horizon Healthcare Inc.

I may need a liver some day and this National program Though it may sound good Will Not Work and will hurt most states!

Tim Bast

422-9292
S74 W14160 Settler way
Muskego WI
53150

MEDICAL
COLLEGE
OF WISCONSIN

Department of Medicine
Nephrology Division

April 1, 1998

Mr Tom Barrett
Congressman
US House of Representatives
Subcommittee on Government Reform and Oversight
Rayburn House Office Building
Washington, DC

Dear Mr Barrett,

I write in regard to the recent proposal to change the organ transplant allocation system. The Secretary for Health and Human Services, Mrs Shalala, has recently pushed for a change in organ allocation that would ostensibly direct organs for transplant to the "sickest" patients , regardless of geographic location. As a Doctor and Specialist in Kidney Disease, I oppose this proposal.

The proposal by Mrs Shalala will significantly damage organ transplantation in Wisconsin. It will divert locally procured organs to centers in other states.

The proposal by Mrs Shalala may actually decrease organ transplant success because of the delay in transportation of an organ from one state to another. That is because the quality of an organ decreases the longer that it is out of the body.

The proposal by Mrs Shalala ignores the success of the present system, which is guided by the non-partisan United Network for Organ Sharing (UNOS). The United Network for Organ Sharing has analyzed the present system using computer modelling and finds it to be well balanced between local and national priorities.

A few large centers may benefit from the new rules. These are centers that are not in Wisconsin. These are centers that have not worked as hard to increase organ donation as have the organ transplant centers in Wisconsin. The new rules/proposal will in effect penalize the centers that have worked to increase organ donation.

It is possible that those few large centers in other states may receive more kidneys under these new rules. But those kidneys will not work as well, and because of transportation expense, will cost more.

The new rules/proposals for organ allocation are misguided and should be eliminated.

sincerely,

Eric P. Cohen, M.D.
Associate Professor of Medicine

Froedtert Memorial Lutheran Hospital
9200 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 259-3070
FAX (414) 259-1937

Gundersen
Lutheran

Department of
Internal Medicine
Nephrology Section
Philip J. Dahlberg, M.D.
Wilfrido R. Yutuc, M.D.

April 2, 1998

Mr. Christopher Shays
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Re: Organ Allocation Changes

Dear Mr. Shays:

As a practicing nephrologist in a medical center that does not do kidney transplants, I would like to voice strong opposition to the proposed Federal legislation designed at reallocating organ distribution.

For the past twenty years I have taken it as a personal responsibility to ensure that every possible organ that becomes available through our medical center is provided to the University of Wisconsin-Madison. This effort is in the best interests of my many patients who are currently awaiting organ transplants. Lutheran Hospital has created a variety of systems in order to facilitate organ donation and harvesting in collaboration with the University of Wisconsin and, as a result, is one of the major organ donors to the citizens of the state of Wisconsin.

We feel that it's part of our obligation to the patients in the greater La Crosse area to be active participants in the Wisconsin program. Our efforts have been greatly facilitated by the hard work of the University of Wisconsin-Madison. That hard work and effort is largely responsible for our success as well as their own success in becoming one of the largest transplant centers in the country.

The proposed legislation would result in the following: 1) Transplant centers who have not invested the effort in an extensive state-wide organ retrieval system will now be the beneficiaries of years of hard work by those centers who have invested the time and effort that it requires. 2) Outcomes will probably diminish because of the prolonged ischemic time that will result. 3) Those of us who have a personal investment in the success of the University of Wisconsin Transplant Program will lose that personal incentive and motivation since it is no longer our patients who will benefit.

Gundersen Clinic, Ltd.
1836 South Avenue • La Crosse, Wisconsin 54601 • (608) 782-7300 • (800) 362-9567

A much better Federal proposal would be to publish the wait time of every transplant center in the country, allowing patients, HMO's, insurance companies, etc. to select centers who have worked hard at keeping the wait times down and incentivize centers to develop the kind of programs that we have in Wisconsin.

Sincerely yours,

Philip J. Dahlberg, M.D.

PJD/rab

cc: Mark B. Adams, M.D.
Professor of Surgery
Medical College of Wisconsin

MIDWEST
NEPHROLOGY
ASSOCIATES, S.C.

James Brandes, M.D.
Amir Daniel, M.D.
Claire Fritsche, M.D.
William Kraklow, M.D.
Todd Muche, M.D.
Gregory V. Warren, M.D.
Paul J. Warren, M.D.

April 1, 1998

Christopher Shays, Chairman
2157 Rayburn House Office BLDG.
Washington, DC 20515-6143

RE: UNOS changes

Dear Mr. Shays:

I am writing in opposition to the proposed UNOS changes. I care for a number of kidney transplant, heart transplant and pancreas transplant patients. I think it unwise to look only at equalization of waiting time, instead of factors such as outcome.

Unfortunately, when we allocate organs to the sickest patients first, we will have fewer successful transplants and this will certainly be a waste of these precious organs. The changes might result in lower organ donations since the local organ drives, which have made such a difference in increasing donation, may not have a reasonable outcome. People will realize that organs may be shipped out of their local area.

This new change is not based on scientific data and will not allocate the organs appropriately. There will not be completely equal access and the number of successful transplants will decrease.

UNOS has been a very effective organization in allocating organs. Should the rules be changed, UNOS will have very little say. This would be a travesty especially considering how many transplant professionals, patients and families have been involved in developing a sound and fare organ allocation system.

I am very much opposed to the changes as proposed by Donna Shalala and I think that the changes must be re-thought so that we don't waste organs.

Sincerely,

Amir Daniel, M.D.
(dictated not read)

AD/lj

1000 NORTH OAK AVENUE
MARSHFIELD, WI 54449-5777

FAX 715-387-5240

715-387-5345

MARSHFIELD CLINIC

DEPARTMENT OF
NEPHROLOGY & HYPERTENSION

April 6, 1998

Christopher Shays
Chairman, Subcommittee on Government
Reform and Oversight
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

RE: Recently announced new rules for organ transplant allocation

Dear Mr. Shays:

Since completing my kidney disease training in 1978, I have been a practicing clinical nephrologist caring for people requiring transplants or who have had transplants. I spent five years at the University of Utah and the last 15 years have been at the Marshfield Clinic in central Wisconsin. Here in Wisconsin we are blessed with excellent transplant centers, and a higher than average rate of organ donation.

These proposed new rules are unfair and will significantly affect organ transplantation. They will first all increase both the cost and the rate of transplant graft failure. This is because transplanting the sickest patients first would result in fewer successful transplants than are done with the current system which more fairly takes into account factors dealing with positive outcomes. Under the new system, Wisconsin and the surrounding region will become a net exporter of organs. This will significantly decrease the local incentive to drive our high rate of organ donation, and may result in a lower rate of organ donation at some point.

I would strongly suggest you review the set up of the current transplant system which is guided by the UNOS Organization. This is a highly effective national organization representing the whole transplant community spectrum. It is supported by hundreds of volunteer hours. Our current system of organ allocation is ethically sound and has stood the test of time. The new rules will basically upend the whole system, and may be ethically unsound.

The new proposed rules seem to support a few large centers, insurance companies, and areas that have not developed organ gifting over time. They politicize a process that is currently solved largely with an effective organization (UNOS) that is supported in part by volunteer hours from transplant professionals, patients, and families. This system represents a working balance between completely equal access and maximizing the number of successful transplants in a cost effective and ethically sound way, I urge you to support the current system.

Sincerely,

Douglas P. Duffy, M.D.
Department of Nephrology and Hypertension

DPD:mcb

cc Mark B. Adams, M.D.

AMF

National Transplant Action Committee
70 Sewall Ave
Brookline, MA 02146
(617) 566-3430 (617) 232-2418 (FAX)
E.mail cfiske@erols.com

March 4, 1998

Congressman Christopher Shays
US Congress
Washington, DC 20515

Dear Congressman Shays,

Dr. Larry Hunsicker, President of United Network for Organ Sharing (UNOS) the federal contractor running the national organ transplant system has asked me to write you about the recent letter (2/26/98) to some members of Congress from HHS Secretary Donna Shalala. In that correspondence, Secretary Shalala states that the goals of the 1984 National Organ Transplant Act and the report of the Task Force on Organ Transplantation which was developed in response to the Act have not been fully realized. She states, "I believe we are falling short of the law's expectations.... In addition, we have not yet achieved many of the important benefits of a national organ-sharing network that were envisioned by NOTA." In the letter the Secretary explains that the responsibility of HHS is to ensure that this resource (donated organs) are made available equitably, subject to sound medical practice. The Department is to provide the framework for the operation of the OPTN as well as define the expectation inherent in the law and apply those to the work of the contractor. We strongly concur and support the Secretary's role and perspective in this matter. Few can disagree with her final comments that American public should be assured that the allocation should be equitable so that, "those who need organ transplants will be treated according to medical need, no matter where in the country they may be hospitalized, or at what center they may be listed."

The Secretary's comments strongly reflect the position and words used by Dr. Hunsicker when he testified before the Organ Transplant Task Force in Chicago on May 22, 1985, " The principle that donated cadaver organs are a national resource implies that, 'in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ as a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organ and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography.'"

Page 2 of 2
3/4/98

The Secretary has challenged that the system can do better for all patients. If the general public understands the system to be fair then there will be a positive reaction to organ donation. We urge you to support the Secretary's effort to challenge the organ transplant system to give first consideration to patients'interests and not those of the federal contractor or the individual transplant centers. As always thank you for your strong support of transplant patients' interests.

Sincerely,

Charles Fiske
Director

cc: Secretary Shalala

Testimony Submitted By Charles Fiske
April 8, 1998

Government Reform and Oversight Committee
Subcommittee for Human Resources

Thank you Mr. Chairman and members of the Committee for allowing me the opportunity to present written testimony before your Sub-Committee on the matter of organ transplantation. In 1982, our then nine-month old daughter, Jamie, needed a liver transplant. At the time, there were only two programs in the country performing liver transplants, the University of Pittsburgh Medical Center and University of Minnesota Hospital. As a result we traveled from Boston to Minnesota for her care. Initially, our insurance company did not want to cover the cost of the surgery, but after a brief public campaign, they reversed their decision. We took Jamie's plight to the attention of the American public through a large media campaign. We also sought the help of Congressman Joe Moakley, and Senators Ted Kennedy the late Paul Tsongas. At the time there was no national system in place. As the result of media reports the Bellon family of Alpine, Utah was aware of Jamie's plight when they consented to the donation of the organs of their son, Jess who was tragically killed in a car-train accident. Jamie had that operation in November of 1982 and today is a healthy 16 year-old and a sophomore in high school. At the time she was the youngest patient to have undergone such a transplant.

Because of the overwhelming difficulty we had faced, we were willing to participate in the April 1983 Congressional hearings that were held before the Oversight subcommittee of the House's Science and Technology Committee chaired by then Congressman Al Gore. We detailed the experiences hoping that others would not have to endure the hardships of while waiting for an organ to be found in time. That Fall, I appeared before the Senate's Labor and Human Resource Committee chaired by Senator Orrin Hatch and again detailed the obstacles we faced when Jamie needed a liver transplant.

In 1990, as a UNOS Board Member I testified at the reauthorization hearings of the National Transplant Act before the Commerce's Health Sub-Committee regarding the need for oversight of the OPTN contract.

Decisions were being made that did not seem to be in the best interest of patients. In 1993 I was again before that same Subcommittee addressing some of the issues I had raised three years previous. In December 1996, I spoke before the HHS panel gathering information on the issue of allocation and organ donations.

I strongly support the Department's March 26th directives issued by the Secretary of Health and Human Services regarding the OPTN. There needs to be a level playing field so that all patients no matter where they live or which transplant center they attend, should equal access to available organs. The accompanying preamble issued with the final rule clearly outlines the Department's expectations that equity and the reasonable equalization of waiting time be considered as the federal contractor, UNOS develops its allocation policy for the wider sharing of organs. In addition, the uniform standardized listing criteria required for all transplant centers would prevent patients from competing against others in similar circumstances no matter where in the country they lived. This would even eliminate the need for "double listing". Perhaps the most encouraging aspect of the Department's regulation is the framework to accomplish the goals of equalizing waiting times. The federal contractor is the group given the authority to now accomplish this task. Though the contractor has made efforts to do so, now for the first time they are being held accountable to get the job done. The regulations give patients and the general public a vehicle through the Department to constructively address concerns. Finally the long-standing battle that UNOS has been waging with the federal government can be put to rest and they can be expected to develop a fair system to benefit all patients. That work can now take center stage.

For waiting patients the urgency is at hand. They don't have the luxury to wait months and years for the contractor to complete its work. To clearly understand the ongoing involvement of the federal government in organ transplantation one only has to look at the amount of federal dollars paid to transplant programs for patient care through Medicare or Medicaid. Also the contractor receives federal dollars to meet the contract requirement. By virtue of receiving the contract the contractor is able to charge a fee of more than $350. per patient to be put on the list.

The Department's final rule in this matter allows the entire transplant community to now address the ongoing shortage of organs. Much attention needs to be given to examining those "best practices" that have been successful for some organ procurement agencies and medical centers. The increase in available organs will not fully solve the allocation dilemma but it will encourage the general public to develop a sense of confidence in the national transplant system. That general sense of confidence is critical if all us are to communicate to the public, the life saving need for organs. National study polls indicate a general favorability towards organ donation. Through the Department's directive we can continue the task of meeting the needs of those countless transplant patients who depend both on a system that is fair and a public that is caring.

National Transplant Action Committee
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(617) 566-3430
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(617) 232-2418 (FAX)

Charle Fiske Boston MA

History of the Organ Transplant involvement in legislative process.

Nov. 1982 – 11 month old daughter, Jamie, underwent a life saving living transplant at the University of Minnesota

April 1983 – Testified before Science & Technology Oversight Subcommitteed chaired by Cong. Gore. Transplant experience.

June 1983 – Participated in the Surgeon General Workshop, Project Hope, Virginia

Oct. 1983 – Testified before Senate Labor & Human Resource Committee chaired by Sen. Orrin Hatch. Transplant experience.

Nov. 1983 Co sponsor with MA Rep. J. Herman – Organ Fund check-off bill for designation on MA State Income Tax forms.

1985 Board of Trustees – New England Organ Bank

1986 – Establish the Family Inn in Boston, housing for families or organ transplantation.

1988 – Board of Director Member – United Network for Organ Sharing

April 1990 – Testified before Commerce's Health and Environment Subcommittee chaired by Cong. Henry Waxman. NOTA reauthorization.

April 1993 – Testified before Commerce's Health & Environment Subcommittee chaired by Cong. Waxman. NOTA reauthorization.

June 1994 Board Member – Partnership for Organ Donation

1994 – Co-found National Transplant Action Committee – patient advocacy group for organ transplant patients

April 1995 General Public Member - United Network for Organ Sharing.

Dec. 1996 – Testified before HHS regarding NPRM on organ transpantation.

MEDICAL
COLLEGE
OF WISCONSIN

Dr. José Franco

Division of Gastroenterology and Hepatology

April 1, 1998

Mr. Christopher Shays
Chairman of the Subcommittee on Government Reform and Oversight
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Mr. Shays:

I am writing to you regarding the recently proposed changes pertaining to the allocation of livers donated for transplantation. As a transplant physician and Medical Director of our transplant program I find many of the recommendations disturbing. As you known, the United Network of Organ Sharing is comprised of numerous members of the transplant community as well as organ recipients and donor families. I feel that this organization is highly effective and represents the transplant community well. In particular, I feel it has done an excellent job addressing this controversial area.

The proposed rules as outlined by Secretary Shalala, in my opinion, would favor a small number of large transplant centers. I feel that it is favorable to various HMO's and insurance companies and not in the patient's best interest. There is no scientific data that the proposed changes would result in better survival or shorter waiting periods. Numerous computer models formulated by UNOS have shown that the current plan provides equal access to individuals regardless of financial status and maximizes the number of donated livers.

In addition to the above, I feel that the changes would prove costly on a local level. In Wisconsin we have a very successful organ procurement organization. Their hard work and dedication has resulted in a large number of organs being made available to our patients. The recommended changes would favor areas of the country who simply have large recipient lists and would not encourage the local organ procurement organization from maximizing organ donation.

The proposed changes would funnel available organs to the sickest patients. Clearly, with this, survival will not be near what it is at the present. With the sickest patients being transplanted fewer successful transplants will result and the need for retransplantation, as well as increased costs, will result in the breakdown of the transplant system.

On an ethical basis, I feel that the current changes are being made without the patients best interest. I have had numerous patients as well as donor families who have stated that if the current proposals are adapted their view of the transplant patient procedure as it pertains to organ allocation will be damaged.

Froedtert Memorial Lutheran Hospital
9200 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 259-3038
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In summary, I am encouraging you to maintain the current allocation of donated livers as currently outlined by UNOS. This system is ethically fair, will benefit the most patients, and the largest number of transplant centers.

Sincerely,

José Franco, MD

José Franco, M.D.
Assistant Professor of Medicine
Medical Director of Liver Transplantation

JF/jr

MIDWEST
NEPHROLOGY
ASSOCIATES, S.C.

James Brandes, M.D.
Amir Daniel, M.D.
Claire Fritsche, M.D.
William Kroklow, M.D.
Todd Muche, M.D.
Gregory V. Warren, M.D.
Paul J. Warren, M.D.

April 1, 1998

Christopher Shays, Chairman
2157 Rayburn House Office BLDG.
Washington, DC 20515-6143

RE: UNOS changes

Dear Mr. Shays:

I am writing in opposition to the proposed UNOS changes. I care for a number of kidney transplant, heart transplant and pancreas transplant patients. I think it unwise to look only at equalization of waiting time, instead of factors such as outcome.

Unfortunately, when we allocate organs to the sickest patients first, we will have fewer successful transplants and this will certainly be a waste of these precious organs. The changes might result in lower organ donations since the local organ drives, which have made such a difference in increasing donation, may not have a reasonable outcome. People will realize that organs may be shipped out of their local area.

This new change is not based on scientific data and will not allocate the organs appropriately. There will not be completely equal access and the number of successful transplants will decrease.

UNOS has been a very effective organization in allocating organs. Should the rules be changed, UNOS will have very little say. This would be a travesty especially considering how many transplant professionals, patients and families have been involved in developing a sound and fare organ allocation system.

I am very much opposed to the changes as proposed by Donna Shalala and I think that the changes must be re-thought so that we don't waste organs.

Sincerely,

Claire Fritsche, M.D.
(dictated not read)

CF/lj

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7701 WEST CLINTON AVENUE • MILWAUKEE, WI 53223 • (414) 760-3090 • FAX: (414) 760-3068

MEDICAL
COLLEGE
OF WISCONSIN

Department of Pediatrics

April 7, 1998

The Honorable Christopher Shays
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Congressman Shays,

I want to inform you of my complete opposition to the recent rule changes for organ transplantation proposed by Donna Shalala. As a physician who cares for the children of Wisconsin, I know that these changes will be detrimental to my patients. These rule changes will also result in less successful organ transplantation nationally and therefore more patients will die waiting for an organ and the list of patients waiting for an organ will increase!

These changes are especially egregious because they have been the result of lobbying by large HMOs and insurance companies. I know how these organizations work. A five-year-old girl under my care needed a kidney transplant. Her father was willing to donate a kidney but her insurance company wanted the family to travel 500 miles for her to receive her transplant despite the availability of a transplant program 20 miles from her home. The fact that this five-year-old and her family would be treated by people who never met her and didn't know her medical history very well was unimportant. The turmoil created for the family was of no consequence. There was no consideration to the lack of supportive friends and family, the care of the patient's younger sister or the financial consequences of lost wages and added personal expense.

Fortunately, the family battled the insurance company and our little patient received her transplant in Wisconsin. She is now thriving, a different girl thanks to the transplant. And because her transplant was in Wisconsin she awoke in the ICU to familiar faces and her transplant was medically successful. There is no doubt in my mind that trust and a relationship were important ingredients for the good outcome.

MACC Fund Research Center
8701 Watertown Plank Road
Post Office Box 26509
Milwaukee, WI 53226-0509
(414) 456-4100
FAX (414) 456-6539

There are scientific reasons why this is a bad change for transplantation in America. I wanted to share with you why this is a bad rule change for the individual patient. This change will allow organs to follow patients as insurance companies send patients to the hospital where they get the best deal. These changes, like rapid hospital discharge for newborns, may have some short-term cost effectiveness advantages for insurance companies, but the long-term results will be bad for everyone. Please do not allow one of the most successful and fair programs in modern medicine to be corrupted by the short-term interests of a few.

Sincerely,

Larry Greenbaum, MD, PhD
Assistant Professor of Pediatrics
Division of Pediatric Nephrology

cc: Tom Barrett

April 2, 1998

Christopher Shays, Chairman
2157 Rayburn House Office Bldg.
Washington, DC 20515-6143

Re: UNOS changes

Dear Mr. Shays:

I want to let you know how wrong it would be for organs to be sent elsewhere when they are needed so badly in our area. I am a donor recipient and the kidney I received was from someone in my own community.

There isn't alot to say only that it would be a shame if people stopped donating organs because of this change. Donna Shalala obviously doesn't know what it feels like to need an organ or have a family member need one. Unfortunately, people like her need to be in a situation like this in order to feel what it is like.

Please don't do this to the many people who need organs.

Kindest Regards,

Angel L. Guenette

Angel L. Guenette
(414) 744-3283
3850 E. Squire Ave.
Cudahy, WI 53110

MILWAUKEE NEPHROLOGISTS, S.C.

JEFFREY D. WALLACH, M.D.
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DANA A. CAMPBELL, M.D.
LISA M. RICH, M.D.
STEPHEN G. SIEVERS, M.D.
MICHAEL I. LEVINE, M.D.

April 1, 1998

Mr. Christopher Shays
Chairman, Subcommittee on
Government Reform and Oversight
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Dear Mr. Shays:

As a nephrologist caring for over 100 patients who have advanced or end-stage renal disease seeking kidney transplantation, I must strongly object to the recently proposed changes in organ allocation.

I feel that these changes would unfairly deny my patients timely transplantation. In addition, the Wisconsin transplant programs at the Medical College of Wisconsin and at the University of Wisconsin would be unfairly denied the use of procured organs that had been donated, in large part, because of the hard work and effort made by the programs and the Wisconsin community and physicians such as myself through increasing public awareness.

I feel that some of the larger transplant programs that would benefit from the proposed changes, have done so through the use of money spent through lobbying rather than dedicating resources toward public education and promotion of organ donation.

More importantly, I do not feel that the proposed changes will improve the already highly successful outcome of transplants and, in fact, could result in a decline in quality outcome due to time delays in organ usage.

I hope that you will give further consideration to the needs of those patients that have been well served by the transplant programs such as the Medical College of Wisconsin and the University of Wisconsin.

Sincerely,

Matthew H Hanna

Matthew H. Hanna, M.D.
MHH:smc

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MEDICAL
COLLEGE
OF WISCONSIN

Department of Medicine
Nephrology Division

April 3, 1998

Christopher Shays, Chairman of the Subcommittee on
Government Reform and Oversight
2157 Rayburn House Office Building
Washington, DC 20515-6143

RE: New rules for organ allocation

Dear Mr. Shays:

I, as a transplant physician at the Medical College of Wisconsin, strongly oppose the new rules for organ allocation. These new rules for organ allocation has come into effect with extensive lobbying, and is also the result of a tremendous amount of pressure from HMOs and insurance companies, who are trying equalize the national waiting period for organ transplantation. I personally oppose these new rules, and I would like to illustrate my opposition with the following points.

1. The concept that dying patients should receive an organ is not appropriate. Patients with liver disease who are severely ill and in the hospital, don't do well after transplantation. In view of this situation, a fair number of patients who are stable should be given consideration, where the long-term benefits can be obtained. About 85% of the patients who are on maintenance dialysis are not candidates for transplantation due to age and diseases such as infection, cardiac disease and malignancy. Only about 15% of patients, who are awaiting transplantation are candidates for transplantation. If we allow the organs to be given to all patients who are on dialysis, the long-term outcome would be extremely poor, and will prevent transplantation from being an available form of treatment for end stage renal disease.

2. We have reached a stumbling block in terms of the number of transplantations that are possible within the USA. Over the last 10 years, there has been a marginal increase in the number of organ donations, and there is a disproportionate increase in the number of patients awaiting transplantation, which has reached an all-time high of about 59,000 at the beginning of 1998. Until we have xenotransplantation, we have to continue to optimize our organs by providing them to suitable candidates. Hence, the government should not interfere in the policy on who should receive the organs, the policy should go according to the current rules, which appear to be very effective.

3. The focus of improving organ transplantation should be on how to retrieve more organs. With this newer concept, the incentive will be given to the transplant center for pushing more patients onto the transplant waiting list, rather than focusing on the increase of organs. This will also lead to the fact that centers who are doing an excellent job in retrieving more organs, will not be rewarded in any way by giving these organs to local recipients, which will reduce the number of organs retrieved over the next few years.

4. Currently, about 10 organs are being transported per day from one city to another. This number would go up to 80-100 transplant organs that will be traveling from one city to another to find a suitable recipient. During that transit time, there will be time loss, and

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there is always a possibility of these organs not being used at a given center. This will promptly reduce the effectiveness of transplantations.

5. It has been very well documented that organs that are retrieved locally do better with local recipients, rather than being transported to another center. This is because prolonging the time of transportation from the retrieval time, will increase the cold ischemia time, which will proportionally decrease the long-term survival. By this newer method which is being introduced by Donna Shalala, we are going to be less efficient, and it will be more time consuming and more expensive to maintain organ transplantation.

In view of these circumstances, I strongly oppose the newer rule. The existing rule will continue to be useful, and the focus should be on how to increase the number of organ donors over the next few years.

Yours sincerely,

Sundaram Hariharan, M.D.
Director of Transplant Services
Associate Professor of Medicine

SH/lsb

1898 1998 UIHC
University of Iowa Hospitals and Clinics
100 Years of Caring

THE UNIVERSITY OF IOWA HOSPITALS AND CLINICS
200 Hawkins Drive, Iowa City, Iowa 52242

April 6 1998

The Honorable Christopher Shays
United States House of Representatives
Washington, DC 20515

Dear Representative Shays:

I appreciate the opportunity to submit on behalf of the University of Iowa Hospitals and Clinics the following comments concerning the recently released HHS Regulations concerning the Organ Procurement and Transplantation Network (OPTN), for inclusion into the record of the Hearing by your Committee that will be held on Wednesday, 8 April, 1998 in Milwaukee. In fact, we have major concerns about the wisdom of these new regulations.

First, it must be said that there is no clear need for the Secretary to issue these regulations now, 14 years after the passage of the National Organ Transplant Act (NOTA) and 11 years after the awarding to the United Network of Organ Sharing (UNOS) of the first contracts for operation of the OPTN and the Transplant Scientific Registry. It is our impression that UNOS has done an excellent job overall in leading the transplant community – including the doctors and other professionals, the hospitals, the patients, and the public – to a great deal of agreement on sound public policy concerning organ transplantation, including such policies as organ allocation. We believe that the input of the government through its issuance and control of the OPTN and Registry contracts has been appropriate and assures the appropriate role of governmental oversight, as was intended by Congress when it passed NOTA. Specifically, we very much doubt the wisdom of assigning to the government unilateral authority over issues with major medical content, which are more appropriately dealt with by medical professionals working with the community stakeholders. This will assure the ability to respond more quickly to changes in the science and other circumstances, with less likelihood of errors in judgment with potentially grave consequences for the patients.

Second, we believe that the specific announced policies concerning the allocation of cadaveric livers are unwise, perhaps an example of the potential for dangerous error when medical policy is made away from the medical community. In our opinion, the best scientific evidence indicates that the government policy will lead to an

R. Edward Howell, Director and Chief Executive Officer
Hospital Administration 319-356-3155, Fax 319-356-3862

increased requirement for retransplantation of liver recipients both because of the greater degree of illness of the recipients and because of the increases in cold ischemia time for the transplantable liver if it is to be shipped far from its place of retrieval. This will have the adverse effect of reducing the total number of patients who can be offered a potentially life-saving transplant, and will in the long run lead to more, not fewer, deaths. Further, the expenses of patient care both prior to and during transplantation will be increased by a policy which would, in effect, mean that patients cannot receive a transplant until their health has deteriorated very seriously. We cannot save any more patients by transplanting only the sickest, but we can both lower the chances of success and increase the costs.

Third, it is not clear that equity will be best served by the effort to equalize waiting times across the country. It should be noted that waiting times for the most seriously ill patients, those in Status 1 and Status 2 are already very similar. Only the patients in the least urgent category, Status 3, have meaningful differences, and much of the difference in waiting times is the consequence of better organ retrieval in those areas with the shorter waiting time. In Iowa the average consent rate among families of potential organ donors is well above 60%, in comparison with rates below 50% in the nation as a whole. Perhaps those communities who are more generous in giving are entitled to some edge in receiving. We believe that it is important to maintain the viability of the smaller liver transplant centers away from the major metropolitan areas. This is necessary if patients are to be able to receive care close to their homes and families. The availability of the regional centers is particularly important for the poor, who often cannot afford travel to a large urban center, or who may not qualify under Medicaid for care outside of their own state.

Fourth, it must be noted that much of the imbalance of waiting time at the larger urban centers (again, only in the least urgent category of patients) is due to the impact of insurance company policies that divert patients from care close to home to the larger centers whose lists of waiting patients already outstrips the availability of local donors. In the particular case of transplantation, the argument that this assures "excellence" is particularly transparent, since the outcomes of transplantation at all US centers are a matter of public record because of the reports provided by UNOS as the contractor for the Scientific Registry. Rather than change the distribution of donor organs, serious thought must be given to the circumstances that have distorted the distribution of patients.

Finally, it must be understood that the policies of HHS, if not changed, would pose a serious threat to the very existence of many smaller local transplant centers, including ours here in Iowa. A team cannot maintain its skills, and a hospital cannot bear the costs of an effective liver transplant program without a reasonable volume of patients. As noted above, the loss of these local centers would disadvantage particularly the poor and disenfranchised. Surely there are better solutions to the problems of distribution than those proposed by HHS.

In sum, then, our hospital, responsible for providing care to all the people of Iowa including the medically indigent, strongly opposes the proposed rules. We urge Congress to pass a moratorium on these HHS Regulations until the issues concerning the nature of government oversight have been clarified, and until alternative solutions to the organ allocation issue have been considered by the OPTN, working with, but not under the rule of, the government.

We thank you for the opportunity to submit these comments.

Sincerely yours,

R. Edward Howell
Director and Chief Executive Officer

REH/wll

United
Network
for
Organ
Sharing

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804•330•8500
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Executive Director
Walter K. Graham

March 30, 1998

The Honorable Christopher Shays
1502 Longworth House Office Building
U.S. House of Representatives
Washington, DC 20515-0704

Dear Congressman Shays:

We are deeply disappointed and profoundly concerned by the regulations issued last week by the Department of Health & Human Services that we fear would cause irreparable harm to an organ transplant program that has resulted in more than 200,000 successful transplants in the last 15 years.

We share the Administration's desire to increase the number of organs available for transplants and recognize the need to have more effective outreach and educational efforts. We are convinced, however, that the impact of the regulations would be to lengthen the amount of time sick people must wait for liver transplants and reduce the number of people who get them. The proposed federalization of the current system would take away control of the transplant system from doctors and patients in almost 300 transplant centers and hand it over to Federal regulators. This defies the clear intention of the National Organ Transplant Act that the medical community, and not the Federal government, be responsible for administering this vital program.

It is indeed unfortunate that the effect of the regulations would be to undermine the very goals that the Administration is seeking to promote. Rather than reducing the waiting time and access to organs, the regulations would make it more difficult for the majority of patients to receive a transplant. For example, the regulations will reallocate donated livers away from the vast majority of the country's transplant centers and shift them to the largest centers. This would force many smaller transplant centers to shut their doors, depriving local communities of life-saving technology and skilled doctors. Even worse, closing down centers is likely to cause a decrease in donations as the efforts of transplant doctors and nurses to increase local donations cease. History shows that organ donation is a local phenomenon -- organ donations rise in communities that have transplant centers, and fall when centers close.

Federalizing the current program will result in fewer patients receiving transplants, thus saving fewer lives than the current system as the future waiting lists expand. By forcing doctors to transplant livers into the very sickest patients, who are statistically the patients most likely to require a second or third transplant, others on the waiting list will be denied access to even one, and survival rates, which have been increasing in recent years, will start to drop.

Furthermore, it is important to remember, that for the very sickest patients--those who are in intensive care units--the current waiting period among all transplant centers is very short, less than 6 days in all regions of the country. This was publicly acknowledged by HHS officials at the same time that they issued the regulations. In this critical respect, the regulations seek to address a problem that does not exist, while causing tremendous new burdens for other patients. The regulations will have a particularly harsh impact on individuals who will have to travel great distances and be separated from their loved ones at a time when they are needed most or who have limited financial resources. The additional travel cost could make it impossible for the twenty percent of transplant patients who are on Medicaid to receive a transplant.

A further problem generated by these regulations is that patients suffering from chronic illness will now have to become critically ill before being transplanted. This will significantly decrease their chances of surviving the surgery and result in additional deaths that would not have occurred under the existing system. UNOS has acted in recent months to give these patients fairer access to transplantation, but the regulations again relegate them to long waits and the ravages of their progressive diseases.

In order to achieve an equitable organ transplant allocation, a balance must be struck among the following four principles: a) enhance the overall availability of organs; b) allocate organs based upon equal considerations of the medical benefits to all transplant patients and equity in the distribution of benefits and burdens among them; c) provide transplant candidates reasonable opportunities to be considered for organ offers within comparable time periods, taking into consideration similarities and dissimilarities in medical circumstances as well as technical and logistical factors in organ distribution; and d) respect the autonomy of individuals. The current system recognizes and embraces these four principles, but the regulations ignore their importance and interrelationship in fashioning sound medical practice by stressing a single performance goal.

We are also concerned by the failure of the Department to provide an appropriate period for public comment and reaction to the regulations. Changes in policy as radical as those set forth in the regulations and as vital to the well being of millions of Americans who may need an organ transplant should not be implemented without thorough Congressional oversight and an opportunity for public scrutiny. Sixty days is insufficient time for this type of review. At a minimum, these regulations should be held in abeyance until the Congress, the medical community, and patients have an opportunity to fully understand them and engage in a meaningful dialogue with the Department.

UNOS volunteer doctors, recipients and donor family members have now contributed more than one million hours of effort to making the transplant system as fair and efficient as is humanly possible. Doing this well is an enormously complex task.

We are committed to strengthening our nation's ability to meet the needs of all organ transplant candidates and recipients, their respective families, and those selfless individuals and their families who make the special gift of life. We are concerned that the HHS regulations do not meet this test. We remain willing and eager to work with the Congress and the Administration to improve our current system and to hasten the day when the benefits of organ transplantation will be available to all who need them.

Sincerely yours,

L. G. Hunsicker, M.D.
President, UNOS

FROEDTERT
Memorial Lutheran Hospital

9200 West Wisconsin Avenue
P.O. Box 26099
Milwaukee, WI 53226-3596
Telephone: 414 259 3000

Primary Affiliate of the
Medical College of Wisconsin.
Member, Horizon Healthcare Inc.

To Whom it Concerns;

I am the wife of a liver transplant which happened in November 1997.

The thought of not having my husband today is unthinkable. That is exactly what ~~[illegible]~~ would have happened if your proposed bill were passed.

To think that your even thinking of doing this is unthinkable. My husband would have died if the transplant had not occured at Froedtert. There will an increase of deaths simply because lack of organs, we are one of the largest donor States, I feel that penalizing our residents is wrong.

I will try to ~~ma~~ fight this bill in anyway possible to end this proposed bill Feel free to call me if you have any questions I would really love to tell you our story.

Sincerely
Holly Koepp
(414) 255-7374

UNIVERSITY OF MASSACHUSETTS
University of Massachusetts Medical Center
Department of Surgery, Room S3-810
55 Lake Avenue North
Worcester, MA 01655-0333 (508) 856-8088 FAX: (508) 856-4466
E-mail: eliezer.katz@banyan.ummed.edu
Eliezer Katz, MD
Associate Professor of Surgery
Director, Liver Transplantation

April 6, 1998

The Honorable Christopher Shays
Chairman of Human Resources Subcommittee
Congress of the United States
House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515-0143

Dear Congressman Shays:

Enclosed please find my written testimony to the Human Resources Subcommittee Hearing on "Oversight of the National Organ Procurement and Transplantation Network" to be held Wednesday, April 8, 1998.

In my testimony, I am expressing my views against the new DHHS proposed regulations.

Thank you for the opportunity to present my testimony to you and the subcommittee in this important matter.

Sincerely,

Eliezer Katz, M.D.
Associate Professor of Surgery
Director, Liver Transplantation

EK:dan
Enclosure

R-97X

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Eliezer Katz, MD
Associate Professor of Surgery
Director, Liver Transplantation

April 5, 1998

Testimony to the Human Resources Subcommittee Hearing on "Oversight of the National Organ Procurement and Transplantation Network".

Eliezer Katz, M.D.

Professional Background:

I am the Director of Liver Transplantation Program at University of Massachusetts Medical Center (UMMC), Worcester, Massachusetts. I am a liver transplant surgeon since July of 1990. I was on the Faculty at Mount Sinai Medical Center, New York, NY as a liver transplant surgeon, and between October of 1994 to October of 1997 I was the director of the liver transplantation program at Oklahoma Transplant Institute, Oklahoma City, OK. In Oklahoma we have performed about 50 liver transplant a year. I was an officer of the Oklahoma Organ Sharing Network, officer of the Oklahoma Transplantation Society and member of most of the important liver national and international transplantation medical societies (ASTS, ILTS, AASLD, ESOT, etc.). I have participated in almost all the meetings of UNOS's liver transplantation committee over the last four years, and just before leaving Oklahoma I was nominated by UNOS region IV as the region representative to the UNOS liver transplantation committee. I am on the Faculty at UMMC since October of 1997. The liver transplantation program in UMMC is a new one, being active for the last 6 months.

My perspective of the reasons behind the recent HHS's regulations:

In the past 10 years UNOS (United Network of Organ Sharing) has provided to the transplantation community the organizational structure and mechanism for creating a fair, rational system for organ allocation. All UNOS committees are composed of experts in all aspects of organ transplantation including patients, physicians, public figures, ethicists etc. Most of these experts are professionals that engage on daily basis in treating transplant patients. In other words UNOS = Transplant Community. Therefore the process of decision making in UNOS's committees is an integral part of the practice of transplantation. The decisions that are made are the expression of the common ground and overall consensus of the transplant community. Of course not every one agrees with all decisions. However this is the basic nature of an academic, public and democratic process.

Over the past 3 years UNOS engaged in a deep discussion of liver allocation policies. This included endless hours of debating in all the relevant UNOS's committees and the use of a sophisticated computer simulation model to analyze various allocation systems. The end result was the introduction of changes in the liver allocation policy, the last one of which became effective on January 17, 1998. As far as the transplant community is concerned we now have the best allocation system that we can get. Not perfect, but one that puts in balance the multiple complex factors that are the basis for an allocation policy. Most importantly, the current allocation system is achieving a balance between "Equity" and "Utility" to assure wise and efficient use of a very scare resource.

Unfortunately, a politically well connected minority of the transplant community Led by the University of Pittsburgh Medical Center (UPMC) did not accept the consensus. This minority has tried over the last two years to enforce its view by using the department of HHS. The recent regulations released by the Department of HHS are the direct result of this effort. American medicine and science have advanced through a deliberative peer review process. DHSS intervention puts political clout ahead of dispassionate evaluation and review. UNOS is in the peer review tradition that ensures the best long-term outcome for our Country.

UPMC, the leader of the minority in the transplant community, is a major pioneer transplant center that experienced a significant reduction of its activity over the past few years. This reduction was the result of the establishment of many new programs around the country. The advanced medical technology that originated from UPMC spread around the country by a number of excellent transplant centers that provide to their communities access to liver transplantation. UPMC's effort to enforce their minority opinion on UNOS is a desperate trial to keep the monopoly and the business at UPMC and few other major transplant centers.

<u>The "sickest patient" argument:</u>

In the current system the sickest patient gets priority. Status 1 gives high priority to patients with acute liver or graft failure. Status 2A gives priority to the sickest patients with chronic liver failure. UNOS data demonstrates that there is no difference in time waiting for patients in status 1 and 2A across the country. The current definition of status 1 and 2A is the result of extensive discussion inside the transplant community in an effort to find the fine balance between "Equity" and "Utility". This balance is a must in the presence of severe shortage of organs. That why we are not transplanting a very sick patient with malignant disease of the liver and that why we have created a very extensive selection process for the alcoholic patient. On the other hand that was also the reason why patients with acute liver or graft failure were put as the highest priority, they are the sickest but have a very favorable outcome if they are done on time.

<u>The negative impact of the new regulations:</u>

If as a result of UPMC effort the new regulations will be implemented, most of the small-medium size liver transplant centers will experience a major setback in their ability to serve their local patients. More specifically the following will be negatively effected:

1. *Access to liver transplantation*: The direct easy access to liver transplantation anywhere in the country is a basic right of all patients. It is somewhat ironic to see that

UPMC which advocates "first priority to the sickest patient", declares in its web site that no patient would be listed for liver transplantation unless all the financial issues are resolved. And if they cannot be resolved a deposit in the amount of $ 300,000 is required from the patient. In other words it is a first priority to the sickest paying patient. So what will happened to the sickest patient who cannot pay? Most of the local transplant centers provide indigent care as a part of their commitment to the community. However, access to transplantation is not only a financial issue. The short existence of the liver transplantation program at UMASS Medical Center demonstrated very clearly that there are many patients who are not referred for liver transplantation as a result of lack of knowledge and awareness in the local rural communities. A liver transplant center in close proximity initiates awareness increases education and has a direct effect on referral patterns. In other words some patients were not referred to far transplant center but they are being referred to a near by close by center. Moreover, patients who were referred to distant centers were lost to follow up over the long period of waiting and were admitted to UMMC at a very late stage of their disease. In some cases too late. The same was true in my long experience in Oklahoma.

2. *Organ procurement rates*: One of the main arguments to justify a change in the allocation system is the difference in waiting time between different regions in the country. However, one must look at the differences in organ procurement rates between regions as a major factor that leads to a difference in waiting time. In these regards, there is enough data to demonstrate that local factors have major impact on the rate of organ procurement. A local transplant center and a highly motivated local OPO have a significant positive impact on the rate of organ procurements. The local effect is reflected by the significant difference in the procurement rates between OPO's. The rate range between 12-15 donors per million per year in some OPO's, to 30-40 donors per million per year in others. The close relationship between the local OPO and the local transplant center are crucial to increase the procurement rates. Since the liver transplant program was opened in UMMC we have engaged in extensive effort with the NEOB to improve overall performance and procurement rates. This fruitful cooperation cannot be done when the OPO and the transplant center are hundreds or thousands miles apart.

3. *Trust among transplant centers*: One of the most important conclusions of the ongoing discussion in UNOS is that trust must be built among transplant centers as a basis to any change in the allocation system. Unified listing criteria, definition of the medically urgent patient, developing of new techniques (split liver) etc., all of these cannot be successfully implemented without constructive cooperation between transplant centers. This cooperation must be based on trust and good faith. UNOS recently introduced the regional review boards (RRB) in an effort to create peer review system to promote trust and cooperation. It is my view that the recent proposed regulation will have a significant destructive effect on the level of trust among transplant centers. Many of my colleges around the country are sharing this view. There is a great mistrust expressed toward UPMC and other major transplant centers that are covering their business motivation with ethical and medical arguments.

In summary, the present allocation system, which was created by UNOS is the best available system at present. A minority in the transplant community should not lead the department of HSS to enforced destructive changes in the current UNOS allocation system. All the effort needs to be directed at increasing the number of donors.

Respectfully submitted,

Eliezer Katz, M.D.
Associate Professor of Surgery
Director, Liver Transplantation

MEDICAL
COLLEGE
OF WISCONSIN

Department of Medicine
Nephrology Section

April 6, 1998

Congressman Christopher Shays
Chairman, Subcommittee on Government Reform & Oversight
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Congressman Shays:

As a nephrologist practicing in the state of Wisconsin, I am writing to urge you to oppose the new rules for organ allocation proposed by the Secretary of Health and Human Services.

These rules would penalize areas of the country that have been effective at increasing the rates of organ retrieval, it will decrease the success of transplanted organs, it will effectively cripple the United Network for Organ Sharing, and, there is little objective evidence that will lead to an improved allocation of organs. The current system, while not perfect, is the result of the good-faith effort of thousands of individuals, many of them on a voluntary basis. Their efforts have resulted in a system that has provided outstanding organ donation services for this state in particular. It should preserve and improved rather than destroyed.

I hope that you will consider our concerns seriously and work strenuously to prevent the proposed rules from going into effect.

Sincerely,

Jack G. Kleinman, M.D.
Professor of Medicine

JGK/js

Department of Veterans Affairs
Medical Center
5000 West National Avenue (111K)
Milwaukee, Wisconsin 53295-1000
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Rep Shays

From: Southpaw4[SMTP:Southpaw4@aol.com]
Sent: Wednesday, April 08, 1998 2:28 PM
To: Rep Shays
Subject: Organ Transplants

I am a recent (6/96) kidney/pancreas transplant recipient at the University of Wisconsin Hospital. There is no finer transplant program in place in the United States than that operating out of UW. It is staggering to behold the amount of time and loving care that they put into their transplant program both in the harvesting of organs and in the caring given to donor's families.

It would be a shame for other centers to reap the benefits of this program without having to lift a finger. Unfortunately, those most needing a transplant are not always able to withstand the rigors of this operation itself not to mention the immuno-suppressive therapy.

My husband and I visited many transplant centers and chose the University of Wisconsin, not based on quickness of organ procurement, but on its sound and demonstrated track records. My insurance company (John Hancock) held it out to be a "Center of Excellence", and it most definitely turned out to be one for us.

Unfortunately, the Northeast suffers from several stumbling blocks--a tainted share of organs (AIDS), a large black population which historically does not donate organs, and very little education to the masses. Until we can overcome some of these obstacles, I feel that we have no right in demanding other area's organs.

I take my hat off to Dr. Hans Sollinger and his extraordinary group of transplant surgeons and nursing staff. Without their excellent and compassionate program, I would not be alive today. I urge you to represent my position and to pass this on to the House Committee on Government Reform and Oversight which is holding a field hearing today in Milwaukee, WI.

Please acknowledge receipt of this E-mail and please keep me informed of all future developments in this matter.

Thank you,

Sharon M. Kloss
New Jersey

Nephrology Associates of Waukesha, S.C.

Adel B. Korkor, M.D. *Elaine M. Worcester, M.D.* *Mohammad Tinawi, M.D.*

March 31, 1998

Christopher Shays
Chairman
Sub Committee of Government Reform and Oversight
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Dear Mr. Chairman:

This letter is in regard to the new rules for organ allocation proposed by Dr. Donna Shalala. I am a practicing nephrologist in the Waukesha area, a growing Wisconsin community. The majority of my patients are currently being transplanted at the Medical College of Wisconsin where intense effort to encourage organ donation has developed. I am very proud of what we have accomplished here and fear that these new rules will jeopardize the timeliness and the quality of the current services my patients are receiving. This is because it will likely increase the waiting period as a large number of the kidneys harvested in Wisconsin will be shipped out of state. This in turn might discourage organ donation as well. The efforts of UNOS over the years has been highly effective as an organization representing the transplant community and would strongly encourage establishing a dialogue with this agency to address the concerns that Dr. Shalala and her committee has.

Thank you.

Sincerely,

Adel B. Korkor, M.D.

ABK/dlm

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Gregory V. Warren, M.D.
Paul J. Warren, M.D.

April 1, 1998

Christopher Shays, Chairman
2157 Rayburn House Office BLDG.
Washington, DC 20515-6143

RE: UNOS changes

Dear Mr. Shays:

I am writing in opposition to the proposed UNOS changes. I care for a number of kidney transplant, heart transplant and pancreas transplant patients. I think it unwise to look only at equalization of waiting time, instead of factors such as outcome.

Unfortunately, when we allocate organs to the sickest patients first, we will have fewer successful transplants and this will certainly be a waste of these precious organs. The changes might result in lower organ donations since the local organ drives, which have made such a difference in increasing donation, may not have a reasonable outcome. People will realize that organs may be shipped out of their local area.

This new change is not based on scientific data and will not allocate the organs appropriately. There will not be completely equal access and the number of successful transplants will decrease.

UNOS has been a very effective organization in allocating organs. Should the rules be changed, UNOS will have very little say. This would be a travesty especially considering how many transplant professionals, patients and families have been involved in developing a sound and fare organ allocation system.

I am very much opposed to the changes as proposed by Donna Shalala and I think that the changes must be re-thought so that we don't waste organs.

Sincerely,

William Kraklow, M.D.
(dictated not read)

WK/lj

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mayo

Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
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DATE: April 3, 1998

TO: Congressman Christopher Shays

RE: Oversight Hearing on the Department of Health and Human Services' (HHS) management of the National Organ Procurement and Transplantation Network (OPTN) under the National Organ Transplant Act of 1984 (NOTA)

INTRODUCTION

After my discussions with Dr. Anthony D'Alessandro, who will testify during the above-referenced hearing and even though I have not been officially invited to testify in this hearing, I would like to submit my written testimony to you.

BACKGROUND

I am the Chairman of the Division of Transplant Surgery in the Mayo Clinic, and Surgical Director, of the Liver Transplant Program since its inception on 1985. After being trained in this field by Dr. Thomas E. Starzl (in Denver) in 1977, and prior to my recruitment to the Mayo Clinic, I was director of the liver transplant program in the Netherlands since 1979 I have witnessed the creation of the United Network for Organ Sharing (UNOS) in 1987 and participated actively in the Liver Subcommittee of which I was chairman from 1989 until 1992.

In this function, I was closely involved in the development and implementation of the basis of the current allocation system, which was amended last year following various hearings by UNOS and HHS.

ISSUES

My testimony will address the following issues: (1) organ allocation and in particular donor liver allocation; (2) socioeconomic impact of liver allocation; (3) the role of UNOS.

1) ORGAN ALLOCATION

The principle problem of any organ allocation system is the significant discrepancy between the number of potential transplant recipients and the number of available donor organs. Currently, ±10,000 patients are on the waiting list for liver transplantation, while only about

4,500 donor livers will become available in 1998. No matter which system of organ allocation is in place, a number of patients will die due to lack of a donor organ.

A system of organ allocation determines for whom a lifesaving donor liver will be available. Will the donor liver be given to the "sickest patient" with a diminished chance of surviving the procedure or to those with a somewhat lesser advanced stage of liver disease, who are known to have a significantly better short-term and long-term outcome. In UNOS this ethical dilemma is known as the balance between "justice and utility." Although there is no scientific method to measure justice and utility, it is obvious that no system based on either justice or utility alone can be satisfactory. A system based on justice can provide donor livers to many patients in intensive care units dying of end-stage liver disease, which may be judged as a laudable goal. However, it has less laudable consequences: (1) as the outcome of liver transplantation in these terminally ill patients is clearly inferior than in patients in a better clinical condition, precious donor livers will be lost due to additional patient loss after transplantation. This is even more of a concern as in the context of the limited availability of donor livers patients will be only allocated a lifesaving organ when their clinical condition has deteriorated to the point that they qualify for the category "the sickest." This implies long pretransplant morbidity, a complicated perioperative and immediate postoperative period with prolonged ICU and hospital stay and a diminished chance for an optimal outcome. In addition to the question if the scarce resource was utilized wisely, one can easily assume a significant incremental cost.

The alternative system, which is solely based on utility and results in the optimal use of the scarce donor liver based on patient and graft survival and cost, is utterly unfair. It denies the fact that despite a desperate clinical condition, some patients can be saved because of younger age, better quality of the donor organ and experience of the transplant center.

Based on the recommendations of the Ethics Committee of UNOS, the balance between justice and utility has been the leading ethical principle in the development and subsequent adjustments of the organ allocation system in UNOS.

The principle of justice and utility does not pertain only to national statistics related to availability of donor organs, but should also count in smaller geographic units. The waiting time for a donor liver differs significantly per UNOS region, which causes perceptions of injustice and concern for patients, transplant centers, and UNOS, HHS, and ultimately, the Secretary of Health Mrs. D. Shalala.

It is beyond doubt that real differences exist between various regions in UNOS. However, the differences are less flagrant than the numbers presented to Mrs. Shalala. Due to the lack of organ donors, many centers implemented a policy to list patients with liver disease early (too early?) in order to compete favorably for a donor liver when the need is there. In order to level this "playing field", UNOS implemented last year the "minimal listing criteria." Its effect is not measurable yet as these minimal listing criteria are indeed "minimal", which will not markedly effect the patient mix, and as patients already on the waiting list are grandfathered in. Moreover, this measure would only be effective when all centers would follow those criteria truthfully. Therefore, without an effective monitoring system, the efficacy of this measure can be seriously questioned.

The policy of listing patients early confounds the waiting time statistics and makes interpretation with regard to justice difficult. Indeed, when one analyzes the waiting time for the "sickest" patients on Status 1 (acute liver disease), the differences appear to be less marked. As the indications to list a patient on this status 1 (high urgency) are well defined and easily to monitor, one can assume that the statistics are reliable. To further equalize the waiting time for status 1 patients one may consider organ sharing at the level of UNOS regions or even larger geographic areas.

Ideally a similar approach should be made for patients on Status 2A, which is the highest urgency level for the "sickest" patients with chronic liver disease. However, the criteria to qualify for this urgency level are not well defined and open to broad interpretation as well as purposeful misstatements. As a consequence of the vague definitions, a large number of patients are listed on Status 2A and the appropriateness of this is impossible to monitor by UNOS unless more resources become available and penalties can be imposed. Because of the different level of compliance with rules for status 2A, the "playing field" has become very uneven. Therefore, without strict criteria, that are easy to monitor by UNOS and possibly supported by sanctions for those centers, that repeatedly violate these criteria, sharing of donor livers in a wider geographic area will be difficult to implement.
The implementation of an allocation system that provides incentives for disobedience should be avoided at all cost, as it will invoke wide spread distrust, which will undermine all positive achievements of UNOS, which are build on consensus.

2) SOCIOECONOMIC IMPACT OF LIVER TRANSPLANTATION

a) Although one can argue that currently the nation has too many liver transplant centers, the accessibility for patients to this complicated lifesaving procedure has dramatically improved since the inception of UNOS in 1987. In those years, patients and families were forced to travel far in order to find a facility that offered this procedure. Nowadays, almost every state in the nation has at least one and often more liver transplant centers, offering patients medical help closer to home. Was liver transplantation a lifesaving option for wealthy in the early years, currently practically everybody has access to liver transplantation.

b) Although the Federal Register only provides the frame for revamping the current organ allocation system, it is clear that Mrs. Shalala has chosen for a system mainly based on "justice" ignoring all arguments for utility. Unfortunately, the honorable quest to equalize waiting time across the nation, which should be achieved by sharing donor organs nationwide, may result in serious negative side effects. Most seriously, based on its allocation test model, UNOS predicts, that ± 800 less patients will receive a liver transplant due to increased incidence of retransplantation and a significantly decreased patient survival rate. Moreover, as donor livers are shared over large distances, the quality of the donor liver diminishes due to prolonged preservation time resulting in a higher incidence of graft failure. This will have a dramatic negative effect in utilizing donor organs from the extended donor pool (donors with increased risk factors and of higher age), which could have been used, if the preservation time was kept to a minimum. Although the University of Wisconsin solution (UW solution) has made extended preservation time possible, the liver function diminishes significant with preservation longer than 12 hours. Even the transplant center in Madison itself, which developed and promoted the UW solution, has abandoned prolonged preservation for this reason. In general, transporting donor livers within a state normally results in preservation times between 8-10 hours. Moreover, in order to prevent extremely long preservation times, small private jets are necessary for transport of donor organs over long distances. This will increase the cost significantly.

c) As large transplant centers always have sick patients eligible for organ sharing, donor organs will leave the donor area by passing local smaller programs. It is predicted that national sharing of donor organs will lead to a significant reduction of these small programs in favor of the larger ones resulting in more difficult access for liver transplantation. Therefore, without a level "playing field" for organ allocation, these negative side effects are difficult to accept.

d)

A dark side of organ transplantation, that is not often addressed, is that fact that having a donor organ allocated to a patient on a center's waiting list implies revenue for that medical center. Therefore, the financial wellbeing of a liver transplant program depends on the number of donor livers allocated to this center. More donor livers mean more personnel and resources; less donor livers may result in lay-off of personnel. This is readily illustrated by the growth and recent decrease of the number of liver transplants per year in Pittsburgh. Financial stress, in addition to stress caused by very sick patients in one's care, might lead to exploring less ethical means to increase the flow of donor organs toward one's program. The nation may benefit from a centralized reimbursement system, which may remove financial incentives while utilizing a scarce national resource.

3) THE ROLE OF UNOS

Since its inception in 1987, UNOS has achieved a remarkable feat: it has developed functional organ allocation systems based on consensus with input of many individuals and groups within the transplant community and in the nation as a whole. It has achieved this result without any other method than consensus and moral accountability. UNOS lacks the tools to punish flagrant violators of the system. When changing circumstances required revisions, UNOS has frequently adjusted its policies following a process of consensus building. One should only consider the impact of the increase in numbers of potential recipients and transplant centers since 1987, as well as the increased oversight by the society on policy making in UNOS.

In addition, UNOS has accepted a major role in enhancing donor awareness to increase organ donation in the nation.

Moreover, UNOS has developed a functional database allowing analysis of outcomes and trends in organ transplantation. This databank provides valuable information in analyzing the effect of changes in allocation policies.

UNOS should be recommended for the important role in support of organ transplantation in our nation.

CONCLUSIONS

In principle, Mrs. Shalala should be complimented for her empathy with the many patients in need for organ transplantation. The injustice of differences in waiting times between geographic areas in the nation is a concern for us all. However, as these differences were even more significant in the past, it is an indication that with the proliferation of transplant centers across the nation, local access has greatly improved. Many patients now benefit from the availability of organs from local donors in local transplant centers. Large tertiary programs with many out-of-state patients have outgrown their local donor organ supply and now actually feel the pressure of the lack of donor availability more acutely than ever before because the many smaller programs are providing transplant services for their local patients.

No one disputes that flagrant differences in waiting times exist partially due to the artificial nature of the UNOS regions and that these differences should be corrected, in particular for the "sickest" patients. However, it is also important to develop a monitoring capability within the system where violations are tracked and penalties imposed upon repeat offenders.

Unfortunately, the time frame in which Mrs. Shalala wishes to resolve this perceived injustice in waiting times is unfairly short. This may lead to implementation of an allocation system that may actually decrease the number of lives saved per year, may increase costs and may lead to diminished local access, as smaller programs may need to discontinue their services. Moreover, because of the potential negative side effects such organ allocation system will not be supported by a consensus within the Transplant Community.

Perhaps, given a more realistic time frame with input and feedback from the entire Transplant Community, the initiative of Mrs. Shalala, to diminish injustices in waiting time, might result in an improved allocation system supported by the Transplant Community which could save even more lives than at present.

I thank you for the opportunity to submit my testimony.

Signed: ____________________________________
Ruud A. F. Krom, M.D., Ph.D.
Chair, Division of Transplantation Surgery
Surgical Director, Liver Transplantation
Mayo Clinic and Mayo Foundation

RAFK:trt

FRANK T. LAMM, P.E.
2780 ALMESBURY AVENUE
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April 10, 1998

Hon. Christopher Shays, Chairman
Subcommittee on Human Resources
Committee on Government Reform and Oversight
Room B-372 Rayburn Building
Washington, D.C. 20515

RE: Oversight of the National Organ Procurement and Transplantation Network

Dear Chairman Shays:

As you indicated at the April 8, 1998 public hearing on this subject held in Milwaukee, you will hold the record open for five days to receive additional written comments on the regulations regarding national, rather than regional, allocation of organs, which I understand is to be codified as 42 CFR Part 121.

I firmly believe the national allocation portion of these regulations to be conterproductive, unnecessary, based on faulty information, and of benefit only to a very few large transplant facilities who have put their own interest above that of the entire organ transplant system.

Rather than implementing these ill-conceived regulations, the Federal government should focus on encouraging more organ donations and making the regional OPOs more effective.

As you were made aware at the public hearing on April 8, the vast majority of persons who understand the existing, regional system are completely in favor of it as compared with the national approach. Most of those attendees were providers or transplant recipients! They are the best informed and aware segment of the population and their opinions should receive more consideration than has been the case to date.

I have enclosed a copy of the comments I have submitted to HCFA. Please consider them in your deliberations.

Mister Chairman, I know you are sympathetic to this issue and its impact on those who either receive or fail to receive a life-saving organ. It must be irritating and exasperating to sit through hours of drivel such as the testimony and responses to your questions from the first panel, or to have to listen to the half truths and outright falsehoods presented in the afternoon by a representative of a large eastern university hospital. To me, the bottom line is simple. The existing system is fair, results in more organs being effectively used, costs less, and will save more lives than the well-meaning but impractical national alternative.

Please do your utmost to delay or cancel the national allocation process.

Sincerely,

Frank T. Lamm

encl: as

cc: Hon. Tom Barrett

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April 10, 1998

Jon L. Nelson, Associate Director
Office of Special Programs
Health Resources and Services Administration
Parklawn Building
12420 Parklawn Drive
Rockville, MD 20857

RE: Public Comment on Proposed Regulations Regarding National Organ Distribution

Dear Mr. Nelson:

HCFA has recently published final regulations dealing, in part, with a change to the distribution of organs to a national, rather than a regional, system. I, as well as most providers and transplant recipients, believe the national approach to be a well-meant but entirely misguided decision based on faulty analysis of outdated information and misinformation provided by a few national transplant facilities that have put their own personal interests above those of the organ transplant system and all individuals in need of a transplant.

Actually, until there are adequate numbers of organs to meet all needs, there can be no one system that is absolutely fair to all. No matter how statistics are manipulated, a system that allows organs to be placed into recipients healthy enough to retain them, and in the shortest period of time practical, will result in fewer organs being wasted or rejected, and more survivors. The national system proposed will result in more deaths than the current system and in more people becoming desperately ill. This will result in higher costs, more frustration, and a reduction in committed volunteers. I also believe that smaller regional transplant facilities will stand a greater chance of becoming weaker.

I was born with an hereditary condition known as Polycystic Kidney Disease which, over a long period of time, robs one's kidneys of their ability to function. Under the national distribution system, that person would have been required to wait until he became deathly ill before being considered for a transplant. Tens of thousands of dollars would have been spent on dialisis and other treatment. In the end, he may not have survived the transplant, because even in his healthier condition, he experienced multiple rejection episodes. Because he was a large person, his body was able to function with a creatinin level almost 50 percent higher than many smaller persons. The many variables encountered in real life make it virtually impossible to develop a single ranking system that can be fair to all. I have three natural children who stand a 50 percent chance of having this disease, and believe the proposed changes will place them in more danger of an extended period of torture followed by eventual kidney rejection.

There is an old and honored saying that, "If it ain't broken, don't fix it!" That maxim is entirely applicable in this case. There is one, single transplant problem crying to be resolved. That problem is, of course, that there are not enough organs to meet the ever-growing demand. Until that problem is solved, the proposed regulations will be unfair to anyone who does not receive a healthy organ in a timely manner. After that problem is solved, there will be no need for such changes.

I believe that since there presently are not enough organs to meet the demand, a few large transplant facilities are supporting these changes, which they selfishly believe will result in more organs going to them and fewer remaining in regional locations In the end, that will be the only "benefit" from these new regulations. No more people will be saved! As indicated above, there is every reason to believe that fewer recipients will survive. Mickey Mantle will become the poster boy for your regulations.

Many organs, such as hearts, lungs, kidneys, livers and pancreases, are extremely perishable. They have a short "shelf life." Preservation cannot be extended by flash-freezing or other methods. They begin to lose the ability to function, or viability, immediately upon removal from the donor, if not sooner. Any step that adds delay, either through decision making, extended transport times, or the like is counter-productive. In my case, there was a delay in harvesting the organs that resulted in reduced viability even though the donor was only one hundred miles away! In addition to the viability issue, total costs of organ harvesting will rise as more organs are sent further away.

Ideally, organs should go to those persons who have the closest antigen match, are healthy enough to retain the organ, and are relatively close the both the donor and the transplant facility. If any of those conditions are not met, each of the few precious organs will stand a greater chance of rejection or waste. I would like to cite a simple example. I was one of two persons to receive a kidney from a single deceased donor. I was relatively healthy and a good antigen match, and was able to be released from the hospital within a few days after the transplant. The other recipient had been ill for a long time and was in desperate condition. His body rejected the kidney and I was told he died shortly after. Lack of a kidney in time resulted in his death. Providing it at the last stages resulted in the waste of an organ that could have saved someone else.

The national system would provide organs to "the most urgent need." As is true for most things in life, such a determination cannot be made by a computer or by a group of bureaucrats sitting in Washington. Such decisions must be made and continually updated "close to the action." Decisions of when to be placed on a waiting list and when to receive a transplant are presently based on opinions from doctors who know the patient and have applied their own criteria to his or her condition. Such individual evaluation is bound to be lost in a nation-wide system. Any such system must have its own built-in prejudices and inequalities.

A simple "Status 1, 2 or 3" system is a seriously flawed decision-making process and will be no improvement to the existing system. The arrogance of proposing such a simple-minded system is breathtaking. Forcing a person to wait until he is more ill than anyone else on his list is both absurd and wasteful.

During my stay in the hospital, and through all my preceeding and followup hospital visits, I have been seen by the same group of physicians and surgeons, all within reasonable distance to my home and work. Anything that may reduce the effectiveness of regional transplant facilities is a danger to me and many like me. The new regulations pose exactly that danger.

Will more persons be encouraged to sign donor forms by creation of a bureaucratic organ assignment system more likely to see their organs rejected or otherwise wasted? I think not.

Is the present system crying for a Federal Organ Distribution monopoly, which will be as effective and efficient as its counterparts throughout government? I think not.Will the systemadequately and in a timely manner inform the recipient of potential future health problems associated with a particular organ? For instance, I was informed that a kidney offered to me was from a donor who had Hepititis A, and was given an opportunity to accept or refuse the organ while it still had viability for use. I was healthy enough to be able to refuse it, as had at least one person before me. If I was on death's door, such would not have been the case.

What is the answer? Obviously, there is a desperate need. However, that need is for more organs, not for an impersonal, error-prone, delaying expensive and arbitrary allocation system.

I suggest looking into incentives and other ways to encourage donors not convinced by altruistic motives. Such incentives could, at the Federal level, include tax incentives to a person's estate, or perhaps a prereqisite for receipt of Federal support such as welfare benefits. Federal legislation prohibiting lawsuits against doctors or hospitals that harvest organs from persons who have signed valid organ donation cards seems to be a minimum action that could materially increase the availability of organs.

In the meantime, my family and I urge rejection of the proposed national distribution policy. We plead that the existing system be allowed to remain and that it be fully supported by the government. Dissention in organ donation efforts is hurtful to the needs of all recipients.

Sincerely,

Frank T. Lamm

April 6, 1998

Chairman Christopher Shays
Committee on Government Reform and Oversight
Subcommittee on Human Resources
House Office Building
Washington, D.C. 20515

Dear Chairman Shays:

The regulations proposed by Secretary Shalala of the HHS, in effect, would sentence my daughter to death.

I am the father of Makenzie Lee, a beautiful five-year-old, with a brutal circumstance. She has a form of liver cancer known a hepatoblastoma. It was diagnosed at the University of Iowa one year ago this past March. In that year she has had three different types of chemotherapy and three surgeries on her liver. A lot to take for most adults and at the time, she was only four!

In February of this year, when it was determined that the last surgery had failed to stop the cancer and that it was growing even while receiving chemo, we were told that our daughter would die. Our primary oncologist suggested that we simply let nature take its course. As parents, this was not an option! It was related to us that different approaches to our daughter's case might be found at another institution.

The knowledge that there might be another view led us to MD Anderson in the Texas Medical Center at Houston. After our oncologist, Dr. C. Herzog, reviewed our case and consulted with a liver surgeon it was decided that Makenzie's only chance was a liver transplant. That is when we met Dr. Patrick Wood. He told us that our daughter was an excellent candidate for a liver transplant and that the success rate for transplants involving hepatoblastoma was 90%!

Imagine what it felt like when we were then told, that the same day in Washington regulations were proposed that would change the current system and deny my daughter her chance at a new liver she desperately needs.

The regulations would put the emphasis on the sickest patients and break down the current regional system. What this would do is channel organs away from the smaller operations, such as the ones in Iowa and Texas, and send them to the largest hospitals in major urban areas.
This effects my daughter directly, for a couple of reasons. First, she is undergoing chemotherapy on an out patient basis, this classifies her as level three. Currently there are no special concessions for those suffering cancer. If Makenzie's liver were to fail she would be ranked higher, depending on her condition.

Her liver is going to fail her, but in another way. The cancer that is in her liver becomes resistant to chemo very quickly. We have already expended four very good and largely successful regimes, successful except for her. At some point, the cancer would spread from her liver and take over her lungs and abdomen. Through this terrible process, her liver would continue to function. For obvious reasons, transplants at that point are ruled out, and rightfully so.

That fact brings me to the second reason my family strongly disagrees with these regulations. If Makenzie were placed on a "national list," with the "sickest" patients at the top, she would have no chance at a transplant. Her window of opportunity is very narrow as it is, without the proposed guidelines for change being implemented.

As I stated earlier, transplants involving hepatoblastoma have a 90% success rate. If Makenzie and other children like her are fortunate enough to receive just one of the kindly donated and precious few organs available, I am sure that you will see the gift of life lived to its fullest potential.

My family is asking, "no", begging that you consider the impact of these well meaning but short-sighted regulations. Makenzie is five years old. She has a super chance to live to the age of Eighty-five, if she can receive the liver she desperately needs. Please consider the viability of the candidate, especially with respect to the young and strong, those with the best chance for a long and high quality life.

Thank you for your attention concerning this highly controversial subject.

Bryan, Connie, Makenzie & Joey Lee

Bryan Lee
1904 N. Court
Ottumwa, IA 52501

Midelfort Clinic
MAYO HEALTH SYSTEM

LUTHER CAMPUS • 1400 Bellinger Street • Eau Claire, WI 54703 • 715 / 838-5222

April 3, 1998

CHRISTOPHER SHAYS
CHAIRMAN OF SUBCOMMITTEE ON
GOVERNMENT REFORM AND OVERSIGHT
2157 RAYBURN HOUSE OFFICE BLDG
WASHINGTON DC 20515-6143

Dear Representative Shays:

I am a nephrologist practicing in Eau Claire, Wisconsin with Midelfort Clinic. I am writing to you to speak against Secretary Shalala's new rules for organ allocation. I believe her strategies are scientifically unsound and morally wrong for the following reasons:

1) This new system is designed only to equalize waiting time. It is not designed to get kidneys most quickly to the patients most suited to receive them. Obviously, there is a large shortage of donor kidneys. The current system attempts to get those kidneys to deserving recipients as quickly as possible, without prolonged travel time, which can damage the eventual function of the kidney. There is no shortage of recipients locally.

This new method would likely lead to fewer successful transplants and increase the cost of transplantation by the inordinate movement of kidneys around the country.

2) In Wisconsin, we have enjoyed relatively good transplantation rates compared with the rest of the country because of strong efforts by Wisconsin healthcare providers and patients to create a good system. If all "local" kidneys are subject to removal elsewhere in the country, local efforts will falter, because of poor availability of those kidneys.

Midelfort Clinic
MAYO HEALTH SYSTEM
LUTHER CAMPUS • 1400 Bellinger Street • Eau Claire, WI 54703 • 715 / 838-5222

Page 2

3) The current system seems to be the best possible method, based on numerous studies done in the past. For the above reasons, changing it seems ill-advised.

4) Finally, the UNOS transplant organization has worked extremely well to this point. Changing rules of distribution of organs now would emasculate the UNOS organization.

I very strongly recommend, therefore, that the current system not be changed for the above reasons. If you have any questions or comments, I would appreciate hearing from you.

Sincerely yours,

William J. Maierhofer, MD, FACP/slm

William J. Maierhofer, MD, FACP

cc Representative Tom Barrett

ROBERT MENENDEZ
13TH DISTRICT, NEW JERSEY

COMMITTEE ON TRANSPORTATION
AND INFRASTRUCTURE
SUBCOMMITTEES:
SURFACE TRANSPORTATION
WATER RESOURCES
COMMITTEE ON INTERNATIONAL
RELATIONS
SUBCOMMITTEES:
AFRICA
WESTERN HEMISPHERE AFFAIRS

CHIEF DEPUTY WHIP

Congreſs of the United States
House of Representatives
Washington, DC 20515–3013

REPLY TO

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April 15, 1998

The Honorable Christopher Shays
Chairman
Subcommittee on Human Resources
House Government Reform Committee
B-372 Rayburn H.O.B.
Washington, D.C. 20515

Dear Mr. Chairman:

As you know, there has been an enormous amount of concern expressed over HHS's proposed rules governing organ transplants. I know that your Subcommittee held a hearing on this issue earlier this month in Wisconsin.

I have been contacted by doctors, hospitals and New Jersey's transplant organization, The Sharing Network, about these new rules and what it will mean to patients in my state. For this reason, I am hoping that you will schedule a hearing in Washington on this matter in the very near future. And, if such a hearing is scheduled, I would like to be apprised of how someone might testify.

These new regulations stand to have an enormous impact on New Jersey's program, and I am certain that other states will be similarly affected. I would urge the Subcommittee to have a hearing on these regulations at your earliest convenience. I look forward to hearing from you on this issue.

Sincerely,

Robert Menendez

Robert Menendez
Member of Congress

RM:kgk

NEBRASKA
HEALTH SYSTEM
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April 6, 1998

HPI - Representative Christopher Shays
Government Center
888 Washington Boulevard
Stamford, CT 06901-2927
FAX: 202-225-2382

Dear Congressman Shays:

Thank you for the opportunity to submit written comments on the final rules governing the operation of the Organ Procurement and Transplantation Network (OPTN). My comments reflect the opinions of the University of Nebraska Medical Center and it's affiliated primary teaching hospital, Nebraska Health System, where over 200 patients receive organ transplants each year.

We applaud Secretary Shalala and her staff for their research and diligence to improve the effectiveness and equity of the Nation's transplantation system. It is important to consider the final rules as a total system to benefit patients which furthers the purposes of the National Organ Transplant Act of 1984. We should look at how encouraging organ donation, improving the organ allocation system, providing the bases for Federal oversight of the OPTN, and providing better information about transplantation will interrelate and work together to build public trust and awareness.

A good beginning has occurred to encourage organ donation with the publication of proposed rules in the Federal Register on December 19, 1997. We look forward to studying and taking action on ideas from the April 1-2, 1998 conference.

Our great country is built around the Bill of Rights and the ability of individuals to exercise freedom of choice. These same principles should apply to the ability of patients, in collaboration with referring physicians, and payors to select their transplant center with the expectation that waiting time for an organ will be comparable to others waiting in other locations with similar medical appropriateness. I have personally witnessed patients incur substantial additional expense, time and energy to be placed on the waiting list at several transplant centers to increase chances of receiving a life saving organ transplant. Not all patients have the knowledge, financial resources, or time to take this step. Equally disturbing is a situation in which a patient was advised by an organ procurement organization to consider a transplant center further away from home that might result in a shorter waiting time. We cannot allow these situations to continue.

The Secretary's performance goals for organ allocation are reasonable and do not interfere with the practice of medicine. Models that have already been presented to committees of the United Network for Organ Sharing (UNOS) may be able to meet the criteria. It is time for us all to support the new rules and accept the leadership provided by the Secretary. Together we can develop the transplantation network into a system that is trusted and understood by the American public.

Sincerely,

Marsha Morien

Marsha Morien
Director, Solid Organ Transplantation

040698.mm

R-96X

MIDWEST
NEPHROLOGY
ASSOCIATES, S.C.

James Brandes, M.D.
Amir Daniel, M.D.
Claire Fritsche, M.D.
William Krahlow, M.D.
Todd Muche, M.D.
Gregory V. Warren, M.D.
Paul J. Warren, M.D.

April 1, 1998

Christopher Shays, Chairman
2157 Rayburn House Office BLDG.
Washington, DC 20515-6143

RE: UNOS changes

Dear Mr. Shays:

I am writing in opposition to the proposed UNOS changes. I care for a number of kidney transplant, heart transplant and pancreas transplant patients. I think it unwise to look only at equalization of waiting time, instead of factors such as outcome.

Unfortunately, when we allocate organs to the sickest patients first, we will have fewer successful transplants and this will certainly be a waste of these precious organs. The changes might result in lower organ donations since the local organ drives, which have made such a difference in increasing donation, may not have a reasonable outcome. People will realize that organs may be shipped out of their local area.

This new change is not based on scientific data and will not allocate the organs appropriately. There will not be completely equal access and the number of successful transplants will decrease.

UNOS has been a very effective organization in allocating organs. Should the rules be changed, UNOS will have very little say. This would be a travesty especially considering how many transplant professionals, patients and families have been involved in developing a sound and fare organ allocation system.

I am very much opposed to the changes as proposed by Donna Shalala and I think that the changes must be re-thought so that we don't waste organs.

Sincerely,

Todd Muche, M.D.
(dictated not read)

TM/lj

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MEDICAL
COLLEGE
OF WISCONSIN

Department of Pediatrics

April 7,1998

The Honorable Christopher Shays
2157 Rayburn House Office Building
Washington D.C. 20515-6143

Dear Congressman Shays,

I am writing to you with grave concerns over the proposed new rules for transplant organ allocation. There are several reasons to question whether this proposal is truly compassionate or medically sound.

First, it is proposed that the organ sharing scheme be changed such that organs procured locally be offered to those waiting across the country who are the sickest and waiting the longest. This plan has the potential to be devastating to all transplant patients in general. The quality of the organs, and hence the final outcome of the transplant and patient, will suffer with longer preservation times, which are known to increase the incidence of organ dysfunction. In addition, the motivation of organ procurement teams to perform quality work will be squelched by the sending of organs to a patient population in which they are not professionally invested. Finally, sending organs routinely outside the donor network will adversely effect the community's commitment to organ procurement. *The work to improve organ donation rates will become more difficult than ever before.*

Second, the proposed scheme is beneficial only to a few large centers and insurance companies whose interest is to transplant large numbers of patients at the cost of other patients served by other smaller, local networks. The rules currently set by UNOS, though not perfect, provide incentive for local networks to procure organs because they have a chance to stay locally, thus reducing waiting times for area patients. As a solution to organ shortage and to serve sick patients who have waited long times, organ procurement, and therefore organ donor awareness and education, should be promoted in each community to serve its own needs first. *Communities, which include professionals and non-professional volunteers, should be rewarded, not penalized, for their successful efforts in organ recovery.*

I applaud any efforts to improve the lives of those who have a need for organ transplantation. I implore that these decisions be based on sound medical evidence and

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that the outcomes, both scientific and economic, be fully explored. The UNOS organization has been effective in doing so for decades. Moreover, its representation of professionals, patients and volunteers has been admirable and necessary in making the process of organ transplantation as equitable and beneficial to all involved. While working to improve a system, let's not jeopardize what is already working.

I thank you for your time and effort in considering these opinions. Your diligence is vital to this important subject and is appreciated.

Sincerely yours,

Cynthia G. Pan, MD

Cynthia G. Pan, M.D.
Associate Professor of Pediatrics
Medical Director of the End-Stage Renal Disease Program
Children's Hospital of Wisconsin

MEDICAL COLLEGE OF WISCONSIN
Physicians
& Clinics

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Ellen T. McCarthy, M.D.
Walter F. Piering, M.D.

Cynthia Prom, R.N.

April 1, 1998

Mr. Christopher Shays
Chairman of the Subcommittee on Government Reform and Oversight
2157 Rayburn House Office Building
Washington, DC 20515-6143

Honorable Christopher Shays:

As a Nephrologists caring for patients with end stage renal disease in Wisconsin, I am most concerned about the new Federal law recommended by Donna Shalala that sets up new rules for organ donor allocation. We have an excellent kidney transplant program in Wisconsin, which has been functioning for over 30 years with centers in Milwaukee and Madison. On the basis of our expertise in kidney transplantation, other programs haven't been developed, including liver, pancreas and heart. Our organ procurement programs are excellent and many Wisconsinites have benefited.

I think that attempts at equalizing waiting time for organs by sending them to centers throughout the United States, is an unsound rule. This rule has been set up by administrators without regard for the medical aspect of organ transplantation. The ethical basis of the rule is unsound and only looking for equalization in waiting time while trying to funnel transplant organs to the sickest patients may result in unsuccessful transplants. This would, of course, increase the cost of the program and increase the rate of graft failure.

This proposed rule would, of course, lower the numbers of organs available for transplantation, because it would remove the local incentive to obtain organs. The National Kidney Foundation of Wisconsin has worked hard on their donor programs. We have been successful in obtaining many organs for Wisconsinites and have sent many organs elsewhere. However, if people of Wisconsin realize that the transplants were not going to people of their own state and locality, they would be much less interested in obtaining kidney grafts and the total program would diminish. It would also remove the incentive from other programs who, thus far, have had poor organ procurement programs. The efforts for organ procurement would benefit programs, which have made little effort to stimulate their own organ procurement. This is a very socialistic viewpoint and does not prompt progress.

I believe the proposed rule is politically driven, so that HMO's, insurance companies, and large transplant programs could survive in the field of continued competition. This desire is not driven by scientific information, but purely for their sole financial benefit without interest in the patient's welfare.

This new rule would essentially eliminate the current United National Organ Sharing Program, which has been working effectively in the United States. It

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would void thousands of volunteer hours donated by transplant professionals, patients and families over the many years and would lead to many less transplants throughout the United States. Now is the time that politics and government should get out of attempts to dictate medical care and let patients be taken care of by the health care workers who know how to do it best. I believe this rule should be defeated and not reborn any other disguise.

Thank you very much for consideration regarding this matter.

Sincerely,

Walter F. Piering, M.D., F.A.C.P.
Professor of Medicine
Medical Director Dialysis Program
Medical College of Wisconsin Affiliated Hospitals

WFP/lz

cc: Tom Barrett

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MARSHFIELD CLINIC

LAKELAND CENTER

April 1, 1998

Christopher Shays
Chairman of the Subcommittee on
Government Reform and Oversight
2157 Rayburn House Office Building
Washington DC 20515-6143

Re: Recently Announced New Rules for Organ Allocations

Dear Sir:

I am not in favor of the new rules for organ allocation as announced by Donna Shalala. I am a nephrologist involved on a day to day basis with chronic renal failure patients, their families, and potential donors. I realize that these initial rules would deal with livers only, but it is clear the expectation is that all other organs will eventually be affected.

The proposed rules would remove the local incentive for organ donation. Almost every time that I am dealing with a grieving family and discussing the possibility of having the deceased donate organs, the question of where is this organ going to go comes up. People are, as a rule, reluctant to offer donations if they feel the chance is significant that the organs will go a long distance away and benefit somebody completely out of their community. These proposed rules will penalize areas of the country, such as Wisconsin, which have been effective in developing organ recovery efforts.

The proposed rules are politically driven by a few large centers, HMOs, and insurance companies, and are not based on scientific data. Conversely, the UNOS organ allocation system has been publicly studied and discussed for years. Although it is not perfect, it has a very good balance between completely equal access and maximizing the number of successful transplants.

These new rules will definitely result in fewer successful transplants than the present system. It will do this because it will be more difficult to obtain consent to donate. And, by always funneling transplants to the sickest patients first, there will be increased cost and rate of graft failure.

Chairman of the Subcommittee
Page 2
April 1, 1998

The proposed rules would gut ONOS and void the hundreds of thousands of volunteer hours donated by transplant professionals, patients, and families. It appears that UNOS would be replaced by a governmental bureaucracy that would reward those areas of the country with large recipient lists and lower donor rates, and penalize areas of the country that have managed to develop a better sense of community and volunteerism.

Sincerely,

Mark A. Rassier, M.D.
Department of Nephrology

db
c: Tom Barrett, Member
Subcommittee on Government
Reform and Oversight

Mark B. Adams, MD
Professor of Surgery
Medical College of Wisconsin

(9/2) UNOS
+ Pruitt

April 9, 1998

Christopher Shays
Chairman of the Subcommittee on Government Reform
2157 Rayburn House Office Building
Washington , DC
20515-6143

Dear Mr. Christopher Shays,

The recent announcement regarding new rules for organ allocation resulting in equal waiting nationally has us in Wisconsin concerned. I would like to raise the following points to support our view.

The ethical basis of the rule is unsound since it looks only at equalization of waiting time and does not take into account the factors that deal with outcome. By always funneling transplants To the sickest patients first, the proposed rule would result in fewer successful transplants than the present system and would increase costs and the rate of graft failure.

The proposed rule would result in lower rate of organ donation since it would reward those areas of the country with large recipient lists and lower donor rates and penalize areas of the country Such as Wisconsin which have been effective in developing organ recovery efforts.

The proposed rule is politically driven by a few large centers, HMOs and insurance companies and is not based on scientific data. Extensive computer modeling of the organ allocation system by UNOS committees and statisticians have shown that the present system although not perfect, is the best current balance between completely equal access and maximizing the number of successful transplants.

The rule would essentially gut UNOS, a highly effective organization representing the spectrum of the transplant community and void the hundreds of thousands of volunteer hours donated by transplant professionals, patients and families over many years in developing a sound, yet dynamic system of organ allocation.

Successful transplantation and rehabilitation of patients into productive citizens is our prime goal. Transplanting the sickest patients first will increase mortality and morbidity.

Sincerely,

Ram Rao MD
Mercy Dialysis Center
Medical Director

Christy A. Rentmeester
Medical College of Wisconsin
8 April 1998

Comment on Proposed Changes To the Department of Health and Human Services Organ Procurement and Transplantation Network Regulations

Securing justice in listing liver transplant candidates according to medical need requires uniformity throughout United States health care in assessing patients' degrees of illness and consensus upon at which point in disease progression a patient must be listed. Additionally, it must be considered that listing liver transplant candidates according to medical necessity may challenge physician integrity, as it is assumed that doctors advocate the best interests of their patients and thereby desire that their patients be "prioritized" among the many transplant candidates listed. It is plausible to suspect that physicians—by the coercive force of their personal, professional, or political conscience—may falsify the severity of their patient's liver disease in order to have their patient placed among the "highest priority" of transplant candidates. Despite that a physician may mean well in promoting her patient's best interests, if it becomes common competitive practice for physicians to exaggerate the infirmity of their patients, the ultimate motive of serving the sickest patients first will become muddled as honorable purposes of patient advocacy cause the reliability of list ranking to dwindle. If OPTN Regulations are to be amended to give the sickest patients "first dibs" on donor livers, safeguards will have to be implemented to ensure that the new guidelines are effectively employed to prevent physicians from being overzealous supporters of their patients' desperate pleas for the continuation of their lives.

MILWAUKEE NEPHROLOGISTS, S.C.

JEFFREY D WALLACH, M.D.
MATTHEW H. HANNA, M.D.
WILLIAM C ELLIOTT, M.D.
DANA A. CAMPBELL, M.D.
LISA M. RICH, M.D.
STEPHEN G. SIEVERS, M.D.
MICHAEL I. LEVINE, M.D.

April 2, 1998

Government Reform and Oversight
Christopher Shays
2157 Rayburn House Office
Washington, DC
20516-6143

TO: House Committee on Government Reform and Oversight:

Milwaukee Nephrologists is a group of seven private practice nephrologists treating patients with kidney disease including a population of patients on dialysis awaiting kidney transplantation. As such, our group feels compelled to comment on the recent proposed changes for organ allocation. There were several distinct issues that need to be addressed.

The first issue is to separate kidney and pancreas transplants from other organs ie. heart and liver transplants. The recent proposal (which would funnel transplants to sickest patients first) did not take into account the difference between a life-saving procedure such as heart and liver transplant, and patients with end-stage renal disease who undergo dialysis treatment. Because patients have widely available opportunities for dialysis, it is not necessary to rank order patients by who is most severely ill. In fact, the most successful kidney transplant patient would be a stable patient on dialysis, not a patient sick from other organ disease who is in the hospital.

Another issue that needs to be addressed is the issue of organ recruitment. Our practice has had involvement in the local National Kidney Foundation chapter which is active in organ recruitment. The state of Wisconsin has been effective in developing organ donors. The proposed changes would certainly diminish local efforts if harvested organs were being sent out of the area. The current wait for a kidney transplant in the state of Wisconsin is 18 months. We would anticipate that local waiting times would increase, potentially doubling if organs were being shipped out of state in the new proposed changes. This is certainly very discouraging for patients who are waiting on dialysis, and those who donate their time for recruitment efforts.

In summary, from the viewpoint of our practice, taking care of patients with end-stage kidney disease on dialysis, the proposed changes for organ allocation would result in an overwhelmingly negative impact on our patients. It would include increasing waiting time, inappropriate allocation of transplants to unstable patients ensuring a higher cost and fewer successful transplants. It would undermine local efforts to recruit organ donors. We are not in favor of the proposed changes to the currently existing UNOS system.

Lisa M Rich MD

Lisa M. Rich, M.D. Jeffrey D. Wallach, M.D., President Milwaukee Nephrologists
cc: Mark Adams, M.D.

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April 2, 1998

Mr. Christopher Shays
Chairman Of the Subcommittee on Government Reform and Oversight
2157 Rayburn House Office Building
Washington, D.C. 20515-6143

Dear Mr. Shays:

I am writing this letter to you concerned over the recent proposal in regard to organ allocation for transplantation. As a nephrologist in a smaller community in the state of Wisconsin, I have taken care of many patients who have received kidney transplants or our awaiting an available transplant. Currently, the average length of time for a patient who is waiting for a cadaveric kidney transplant in the state of Wisconsin is approximately two years. I do believe that the current proposed plan to change the way organs are distributed across the county would adversely affect those of my patients who are yet waiting for kidney transplants. Although I do believe it is important to have some preference to providing transplants to those patients who are in greatest need, I also know that the complication rates in those patients who are significantly debilitated because of their illnesses, is high in comparison to the general population. Therefore, the end result would be the increase in unsuccessful transplants at a greater cost to the system. I have been certainly happy with the current system as it has provided good assessment of need as well as outcome.

I have also been very happy with the local access to transplants and control in regard to both the allocation and distribution of transplants. I believe that the current system where a larger number of transplants are resulting from local donors enhances the numbers of available donors and increases overall awareness of this issue. There is also an enhanced incentive for the local organ transplant centers to go out into the communities and increase awareness and assist in increasing the number of donors that are available. Please reconsider your proposed changes to the organ allocation system and consider keeping the current system as close to where it is at which in my opinion has been working well for the patients that I have been involved with.

Thank you very much for considering this issue.

Sincerely,

Thomas G. Schneider, M.D.

js/TGS

c: Mr. Thomas Barrett, U.S. Congressman

D: April 2, 1998
T: April 2, 1998

FROEDTERT
Memorial Lutheran Hospital

9200 West Wisconsin Avenue
P.O. Box 26099
Milwaukee, WI 53226-3596
Telephone: 414 259 3000

Primary Affiliate of the
Medical College of Wisconsin.
Member, Horizon Healthcare Inc.

4/8/98

My name is Kathy Liegnick
and received a liver transplant
June 2, 1991 at Froedtert Hospital.

I feel it is very important that organ donation remain regional. Froedtert has worked very hard to reach out to the public and make them aware of the importance of organ donation. Other centers should also do so. The real problem is educating people as to the importance of organ donation - We need to ~~increase~~ increase the donation of organs. Education will do that.

Cutting the pie in 8 pieces is better than cutting it in 4. Everyone will benefit. It is beneficial to everyone to keep the regional centers open.

MEDICAL
COLLEGE
OF WISCONSIN

Department of Pediatrics

April 6, 1998

Christopher Shays
Chairman of the Subcommittee
on Government Reform and Oversight
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Chairman Shays:

This letter is in regard to proposed new rules for changes in organ allocation to equalize the waiting times.

Personally, I am against the change. I am involved in preparing children for organ transplantation. Organs harvested in Wisconsin would be shipped to another center about 50% of the time which would increase the already prolonged wait for organs in our population. More over, the requirement to ship organs will increase the cost, the time of ischemia and risk of non-functioning.

This proposed rule only takes into consideration of equalizing of waiting times but does not take into account factors that deal with outcomes. By transferring the organs to the sickest patients first could result in fewer successful transplants than the present system. To me the most worrisome problem will be lowering of organ donations at a local level. The incentive to procure organs will decrease as the organs will be transferred to the sickest. This would slight UNO, a highly effective organization which with the help of transplant professionals, patients, and families has developed a sound, dynamic system of organ allocations. Oddly, it will penalize Wisconsin which has an effective organ recovery efforts. It would reward areas with historically lower donor rates.

MACC Fund Research Center
8701 Watertown Plank Road
Post Office Box 26509
Milwaukee, WI 53226-0509
(414) 456-4100
FAX (414) 456-6539

I believe the proposed rule is not based on scientific data but is politically driven by HMO's, large insurance companies and large centers. These large centers have not invested in time and efforts in improving organ donation. Although not perfect, the computer modeling of the organ allocation system by UNO is the best current balance between completely equal access and maximizing the number of successful transplants.

Sincerely,

Kumudchandra J. Sheth, M.D.
Professor of Pediatrics
Pediatric Nephrology

KJS/mcr

FAX

Date: 4/13/98

To: Anne Marie Finley

Phone: 630-978-1660
Fax: 630-978-1660

Company: Subcommittee for Human Resources

Fax Number: 1-202-225-2382

From: Deborah C. Surlas

No. of pages incl. cover sheet: 4

Remarks:

Congressman Shays offered a five day period for additional written testimony to the Congressional Field Hearing on Organ Donation, Allocation and Transplant held in Milwaukee on April 8, 1998.
I am respectfully submitting the included additional testimony to be added to the hearing..

Thank you.

Testimony submitted by Deborah C. Surlas, RN, April 11, 1998.

Submitted written testimony for the Congressional Field Hearing on Organ Donation, Allocation and Transplant, held in Milwaukee on Wednesday, April 8, 1998,

Government Reform and Oversight Committee
Subcommittee for Human Resources

Mr. Chairman and members of the Committee,

Thank you for the opportunity to submit written testimony to this hearing for an extended five day period. I presented *oral testimony from* the floor at the hearing held in Milwaukee on April 8, 1998, and would like to add the following to my testimony.

I would like to discuss an issue that was not covered to any extent at the hearing. I am very concerned about the increased costs to the consumer that a national allocation system would cause.

1) If organs are shipped all over the country instead of being used locally if possible, the added cost of the transportation of the organs and/or the transplant teams to retrieve the organs (thousands of dollars per organ) will be passed on to the recipients, usually through their health insurance.

2) Shipping organs around the country adds to their cold ischemic time (time out of the body and without a blood supply) and can affect the viability of the organ. This increased transport time can increase the likelihood of increased medical costs for the recipient. Putting an organ with any decreased viability into the most critical patient = increased medical costs.

3) If patients are not transplanted until they are critically ill, the costs of their pre and post transplant care will be extremely increased, as well as a potential decrease in their post transplant survivability, an increase in the need for second or third transplants and wasted organs, and a potentially poorer "quality of life" post transplant.

I am concerned about the "trickle down " effects to the consumer of the above scenarios. Transplantation is an already expensive treatment modality. Any added costs to this treatment will cause insurance companies to increase their premiums. This, in turn, will cause more employers to increase their employees' share of the premium costs as well as causing many employers to start cutting insurance benefits such as transplantation and medication coverage as a cost containment method.

Many patients have a lifetime "cap" (maximum amount of insurance dollars) of $250,000. In addition to the transplant itself, recipients face a lifetime of expensive medications, lab tests and follow up medical care. These new regulations will just mandate that these patients will be in a more complicated situation which will quickly use up their insurance dollars. In one case that I remember very well from my work as a Clinical Audit

Testimony submitted by Deborah C. Surlas, RN, April 11, 1998.

Specialist, a woman received three liver transplants. The bill for that hospital stay alone was almost $1.5 million. She was in rehabilitation for many months after leaving the hospital. What happens to the patient when they run out of insurance dollars? They end up losing their homes, their life savings, retirement savings, etc. just to pay the ongoing medical bills. These patients can then end up on Medicaid, stressing the government system even more.

Although charges at transplant centers vary considerably across the country, I recently reviewed charges on two liver transplants at another facility. The patient was not critical at the time of liver transplant. The total hospital charges for the two transplants were $62,365.00 and $60,477.00, as opposed to the $1.5 million in the above case.

Other patients who develop many more complications because they are not transplanted when they are more stable, may not have as good an outcome and either stay disabled or go on disability, many times financed by the government. These added costs to the government system affect us all.

I feel that this new system of transplanting the most critical patients *first* may discourage some candidates from staying in the best health possible (which leads to a better post transplant outcome and lower medical costs) while awaiting their transplant, especially when they know that they will never receive the transplant until they are critically ill. Would some of these patients give up fighting and become non-compliant and critical in order to receive their transplant earlier?

I worry about the fears of the cirrhotic patient who is stable and not in the hospital, but who has the potential for a lethal bleed due to variceal rupture. I worry about the emotions of the patients who are not critical but don't feel well, sleep most of the time, can't work, and can't even keep up with family and friends. How discouraging for them to exist like this for months to years before they are finally within weeks of dying and then hope that they might survive a transplant. They then face months of rehabilitation after being incapacitated for so long, if they still have the finances to afford it.

I am very disturbed by a question that a liver candidate recently posed to me. He has been waiting for a liver transplant for a year and a half. He is now a Status 2B. His medical condition keeps him from working anymore. He is on disability and is concerned that he is no longer a productive, tax paying citizen. He is very frightened that this new system will keep him from being transplanted until he is in critical condition. He doesn't know if he can hang on that long with the "quality of life" he is now experiencing. He recently asked me if he should "take a whole bottle of Tylenol to destroy what is left of my liver so I'll become critical enough to get my transplant and get on with living". It is so sad that someone would think they had to go to such means to get a transplant under a national allocation system.

The new regulations mention provisions for patients currently on the waiting list. But how will these provisions work? We can't transplant these patients under the current system

Testimony submitted by Deborah C. Surlas, RN, April 11, 1998.

while a national system is undertaken. It would take years to transplant all the patients currently on the waiting list before changing the system. I know the regulations require that the Organ Procurement and Transplantation Network (OPTN) figure this out, but I just don't see any way that a transition could be accomplished without penalizing patients already on the list.

Now that the final regulations have been published, I think there needs to be much more dialogue between UNOS and all of their volunteer experts (including the patient population which I think is well represented at UNOS), the Department of Health and Human Services and the transplant community at large. If this is to be a patient-driven allocation system, then my concerns need to be addressed, because they affect all patients going through the transplant journey.

Respectfully submitted,

Deborah C. Surlas

Deborah C. Surlas, RN
Vice Chair, UNOS Patient Affairs Committee
Member, Subcommittee for Patient Access to Transplantation
Executive Director, Organ Transplant Support, Inc.
Kidney/pancreas Transplant Recipient

KERRY THOMAS
9200 LONGS ROAD
SAYNER, WISCONSIN 54560-9787
(715) 542-3372

April 1, 1998

Hon. Christopher Shays, Chairman
Subcommittee on Human Resources
Room B-372 Rayburn Building
Washington DC 20515

Dear Mr. Chairman;

{I ask that this letter be considered with the testimony to be heard Wednesday April 8, 1998 at the Subcommittee's oversight hearing on the Department of Health and Human Services' (HHS) management of the National Organ Procurement and Transplantation Network (OPTN) under the National Organ Transplant Act of 1984 (NOTA) at the Medical College of Wisconsin, Milwaukee, Wisconsin.}

Good morning. My name is Kerry Thomas. In January, 1991 I was diagnosed with chronic renal failure, after having diabetes for nearly 20 years. Diabetes had already rendered me legally blind, and now it had done irreparable damage to my kidneys. I was faced with a decision: How badly did I want to live?

After having my options explained to me (death, dialysis, organ transplantation) I decided to go on dialysis in preparation for a future organ transplant operation. While I was not as yet so ill as to require immediate dialysis, it was only a matter of 2 1/2 months before I was to begin dialysis, performed as an emergency procedure while I was in Eau Claire, Wisconsin, returning from the University of Minnesota, where I had gone to be evaluated as a candidate for organ transplantation. After being stabilized there, I was allowed to return home. There I began regular hemodialysis treatments on (ironically) April 1, 1991, at the Howard Young Medical Center in Woodruff, Wisconsin.

On July 3, 1991 I was given final approval to be placed on the waiting list at the University of Wisconsin School of Medicine in Madison, Wisconsin. I was told I could expect to wait for up to two years for a suitable match to my body and tissue type. During that time I was to continue thrice-weekly hemodialysis treatments, in an effort to merely maintain my life. I did not have to wait that long.

Incredibly, just four weeks later, at 10:03 pm on the night of July 30, 1991 I received a call from the transplant center in Madison. They told me a potential donor had come in, and was not expected to survive. I was told to pack my bags and wait for another call, which came at 10:35 pm, telling me to come to Madison. At 12:05 am on July 31, 1991 my Mother and I left the driveway, heading south. Five hours later we arrived at the emergency room entrance to the hospital. I was escorted upstairs, and began the preparations for my surgery. Shortly thereafter, I was told that my surgeon, Dr. Hans Solinger, was in Washington, and wouldn't be able to return for another six hours. To pass the time, I had another dialysis treatment.

Finally, just after 5 pm, I was taken to the operating room area. But the excitement was not yet over. As my preliminary anesthesia was being administered via IV, I was informed that there was a slight complication. It seems that there was a small cancerous spot on the *other* kidney of my donor, making that kidney useless for transplant. However, I was repeatedly assured that *my* kidney and pancreas (or, rather, the kidney and pancreas I was to receive) were clean. The transplant team felt these were good organs, and were prepared to proceed. The choice was mine.

I decided the transplant team was right, and gave them the OK to proceed with my operation. I have been told that the operation took about 5 1/2 hours, and that I came out of the operating room just before midnight. I spent the next two days in ICU recovery, on a slow IV morphine drip for pain. My memories of those two days are foggy. When I began to regain coherent consciousness I was moved to the transplant floor, there to begin to rebuild my life.

I think it is important to pay attention to the timeline of my experiences, for in the matter of organ transplantation, time is a very critical factor. The less time spent between organ harvesting and transplantation, generally, the better the chances for a successful transplant operation. In my case there was almost exactly 24 hours between the time the donor died and this person's organs were transplanted into my body. I'm convinced this was a significant contributing factor to my survival, and my being able to write this today.

If my understanding is correct, the Department of Health and Human Services (HHS) is proposing that the management of the National Organ Procurement and Transplantation Network (OPTN) under the National Organ Transplant Act of 1984 (NOTA) will be significantly modified, in that the Program will consider allocation of potential organs for transplant on a nation-wide basis, rather than on a regional basis, as is now the case. Two obvious questions come to mind: (1) What will be the effect of this change with regard to transportation times and costs; and, (2) [I apologize for my language] Just what the he** business is it of HHS to be dictating from on high the methods and procedures transplant centers use to determine who receives organs?

I'm sure others who will be testifying on this matter will be able to better describe the many obstacles faced by procurement and transplant teams with regard to time and distance considerations in the organ allocation process. More time means lower success rates, which translates to wasted organs and death. We are literally talking about life and death situations here.

Which is why my second objection to these proposed changes is so strong. It is unfortunate that our federal government feels it has the power and authority to be so intimately involved in life and death medical decisions, decisions which should be based upon medical and personal judgements. Period. No government agency should have the power to dictate medical treatments. OPTN has done a very good job in devising, implementing, maintaining, and monitoring our nation's organ procurement and transplant program. Let's not ruin it with a group of government bureaucrats. If the bureaucrats' ideas had merit, they would have been implemented by the medical profession, or another private sector body. If we were to leave innovation, creativity, and productivity to the government to figure things out, we would still be blaming evil spirits for diseases, and using unsterilized tools for medical procedures.

Mr. Chairman, let's leave the medical decisions to the medical profession. I thank you and the committee for your consideration.

Most sincerely yours,

Kerry Thomas

Kerry Thomas

TOMMY G. THOMPSON

Governor
State of Wisconsin

Committee on Government Reform and Oversight
Subcommittee on Human Resources

Testimony: "Public Health 2000: Oversight of the National Organ Procurement and Transplantation Network"
Governor Tommy G. Thompson
Milwaukee, Wisconsin
April 8, 1998

Thank you Mr. Chairman for allowing me to submit written testimony for the official record. This proposed rule for federal oversight of the National Organ Procurement and Transplantation Network is an issue of grave importance to the people of Wisconsin.

This rule, while intended to provide equitable distribution of organs to critically ill individuals nationwide, will have a negative impact on the transplant programs in Wisconsin and ultimately the people who live in this state and this region of the Midwest.

Specifically, the proposed allocation policy would mandate that organs be referred to the sickest patients (Status 1) in the region, or even the nation. This proposal could ultimately result in a net increase in deaths throughout the nation.

Organs transferred across a region or the nation could be damaged due to factors related to increases in preservation time. These factors could have an adverse affect on the functionality of organs, and could ultimately increase the number of re-transplanted organs.

Centers such as the University of Wisconsin and the Wisconsin Donor Network, which have historically been extremely successful in organ procurement and have kept their waiting times low, will be particularly affected by this change in policy.

If organs, such as livers, are donated in Wisconsin but must be shipped outside the region to another center, it could result in a loss to Wisconsin of up to 50 livers per year. These are 50 lives needlessly put in jeopardy.

Furthermore, as a result of the organ allocation requirement in this rule, it is unlikely that livers will be returned to Wisconsin due to the large number of Status 1 patients outside our region.

Room 115 East, State Capitol, P.O. Box 7863, Madison, Wisconsin 53707 • (608) 266-1212 • FAX (608) 267-8983

In reality, with this rule, no more lives will be saved regionally or nationally; however, more residents of Wisconsin will suffer or lose their lives due to a reduction in available organs throughout our state.

During a December 1996 national hearing, representatives from 83 percent of the country's liver transplant centers agreed that the current allocation policy, despite its imperfections, remains the best way to allocate livers; not only to the sickest patients, but also to the patients who have the best expected long-term outcome.

In addition to this study, all major professional societies, including the American Society of Transplant Surgeons and American Society of Transplant Physicians, as well as recipient and donor organizations, are in agreement that the current allocation policy should not be changed.

In fact, the independent United Network for Organ Sharing reviewed 15 different systems for organ procurement. The study rated the current system the best and it ranked the system Secretary Shalala is pursuing the worst of the 15 options.

So in essence, the Department of Health and Human Services is moving to scrap what is commonly held as the best system for organ procurement in order to replace it with a system experts consider the worst option available.

Given these facts, why is DHHS changing the system? It not only flies in the face of common sense; it flies in the face of good science and good medicine. All these experts cannot be wrong.

My fear is that a political decision is being made that will compromise the lives of Wisconsin residents as well as residents of other states with strong organ procurement programs.

In Wisconsin, we are a national leader in organ procurement and organ transplantation. Our citizens are among the most generous and giving in the nation. Perhaps this is why larger hospitals in bigger states want access to organs donated by our citizens.

But here is the truth: Wisconsin residents will be far less likely to give the gift of life through organ donation if they know that organ is going to someone in a state far away. This is the message that was sent to us loud and clear when news of Secretary Shalala's decision came down.

So in reality, the big money hospitals on the East Coast will not have access to more organs in Wisconsin because fewer people will be giving because they will not feel as if they can make a difference.

Some may call this protectionist, but it is reality. It is human nature. People who give organs want to know they are making a difference, and it is much easier for them to feel that way if a neighbor in their state or the state next door benefits from the tragic death of their loved one. They can more readily see the impact of their gift.

The current system works fine. It saves hundreds of lives each and every year in Wisconsin. If there is a problem, it may be that certain states and transplant hospitals need to do a better job of persuading their residents to donate organs. Do not penalize the states that do a good job in this arena. Help the states doing a poor job to bolster their efforts. We would be happy to share our experience and expertise with any state or hospital looking for a model of excellence when it comes to organ procurement and transplantation.

Therefore, it is with great respect that I strongly urge the committee to turn back the proposed rule by the Department of Health and Human Services. Don't make a needless mistake that will cost far more lives than it saves.

MEDICAL
COLLEGE
OF WISCONSIN

Rajiv R. Varma, M.D.
Director, Hepatology Unit

Division of Gastroenterology and Hepatology

April 6, 1998

Honorable Congressman Thomas Barrett
135 W. Wells Street
Milwaukee WI 53203

Dear Congressman Barrett:

As a health professional actively involved in organ transplantation, especially liver transplantation I am writing this letter to you opposing changes proposed by Secretary of Health & Human Services, Donna Shalala.

The whole concept seems to be based on the criteria or dealing with the sickest patient first, without regards for other very important factors. The ethical basis of the rule is questionable because it only considers equalization of waiting time and does not take into account factors such as outcome. By always funneling transplants to the sickest patient first the proposed rule would result in fewer successful transplants than the present system and would increase cost and rate of their failure.

The purposed rule would result in lower race of organ donation as it would largely remove the local incentive which has historically driven these efforts. It would reward those areas of the country with large recipient lists and lowers donor rates and penalize areas of the country such as Wisconsin which have been effective in developing organ recovery efforts.

The purposed rule is politically driven by a few large centers, HMO's and Insurance Companies and is not based on scientific data. Extensive computer modeling of the organ allocation system by UNOS (United Network of Organ Sharing) committees and statisticians have shown that the present system, although not perfect, is the best current balance between completely equal access and maximizing the number of successful transplants.

The rule would essentially politicize organ sharing. It will take the decision out of the hands of physicians and other health care professionals who are trained and currently actively involved in the decision making dealing with patients. The rule would essentially cut UNOS, a highly effective organization representing the spectrum of transplant community and void hundreds or thousands of volunteer hours donated by transplant patients, professional and families over the many years of developing a sound, yet dynamic system of organ allocations.

Finally, In Wisconsin we have one of the highest rates of organ procurement in the nation. **According to our present projections, nearly half of the livers available locally will be lost to areas outside Wisconsin. It will have a dramatic adverse impact on the organ transplantation**

Froedtert Memorial Lutheran Hospital
9200 West Wisconsin Avenue
Milwaukee Wisconsin 53226
(414) 259 3038
FAX (414) 259 1533

in the State of Wisconsin. Your committee's efforts in this regards opposing the purposed changes will be greatly appreciated.

Sincerely,

Rajiv R. Varma, M.D.
Director Liver Unit

RRV/jr

MEDICAL
COLLEGE
OF WISCONSIN

Rajiv R. Varma, M.D.
Director, Hepatology Unit

Division of Gastroenterology and Hepatology

April 6, 1998

Mr. Christopher Shays
Chairman of the Subcommittee on Government Reform & Oversight
2157 Rayburn House Office Building
Washington DC 20515-6143

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Froedtert Memorial Lutheran Hospital
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Milwaukee, Wisconsin 53226
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Finally, In Wisconsin we have one of the highest rates of organ procurement in the nation. According to our present projections nearly half of the liver available locally will be lost to areas outside Wisconsin. Your committee's efforts in this regards opposing the purposed changes will be greatly appreciated. Let us try to keep the organ allocation system as nonpolitical as possible.

Sincerely,

Rajiv R. Varma, M.D.
Director, Liver Unit

RRV/jr

MIDWEST
NEPHROLOGY
ASSOCIATES, S.C.

James Brandes, M.D.
Amir Daniel, M.D.
Claire Fritsche, M.D.
William Krakow, M.D.
Todd Muche, M.D.
Gregory V. Warren, M.D.
Paul J. Warren, M.D.

April 1, 1998

Christopher Shays, Chairman
2157 Rayburn House Office BLDG.
Washington, DC 20515-6143

RE: UNOS changes

Dear Mr. Shays:

I am writing in opposition to the proposed UNOS changes. I care for a number of kidney transplant, heart transplant and pancreas transplant patients. I think it unwise to look only at equalization of waiting time, instead of factors such as outcome.

Unfortunately, when we allocate organs to the sickest patients first, we will have fewer successful transplants and this will certainly be a waste of these precious organs. The changes might result in lower organ donations since the local organ drives, which have made such a difference in increasing donation, may not have a reasonable outcome. People will realize that organs may be shipped out of their local area.

This new change is not based on scientific data and will not allocate the organs appropriately. There will not be completely equal access and the number of successful transplants will decrease.

UNOS has been a very effective organization in allocating organs. Should the rules be changed, UNOS will have very little say. This would be a travesty especially considering how many transplant professionals, patients and families have been involved in developing a sound and fare organ allocation system.

I am very much opposed to the changes as proposed by Donna Shalala and I think that the changes must be re-thought so that we don't waste organs.

Sincerely,

Gregory V. Warren, M.D.
(dictated not read)

GVW/lj

3267 SOUTH 16TH STREET • SUITE 203 • MILWAUKEE, WI 53215 • (414) 672-8282 • FAX: (414) 672-8284
4021 NORTH 92ND STREET • MILWAUKEE, WI 53216 • (414) 873-3600 • FAX: (414) 873-6479
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James Brandes, M.D
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April 1, 1998

Christopher Shays, Chairman
2157 Rayburn House Office BLDG.
Washington, DC 20515-6143

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Sincerely,

Paul Warren, M.D.
(dictated not read)

PW/lj

3267 SOUTH 16TH STREET • SUITE 203 • MILWAUKEE, WI 53215 • (414) 672-8282 • FAX: (414) 672-8284
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Children's
Hospital
® of Wisconsin ™
9000 West Wisconsin Avenue • P O Box 1997 • Milwaukee, WI 53201 (414) 266-2000

April 2, 1998

The Honorable Christopher Shays
2157 Rayburn House Office Building
Washington D.C. 20515

Dear Representative Shays:

I am very concerned about the recently announced new rules for organ allocation proposed by Donna Shalala. These new rules will shunt organs harvested in many regions of the country to large transplant centers. The ethical basis of this rule is unsound as it only looks at equalization of waiting time for transplant. Since there is a shortage of organs available, there will always be some patients who die untransplanted. The new rules will not increase the number of patients who receive transplants, only change which patients die. The only true solution is to find a method to increase the availability of organs for transplant. According to the new rules, the sickest patients will be transplanted first. This will clearly result in fewer successful transplants. This will increase total cost ant rate of graft failure.

The proposed new rules also will result in lower rates of organ donation and procurement. The local incentive which drives procurement, will be weakened. Areas of the country which have short waiting lists, are often those who have developed effective organ recovery efforts. These areas of the country, should not be penalized.

The new rules will harm the present system which is highly effective and has led to increasing rates of survival.

Sincerely,

Steven L. Werlin, M.D.
Professor - Director
Pediatric Gastroenterology
Medical Director Liver Transplantation

SLW/dlt

Member — Milwaukee Regional Medical Center
A major teaching affiliate of The Medical College of Wisconsin